Shenzhen Hawk Medical Instrument Co., Ltd.

Safety and Performance Information Relevant to The User or Other

Powered Contrast Media Injector

Model: HK-CD115,HK-CD200,HK-CD115-A,HK-CD200-A

Please read the Manual before installing and using the product.

Please keep it for future reference.

CE 0197

057-00655-01

Contents

Revision Notes

On the premise of comply with relevant laws and regulations, we'll revise the manual timely according to the improvement of products or update of laws and regulations.

This Manual applies to Powered Contrast Media Injector:

Document No.	Revision	Revision date
057-00655-00	V1.0.0	30-07-2025
057-00655-01	V1.0.1	10-11-2025

User manual version upgrade instructions:

V X.Y.Z

V means version No. of user manual.

X means device has big upgraded: When software, hardware and construction of device have big modified, the user manual should be upgraded accordingly.

Y means the device has small improvement: In order to better using the device, the software, hardware and construction of device have been tiny improved (it is not necessary for re-registration after evaluation), the user manual should be upgraded accordingly.

Z means correcting information of user manual while the device has no changed. It only correct the wrong word/ diagram/explanation and so on.

Operation Manual

The Powered Contrast Media Injector has an expected service life of 8 years from the date of product installation when operated according to the instructions provided with this device.These 8 years include suggested or mandatory actions of preventative maintenance and repair activities, as well as required calibration(s) that are needed. Required reading includes the instructions for use and other materials provided with the device. This also includes any hardware and software updates that may be required.

Expected service life: 8 years. The date of manufacture is shown on the label.

Please report any serious incidents involving this device to Shenzhen Hawk Medical Instrument Co., Ltd and your local authority (or, if applicable, to the appropriate regulatory authority in the country where the incident occurred).

Please refer to Section 2 of this Manual for a glossary of symbols used for the Powered Contrast Media Injector of Shenzhen Hawk Medical Instrument Co., Ltd.

1. Introduction

This Manual applies to the Powered Contrast Media Injector from Shenzhen Hawk Medical Instrument Co., Ltd. Please read all the information included in this Manual. Understanding these information will help the user to operate this equipment safely.

1.1 Certification

This device operates at 100-240 VAC, 50/60 Hz, 300 VA ,and is designed to comply with EN60601-1:2006+A1:2013+A12:2014+A2:2021 and EN60601-1-2:2015+A1:2021 standards. Special attention needs to be paid to precautions regarding electromagnetic compatibility (EMC) when installing and using the injection system. For more information on EMC, please refer to the "Appendix 1 Information of Electromagnetic Compatibility" section of this Manual.

1.2 Product Feature

The Powered Contrast Media Injector is a contrast media injection system designed for use during CT examinations,and is a software-controlled dual channels injection medical device,it is designed to allow a user to fill disposable syringes to perform an injection with a user-programmed volume, flow rate and/or duration.

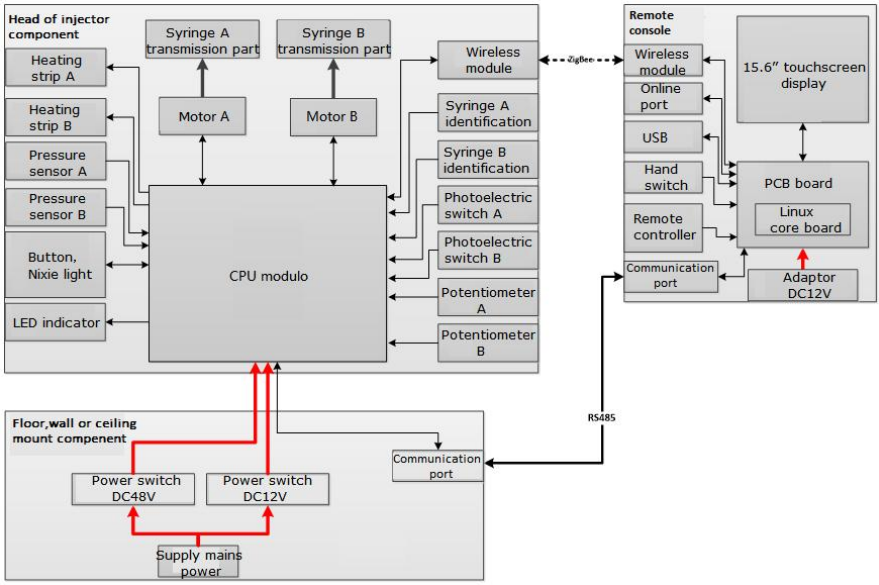
The Powered Contrast Media Injector consists of Injecton host, remote console, remote controller and hand switch,etc, the remote console is to be connected by wired or Zigbee communication channel when using. The injection host is used to carry out the injection action according to the setting procedure, and the remote console is used to set and manage the technical parameters such as volume delivered range,flow rate range,injection pressure and time,etc,and also display the data from settings and injections.

The Powered Contrast Media Injector is intended to be used in combination with disposable syringe sets to achieve the intended use,however, the disposable syringe sets are not included as the part of the device,the user should match the disposable sets recommended by Hawk Medical that has been legally marketed on the EU market.

1.3 Principles of Operation

Powered Contrast Media Injector can be used on the remote console to set injection parameters and system configuration for the two channels injection, and also through the buttons on the head of injector to achieve suction, venting, pre-injection, injection functions.The principle of operation is that the microprocessor chip sends out a signal to control the motor rotation, and then the motor drives the roller screw to turn the rotary motion into a linear motion, and pushes the piston of the syringe to inject, accordingly the contrast agents in the syringes are pumped into the human body, so as to realise high-precision, smooth and pulsation-free injection.

The schematic is as follows:



1.4 Intended use

The Powered Contrast Media Injector is indicated for the specific purpose of injecting intravenous contrast media or saline into humans for diagnostic studies in computed tomography(CT) applications.

The device is intended for use in general patient population who requiring contrast media injection for diagnostic imaging in medical institutions.

The device is intended to be used by trained personnel with experience in diagnostic imaging studies in in hospital institutions,such as hospitals and clinics.

Contraindications: none known.

1.5 Disclaimer

External wiring and modifications disclaimers: Shenzhen Hawk Medical disclaims liability for any modifications or interfaces with other equipment that are not in conformity with the specifications and information contained within this manual.

Anyone who connects additional equipment to the device or configures a medical system is responsible that the system complies with the relevant requirements of EN60601-1:2006+A1:2013+A12:2014+A2:2021. Any accessory or equipment connected to the device must be certified to either EN60601-1:2006+A1:2013+A12:2014+A2:2021 (Operator or Patient Environment Use) or, outside the patient environment, the level of safety must be equivalent to equipment complying with their respective EN or ISO safety standards, and must comply with the relevant requirements according to EN60601-1:2006+A1:2013+A12:2014 +A2:2021. Consult Shenzhen Hawk Medical for any modifications to the equipment.Screen images in this manual are for illustration purposes only.

1.6 Equipotential Connector (EPC)

The Equipotential Connector (EPC) is an electrical connection port on the injector used as a connection point between other equipment. The function of the EPC is to minimize potential voltage differences between all connected equipment.

1.7 Installation

The manual below describes the general installation guide,and the device must be installed by Hawk Medical-trained personnel. For more installation information, please contact Shenzhen Hawk Medical Instrument Co.,Ltd.

1.8 Patient environment

The injection host of Powered Contrast Media Injector is suitable for use within the PATIENT ENVIRONMENT.

1.9 Clinical benefits

The Clinical benefits of Powered Contrast Media Injector are defined as follows:

1) Enhance the contrast of blood vessels for diagnostic CT studies
2) Reduce the effective contrast media dosage

1.10 Statement

The Powered Contrast Media Injector is compliant with Medical Devices Regulation 2017/745.

According to this regulation, it is a class IIb device. This device carries the marking:

CE XXXX

Date of first CE marking: on going

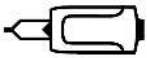
In accordance with the requirements of the Medical Device Regulation 2017/745, the Powered Contrast Media Injector is compliant with the following standards:

No.	Standard No.	Standard Description
1	EN60601-1:2006+A1:2013 +A12:2014+A2:2021	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
2	EN60601-1-2:2015+ A1:2021	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance-Collateral standard: Electromagnetic compatibility-Requirements and tests

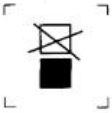
2. Symbols

2.1 Common Symbols

	**"Caution"** The occurrence of this condition or action may result in equipment damage or malfunction
	**"Warning"** The occurrence of this condition or action may result in personnel injury or life threatening risks
Caution	It indicates that this information is a caution. Caution reminds you of a situation that may cause minor or moderate injury to the patient or operator. Please read and understand the contents of the caution carefully before operating this injection system
Attention	It indicates that this information is an attention. Attention reminds you of a situation that may cause damage to the equipment. Please read and understand the contents of the attention carefully before operating this injection system
Note	It indicates that the following information is additional important information, or a reminder to help you recover from an error, or to point you to relevant information in this Manual

	BF applied part
	Refer to instruction manual/booklet
CLASS 1	Indicates the injection system is Class 1 medical equipment as defined by EN60601-1 standards.
IPX1	IPX1 identifies the degree of protection against fluid as drip proof for injector head of Powered Contrast Media Injector
	AC
	Injector head connection
	USB interface
	Remote controller
	Power switch
	Power connection cable
	Identifies DC power supply
	Identifies connection of the handswitch.
	Power unit on/off switch

	Syringe heater connection position
	Manufacturer
	European Authorized Representative
	Production date
	Humidity limitation
	Temperature limit
	Atmospheric pressure limitation
	Serial number
PN	Part number
	Reference number
	This side up
	Keep dry

	The device is an electrical and electronic device and must be disposed according to WEEE Directives
	Equipotential column
	Non-ionising electromagnetic radiation
	Importer
	Indicates a carrier that contains Unique Device Identifier information
	Indicates the item is a medical device
	This device is provided with a CE marking in accordance with the Medical Device Regulation 2017/745. XXXX is the Notified Body number
	Fragile , handle with care
	No stacking
	No tumbling

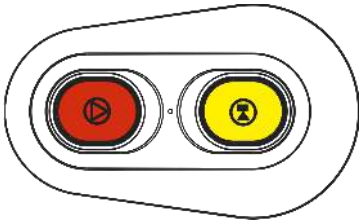
2.2 Injector Head Buttons

Figure 2-1 Single syringe injector head

Button/Icon	Description	Button/Icon	Description
B	Syringe B	**A**	Syringe A
	Syringe B Auto fill		Syringe A Auto fill
	Syringe B fast forward		Syringe A fast forward
	Syringe B slow forward		Syringe A slow forward
	Syringe B fast backward		Syringe A fast backward
	Syringe B slow backward		Syringe A slow backward
	Test B		Test A

KVO	KVO		Air exhaust confirmation
	Start/Pause		Stop injection and cancel ready

2.3 Remote controller buttons



Button/Icon	Description	Button/Icon	Description
	Start/Pause		Stop injection and cancel ready

3. Warning, Caution and Attention

3.1 Warning

Warning
Air embolism hazard - It may result in serious injury or death to patients. • Use only the components supplied by Hawkmed. • Use catheters and connectors with pressure ratings compatible with this system.
Environmental contamination hazard - It may result in serious injury or death to patients or staff. • Please visually inspect all components before use. • Do not use damaged components.

Electric shock hazard - It may result in serious injury or death to patients and/or staff.

• The system should only be turned on and repaired by qualified maintenance personnel.

• Use only the power cord provided with the system.

• Use only the power adapter provided by Hawkmed to avoid that may result in serious injury or death to patients/operator.

• Connect this equipment only to a power supply equipped with a protective grounding device.

Fire hazard - It may result in serious injury or death to patients and/or staff.

• Have the correct type of fuse replaced by Hawk Medical or Hawk Medical-trained personnel.

Application restriction - It may result in serious injury or death to patients.

• Do not use this system to inject any liquids other than intravenous contrast and commonly used saline.

• This equipment should not be used for drug injections, chemotherapy, or any other applications not indicated by this equipment.

• Follow the manufacturer's instructions for operation and use of contrast and saline.

• Connect only items that have been specified as part of ME SYSTEM or specified as being compatible with ME SYSTEM.

Danger

• Do not service or perform maintenance while the patient is using the injection system.

• The reconfiguration of ME SYSTEM by OPERATOR or the RESPONSIBLE ORGANIZATION is not permitted, please contact the manufacturer.

Reuse of disposable liquid sources may result in biological contamination.

• Please refer to the instructions for use provided by the liquid source manufacturer.

Mechanical hazard - Leakage or rupture of the connecting tube during injection may result in serious injury to patients.

• It is required to use the disposable components recommended by Hawk Medical.

• Use only syringes and connecting tubes rated up to 325 psi (2241 kPa). If using a pre-aspirated syringe adapter, please refer to the relevant operation manual for maximum pressure limits.

Danger

• Do not lean on the injection system in any type of installation configuration.

Warning

• To avoid the risk of electric shock, this equipment must be connected to a protective grounding supply mains.

Warning • The pump is susceptible to interference with magnetic field generated by the MRI devices. • Use the device within a MRI environment is unavoidable. Keep a safe distance from the magnetice field outside the area that list.
Warning • Any other equipment or network/data coupling cannot be connected except for the signal input/output parts that make up the system part that can be connected.
Warning • Unauthorized modifications to this equipment are not permitted,that may result in serious injury o patients.
Warning • This equipment is not compatible with HF SURGICAL EQUIPMENT, and should not use in the presence of active HF SURGICAL EQUIPMENT.

3.2 Caution

Caution
Mechanical hazard - It may cause minor or moderate injury to patients and/or staff. • Follow the instructions in this Manual to use the system. If there is an error or malfunction in the system, follow the system notifications. Follow the error message. • Do not use the system in an environment with flammable/combustible gases (e.g., anesthetics) or other reagents. • The device cannot be used in an OXYGEN RICH ENVIRONMENT. • Do not to position device to make it difficult to operate the disconnection device.
Electric shock hazard - It may cause minor to moderate injury to patients and/or staff. • Only plug the system directly into a power supply. Do not plug the system power cord into an extension cord or into a power strip with multiple jacks.
Program delay hazard - It may result in serious injury or death to patients and/or staff. • Turn off any equipment that may generate high intensity electrostatic discharge.
Danger • Do not connect or disconnect accessories while the patient is using the system.

3.3 Attention

Attention
Electromechanical hazard - It may cause damage to the equipment. • Since condensation may damage electronic components, wait until the system has stabilized to room temperature before starting use.
Mechanical hazard - It may cause damage to the equipment. • Do not use sharp objects to touch the display screen for calibration. • Improper installation of components may damage them. Make sure all connections are secure and not too tight. This will help minimize the risk of leaks, disconnections and component damage.

4. System Overview

4.1 System Diagram

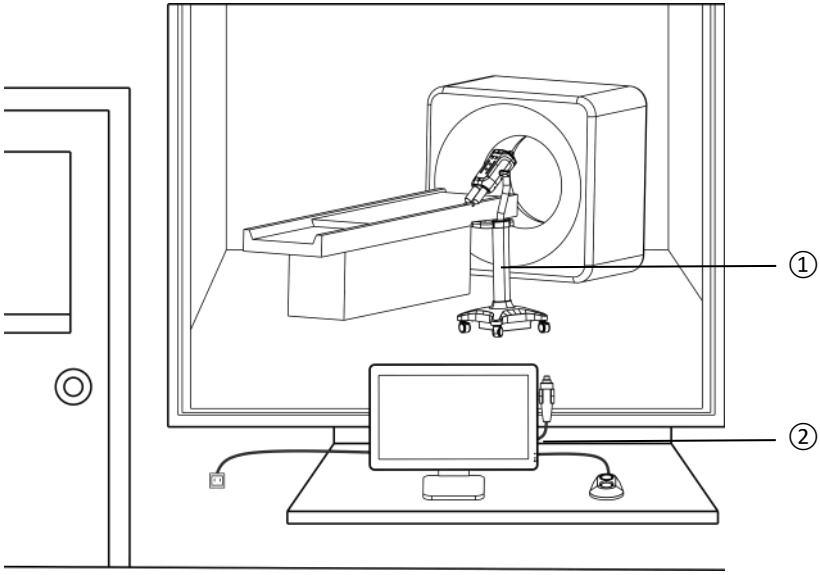


Figure 4-1 Trolley-type System Diagram

1-Host 2-Remote Console

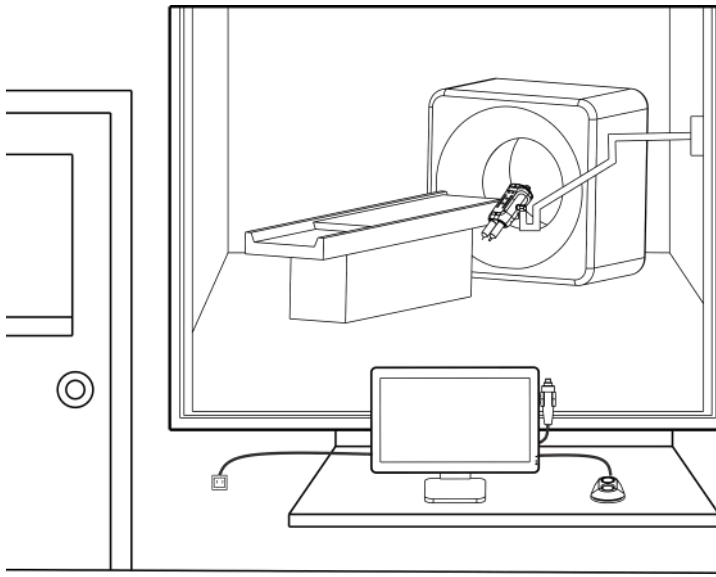


Figure 4-2 Wall-Mount System Diagram

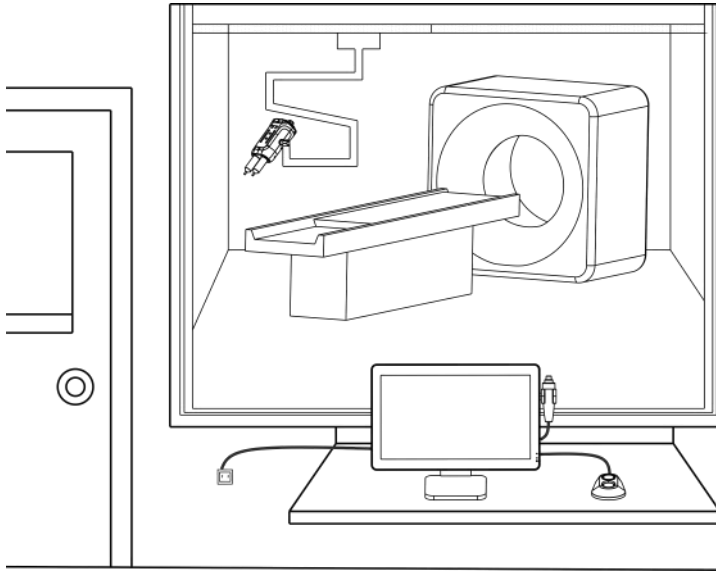


Figure 4-3 Ceiling-mount System Diagram

4.1.1 Movement in the room

When moving the system, grasp the base below the position shown on the label of the host. If the host does not have this label, grasp the host no more than 100cm above the floor.

4.1.2 Composition

This device consists of injection host, remote console, remote controller, hand switch, communication cable, AC adapter and syringe heater.

4.1.3 Software information

1) Software name: Powered Contrast Media Injector software

2) Software release version: V01

3) Minimum software environment:

- Main control module: MCU: STM32F103 or GD32F103 series microcontroller, memory: 512kbytes;
- Monitor module: MCU: STM32F103 or GD32F103 series microcontroller, memory: 256kbytes;
- HMI module: ARM Cortex-A7 or above processor, Linux system.

Functionality

This system is based on embedded software design, embedded software must rely on the corresponding target hardware board to run.The corresponding hardware circuit boards are designed for the software function modules, and the interface circuit design between the hardware circuit boards interacts with the system software architecture synchronously, so as to realize the whole machine functions, such as drug suction, exhaust and injection.

4.2 Product model difference

The models of device include HK-CD115, HK-CD200, HK-CD115-A, HK-CD200-A,the differences are listed below:

Table 1-Model Differences

Models	Different items		Same items				
	Syringe volume (ml)	Installation method	Structure	Power supply	Control circuit	User interface	Software
HK-CD115	115	Floor	Dual syringe	Same	Same	Same	Same

HK-CD200	200	Floor	Dual syringe	Same	Same	Same	Same
HK-CD115-A	115	Ceiling /Wall mount	Dual syringe	Same	Same	Same	Same
HK-CD200-A	200	Ceiling /Wall mount	Dual syringe	Same	Same	Same	Same

4.3 Basic information on liquid transfer

This page intentionally left blank.

4.4 Syringe Installation Characteristics

This page intentionally left blank.

4.5 Liquid Pressure and Pressure Limit

This page intentionally left blank.

5. Display Screen

This page intentionally left blank.

6. Injector Head and Hand switch

This page intentionally left blank.

7. Turn on and off system power

This page intentionally left blank.

8. Protocol Management

This page intentionally left blank.

9. Preparation for Injection

9.1 Control Room Preparation

Warning
Vascular hazard - It may result in serious injury or death to patients. • Please ensure that the rate set conforms to the regulations of the medical institution.

Caution
It may result in minor or moderate injury to patients. • Before selecting "Ready" on the display screen, make sure that you have set the correct protocol.

This page intentionally left blank.

9.2 Scan Room Preparation

Warning
Air embolism hazard - It may result in serious injury or death to patients. • Before connecting the system to the patient, exhaust all air remaining in the syringe, connector, connecting tube and catheter. • To minimize the chance of air embolism, ensure that one operator is designated to administer the syringe. Do not change the operator during operation. If the operator must be changed, ask the new operator to confirm that the air in the liquid tube has been exhausted. • To minimize the potential for accidental aspiration and injection, ensure that the patient is disconnected from the injector when using the forward and backward piston controls.

Biological contamination hazard - It may result in serious injury or death to patients and/or staff.

• After using liquid source containers and disposable items (check the labels of disposables for specific information), or when you suspect that equipment may have been contaminated, discard it in an appropriate manner.

• Do not reuse disposable liquid sources. Refer to the instructions for use provided by the liquid source manufacturer.

Environmental contamination hazard - It may result in serious injury or death to patients or staff.

• When handling disposable components,please maintain the sterility of all disposable components.

• Do not disassemble any disposable components.

• Please check the package and the contents before each use.

Bacterial contamination hazard - It may result in serious injury or death to patients and/or staff.

• Syringes should not be used as storage containers. Do not use syringes to store liquid.

Mechanical hazard - Leakage or rupture of the connecting tube during injection may result in serious injury to patients.

• Use only disposable components recommended by Manufacturer

• Use only syringes and tubes rated for pressure greater than the upper settable pressure limit of the injection system of 325 psi (2241 kPa).

Adverse reaction hazard - It may result in serious injury or death to patients.

• Check the patient's medical history to determine if he or she is allergic to the liquid source.

Impaired efficacy - It may result in serious injury to patients.

• Setting or loading an incorrect liquid source or concentration may result in patient injury or poor imaging.

Vascular hazard - It may result in serious injury or death to patients

• Use tubes and connectors with pressure ratings compatible with this system.

Caution

Mechanical hazard - Improper use of the syringe may result in serious injury to patients.

• Before injection, ensure that the syringe is properly installed to the front of the injector head. Improper fitting or improper rotation of the syringe may result in leakage, damage or loosening of the syringe during injection, as well as insufficient infusion volume and ineffective syringe operation.

This page intentionally left blank.

9.3 Installation Environment

Warning

Mechanical hazard - It may result in serious injury or death to patients.

• Electrical connection, installation, dismantling and maintenance of Powered Contrast Media Injector must be carried out by qualified technicians

• Powered Contrast Media Injector must be not installed in the MRI room.

• Prior to installation, the structural engineer must confirm that the ceiling or wall is strong enough to support the Powered Contrast Media Injector.

• Installation of equipment or hardware must follow local building specification.

Note: The HK-CD200/115 devices do not need to be installed, and only consider the use of the distance from the CT that is not less than 100cm to minimise interference with CT, and should be connected to a grounded outlet.

9.3.1 Ceiling mount environment

1) The installation of ceiling mount system should be carried out by qualified personnel in a scanning room with an area of not less than $30m^2$ and a height of not less than 3.3m.

2) The ceiling on which the device is installed should be able to withstand a tensile force of not less than 60kg.

3）Before installation of ceiling mount system, please read the mounting dimensions in Figure 15-7, as well as of the rotational degrees of freedom in detail.

4）The ceiling mount system can be installed on both sides of the CT, the minimum distance between the CT and the device is 100cm, it is recommended to determine the installation distance according to the actual scene to ensure the maximum swing of the ceiling mount, also can reduce the interference between the device and the CT. Below is the size information:

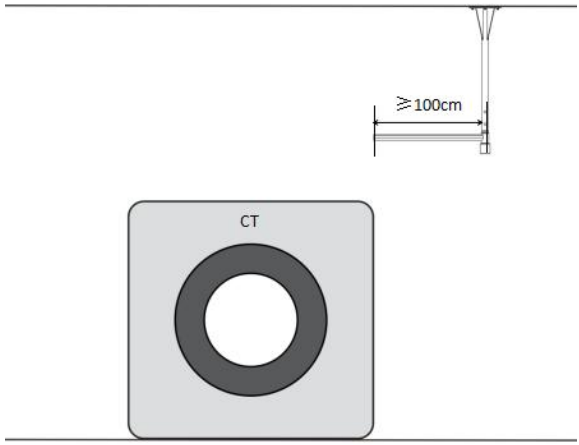


Figure 9.3-1 Distance of CT

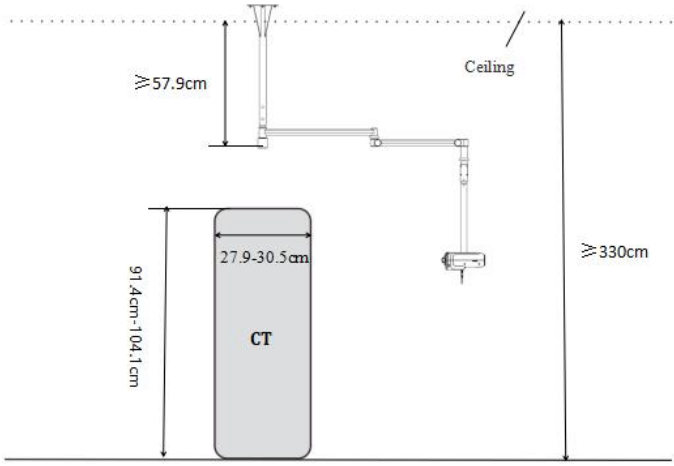


Figure 9.3-2 Distance of ceiling mount

5) When shipping,the internal cable and electrical connections of ceiling mount system has been made by the manufacturer and do not need to be reconnected by the operator.

6) The scanning room must be equipped with grounding wire. When in use, connect the Powered Contrast Media Injector to a grounded outlet for protection.

9.3.2 Wall mount environment

1) The installation of wall mount system should be carried out by qualified personnel in a scanning room with an area of not less than $30m^2$ and a height of not less than 3.3m.

2) The wall on which the device is installed should be able to withstand a vertical tensile force of not less than 50kg.

3) Before installation of wall mount system, please read the mounting dimensions in Figure 15-8, as well as of the rotational degrees of freedom in detail.

4) The wall mount system can be installed on both sides of the CT, the distance between CT and device is not less than 100cm as Figure 9.3-3 or 100-185cm Figure 9.3-4, it is recommended to determine the installation distance according to the actual scene to ensure the maximum swing of the ceiling mount, also can reduce the interference between the device and the CT. Below is the size information:

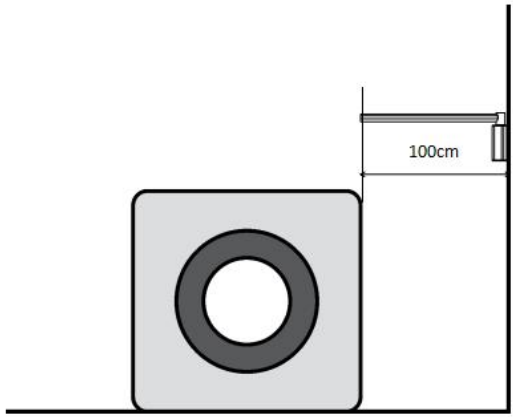


Figure 9.3-3 Distance of CT

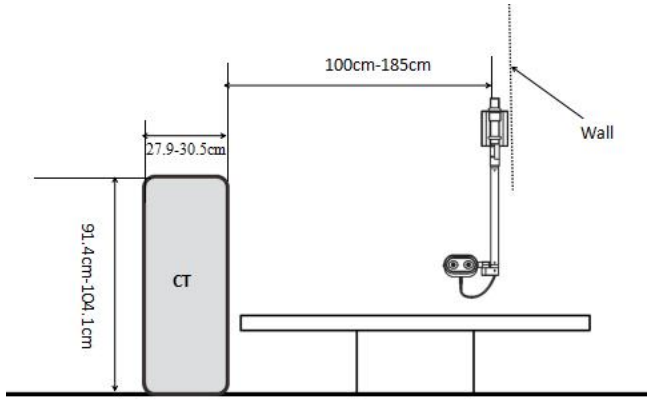


Figure 9.3-2 Distance of wall mount

5) When shipping,the internal cable and electrical connections of ceiling mount system has been made by the manufacturer and do not need to be reconnected by the operator.

6) The scanning room must be equipped with grounding wire. When in use, connect the Powered Contrast Media Injector to a grounded outlet for protection.

10. Ready and Injection

This page intentionally left blank.

11. Complete Injection

This page intentionally left blank.

12. Dismantle syringe and connecting tube

This page intentionally left blank.

13. Cleaning, Disinfection and Maintenance

Attention

Electromechanical hazard - It may cause damage to the equipment.

• Do not soak or immerse any components in water or disinfection solution.

• Do not use cleaning or disinfection agents that contain phenol,ethanol and strong aromatic, chlorinated, ketone or ether solvents.

• Do not let liquid seep into the device casing.

• Do not spray cleaner or disinfectant directly onto the console and injector host .

13.1 Daily

13.1.1 Check injection system

Frequency: daily

• Check for damage or cracking of various housings that cause liquid to leak into the interior or weaken the integrity of the device.

• Inspect all cables and power source that connect to the system. Look for cuts, cracks, frayed areas, or other obvious damage to the cables,if necessary,replace new one. Make sure all connectors are properly connected.

• Inspect the base, pedestal, overhead counterbalance and support arms for cracks and other defects that may damage the structure.

• Make sure all mounting bolts and screws are securely attached.

• Check that the rotation axis point and the vertical direction of the injector head must rotate freely.

• Make sure the caster rolls smoothly without sticking or friction.

• Make sure the locking devices on all casters are working properly.

Note: Follow all relevant guidelines for institutional, local or national safety recommendations related to cable wiring and installation.

Note: Contact Hawk Medical or your local distributor for service or repair.

13.1.2 Injector head cleaning

Frequency: daily and when stains are visible

13-1 Injector Head

Materials:

• Clean, soft and lint-free wipe

• Warm water

• Cleaner: 70% isopropanol

1) Turn off the injector power,and and the power cords must be disconnected from the device.

2) Clean the surface of the injector head with a clean, soft and lint-free wipe soaked in warm water (damp but not dripping) for at least 1 min until no stain is visible. If the wipe is visibly stained, replace it. During the 1 min cleaning time, ensure that all seams, grooves and buttons are clean.

3) Use a dry, clean, soft and lint-free wipe to thoroughly dry the injector head.

4) Wipe all external surfaces except the syringe piston and syringe connector with cleaner for 1min or until no stain is visible. Make sure all seams, grooves and buttons are clean.

5) Make the injector head dry completely.

6) Check the injector head to ensure that all surfaces are clean.

7) If any contrast or other debris can be seen, repeat steps 2 through 6 of the cleaning instructions until no stain is visible.

13.1.3 Injector head disinfection

Frequency: daily and when stains are visible

Materials:

• Disinfectant: 0.25%-0.30% quaternary ammonium compounds

1) Make sure the injector head has been thoroughly cleaned.

2) Wipe all external surfaces with cleaner. Make sure all seams, grooves and buttons are clean.

3) .Use disinfectant to keep the surface visibly wet for 3min. If needed, use an additional wipe to ensure the surface remains wet throughout the entire duration.

4) .Make the injector head dry completely.

13.1.4 Remote console cleaning

Frequency: daily

Materials:

• Clean, soft and lint-free wipe

• Warm water

• Cleaner: 70% isopropanol

1) Turn off the injector power,and and the power cords must be disconnected from the device.

2) Use a clean, soft and lint-free wipe soaked in warm water to wipe the remote console screen for 1min.

3) Wipe the remote console with cleaner for 1min until no stain is visible.Check the screen to ensure all surfaces are clean.

4) If any contrast or other debris can be seen, repeat steps 1 through 3 of the cleaning instructions until no stain is visible.

13.1.5 Base and other components cleaning

Frequency: daily

Materials:

• Clean, soft and lint-free wipe

• Cleaner: 70% isopropanol

1) Turn off the injector power.

2) Wipe the base and other components with a clean, soft and lint-free wipe soaked in warm water for 1min.

3) Wipe the base and other components with cleaner for 1min, or until no stain is visible.

If any contrast or other debris can be seen, repeat steps 2 through 3 of the cleaning instructions until no stain is visible.

13.2 Monthly

Perform an operation inspection on a monthly basis.

13.2.1 Operation inspection

The inspection of basic functions of the system should be an integral part of routine maintenance. Inspecting the system for proper operation will help identify problems that are not noticed during routine operation. The following shows a series of recommended steps related to the standard operation of the system. Please read the following operation steps carefully before beginning the inspection. If you find any problem, please contact .

Note: All problems found during this or any other inspection step should be solved before the system is used on the patient.

System labels

Ensure that all system safety and warning labels are properly located and clearly readable.

Turn on the power

1) Turn on the power of the system.

2) Check whether the prompt tone function of the equipment is working properly.

3) Check whether all displays and indications are working properly.

4) Check whether the ready indicator light on the injector head is working properly.

Turn on the home screen, and check whether the following controls are working properly.

1) Make sure the syringe heater is connected. (if heater accessory is selected)

2) Fully advance and retract all pistons using the move piston button and advance/retraction piston controls.

3) Ensure that "Auto Advance" and "Auto Retraction" are enabled.

4) Enter and lock the following program:

Phases	Syringe type	Flow Rate	Injection Volume
Phase 1	Syringe A	10ml/s	70ml
Phase 2	Syringe B	2.5ml/s	29ml
Phase 3	Syringe A	5ml/s	100ml
Phase 4	Syringe B	0.1ml/s	1ml

5)Install the syringe and ensure that the piston is automatically docked and that the syringe plunger can be fully advanced. (If the syringe identification function is enabled)

6) Perform automatic liquid aspiration.

7) Get ready and start injection.

8) Activate the hold function for at least 10s during one of the phases.

9) Resume the injection and confirm that the injection is completed properly and the results will be displayed on the injection completion screen.

10) Fully advance the plunger to the top of the syringe, remove the syringe and ensure that the piston retracts automatically. (If the syringe identification function is enabled)

11) Check the insulation sleeve. Ensure that the device is warm and that the fault indicator light is not on.

12) Ensure that all injector functions are working properly (e.g., aspirate, reset, etc.).

13.3 Annually

Hawk Medical offers preventive maintenance protocols. These annual maintenance protocols are very beneficial in maintenance accuracy and reliability, as well as extending the service life of the system. Please contact Hawk Medical or local distributor for detailed information. See the back cover of this Manual for address, phone and fax information.

13.3.1 Injection system calibration

Hawk Medical recommends performing a full system calibration and performance check once a year. Please consult Hawk Medical.

13.3.2 Leakage inspection

As part of the annual maintenance protocol, leakage inspection and protective grounding continuity inspection should be performed by a qualified service representative or authorized dealer.

Note: Local regulations or medical institution's rules may require more frequent periodic leakage inspection. If applicable, local leakage inspection regulations must be followed.

13.3.3 Re-installation of the system in another room

If you need to reinstall the system in another room, disconnect the cable and place the injector head vertically. When moving the injector, grasp the base no more than 90cm above the floor. When crossing a threshold or other obstacles, firmly grasp the Powered Contrast Media Injector.

13.3.4 Repair procedure

The service and repair should be performed by manufacturer or distributor. Hawk medical will supply circuit diagrams, components part lists, or other information that will assist qualified technicians to repair components classified as repairable upon request.

13.4 Safely disposal

Dispose of system components or accessories must follow the local laws, regulations or the hospital's waste disposal system.

14. Options and Recommended Accessories

Attention
It may cause damage to the equipment or malfunction in the operation of the system. • This system is intended for connection to the specific equipment listed in **"Options and Recommended accessories"** and should not be used with other medical equipment or medical equipment technology.

14.1 Optional accessories

Name	**Description**
Communication cable	Communication between control console and host
Syringe heater	Heating the syringe

14.2 Recommended accessories

Name	Model	Manufacturer

Disposable High-pressure Angiographic Syringes	115ml,200ml	Jiangxi Hawk Medical Supplies Co. Ltd.

Remark：You are highly recommended to use the disposable syringe accessory specified for the Powered Contrast Media Injector. Otherwise, the injector accuracy cannot be guaranteed.

14.3 Replaceable and detachable parts

Name	**Description**
Communication cable	Communication between control console and host
Syringe heater	Heating the syringe
Handswitch	Start/Pause, restart injecting
Remote controller	Start/Pause, restart and stop injecting
Power adapter	DC12V,48VA
AC power cord	250V 10A,3m

Note：The replacement should comply with the product standards or contact Hawk Medical or local distributor for replacement,self-replacement is prohibited..

14.4 Packing list

The following lists standard configuration in package:

Name	**Units**
Injector host	1
Remote console	1
Remote controller	1
Handswitch	1
Mount component	1
Cantilever component	1
AC Power cord	2
Power adapter	1
User manual	1

Product warranty card	1

15. Specifications

15.1 Remote console specifications

15.1.1 Remote console dimensions and weight

This page intentionally left blank.

15.1.2 Remote console interfaces

This page intentionally left blank.

15.1.3 Remote console power requirements

Power supply mode: power adapter

Input voltage: DC12V

Input power: greater than or equal to 30VA

15.2 Host specifications

15.2.1 Host dimensions and weight

This page intentionally left blank.

15.2.2 Host interfaces

This page intentionally left blank.

15.2.3 Host power requirements

Power supply mode: grid electricity

Input voltage: 100~240VAC

Frequency: 50/60Hz

Input power: greater than or equal to 250VA

15.3 Components specifications

This page intentionally left blank.

15.4 Wall-mounted component and ceiling-mounted component

15.4.1 The specifications of wall-mounted component and ceiling-mounted component

This page intentionally left blank.

15.4.2 The power requirements of wall mount components and ceiling mount components

1) Electrical box power supply:

Power supply mode: AC power

Input voltage: 100~240VAC 50/60Hz

Input power: 300VA

2) Remote console power supply:

Power supply mode: power adapter

Input voltage: 100~240VAC

Input power: 48 VA

15.5 Environmental requirements

15.5.1 Operation conditions

Temperature range: +5℃ - +40℃

Humidity range: 10% - 95%, non-condensing

Atmospheric pressure range: 56kPa - 106kPa

15.5.2 Transportation and storage conditions

Temperature range: -30℃ - +70℃

Humidity range: 10% - 95%RH, non-condensing

Atmospheric pressure range: 56kPa - 106kPa

15.5.3 Electric shock protection

According to EN60601-1:2006+A1:2013+A12:2014+A2:2021,the system is designed as a Class I medical equipment with the type BF,the BF applied part is the syringe kits including syringe and connection tube that are not included as part of the device. Class BF corresponds to the degree to which the application components of the medical equipment are resistant to electric shock. Class I equipment must have protective grounding (electrical grounding) to ensure protection against electric shock in the event of a fault in the basic insulation system.

15.5.4 EMI/RFI

This injection system is classified as a Group 1, Class A equipment according to EN60601-1-2:2015+A1:2021. Hawk Medical provides the Parts that also meet this standard.

15.5.5 Liquid penetration protection

The injector head is classified as a drip-proof equipment according to EN60601-1:2006+A1:2013+A12:2014+A2:2021. This system component is provided with a shield to prevent a certain amount of dripping liquid from soaking in so as not to interfere with the safe operation of the injector, as indicated by the IPX1 for injector head of Powered Contrast Media Injector on the label.

Note: If liquid leaks or seeps into the injection system, please be sure to disconnect and dry all equipment and accessory connections and inspect them. Perform appropriate electrical safety and operation inspection in accordance with hospital policies and procedures prior to use, or contact Hawk Medical's maintenance personnel.

15.5.6 Operation mode

According to EN60601-1:2006+A1:2013+A12:2014+A2:2021, the operation mode of both the host and the monitor is continuous operation. They can operate continuously and uninterruptedly under normal load without causing excessive temperature.

The operation mode of the injector head is continuous operation with intermittent aspiration characteristics. Although the power supply to the injector head is continuous, intermittent aspiration and injection operation will result in internal temperature to be lower than that of continuous aspiration operation, but higher than that of aspiration-free operation. Under routine operation conditions with injection intervals of not less than 10min, the increase in the internal temperature of the injector head will not affect the safety, performance or reliability of the system.

15.5.7 Technical characteristics and parameters

Description	Specifications	
Product model	HK-CD115 HK-CD115-A	HK-CD200 HK-CD200-A
Syringe capacity	115ml	200ml
Injection Volume	1-115ml	1-200ml
Volume delivered accuracy	Single syringe injection: • +/- (2% + 1) ml Simultaneous (DualFlow) injection: • +/- (4% + 2) ml	
Flow Rate	1-10ml/s, increment: 0.1ml/s	
Flow rate accuracy	Single syringe injection: • ±(5%+0.1) ml/s Simultaneous (DualFlow) injection: • ±(5%+0.1) ml/s	
Pressure limit	50-325psi, increment: 1psi	
Pause	Time range: 1s-3599s, increment: 1s.	
Hold	Hold time not less than 40min	
Injection Phase	Max. 8	
KVO	30-180s, increment: 1s	
Heater	35℃±5℃, external heater	
History records	400	
Injection protocols	120	
Pressure curve graph	Real-time display during injection	

16. Network Security

16.1 USB

Data type	Equipment data
User access control mechanism	Use of identification information
Electronic interface	USB

Technical features	The USB interface features faster transfer speeds, support for hotplug , and a point for connecting multiple devices, with a USB2.0 transfer rate of 240Mbps.
Network security feature configuration	Non-remote non-real-time one-way electronic data interchange
Data backup and disaster recovery	The relevant records on the equipment cannot be deleted.
Running environment	Linux and compatible versions, Powered Contrast Media Injector software V01 and compatible versions
Security software	None
External software environment	N/A
Security software update	N/A
Canned software	None
Canned software list	N/A
Communication protocol	USB2.0 communication protocol

16.2 Zigbee

Date type	Equipment data
User access control mechanism	Use of identification information
Electronic interface	Zigbee
Technical features	It is mainly used for data transmission between various electronic devices with short distance, low power consumption and low transmission rate as well as typical applications with periodic data, intermittent data and low response time data transmission.
Network security feature configuration	The data transmission type is two-way transmission; The relevant records on the equipment cannot be deleted.
Data backup and disaster recovery	The relevant records on the equipment cannot be deleted.
Running environment	Linux and compatible versions, Powered Contrast Media Injector software V01 and compatible versions
Security software	None

External software environment	N/A
Security software update	N/A
Canned software	None
Canned software list	N/A
Communication protocol	Zigbee communication protocol

16.3 RS485 communication

Date type	Equipment data
User access control mechanism	Use of identification information
Electronic interface	RS485 serial port
Technical features	RS-485, as the electrical standard for serial communication interface, defines the interface information between data terminal equipment (DTE) and data communication equipment (DCE) for bitwise serial transmission, and rationalizes the electrical signal and mechanical requirements of the interface, which has been widely used in the world.
Network security feature configuration	The data transmission type is two-way transmission; The relevant records on the equipment cannot be deleted.
Data backup and disaster recovery	The relevant records on the equipment cannot be deleted.
Running environment	Linux and compatible versions, Powered Contrast Media Injector software V01 and compatible versions
Security software	None
Canned software	None
Canned software list	N/A
Communication protocol	RS485 communication protocol

17. Fuse Specifications

Fuse specifications are 5A, 250V, 5X20MM

Appendix 1: Information of Electromagnetic Compatibility

1. Note:

- HK-CD Powered Contrast Media Injector meets the electromagnetic compatibility requirements of EN60601-1-2:2015+A1:2021.
- Users should install and operate the device in accordance with the EMC information provided in the documentation.
- Portable and mobile RF communication devices may affect the Essential Performance of the Powered Contrast Media Injector. Avoid strong electromagnetic interference when using it, e.g. near cell phones, microwave ovens, etc.
- See attachments for the manual and manufacturer's statement.

2. Warning:

- HK-CD Powered Contrast Media Injector should not be used in proximity or in stack with other devices, and if it must be used in proximity or in stack, it should be observed and verified to operate normally in the configuration used;
- HK-CD Powered Contrast Media Injector may have a certain amount of electromagnetic radiation, which may interfere with other equipment. In this case, appropriate measures should be taken to reduce interference, such as relocating the enteral feeding pump or introducing electricity from different places.
- Except for cables supplied by the manufacturer of HK-CD Powered Contrast Media Injector as spare parts for internal components, the use of accessories and cables other than specified may result in increased emission or reduced disturbance immunity of Powered Contrast Media Injector.

- ZigBee module frequency range 2400~2483.5MHz, modulation type: O-QPSK,transmission rate: 250kbps, receive sensitivity: -99dBm, transmit power is 19dBm.

List below the Cables information:

No.	Cable name	Length(m)	Shield or not
1	Power cord	3m	No
2	Communication cables	15m	No
3	Remote controller	1m	No
4	Hand switch	3m	No

3. Guidelines and manufacturer's statements:

Comply with the following standards:EN60601-1-2:2015+A1:2021 Medical Electrical Equipment - Part 1-2: General Basic Safety and Basic Performance Requirements - Subsidiary Standards: Electromagnetic Compatibility - Requirements and Testing Special considerations related to electromagnetic compatibility required by the system.

It is installed and put into service according to the EMC information provided below:

<table>
<tr><td colspan="3">Guidance and manufacturer’s declaration - electromagnetic emissions</td></tr>
<tr><td colspan="3">The Powered Contrast Media Injector is intended for use in the electromagnetic environment specified below. The customer or the user of the Powered Contrast Media Injector should assure that it is used in such an environment.</td></tr>
<tr><td>Emissions test</td><td>Compliance</td><td>Electromagnetic environment - guidance</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td>The Powered Contrast Media Injector use RF energy only for its internal function. Therefore, its RF emissions is very low and is not likely to cause any interference in nearby electronic equipment.</td></tr>
<tr><td>RF emissions
CISPR11</td><td>Class A</td><td rowspan="3">The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.</td></tr>
<tr><td>Harmonic emissions
lEC 61000-3-2</td><td>N/A</td></tr>
<tr><td>Voltage fluctuations / flicker emissions
IEC 61000-3-3</td><td>N/A</td></tr>
</table>

Guidance & Declaration — electromagnetic immunity			
The Powered Contrast Media Injector is intended for use in the electromagnetic environment specified below. The customer or the user of the Powered Contrast Media 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	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±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 %.
Electrical fast transient/burst IEC 61000-4-4	±2kV for power supply lines ±1kV for SIP/SOP	±2kV for power supply lines ±1kV for SIP/SOP	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5 kV, ±1 kV line to line ±0.5kV,±1kV, ±2kV Line to ground	±0.5 kV, ±1 kV line to line ±0.5kV,±1kV, ±2kV Line to ground	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11.	<5 % UT (>95% dip in UT.) for 0.5 cycle <5 % UT (>95% dip in UT) for 1 cycle 70% UT (30% dip in UT) for 25/30 cycles <5% UT (>95 % dip in UT) for 5/6 sec	<5 % UT (>95% dip in UT.) for 0.5 cycle <5 % UT (>95% dip in UT) for 1 cycle 70% UT (30% dip in UT) for 25/30 cycles <5% UT (>95 % dip in UT) for 5/6 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Powered Contrast Media Injector require continued operation during power mains interruptions, it is recommended that the Powered Contrast Media Injector be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field lEC 61000-4-8.	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Guidance & Declaration - Electromagnetic immunity			
The Powered Contrast Media Injector is intended for use in the electromagnetic environment specified below. The customer or the user of the Powered Contrast Media Injector should assure that they are 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 6 Vrms in ISM bands	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM bands	Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Powered Contrast Media Injector, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz 385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014+ A1:2020)	3 V/m 80 MHz to 2.7 GHz 385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014+ A1:2020)	

Appendix 2: Prompt code and troubleshooting

When occurring the prompt code of system abnormality below, the syringe A and syringe B are always on the red light:

Code No.	Explanation	Processing method
E01	The pressure exceeds the limit, please check the connecting tube.	Cancel the pressure over limit prompt and check the tube.
E09	Communication with the injection head is interrupted	Shut down and restart. If it continues to prompt communication failure, contact the manufacturer.
E10	Injection head monitoring chip communication failed;	Shut down and restart. If the code continues to pop up, contact the manufacturer.
E11	Injection machine head button error	Shut down and restart. If the code continues to pop up, contact the manufacturer.
E12	EEPROM error	Shut down and restart. If the code continues to pop up, contact the manufacturer.
E17	Motor (A) error	Shut down and restart. If the code continues to pop up, contact the manufacturer.
E18	Encoder (A) error	Shut down and restart, and re-do volume calibration. If the calibration fails, contact the manufacturer.
E19	Potentiometer (A) error	Shut down and restart, and re-do volume calibration. If the calibration fails, contact the manufacturer.
E20	Front limit (A) error	Shut down and restart, and re-do the front and back limit calibration. If the calibration fails, contact the manufacturer.
E21	Back limit (A) error	Shut down and restart, and re-do the front and back limit calibration. If the calibration fails, contact the manufacturer.

E22	Pressure sensor (A) error	Shut down and restart. If the code continues to pop up, contact the manufacturer.
E25	Motor (B) error	Shut down and restart. If the code continues to pop up, contact the manufacturer.
E26	Encoder (B) error	Shut down and restart, and re-do volume calibration. If the calibration fails, contact the manufacturer.
E27	Potentiometer (B) error	Shut down and restart, and re-do volume calibration. If the calibration fails, contact the manufacturer.
E28	Front limit (B) error	Shut down and restart, and re-do the front and back limit calibration. If the calibration fails, contact the manufacturer.
E29	Back limit (B) error	Shut down and restart, and re-do the front and back limit calibration. If the calibration fails, contact the manufacturer.
E30	Pressure sensor (B) error	Shut down and restart. If the code continues to pop up, contact the manufacturer.

Manufacturer:

Shenzhen Hawk Medical Instrument Co., Ltd.

1st-5th Floor, Building C, Jianyetai Industrial Zone, No.11 Minhuan Road, Fukang Community, Longhua Street, Longhua District, Shenzhen, 518109, Guangdong,P.R.China

Tel: +86-755-8315 1901

Fax: +86-755-8315 1906

E-mail: szhk@hawkmedical.cn

Website: www.hawkmedical.cn

EU Authorised Representative:

Umedwings Netherlands B.V.

Treubstraat 1,2288EG,Rijswijk,the Netherlands

Tel: +31(0) 642758955

E-mail: ar@umedwings.eu