

BeneFusion eVP

Infusion Pump

Data Sheet



Physical Specifications

Weight	≤ 1.7kg
Size	≤ 210x 140 x73mm
Screen	3.5 inch touchscreen, TFT color LCD, 200x400 pixels
Brightness	1-8 levels, adjustable
Display	Infusion status (drug name, infusion parameters, real-time in-line pressure) System status information (infusion mode, IV set brand or bed number, alarm symbol, battery status, network status, relayed status, and system time)
Indicator on the door	Infusion status indicator

Parameters Specifications

Accuracy	≤ ±4.5 % (for recommended sets)
Mode	Rate mode, Dose Mode, Dose Time Mode, Time mode, Sequential Mode, Intermittent Mode, Loading Dose Mode, Ramp Mode, Micro-infusion Mode, Drip Mode
Application supported	IV drug infusion, enteral nutrition feeding, and blood transfusion
Flow rate	0.10ml/h - 2300ml/h (0.10-2000ml/h for blood transfusion)
Increment	0.01ml/h (0.10-99.99ml/h), 0.1ml/h (100-999.9ml/h), 1ml/h (1000-2300ml/h)
Preset volume (VTBI)	0.10 – 9999.99ml (increment: 0.01ml)
Preset time	00:00:01 – 99:59:59
Accumulated volume	0.00 - 99999.99 ml
KVO	0.1 - 5.0ml/h, increment: 0.01ml/h
Purge rate	0.1 - 2300ml/h
Bolus rate	0.1 - 2300ml/h (automatic or manual)
Occlusion detection	50-1125mmHg (15 levels selectable, respectively are 50, 150, 225, 300, 375, 450, 525, 600, 675, 750, 825, 900, 975, 1050, 1125mmHg) Default is 450 mmHg Pre-alarm: an alert will pop out when the pressure is continuously going up Auto-restart: On/Off, restart the infusion when the occlusion pressure is reduced. 4 units of pressure selectable: mmHg/kPa/bar/psi
Anti-bolus	Unexpected bolus reduced when the occlusion occurs
Dose rate units	ng/kg/min, ng/kg/h, ng/kg/24h, ug/kg/min, ug/kg/h, ug/kg/24h, mg/kg/min, mg/kg/h, mg/kg/24h, g/kg/min, g/kg/h, g/kg/24h, mU/kg/min, mU/kg/h, mU/kg/24h, U/kg/min, U/kg/h, U/kg/24h, kU/kg/min, kU/kg/h, kU/kg/24h, EU/kg/min, EU/kg/h, EU/kg/24h, mmol/kg/min, mmol/kg/h, mmol/kg/24h, mol/kg/min, mol/kg/h, mol/kg/24h, mcal/kg/min, mcal/kg/h, mcal/kg/24h, cal/kg/min, cal/kg/h, cal/kg/24h, kcal/kg/min, kcal/kg/h, kcal/kg/24h, mEq/kg/min, mEq/kg/h, mEq/kg/24h
Air bubbles detection	6 levels selectable: 15/50/100/250/500/800μL, accumulate air: 0.1-1.0ml/15min
Auto-lock time	1 - 5 minutes selectable, ON/OFF switchable

History log	up to 3500 events
Volume collection	available in 4 methods: 24h total, current total, period, timing volume, support history rate review
Drug library	Up to 5000 drugs, 30 categories, support color-coding drug name
DERS (Dose Error Reduction System)	Available, definition of dose limits, automatic alarms when reaching dose limits

IV administration sets

Compatibility	universal IV sets
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Alarms

Type	Audible and visual alarm
2 Levels	High: Air in Line/ Accumulated Air/ Empty/ Drop Error/ Upstream Occlusion/ Downstream Occlusion/ Infusion Set Disengaged/ No Infusion Tube/ Infusion Set Error /No Drop Sensor/ Battery Depleted/ VTBI Complete/ KVO Finish/ Relay Invalid/ System Error

Low: KVO Running/ Battery in Use/ Battery Error/ CMS/eGW Disconnected/ Standby Time Expired/ Dock Connection Interrupted/ System Time Error/ Relay Invalid Soon/ Time Near End/ Reminder/Low Battery

Sound volume	1-8 levels selectable, default is level 6
Reminder	1-5 minutes selectable, ON/OFF switchable

Connectivity

Communication	Wired/wireless
USB	Support drug library import, patient data import/export, history record export, calibration data import/export
Multifunctional connector	RS232, nurse call connector, DC adapter
Integration	Connect with BeneFusion nCS infusion central station Connect with BeneVision Central Monitoring System (CMS)

Battery

Operating time	≥ 5 hours at 25ml/h (≥ 11 hours at 25ml/h for smart battery)
Charging time	≤ 5 hours to full capacity (≤ 6 hours for smart battery)

Power Supply

Voltage 100-240 V~, frequency 50/60Hz, current 0.5-0.21A

Work Environment

Temperature	5-40°C for operating, -30-70 °C for storage
Relative humidity	15-95% for operating, 10-95% for storage
Atmosphere pressure	57.0-107.4 kPa for operating, 16.0-107.4 kPa for storage
Classification	Type CF, Class I, IP33
Stackability	Supported with stack rack, maximum of 3 pumps can be stacked

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BeneFusion eSP/eVP/eDS

Infusion System

Efficiency in every droplet





Efficiency in Workflow

Intuitive interaction

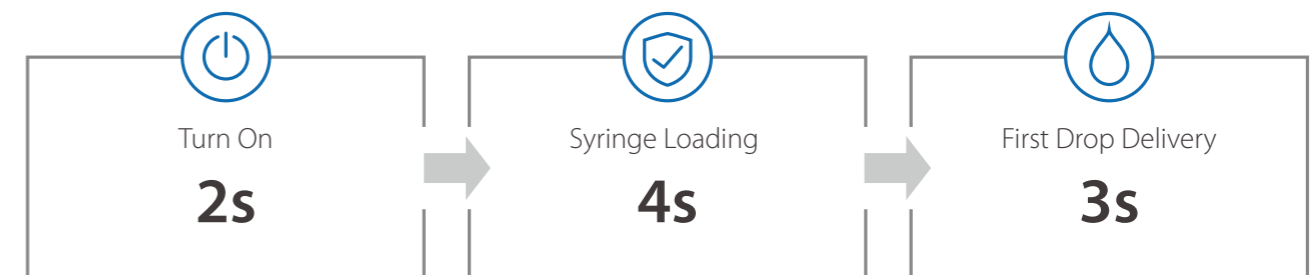
- 3.5" Colored capacitive touchscreen brings users an excellent experience with smooth operation.
- Intuitive user interface enables quick programming of key parameters, making workflow process much easier.



Fast preparation

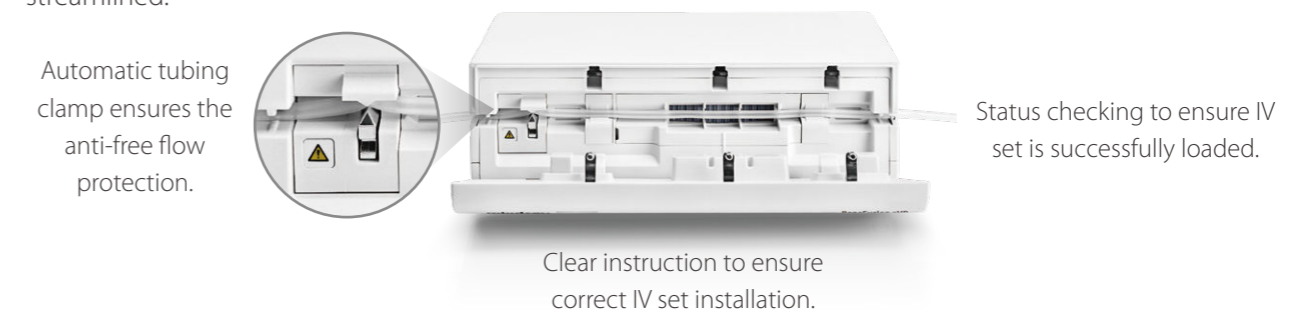
SmartRapid™

SmartRapid™ ensures timely infusion by significantly shortening the start-up time, from turning on the pump to delivering the first drop of medication.



Efficient IV set loading process

BeneFusion eVP is designed to simplify the process of loading an IV set, making it more efficient and streamlined.



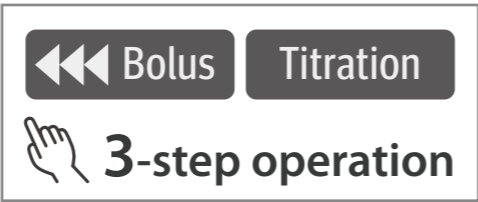
SafeDose™

- The color coding of drug name assists users to easily select and verify the correct drug.
- SafeDose™ Info software enables programming infusion parameters automatically to enhance efficiency.
- SafeDose™ DERS helps prevent dosing error with hard or soft limits restriction.



Flexible infusion adjustment

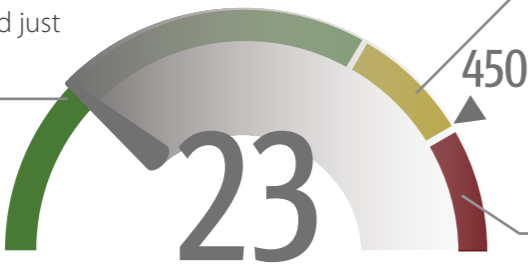
Easily adjusting the infusion therapy within 3 steps.



Quick problem solving

Dynamic Pressure System

Speedometer style indicator with numerical pressure to monitor the in-line pressure trend just with a glance.

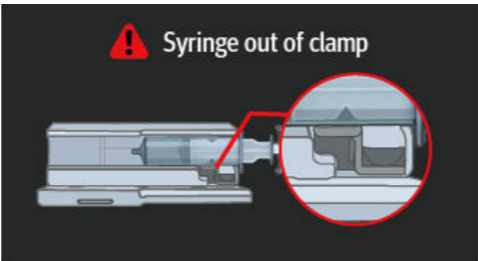


Alert with a visual message about the possible occlusion before interrupting the infusion.

Auto-attempting mechanism enables infusion resume as early as possible to ensure continuous infusion.

Intuitive Alarm System

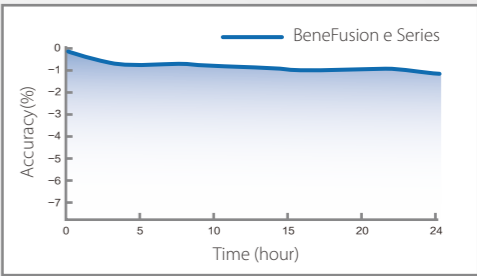
Instructional animation pops up to guide users to quickly solve the problem.



Efficiency in Safety

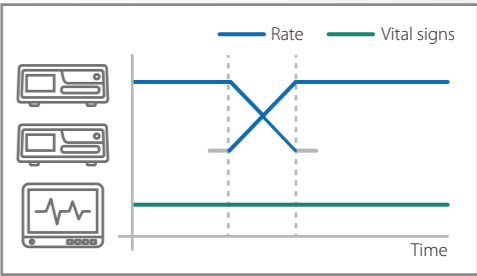
Precise infusion performance

- High accuracy: eSP $\pm 1.8\%$; eVP $\pm 5\%$
- Long-hour accuracy assured



Automatic multi-channel relay

- BeneFusion e series supports both circular and customized relay to make sure the continuity of infusion.
- Smooth relay workflow ensures stable and seamless drug-giving process.



SmartAIR™

With SmartAIR™, BeneFusion eVP significantly enhances the safety level of IV administration.

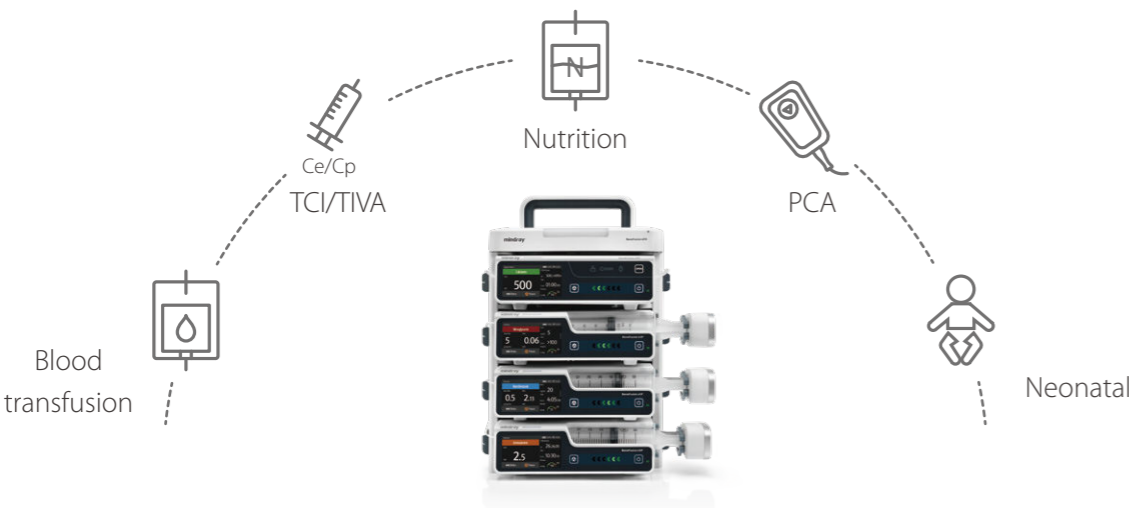
- Dual ultrasound sensor to detect the air bubbles more precisely, avoiding missing or false air-in-line alarm.
- 15ul air bubble detection size on BeneFusion eVP, ensuring patient safety throughout the infusion, even for neonates.



Efficiency in Application

All in one

BeneFusion eSP and eVP satisfy various infusion purposes by combining all functions together.

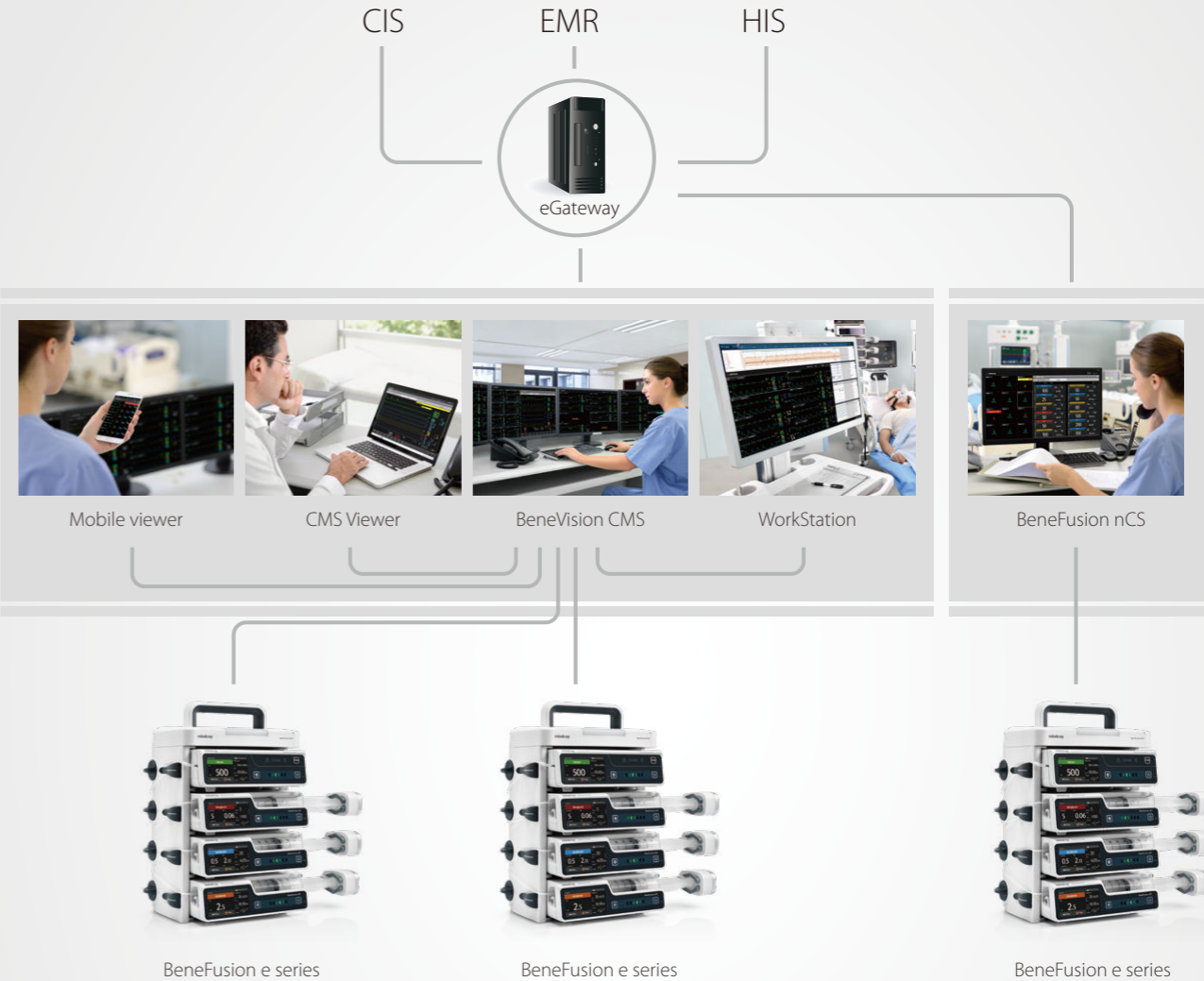


Flexible docking solution

- Modular docking design of BeneFusion eDS enables easy expansion from 2 to 16 slots.
- Ingenious design ensures easy plug-in of pumps.



Efficiency in Informatics



Integrated central monitoring

BeneVision CMS™ offers one-stop monitoring of all patients' vital sign and infusion treatment details, providing comprehensive information for clinical workers to improve the quality of patient care.



Easy management with multi-beds



Comprehensive data for single bed

BeneFusion eVP

BeneFusion eVP ex

BeneFusion eVP Neo

Infusion Pump

Operator's Manual



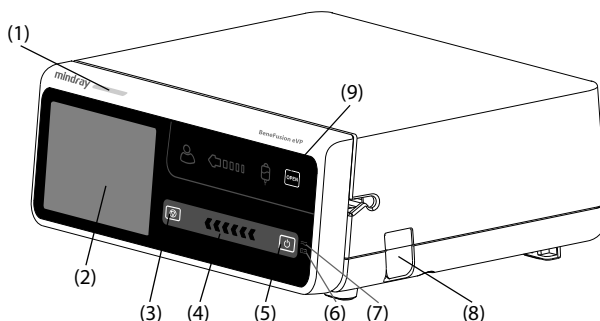
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Revision: 5.0

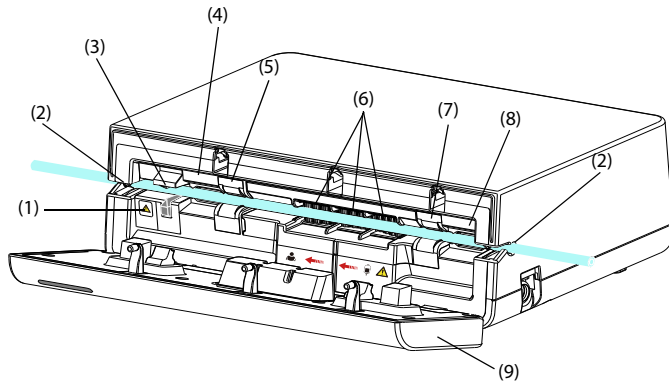
2.3 Main Unit

2.3.1 Front View



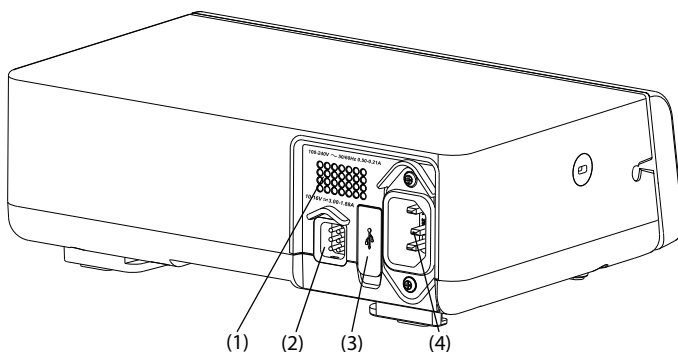
- (1) Alarm light
When an alarm occurs, this lamp lights and flashes corresponding with the alarm priority:
 - High priority alarms: the lamp quickly flashes red.
 - Low priority alarms: the lamp lights in yellow without flashing.
- (2) Display
- (3) Stop key
When an emergency happens during an infusion and unlocking the touchscreen fails, press this key to stop infusion.
- (4) Infusion status indicator
The indicator is on during infusion, purging, and bolus.
- (5) Power switch
- (6) Battery LED
 - Green: the battery is being charged.
 - Flashing green: the pump runs on battery power.
 - Off: no battery is installed, or no external power is connected when the equipment is off.
- (7) External power LED
 - On: when external power supply is connected.
 - Off: when external power supply is not connected.
- (8) Drop sensor connector
Connects the drop sensor.

- (9) Door opening key
Pressing this key opens the pump door.



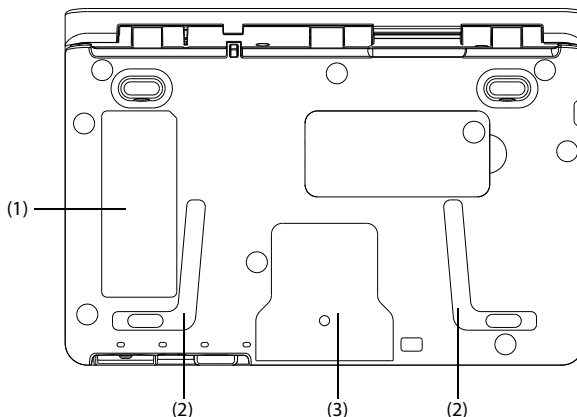
- (1) Anti free-flow clamp indicator
Indicates the state of the anti free-flow clamp. The indicator flashes when the anti free-flow clamp is open or malfunctions.
- (2) Tubing channel notches
Secures the infusion set.
- (3) Anti free-flow clamp
Occludes the tubing.
- (4) Downstream pressure sensor
Detects the downstream pressure in the infusion set.
- (5) Downstream air in line sensor
Detects air in the infusion set.
- (6) Pumping Mechanism
Includes the pumping fingers and a waterproof membrane covering them to keep fluid from entering the mechanism.
- (7) Upstream air in line sensor
Detects air in the infusion set.
- (8) Upstream pressure sensor
Detects the upstream pressure in the infusion set.
- (9) Door
Open the door to load or unload the infusion set.

2.3.2 Rear View



- (1) **Speaker**
Provides sound for audible alarms and reminder.
- (2) **Multifunctional connector**
 - Connects the equipment to the hospital's nurse call system through the nurse call cable.
 - Uses as a DC power input connector when the equipment is connected to the dock.
 - Uses as a RS232 connector for connecting the external devices.
- (3) **USB connector**
Connects the USB device.
- (4) **AC power input connector**
Connects the AC power cord.

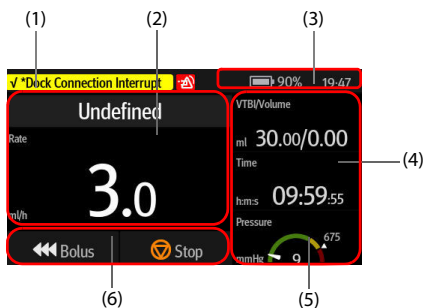
2.3.3 Bottom View



- (1) Product label
- (2) Placement area for stacking pumps
This area is for stacking the pumps with the handle.
- (3) Placement area for pole clamp
This area is for mounting the pump to a pole clamp.

2.4 Screen Display

The screen may look slightly different in different infusion modes. The following figure shows the infusion screen of the rate mode:













- (1) System status information area
Displays the alarm information, infusion mode, or bed number.

- (2) Infusion status area
Displays the drug name and major infusion parameters.
- (3) System status information area
Displays the battery status, network status, relayed status, and system time. For more information, see **2.4.1 On-screen Symbols**.
- (4) Infusion status area
Displays other infusion parameters and pressure status.
- (5) Pressure status area
Displays the real-time pressure status.
 - Green: Pressure is normal.
 - Yellow: Pressure is near the threshold for the infusion.
 - Red: Pressure is beyond the threshold for the infusion.
- (6) Key area
Displays keys. For more information, see **2.4.3 Operation Keys**.

2.4.1 On-screen Symbols

The following table lists the on-screen symbols:

Symbol	Description	Symbol	Description
	Audible alarm tones are paused.		Alarms are acknowledged and the alarm is reset.
	Alarms are acknowledged and the reminder sound is given.		Night mode
	Wireless network is connected. The solid part indicates network signal strength.		Wireless network is not connected.
	Customized relay		Circular relay
	The battery works correctly. The solid portion represents the remaining charge.		The battery is being charged.

NOTE

- **Save the packing case and packaging material as they can be used if the equipment must be reshipped.**
 - **This equipment is in accordance with the EN 1789:2007+A2:2014 standard.**
-

3.2 Environmental Requirements

The operating environment of the equipment must meet the requirements specified in this manual.

The environment where the equipment is used shall be reasonably free from noises, vibration, dust, corrosive, flammable, and explosive substances. Moreover, to maintain good ventilation, the equipment shall be at least 2 inches (5cm) away from around the cabinet.

When the equipment is moved from one place to another, condensation may occur as a result of temperature or humidity differences. In this case, never start the system before the condensation evaporates.

CAUTION

- **Make sure that the equipment operating environment meets the specific requirements. Otherwise unexpected consequences, e.g. damage to the equipment, could result.**
-

3.3 Installation

3.3.1 Pole Clamp Installation

The pole clamp secures the pump to either a horizontal or vertical bar of the medical supply unit or IV pole. For detailed information on how to install the pole clamp, see *The Pole Clamp Installation Guide*.

3.3.2 Stack Rack Installation




Use a stack rack for pump transport or for stacking several pumps together. For detailed instructions on stack rack installation, see *The Stack Rack Installation Guide*.

NOTE

- **Check the medical supply unit and IV pole for stability before mounting the pumps.**
- **Install a single pole clamp to each pump before mounting the stacked pumps to the medical supply unit or IV pole.**


4 Getting Started

4.1 Quick Start Guide

1. Press the power switch  to turn on the pump.
2. Load the infusion set. For detailed information, see **4.4 Loading the Infusion Set**.
3. Set the infusion parameters. For detailed information, see **4.5 Starting Infusion**.
4. If required, purge the line. For detailed information, see **4.6 Purge**.
5. Connect the infusion set to the patient access device.
6. Press  to start infusion.
7. Press  to pause infusion.

4.2 Setting Up the Pump

Before getting started, ensure that the pump is properly set up:

- The pump is placed on a stable surface or secured in the Dock, or properly mounted to an IV pole using the pole clamp.
- The pump is plugged into a properly-grounded AC power outlet. See **3.4.1 Connecting the AC Mains**.
- Press the power switch  to turn on the pump. The pump automatically performs a self test at startup. Check that the alarm tone is heard and the alarm lamp illuminates, one after the other, in red and yellow. This indicates that the visible and audible alarm indicators function correctly. The loading guide screen displays. If required, select **Exit** to enter the infusion parameters setting or drug selection screen, set infusion parameters or select drug before loading the infusion sets.
- If the pump is run on battery power, ensure that the battery is adequately charged.

WARNING

- **Before putting the system into operation, the operator must verify that the equipment, connecting cables and accessories are in correct working order and operating condition.**
- **Check that visual and auditory alarm signals are presented correctly when the equipment is powered on. Do not use the equipment if you suspect it is**

not working properly, or if it is mechanically damaged. Contact your service personnel or us.

NOTE


- **Stay within 1 meter (39 inches) of the pump while setting it up and operating it, making sure that you have a clear view of the pump interface.**
 - **The equipment uses a mains plug as isolation means to the mains power. Do not locate the equipment in a place difficult to operate the mains plug.**
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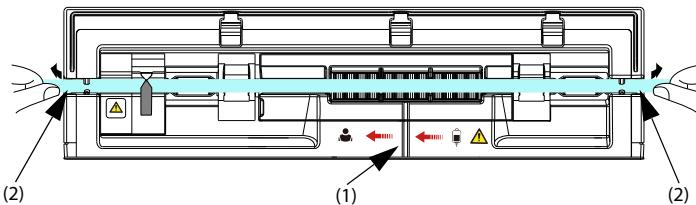
4.3 Preparing the IV Container

The height between the IV container and the pump is critical to the flow accuracy. To prepare the IV container, follow this procedure:

1. Hang the IV container.
2. Adjust the height of the pump so that there is 51 ± 5 cm (20 ± 2 in.) between the fluid line and the middle of the pump. Distances outside of this tolerance can adversely affect flow accuracy.

4.4 Loading the Infusion Set

1. Close the roller clamp or Robert clamp.
2. Press  to open the pump door.
3. Avoiding any slack, insert the infusion line into the slot, following the flow direction indicator(1). Ensure that the infusion set is straightly and firmly clipped into the tubing channel notches(2) on both sides of the casing.



4. Close the pump door.


WARNING

- **To ensure the accuracy of air bubble detection, check and remove the remained fluid in the infusion set slot before loading the infusion set.**

- While loading the infusion set, do not touch the anti free-flow clamp to avoid being hurt.
 - The pump must be mounted to the same level as the patient's heart. The most accurate pressure monitoring in the infusion set is achieved when the pump is positioned close to the patients heart level.
 - This pump uses standard, single use infusion set with Luer lock connections.
 - We recommend you to use an infusion set stated in this manual. If a non-recommended infusion set must be used or a different set needs to be changed, perform the calibration and performance test before use. Otherwise, the accuracy of the infusion and the performance of the pump may be adversely affected.
 - To ensure the accuracy of rate and alarm detection, the infusion set should be calibrated in this pump before first use.
 - When using the pump for blood transfusion, only use disposables dedicated and labelled for transfusion.
 - Single use accessories are not designed to be reused. Reuse may cause a risk of contamination and affect the measurement accuracy.
 - Take care that your hands are not squeezed when you close the pump door.
 - Make sure that the infusion set is located in both sides of the tubing channel notches after loading the infusion set.
-

4.5 Starting Infusion

The setup screen displays after the infusion set is loaded properly.

1. Select the drug. If the prescribed drug is not available, exit the drug selection screen, or select **Other Drug**.
2. If required, set the infusion mode. For more information, see chapter **8 Infusion Modes**.
3. Set infusion parameters.
4. Open the roller clamp or Robert clamp.
5. Purge the line. For more information, see **4.6 Purge**.
6. Connect the infusion set to the patient access device.
7. Check the following:
 - ◆ Verify parameter settings according to the prescriber's order.
 - ◆ Verify that the displayed infusion set brand and type correspond with the currently used infusion set.
8. Press  to start infusion.

NOTE

- **The predefined parameters can be changed during a therapy. This does not affect the embedded library.**
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9.3 Dose Error Reduction Systems (DERS)

DERS is for drug library only. If the predefined parameter limit is violated during a therapy, the pump gives prompts.

9.3.1 Hard Limits

If the set rate, dose rate, or bolus rate exceeds the lower or upper hard limit configured in the drug library, the setting will be rejected. Reconfigure the parameter as needed.

9.3.2 Soft Limits

If the set rate, dose rate, or bolus rate exceeds the lower or upper soft limit configured in the drug library, you can choose to accept or reject the setting.

- **Accept the current setting:** The current setting takes effect. The parameter that exceeds the soft limit is marked with an orange background.
- **Reject the current setting:** The pump returns to the previous menu, and you need to make the setting again.

9.4 Predefining the Infusion Mode

You can predefine the infusion mode and corresponding parameters in the drug info library. When the drug is selected, the pump automatically load the infusion mode and corresponding parameters.

15Accessories

The accessories listed in this chapter comply with the requirements of IEC 60601-1-2 when in use with the equipment. For details about the accessories, refer to the instructions for use provided with the accessory.

WARNING

- **Use accessories specified in this chapter. Using other accessories may cause damage to the equipment or not meet the claimed specifications.**
-

CAUTION

- **The accessories may not meet the performance specifications if stored or used outside the specified temperature and humidity ranges. If accessory performance is degraded due to aging or environmental conditions, contact your service personnel.**
 - **Check the accessories and their packages for any sign of damage. Do not use them if any damage is detected.**
 - **Use the accessories before the expiry date if their expiry date is indicated.**
-

PN	Description
0020-20-12522	Power cord, 10A, 250V, 2.5m, International
009-001075-00	Power cord, 250V, 10A, 3m, Brazil
009-001791-00	Power cord, 250V, 16A, 3m, South Africa
009-002636-00	Power cord, 10A, 1.5m, Australia standard
009-007190-00	Power cord, 3m, India
DA8K-10-14452	Power cord, USA
DA8K-10-14453	Power cord, UK
DA8K-10-14454	Power cord, Europe
009-009837-00	Serial port adapting cable
009-009838-00	Nurse call cable
009-011163-00	DC power cord

PN	Description
115-032580-01	Drop sensor
115-070532-00	Stack rack
115-074974-00	Quick install pole clamp
115-074975-00	Standard pole clamp
045-001434-00	Multi-pump bracket

A Product Specifications

A.1 Classifications

The equipment is classified, according to IEC60601-1:

Type of protection against electrical shock	CLASS I EQUIPMENT, equipment energized from an internal electrical power source.
Degree of protection against electrical shock	Defibrillation-proof type CF applied part (direct cardiac application)
Mode of operation	Continuous
Degree of protection against harmful ingress of water	IP33
Degree of safety of application in the presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide	The equipment is not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide
Degree of mobility	Portable

A.2 Environmental Specifications

Item	Temperature (°C)	Relative humidity (noncondensing)	Barometric (kPa)
Operating conditions	5 to 40	15% to 95%	57.0 to 107.4
Storage conditions	–30 to 70	10% to 95%	16.0 to 107.4

Storage Conditions: Corrosive-free and ventilated

WARNING

- **The pump may not meet the performance specifications if stored or used outside the specified temperature and humidity ranges. If the performance of the equipment is degraded due to aging or environmental conditions, contact your service personnel.**
-

A.3 Power Supply Specifications

A.3.1 External Power Supply Specifications

Item	External AC Power Supply	External DC Power Supply
Voltage	100 VAC to 240 VAC	10 VDC to 16 VDC
Current	0.5A to 0.21A	3 A to 1.88A
Frequency	50/60 Hz	/

A.3.2 Battery

Battery Type	Rechargeable lithium-ion
Run time	At least 11 hours for smart battery and at least 5 hours for normal battery (operating at a rate of 5ml/h or 25ml/h, under standard operating conditions*) At least 2.5 hours for smart battery and at least one hour for normal battery (operating at a rate of 2300ml/h, under standard operating conditions*)
Charge time	≤ 20 hours for smart and normal battery (operating at a rate of 25 ml/h, charged by the Dock); ≤ 6 hours for smart battery and ≤ 5 hours for normal battery (the pump is off, and charged by the AC power supply).
Shutdown delay	At least 30 minutes after first low battery alarm (operating at a rate of 25ml/h, under standard operating conditions*)
*Operating with a fully charged new battery at 20°C ± 2°C, screen brightness configured to 2, default volume, Wi-Fi disabled, drop sensor disconnected.	

A.4 Physical Specifications

Item	Maximum Weight (kg)	W × H × D (mm)	Remark
Main Unit	≤ 1.7	≤ 210x 140 x73	with battery, without accessories