

# **Safety and Performance Information of SinoAngio-1200 High-Pressure Injector**

**Sino Medical Device Technology Co., Ltd.**

## Statement:

The information in this Manual is based on the product-related experience and knowledge which has been acquired by Sino Medical-Device Technology Co., Ltd. ("SINOMDT") before the release of this Manual.

This manual is only for the purpose of directing the use, operation and maintenance of SinoAngio Series High-Pressure Injector. The company will not be liable for any damage or personal injury caused by referring to the contents of this manual for other purposes.

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Contents of this manual are subject to change for product upgrades or design improvements without prior notice.

For any doubts, please contact us or our authorized service agency. Please read this manual carefully before installing the SinoAngio Series High-Pressure Injector.



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# 1. Safety Information

## 1.1 Conventions

Three types of information are used to emphasize relevant information about the patient or device and to indicate potential risks.

	<p><b>CAUTION:</b></p> <p>It is used to alert you to situations in which product or environmental damage may cause property damage.</p>
	<p><b>WARNING:</b></p> <p>It is used to alert you to situations that may result in personal injury or death.</p>
<p><b>NOTE:</b></p> <p>It is used to highlight important instructions that affect how this manual and the product in this manual are used.</p> <p>It also provides additional information such as detailed explanations, tips, or reminders.</p>	

## 1.2 Product Composition

The SinoAngio series includes the following models:

- SinoAngio-1200 High-Pressure Injector

The injector consists of a single-barrel injector head and a local console integrated with the main unit. Optional accessories include a remote console, a warmer, and an online line (determined by compatibility with DSA equipment).

<p><b>NOTE:</b></p> <p>The product must be operated and maintained by individuals who have received training and have rich knowledge of its operation and maintenance. For the sake of safety, please carefully read safety precautions before use and adhere to all cautions, warning and notes specified in the Manual.</p>
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## 1.3 Safety Overview

The device is classified as Class I with type CF applied part, IPX1, designed for continuous operation, and is not to be used in oxygen-rich environments.




Key safety precautions include:

- The operator shall not open the housing of the device under any circumstances.
- DO NOT disable or short-circuit the safety features of the device.
- The device is a mobile device, and its casters need to be locked in work condition.
- DO NOT attempt to repair the device by yourself if it cannot work normally. Immediately contact SINOMDT or a qualified serviceman authorized by SINOMDT.
- DO NOT open the housing since no user serviceable parts are inside.
- Follow all WARNINGS and CAUTIONS, whether express or implied.
- Follow all safety signs on the device.
- Disconnect the device from the mains supply using the main power switch. In addition, the red button on the right of the device is the emergency switch for quickly cutting off the power supply in case of emergency. DO NOT use this switch as the main power switch.
- Both remote and local consoles can control the injector (if a remote console is equipped), but only one console should be operated at a time to prevent conflicting commands that could harm the machine and the patient. In the preparatory phase, only the local console can respond to user's operations, while the remote console is locked in this phase. A prompt window will be popped up when users click the touch screen of the remote console during this phase to avoid accidents.








## 1.4 Electrical/Mechanical Safety


Only qualified serviceman who are trained and authorized by SINOMDT can open the housing of the device to replace the electrical and mechanical components; otherwise device safety may be compromised. Warnings are listed below:

### 1.4.1 Mechanical Safety





	<p><b>WARNING:</b></p> <p>The device is a mobile device, and its casters should be locked before the operating the product.</p>
	<p><b>WARNING:</b></p> <p>DO NOT operate the device with its housing open.</p>
	<p><b>CAUTION:</b></p> <p>The connection port between the device and the syringe is a special one. The high-pressure injector and its accessories must be the special products recommended to be used with the device by our company.</p>

## 1.4.2 Electrical Safety


	<p><b>WARNING:</b></p> <p>To prevent the risk of electric shock, connect this device only to a properly grounded power supply, and DO NOT use a three-pin plug in a two-pin socket.</p>
	<p><b>WARNING:</b></p> <p>The earth wire of the device must be connected to the grounded connector correctly and securely. DO NOT remove or disconnect the earth wire for any reason during operation.</p>
	<p><b>WARNING:</b></p> <p>Risk of electric shock! DO NOT open the housing of the device during operation or when the device is in power-on status; only an authorized maintenance engineer is allowed to do so.</p>
	<p><b>WARNING:</b></p> <p>It is not allowed to modify the device.</p>
	<p><b>CAUTION:</b></p> <p>Prior to use, user must check that the device and cables have no obvious damage that may affect patient safety or device performance. The recommended check interval is at least once a week. It is suggested to replace any component with obvious damage before use.</p>
	<p><b>CAUTION:</b></p> <p>The device should undergo periodic safety testing to ensure safety, including leakage current testing and grounding performance testing. The recommended testing frequency is once a year, or in accordance with local regulations and inspection procedures.</p>
	<p><b>CAUTION:</b></p> <p>Turn off the device before cleaning. Cleaning includes wiping the dust on the surface of the device with a soft brush or a soft cloth, using a brush to sweep off the dust on the connector and the edges of the panel, or wiping with a soft cloth dampened with neutral detergent/neutral disinfectant or 70% alcohol. Prevent any detergent or disinfectant from infiltrating into the device. Pay special attention to connectors, touch screens, panel edges and other parts.</p>









	<p><b>CAUTION:</b></p> <p>The fuses located at the lower back of the device are rated T4AH 250V (Φ5x20, slow-blow, high-breaking capacity). Use only fuses of the same specification for replacement to prevent electric shock or fire.</p>
<p><b>NOTE:</b></p> <p>In case of emergency while operating the device, immediately press the red emergency switch to cut off power and terminate operation.</p>	



### 1.4.3 Environmental Safety

	<p><b>WARNING:</b></p> <p>Make sure the operating environment of the device meet requirements, otherwise abnormal operation may be caused.</p> <p>The limits of the operating environment are as below:</p> <p>Operating temp.: +5 ~ +40°C, relative humidity: 20% ~ 80%</p> <p>Atmospheric pressure: 860hPa ~ 1060hPa</p> <p>Power voltage: AC 230V ± 10%, frequency: 50/60 ± 1Hz.</p> <p>Rated power: SinoAngio-1200: 750VA SinoAngio-1200L: 750VA</p> <p>External fuse: T8AL, 250V</p>
	<p><b>WARNING:</b></p> <p>In order to avoid the possible risk of explosion, avoid using the device in an environment with any flammable anesthetic gas mixed with oxygen or nitrous oxide.</p>
	<p><b>CAUTION:</b></p> <p>Keep the environment clean, and avoid vibration. Keep away from corrosive drugs, dust, heat, and moisture.</p>
	<p><b>CAUTION:</b></p> <p>EMI! Make sure the installation and operating environment are free from intensive EMI, such as radio transmitters or cell phones.</p>

### 1.4.4 Operational Safety








	<p><b>WARNING:</b></p> <p>Air must be expelled before formal injection, and the injection can only be carried out after air expelling is completed, otherwise it is very likely to cause air embolism in the patient.</p>
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	<p><b>WARNING:</b></p> <p>Both remote and local consoles can control the injector (if a remote console is equipped), but only one console should be operated at a time to prevent conflicting commands that could harm the machine and the patient.</p>
	<p><b>WARNING:</b></p> <p>This device must be used in combination with its supporting syringes and accessories.</p> <p>Recommended accessories specifications are provided with the product. Please use accessories of the same specifications or fully compatible with the device.</p>
	<p><b>WARNING:</b></p> <p>Syringe is disposable and cannot be recycled in order to avoid cross-infection.</p> <p>Please use it promptly once unpacked.</p>
	<p><b>WARNING:</b></p> <p>A special pipette (J-shaped tube) in the sterile syringe kit should be used, and connecting tube should not be used to take in drugs to prevent cross-infection.</p>
	<p><b>WARNING:</b></p> <p>In case of an accident such as adverse reactions, needle slips, etc. during injection, immediately press [<b>Pause</b>] or [<b>Stop</b>] button to stop the injection or directly press the <b>red emergency switch</b> on the side of the device to cut off the power.</p>
	<p><b>CAUTION:</b></p> <p>When connecting the extension tube (flexible tube) to both ends of the syringe, align and tighten appropriately to ensure a secure and reliable connection, avoiding excessive force that may cause the connector to break.</p>
	<p><b>WARNING:</b></p> <p>During injection, injector head should keep tilted downwards to ensure that the drug sinks to the front of the syringe to avoid air embolism.</p>
	<p><b>WARNING:</b></p> <p>To remove syringe from the injector after injection, the connecting flexible tube must be removed from the syringe before pressing [ ◀ ],</p>

	[◀◀] or [Back To The Start] button, so as to avoid accident.
	<b>CAUTION:</b> Take care not to pinch your fingers or palms while turning the injector head.
	<b>WARNING:</b> This device is specifically intended for: Injecting contrast agents into human patients via arterial or venous routes for diagnostic studies. DO NOT attempt to use this product for any other purposes. This device is not suitable for use in conjunction with MRI or CT systems.

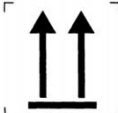




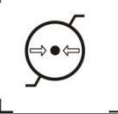

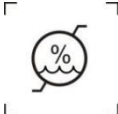
## 1.5 Symbols and Labels

### 1.5.1 Safety Symbols


	"ON" or power on
	"OFF" or power off
	Protective Earthing (Ground)
	Warnings
	Emergency Stop
	The device itself does not have an applied part. Patient connection and patient piping used with this device are considered as applied parts and are of type CF.
	Alternating Current
AC	Alternating Current








	Refer to the accompanying documentation
	Equipotential
	Non-Ionizing electromagnetic radiation

### 1.5.2 Transport Protection Symbols

	This Side Up
	Fragile. Handle with Care.
	Keep dry.
	DO NOT roll
	Temperature Limit
	Atmospheric Pressure Limit
	Stacking Layer Limit
	Humidity Limit

### 1.5.3 Other Symbols

	Manufacturer
---	--------------

	Manufacturing Date
	S/N
	Product Identification
	According to GB 4208-2008 Degrees of Protection Provided by Enclosure, the device is rated IPX1, against ingress of dripping water.
	CE certification mark. The numeric code of the mark is the code of certificate authority.
	Indicates the item is a medical device
	Indicates the authorized representative in the European Community/European Union

## 1.6 EMC Statements



NOTE:

- Please follow the EMC instructions in the User Manual to install and use the device.
- Portable and mobile RF communication devices may affect the performance of the [SinoAngio Series High-Pressure Injector]; keep away from sources of strong electromagnetic interference (e.g., mobile phone, microwave oven) during use.
- Refer to the Annexes for the Guide and Manufacturer's Declaration.



WARNING:

- DO NOT stack [SinoAngio Series High-Pressure Injector] on/under or get it close to any other equipment. If you have to use it this way, observe and verify whether it works properly in such conditions first.
- According to the intended use of the [SinoAngio Series High-Pressure Injector] and the electromagnetic environment where it is used, the device is defined as Class A equipment, and will not be used in living environments since it is impossible to provide adequate protection for radio reception in such environments.
- Using any accessory or cable other than those provided by the manufacturer as spare parts may cause higher electromagnetic emission or lower electromagnetic immunity.

Guidance and manufacturer's declaration—electromagnetic emission for the High Pressure Injector.

Guidance and manufacturer's declaration – electromagnetic emissions

The SinoAngio series high-pressure injector is intended for use in the electromagnetic environment specified below. The customer or the user of the SinoAngio series high-pressure injector should be assured that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - Guidance
Conducted and radiated RF emissions CISPR 11	Group 1	The SinoAngio series high-pressure injector uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Conducted and radiated RF emissions CISPR 11	Class A	
Harmonic distortion IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker IEC 61000-3-3	Not applicable	


## Guidance and manufacturer's declaration – electromagnetic immunity

The SinoAngio series high-pressure injector is intended for use in the electromagnetic environment specified below. the customer or the user of the SinoAngio series high-pressure injector should assure that it is used in such an environment			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
Electrostatic Discharge(ESD) IEC 61000-4-2	Contact ±8kV	Contact ±8kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
	Air ±2 kV, ±4 kV, ±8 kV, ±15 kV	Air ±2 kV, ±4 kV, ±8 kV, ±15 kV	
Electrical fast transients/bursts IEC 61000-4-4	±2 kV for input power port ±1 kV for signal input/output parts port 100 kHz repetition frequency	±2 kV for input power port ±1 kV for signal input/output parts port 100 kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	line-to-line ±0.5 kV, ±1 kV Line-to-ground ±0.5 kV, ±1 k, ±2 kV	line-to-line ±0.5 kV, ±1 kV Line-to-ground ±0.5 kV, ±1 k, ±2 kV	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips IEC 61000-4-11	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	Mains power quality should be that of a typical commercial or hospital Environment .If the user of the SinoAngio series high-pressure injector requires continued operation during power mains interruptions, it is recommended that the SN-M Series Pump be power from an uninterruptible power supply or a battery
	0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0°	0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0°	
Voltage interruptions IEC 61000-4-11	0 % UT; 250/300 cycle	0 % UT; 250/300 cycle	

Rated power frequency magnetic field IEC 61000-4-8	30A/m	30A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level UT =230V/50Hz			

## Guidance and manufacturer's declaration – electromagnetic immunity

The SinoAngio series high-pressure injector is intended for use in the electromagnetic environment specified below. The customer or user of the SinoAngio series high-pressure injector should assure that it is used in used in such an environment.

IMMUNITY test	IEC 60601 TEST LEVEL	Compliance level	Electromagnetic environment - guidance
Conducted disturbances induced by RF fields IEC 61000-4-6	3 V 0,15MHz–80MHz 6 V in ISM bands between 0,15MHz and 80 MHz 80 % AM at 1kHz	3 V 0,15MHz–80MHz 6 V in ISM bands between 0,15MHz and 80 MHz 80 % AM at 1kHz	Portable and mobile RF communications equipment Should be used no to any part of the SN-M Series Pump, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter  Recommended separation distance $d=1.2\sqrt{P}$ $d=1.2\sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d=2.3\sqrt{P} \quad 800 \text{ MHz to } 2,5\text{MHz}$ Where P is the maximum output power rating of the transmitter in watts(w) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should
Radiated RF EM Fields IEC 61000-4-3	3 V/m 80MHz to 2,7GHz 80% AM at 1kHz	3 V/m 80MHz to 2,7GHz 80% AM at 1kHz	Be less than the compliance level in each frequency range. b Interference may occur in the vicinity of equipment marked with the following symbol:  

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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 SinoAngio series high-pressure injector is used exceeds the applicable RF compliance level above, the SinoAngio series high-pressure injector should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the SinoAngio series high-pressure injector.

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

Guidance and manufacturer's declaration –

#### ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	Immunity test/ compliance level (V/m)
385	380-390	TETRA 400	Pulse Modulation 18Hz	1.8	0.3	27
450	430-470	GMRS 460 FRS 460	FM ±5kHz deviation 1kHz sine	2	0.3	28
710	704-787	LTE Band 13,17	Pulse Modulation 217Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse Modulation 18Hz	2	0.3	28
870						
930						
1720 1845 1970	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3,4,25; UMTS	Pulse Modulation 217Hz	2	0.3	28

2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse Modulation 217Hz	2	0.3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse Modulation 217Hz	0.2	0.3	9
5500						
5785						

**ATTENTION:**

If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

For some services, only the uplink frequencies are included

The carrier shall be modulated using a 50 % duty cycle square wave signal.

As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

Recommended separation distances between portable and mobile RF communications equipment and SinoAngio series high-pressure injector

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

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d=1.2\sqrt{P}$	80 MHz to 800 MHz $d=1.2\sqrt{P}$	800 MHz to 2,5 GHz $d=2.3\sqrt{P}$
0.01	0.12	0.23	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3

100	12	12	23
<p>For transmitters rated at a maximum output power not listed above, the recommended separation distance <math>d</math> in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where <math>P</math> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.</p> <p>NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.</p> <p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			

## 2. Product Introduction

### 2.1 Overview

The SinoAngio Series High-Pressure Injector, developed by Sino Medical-Device Technology Co., Ltd., are designed for vascular imaging. This series includes the models SinoAngio-1200 .

Product Model	SinoAngio-1200
Product Name	High-Pressure Injector
Product Usage	Used for cardioangiography & peripheral angiography
Targeted Part	Cardiovascular and peripheral vascular
Servo Motor and Servo Driver	SYNTRON servo driver MS0075A SYNTRON servo motor 60CB060C
Range of Pressure	100-1200Psi
Range of Injection Rate	0.1-50ml/s
Dosage	0-150ml
Warmer	yes

### 2.2 Application Scope

It only applies to injection of contrast agent for angiography.

DO NOT use this product series together with a CT or MRI device.

### 2.3 Intended Use

Designed for use with disposable syringes, the SinoAngio series is intended for medical facilities to administer contrast media for enhanced angiography.

### 2.4 Intended Users

The intended users are professional medical staff with medical knowledge and clinical experience of corresponding fields.

### 2.5 Usage Environment

The product is intended for use in interventional radiology, interventional surgery rooms, and hybrid operating rooms (not recommended for radiology departments. For radiology applications, SINOMDT

offers other models such as SinoPower-S, -D, etc.), and are recommended for use with DSA equipment (such as large C-arms, medium C-arms, etc.).

## 2.6 Indication

None.

## 2.7 Intended Patient Population

This product is suitable for general patients. Patient physiological information and institutional guidelines should be taken into account to select catheter size and injection protocol.

## 2.8 Contraindications

The device is not to be used for transfusion, chemotherapy, or any purposes not explicitly stated.

Intended PATIENT Population: This product is generally applicable to patients of all ages, weights, and health conditions. However, the following contraindications apply:

Patients allergic to iodide;

Patients with extremely weakened body;

Patients with severe heart, lung, liver, or kidney dysfunction (one or more);

Hyperthyroidism;

It is prohibited to use this product for contrast agent injection for patients falling into the above categories.

Furthermore, it should not be used in patients deemed unsuitable for angiography by a physician, those with severe vascular sclerosis, vascular leiomyomas, history of spontaneous vascular rupture, or pregnant women.

## 2.9 Clinical Benefits

The device can achieve consistent delivery of contrast media for enhanced imaging.

## 2.10 Side effect

There is no side-effect directly associated to the use of the device.

## 2.11 Function Introduction

- The 150ml syringe can meet all injection needs.
- Injection Rate Settings: SinoAngio Series: 0.1~50.0ml/s;

- Set and store up to 120 injection protocols.
- At most 8 injection steps can be set for each protocol, thus various clinical needs can be satisfied (e.g., multi-phase injection).
- Dual-console operation (remote console available as an optional accessory) provides fully synchronized displays and touch control operation. Users can set injection protocols and control injections both from the scanning room and the observation room, enhancing convenience and significantly improving work efficiency.
- The graphical interface is displayed in the large-size color screen and the easy-to-operate touch screen responds to the touch operation on a real-time basis.
- The LED indicator at the end of the injector head visually reflects the state of the injector.
- Air Bubble Removal Protection is used for reminding the operator to thoroughly exhaust the air within the syringe and tube, otherwise injection will not be carried out. It effectively eliminates the risk of air embolism.
- The particular tilt sensor protection can better prevent air embolism.
- The independent pressure probe can monitor the pressure inside the syringe on a real-time basis. In case the pressure exceeds the limit value, the unit will stop injection automatically and send sound-light alarms, so that the patient is well protected.
- The high-quality hardware module can truly support the console cable with a length up to 20m;
- "One touch" function: such two buttons as "To The End" and "Back to The Start" greatly reduces the complexity of liquid medicine preparation and improves the efficiency.
- The special button "Delete this Procedure" in the [Protocol Preparation] interface makes it extremely easy for the user to prepare multi-procedure protocols.

## 2.12 Structural Composition

The SinoAngio series structure is as illustrated in Fig. 2.1.

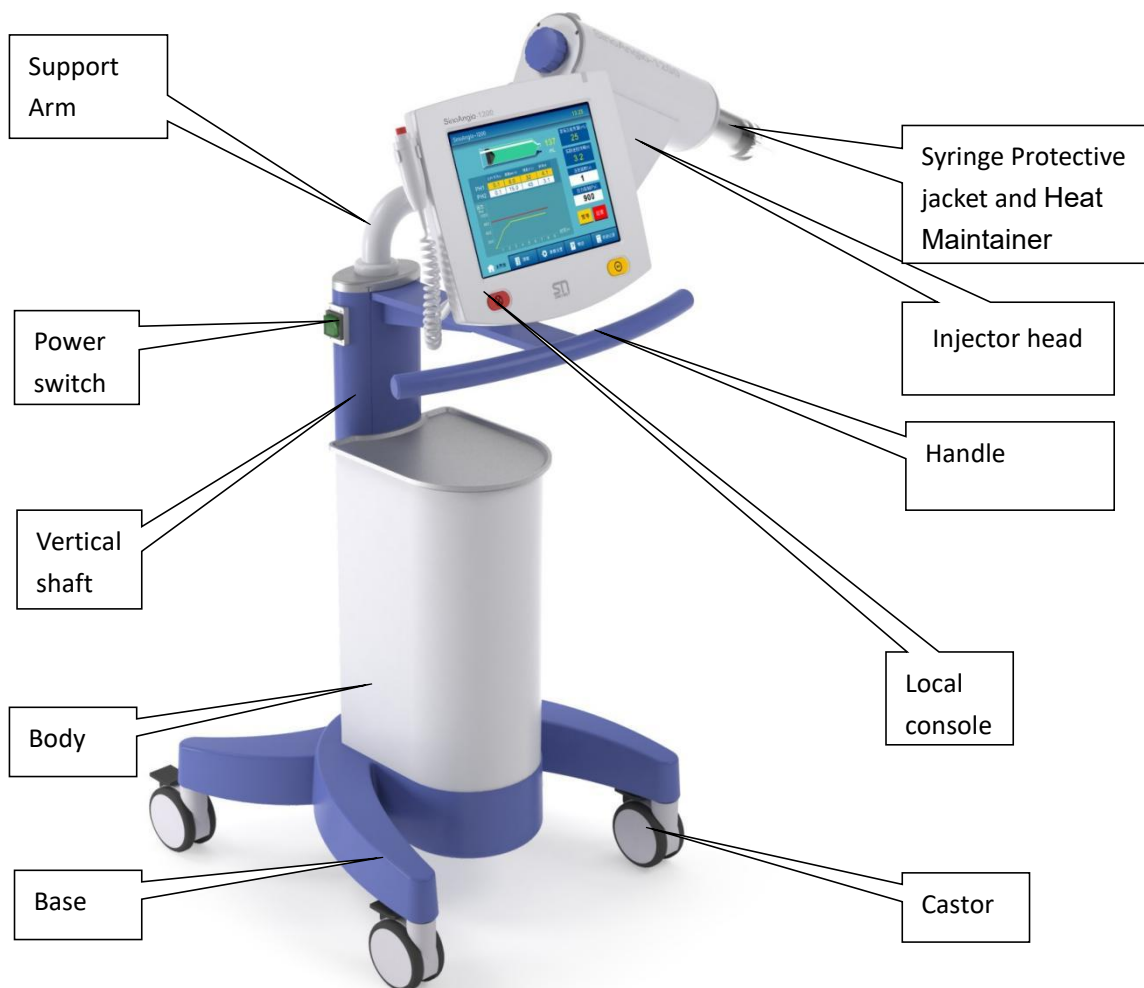


Fig. 2.1 Structure of SinoAngio Series

## 2.13 Maintainability

As shown, the device features a straightforward construction. All the key internal components are made of quality materials that meet safety regulations. The main driving parts such as servo motors, screw rods and bearings are procured from first-class manufacturers at home and abroad, and they can continuously and stably work within the service life of this product.

Replaceable parts, like fuses, are designed for easy access near the power input and can be changed using simple tools. Additionally, internal circuit boards can be quickly replaced after opening the easily removable cover plate if faults occur, with all parts and cables easily visible and accessible, ensuring good maintainability.

## 2.14 Specification

1. This injector can be used with 150ml disposable sterile syringes of specified specifications as well as its accessories.
2. Range of injection volume: 0~150.0ml; incremental volume: 0.1ml.
3. Injection volume accuracy: Injection rate  $\leq 15\text{ml/s}$ , injection dose deviation should not exceed  $\pm 5\%$ ; Injection rate  $> 15\text{ml/s}$ , injection dose deviation should not exceed  $\pm 10\%$ .
4. Range of injection rate: SinoAngio Series: 0.1~50.0 ml/s, minimum increment: 0.1ml/s.
5. Injection rate accuracy: Deviation should not exceed  $\pm 5\%$ .
6. Range of injection pressure: SinoAngio-1200: 100~1200Psi; incremental volume: 1 Psi  
The unit can be switched to Psi or Kpa.
7. Injection pressure accuracy: Deviation should not exceed  $\pm 50\text{psi}$  at  $\leq 600\text{psi}$  pressure limit; and  $\pm 70\text{psi}$  above 600psi.
8. The device will issue audible and/or visual alarms and display a warning popup when injection pressure exceeds the set protection value.
9. To auto-load medicine, click the "Auto-fill" button on the Home interface; the device will then automatically draw medication into the syringe.

## 2.15 Other performance parameters

- Trial injection rate: 0.1~3.0ml/s, default: 1ml/s.
- Trial injection volume: 0.1~5.0ml, default: 3.0ml.
- Up to 120 protocols can be saved, with a maximum of 8 steps per protocol.

## 2.16 Requirements for Transport and Storage Environment

Transport and Storage temperature range:  $-20^{\circ}\text{C} \sim +60^{\circ}\text{C}$

Relative humidity range:  $\leq 93\%$  (without condensation)

Atmospheric pressure: 50kPa  $\sim$  106kPa

## 2.17 Product Life Expectancy

The life expectancy of the device is 10 years.

## 2.18 Pollution Degree

The device's pollution degree is Level 2.

## 2.19 Waste Disposal

The device itself generates no waste during its operation.

Accessories, such as disposable sterile syringe kit used with contrast agents, may pose a biological contamination risk and must be disposed of according to hospital procedures.

The device should be disposed in compliance with the local regulations when reaches the end of life expectancy.

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