ThermaSolutions

Zenith-C20, Zenith-C22

CONTRAST MEDIA INJECTOR

USER'S MANUAL

This manual should be read carefully before installing and operating the system. It is recommended to keep this manual well for further reference.

CE 0482

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Reversion History

Initiated on 01/29/14

Version	Date	Description
A/1	05/04/2015	Updated description error.
B/0	13/01/2016	Updated the new monitor screen description.
C/0	01/11/2016	Corrected error codes and part numbers
C/1	10/05/2018	Update the new logo and file No.
C/2	28/11/2018	Added optional part descriptions, warrant terms and corrected print errors.
C/3	14/12/2018	Added the [S] button function instruction.
C/4	15/04/2022	Added Syringe locking function
C/5	23/08/2023	Added wireless function.
C/6	17/10/2023	Update Contraindications information.

FOREWORD

The Zenith CT contrast media injector is a syringe-based fluid delivery system indicated for delivery of contrast media during computed tomography (CT) procedures, and is intended to be used by licensed medical practitioners for the specific purpose of injecting intravenous contrast medium into the human vascular system for computed tomography studies. This device is designed to correspond to the various injection methods of contrast media that were established with the use of multi-slice CT scanners.

This manual applies to the systems in the following models: Zenith-C20 and Zenith C22. Model Zenith-C20 is single syringe system. Model Zenith- C22 (i.e. Zenith- C22) is two syringe system.

Misuse or abuse may occur unintentionally because the user does not know proper method of operating the system. Read this manual carefully before installing and operating the system and keep it well for future reference.

You can call SEACROWN for any service requirement when you need.

SEACROWN TECHNICAL SUPPORT
Phone No. +86 755 26060959

ThermaSolutions
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International: +31 76 579 1144

This copy of PT-010-203 Rev. C/5 is valid as of August 23, 2022 .
The signed original is maintained in Documentation Systems.
You should confirm this copy's reversion is the latest released before use it.

CAUTION: Federal law (US) restricts this device to sale by or on the order of a physician.

Shenzhen Seacrown Electromechanical Co., Ltd

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EC REP **MedNet EC-REP GmbH**
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Table of Contents

1 Basic Introduction 1

1.1 Product Identification 1
1.2 Indications for use 1
1.3 Contraindications 1
1.4 User Qualification 1
1.5 Symbols 2
1.6 Warnings, Cautions and Important Notice 5
1.7 Features 10
1.8 System Response to Occlusions 10
1.9 Over and Under Injection Protection 10
1.10 Maximum Flow Rate 10
1.11 Disposables 11
1.12 Warranty Terms 12
1.13 Brief Instruction of RFID and wireless model 12

2 System Overview 1

2.1 Zenith-C22 2
2.2 Zenith-C20 3
2.3 Specifications 4
2.3.1 Dimensions and Weights 4
2.3.2 Environmental Requirements 7
2.3.3 Electrical Requirements 7
2.3.4 Fluid Delivery Performance 7
2.4 Injector Arm 8
2.4.1 Moving Piston Rod 11
2.4.2 Getting System Ready on Arm 12
2.4.3 Test Injection 12
2.4.4 Controlling Injection 12
2.4.5 Volume Display 12
2.4.6 System Status 12
2.5 Monitor 13
2.5.1 Monitor Buttons 13
2.5.2 Monitor Display Screens 14
2.5.3 Home Screen 15
2.5.4 Protocol Screen 21
2.5.5 System Setup and Test Screens 25
2.5.6 History Screen 35
2.5.7 Help Screen 36
2.6 Main Controller 37

3 Power On/Off 1

3.1 Turning the System Power On 1
3.2 Turning the System Power Off 2

4 Readying Sequence 1
4.1 Deciding on Injection Protocol 2
4.1.1 Programming Protocol 2
4.1.2 Recalling Protocol 3
4.2 Installing Syringe 4
4.3 Interface display 6
4.4 Filling Syringe 7
4.4.1 Filling Syringe Manually 8
4.4.2 Filling Syringe Automatically 8
4.5 Attaching Tubing to Syringes 9
4.6 Purging Air from Syringe 10
4.7 Priming Tubing 11
4.7.1 Priming Tubing with Saline 11
4.7.2 Priming Tubing with Contrast 11
4.8 Connecting to Patient 11
4.9 Getting System Ready on Monitor 12
5 Performing Injection 1
5.1 Reviewing Parameters 2
5.2 Test Injection 3
5.3 Running KVO Injection 4
5.4 Bolus Tracking Injection 5
5.5 Protocol Injection 7
5.5.1 Starting Protocol Injection 8
5.5.2 Pausing an Injection 9
5.5.3 Restarting an Injection 10
5.5.4 Terminating an Injecting 10
5.6 Removing Syringe 11
6 Installation 1
6.1 Assembling Parts 1
6.1.1 Assembling Parts of Zenith-C22 1
6.1.2 Assembling Parts for Zenith-C10 6
6.2 Locating Parts 8
6.2.1 Locating Parts of Zenith-C22 8
6.2.2 Locating Parts of Zenith-C20 9
6.3 Connecting External Cables 10
6.3.1 Connecting Zenith-C22 External Cables 10
6.3.2 Connecting Zenith-C20 External Cables 12
7 Maintenance 1
7.1 Routine Maintenance 1
7.2 Monthly Inspection 1
7.3 Annual Maintenance 2
7.4 Cleaning 2
7.4.1 Cleaning Injector Arm 2

7.4.2 Cleaning Monitor 3
7.4.3 Cleaning Main Controller 3

8 Messages 1

8.1 Injector Ready Messages 1
8.2 Injection Messages 2
8.3 Protocol Messages 3

9 EMC Information 1

10 Index 1

1 Basic Introduction

1.1 Product Identification

Protection against electric shock

According to IEC60601-1, the system is designed as a Class Ⅰ Medical Device with a type BF applied part.

Degree of protection against ingress of water

The system is classified Ordinary Equipment.

Electromagnetic compatibility

The system meets the radiated emissions (Class B) and immunity standard IEC 60601-1-2 for medical devices.

Mode of Operation

According to EN60601-1 the mode of operation for the main controller and monitor is continuous operation. They are capable of operation under normal load for an unlimited period, without excessive temperature being developed.

The mode of operation for the injector arm is continuous operation with intermittent loading. Although power is applied to the injector arm continuously, the intermittent use of loading and injecting will result in an internal temperature less than the continuous load operating temperatures, but greater than the no load operating temperatures. Under normal operating conditions with a minimum of 10 minutes between injections, the internal temperature of the injector arm will not raise enough to degrade safety, system performance or reliability.

1.2 Indications for use

The system is intended for the specific purpose of injecting intravenous contrast media or saline into humans for diagnostic studies in computed tomography (CT) applications.

All kinds of iodinated contrast media and saline can be delivered by the system.

1.3 Contraindications

The injector is not be used in the arterial side of the vascular system, for medical fluid infusion, or any other use which the user's guide is not mentioned.

If proper flow rate and volume are programmed, using the injector instead of by hand to inject contrast medium will not provide new risk. The injector is suitable for all patients who are not hypersensitive to contrast medium.

1.4 User Qualification

The system should be operated ONLY by qualified personnel who:

- are completely familiar with the unit, have read and understood this User's Manual,
- are otherwise properly trained in the use of equipment and procedures of this type.

1.5 Symbols

The following symbols are used on the system and throughout this manual.

Warning statements describe conditions or actions that can result in personal injury or loss of life..

Caution statements describe conditions or actions than can result in damage to the equipment or loss of data.

Indicates that the information that follows is additional important information or a tip that will help you recover from an error or point you to related information within the manual.

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

Identifies a type B applied part complying with EN 60601-1 standards.

Manufacture address

European Representative

Serial Number

Keep Dry

This way up

Fragile

Do not roll

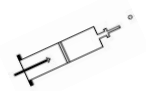
User's manual

Safety ground

Previous Page

Next Page

Class I — Indicates the system is Class I medical equipment as defined by EN 60601-1 standards.



Expel Air

Autofill

Forward

Test

Ready

Stop

Inject

LCD Power Button

[S] Save Button

[I] Inject Button

1.6 Warnings, Cautions and Important Notice

IMPROPER USE WITH THE SYSTEM COULD RESULT IN SERIOUS INJURY TO THE PATIENT OR THE USER.

The system should be operated only by qualified personnel who have read and understood this manual or are properly trained in the use of this equipment.

AIR EMBOLISM COULD CAUSE PATIENT INJURY OR DEATH!

Always verify all air in the fluid path have been expelled before connecting the system to the patient. Carefully read the instructions for loading to reduce the chance of air embolism.
The system is not able to check for air in the syringe and tubing. The user is responsible for removing all air from the system.
To minimize air embolization risks, ensure that one user is designated to complete all injection procedures. If the user must to be changed, ensure that the new user verifies that no air in the fluid path.

ELECTRIC SHOCK HAZARD!

Serious electric shock injury will be caused by contact with the internal systems. Only professional personnel should open the system case.
If any worn or damaged cables are detected, do not use the system. Call SEACROWN for assistance.

THE OCCURRENCE OF CROSS-CONTAMINATION AND INFECTION WILL CAUSE SERIOUS HARM TO THE PATIENT!

Using aseptic technique, install syringe, connect tube and connect to patient.
Syringes may not be used to store contrast media for long periods of time. The syringe with contrast media in it should be immediately used.
Do not remove the plunger to fill the syringe.
Disposables whose packaging has been opened or damaged may not be used.
All disposables are intended for single patient use only. Do not reuse any disposables.

NON-COMPLIANT DISPOSABLES COULD RESULT IN PATIENT INJURY, OPERTOR INJURY AND/OR QUIPMENT DAMAGE.

The system has been approved for use with only the consumables listed in section 1.8 Disposables.
Patient injury could result if the syringe is not properly engaged. Ensure the syringe is properly snapped into the front of the injector arm before injecting. Improper engagement may cause the syringe to leak, become damaged, or to come off during the injection and result in an under-volume delivery.

WARNING! **PATIENT INJURY MAY RESULT FROM A SYSTEM MALFUNCTION.**
If a system malfunction occurs, immediately remove and disconnect the system from the patient. If a fault message is displayed that cannot be corrected, and/or the system is not operating correctly, do not use the system.

WARNING! **EXPLOSION HAZARD!**
Patient injury could result from explosion caused by using the system in the presence of flammables. Do not use the system when flammables are present.

WARNING! **FIRE HAZARD!**
Patient injury could result from a fire caused by using incorrect fuses. To avoid an electrical fire assure the same type of fuse as original is used for replacement.
Only use the power cord supplied with the system. Do not plug the power cord into an extension cord or multi-outlet power strip.

WARNING! **MATERIAL TOXICITY HAZARD!**
Patient injury could result from potentially hazardous system electronic assembly material. Dispose of system components or accessories properly. Follow local regulations for proper disposal or contact SEACROWN Service for assistance.

WARNING! **IMPROPER MEDICAL FLUID VOLUME AND FLOW RATE MAY HARM PATIENTS.**
Configure the injection contrast media volume and flow rate according to the patient's weight and physical condition.
Fill syringes only with the minimum amount of contrast required by the procedure to be performed on the patient.
Prior to commencing the injection, review all parameters thoroughly to ensure that they are correct and appropriate for the procedure.

WARNING! **The system must only be connected to a supply main with protective earth.**

WARNING! **Failure to use the hand switch could result in Electro Magnetic Emissions not meeting specification**.

If the contrast media permeates into the injector arm or accumulates on the piston rod, short circuits can occur or the movement of the piston rod may be inhibited. Both could cause damage to the system. Be absolutely sure to promptly clear away residual contrast media. Place the injector arm in a downward-facing position of the syringe to prevent contrast media and other medicinal liquids accessing the injector arm.

In the event of water vapour condensation, connecting the power may damage the system's electronic components. System taken indoors from outdoor environments of extreme temperatures should not be immediately used. Only use the system once there is no more water vapour condensation indoors.

Incorrect voltage can cause system damage. Check that the power source voltage and frequency are identical to those marked on the system label on the injector arm.

When calibrating the touch-screen, do not use sharp objects to make contact with the touch-screen.

Failing to carry out routine maintenance may cause system malfunctions. It is recommended that regular maintenance be carried out to ensure the system remains in a well calibrated operational state. For details, please review the manual or contact SEACROWN for more information.

Do not use strong chemicals such as acetone to clean the system. Warm water and mild disinfectants are sufficient.

To avoid damage to the touch-screen, do not directly spray cleaning liquid onto the touch-screen. Wipe it using a non-abrasive cloth or paper towel that has been dipped in soluble cleaning liquid.

Improper or careless cleaning methods may result in equipment damage. Do not soak or immerse any part of the system in water. While cleaning any outside portion of the system, avoid allowing any water to leak inside system components.

Component damage may occur if not installed properly. Ensure all connections are secure; do not over tighten. This will help minimize leaks, disconnection, and component damage.

In circumstances where strong electromagnetic fields generated by wireless electrical transmitters or strong static electricity discharges are present, the system may be unable to operate normally.

IMPORTANT! The use of disposables not complying with the equivalent safety requirements of this equipment may lead to a reduced level of safety of the resulting system. Consideration relating to the choice shall include evidence that the safety certification of the disposables has been performed in accordance to the appropriate EN 60601-1 and/or EN 60601-1-1 harmonized national standard.

IMPORTANT! If any anomalies in the system performance are noticed, identify devices within the immediate area that are capable of producing electromagnetic interference and call a qualified service representative.

Above or additional warnings, cautions and notes are located throughout this manual, where applicable.

1.7 Features

The basic features of the system include:

- Store and recall of protocols
- Remote setting system Ready
- Scan delay
- Pressure graph display
- Duration by phase
- Elapsed injection time indicator
- Remote check for air
- Remote Start
- Test Inject
- Selectable Pressure Limit

1.8 System Response to Occlusions

When injecting into an occlusion, a stall condition (flow rate less than 10% of programmed rate) or a very high pressure, the system will terminate injection. If the system terminated injection for stall or high pressure, check the fluid path for blockage and inspect the disposable set for damage. If no blockage is found consider increasing the catheter size or decreasing the flow rate. Re-check the fluid path for air before press the “Ready” button then start to inject.

1.9 Over and Under Injection Protection

The system provides the following means to protect against over and under injections:

Warnings in this manual remind the user to fill syringes only with the minimum amount of contrast required by the procedure to be performed on the patient and to check the programmed protocol prior to the system staring injection.

An indication of insufficient volume is provided on the screen when intending to start injection if the protocol total volume is greater than the amount of fluid in the syringe.

The system detects the delivered volume and terminates the injection once the delivered volume is same as the total programmed volume for the protocol. When a fault condition, hold or stop is detected, the injection will stop within 5 mL. Once the system has terminated the injection a message will be displayed on the monitor screen.

1.10 Maximum Flow Rate

Using recommended syringe kits, maximum flow rate at 35°C +/-±5°C of contrast with different cather-over-needle are:

18 Gauge cather-over-needle (BD PN 381144)

- Ultravist 300 8.5 mL/s
- UltraVist 370 8.5 mL/s
- Saline 8.5 mL/s

20 Gauge cather-over-needle (BD PN 381134)

- Ullravist 300 7 mL/s
- UltraVist 370 7 mL/s
- Saline 7.0 mL/s

22 Gauge cather-over-needle (BD PN 381123)

- Ullravist 300 6 mL/s
- UltraVisl 370 5 mL/s
- Saline 6.0 mL/s

1.11 Disposables

The use of syringe kit not complying with the equivalent safety requirements of this equipment may lead to a reduced level of safety of the resulting system. Consideration relating to the choice shall include evidence that the safety certification of the syringe kits has been performed in accordance to the appropriate EN 60601-1 and/or EN 60601-1-1 harmonized national standard.

The following syringe kits are verified and recommended to be use with the contrast media injector:

Manufacture: Shenzhen Seacrown Electromechanical Co., Ltd
Model: C01-008-10,
Contents：1-200ml Syringe;
Model: C01-006-10
Contents：2-100ml Syringe;
Model: C01-010-10
Contents：2-200ml Syringe;

Use only safety-approved catheters suitable for connection to the LLN-K-A Luer male-threaded locking coupler. The following Cather-over-needle is verified and recommended to be use with the contrast media injector:

FDA cleared in k151698
Manufacture: Becton Dickinson Infusion Therapy Systems, Incorporated
P/N: BD PN 381144, BD PN 381134, BD PN 381123

Though the system is opened to use disposables from different manufactures, theses disposables must be compatible with the system and must be CE marked in European countries or FDA cleared in America market.

1.12 Warranty Terms

Shenzhen Seacrown Electromechanical Co. Ltd. and its Distributor warrant to the original purchaser who purchased the accompanying equipment ("Product") through an authorized dealer that the Product, including any accessories supplied with the Product, is free from defects in materials and workmanship for a period of one (1) year from the date of original purchase.

WARRANTY ON REPAIRED/REPLACED PRODUCTS: Subsequent replacement, resale or replacement or subsequent repair of the product will not extend the warranty period or commence a new warranty period. However, any parts that have been repaired or replaced during the warranty period will be covered by the warranty for the remainder of the warranty period, or at least for ninety (90) days from the date of repair or replacement.

This warranty is not transferable to third parties, including, but not limited to, subsequent purchasers or owners of the product. The transfer or resale of any product will automatically terminate the warranty for this product.

This warranty covers the Product only as originally supplied and is void with respect to the following:

(i) Products which have been subjected to misuse, abuse, accident, physical damage, abnormal use or operation, improper handling or storage, lack of proper maintenance, neglect, exposure to fire, water or excessive moisture or dampness or extreme changes in climate or temperature; (ii) damage resulted from fire, flood, acts of God or other acts which are not the fault of Manufacture; (iii) any Products which have been opened, repaired, modified or altered by anyone other than Manufacture.

Please contact your service representative at the addresses and phone numbers listed in the foreword for warranty and service questions.

1.13 Brief Instruction of RFID and wireless model

1.13.1 wireless model

Zenith contrast medium injection system is mainly composed of a monitor, an injection arm and a main controller.
The main controller is placed in the examination room, and the monitor is placed in the control room. The monitor and the injection arm use wireless transparent transmission module for data transmission and reception, no need to connect arm cable.

1.13.2 Function of RFID

a) With RFID, the syringes will have chip on the head of syringe, the injector need to detect the syringe with chip then can work normally otherwise if the injector cannot detect the syringe, then will show ERROR 57&ERROR 58.
b) The injector with RFID, firstly can only use syringes with chip, if syringes without chip then cannot be install in injector. Secondly the injector detects the first use of syringe with RFID tag will automatically exhaust the air. If the RFID tag has been detected and used, it will not automatically exhaust air again.
c) When you install the syringes with chip, pls make the chip on the left side of injector, then install it and rotate the syringe by 90ºin clockwise, when the RFID tag on the syringe is detected, a beep will be heard, indicating that the syringe is in place. At the same time, the push rod will automatically move forward to exhaust air until it reaches the front limit.
d) Once the injector detected the syringe with RFID, the “syringe” on monitor will change color from grey to green and blue.

2 System Overview

The contrast media injector is comprised of an injector arm, a main controller, and a monitor. The monitor is the primary interactive interface between the system and the user. The hand switch is basically an on/off button. It gives the user very convenient to control injection by hand pressing instead of clicking icons on the screen. The injector arm is the system's execution assembly consisting of ball screws, reduction gears, and motors. The execution assembly implements injection, filling, and expelling. The injector arm incorporates a portion of the user interface. The injector arm control board processes the button, limit switch and encoders signals.

The electric units in the main controller including the main control board, power unit and motor drivers process user commands from the monitor and the injector arm, sending back the processed results to them to be provided to the user. In addition, the motor drivers control the motor on injector arm to carry out injection, medical fluid suction, and expelling air. The power unit is sole power source of the system and applies electric power to the monitor and injector arm.

Data and commands transmission between the monitor and main controller is the way of serial communication. Same is between the main controller and injector arm.

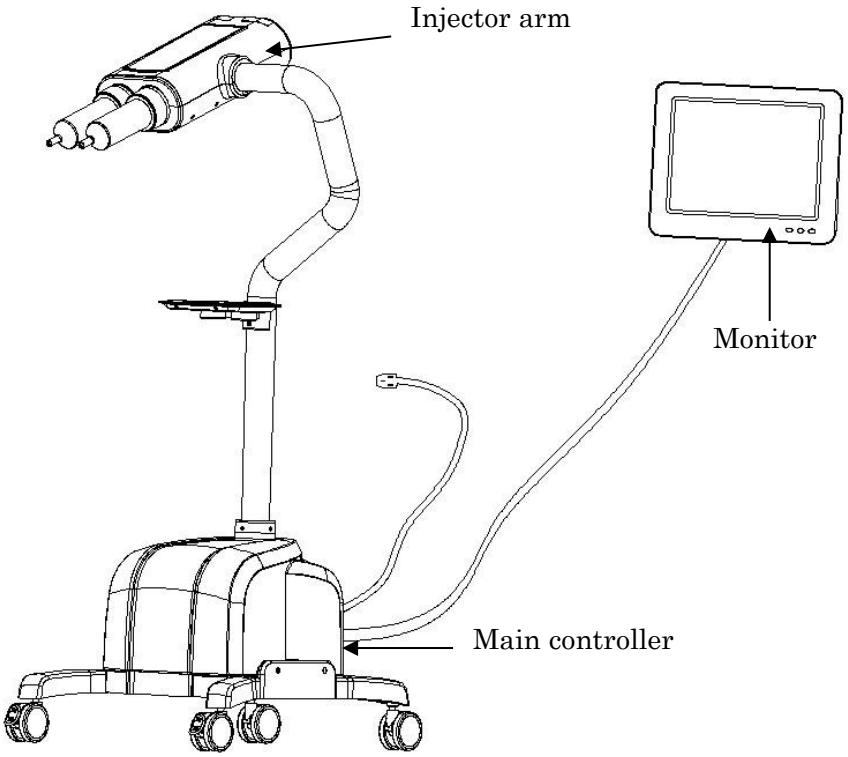
Three configurations of the contrast media injector made by Seacrwon company are defined into these three modes according the way to install the injector arm: trolley mount, ceiling mount, and wall mount. This manual is focused on the trolley mount injectors. The users ordered ceiling mount or window mount should install and use the injector according to PT-010-218 SAS Instruction Manual.

The manufacture offers the users the IV pole and the heat maintainer as optional parts. The users ordered the options of the IV pole and the heat maintainer should read PT-010-219 IVPS Instruction Manual and PT-100-005 HM User’s Manual carefully before installing and using.

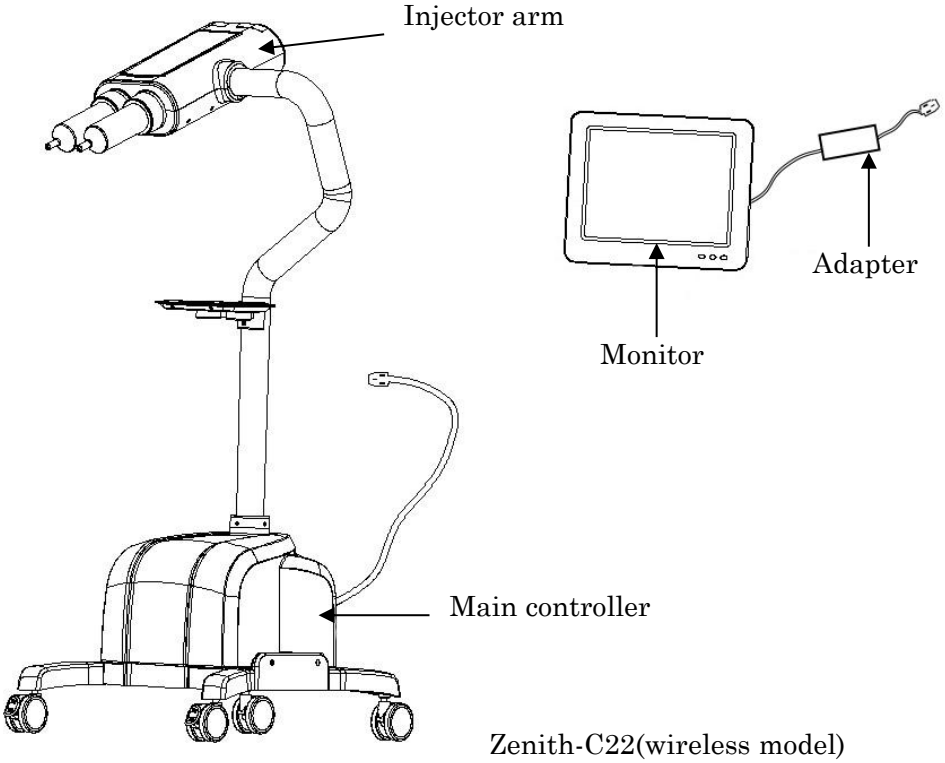
2.1 Zenith-C22

The Zenith-C22 is dual syringe systems.

The injector arm and main controller of model Zenith-C22 are located in the scanning room. Its monitor is typically located in the control room.



Zenith-C22(Standard)

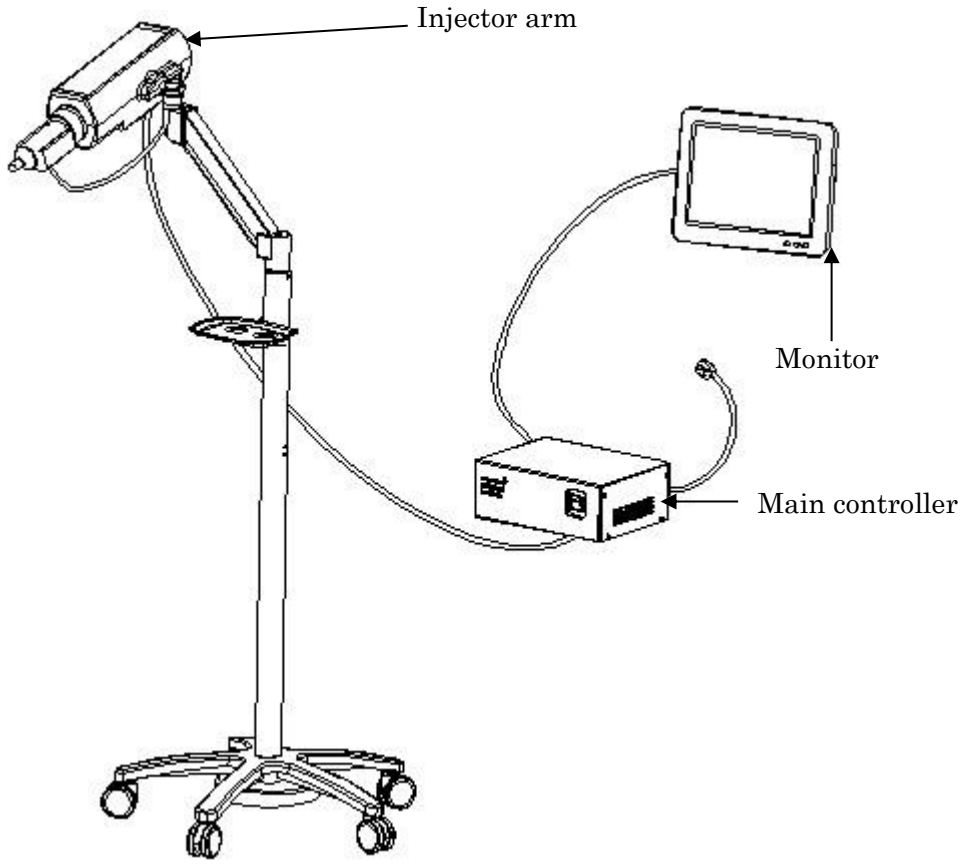


Zenith-C22(wireless model)

2.2 Zenith-C20

The Zenith-C20 has one syringe configuration.

Zenith-C20 injector arm is located in the scanning room, while the main controller and monitor are typically located in the control room.



Zenith-C20

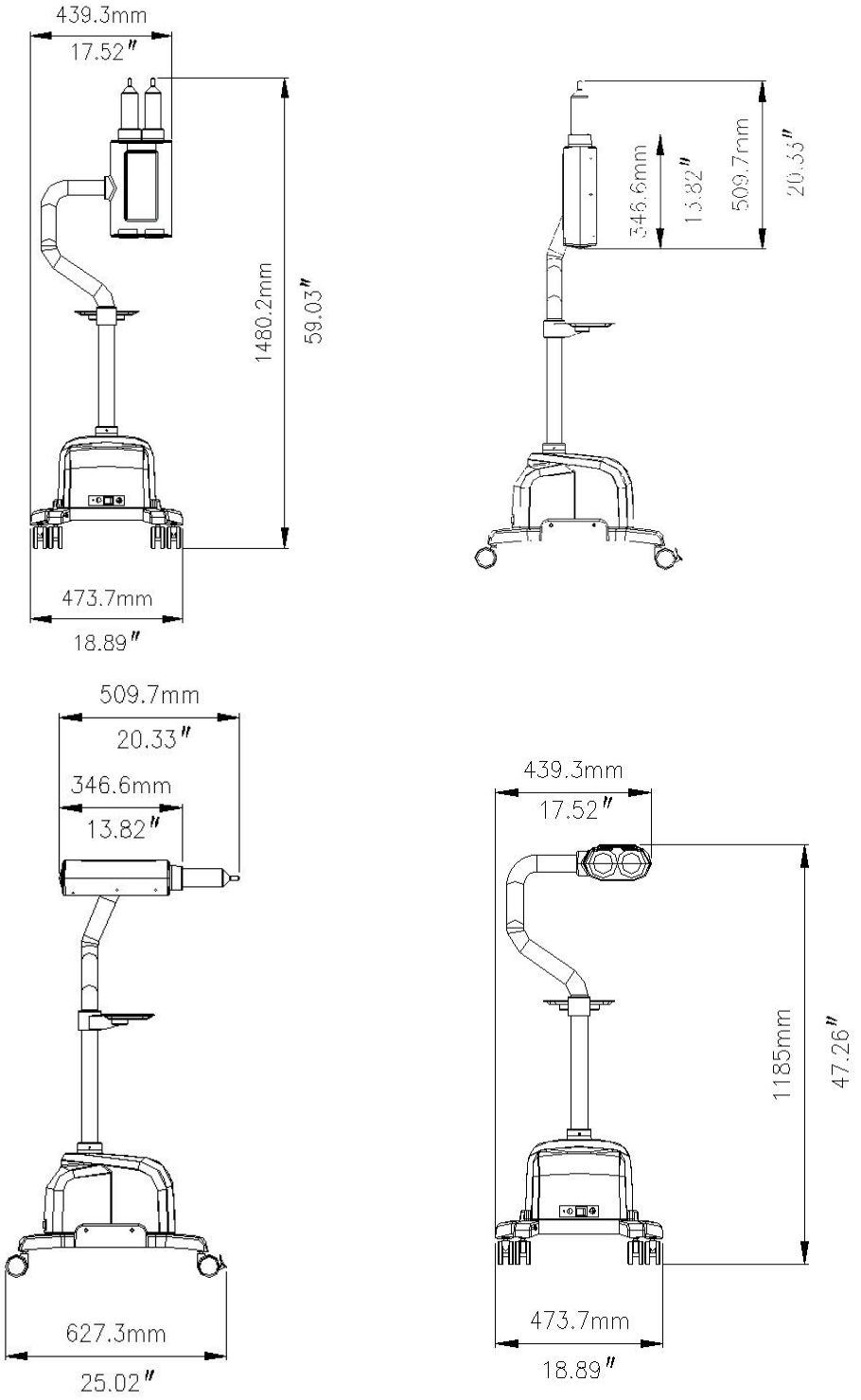
2.3 Specifications

2.3.1 Dimensions and Weights

Assembly of Injector Arm and Main Controller of Zenith- C22

Weigh of: 19.5 Kg

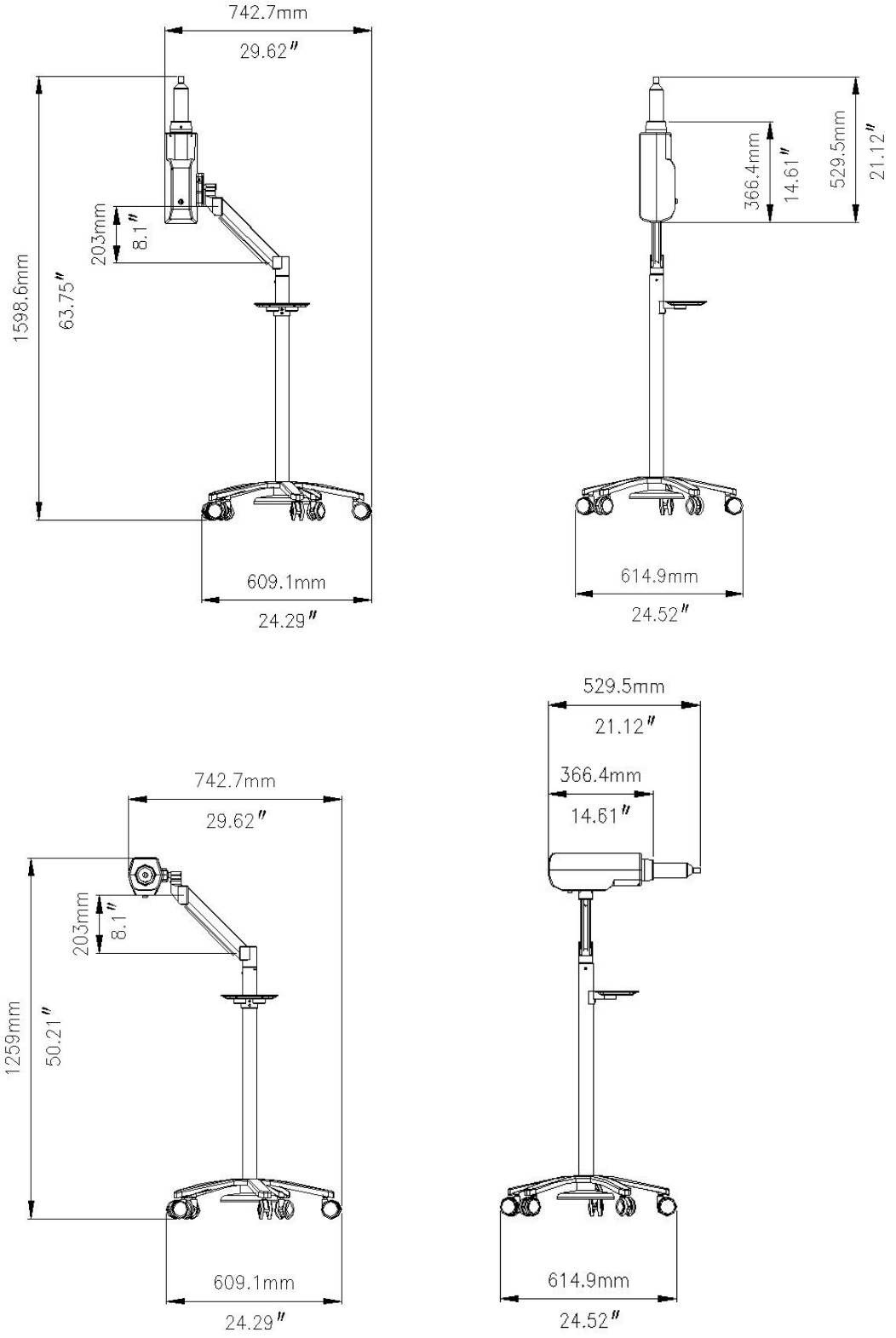
Dimension:



Assembly of Injector Arm and Main Controller of Zenith- C22

Zenith-C20 Injector Arm and Stand

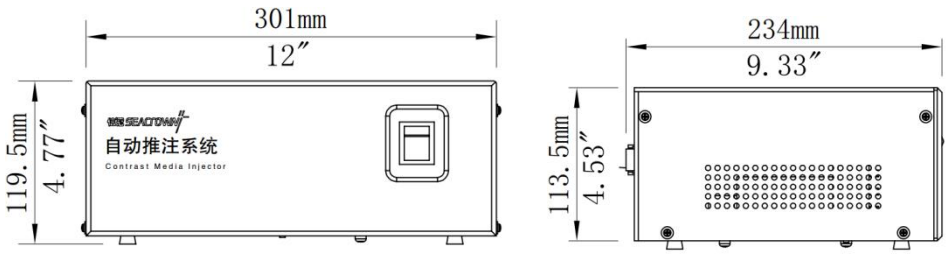
Weight: 16.5 Kg
Dimension:



Zenith-C20 Injector Arm and Stand

Zenith-C20 Main controller

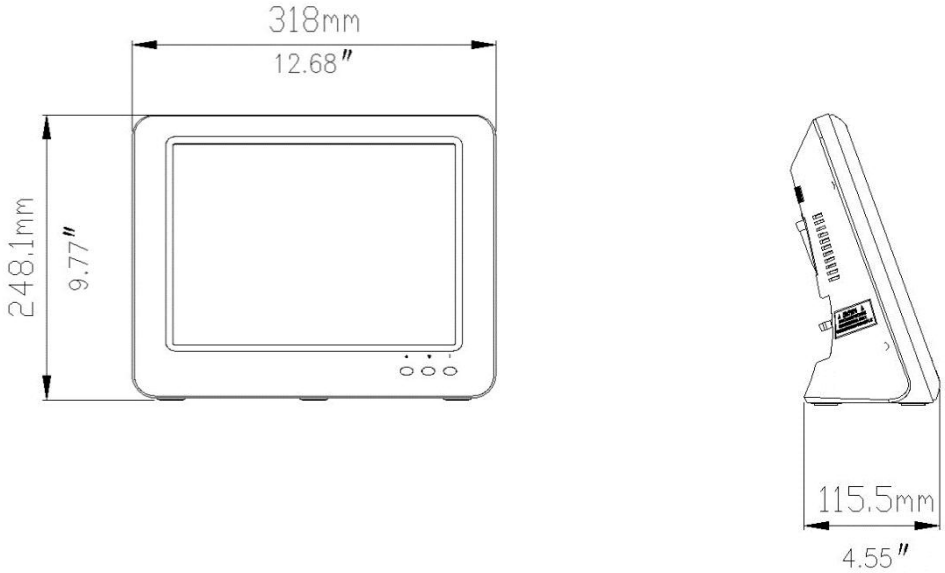
Weight: 6.2 Kg
Dimension:



Zenith-C20 Main controller

Monitor

Weight: 4.1 Kg
Dimension:



Monitor

2.3.2 Environmental Requirements

Transportation and Storage:

Temperature: -25℃ to 70℃

Humidity: 5% to 100% R.H.non-condensing

Air Pressure: 48kPa to 110kPa

Operating:

Temperature: 10℃ to 40℃

Humidity: 20% to 90% R.H.

Air Pressure: 69kPa to 110kPa

2.3.3 Electrical Requirements

a.c.220，50Hz，200VA

2.3.4 Fluid Delivery Performance

Description	Specification
Syringe System	Zenith-C22: two 200mL Zenith-C20: one 200mL
Volume	0.1 mL to maximum syringe capacity in0.1mL increments
Flow Rate	0.1 to 10 mL/sec in 0.1 mL/sec increments
Programmable Pressure Limit	300 psi default, user settable 50 to 350 psi
Hold Capability	More than 30 minutes.
Injection or Scan Delay	0 to 3600 seconds in 1 sec. increments
Multi-Phases	1-8 phases per injection
Programmed Volume	Zenith-C22 and Zenith-C20:1 to 200 mL
Fill Rate	3.0 to 8.0mL/sec
Pause	Programmable- 0 sec. to 999 sec. in 1 sec increments
Autofill	Fill rate 3.0 mL/sec to 8.0 mL/sec in 0.1mL/sec increments
Protocol Storage capability	100 protocols

2.4 Injector Arm

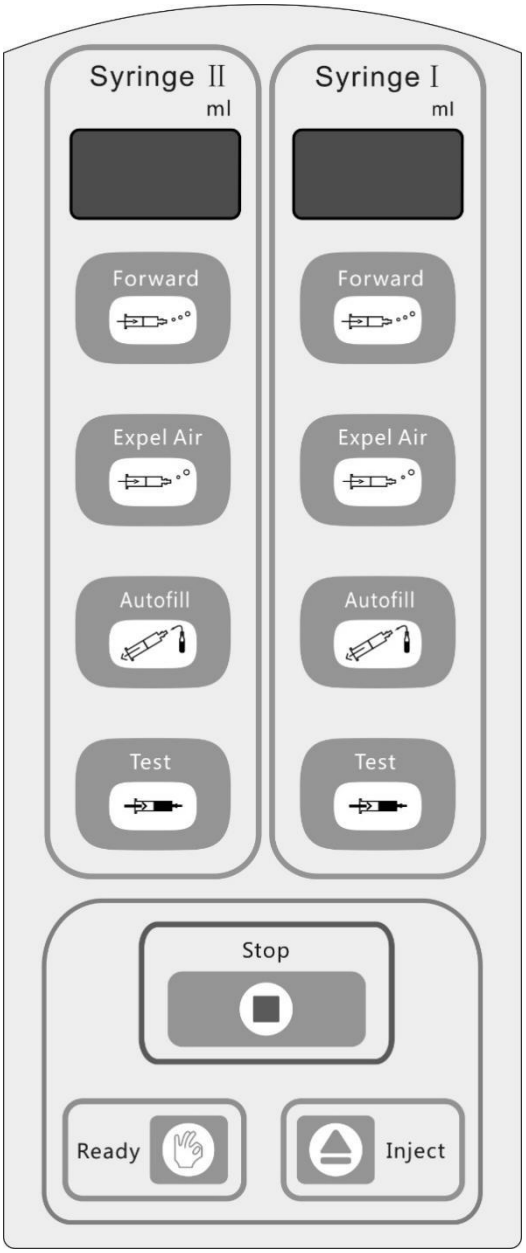
Operating the system requires knowledge of the user interfaces located on both the monitor and the injector arm.

The injector arm contains a membrane switch and monitor contains a touch screen display in order to interact with the user.

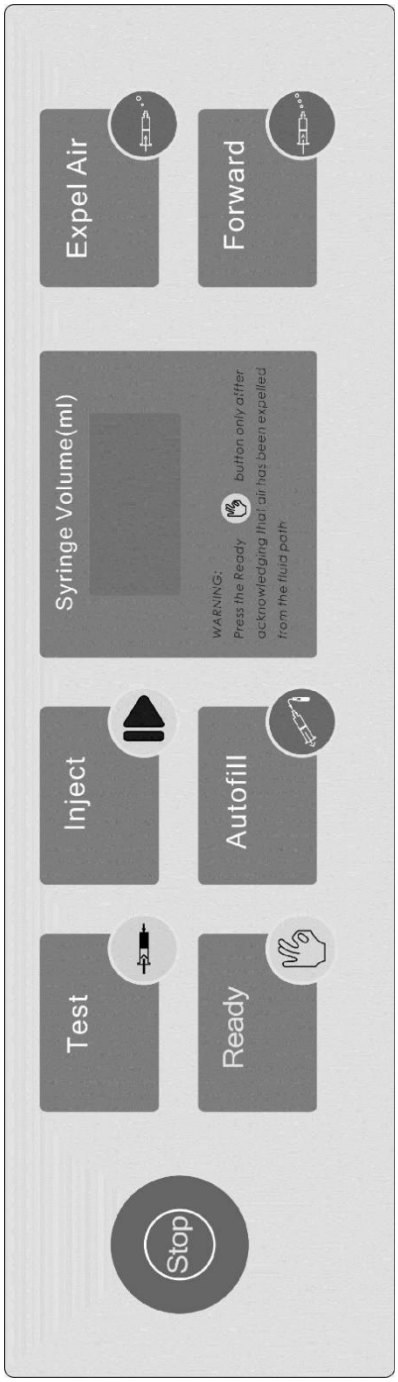
Through use of the injector arm, the user can:

- fill/expel syringe(s)
- make system ready
- test injection
- start/stop injection.

Zenith- C22 injector arm overlay:



Zenith-C20 injector arm overlay:



2.4.1 Moving Piston Rod

[Expel Air] button

Pressing on the **[Expel Air]** advances piston rod. Releasing the button will stop the movement of the piston rod immediately.

If the piston rod is at fully advanced position or the injector being Ready statue, this button will be unavailable.

The **[Expel Air]** is used to expel air from the fluid path at a lower flow rate.

The flow rate is programmable through the setup Screen.

[Forward] button

Pressing the **[Forward]** button fully advances the piston rod. Pressing the **[Stop]** button stops the movement of the piston rod.

When the piston rod is at fully advanced position or the injector being Ready statue, this button will be unavailable.

The **[Forward]** button is used to expel air from syringe at high flow rate. The flow rate is programmable through the setup Screen.

[Autofill] button

Pressing on the **[Autofill]** button less than three seconds fully retracts the piston rod unless pressing the **[Stop]** button.

Pressing on the **[Autofill]** button more than three seconds, the system acts integrated movements. First the piston rod is retracted to fill the protocoled Autofill volume. Then it will be advanced to expel the protocoled Auto Expel volume.

[Stop] button

Press this button to stop the movement of the piston rod immediately at any time.

2.4.2 Getting System Ready on Arm

The **[Ready]** button is only active after pressing **[Expel Air]** button to purge air from both syringes (piston rod must move forward to expel a minimum of 1 (one) mL of contrast/saline).

After pressing the **[Ready]** button, the system is Ready to injection and the indicator light illuminates orange.

WARNING! Press the [Ready] button only after expelling air and after completing other preparations (such as checking the correctness of the injection protocol).

IMPORTANT! If the system is in Ready status any buttons on the injector arm will be unavailable. Press [Stop] button is a way to make the system not ready.

2.4.3 Test Injection

Press **[Test]** button to start test injection when the injector being Ready. The piston rod will move from the inner to the outer for protocoled volumes at protocoled flow rate.

The **[Test]** button is used to check whether the venipuncture procedure is correct and safe.

The flow rate and volume can be programmed through the setup Screen.

CAUTION! It is very important way to improve the safety of the injection and to check whether the venipuncture procedure is correct. The system should always perform the test injection before beginning to inject automatically.

2.4.4 Controlling Injection

When the injector is ready and accesses the Injection screen on the monitor, press the **[Inject]** button to start injection.

Press the **[Stop]** button to stop injection.

2.4.5 Volume Display

The displayed volume on the digital LED indicates the volume that the syringe should contain as it corresponds to the current position of the piston rod of the injector arm.

2.4.6 System Status

(Zenith- C22 Only)

When the system is powered on and operates normally, the status indicators will light in green.

The status indicators will light in orange after the **[Ready]** button on the injector arm is pressed or the monitor has accessed the Injection screen.

The indicator flashes in orange indicating the system is injecting with the flashed syringe.

When the system detected some part malfunction, the indicators will light in red.

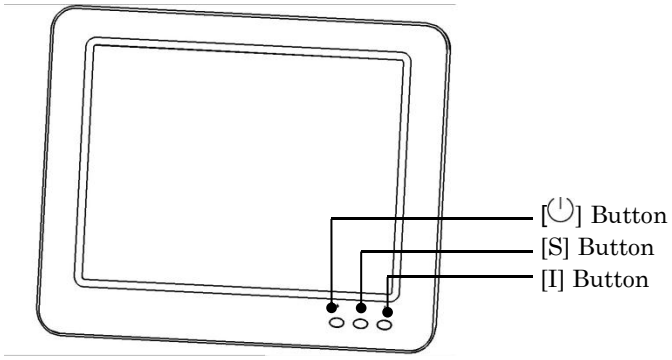
2.5 Monitor

Through use of the monitor's touch screen display, the user can:

- enter protocol parameters
- save protocols
- delete protocols
- recall protocols
- ready/start/pause/stop a KVO injection
- ready/start/pause/stop an injection
- review achieved parameters of delivered protocols
- setup system parameters
- read operation guide

2.5.1 Monitor Buttons

Three buttons are located on the monitor.



Monitor Buttons

All buttons are active on the Home Screen.

[⏻]

The **[⏻]** button turns on or off only the LCD power.

[S]

Press the **[S]** button to access the Protocol Screen. The current protocol display on the Home Screen will be saved by inputting protocol name and clicking the **[Save]** icon.

When the system is in the inject screen, the current injection stage is syringe I, and the next stage is in syringe II, press the [S] button, the system will stop the injection process of syringe I and begin to inject for syringe II automatically.

[I]

The **[I]** button is designed to control injection and renew the monitor software.

Press the **[I]** button to start inject. When the system is injecting, pressing the **[I]** button can pause inject.

When a flash disk storing monitor software is connected to the monitor USB socket, pressing the **[I]** button will start to renew the monitor software. The monitor buzzer will make sounds till the updating finished. The system will run on updated software after reboot.

2.5.2 monitor Display Screens

Start screen— Upon power-up, this screen is automatically displayed. Four notional flags, representing Chinese, English, German, and French, are located along lower right corner of the display. The user has 8 seconds to select the system language by clicking one of the national flags to select its native language. After displaying the Start screen for 8 seconds, the system will display the Home Screen in selected language or in the language last selected if not clicking any flag.

Located along the lower portion of the monitor display are the following 5 icons: **[Home]**, **[Protocol]**, **[System]**, **[History]** and **[Help]**. These icons allow access to their respective modes of operation.

Home Screen — The system will enter the Home Screen after the start screen is displayed for 8 seconds. All protocol information needed by the system is contained within the Home Screen. To access the Home Screen when displaying any other screen, click the **[Home]** icon located on the lower right-hand side of the screen.

Protocol Screen — All stored protocol information can be searched within the Protocol Screen. Accessing this screen allows the user to recall, store, rename and delete protocols. To access the Protocol Screen, click the **[Protocol]** icon located on the lower portion of the Home Screen.

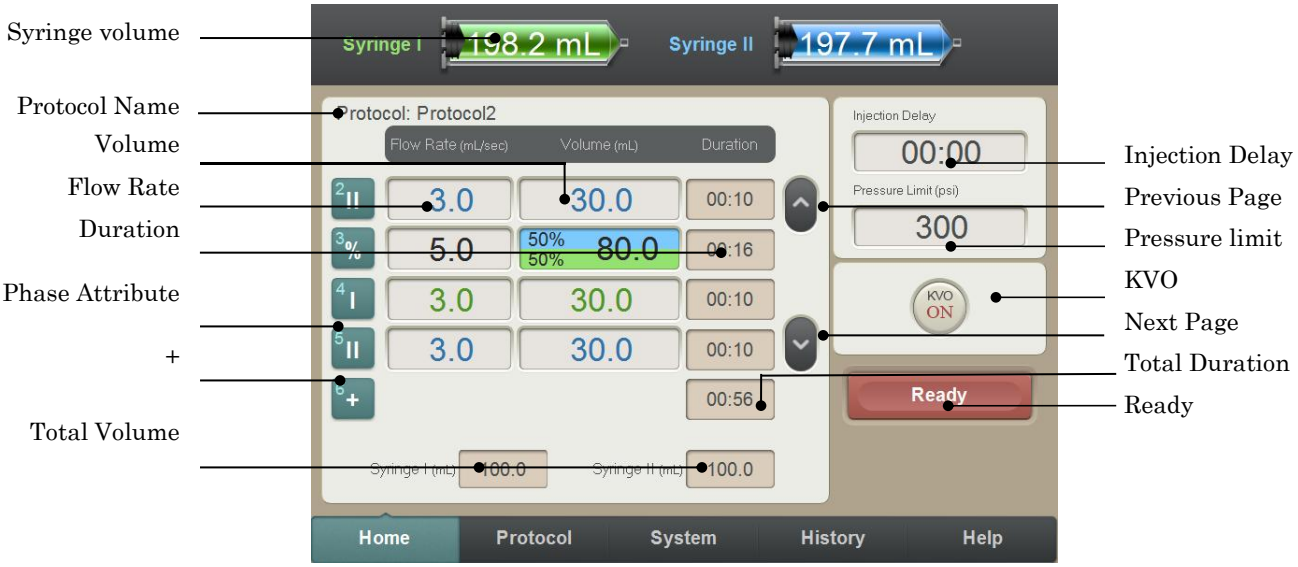
System screen — Accessing this screen allows the user to set parameter defaults, change the language, set the time, perform detections or calibrations, and read the product information. To access the System screen, click the **[System]** icon located on the lower portion of the Home Screen.

History Screen — All information pertaining to the results of a delivered injection is located within the History Screen. To access the History Screen, click the [History] icon located on the lower portion of the Home Screen. The Home Screen appears after a self-checking sequence is performed. All other screens are accessed from the Home Screen.

Help Screen — To access the Help Screen, click the **[Help]** icon on the lower portion of the Home Screen. The Help Screen information includes the operation guides to power on/off the system, prepare injection, control and injection.

2.5.3 Home Screen

Zenith- C22 Home Screen



Home Screen of Zenith-C22

Zenith-C20 Home Screen

Home Screen of Zenith-C20

The information displayed on the Home Screen which could not be programmed directly is the following:

“Syringe Volume”

“Syringe Volume” indicates the relative position of the plunger in the syringe thus indicating how much fluid may be in the syringe.

“Total Volume”

“Total Volume” is the total volume programmed to be delivered in a protocol for a syringe.

“Duration”

The value in this column indicates the duration of a protocol phase (i.e., time to complete injection in seconds) based on the entered volume and flow rate values.

The sum of all phase durations is displayed at the end of this column on Zenith-C22 screen, but in the Total Time column in Zenith-C20 screen.

“Protocol Name”

The name of the protocol currently displayed on the Home Screen is located in this area of the screen.

The injector can store as many as 100 sets of injection protocols, each of which has an identification number defined as **Protocol name**.

The following parameters can be setup by the user:

[Flow rate]

The values entered in this column indicate rate of delivery of the contrast medium and saline during each respective phase. Flow is expressed in milliliters/second.

The values can be set by clicking the number area.

[Volume]

The values entered in this column indicate the volume of contrast medium and saline to be delivered during each respective phase. Volume is expressed in milliliters.

The values can be set by clicking the number area.

[Injection Delay] or [Scan Delay]

The value entered in this column is time of injection or scan delay. The text at above this column defines injection or scan delay.

Inject Delay is a countdown timer that begins counting when the Inject command is activated. The injection is started when the inject delay counter reaches 0 (zero).

Scan Delay is a countdown timer that begins counting when the Start command is activated and stops when the counter reaches 0 (zero). The scan start signal will initiate once the timer reaches 0 (zero).

[Pressure Limit]

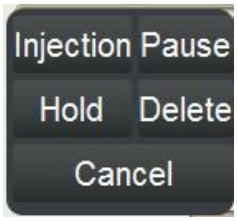
The value entered in this column is pressure limit. The pressure limit is the maximum thrust which the injector can provide. When the required power to implement the protocol injection is greater than the maximum thrust, the injector can't complete correctly in accordance to the protocol parameters.

[Phase Attribute]

Located along the left line of the screen are **[Phase Attribute]** icons**.** The number on the icon indicates the Phase order, and the character indicates the Phase Attribute.

Click any one of **[Phase Attribute]** icons and the Phase Attribute setup window appears.

Phase Attribute setup window of Zenith-C22



Phase Attribute setup window of Zenith-C20

The abbreviations of the words on the Phase Attribute setup windows are the following characters: **I**, Ⅱ, **I**+Ⅱ, **H**, and **P**.

I is the abbreviation of **Injection** on Zenith-C20 screen, **Syringe I** on Zenith- C22 screen. Phase Attribute **I** indicates injecting from the syringe (Syringe **I** of Zenith- C22).

Ⅱ is the abbreviation of **Syringe** Ⅱ. Phase Attribute Ⅱ indicates injecting from syringe Ⅱ.

I+Ⅱ is the abbreviation of **Syringe I**+Ⅱ. Phase Attribute **I**+Ⅱ is defined as mixture injection. It indicates injecting from syringe I and syringe Ⅱ at the same time. The flow rate column defines the final delivery rate added by the rate of the two syringes. The volume column contains three parameters. The right part defines the sum of volume will be delivered from the two syringes. At the left there are two percentages to define the ratio of the volume will be delivered from syringe I and Syringe II. Above percentage defines the ratio for syringe I, and low for syringe II.

As an example, calculate the flow rate and volume for each syringe in the protocol on the Home Screen in Page 26. Phase 4 is mixture injection of flow rate 5.0mL/s and volume 80mL. The duration is 16 second (80mL over 5mL/s). The syringe I will deliver 48mL (60% of 80mL) at flow rate 3mL/s (48mL over 16 second). The syringe II will deliver 32mL (40% of 80mL) at flow rate 2mL/s (32mL over 16 second).

H is the abbreviation of **Hold**. Phase Attribute **H** indicates **Hold**. When injection procedure goes to Hold phase, the injector will suspend injection. Click **[Continue]** icon or press the hand switch to continue the injection. Click the **[Stop]** icon to stop the injection.

P is the abbreviation of **Pause**. Phase Attribute **P** indicates **Pause.** When injection procedure goes to Pause phase, the injector will suspend injection. Pause time is a countdown timer that delays the start of the next phase. The next phase will start when the pause time counter reaches 0 (zero).

Click **[Delete]** icon to delete the selected phase. Click **[Cancel]** icon to cancel editing protocol.

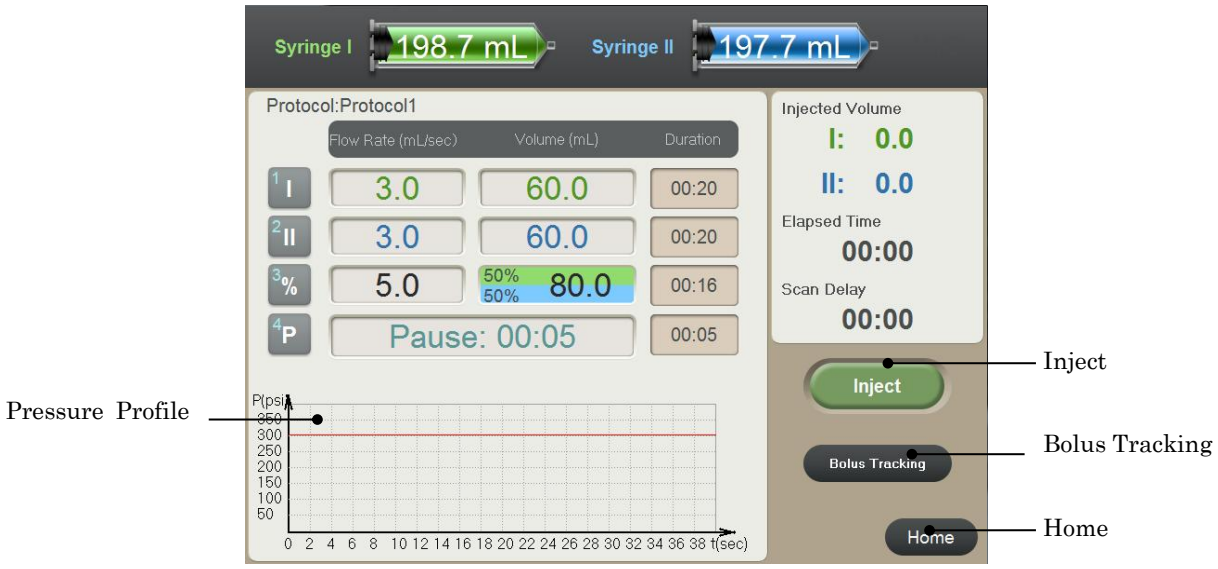
The function icons on the Home Screen are following:

[+] icon
Click **[+]** icon to insert a new phase.

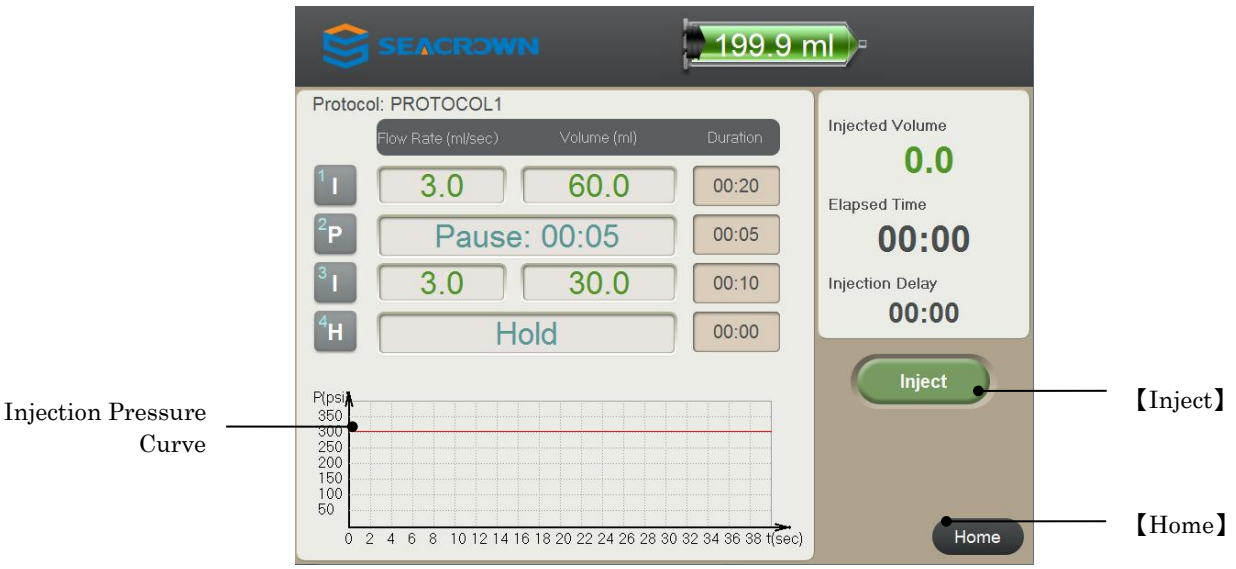
[∧] and [∨]icon**s**
[∧]- Previous Page icon
[∨]- Next Page icon
Because on the Home Screen only four protocol phases could be displayed, the two icons help user to check all phases of protocol of more than four phases.

[Ready] icon
Click the **[Ready]** icon on the Home Screen to access the Injection screen.

Injection Screen



Injection Screen of Zenith-C22

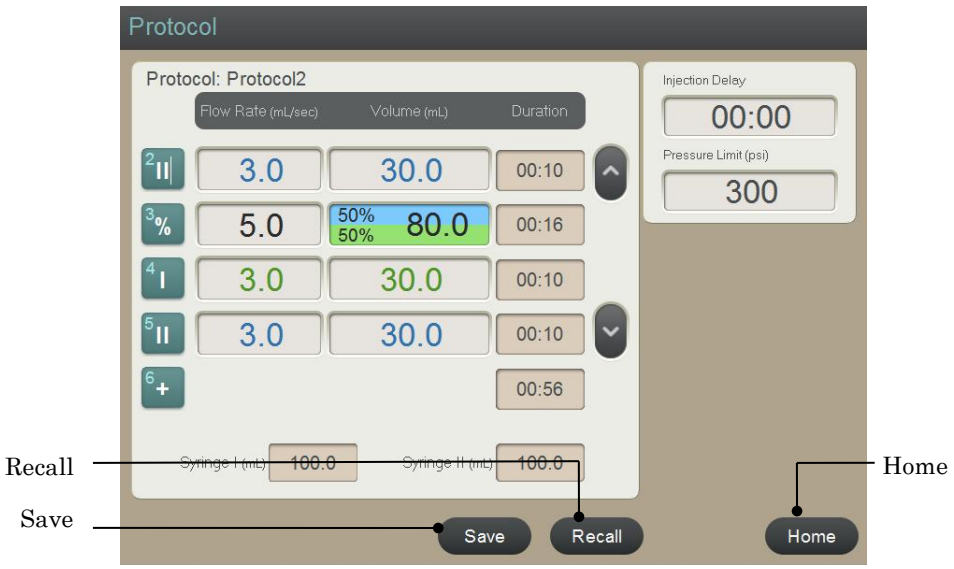


Injection Screen of Zenith-C20

2.5.4 Protocol Screen

Click the **[Protocol]** icon on the **Home Screen** to access the Protocol Screen on which the user can store or recall injection protocols.

The system can store up to 100 eight-phase protocols. Each protocol can have a name consisting of up to 20 alpha-numeric characters.



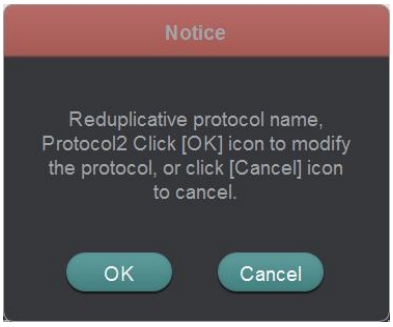
Protocol Screen

Store Protocol

Click [**Save]** icon of the Store or Recall Protocol Screen to access the Store Protocol Screen.

Store Protocol Screen

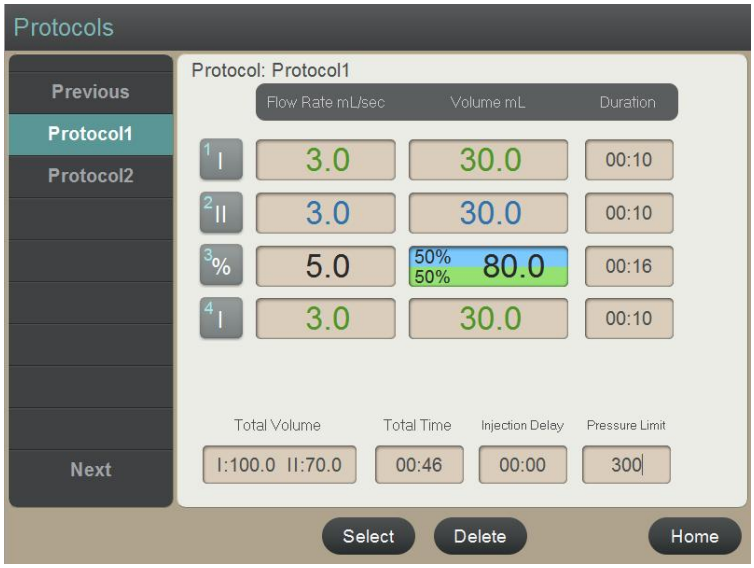
Input a name for the displayed injection parameter and click **[Save]** icon in above screen to store a new protocol. If the name is duplicated, a notice will appear to guide you to rewrite protocol with new parameters by clicking **[OK]** icon or discard any change to previous protocol by clicking **[Cancel]** icon.



Notice of duplicated protocol name

Recall Protocol

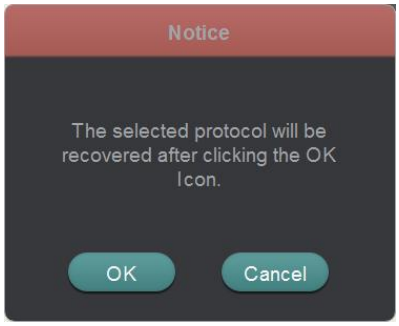
Click **[Recall]** icon on the Protocol Screen to access the Recall Protocol Screen. A segment of stored protocols will be displayed on the left of the screen. Use **[Previous]** or **[Next]** icon to view all stored protocols. The right of the screen displays one protocol with its name and parameters. Click **[Select]** icon on this screen to select displayed protocol and return to Home Screen.



Recall Protocol Screen

Delete Protocol

On Recall Protocol Screen click **[Delete]** icon to delete the protocol selected.



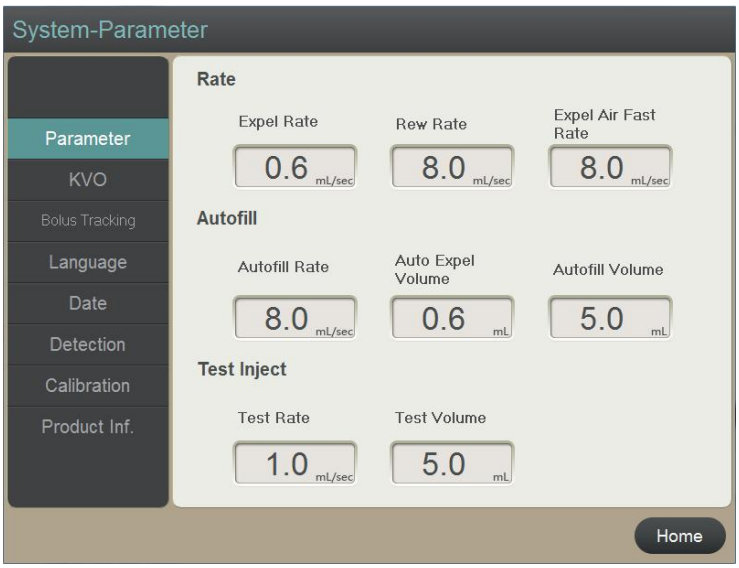
Notice to delete protocol

Click **[ok]** icon to confirm to delete the protocol.
Click **[Cancel]** icon to return to Recall Protocol Screen without deleting.

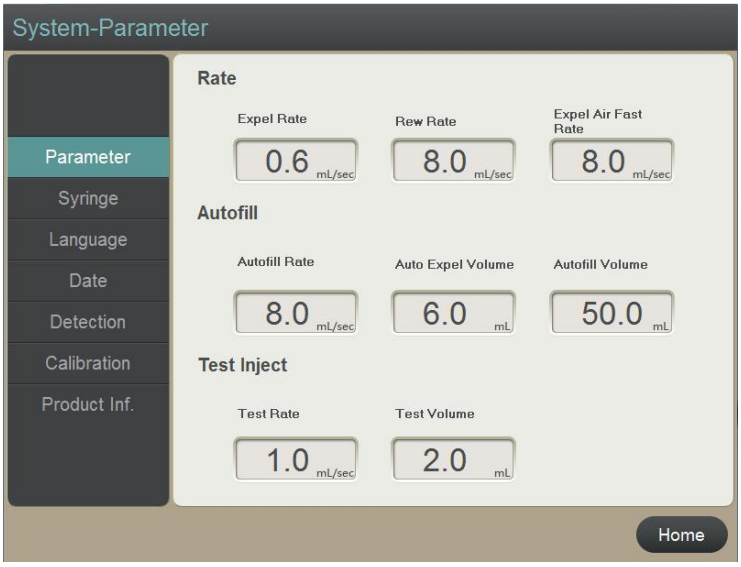
2.5.5 System Setup and Test Screens

Click the [**System**] icon on the Home Screen to access the first screen of the System Setup and Test Screens.

The Zenith-C22 monitor screen is used to describe system setup and test. Except KVO and Bolus Tracking, the single syringe system monitor has the same setup and test with the Zenith-C22.



Parameter Setup Screen of Zenith-C22



Parameter Setup Screen of Zenith-C20

Parameter setup

Click **[Parameter]** icon to access the Parameter Setup Screen. All parameters can be set by clicking their value columns. Click any programmable block. The selected block will be blank. A numeric keypad and parameter range window appears. Enter the desired values.

・**Expel Rate**, ranged from 0.1 mL/sec to 0.6 mL/sec, is the flow rate of the system when **[Expel Air]** button being pressed.

・**Rew Rate**, ranged from 3.0 mL/sec to 8.0 mL/sec is the flow rate after press **[Autofill]** button.

・**Expel Air Fast Rate**, ranged from 3.0 mL/sec to 8.0 mL/sec, is the flow rate after press the **[Forward]** button.

・**Autofill Volume**, ranged from 0.0 mL to 200.0 mL, is the volume of autofill after press **[Autofill]** button on for more than 3 seconds.

・**Autofill Rate**, ranged from 3.0 mL/sec to 8.0 mL/sec, is the flow rate after **[Autofill]** button on for more than 3 seconds.

・**Auto Expel Volume**, ranged from 0.0 mL to 10.0mL, is the volume of expel air of the autofill protocol.

When using a Quick Fill Tube (QFT), program the expel volume being 30 mL.

For other filling devices, consult the manufacturer's instructions for use.

・**Test Rate**, ranged from 0.1 to 5.0 mL/sec, is the flow rate of test injection.

・**Test Volume:** Ranged from 0.1 to 10.0 ml is the volume of test injection.

KVO Parameter setup

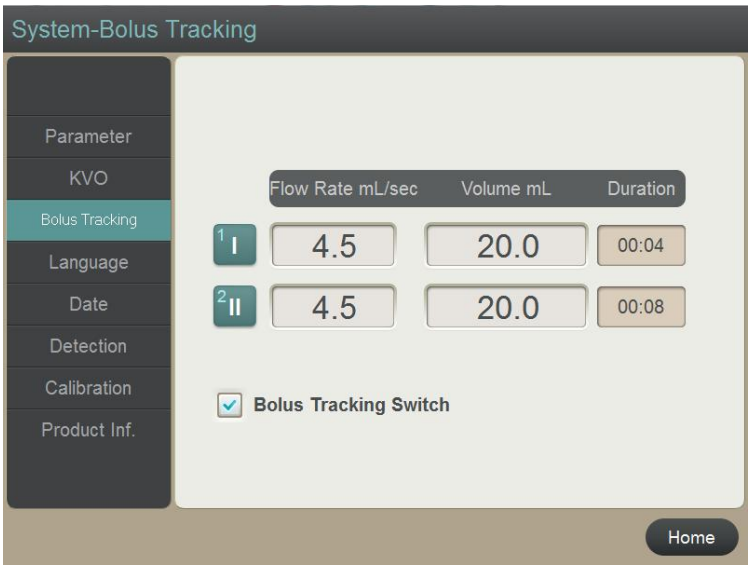
Click **[KVO]** icon to access the KVO Parameter Setup Screen. On this screen click the pane before a flow rate to select it as KVO injection flow rate. The √ symbol directs the language selected.

KVO Parameter Setup Screen

Bolus Tracking Parameter

Bolus Tracking Injection --an injection of a small volume of contrast, followed by a small volume of saline--can be delivered to the patient to determine the optimal scan delay needed to capture the contrast agent in the area of interest.

Bolus Tracking is programmable protocol with two phases, and users can set the protocol parameter. Click **[Bolus Tracking]** icon to access the Bolus Tracking Parameter Setup Screen.



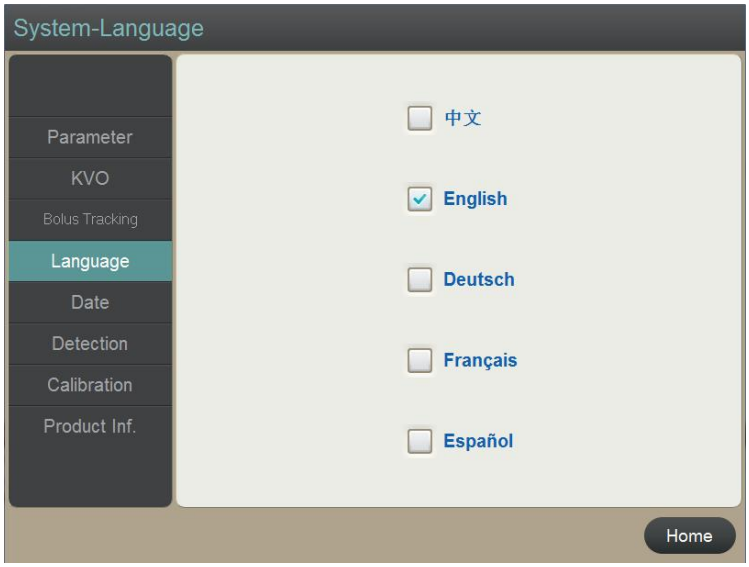
Bolus Tracking Parameter Setup Screen

On this screen click the pane before Bolus Tracking Switch to display √ to enable the Bolus Tracking. When the Bolus Tracking is enabled, the Bolus Tracking icon is on the Injection screen (chapter 5.7). When the pane is blank, the Bolus Tracking is not enabled and no Bolus Tracking icon is on the Injection screen.

Click value columns to input desired flow rate and volume values.

Language Selection

Click **[Language]** icon to access the Language Selection Screen.

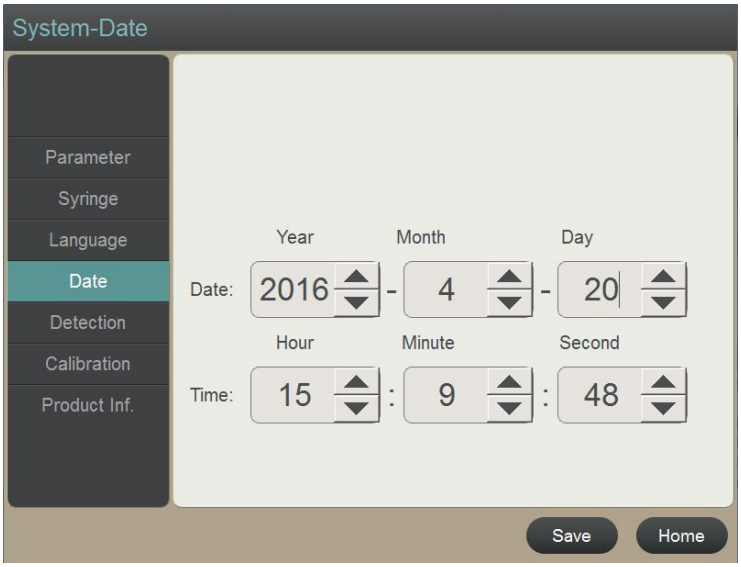


Language Selection Screen

The √ symbol directs the language selected. The system screen language can be selected in Chinese, English, German or French.

Date and Time setup

Click **[Date]** icon to access the Date and Time Setup Screen.



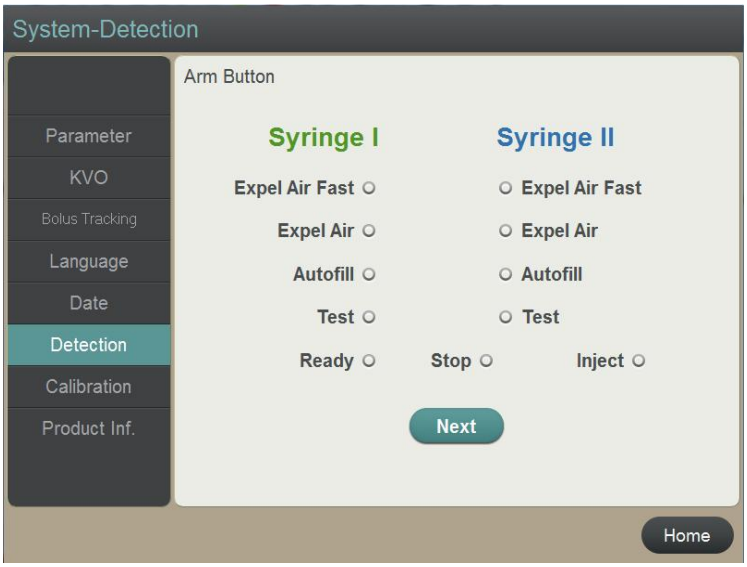
Date and Time Setup Screen

Click the relevant up and down arrows to set the time and date. The modification would be stored by clicking the **[Save]** icon. If not clicking the **[Save]** icon, the setup value would be ignored.

Detection

Click the **[Detection]** icon to access the Arm Button Test Screen.

The system will not do anything except test when the system is in the Arm Button Test Screen.

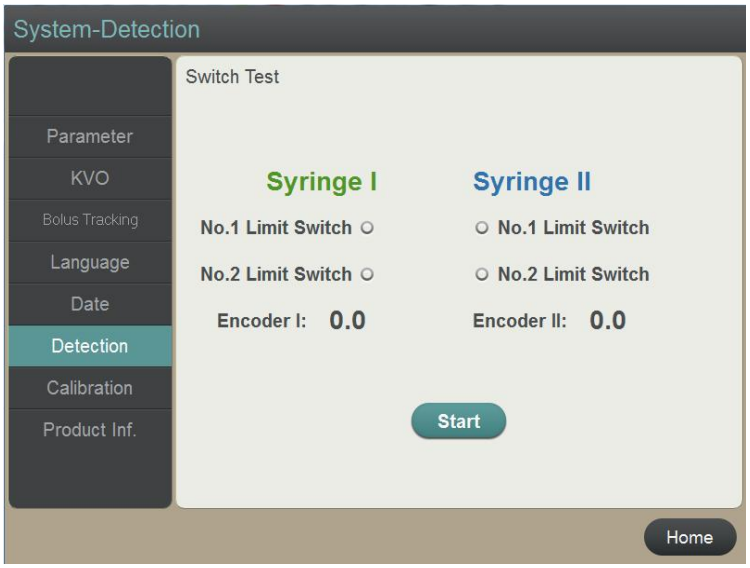


Arm Button Test Screen

Press all buttons orderly on the system arm panel. The cycle on the screen with the same name as pressed button should be replaced by √. If there is any button name followed with √ on the screen without pressing same button or not response for any pressed button, the arm panel was defected.

Detection

Click **[Next]** icon on the Arm Button Test Screen. Test Screen to assess the Sensor Test Screen to check the sensors.



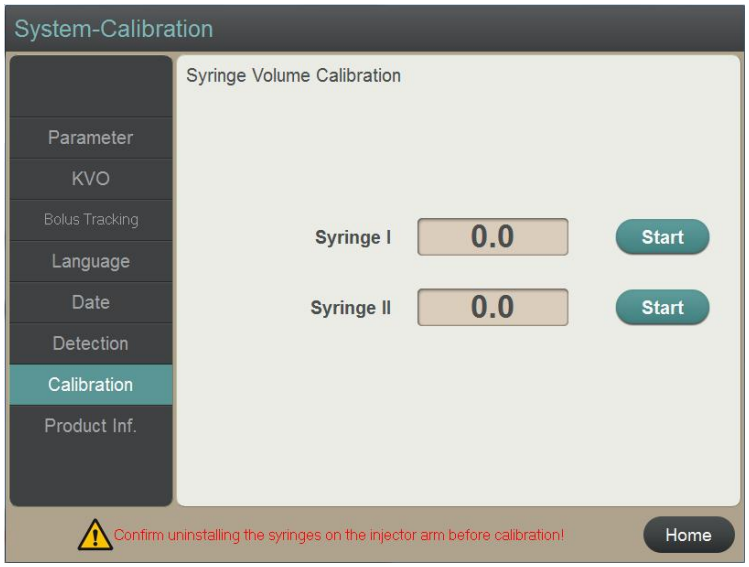
Sensor Test Screen

After confirming no syringe was installed, click **[Start]** icon to start testing. The user can stop the testing by clicking the **[Stop]** icon. The √ symbols will display for the sensors in good conditions in the testing. The sensor would be defected if there is no √ symbol with is after the test.

The values with the encoders should change continuously and should be around 200. If there is not any change of an encoder digital, this encoder would be defected.

Calibration

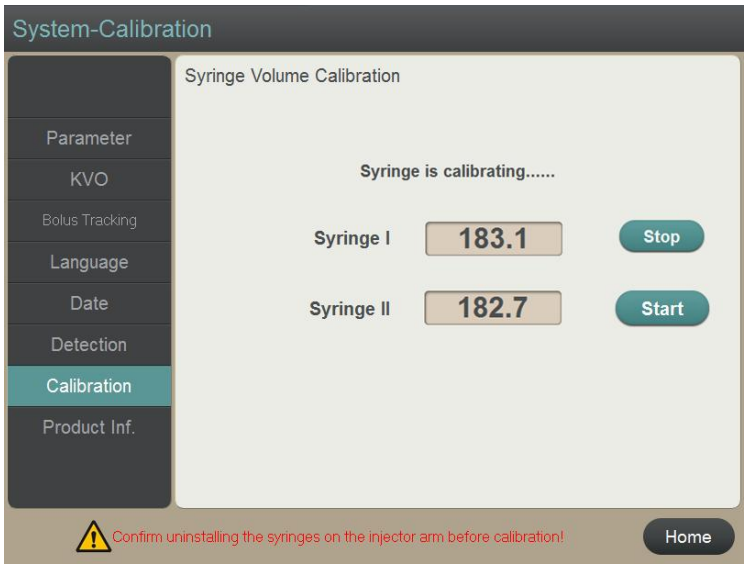
Click the **[Calibration]** icon to access the Volume Calibration Screen.



Volume Calibration Screen

The volume calibration should be run after any limit switch adjusting or injection pressure error reported.

After confirming no syringe was installed, click **[Start]** icon to start calibration. The values should be 0.0 after the calibration finished.

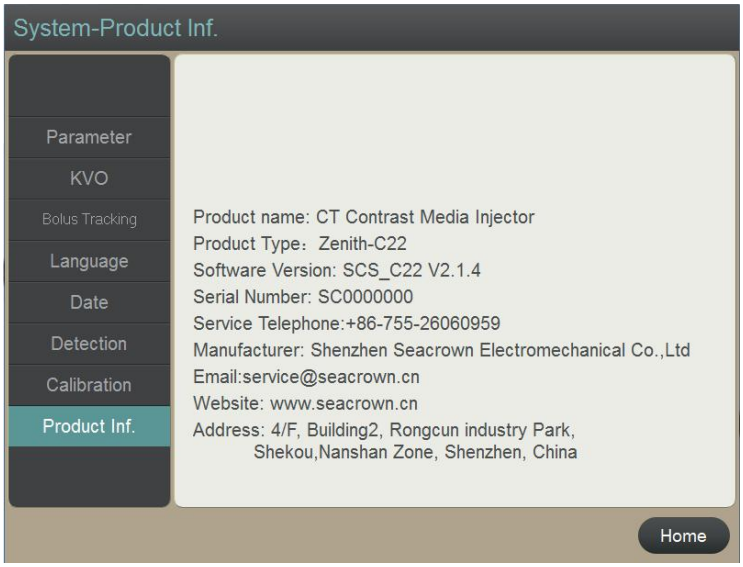


Volume Calibrating Screen

User can stop calibrating by clicking the **[Stop]** icon at any time.

Product Information

Click the **[Product Inf.]** icon to access the Product Information Screen.

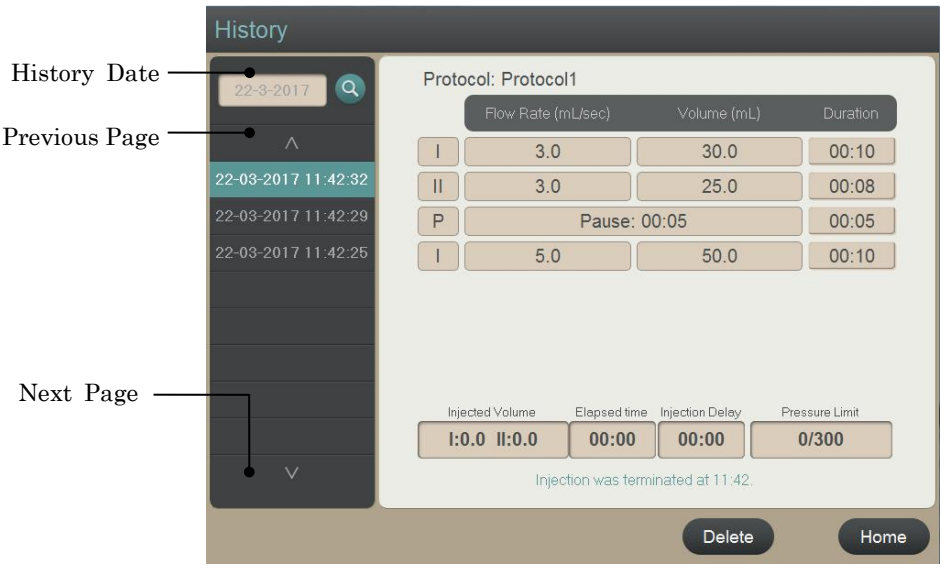


Product Information Screen

On this screen the user can get the product information, including the manufacture information, product model, serial no., software version, service contact phone no..

2.5.6 History Screen

Click the **[History]** icon on the **Home Screen** to access the Injection Record Screen.



Review Injection Record Screen

The system saves all injection data in reverse chronological order. The injection records include the protocol, elapsed time, injected volume, etc.

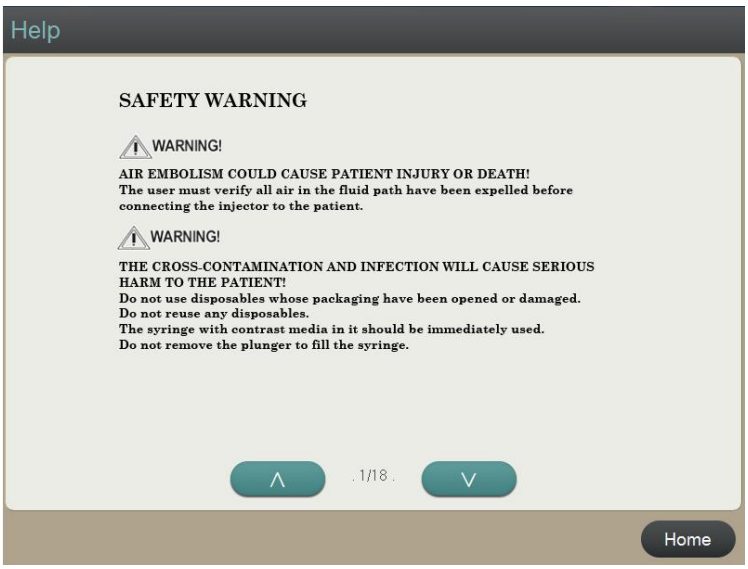
Click the **[∧]** icon or [∨] icon to search the date you intend to view. Click the line labeled date and time to view this injection record.

Click the search icon and input the date to get directly the injection records completed in that day.

The user can delete the selected record by clicking the **[Delete]** icon.

2.5.7 Help Screen

The Help Screen can be accessed by clicking **[Help]** icon on the Home Screen.



Help Screen

The Help Screen contains information about:

・The system safety warning

・The procedures to perform injection.

Clicking [∧] and [∨] to search the information you concern.

2.6 Main Controller

The primary functions of the main controller are to control and process communications with the monitor, control the motor driver, and to provide power to the system.

Components of the main controller include: main control board, system power units, and motor driver(s).

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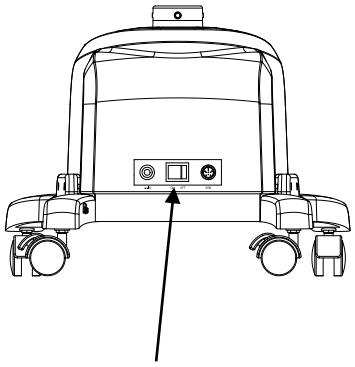
3 Power On/Off

3.1 Turning the System Power On

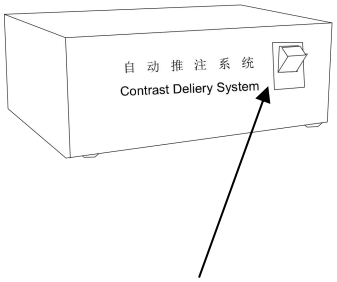
At the front of the main controller, place the switch to the ON position.

The indicators located on the top of the Zenith-C22 injector arm and the light located in the Zenith-C20 main controller power switch will illuminate green indicate the system power is ON.

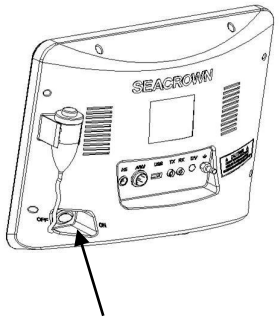
The monitor has its own power switch. At the rear of the monitor, place the switch to the On position. The Start screen is displayed to indicate the monitor power is On and the monitor computer starts power –up check sequence.



Zenith-C22 Main controller power switch



Zenith-C20 Main controller power switch



Monitor power switch

3.2 Turning the System Power Off

At the front of the main controller, place the switch to the OFF position to switch the system power. The monitor can be left ON. This allows for quicker and easier restarts the monitor.

4 **Ready**ing **Sequence**

This chapter discusses the proper techniques for programming protocol, loading syringe(s), filling syringe(s), purging air from the syringe(s) and tubing, priming the tubing, connecting the patient, and setting the system ready to inject.

The following instructions apply to Zenith-C20 or Zenith-C22, except the instructions on two syringes, KVO, and Bolus tracking only for Zenith-C22.

WARNING! AIR EMBOLISM COULD CAUSE PATIENT INJURY OR DEATH!
Always verify all air in the fluid path have been expelled before connecting the system to the patient.
The user is responsible for removing all air from the system.
To minimize air embolization risks, ensure that one user is designated to complete all injection procedures. If the user must to be changed, ensure that the new user verifies that no air in the fluid path.

WARNING! THE OCCURRENCE OF CROSS-CONTAMINATION AND INFECTION WILL CAUSE SERIOUS HARM TO THE PATIENT!
Do not reuse any disposables.
Using aseptic technique, install syringe, connect tube and connect to patient.
Syringe may not be used to store liquid for long periods of time.
Do not remove the plunger to fill the syringe.
Do not use disposables whose packaging has been opened or damaged.

WARNING! NON-COMPLIANT DISPOSABLES COULD RESULT IN PATIENT INJURY, OPERTOR INJURY AND/OR QUIPMENT DAMAGE.
Use the certified consumables recommended in this manual.

WARNING! IMPROPER MEDICAL FLUID VOLUME AND FLOW RATE MAY HARM PATIENTS.
Review Parameters! Prior to starting an injection, review all parameters thoroughly to ensure that they are correct and appropriate for the procedure.

IMPORTANT! Rotate injector arm down prior to injecting
Preheating the contrast media will help in the removal of air bubbles.

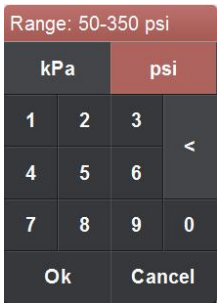
4.1 Deciding on Injection Protocol

The injection protocol which the system will inject according to is the protocol currently displayed on the Home Screen. The injection protocol can be programmed on the Home Screen. A stored protocol can be called to be the injection protocol.

4.1.1 Programming Protocol

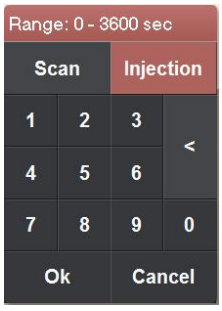
Refer to 2.5.3 Home Screen.

1. Click **[+]** icon to add a phase.
2. Click a [**Phase Attribute**] icon to change Phase Attribute.
3. Click any programmable block, such as Flow Rale or Volume or Delay or Pressure Limit. The selected block will be blank. A numeric keypad and parameter range window appears. Enter the desired values.
4. Click [**Pressure Limit**] column the Pressure limit setup window appears. Pressure is expressed in either PSI or kPa. Select pressure unit on this window.



Pressure limit setup window

5. Click [**Injection Delay**] (may be [**Scan Delay**]) column the Delay setup window appears. Select Injection or Scan Delay on this window.



Delay setup window

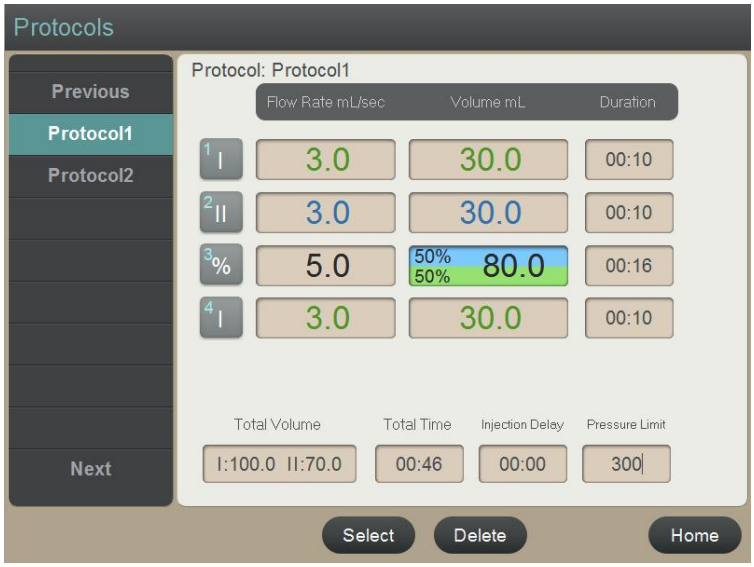
On all numeric keypad and parameter range windows, click **[ok]** icon to save the new values, or click **[Cancel]** to complete setup and remain original values..

Refer to 2.5.4 Protocol Screen to store a protocol.

4.1.2 Recalling Protocol

Refer to 2.5.4 Protocol Screen.

Click **[Recall]** icon on the Protocol Screen to access the Recall Protocol Screen. A segment of stored protocols will be displayed on the left of the screen. Use **[Previous]** or **[Next]** icon to view all stored protocols. The right of the screen displays one protocol with its name and parameters. Click **[Select]** icon on this screen to select displayed protocol and return to Home Screen.



Recall Protocol Screen

4.2 Installing Syringe

WARNING! The occurrence of infection will cause serious harm to the patient. Do not touch the interior of the syringe or expose the interior of the syringe to prevent contaminating the syringe.

Ensure that the piston rod has been fully retracted, or pressing the **[Autofill]** button retracts piston rod till it stopping automatically.

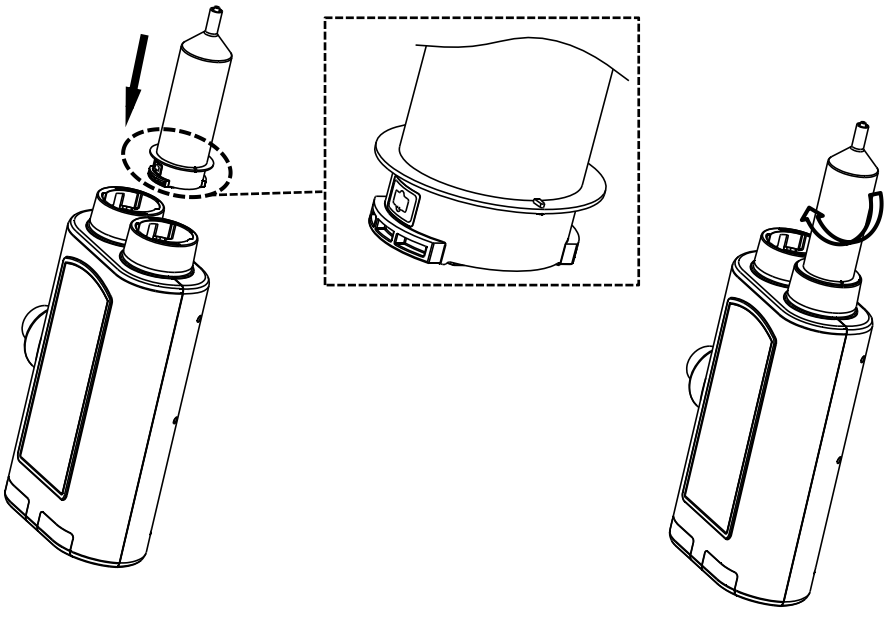
Get syringes out of packages (attention aseptic operation).

Hold on the middle part of the syringe with right hand to make the frame and circular ears align the frame and notches of the syringe chuck on the injector arm separately. Note that the syringe RFID tag is inserted in the direction of the membrane switch, as shown in the figure below.

Insert the Syringe into the syringe chuck until the syringe limit piece contact the plane.

Rotate the syringe by 90º in clockwise, when the RFID tag on the syringe is detected, a beep will be heard, indicating that the syringe is in place. At the same time, the push rod will automatically move forward to exhaust air until it reaches the front limit.

IMPORTANT! 1. The lock function must use a syringe with an RFID tag to operate normally.
2. The injector with the syringe locking function has an automatic exhaust function. The first use of the syringe with the RFID tag will automatically exhaust the air. If the RFID tag has been detected and used, it will not automatically exhaust air again.



Insert the syringe into the chuck

Rotate the syringe by 90º in clockwise

4.3 Interface display

The injector with a syringe locking function, when the syringe is not installed, the syringe is displayed in gray on the interface, and the device cannot be used normally.

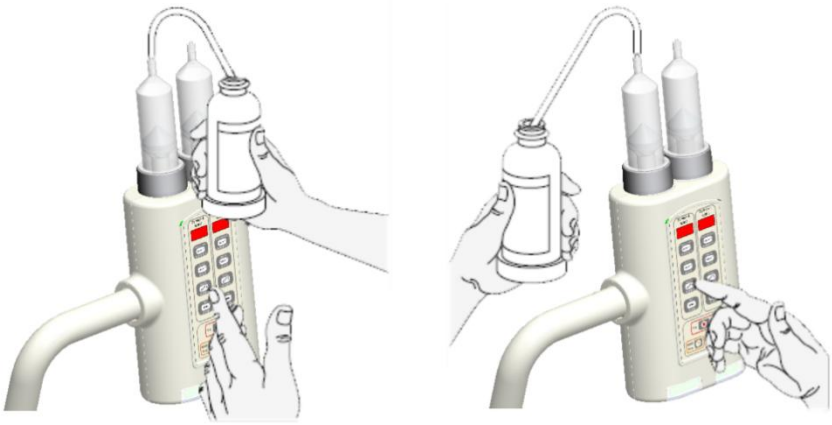
No Syringe installed

When the system detects that a valid injector is installed, the injector display on the interface lights up and the device is in normal use.

Successfully installed RFID syringe

4.3 Filling Syringe

Refer to the following figures to fill syringe(s).



Fill syringe right handed/left handed

After installing the syringe,

1. Rotate the injector arm to the vertical position.
2. Remove the protective cap from the syringe tip and store in a safe place for reuse in step 8.
3. Install the spike or slide the end of the shorter section of the QFT over the syringe tip. DO NOT TOUCH THE TIP.
4. Insert the spike or place the end of the longer section of the QFT into the container of medical fluid. To keep aeration to a minimum, verify that this end of the QFT is in the media and is NOT drawing air.
5. Press **[Autofill]** button following 4.3.1 to fill syringe manually or 4.3.2. to fill syringe automatically.
6. Carefully remove the spike or QFT from the syringe tip by twisting while pulling off.
7. To prevent contamination, replace the protective cap on the syringe tip. The injector arm should remain in the vertical position (to prevent leakage) until ready for injection.

4.3.1 Filling Syringe Manually

Press on the **[Autofill]** button and the piston rod is retracted to drawing the fluid into the syringe. Press the **[Stop]** button when either sufficient contrast medium or all of the contrast medium in the bottle has been drawn up.

4.3.2 Filling Syringe Automatically

Refer to 2.4.5 System screen to set the desired parameters of Autofill.

The Auto-Fill sequence is designed to automatically fill the syringe while minimizing the introduction of air to save operation time.

Press on the **[Autofill] button more than three seconds**. The system will automatically retract piston rod and expel air.

Pressing the **[Stop]** button on the injector arm will stop the Auto-Fill sequence.

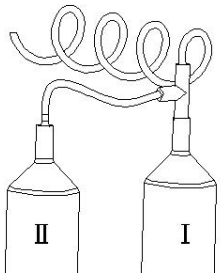
Carefully remove the QFT from the syringe tip by twisting while pulling off.

4.4 Attaching Tubing to Syringes

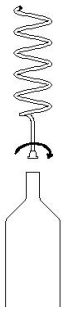
Using aseptic technique, attach the tubing to syringes as following steps:

1. Remove the connector tube from the package.
2. Remove the dust covers to expose male and female luer fittings.
3. Attach the connector tube to the syringe.

If you are using a connector tube with a T-connector, attach the straight portion to the contrast Syringe Ⅰ and the extension to the saline Syringe Ⅱ.



T-connector tube to Syringes of Zenith-C22



Connector tube of Zenith-C20

4. Verify that the connector tube is not kinked or obstructed.

4.5 Purging Air from Syringe

Keep the injector arm to the vertical position (90º) to point the tip of the syringe(s) upward to allow any air bubbles or the air pocket to rise to the tip.

Pressing on the **[Expel Air]** button advances the piston rod to push the air pocket out the syringe tip(s) and through the tubing. The system requires a minimum of 1 mL of piston rod movement to allow the system to be ready for a procedure.

Verify that both the syringe have been properly cleared of all air.

☞ **IMPORTANT!** If bubbles appear in the syringe DO NOT hit the syringe to remove them. Reverse the plunger 3-5 ml, then rock the injector arm on the pivot to gather and accumulate the small bubbles. Expel the remaining air.

4.6 Priming Tubing

4.6.1 Priming Tubing with Saline

Prime the tubing with saline if KVO injection is to be performed.

Press the **[Expel Air]** button of the contrast Syringe Ⅰ in order to push contrast just past the T-intersection of the T-connector tube.

Press the **[Expel Air]** button of the saline syringe to push the saline past the T-intersection and out through the remaining tubing.

Verify that all air has been removed from the syringes and tubing.

4.6.2 Priming Tubing with Contrast

Press the **[Expel Air]** button of the saline Syringe Ⅱ in order to push saline just past the T-intersection of the T-connector tube.

Press the **[Expel Air]** button of the contrast syringe Ⅰ to push the contrast past the T-intersection and out through the remaining tubing.

Verify that all air has been removed from the syringes and tubing.

With all air removed and the tubing primed, the injector arm should remain in the vertical position to prevent leakage until ready to inject. Once press the **[Ready]** button or access Injection screen on the monitor to make the system being ready, the injector arm should be rotated about 45° below horizontal.

Injector arm in below horizontal position

4.7 Connecting to Patient

Follow proper venipuncture technique to connect the patient to the system. Have at least *1/2* inch of the catheter positioned in a good vein. After correct venipuncture, tape the catheter securely to avoid catheter movement.

☞ IMPORTANT! The connection of the syringe, tubing and cather-over-needle relies on luer tapers. Make sure the connection is tight so as to avoid leakage while injecting.

4.8 Getting System Ready on Monitor

The operator is responsible for ensuring that all air has been completely evacuated from the syringe and tubing prior to delivering the injection. Prior to Ready an injection, review all parameters thoroughly to ensure that they are correct and appropriate for the procedure. Also, ensure that the contrast fluid is installed on the correct side of the injector arm. Follow the Ready Sequence stated in Chapter 4 to load and fill syringes properly, purge air and prime the tubing.

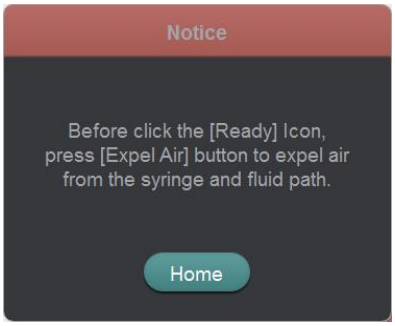
Rotate the injector arm at least 30° below horizontal. This safety precaution reduces the possibility of an air emboli. Any small remaining air bubbles will tend to float away from the tip and will not be injected into the patient.

To ready the system, the user can press the **[Ready]** button located on the injector arm or click the **[Ready]** icon on monitor screen.

The following two requirements should be complied to ready the system:

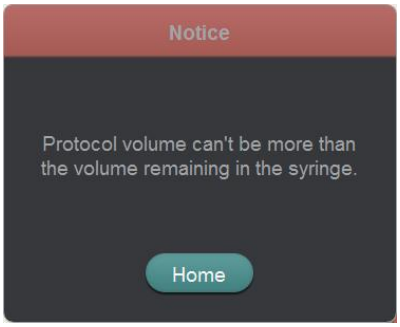
1. The user has Pressed **[Expel Air]** buttons to purge air from both syringes (piston rod must move forward to expel a minimum of 1 (one) mL of contrast/saline).
2. The syringe volume is sufficient to deliver the total volume.

Before expelling air clicking **[Ready]** button (icon), a notice to expel air window appears.



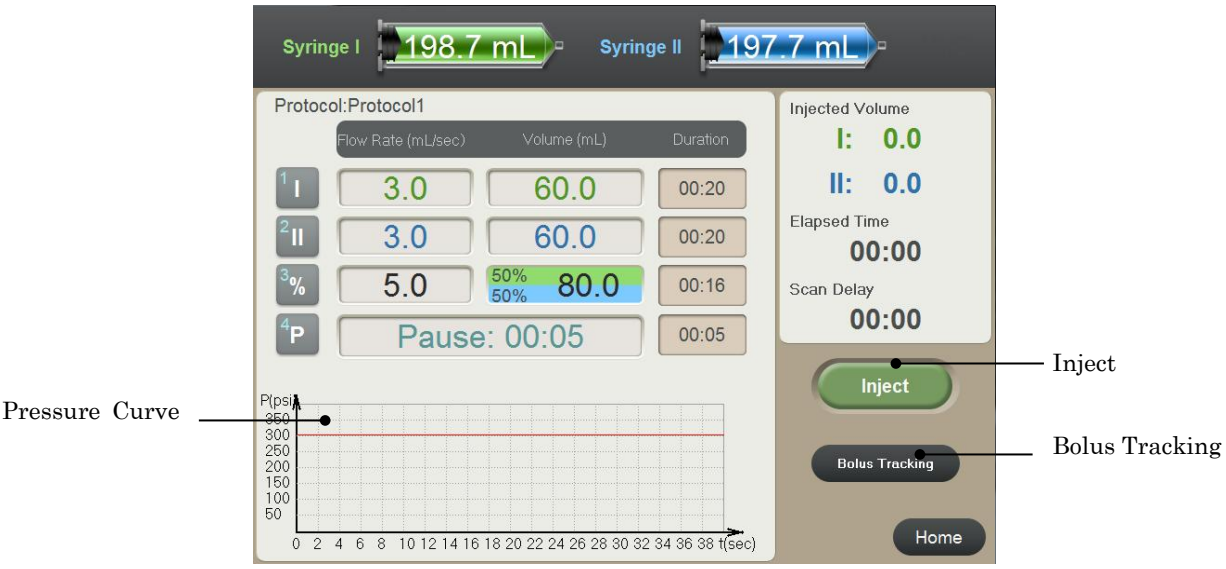
Notice to expel air

If the total volume programmed to be delivered is greater than the amount of fluid in the syringe and the **[Ready]** icon is clicked, a notice of insufficient volume.

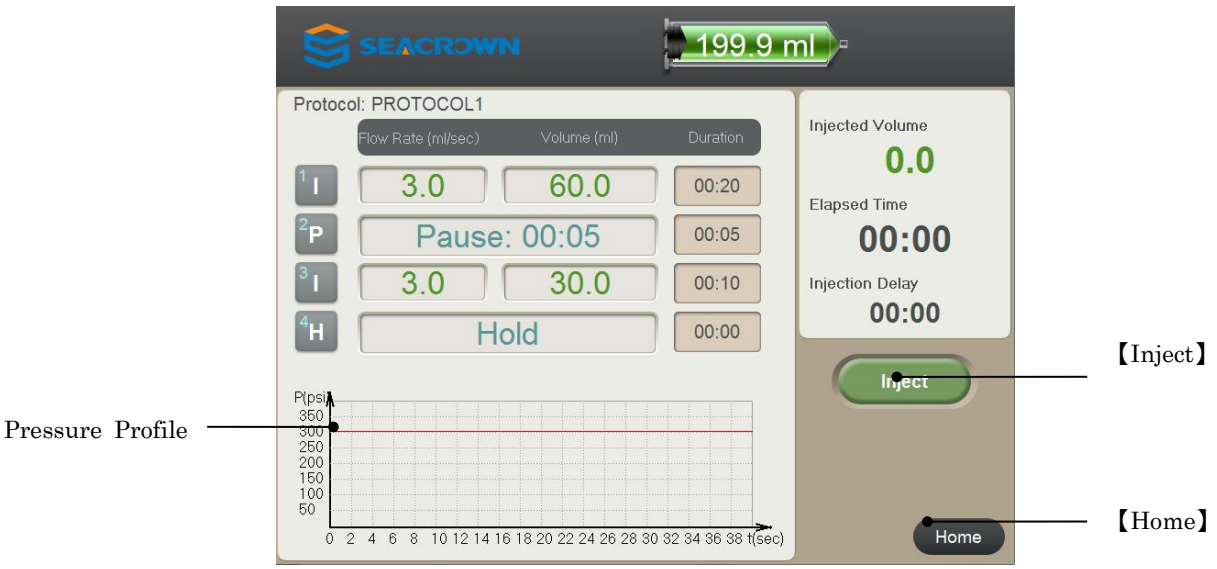


Notice of insufficient volume

When the two conditions are matched, clicking the **[Ready]** icon successfully access the Injection screen.



Injection Screen of Zenith-C22



Injection Screen of Zenith-C20

5 Performing Injection

Before starting injection, user should do the following:

- Ensure all air has been expelled from the fluid path.
- Ensure the programmed parameters are correct.
- Make CT scanner in the controllable and beginning state, namely button pressing can confirm time of beginning scan.
- Perform test injection to confirm the correctness of venipuncture.

DANGER! AIR EMBOLISM HAZARD!
Air entrapped in the syringe and tubing can cause patient injury or death. Always verify that both the syringe and tubing have been properly cleared of air just prior to starting the injection! The system does not have the capability to check for air in the syringe and tubing. The operator is responsible for removing all air from the system.

REMOVE SYRINGE AFTER COMPLETION OF INJECTION!
Disposable syringes are designed for single use only. Used syringes should be promptly removed from the injector after a procedure is completed to avoid accidental reuse of an empty syringe. Failure to remove the syringe after completion of a procedure may lead to an inadvertent injection of air. Injecting air can cause patient injury or death.

5.1 Reviewing Parameters

Prior to delivering an injection, review all parameters thoroughly to ensure that they are correct and appropriate for the procedure. Also, ensure that contrast fluid is installed on the correct side of the powerhead.

Refer to 4.1.1 or 4.1.2 to set desired parameters or recall desired protocol.

5.2 Test Injection

Extravasation can be minimized through the following precautions:

- When choosing an I.V. site, use the largest vein possible.
- Use lowest flow rate practical to achieve enhancement.
- Use largest gauge teflon type catheter possible.
- Insure good backflow from catheter.
- Continue to monitor from remote location.
- Instruct patient to notify operator of any abnormal pain, pressure or swelling.

Test injection aims to check the patency of the I.V. site and to reduce the risk of the extravasation.

The **[Test]** button is active when the system is Ready.

Refer to 4.8 to Ready the system.

The Test injection flow rate and volume can be programmed on the System setup and test screen. Refer to 2.5.5.

After Test injection, there should be no swelling at the venipuncture point. If there is swelling, you should perform venipuncture again before protocol injection.

The users can also do backflow test to make sure the venipuncture is correct. Press the **[Stop]** button to set the system being not Ready status, then continually press the **[Test]** button to check if there is blood in the Cather-over-needle.

5.3 Running KVO Injection

Refer to 2.5.3, and 2.5.5.

KVO is the abbreviation for Keep Vein Open. It is a low flow rate injection of a small volume of saline delivered to keep the fluid pathway open.

The system runs KVO by injecting fluid from syringe Ⅱ.

Run the KVO for a patient who has been connected to the system for five minutes to waiting for injection.

The **[KVO ON]** icon and **[KVO OFF]** icon on the Home Screen control the KVO program running.

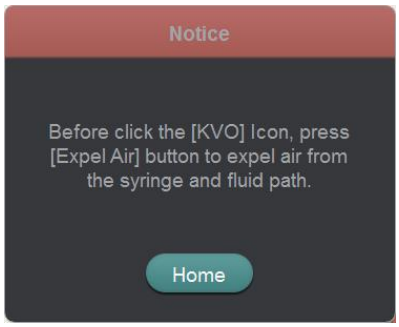
When the system is Ready, click **[KVO ON]** icon to run KVO injection. When the system run KVO injection, the **[KVO ON]** icon is replaced by **[KVO OFF]** icon and a message "KVO is running" is display at the right bottom corner of screen.

KVO running message

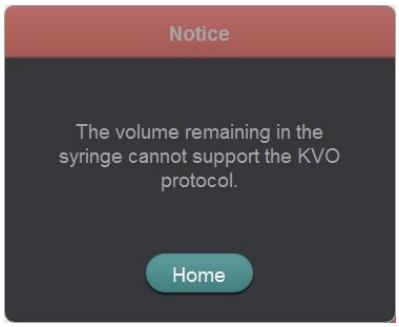
Click **[KVO OFF]** icon to stop running KVO injection.

The user can program the KVO protocol on the System screen. Refer to Chapter 2.5.5.

When the **[Expel Air]** buttons were not both pressed or there is not sufficient volume in syringes, the below notices remind the user to expel air or fill syringe.



Notice to expel air to run KVO injection

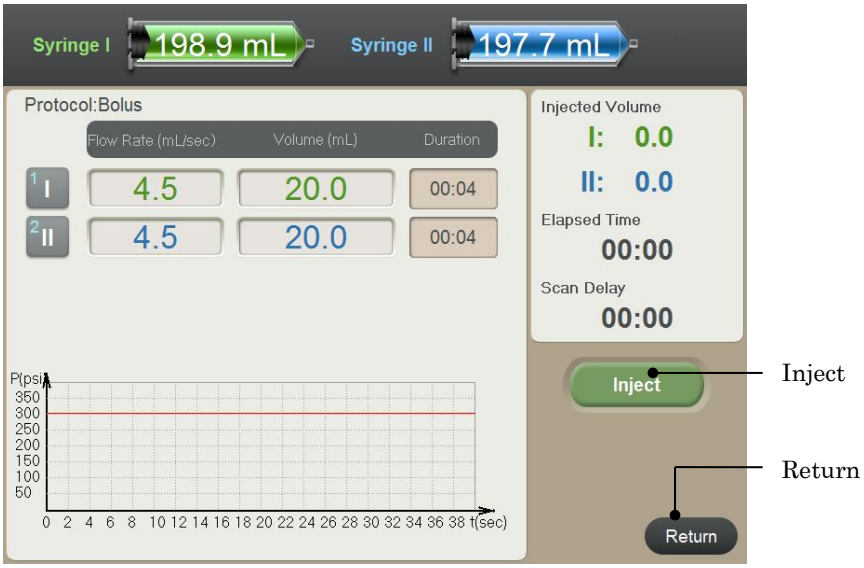


Notice of insufficient syringe Ⅱ volume

5.4 Bolus Tracking Injection

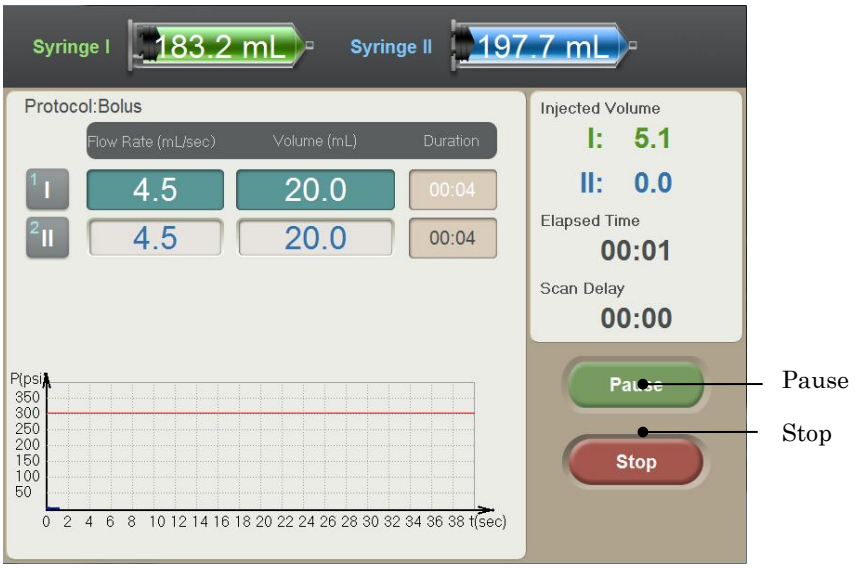
Refer to Chapter 2.5.5 to set bolus tracking injection enable and its parameters.

Click **[Bolus Tracking]** icon on the Injection screen to access the Bolus Tracking Injection Screen.



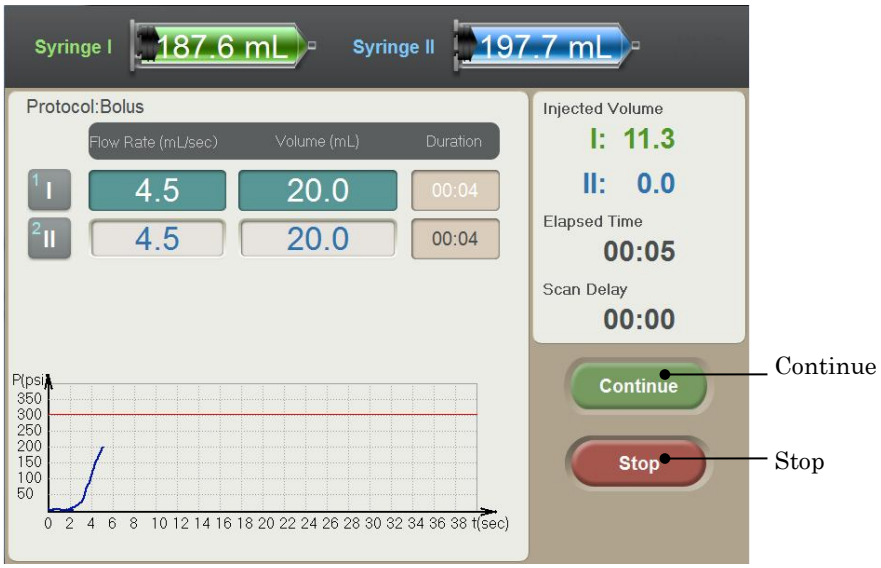
Bolus Tracking Injection Screen

Click **[Inject]** icon to start injection.



Bolus Tracking Injection Screen

Click **[Pause]** icon to suspend injection and Click **[Continue]** icon in the suspend screen to inject again. Click **[Stop]** icon to stop injection.



Bolus Tracking is suspend screen

5.5 Protocol Injection

Air entrapped in the syringe and tubing can cause patient injury or death. Always verify that both the syringe and tubing have been properly cleared of air before connecting to the patient and just prior to starting the injection! The system does not have the capability to check for air in the syringe and tubing. The user is responsible for removing all air from the fluid path.

REVIEW PARAMETERS
Prior to delivering an injection, review all parameters thoroughly to ensure that they are correct and appropriate for the procedure.

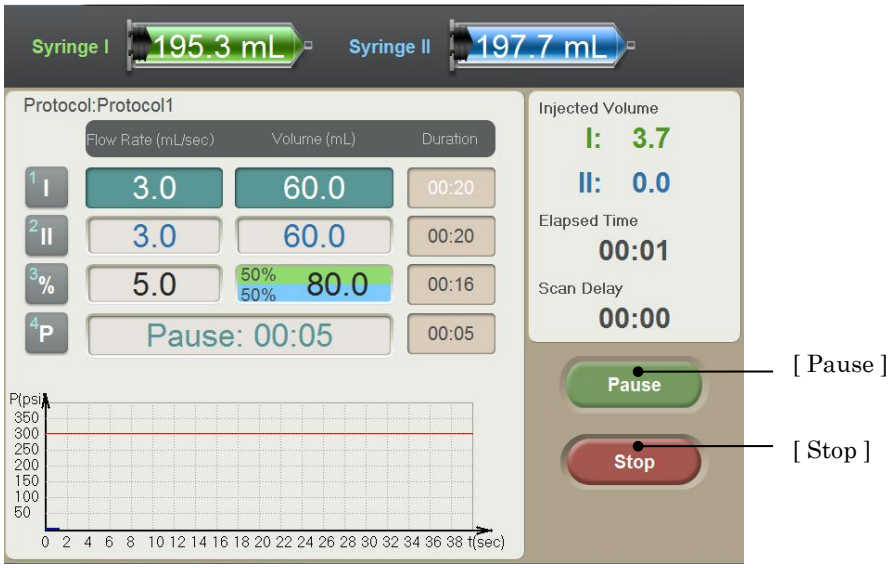
5.5.1 Starting Protocol Injection

The protocol can be delivered by pressing the **[Inject]** button on the injector arm, by clicking the **[Inject]** icon on the Injection screen or by pressing the hand switch. Once the injection is initiated, the Injecting Screen is displayed.

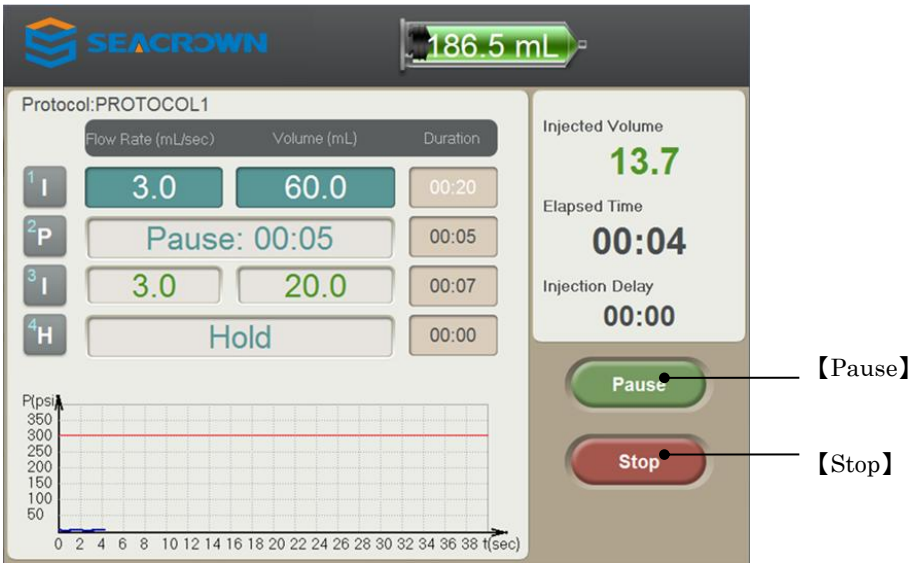
While injecting, Total Time increments and syringe volume decrement. The contrast and saline delivered volume is updated on the monitor screen during the Injection.

The **[Pause]** icon is available to pause the injection, and the **[Stop]** icon to stop the injection at any time.

Note that the Pressure Limit parameter is indicated by the red line. The real-time injecting pressure curve is displayed on the monitor screen.



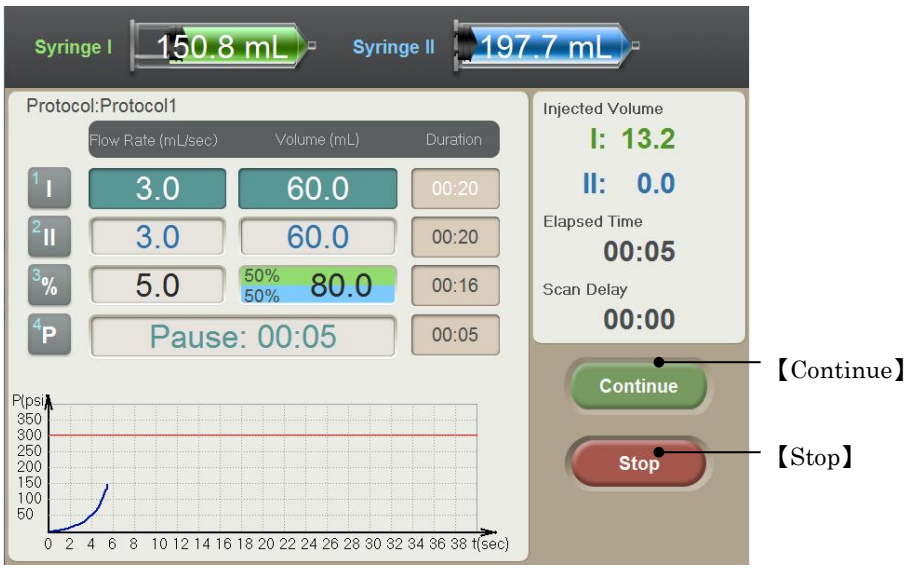
Injecting Screen of Zenith-C22



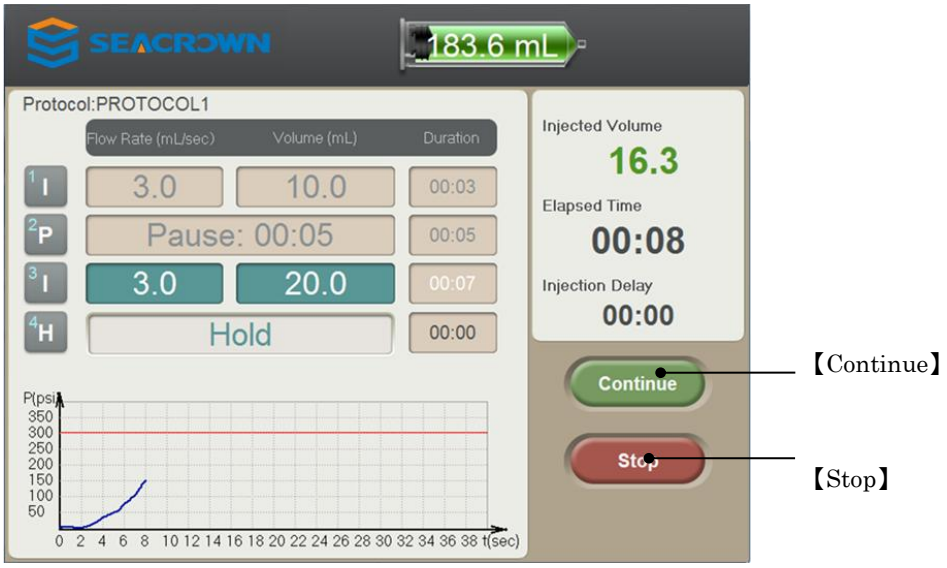
Injecting Screen of Zenith-C20

5.5.2 Pausing an Injection

An injection may be immediately paused by pressing the **[Pause]** icon on the monitor display or by depressing once on the hand switch. When the injector is paused, Protocol injection suspend screen appears.



Protocol injection suspend screen of Zenith-C22



Protocol injection suspend screen of Zenith-C20

5.5.3 Restarting an Injection

Click the **[Continue]** icon or press hand switch to continue the injection process.

5.5.4 Terminating an Injecting

The injection process can be stopped immediately by pressing the **[Stop]** button on the injector arm or by clicking the **[Stop]** icon on the Injecting Screen.

5.6 Removing Syringe

Dismount the Y-connector tube from the syringes and press the **[Autofill]** button to move the piston rod to the fully retracted position and then remove the syringe by twisting counterclockwise 1/4 turn and pulling out.

All disposables are intended for single patient use only. When those unloading should be disposed according the local related laws and regulations.

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6 Installation

Carefully check the packing carton before unpacking. If the packing case is damaged, the inner equipment may be broken. If there is damage to the case, do not unpack the case, but take photographic evidence and contact your supplier.

When unpacking the case and if there is anything missing or damaged, take a note and contact your supplier. Check off all the parts against the content of packing list and note the condition of items.

The following tools are needed to install the system:

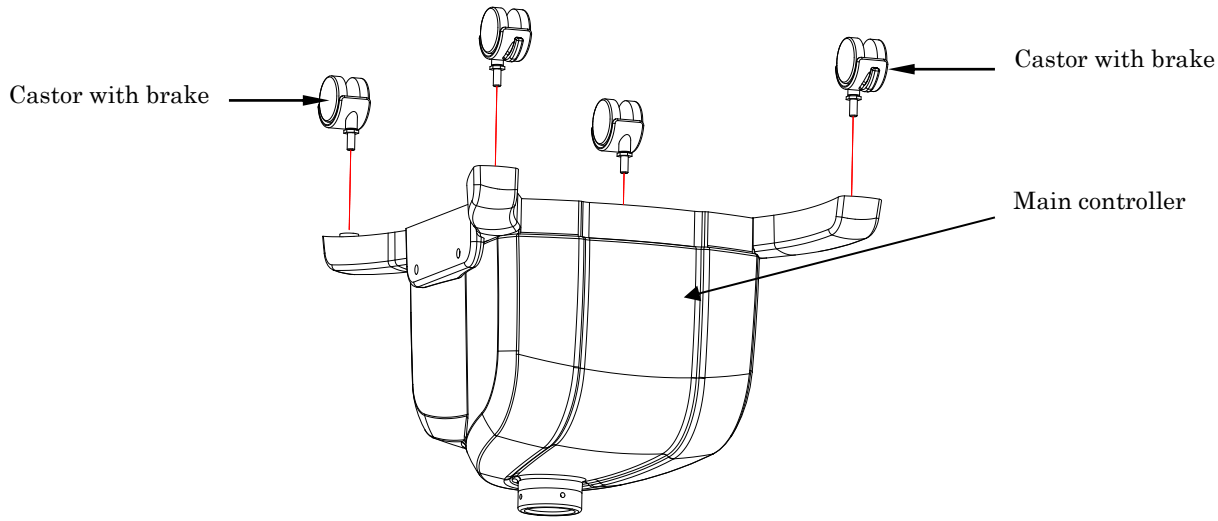
- 13mm solid wrench
- 5 inch diagonal pliers
- 5mm hex head wrench
- 6mm hex head wrench
- 3mm hex head wrench
- Cross screwdriver

6.1 Assembling Parts

6.1.1 Assembling Parts of Zenith-C22

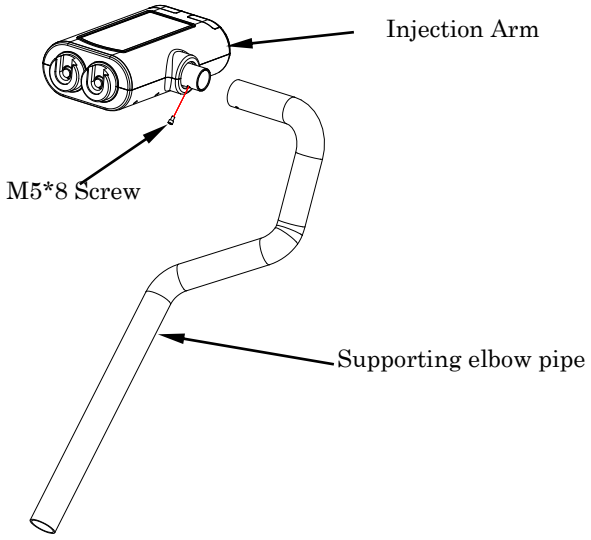
1. Install the castors of main controller

   Screw the castors to the nuts on the main controller by a solid wrench.



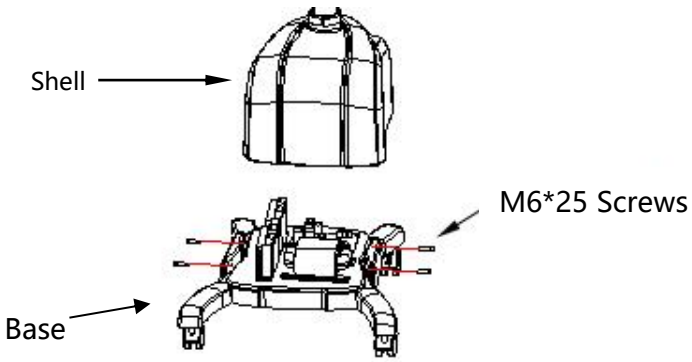
Install castors

2. Connect injector arm with supporting elbow pipe
   First screw out the M5*8 socket head cap screw on the spindle of the injector arm with 5mm hex head wrench. Insert the spindle into the pipe. Through the hole of pipe Tighten the M5*8 socket head cap screw to the spindle.



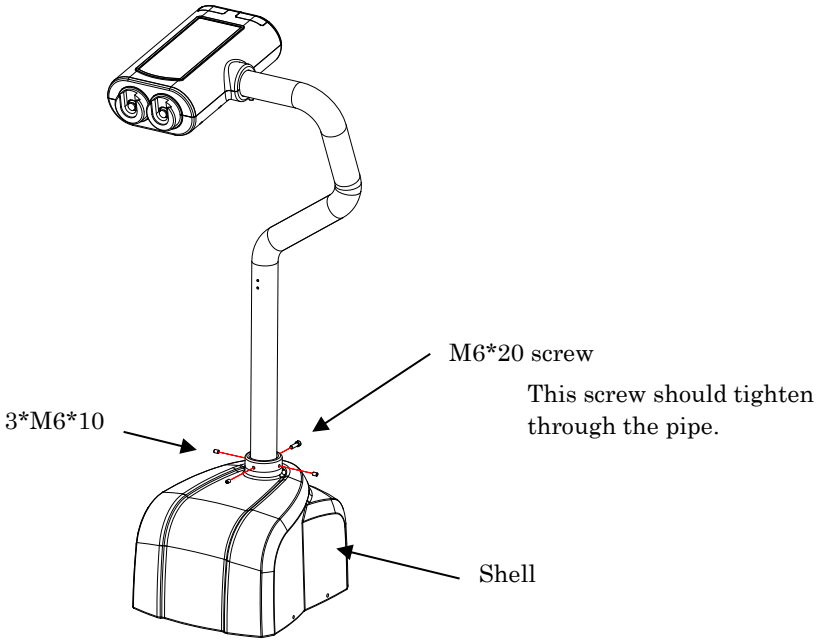
Connect injector arm with pipe

3. Install the pipe onto the main controller cover
   a) Screw out four M6*25 socket head screws to separate the main controller cover from the main controller base with a 6mm hex head wrench.



Separate the main controller cover from the base

   b) Insert the pipe with all cables into the main controller cover hole. Turn the pipe at the same direction as the following figure and stop it at the position of a nut on the main controller cover meeting the hole on the pipe.
   c) Tighten four screws.



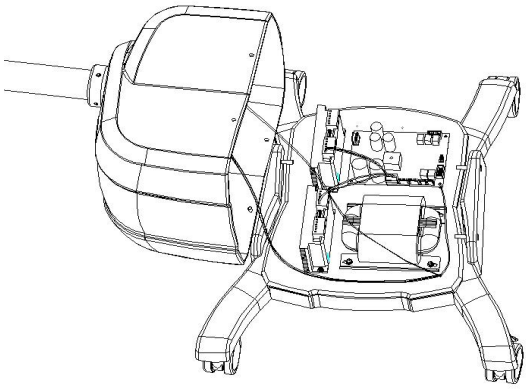
Fix elbow pipe with main controller cover

4. Connect the cables to the main controller

☞ IMPORTANT! **Take care to connect the cables in correct direction. Wrong direction or unmatched connection could result part malfunction.**

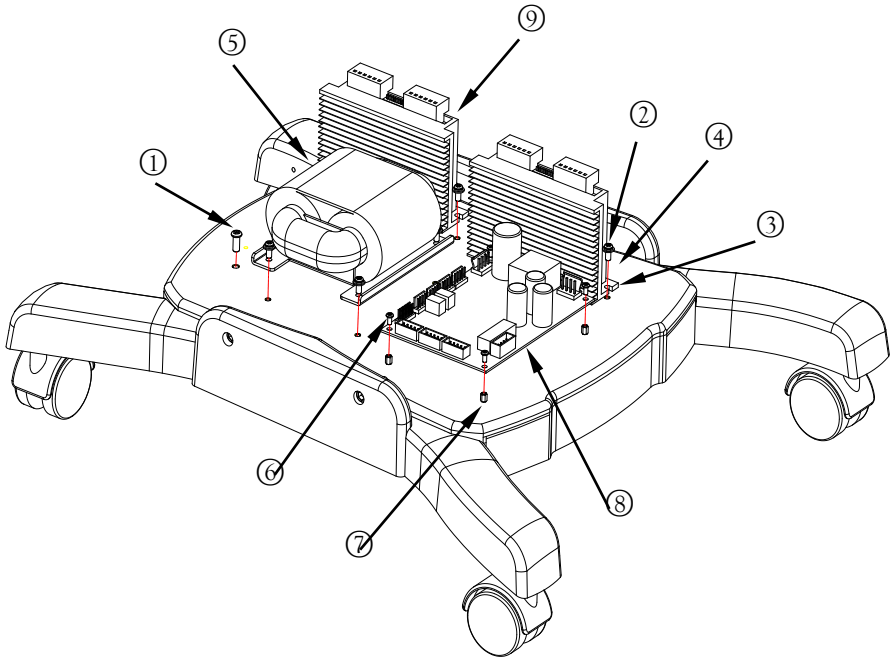
Three cables from the injector arm through the pipe need be connected to the parts on the main controller base.

a) Put down the injector arm, elbow pipe and the main controller cover as the following figure showing.



Opening the main controller cover for cable connection

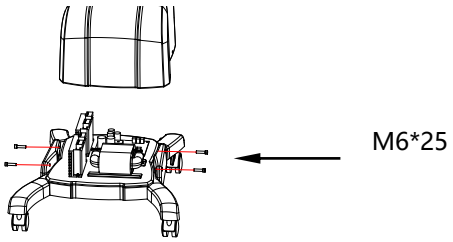
b) The parts located on the main controller base that having cables to connect the injector arm are the following parts:
Driver A④, Driver B⑨ and main control board⑧.
Connect labeled A07011-A cable to driver A, and labeled A07011-B cable to driver B, and labeled A07012 cable to JP3 of the main control board.



Parts on the main controller base

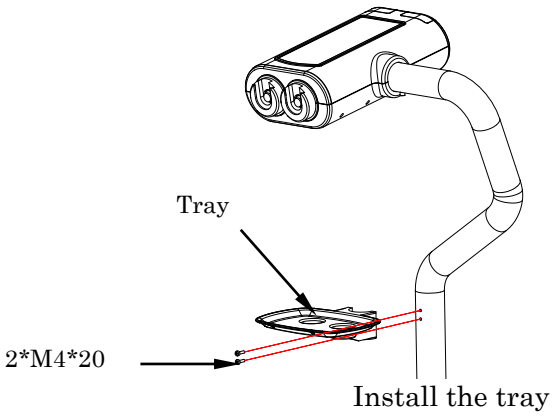
5. Combine the main controller
   After connect all injector arm cables to the main controller base, take the main controller cover to cover on the main controller base. Tighten four M6*25 screws.

IMPORTANT! **Take care to avoid compressing cables by the edge of the main controller cover.**



Install the main controller cover onto the main controller base

6. Install the tray
   With cross screwdriver tighten two M4*20 screws through the tray holes to the pipe.



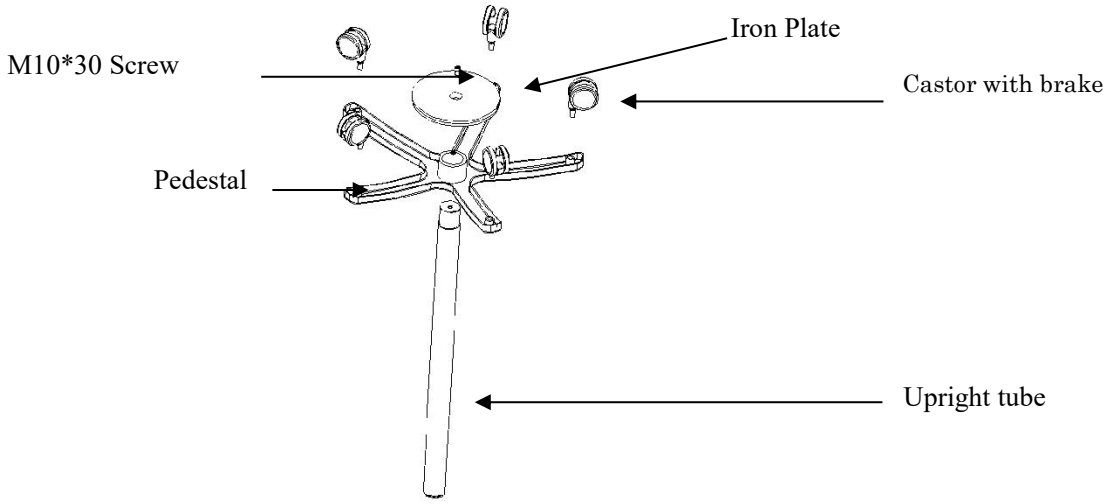
Install the tray

6.1.2 Assembling Parts for Zenith-C10

1. Installation of lower straight-bar, iron plate , and the movable pedestal

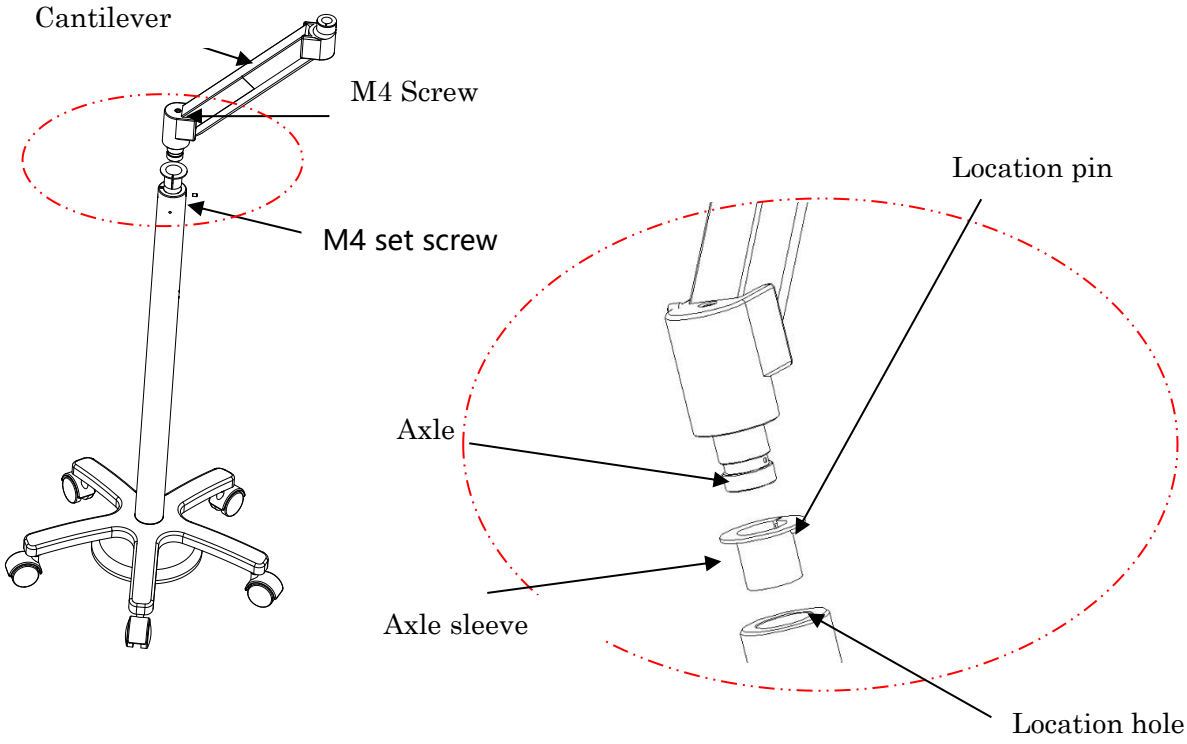
   Screw the castors to the nuts on the pedestal by a solid wrench. The castors with brake should be placed alternatively by a castor without brake.

   By screwing the M10 bolt through the iron plate and the pedestal to the lower straight-bar's nut to combine the three parts.



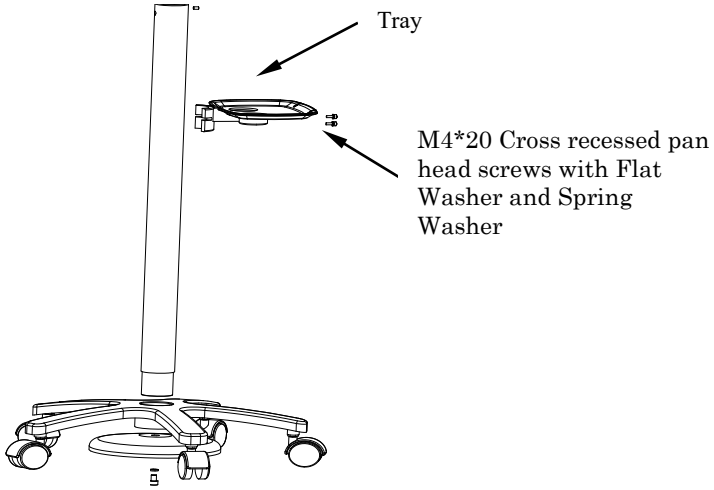
2. Install cantilever

   Put the axle sleeve into the upright tube at the location of the pin of sleeve in hole on tube. Tighten two M4 screws to fix the cantilever and limit its rotation angles.



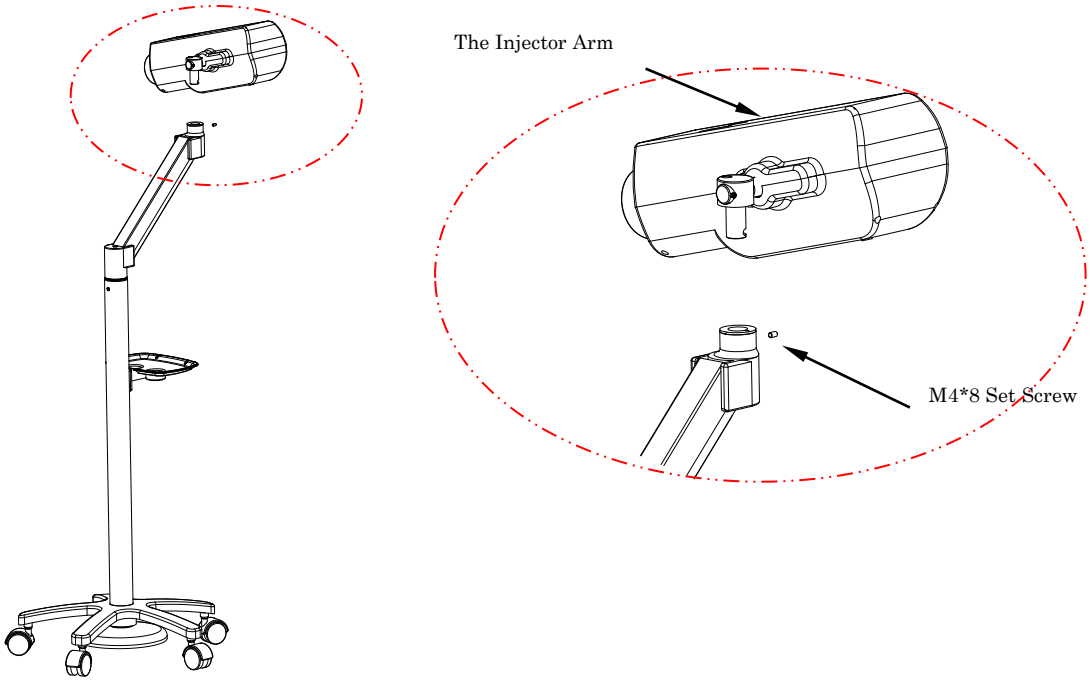
Installation Cantilever

3. Install the tray
   Place the accessory tray in the correct position. Screw tightly the two M4 screws below the tray.



Install the accessory tray

4. Installation of injector arm
   First unscrew the M4*8 set screws from the upper of cantilever, insert the swivel on the injector arm into the hole, which at the upper of cantilever, regulate the degree of tightness of the set screws, then fixed it.

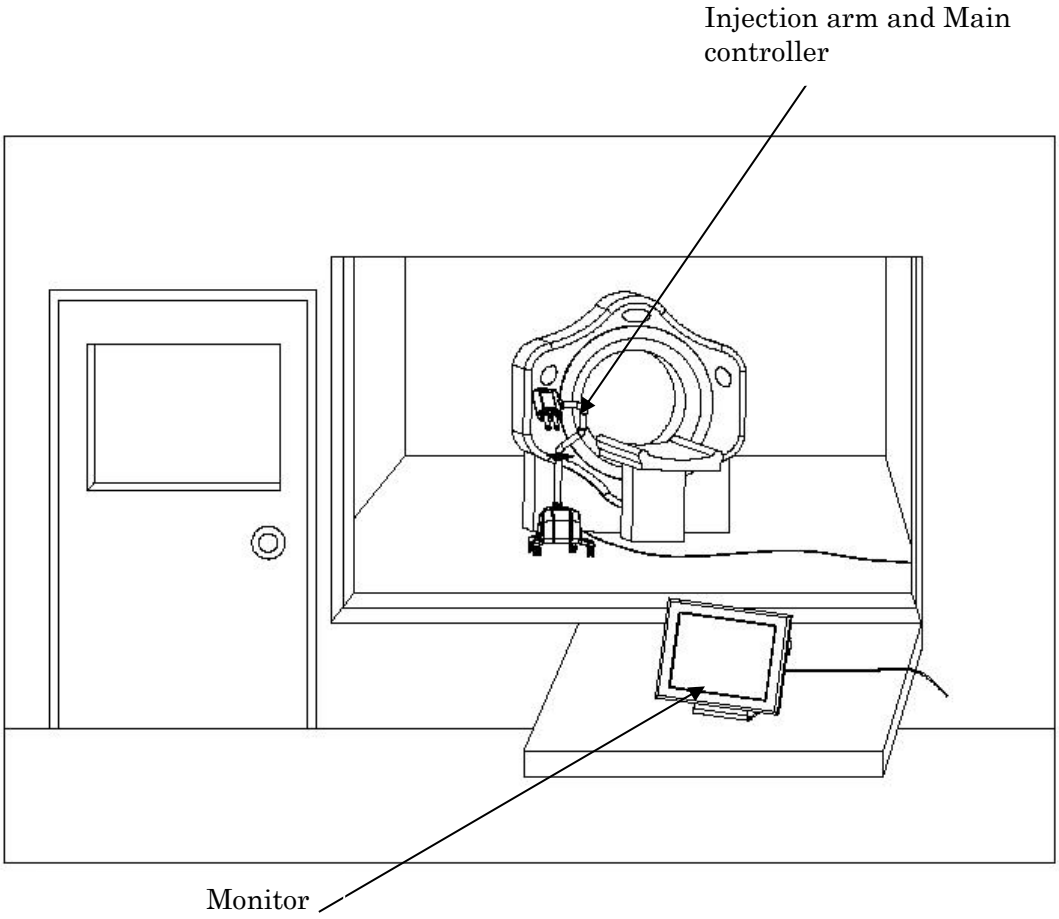


Installation of injector arm

6.2 Locating Parts

6.2.1 Locating Parts of Zenith-C22

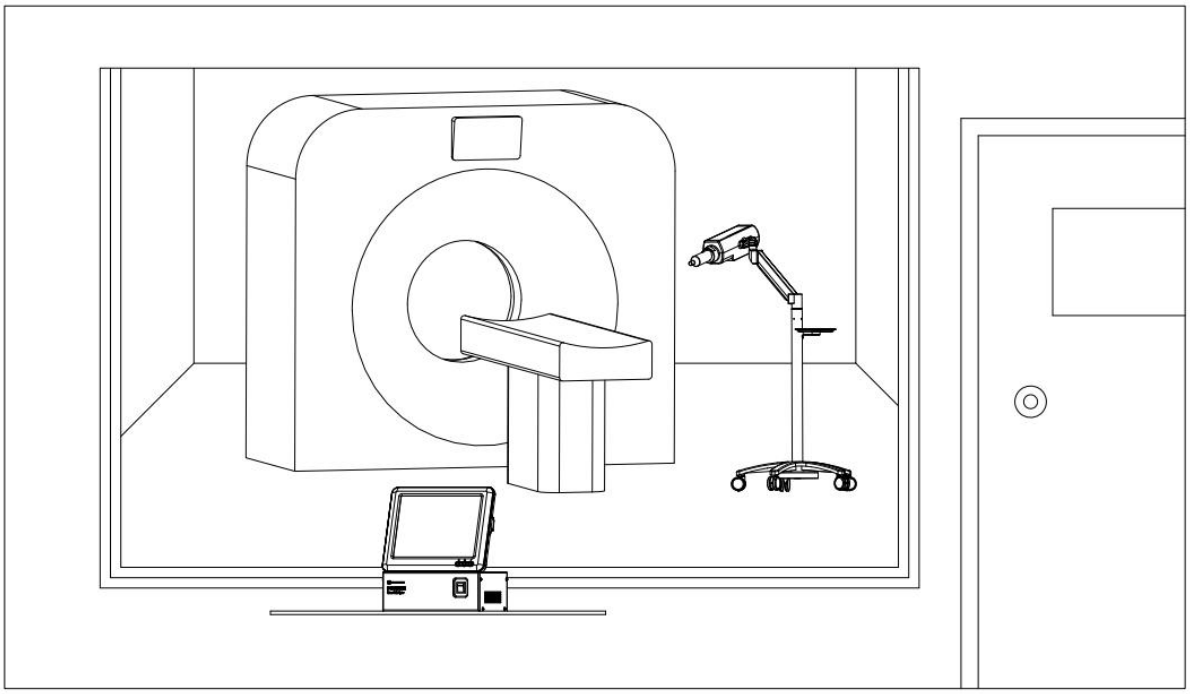
1. Placed the injector arm and main controller at one side of CT scanner disk.
2. Placed the monitor on the operation desk in the control room.



Location of Zenith-C22 Parts

6.2.2 Locating Parts of Zenith-C20

1. Placed the injector arm at one side of CT scanner disk.
2. Placed the monitor and main controller on the operation desk in the control room.



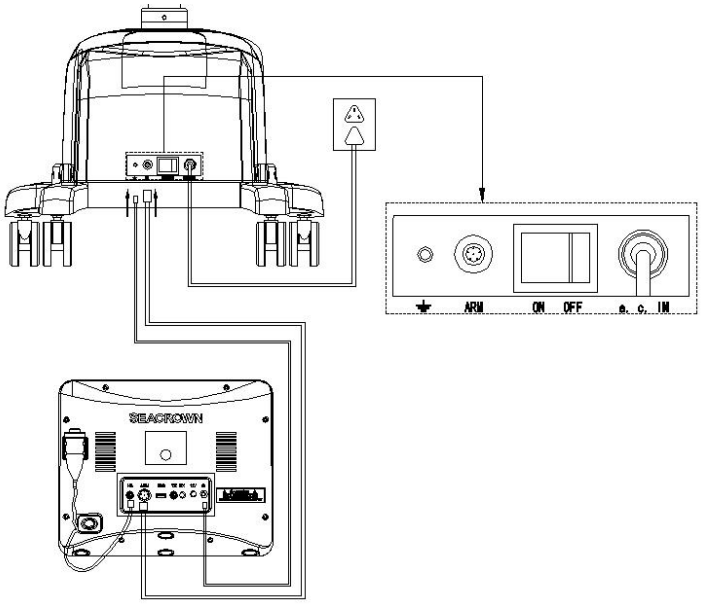
Location of Zenith-C20 Parts

6.3 Connecting External Cables

6.3.1 Connecting Zenith-C22 External Cables

Zenith-C22 system cables connecting to different parts include the monitor cable, hand switch cable, and power cable. Lay the monitor cable along with CT scanner cable path through the wall between the scanning room and the control room.

6.3.1.1 Standard Model



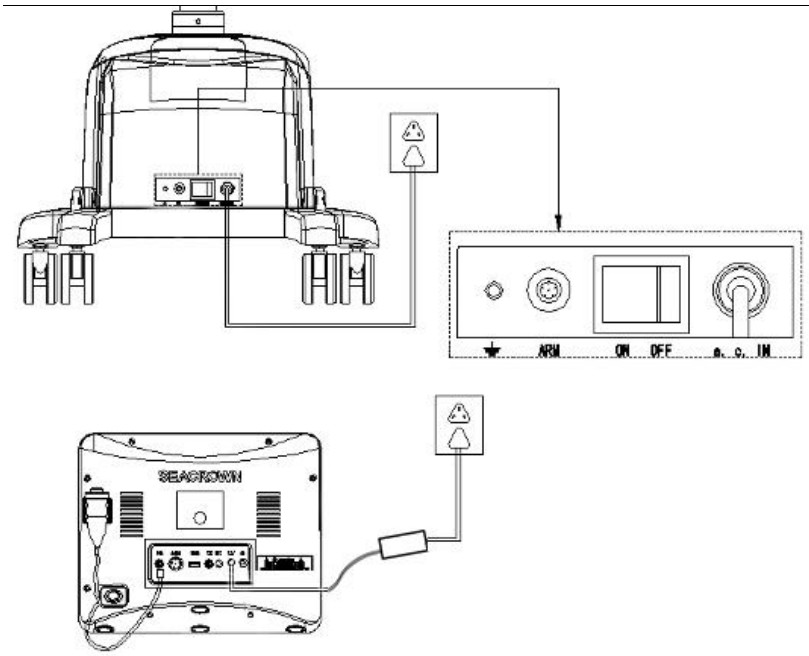
System Cable Connection of Zenith-C22 (Standard)

1. Connect the monitor cables
   a) Connect one end of the monitor cable to ARM connector located on the rear of the monitor. Tighten the cable screw to connect the connector well.
   b) Connect the ground lead to the earthing rod.
   c) Connect the hand switch terminal to H.SW connector located on the rear of the monitor.

2. Connect the main controller cables
a) Connect one end of the monitor cable to ARM connector at the interface of the main controller. Tighten the cable screw to connect the connector well.
b) Connect the ground lead to the earthing rod.
c) Confirm the power switch of the main controller being at OFF position and plug the cord of the power cables from the main controller into an AC outlet.

The monitor and power cables should be fastened using nylon line at cable fastener on the main controller foot.

6.3.1.2 Wireless Model



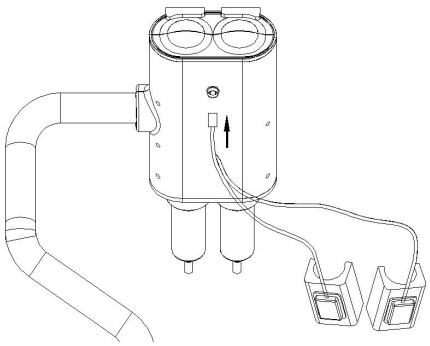
System Cable Connection of Zenith-C22 (Wireless Model)

1. Connect the monitor cables
   a) Connect the ground lead to the earthing rod.
   b) Connect the hand switch terminal to H.SW connector located on the rear of the monitor.
   c) Connect one end of the adapter to the 12V interface of the monitor and the other end to the socket.

2. Connect the main controller cables
a) Connect the ground lead to the earthing rod.
b) Confirm the power switch of the main controller being at OFF position and plug the cord of the power cables from the main controller into an AC outlet.

The monitor and power cables should be fastened using nylon line at cable fastener on the main controller foot.

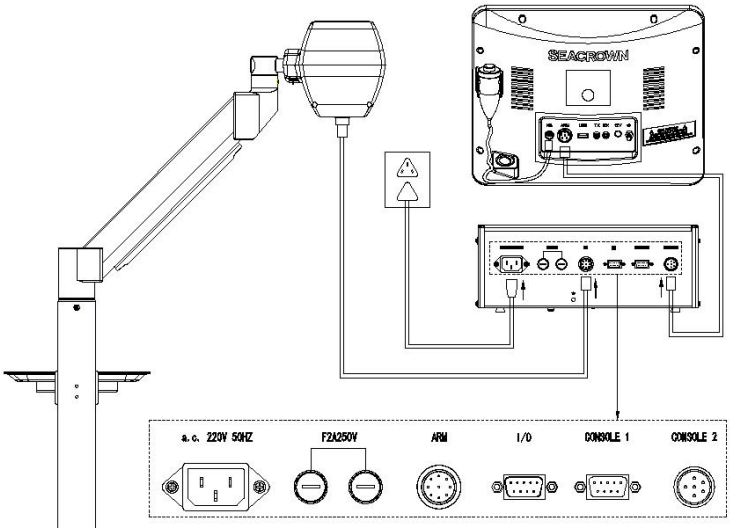
6.3.1.3 Connect the heater cable



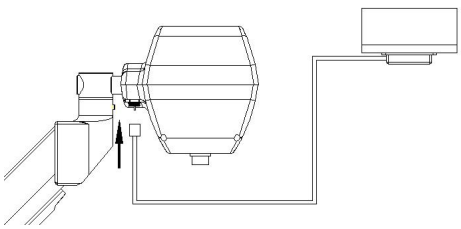
6.3.2 Connecting Zenith-C20 External Cables

Zenith-C20 system cables connecting to different parts include the monitor cable, arm cable, switch cable, and power cable.

Lay the arm cable along with CT scanner cable path through the wall between the scanning room and the control room.



1. Connect injector arm cable
   Connect one end of the arm cable to ARM connector located on the bottom of the injector arm. Tighten the cable screw to connect the connector well.
   The arm cable should be fasted at the cable clamp located with the tray.
2. Install the main controller cable
   a) Connect one end of the arm cable to ARM connector located on the rear of the monitor. Tighten the cable screw to connect the connector well.
   b) Connect one end of monitor cable to the monitor 1 connector located on the rear of the monitor and fasten the set screw of cable plug.
   c) Confirm the power switch being at the OFF position. Connect the power cord to the rear of the main controller, then plug the cord into an AC outlet.
3. Installation of monitor cable
   a) Connect one end of the monitor cable to ARM connector located on the rear of the monitor. Tighten the cable screw to connect the connector well.
   b) Connect the hand switch terminal to H.SW connector located on the rear of the monitor.
3. Installation of heater cable



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7 Maintenance

The maintenance of the system is extremely important. The user should properly handle routine maintenance, cleaning, and monthly inspection. The authorized technicians should do preventive maintenance at least once in a year. The preventive maintenance schedule and service procedures are in the Service Manual**.**

Only the disposables contact directly the patients' blood path. There are not any components of the device that directly or indirectly contact the patients' blood path. All parts of the device are reusable for multiple patients. Clean the system outside the sterile field.

The system's power must be disconnected when cleaning any component. There is risk of electric shock when cleaning with the power on.

Do not use an overly wet cloth to clean the system. Water droplets accessing the internal components can damage the system.

The cleaned components must be confirmed to be dry before plugging in the power and giving power to the system.

7.1 Routine Maintenance

Each day when in use, it is necessary to promptly clean away residual contrast media. The product is not a waterproof apparatus. If medicinal liquid is accidentally spilled, use a moist towel to wipe away residual contrast media on the injection Syringe Ⅰ installation frame, piston rod, bend pipe, tray, and base.

If contrast media is found to have permeated the internals of the system, it is necessary to promptly open the exterior case and wipe clean. This work may only be completed by an authorized technician. Please promptly contact the manufacturer or your distributor.

7.2 Monthly Inspection

A complete inspection and cleaning is recommended for the system every three months. The goal of the inspection is to uncover potential system malfunctions and safety incidents.

Items to check: Is there damage to exterior wiring, are plugs loose, is the system ground reliable, and are any casings cracked. During inspection, clean dust from all components. Before cleaning, power must be shut off and the power plug must be unplugged. Use a warm cloth to wipe dust from the machine frame, main controller, and monitor.

7.3 Annual Maintenance

It is recommended that the manufacturer conduct a complete inspection and calibration of the system once every year. Manufacturer authorized technicians will carry out inspection and cleaning of the system's mechanical components and sensors, focusing on removal of residual contrast media in the system . Please contact Seacrown or your dealer to do annual maintenance.

7.4 Cleaning

Using a soft non-abrasive cloth, warm water, and a mild disinfectant, carefully clean the assembly, paying particular attention to the piston rod and the syringe chuck.

Do not use alcohol-based detergents. The water should not contain the following substances, even in trace amounts:

- esters
- ethers
- ketones
- chlorides
- n-Alkyl
- alcohols (other than ethyl alcohol)
- cleaners and disinfectants (such as SaniZide and TB-Cide Quat)
- products containing: dimethyl benzyl, ammonium chlorides, and dimethyl ethylbenzyl

7.4.1 Cleaning Injector Arm

To clean the injector arm:

Uninstall the syringe from the injector arm.

Fully advance the piston rod by pressing **[Forward]** button**.**

Place the injector arm in a vertical position.

Clean the piston rod with a soft cloth or paper towel dampened with cleaning solution.

Clean the inner area of the syringe chuck with a soft cloth, paper towel or cotton-tipped applicator dampened with cleaning solution or warm water.

Wipe the injector arm cover with a soft cloth or paper towel dampened with cleaning solution or warm water.

Thoroughly dry the injector arm cover with a paper towel.

To clean harden contrast in the syringe chuck:

Place the injector arm in a vertical position.

The entire syringe chucks may be placed or soaked in warm water for ten minutes.

Thoroughly dry the syringe chucks with a paper towel.

.

7.4.2 Cleaning Monitor

The monitor may be dusted by using a lint-free cloth. To clean the touch screen, use a nonabrasive cloth towel and any commercially available non-ammonia window cleaner to regularly clean the surface. The cleaning solution should be applied to the towel rather than the surface of the touch screen. The touch screen has air vents and is not designed with water tight bezels so fluid ingress may occur from behind the panel if not cleaned carefully.

☞ IMPORTANT! **Do not use solvent cleaners to clean the apparatus.**
Do not directly spray cleaner onto the touch-screen.

7.4.3 Cleaning Main Controller

Clean the exterior of the main controller by spraying a cloth with an all-purpose household cleaner, then gently wipe clean.

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8 Messages

The monitor screen displays system messages when system malfunction, or injection terminated abnormally, or incorrect input. The system messages fall into two categories:

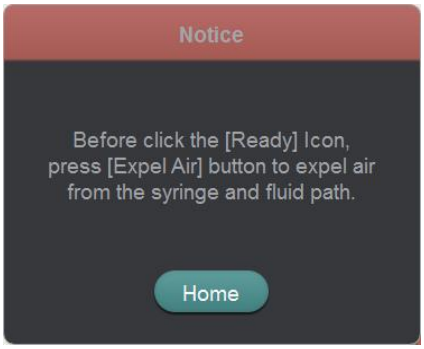
Error Codes — The right corner of the monitor displays a unique error code for the service staffs to categorize the problem. Details of the error codes could be read in service manual.

User Error Messages — Those messages that appear in response to incorrect user input or to inform the user of the status of the system.

This chapter contains instructions on responding to notice messages. Messages are displayed on the monitor screen in response to incorrect user input or action and equipment status.

8.1 Injector Ready Messages

Message: Before click the [Ready] icon, press **[Expel Air]** button**s** to expel air from the syringe and fluid path.

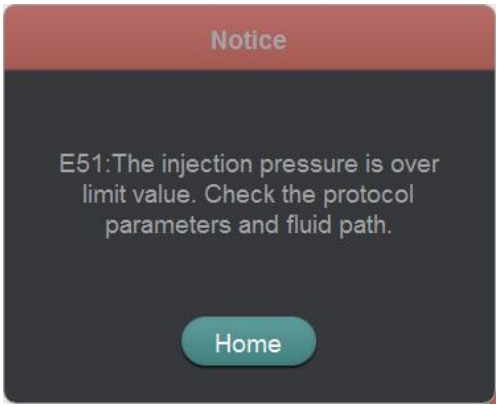


Occur when: Click **[Ready]** icon when not pressing both **[Expel Air]** button**s** on the injector arm.

Action: Press both **[Expel Air]** button**s** and then make the system Ready.

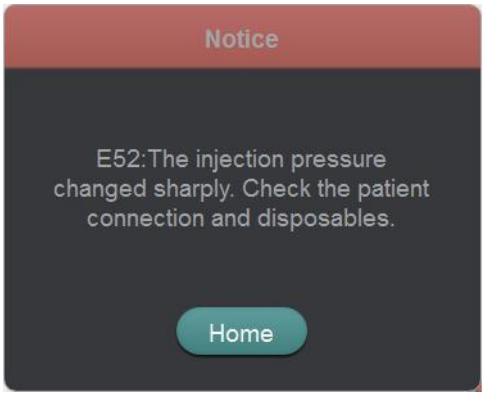
8.2 Injection Messages

Message: The injection pressure is over limit value. Check the protocol parameters and fluid path.



Occur when: Programmed an unreasonable protocol, or set low pressure limit, or use incompetent disposables.
Action: Modify the protocol flow rate or the pressure limit. Verify to use qualified disposables.

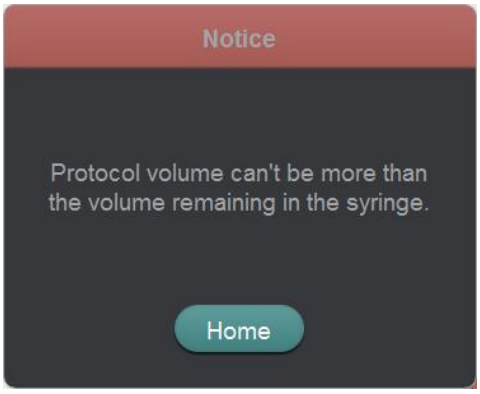
Message: The injection pressure changed sharply. Check the patient connection and disposables.



Occur when: Mostly extravasation or disconnect of disposables happened.
Action: Check patient puncture and tube connection.

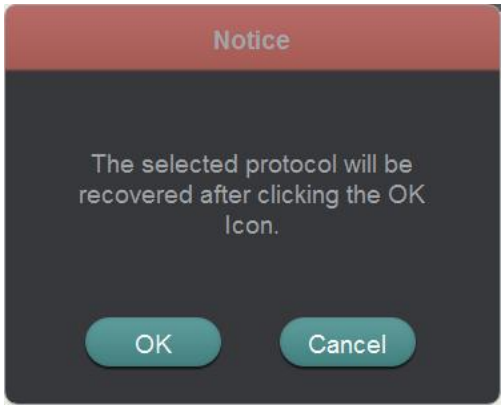
8.3 Protocol Messages

Message: Total Volume can't be more than the volume remaining in the syringe.



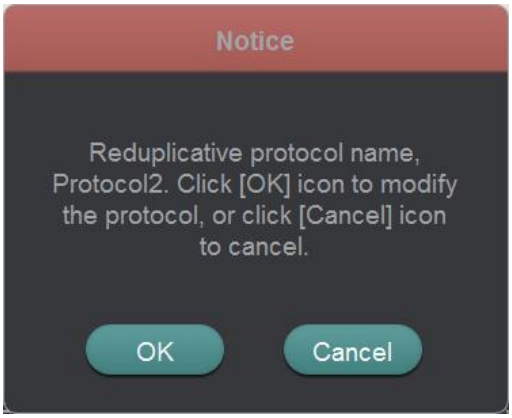
Occur when: Programed a unreasonable protocol.
Action: Decrease the Total Volume or fill more fluid to the syringe.

Message: The selected protocol will be deleted and can't be recovered after clicking the [OK] icon.



Occur when: Delete a stored protocol.
User action: None.

Message: Reduplicative protocol name. Click [OK] icon to modify the protocol or click [Cancel] icon to cancel.



Occur when: Input reduplicative protocol name.
Action: Rename the protocol or update the stored protocol.

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9 EMC Information

This medical device manufactured by Seacrown conforms to this IEC60601-1-2:2014 standard for both immunity and emissions.

Table 1

Guidance and manufacturer's declaration – electromagnetic emissions		
The system is intended for use in the electromagnetic environment specified below. The customer or the user of the system should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
Mains Terminal Disturbance Voltage (Conducted Emission) CISPR 11	Group1 Class B	The system 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.
Electromagnetic Radiation Disturbance (Radiated Emission) CISPR 11	Group1 Class B	The system is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes..
Harmonic emissions IEC 61000-3-2	N/A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	N/A	

Table 2

Guidance and manufacturer's declaration – electromagnetic immunity			
The system is intended for use in the electromagnetic environment specified below. The customer or the user of the system 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	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrostatic transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output, Signal lines	±2 kV for power supply lines ± 1 kV for input/output, Signal lines	Mains power quality should be that of the professional healthcare facility environment
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of the professional healthcare facility 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 30 cycles <5 % *U*T (>95 % dip in *U*T) for 300 cycles	<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 30 cycles <5 % *U*T (>95 % dip in *U*T) for 300 cycles	Mains power quality should be that of the professional healthcare facility environment. If the user of the system requires continued operation during power mains interruptions, it is recommended that the system be powered from an uninterruptible power supply.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30A/m	30A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in the professional healthcare facility environment.
NOTE*U*T is the a.c. mains voltage prior to application of the test level.			

Table 3

Guidance and manufacturer's declaration – electromagnetic immunity			
The system is intended for use in the electromagnetic environment specified below. The customer or the user of the system 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 V	Portable and mobile RF communications equipment should be used no closer to any part of the system including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2,7 GHz	10 V/m	
Immunity to Proximity Fields from RF Wireless Communications Equipment IEC 61000-4-3	0.3m Distance See Table 9 for test level	0.3m Distance See Table 9 for test level	
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.			
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 system is used exceeds the applicable RF compliance level above, the system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the system. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

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10 **Index**

A
Annual maintenance 7-2
Assembling Parts 6-1
Attaching Tubing to syringes 4-7
Autofill 2-7
Autofill Button 2-11

B
Blous Tracking Injection 5-5
Bolus Tracking Parameter 2-28

C
Cleaning 7-2
Cleaning monitor 7-3
Cleaning Injector arm 7-2
Cleaning Main controller 7-3
Contraindications 1-1
Controlling Injection 2-12
Connecting to Patient 4-9
Connecting Cables 6-10
monitor 2-13
monitor Buttons 2-13
monitor Display Screen 2-14

D
Date and Time Setup 2-30
Deciding on Injection Protocol 4-2
Disposables 1-9
Dimensions and weights 2-4
Duration 2-16

E
Electrical Requirements 2-7
Electromagnetic compatibility 1-1
EMC Information 9-1
Environmental 2-7
Expel Air Button 2-11

P
Pause 2-18
Pausing an Injection 5-9
Pressure Limit 2-17
Phase Attribute 2-18
Priming Tubing 4-9
Priming Tubing with Saline 4-9
Priming Tubing with Contrast 4-9
Product Identification 1-1
Protection against electric shock 1-1
Protocol Injection 5-7
Protocol name 2-16
Protocol Messages 8-3
Protocol Screen 2-21
Power On/Off 3-1

F
Features 1-8
Fill Syringe 4-5
Filling Syringe Automatically 4-6
Filling Syringe Manually 4-6
Flow Rate 2-17
Fluid Delivery Performance 2-7
Forward Button 2-11

H
Help Screen 2-36
History Screen 2-35
Hold 2-18
Home Screen 2-15

I
Indications for use 1-1
Injection Delay 2-17
Injection Messages 8-2
Injector Arm 2-8
Injector Ready Messages 8-1
Installation 6-1

K
KVO 2-15
KVO Parameters Setup 2-27

L
Locating Parts 6-8
Locating parts of Zenith-C22 6-8
Locating parts of Zenit-C20 6-9
Language Selection 2-29

M
Main controller 2-37
Maintenance 7-1
Maximum Flow Rate 1-8
Messages 8-1
Mode of Operation 1-1
Monthly Inspection 7-1
Moving Piston Rod 2-11

O
Over and Under Injection Protection 1-8

T
Test Button 2-12
Test Injection 2-12
Terminating an Injecting 5-10
Total time 2-15
Total Volume 2-16
Turing the System Power On 3-1

Purging Air from Syringe 4-8
Turing the System Power Off 3-2

R
Ready Button 2-12
Ready Injection 2-12
Readying System 4-10
Readying Sequence 4-1
Recalling Protocol 4-3
Removing Syringe 5-11
Restarting an Injection 5-10
Reviewing Parameters 5-2
Routine maintenance 7-1
Running KVO Injection 5-4

S
Scan delay 2-17
Specifications 2-4
Store Protocol 2-21
Stop Button 2-11
Symbols 1-2
System Installation 6-1
System Overview 2-1
System Response to Occlusions 1-8
System Status 2-12
System Setup and Test Screen 2-25

U
User Qualification 1-1

V
Volume Display 2-12

W
Warnings 1-4
Weight 2-4

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