1. Safety Instructions

1.1 Conventions

In this Manual, the following information is used to highlight information related to the patient or device, or alert user of potential risks.

	**CAUTION:** Indicates a hazardous situation which, if not avoided, could result in damage to the device or environment.
	**WARNING:** Indicates a hazardous situation which, if not avoided, could result in injury or death.
NOTE: Emphasizes important guidance information which may affect the ways in which this Manual and the product are used, or provides additional information such as detailed explanations, prompts or reminders.	

1.2 Safety Overview

Classification of Device:

Class I equipment, Type BF applied parts, IP32, continuous operation equipment and not intended for use in an oxygen rich environment.

The IP32 means the device is resistant to vertical dripping when tilted 15 degrees.

Use of transfusion/infusion set: the user must use disposable transfusion/infusion sets that meet national standards and have a certificate of marketing approval. The recommended infusion sets are 20 drip/ml of BOON's and B.Braun's IV tubings and the recommended transfusion set are 20 drip/ml of Kindly's and B.Braun's transfusion tubings.

The transfusion/infusion set should have been sterilized, and the user must check whether the sterilized packaging is in good condition prior to use. The device can use Φ3.5mm~5mm (inner diameter) transfusion/infusion sets.

Below is an overview of safety precautions:

- DO NOT disable or short-circuit the security functional parts of the device.
- DO NOT attempt to repair the device if it cannot work normally. Immediately contact a qualified serviceman with authorization by SinoMDT. The authorized serviceman can ask for relevant information from SinoMDT.
- There is no user-serviceable part inside the device.
- Follow all WARNINGS and CAUTIONS, whether expressed or implied.
- Follow all safety labels on the device.

- To ensure the temperature accuracy, the temperature sensor should be calibrated before delivery of the device.

1.3 Electrical/Mechanical Safety

Only qualified personnel who are trained and authorized by SinoMDT can open the housing of the device to replace the electrical and mechanical parts, otherwise equipment safety problems may be caused.

Warnings are listed below.

1.3.1 Electrical Safety

	**WARNING:** Electric shock hazard – DO NOT open the heating plate or the front/rear housing during operation or in power-on state. Only authorized maintenance engineers are allowed to open the heating plate or the front/rear housing, if the AC power supply is disconnected.
	**WARNING:** The device should be connected to an electrical outlet with protective grounding. NEVER use any electrical outlet that is not connected to a grounding wire.
	**NOTE:** Prior to use, user must check that the device and its 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.
	**NOTE:** Safety test should be performed on a regular basis to ensure device safety. Leakage current measurement and insulation test are included in the safety test. The recommended test cycle is every two years or according to regulatory requirements and inspection procedures.
	**CAUTION:** Before connecting the device to the power supply, please check whether the voltage and frequency of the power supply meet the requirements specified on the nameplate or in the User Manual.
	**CAUTION:** Disconnect the power supply before cleaning. Use soft brush or cloth to wipe off dust on the surface of the device; use a brush to remove dust on connectors and panel edges; or use a soft cloth dipped with neutral detergent or disinfectant to wipe the surface of the device. Prevent any detergent or disinfectant from infiltrating into the device. Pay special attention to connectors, panel edges, etc.

1.3.2 Operation Safety

	**WARNING:** DO NOT operate the device beyond the operating environment requirements; otherwise, the device will work abnormally.
	**WARNING:** DO NOT use the device in the environment of high frequency equipment and MRI equipment.
	**WARNING:** The device cannot work in anesthetic environment where the air is mixed with O_2, nitrogen oxides or flammable anesthetics, which may cause an explosion.

	**WARNING:** the device is not intended for use in a hyperbaric oxygen chamber or MRI environment.
	**WARNING:** In the event of malfunction of the device or changes in its performance that may affect safety, the device should be placed out of use and contact qualified serviceman.
	**WARNING:** the applied part of this device is the disposable transfusion/infusion set. The disposable transfusion/infusion sets should meet the corresponding national health and quality standards; cross-use of them is not allowed; they should be disposed of as medical waste after use.
	**WARNING:** this product must be hung or fixed onto a stable infusion stand or rail hanger through a bracket.
	**WARNING:** during the use of this product, the patient and the operator should not touch or remove the Drip detection clamp.
	**WARNING:** DO NOT perform repair or maintenance of the device or any parts during use.
	**WARNING:** the device should be operated by professional and trained medical personnel under appropriate conditions.
	**WARNING:** you must stop using the device immediately when an over-temperature alarm occurs.
	**WARNING:** if the alarm sound is lower than the ambient sound, it may be difficult for you to identify the alarm condition; please set an appropriate alarm volume.
	**CAUTION:** Keep the environment clean, and avoid vibration. Keep away from corrosive drugs, dust, overheat and moisture.
	**NOTE:** make sure that there is no strong electromagnetic interference (of wireless transmitter or mobile phone) in the installation and operating environment of the device.
	**WARNING:** Use of accessories, transducers or cables other than those sold as spare parts for internal components by the manufacturer of the device may result in increased emission or reduced immunity of the device.
	**WARNING:** The device complies with the applicable EMC requirements in YY0505.
	**WARNING:** Pay attention to EMC performance: the device should be installed and used according to the EMC information provided in the accompanying documents.
	**WARNING:** This device is defined as a Class-B equipment based on its intended use and EMC performance. It can be powered by the public low-voltage supply network that contains household measures or is connected directly to household dwellings, where adequate protection of radio reception is provided.
	**WARNING:** The device should not be used near or stacked with other equipment. If it has to be used like that, it should be observed and verified if it works properly under the corresponding configurations.
	**NOTE:** this product must be operated by professionally trained medical personnel.
	**NOTE:** any accessory at the end of service life or any replace accessory should be properly disposed of so as to prevent environmental pollution.
	**NOTE:** Please observe the local regulations or the hospital's waste disposal policy when disposing of packaging materials. Keep the packaging materials out of the reach of children.

⚠	**NOTE:** This Manual introduces the product in the most complete configuration and functions. The product you've purchased may not have certain configurations or functions. Please keep this Manual near the device for easy and prompt access when needed.
⚠	**Note:** In case of any serious incident that has occurred in relation to the device the user and/or patient should report to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

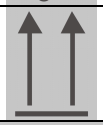
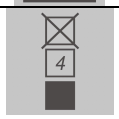
1.4 Symbols and Labels

1.4.1 Symbols

~	Alternating current
AC	Alternating current
⎓	Direct current
DC	Direct current
	Caution
	Refer to the accompanying documents.
	Medical device
	Authorized representative in the European Community
	Type BF applied parts
	Manufacturing date
	Manufacturer Logo
IPxx	IP level
	Serial number
	Unique device identifier
	Non-ionizing electromagnetic radiation

	Grounding (earthing)
	CE mark (EU)
	ON/OFF key
	Increase the temperature
	Reduce the temperature
	Start/Pause key
	Temperature unit selector
	Mode selector

1.4.2 Transport Symbols

	Fragile. Handle with Care.
	Keep Dry
	This Side Up
	Stacking Layer Limit
	Humidity Limit
	Atmospheric Pressure Limit
	Temperature Limit
	Separate collection of electronic/electrical products (EU)
	Package Recycling

2. Product Introduction

2.1 Overview

By heating and preserving the heat of the continuously flowing liquid, the heat in the heat exchanger is transferred to the liquid in the extended infusion line. The operator can set the temperature to 32.0℃~42.0℃ based on the needs of the patient. The device will control the work of the heating tube to achieve the set temperature.

Main features of the device:

● Stable temperature control.

● High-definition digital screen or LCD screen (display the temperature value); audible and visual alarm.

● Multiple over-temperature protection, safe and reliable.

● Drip detection: display the current infusion rate.

2.2 Model Differences

This series includes the following models: H20SS, H20SL, H20DS and H20DL. The differences among such models are listed in Table 2-1.

Table 2-1 Product Models

Difference description		Model No.			
		H20SS	H20SL	H20DS	H20DL
Infusion Warmer	One-channel	√	√	--	--
	Two-channel	--	--	√	√
	8-inch digital screen	√	--	√	--
	8-inch LCD screen	--	√	--	√
	Drip sensor	Optional	Optional	Optional	Optional

Note: "√": this function is available; "--": this function is not available. The Drip detection function is optional.

2.3 Scope of Application

2.3.1 Intended Use

It is intended for in-line heating of solutions and fluids prior to administration to patient.

2.3.2 Target Population

It is suitable for adult, pediatric and neonate patients.

2.3.3 Intended Users

Doctors, nurses or trained and qualified professional medical workers in hospitals.

2.3.4 Contraindications

Do not use for heating analgesics, chemotherapy drugs, insulin, etc.

Prohibited to use an infusion warmer for heating medicinal liquids that may affect the normal efficacy.

It isn't suitable for patients with fever and severe cardiopulmonary insufficiency.

2.3.5 Indication

None

2.3.6 Clinical benefit

The infusion warmer could warms infused fluids to near body temperature or slightly above, from optional 32ºC to 42ºC, to prevent hypothermia due to infusion of cold fluids prior to administration to patient.

2.3.7 Side-effect

Potential air/bubble emboli could form in the heating process and could be fatal in infants and children patients although it is rare in low rate infusion and should be taken into account.

2.4 Technical Features and Parameters

2.4.1Adjustable Range of Temperature

32.0℃~42.0℃ (89.6℉~107.6℉). Default: 37.0℃.

2.4.2 Step Size / Display Resolution of Temperature

0.1℃/0.1℉; Display Resolution: ℃/℉ (at your option).

2.4.3 Temperature Control Accuracy

±1℃/±1.8℉.

2.4.4 Preheating Time

Heat from room temperature to 36.0℃: <1.5min.

Heat from room temperature to 42.0℃: <3min.

2.4.5 Drip Detection Function

a) Infusion rate detection: assist in detecting the infusion rate.
b) Infusion rate detection accuracy: ±20% at infusion rate of 200d/min, or ±25% at infusion rate of 201d/min~400d/min.

Model：H20SS/H20DS:

c) Identification of infusion set: click the mode selector to select 20d/ml (default) or 60d/ml as the type of infusion set.

d) Unit of infusion rate: click the mode selector to select d/min (default) or ml/h.

For H20SL/H20DL:

e) Identification of infusion set: click the H20 icon to go to the [Configuration] screen, and then select 20d/ml (default) or 60d/ml as the type of infusion set.

f) Unit of infusion rate: click the H20 icon to go to the [Configuration] screen, and then select d/min (default) or ml/h as the unit of infusion rate.

2.4.6 Over-temperature Protection

When the heating temperature exceeds the alarm limit of 43°C, the device will automatically cut off the heating power and trigger an Over Temperature alarm.

2.4.7 Alarm

To ensure safety, this series of products provide the following alarm or reminder functions:

Over Temperature alarm, Low Temperature alarm, System Error, and Empty Bottle alarm. See the **"Alarms/Reminders"** section for more information.

2.4.8 Power Supply

AC input: 100V-240V～; mains frequency: 50Hz/60Hz

Rated power: 200VA.

2.4.9 Environment

Operating environment:

Temperature: ＋5℃ - ＋40℃

Humidity: 15% - 95%

Barometric pressure: 57kPa - 106kPa

Transportation and storage environment:

Temperature: -20℃ - ＋70℃

Humidity: 10% - 98%

Barometric pressure: 50kPa - 106kPa

2.4.10 Dimension

236mm (width) × 174mm (height) × 65mm (thickness).

2.4.11 Net Weight

<2.0Kg (including the back-clip battery).