1 Safety Information

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.

WARNING:

- Indicates a hazardous situation which, if not avoided, could result in injury or death.

CAUTION:

- Indicates a hazardous situation which could result in damage to the device or environment.

ATTENTION:

- Highlights 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

Safety classification

Powered by adapter of class Ⅱ and internal power supply, Defibrillation-proof Type CF applied parts, Continuous operation, not intended for use in an oxygen rich environment.

IP32, protection of equipment against ingression of solid foreign objects with diameter more than 2.5mm and against ingression of dripping water (15° titled).

Applied part: infusion set and connecting tube used with infusion pump.

Use of infusion set

User must use infusion sets compliant with national standard and having the medical access certificate. The brand specifications of the infusion set recommended for this infusion pump are shown in the following table, Infusion sets of other brands can be used only after calibration through the infusion set calibration function of the pump (see **4.4 Calibration of Infusion Set** for the calibration method).

Brand and specification of infusion set recommended for this infusion pump:

No.	Product Name	Brand	Specification
1	Infusion set	BOON	20 d/ml
2	Infusion set	B.Braun	20 d/ml

3	Infusion set	KDL	20 d/ml

Overview of Safety Precautions:

- Operator shall not open the housing of the device under any circumstances.
- Avoid malfunction or short circuit of safety function components built in the device.
- Do not attempt to repair the device by yourself if it cannot work normally. Immediately contact Sinomdt or a qualified serviceman authorized by Sinomdt. The authorized serviceman can ask for relevant information from Sinomdt.
- No user-serviceable parts are inside the device.
- Follow all WARNINGS and CAUTIONS, whether express or implied.
- Follow all safety signs on the device.

1.3 Safety Notice

Only a trained and qualified serviceman with authorization by Sinomdt can open the housing of the device to replace electrical and mechanical components; otherwise, there may be problems related to safety of the device.

The following is an overview of warning information:

1.3.1 Electrical Safety

WARNING:

- Electric Shock Hazard — Do not open the housing of the device during operation or when the device is in power-on state; only an authorized maintenance engineer is allowed to do so.
- Modification of this equipment is not permitted.

CAUTION:

- Prior to use, user must check that the device and its cable have no obvious damage that may affect patient safety or device performance. It is suggested to replace any component with obvious damage before use.
- Safety test should be performed on a regular basis to ensure device safety. The recommended check interval is at least once a year.
- The device must receive function calibration on a regular basis according to local regulations or rules of the medical organization, and the calibration information shall be traceable.

- Disconnect the adapter power supply before cleaning.

1.3.2 Operation Safety

WARNING:

- Do not operate the device beyond the operating environment requirements; otherwise the device will work abnormally.
- The infusion pump is for clinical use only, and can be used only by professional clinicians, professionals or trained medical workers under proper conditions.
- Close attention needs to be paid to the actual clinical condition of the patient and the working condition of the infusion pump regularly, and the alarm volume and alarm limit need to be set according to the facts. It is not possible to rely solely on the auditory alarm system to infuse the patient, and the alarm volume that is adjusted to a lower volume may put the patient in danger
- As a non-portable device, it is not suitable to be carried by the patient.
- Prior to use, user must check the SN-S series infusion pump and its accessories to ensure normal and safe operation.
- The pressure sensor cannot work normally under high pressure, for example, in an environment with hyperbaric oxygen.
- Do not use the infusion pump to perform infusion when an alarm is generated.
- Before operating SN-S series infusion pump, please confirm the infusion set used is consistent with the infusion set manufacturer set in SN-S series infusion pump. Inconsistency will result in inaccurate infusion rate and alarm.
- In order to avoid accuracy abnormality or other problems, do not connect other infusion tube to the infusion tube of this device.
- Infusion sets or infusion tubes (including shading infusion tubes) used must be products having access to the local medical device market. Also, infusion sets used should have been calibrated; otherwise incorrect infusion accuracy may be caused. Reuse is forbidden in order to prevent possible cross infection among patients.
- It is recommended to use infusion sets special for the pump; the infusion accuracy cannot be guaranteed if other types of infusion sets are used.
- In order to ensure a safer infusion process, it is suggested to use the drip clip alarm function. If “Drip Mode” is used, the drip sensor should be installed between the nozzle top of Murphy’s dropper and the liquid level, and the Murphy’s dropper should be positioned as vertically as possible so that the sensor can correctly detect the liquid drop condition in the Murphy’s dropper; ensure that the liquid level in the drip pot of infusion set reaches above 1/3.

- Infusion sets special for the infusion pump, which have been precisely calibrated, must be used; otherwise inaccurate infusion rate, occlusion pressure error alarm, infusion set damage or other phenomena will be caused. However, we only identify the overall structures and dimensions of the specified infusion sets; their biochemical, physical, metric and other indicators must be tested and approved by relevant supervision authority.
- The operator should not set the alarm limit to an extreme value that can cause failure of the alarm system; for example, the sound pressure level of sound alarm signal is lower than the ambient noise.
- Improper bubble detection and calibration may result in bubble detection error alarm or absence of alarm, which may cause injury to the patient.
- In order to avoid improper operations which may put the patient at risk, this pump shall not be operated by a family member of the patient.
- In case that bubbles in the tube between the pump and the patient cannot be detected, they must be fast eliminated manually.
- When installing the infusion set, its roller clamp should be positioned at the tube between the infusion pump and the patient.
- When re-install the infusion tube, the compressed infusion tube should not be installed at the bubble sensor; otherwise the tube bubble error alarm will be caused.
- When the infusion tube of infusion set is used for a period of time, its resilience will be degraded. Therefore, after the infusion pump works continuously for 6h, please stop the pump and slightly moves the tube to ensure that the tube between the pump tablet and the pressing plate is not compressed; or when the infusion pump works continuously for 6 hours, it is recommended to stop the machine and replace the infusion set and connecting tube.
- In order to avoid the possible risk of explosion, avoid using the device in an environment with any flammable anesthetics.
- The device may have errors under single fault, causing overflow or underflow, further resulting in system error alarms.
- When using the device, take care to prevent air from entering into the patient’s body because this may cause injury to the patient.
- The device should not be used close to or in a stack with other devices. If such use is required, please observe this device and such other devices to verify if they can work normally in the current configuration.
- Use of spare parts or cables other than those specified may result in increased device emissions or reduced immunity.
- Pay special attention to EMC-related issues of the device; install and use the device according to this User Manual.

- Portable and mobile RF communication devices may have some influence on this device. Regular monitoring of the infusion process by professional medical workers is required during use.
- Portable RF communication devices (including peripherals such as antenna cables and external antennas) should be at least 30cm away from any part of this device (including cable); otherwise the device performance may be degraded.
- Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

CAUTION:

- Keep the environment clean, and avoid vibration. Keep away from corrosive drugs, dust, heat and moisture.
- The expected service life of the device is 8 years. When SN-S series infusion pump reaches the recommended service life, it must be disposed of according to local regulations or rules of your hospital. If you have any question, please contact your dealer or the manufacturer.
- Make sure the device is installed and used in an environment without strong electromagnetic interference; devices placed beside SN-S series infusion pump must comply with the EMC standard. Radio transmitters, telephones, X-ray machines, MRI equipment, etc. are all potential sources of strong interference since they can generate high-intensity radiation.
- Prior to use, confirm the battery level is high enough; charge the battery if necessary.
- During use of equipment, the infusion process should be regularly monitored by a medical professional.
- When the infusion pump is used within 100 cm above and below the height of the patient’s heart, the extension tube shall be kept at the same level as the pump before connecting the patient. The more accurate the pressure detection in the injection tube is when the height difference between the neonatal enteral feeding pump and the patient's heart is smaller.
- When the pump door opens and closes, the roller clamp of the infusion set must be locked, otherwise there is a risk of reverse blood drawing. For replacement of the liquid medicine container, it is recommended to firstly stop infusion, then lock the roller clamp of the infusion set, replace the liquid medicine container, open the roller clamp, and finally start to continue the infusion.
- Attention should be paid to environmental protection and recycling. In case of disposal or recycling, it is recommended to contact the distributor where the user purchased the

product, who will make reasonable recycling, or dispose of this product in accordance with local laws and regulations.

- Improper drug infusion may cause adverse physiological effects for the patient. Therefore, the doctor's instructions need to be followed for liquid infusion.

ATTENTION:

- Close the protective cover when the general port and the DC power port on the device is at standby.
- Infusion sets used are disposable and must comply with applicable national health and quality standards; it is forbidden to cross use. After used, the disposable infusion sets shall be disposed of as medical waste by the operator.
- During infusion, the infusion pump precisely controls the infusion flow rate, infusion volume and infusion time and monitors the rate and direction of the stepper motor in real time, which can effectively prevent overflow, underflow and back suction.
- This device will not directly contact drugs/patients; therefore biocompatibility test is not necessary.
- When this device is connected to the same infusion port as other infusion systems, backflow may occur due to interaction between the infusion tubes, or the response time of an occlusion alarm may be prolonged. Therefore, when it is necessary to connect with other infusion systems, the operation should be performed at the end of the infusion tube with a one-way valve or under the guidance of the local hospital.

1.4 Symbols and icons

1.4.1 Safety Symbols

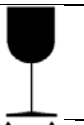
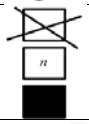
Table 1-1

~	Direct current		Standby
⎓	Direct current		Caution
AC	Alternating current		DEFIBRILLATION-PROOF TYPE CF APPLIED PART
DC	Direct current		Serial Number
	Class II Device	IP32	IP degree

	Date of manufacture		Non-Ionizing Electromagnetic Radiation
	Manufacturer		CE Mark (EU)
	Refer to instruction manual/ booklet		Medical device
	Unique device identifier		Separate collection of electronic/electrical products (EU)
	Authorized representative in the European Community/ European Union		Batch code

1.4.2 Transport Symbols

Table 1-2

	Fragile, handle with care		Keep dry
	This Way Up		Stacking limit by number
	Humidity limitation		Atmospheric pressure limitation
	Temperature Limit		Package Recycling

1.4.3 Operational icons and indicators

Table 1-3

	Battery Powered Indicator		Mains Powered Indicator
	Move Leftward		Start/Pause
	Move Upward/Increase		Move Rightward
	Confirm/Select		Move Downward/Decrease

	Cancel/Return		Mute/Reset
	Battery Level		Bolus infusion
	Alarm Icon		Battery Charging
	Interface Locked		Battery Not Connected
	Interface Unlocked		WIFI Connection Indication
	Running Icon		Night Mode
	Connecting Icon		Bed Number
	Drip Sensor on		Drip Sensor off
	General alarm		

1.4.4 Abbreviations

Table 1-4

Abbreviation	Meaning	Abbreviation	Meaning
AC	Alternating current	EMC	Electromagnetic compatibility
DC	Direct current	EMI	Electromagnetic interference
BOLUS	Bolus	KVO	Keep vein open
CPU	Central processor unit	FLASH	Flash memory
EEPROM	Electrically erasable programmable read-only memory	SN	Serial number
VTBI	Volume to be infused	TIVA	Total intravenous anesthesia.
Anti-Bolus	Anti-Bolus	LOGO	Logo
LED	Light emitting diode	MRI	Magnetic resonance imaging
mAh	Milliampere hour	USER	User-defined

MAT	Product code	Qty	Quantity
N.W	Net weight	G.W	Gross weight
MEAS	Packing box dimension		

2 Product Introduction

2.1 Product Description and Structure

The infusion pump uses a microprocessor to precisely control the motor which drives the finger-press peristaltic pump tablet to compress drug solution in the tube of infusion set; in this way, drug can safely enter the patient's body with uniform rate and accurate volume guaranteed. It is intended for infusion of liquid to be infused into the patient's body in clinical departments, used in conjunction with a transfusion set for blood transfusion, or used in conjunction with an enteral giving set for enteral nutrition.

SN-S series infusion pump consists of a housing, a power supply system, a motor drive system, an input system, a storage system, a control system, a display system, a tube peristalsis module, a sensor monitoring system, an alarm system, a communication module, a drip sensor (optional), a handle (optional), a pole clamp, integrated I/O connector, and an adapter.

WARNING:

- Check the SN-S series infusion pump and its accessories before use in order to ensure normal and safe operation.

2.2 Product Models

This series of products is applicable to SN-S1A, SN-S1, SN-S2A and SN-S2 infusion pumps.

As the equipment with full extrusion, SN-S1A and SN-S1 infusion pumps have the same working principle and design method.

As the equipment with semi-extrusion, SN-S2A and SN-S2 infusion pumps have the same working principle and design method.

SN-S1 series and SN-S2 series infusion pumps have the same intended purpose.

The models and differences of this series of products are as follows:

Table 2-1

Model		**SN-S1A**	**SN-S1**	**SN-S2A**	**SN-S2**
Extrusion Mode		Full-Extrusion	Full-Extrusion	Semi-Extrusion	Semi-Extrusion
Infusion Mode	Rate Mode	√	√	√	√
	Drip Mode	√	√	√	√
	Time Mode	√	√	√	√
	Body Weight Mode	√	√	√	√
	Micro Mode	--	√	--	√

	Sequential Mode	--	√	--	√
	Gradient Mode	--	√	--	√
Additional Functions	Drug Library	√	√	√	√
	Wireless	√	√	√	√

Note: √ indicates this function is supported; -- indicates this function is not supported.

2.3 Operating Principle and Scope of Application

2.3.1 Operating Principle

The infusion pump is designed with a dual processor structure, realizing precise motor control. System status parameters can be displayed on the LCD touch screen; system configuration parameters can be preset and changed directly on the touch screen or by pressing keys. Driven by the motor, the mechanical transmission unit drives the peristaltic tablet to compress the infusion tube for infusion; sensors and the infusion process are monitored in a real-time manner; in case of any abnormality, sound-light alarm signals will be generated.

2.3.2 Intended Purpose

This product is intended to be used in conjunction with an infusion set to control the dose of liquid to be infused into the patient’s body in clinical departments, used in conjunction with a transfusion set for blood transfusion, or used in conjunction with an enteral giving set for enteral nutrition.

2.3.3 Target Population

The product is suitable for adult, child and neonate patients.

2.3.4 Intended Users

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

2.3.5 Contraindications

Not for infusion of analgesics, chemotherapeutics, insulin.

2.3.6 Indications

None.

2.3.7 Clinical benefits

The pump provides a controlled and reliable system for intravenous infusion, parenteral and enteral nutrition infusion, or blood transfusion, and provides users with safety features and relevant alarms that improve infusion safety and prevent unexpected infusion discontinuation.

2.3.8 Undesirable Side-effects

The infusion pump has no undesirable side-effects when used in accordance with this user manual.

2.4 Technical Features and Parameters

Table 2-2

Parameter	Specification
Infusion mode	Rate Mode, Drip Mode, Time Mode, Body Weight Mode, Sequential Mode, Micro Mode, Gradient Mode. Differences among different models can be found in 2.2 Product Models.
Infusion rate and step	0.1ml/h-99.99ml/h, incremental step: 0.01ml/h; 100.0ml/h-999.9ml/h, incremental step: 0.1ml/h; 1000ml/h-2200ml/h, incremental step: 1ml/h;
Infusion Accuracy	±5%
Bolus Function (default)	Default：Manual bolus； Manual bolus 5ml/h-2200ml/h; default: 600 ml/h; Auto bolus 5ml/h-22000ml/h; default: 0; Bolus infusion accuracy ±5%. Note: 1. The default value is 0 when the device is set to Auto Bolus Mode; before startup, it is necessary to set the bolus infusion rate and VTBI; 2. When the set bolus infusion rate is not higher than the infusion rate, the device will not perform bolus infusion and will generate an alarm.
Accumulated volume	0.01ml-999999.99ml; step: 0.01ml

Occlusion Alarm Threshold	12 levels available from level 1 to level 12, for Micro Mode, the default is Level 5; for other modes, the default is Level 8. Pressure thresholds are evenly spaced from 13.3kPa to 120kPa Pressure accuracy: ±13.3kPa or ±25%, whichever is larger.
KVO Rate	Default mode is Manual Mode. Manual mode 0.10-5.00ml/h; default: 1.00ml/h Auto Mode For injection rate ≥ 10ml/h, the KVO rate is 3 ml/h; For 10ml/h> injection rate ≥ 1 ml/h, the KVO rate is 1 ml/h; For injection rate < 1ml/h, the KVO rate is equal to the injection rate.
History	≥ 2,000 pcs;
Alarms	No Operation, Nearly Complete, IV No Calibration ,Occlusion, Bubbles, Door open, Clamp Not Closed, Infusion Complete, KVO Complete, Drip Abnormal, Rate Over Limit, No Battery , Battery Low, Battery Exhausted, No AC Power, Power Interruption, System Failure, Infusion Rate Abnormal.
Battery Level	≥ 5h for 2600mAh battery at the rate of 25ml/h and ≥ 2h at the highest rate; ≥ 10h for 5200mAh battery at the rate of 25ml/h and ≥4h at the highest rate.
Anti-Bolus	Anti-bolus function, unintended bolus volume ≤0.2ml
VTBI	Micro Mode： 0.01-1000ml other modes：0.01ml~9999.99ml
Bubble Detection	There are 8 bubble detection levels, the default is Level 3
Product Size	240 x 168 ×82 mm (pump main unit size, excluding accessories)
Product Weight	≤2.1kg (net weight of pump main unit, without accessories)