2 Safety

This chapter describes important precautions for operating the HP-60/HP-60C infusion pump. To ensure the safety of both the operator and the patient, read this chapter carefully before using the pump. You should be fully aware of the precautions provided in this manual. Otherwise, the manufacturer is not responsible for the safety, reliability, and performance of the pump.

2.1 Warnings and Cautions

- Report any serious incident related to the pump to the local distributor or authority immediately.
- The infusion pump must be operated by or under the guidance of clinically trained and qualified technicians who have received a training related to the use of this pump.
- To avoid the risk of electric shock, ensure that the power supply system for the infusion pump has a protective earth. In case that the power supply system does not have protective earth, disconnect the power cable of the infusion pump from the power supply system and use the built-in battery to power the infusion pump.
- Before use, power on the infusion pump and wait until the self-check is finished. If an error message appears, handle the error accordingly as described in Chapter 8.
- Before you start an infusion, ensure that no twist or knot exists in the infusion line, especially when the infusion rate is low. The lower the infusion rate is, the longer it takes to detect an occlusion. If a twist or knot exists in the infusion line, an occlusion may occur and cause a long infusion pause and thus an under infusion.
- Do not use this infusion pump in a flammable environment.
- Take appropriate measures to prevent an over infusion caused after the elimination of an occlusion. During an infusion, the pressure in the infusion tube may rise in case of an occlusion caused by tube twisting, filter condensation, or puncture. In this case, excessive liquid may be infused into the patient's body after the occlusion is eliminated. Therefore, appropriate preventive measures must be taken.
- It is recommended that infusions sets of designated brands should be used. Otherwise, infusion accuracy is not guaranteed and the alarm function may fail.
- The infusion set, tube, infusion needle, and other medical parts used together with this infusion pump must all comply with local laws and regulations. For details, contact your local distributor.
- Failure to follow the requirements, procedures, warnings or cautions in this manual may lead to infusion exceptions, which may further cause under infusions, over infusions, or other potential risks.
- It is recommended that a drop sensor should be installed and the drop detection function should be enabled during an infusion.

- During use of the infusion pump, the pump and the patient should be monitored regularly by professional medical personnel.
- During use, keep the infusion pump away from devices that may cause interference, such as high-frequency surgical equipment, mobile phones, wireless devices, and defibrillators.
- The pump contains ferromagnetic materials which are susceptible to interference with magnetic field generated by the MRI devices. Therefore, the Pump is not considered an MRI compatible Pump as such. For the safe use of the pump in the MRI the HP-80 MRI cabinet is need used. For further information, contact your local distributor for further guidance.
- Do not connect other infusion systems or accessories to the patient's infusion line, in case the infusion rate is changed or air is infused into the patient's body.
- The infusion pump does not have a patient connection circuit. Do not let the patient touch the infusion pump.
- Do not touch the infusion pump and the patient simultaneously when you operate the pump.
- Do not use the infusion pump as an ambulatory device. Otherwise, unknown risks may be caused.
- When operating the pump or checking its alarm system, stand in front of the pump and keep a distance of 1 m.
- Ensure that the IV container is positioned less than 100 cm higher than the patient's heart or the infusion pump. Otherwise, infusion accuracy is not guaranteed and the occlusion alarm function may fail.
- Do not disassemble or try to repair the infusion pump. The manufacturer and distributor shall not be responsible for any infusion pump that has been disassembled, modified or used for any purpose other than its intended use.
- If the infusion pump falls to the ground or it is affected by an external force, stop using the pump even if it appears normal. Contact your local distributor and have an inspection performed to check whether the pump can still operate properly.
- Do not service or maintain the infusion pump or its accessory when it is being used on a patient.
- Do not try to upgrade the software of the infusion pump. To upgrade the software, contact your local distributor. The software upgrade must be executed by trained technicians. Otherwise, errors may occur. After the software upgrade, the infusion pump must be validated by trained technicians before use.
- This infusion pump supports blood transfusion. When used for blood transfusion, the pump must be used in conjunction with disposable consumables dedicated to blood transfusion and must be operated in accordance with clinical transfusion guidelines.
- When you install an infusion set into the infusion pump, refer to the instructions for use or packaging materials of the infusion set for its installation and usage methods.
- This infusion pump supports enteral nutrition. When used for enteral nutrition, the pump must be used in conjunction with disposable consumables dedicated and labeled for enteral nutrition, and must be operated in accordance with clinical enteral nutrition guidelines. Do not use enteral fluids for intravenous infusion, because this may cause patient hazard.
- The drip mode does not support blood transfusion and enteral nutrition infusion.

- When multiple pumps are connected to a patient, label enteral nutrition and epidural infusion channels or use other standard interfaces (non-Luer locks) to distinguish them from intravenous infusion channels.

CAUTION

- The applied part of the infusion pump consists of an infusion tube and an infusion needle.
- Keep the infusion pump out of the reach of the patient and irrelevant personnel.
- Ensure that the infusion pump is always equipped with a battery during use. Otherwise, in case of an external power failure or interruption, the infusion pump will be shut down without triggering an alarm, which will cause risks.
- If the infusion pump fails to function as described herein for some unknown reason, power it off and report the conditions (including the infusion set used, infusion rate, serial number of the infusion pump, and liquid type) to your local distributor or the after-sales service department of the manufacturer.
- Do not touch the display screen by using a sharp object. Otherwise, the screen may be damaged.
- Do not disassemble or modify the infusion pump without permission.
- A short circuit may occur if infusion liquid flows into the AC power socket or any USB port of the infusion pump. Before connecting the power cable, check whether the connecting parts are dry. If any liquid splashes onto the infusion pump, use a dry cloth to wipe it off and contact local maintenance personnel to have the pump checked before use.
- The delay of the infusion pump's alarm system is no longer than 1.5s.
- The delay from the onset of an alarm condition to the point where representation of alarm condition leaves the signal output part is no longer than 3s.
- The maintenance of this infusion pump must be conducted by authorized personnel. The authorized personnel can ask the manufacturer for materials such as the circuit diagram and component list.
- After the infusion pump is exposed to defibrillation voltage, the recovery time of the pump is shorter than 1s. The pump functions properly when exposed to defibrillation voltage.
- For enteral nutrition infusion, it is recommended to set the OCCL level to the highest and the bubble level to a high level.

2.2 Symbol Description

The following table describes the symbols in this manual and on the labels of the infusion pump.

Symbol	Meaning
	Model number
	General warning sign
	Defibrillation-proof type CF applied part

Symbol	Meaning
IP33	Protected against solid foreign objects of 2,5 mm Ø and greater; protected against spraying water
	Manufacturer
	Date of manufacture
	Nurse call
	Non-ionizing electromagnetic radiation
	Alternating current
	Direct current
	Refer to instruction manual/booklet
	DISPOSAL: Do not dispose of this product as unsorted municipal waste. Separate collection of such waste for special treatment is necessary.
	This way up
	Fragile, handle with care
	Keep dry
	Keep away from sunlight
	Atmospheric pressure limitation
	Temperature limit
	Humidity limitation

Symbol	Meaning
	Stacking limit by number
EC REP	Authorized representative in the European Community/European Union
MD	Medical device
UDI	Unique device identifier
SN	Serial number
CE 0123	The device complies with the requirements of the Medical Device Regulation 2017/745.
HOME	**HOME** button. Press this button to access the setting interface or return to the infusion preparation interface.
ON\OFF	**ON/OFF** button. Press this button to power on or off the pump.
OPEN	**OPEN** button. Press this button to open the pump door.
	Protective earth (ground)
	USB 2.0 port
	USB 3.0 port
	RJ-45 port
	Direction of infusion
	Insert position of the anti-free-flow clamp

3 Product Specifications

Name	Infusion pump
Model	HP-60/HP-60C
Dimensions	214 mm (W) × 75 mm (H) × 142 mm (D)
Weight	About 1.4 kg (battery included)
Operating Conditions	Ambient temperature: 5°C - 40°C Relative humidity: 15% - 95%, non-condensing Atmospheric pressure: 57.0 - 106.0 kPa Operating altitude: ≤3000 m
Storage and Shipping Conditions	Ambient temperature: -20°C - 55°C Relative humidity: 10% - 95%, non-condensing Atmospheric pressure: 22.0 - 107.4 kPa
Service Life	10 years
Classification	1. Class I: Internally powered equipment 2. Defibrillation-proof type CF applied part 3. IP33 4. Not sterilized 5. Not category AP/APG equipment 6. Mode of operation: continuous

Power Supply	AC power supply: 100 - 240 V AC, 50/60 Hz Input power: 45 VA External DC power supply: 12 V DC Input current (DC): 2.5 A Internal lithium battery: 10.8 V, 3000 mAh; model: 18650-3S1P Continuous operation duration of the lithium battery: ● ≥10 hours at the infusion rate is 25 ml/h(Test conditions: A fully-charged brand new battery is used, the screen brightness is set to the lowest level, Wi-Fi is disabled, and the test is performed at room temperature). ● ≥4 hours at the infusion rate is 2000 ml/h(Test conditions: A fully-charged brand new battery is used, the screen brightness is set to the lowest level, Wi-Fi is disabled, and the test is performed at room temperature). ● ≥8 hours at the infusion rate is 125 ml/h(Test conditions: A fully-charged brand new battery is used, the screen brightness is set to the lowest level, Wi-Fi is disabled, and the test is performed at room temperature). Charge time of the lithium battery: ≤4 hours (with the pump powered off) Charge mode of the lithium battery: The battery can be charged when the infusion pump is connected to an AC or DC power supply.
Display Screen	3-inch, resistive color LCD touchscreen Resolution: 480 × 320 pixels Angle of visibility: 80 degrees in each direction
Indicator	Power indicator: yellow or green Work/alarm indicator: yellow or red Button backlight
Ports	● Micro USB 2.0 port: used to connect to the drop sensor. ● USB 3.0 port: used to connect to the nurse call button. ● USB 2.0 port: used to connect to the barcode scanner or an infusion workstation for communication based on the RS-232 protocol, and also used for DC power input. ● RJ-45 network port: 10/100Mbps self-adaptive Ethernet port. ● Wi-Fi network port: used to communicate with an infusion central monitoring system based on IEEE 802.11 b/g/n.
Infusion Rate	0.10 - 2000 ml/h
Minimum Increment of Infusion Rate	● 0.01 ml/h if the infusion rate is from 0.10 to 99.99 ml/h ● 0.1 ml/h if the infusion rate is from 100.0 to 999.9 ml/h ● 1 ml/h if the infusion rate is from 1000 to 2000 ml/h

VTBI (Volume to be infused)	0.10 - 9999.99 ml (minimum increment: 0.01 ml)
Total Volume Display	0.00 - 9999.99 ml (minimum increment: 0.01 ml)
Time	00:00:01 - 99:59:59 (minimum increment: 1s)
Bolus Rate	0.10 - 2000 ml/h
Bolus VTBI	0.10 - 999.90 ml (minimum increment: 0.01 ml)
Purge Rate	0.10 - 2000 ml/h
Anti-Bolus	Anti-bolus function, unintended bolus volume ≤ 0.2 ml
KVO Rate	0.10 - 30.00 ml/h (minimum increment: 0.01 ml/h)
Infusion Accuracy	HP-60: ● ±3% (Use MC-SI infusion set and test per IEC60601-2-24.) ● ±5% (Use other infusion set recommended in *6.3 Selecting an Infusion Set Brand* and test per IEC 60601-2-24.) HP-60C: ● ±3% (Use the infusion set recommended in *6.3 Selecting an Infusion Set Brand* and test per IEC 60601-2-24.)
Occlusion Level	● Fluid-side occlusion: The **Fluid Side OCCL** alarm is supported. ● Patient-side occlusion: 150 - 975 mmHg Twelve occlusion levels are available for selection. The default occlusion level is level 6.
Single Bubble	Air bubble alarm accuracy: ±15 µl or ±20% (whichever is greater) Bubble level: 25, 50, 100, 200, 300, 500, and 800 (µl)
Total Bubbles	Bubble level: 100, 200, 400, 500, 600, 800, and 1000 (µl/15min)
Infusion Modes	Rate mode, time mode, weight mode, sequence mode, trapezia mode, micro mode, LoadingDose mode, and drip mode
Drug Library	A maximum of 5,000 drug types can be stored.
Alarm Messages	Infusion End, BAT Empty, Patient Side OCCL, Fluid Side OCCL, Infusion End KVO Start, KVO End, Relay Failed, Air Bubble In Line, No Drop, Too Many Drops, Too Few Drops, Standby End, No Drop Sensor, Infusion Near End, No Battery, No AC Power, BAT Low, Reminder Alarm, and Pre OCCL

Special Functions	● Power supply mode switching: automatically switch to battery mode in case of an AC/DC power failure and switch back to AC/DC power supply mode when the AC/DC power supply recovers from the failure. ● Permission management: assign the permissions on various operations, such as viewing data and modifying data. ● The infusion rate can be changed during an infusion. ● Key parameters are automatically saved in case of a power failure.
Networking Function	The infusion pump can be connected to an infusion central monitoring system over a wired or wireless network.
Date of Manufacture	See the product label.
Main Safety Standards	IEC 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance IEC 60601-2-24 Medical electrical equipment – Part 2-24: Particular requirements for the basic safety and essential performance of infusion pumps and controllers IEC 60601-1-8 Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance - Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems IEC 60601-1-2 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests

2 Safety

This chapter describes important precautions for operating the HP-60 PRO/HP-60C PRO infusion pump. To ensure the safety of both the operator and the patient, read this chapter carefully before using the pump. You should be fully aware of the precautions provided in this manual. Otherwise, the manufacturer is not responsible for the safety, reliability, and performance of the pump.

2.1 Warnings and Cautions

- Report any serious incident related to the pump to the local distributor or authority immediately.
- The infusion pump must be operated by or under the guidance of clinically trained and qualified technicians who have received a training related to the use of this pump.
- To avoid the risk of electric shock, ensure that the power supply system for the infusion pump has a protective earth. In case that the power supply system does not have protective earth, disconnect the power cable of the infusion pump from the power supply system and use the built-in battery to power the infusion pump.
- Before use, power on the infusion pump and wait until the self-check is finished. If an error message appears, handle the error accordingly as described in Chapter 8.
- Before you start an infusion, ensure that no twist or knot exists in the infusion line, especially when the infusion rate is low. The lower the infusion rate is, the longer it takes to detect an occlusion. If a twist or knot exists in the infusion line, an occlusion may occur and cause a long infusion pause and thus an under infusion.
- Do not use this infusion pump in a flammable environment.
- Take appropriate measures to prevent an over infusion caused after the elimination of an occlusion. During an infusion, the pressure in the infusion tube may rise in case of an occlusion caused by tube twisting, filter condensation, or puncture. In this case, excessive liquid may be infused into the patient's body after the occlusion is eliminated. Therefore, appropriate preventive measures must be taken.
- It is recommended that infusions sets of designated brands should be used. Otherwise, infusion accuracy is not guaranteed and the alarm function may fail.
- The infusion set, tube, infusion needle, and other medical parts used together with this infusion pump must all comply with local laws and regulations. For details, contact your local distributor.
- Failure to follow the requirements, procedures, warnings or cautions in this manual may lead to infusion exceptions, which may further cause under infusions, over infusions, or other potential risks.
- It is recommended that a drop sensor should be installed and the drop detection function should be enabled during an infusion.

- During use of the infusion pump, the pump and the patient should be monitored regularly by professional medical personnel.
- During use, keep the infusion pump away from devices that may cause interference, such as high-frequency surgical equipment, mobile phones, wireless devices, and defibrillators.
- The Pump contains ferromagnetic materials which are susceptible to interference with magnetic field generated by the MRI devices. Therefore, the Pump is not considered an MRI compatible Pump as such. For the safe use of the pump in the MRI the HP-80 MRI cabinet is need used. For further information, contact your local distributor for further guidance.
- Do not connect other infusion systems or accessories to the patient's infusion line, in case the infusion rate is changed or air is infused into the patient's body.
- The infusion pump does not have a patient connection circuit. Do not let the patient touch the infusion pump.
- Do not touch the infusion pump and the patient simultaneously when you operate the pump.
- Do not use the infusion pump as an ambulatory device. Otherwise, unknown risks may be caused.
- When operating the pump or checking its alarm system, stand in front of the pump and keep a distance of 1 m.
- Ensure that the IV container is positioned less than 100 cm higher than the patient's heart or the infusion pump. Otherwise, the infusion accuracy is not guaranteed and the occlusion alarm function may fail.
- Do not disassemble or try to repair the infusion pump. The manufacturer and distributor shall not be responsible for any infusion pump that has been disassembled, modified or used for any purpose other than its intended use.
- If the infusion pump falls to the ground or it is affected by an external force, stop using the pump even if it appears normal. Contact your local distributor and have an inspection performed to check whether the pump can still operate properly.
- Do not service or maintain the infusion pump or its accessory when it is being used on a patient.
- Do not try to upgrade the software of the infusion pump. To upgrade the software, contact your local distributor. The software upgrade must be executed by trained technicians. Otherwise, errors may occur. After the software upgrade, the infusion pump must be validated by trained technicians before use.
- This infusion pump supports blood transfusion. When used for blood transfusion, the pump must be used in conjunction with single-use consumables dedicated for blood transfusion and must be operated in accordance with clinical transfusion guidelines.
- When you install an infusion set into the infusion pump, refer to the instructions for use or packaging materials of the infusion set for its installation and usage methods.
- This infusion pump supports enteral nutrition. When used for enteral nutrition, the pump must be used in conjunction with single-use consumables dedicated and labeled for enteral nutrition, and must be operated in accordance with clinical enteral nutrition guidelines. Do not use intravenous infusion for enteral fluids, because this may cause patient hazard.
- The drip mode does not support blood transfusion and enteral nutrition infusion.

- When multiple pumps are connected to a patient, label enteral nutrition and epidural infusion channels or use other standard interfaces (non-Luer locks) to distinguish them from intravenous infusion channels.

CAUTION

- The applied part of the infusion pump consists of an infusion tube and an infusion needle.
- Keep the infusion pump out of the reach of the patient and irrelevant personnel.
- Ensure that the infusion pump is always equipped with a battery during use. Otherwise, in case of an external power failure or interruption, the infusion pump will be shut down without triggering an alarm, which will cause risks.
- If the infusion pump fails to function as described herein for some unknown reason, power it off and report the conditions (including the infusion set used, infusion rate, serial number of the infusion pump, and liquid type) to your local distributor or the after-sales service department of the manufacturer.
- Do not touch the display screen by using a sharp object. Otherwise, the screen may be damaged.
- Do not disassemble or modify the infusion pump without permission.
- A short circuit may occur if infusion liquid flows into the AC power socket or any USB port of the infusion pump. Before connecting the power cable, check whether the connecting parts are dry. If any liquid splashes onto the infusion pump, use a dry cloth to wipe it off and contact local maintenance personnel to have the pump checked before use.
- The delay of the infusion pump's alarm system is no longer than 1.5s.
- The delay from the onset of an alarm condition to the generation of its alarm signal is no longer than 3s.
- The maintenance of this infusion pump must be conducted by authorized personnel. The authorized personnel can ask the manufacturer for materials such as the circuit diagram and component list.
- After the infusion pump is exposed to defibrillation voltage, the recovery time of the pump is shorter than 1s. The pump functions properly when exposed to defibrillation voltage.
- For enteral nutrition infusion, it is recommended to set the OCCL level to the highest and the bubble level to the a high level.

2.2 Symbol Description

The following table describes the symbols in this manual and on the labels of the infusion pump.

Symbol	Meaning
	Model number
	General warning sign
	Defibrillation-proof type CF applied part

Symbol	Meaning
IP33	Protected against solid foreign objects of 2,5 mm Ø and greater; protected against spraying water
	Manufacturer
	Date of manufacture
	Nurse call
	Non-ionizing electromagnetic radiation
	Alternating current
	Direct current
	Refer to instruction manual/booklet
	DISPOSAL: Do not dispose of this product as unsorted municipal waste. Separate collection of such waste for special treatment is necessary.
	This way up
	Fragile, handle with care
	Keep dry
	Keep away from sunlight
	Atmospheric pressure limitation
	Temperature limit
	Humidity limitation

Symbol	Meaning
	Stacking limit by number
EC REP	Authorized representative in the European Community/European Union
SN	Serial number
MD	Medical device
UDI	Unique device identifier
CE 0123	The device complies with the requirements of the Medical Device Regulation 2017/745
HOME	**HOME** button. Press this button to access the setting interface or return to the infusion preparation interface.
ON\OFF	**ON/OFF** button. Press this button to power on or off the pump.
OPEN	**OPEN** button. Press this button to open the pump door.
	Protective earth (ground)
	USB 2.0 port
	USB 3.0 port
	RJ-45 port
	Direction of infusion
	Insert position of the anti-free-flow clamp

3 Product Specifications

Name	Infusion pump
Model	HP-60 PRO/HP-60C PRO
Dimensions	214 mm (W) × 75 mm (H) × 142 mm (D)
Weight	About 1.4 kg (battery included)
Operating Conditions	Ambient temperature: 5°C - 40°C Relative humidity: 15% - 95%, non-condensing Atmospheric pressure: 57.0 - 106.0 kPa Operating altitude: ≤3000 m
Storage and Shipping Conditions	Ambient temperature: -20°C - 55°C Relative humidity: 10% - 95%, non-condensing Atmospheric pressure: 22.0 - 107.4 kPa
Service Life	10 years
Classification	1. Class I: Internally powered equipment 2. Defibrillation-proof type CF applied part 3. IP33 4. Not sterilized 5. Not category AP/APG equipment 6. Mode of operation: continuous

Power Supply	AC power supply: 100 - 240 V AC, 50/60 Hz Input power: 45 VA External DC power supply: 12 V DC Input current (DC): 2.5 A Internal lithium battery: 10.8 V, 3000 mAh; model: 18650-3S1P Continuous operation duration of the lithium battery: ● ≥10 hours at the infusion rate is 25 ml/h(Test conditions: A fully-charged brand new battery is used, the screen brightness is set to the lowest level, Wi-Fi is disabled, and the test is performed at room temperature.) ● ≥4 hours at the infusion rate is 2000 ml/h(Test conditions: A fully-charged brand new battery is used, the screen brightness is set to the lowest level, Wi-Fi is disabled, and the test is performed at room temperature.) ● ≥8 hours at the infusion rate is 125 ml/h(Test conditions: A fully-charged brand new battery is used, the screen brightness is set to the lowest level, Wi-Fi is disabled, and the test is performed at room temperature). Charge time of the lithium battery: ≤4 hours (with the pump powered off) Charge mode of the lithium battery: The battery can be charged when the infusion pump is connected to an AC or DC power supply.
Display Screen	3-inch, resistive color LCD touchscreen Resolution: 480 × 320 pixels Angle of visibility: 80 degrees in each direction
Indicator	Power indicator: yellow or green Work/alarm indicator: yellow or red Button backlight
Ports	● Micro USB 2.0 port: used to connect to the drop sensor. ● USB 3.0 port: used to connect to the nurse call button. ● USB 2.0 port: used to connect to the barcode scanner or an infusion workstation for communication based on the RS-232 protocol, and also used for DC power input. ● RJ-45 network port: 10/100Mbps self-adaptive Ethernet port. ● Wi-Fi network port: used to communicate with an infusion central monitoring system based on IEEE 802.11-b/g/n.
Infusion Rate	0.10 - 2000 ml/h
Minimum Increment of Infusion Rate	● 0.01 ml/h if the infusion rate is from 0.10 to 99.99 ml/h ● 0.1 ml/h if the infusion rate is from 100.0 to 999.9 ml/h ● 1 ml/h if the infusion rate is from 1000 to 2000 ml/h

VTBI (Volume to be infused)	0.10 - 9999.99 ml (minimum increment: 0.01 ml)
Total Volume Display	0.00 - 9999.99 ml (minimum increment: 0.01 ml)
Time	00:00:01 - 99:59:59 (minimum increment: 1s)
Bolus Rate	0.10 - 2000 ml/h
Bolus VTBI	0.10 - 999.90 ml (minimum increment: 0.01 ml)
Purge Rate	0.10 - 2000 ml/h
Anti-Bolus	Anti-bolus function, unintended bolus volume ≤ 0.2 ml
KVO Rate	0.10 - 30.00 ml/h (minimum increment: 0.01 ml/h)
Infusion Accuracy	HP-60 PRO: ● ±3% (Use MC-SI infusion set and test per IEC60601-2-24.) ● ±5% (Use other infusion set recommended in *6.3 Selecting an Infusion Set Brand* and test per IEC 60601-2-24.) HP-60C PRO: ● ±3% (Use the infusion set recommended in *6.3 Selecting an Infusion Set* and test per IEC 60601-2-24.)
Occlusion Level	● Fluid-side occlusion: The **Fluid Side OCCL** alarm is supported. ● Patient-side occlusion: 50 - 1125 mmHg Fifteen occlusion levels are available for selection. The default occlusion level is level 7.
Single Bubble	Air bubble alarm accuracy: 15^{+15}_{-10} µl at level 1 and ±15 µl or ±20% (whichever is greater) at other levels Bubble level: 15, 25, 50, 100, 200, 300, 500, and 800 (µl)
Total Bubbles	Bubble level: 100, 200, 400, 500, 600, 800, and 1000 (µl/15min)
Infusion Modes	Rate mode, time mode, weight mode, sequence mode, trapezia mode, micro mode, LoadingDose mode, drip mode, and intermittent mode
Drug Library	A maximum of 5000 drug types can be stored.
Alarm Messages	Infusion End, BAT Empty, Patient Side OCCL, Fluid Side OCCL, Infusion End KVO Start, KVO End, Relay Failed, Air Bubble In Line, No Drop, Too Many Drops, Too Few Drops, Standby End, No Drop Sensor, Infusion Near End, No Battery, No AC Power, BAT Low, Reminder Alarm, and Pre OCCL

Special Functions	● Power supply mode switching: automatically switch to battery mode in case of an AC/DC power failure and switch back to AC/DC power supply mode when the AC/DC power supply recovers from the failure. ● Permission management: assign the permissions on various operations, such as viewing data and modifying data. ● The infusion rate can be changed during an infusion. ● Key parameters are automatically saved in case of a power failure.
Networking Function	The infusion pump can be connected to an infusion central monitoring system over a wired or wireless network.
Date of Manufacture	See the product label.
Main Safety Standards	IEC 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance IEC 60601-2-24 Medical electrical equipment – Part 2-24: Particular requirements for the basic safety and essential performance of infusion pumps and controllers IEC 60601-1-8 Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance - Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems IEC 60601-1-2 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests

About This Manual

Before using the BD neXus V700 Volumetric Pump, read this Manual carefully and follow the safety precautions and operating instructions contained herein.

The user must be thoroughly familiar with the BD neXus V700 Volumetric Pump (hereinafter referred to as *Pump*) described in this manual prior to use.

All illustrations used in this manual show typical settings and values which may be used in setting up the functions of the Pump. These settings and values are for illustrative use only. The complete range of settings and values are detailed in the Technical Data section.

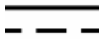
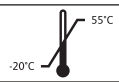
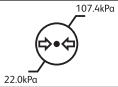
- Keep this manual for future reference during the Pump's operational life.
- It is important to ensure that you only refer to the most recent version of the Directions For Use for your BD products. Paper copies of the Directions For Use can be obtained free of charge by contacting your local BD representative. An estimated delivery time will be provided when the order is placed.

Conventions Used in this Manual

Bold	Used for Warning, Cautions, Display names, software commands, controls and indicators referenced in this manual, for example, **Battery Indicator, Prime, ON/OFF** button.
'Single quotes'	Used to indicate cross-references made to another section of this manual. For example, see 'Associated Products' section.
Italics	Used to refer to other documents or manuals. For example, Refer to the relevant *Directions For Use* (DFU) for further information. Also used to define custom terminology specific to a manual e.g. The BD neXus V700 Volumetric Pump (hereinafter referred to as *Pump*).
	Warning symbol. A *warning* is a statement that alerts the user to the possibility of injury, death, or other serious adverse reactions associated with the use or misuse of a Pump.
	Caution symbol. A *caution* is a statement that alerts the user to the possibility of a problem with a Pump associated with its use or misuse. Such problems may include Pump malfunction, Pump failure, damage to a Pump or damage to other property. The caution statement includes the precaution(s) that should be taken to avoid the hazard.
Note:	*Notes* contain supplementary information or emphasize a point or procedure.

User	Trained and qualified users who interact with the Pump. See 'Intended Users'.
Qualified Service Personnel	Trained and qualified personnel who perform service and repair activities, and upload and download data to the product.

Labelling Symbols

Symbol	Description
	Consult accompanying documents.
	Nurse call.
	Defibrillation-proof type CF applied part (Degree of protection against electrical shock).
IP33	Protected against solid foreign objects of 2.5 mm and greater, protected against spraying water.
	Alternating current.
	Direct current.
CE 0123	The device complies with the requirements of the Medical Device Regulation 2017/745.
	Date of manufacture.
	Manufacturer.
	Dispose according to local environmental electronic waste disposal regulation.
	Protective earth.
	USB2.0 interface.
	USB3.0 interface.
	RJ-45 network interface.
CH REP	Authorized representative in the Switzerland.
EC REP	Authorized representative in the European Community.
MD	Medical device.
SN	Serial number.
REF	Catalogue number
UDI	Unique device identification.
LOT	Batch code.
	Transport and storage temperature limit.
	Transport and storage atmospheric pressure limitation.
	Transport and storage humidity limitation.
	Keep dry.

Symbol	Description
	Keep away from sunlight.
	This way up.
	Fragile, handle with care.
	Stacking limit by number. Up to n layers can be stacked.

Operating Precautions

Disposable Infusion Sets	
	It is highly recommended that luer Lock or equivalent locking connectors infusion sets of specified brands be used. If using any infusion set not specified by the manufacturer, the infusion accuracy and alarm function cannot be guaranteed.
	The infusion set, catheter, and other medical parts used together with this Pump must all comply with local laws and regulations. For relevant information, please contact your local BD representative.
	When infusing critical or life sustaining medications, it is recommended to always use a drop sensor in addition to setting a Volume To Be Infused (VTBI).
	The altitude difference between the heart of patient (or Pump) and the infusion container above the Pump must not be greater than 100cm. Otherwise, the infusion accuracy and occlusion alarm accuracy cannot be guaranteed.
	If an infusion set of brands other than manufacturer is used or the infusion parameters are not defined correctly, the infusion accuracy may be affected.
	This Pump supports blood transfusion. When used for blood transfusion, the pump must be used in conjunction with disposable consumables dedicated to blood transfusion and must be operated in accordance with clinical transfusion guidelines.
	This infusion pump supports enteral nutrition. When used for enteral nutrition, the pump must be used in conjunction with disposable consumables dedicated and labeled for enteral nutrition, and must be operated in accordance with clinical transfusion guidelines. Do not use enteral fluids for intravenous infusion, because this may cause patient hazard.
	For enteral nutrition infusion, it is recommended to set the OCCL level to the highest and the bubble level to the a high level.
Mounting the Pump	
	When more than one Pump is being used on a patient, those containing high risk, critical medications must be positioned as close to the patient's heart level as possible to avoid the risk of variations in flow or siphoning.
	When multiple Pumps are connected to a patient, label enteral nutrition and epidural infusion channels or use other standard interfaces (non-Luer locks) to distinguish them from intravenous infusion channels.
	Raising the Pump while infusing may result in a bolus of the infusate, whereas lowering the Pump while infusing may result in a delay in the infusion (an underinfusion).
Operating Environment	
	The Pump and patient should be monitored regularly by professional medical personnel during use.
	When checking the Pump's alarm system, stand in front of the Pump, keep one metre away from the Pump.
	The Pump is not intended to be carried continuously by the patient (ambulatory use).
	Do not use the Pump in a flammable environment.
	Before use, power on the Pump, wait until the self-check is finished, and confirm that no error message is displayed.

	Do not set the alarm volume to a level lower than the ambient noise to ensure that the alarm can be properly identified.
	The alarm system may fail if the alarm volume is set to a low level. Please check the alarm volume setting based on the clinical environment.
Operating Pressure	
	During infusion, the pressure in the infusion set may rise in case of an occlusion caused by set twisting, filter condensation, or puncture. In this case, excessive liquid may be infused into the patient's body after the occlusion is eliminated and therefore appropriate preventive measures must be taken.
	A lower infusion rate will result in a longer interval between the occlusion occurrence time and detection time, which will cause a long infusion pause, thereby causing insufficient dose. For this reason, verify that the infusion set does not kink especially when initiating a low-rate infusion.
Hazards	
	The Pump must be operated by or under the guidance of clinically trained and qualified technicians who have received a training related to the use of this Pump.
	If a user does not follow the requirements, procedures, warnings or cautions provided in this manual, an infusion exception may be incurred. This exception may cause insufficient dose, excessive dose, and even other potential risks.
	To avoid the risk of electric shock, ensure that the power supply system of the Pump has a protective earth.
	Do not touch the Pump and patient simultaneously when operating the Pump.
	If the Pump falls to the ground or it is affected by an external force, stop using the Pump. Contact your local BD representative and have an inspection performed to judge whether the Pump is operating properly.
	Do not service or maintain the Pump or its accessories when it is being used on a patient.
	To upgrade the software, contact your local BD representative for help. The software upgrade must be executed by qualified service personnel. After software upgrade, the Pump must be validated by trained technicians before use.
	Do not touch the display by using sharp objects.
	The Pump or its accessories should be disposed of according to local laws and regulations or the hospital's regulations. For details, contact your local BD representative.
	Short circuit may occur if infusion liquid flows into the AC power socket or any USB socket. Before connecting the power cable, check if the connecting parts are dry. If any liquid splashes onto the Pump, use a dry cloth to dry it and contact local maintenance personnel to test it before use.
	BD neXus V700 Volumetric Pump should not be modified or altered in any way, except where explicitly directed or authorised by MC. Any use of BD neXus V700 Volumetric Pumps which have been altered or modified otherwise than in strict application of directions provided by MC, is at your sole risk, and MC does not provide any warranty for or endorsement on any BD neXus V700 Volumetric Pump that has been so modified or altered. MC product warranty shall not apply in the event the BD neXus V700 Volumetric Pump has suffered damage or premature wear, or malfunctions or otherwise operates incorrectly, as a result of unauthorised modification or alteration of the BD neXus V700 Volumetric Pump.
	Ensure that the battery is always installed in the Pump during use. Otherwise, the Pump will be shut down without triggering an alarm in case of an external power failure or interruption.

	When using an IV pole for Pump installation, ensure that the Pump is fixed tightly on the IV pole and the IV pole is stable.
	If the Pump fails to act as specified herein for unknown reason, power it off and report the conditions (including the infusion set used, infusion rate, serial No. of the Pump, and liquid type) when the fault occurs to your local BD representative.
	The delay of the Pump's alarm system is no longer than 1.5 seconds.
	BD will provide circuit diagrams, component part lists, descriptions, and calibration instructions to assist personnel in parts repair.
	The applied part of the Pump is the infusion catheter, and infusion set.
	This product requires maintenance by authorized personnel. The authorized personnel can ask for such materials as the service manual and list of spare parts from the manufacturer.
	The delay time from onset of alarm condition to the point where representation of alarm condition leaves the signal output part is no longer than three seconds.
	After the Pump is exposed to a defibrillation voltage, the recovery time of the Pump is shorter than one second (the Pump functions properly during exposure to the defibrillation voltage).
	Do not insert accessories which are not specified by the manufacturer into the external inlets.
	Additional equipment connected to medical electrical equipment through the network/data coupling (USB or LAN port) must comply with the respective IEC or ISO standards (e.g. IEC 62368-1 for data processing equipment). Furthermore all configurations shall comply with the requirements for medical electrical systems (see clause 16 of the 3rd Ed. of IEC 60601-1, respectively).
	User connecting additional equipment to medical electrical equipment configurations of a medical system is responsible that the system complies with the requirements for medical electrical systems. Attention is drawn to the fact that local laws take priority over the above mentioned requirements. In case of any doubt, consult your local BD representative or the after-sales service department of the manufacturer.

Electromagnetic Compatibility and Interference	
	Medical Electrical Equipment requires additional precautions regarding EMC. Commissioning, installation and use should be in accordance with the EMC information provided within this *Directions For Use* and the *Technical Service Manual*.
	Therapeutic Radiation equipment: Do not use the Pump in the vicinity of any Therapeutic Radiation Equipment. Levels of radiation generated by the radiation therapy equipment such as Linear Accelerator, may severely affect functioning of the Pump. Consult manufacturer's recommendations for safe distance and other precautionary requirements. For further information, contact your local BD representative.
	Magnetic Resonance Imaging (MRI): The Pump contains ferromagnetic materials which are susceptible to interference with magnetic field generated by the MRI devices. Therefore, the Pump is not considered an MRI compatible Pump as such. If use of the Pump within an MRI environment is unavoidable, then it is highly recommends securing the Pump at a safe distance from the magnetic field outside the identified 'Controlled Access Area' in order to evade any magnetic interference (EMI). For further information, refer to the product *Technical Service Manual* (TSM). Alternatively, contact your local BD representative for further guidance.
	High-frequency surgical equipment, mobile phones, wireless devices, and defibrillators may cause interference on the Pump. Therefore, keep the Pump away from these devices when using the Pump.

	Accessories: Do not use any non-recommended accessory with the Pump. The Pump is tested and compliant with the relevant EMC claims only with the recommended accessories. Use of any accessory, transducer or cable other than those specified by BD may result in increased emissions or decreased Pump immunity.
	The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it 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 repositioning the Pump. This Pump emits a certain level of electromagnetic radiation, which is within the levels specified by EN/IEC 60601-2-24 and EN/IEC 60601-1-2.
	The Class B digital Device limits are designed to provide reasonable protection against harmful interference when the device is operated as intended. The device generates, uses and can radiate radio frequency energy. If it is not installed and used in accordance with the applicable Directions For Use, it might cause harmful interference to radio communications. Operation of this device in a residential area is likely to cause harmful interference, in which case the user is required to correct the interference at their own expense. There is, however, no guarantee that the interference will not occur in a particular installation.
	Portable RF Communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30cm to any part of the Pump including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
	In some circumstances the Pump may be affected by an electrostatic discharge through air at levels close to or above 15kV; or by radio frequency close to or above 10V/m. If the Pump is affected by this external interference the Pump will remain in a safe mode; the Pump will duly stop the infusion and alert the user by generating a combination of visual and audible alarms. Should any encountered alarm condition persist even after user intervention, it is recommended to replace that particular Pump and quarantine the Pump for the attention of appropriately trained personnel (Consult *Technical Service Manual* for further information).

Technical Data

Infusion Specifications

Maximum infusion rate is a configurable item. Contact the local BD representative to change the configuration.

Infusion and Prime Rate: 0.1ml/h to 2000ml/h

Minimum Increment of Infusion Rate:

Rate Range (ml/h)	Minimum Increments (ml/h)
0.1 to 99.99	0.01
100 to 999.9	0.1
1000 to 2000	1

Total Volume Display

0–9999.99ml (minimum increment: 0.01ml)

Bolus Specifications

Bolus Rate: 0.1-2000ml/h

Bolus VTBI: 0.1-50ml (minimum increment: 0.01ml)

Anti-Bolus

Anti-bolus function, post occlusion unintended bolus ≤ 0.2ml.

Keep Vein Open (KVO) Rate

0.1–30ml/h (minimum increment: 0.01ml/h)

Volume To Be Infused (VTBI)

0.1–9999ml (minimum increment: 0.01ml)

Occlusion Level

- Patient side occlusion: 50~1125 mmHg, 15 levels are available for selection.
- Fluid side occlusion: Fluid side occlusion alarm is supported.

Bubble Specifications

- Single Bubble
  - Air bubble alarm accuracy: the first level is 15^{+15}_{-10}µl, the other level is ±15µl or ±20% (whichever is greater).
  - 8 detection sensitivity levels: 15, 25, 50, 100, 200, 300, 500, and 800 µl.
- Total Bubbles
  - Bubble Level: 100µl/15min, 200µl/15min, 400µl/15min, 500µl/15min, 600µl/15min, 800µl/15min, and 1000µl/15min.

Infusion Accuracy

Infusion Accuracy is ±3%, achieved under the infusion rate ≥1ml/h.

Infusion Accuracy is ±10%, achieved under the infusion rate <1ml/h.

Display Screen

3-inch LCD with a resistive touch screen.

Resolution: 480x320 pixels.

Indicator

Power indicator: yellow or green.

Alarm/Operational indicator: yellow, green or red.

Time

00:00:01–99:59:59 (minimum increment: one second).

Infusion Mode

ml/h mode, Guardrails mode, Loading Dose Mode, Multistep Mode, and TPN Mode.

Classification

- Class I/ Internally powered equipment.
- Defibrillation-proof type CF applied part.
- Continuous Mode Operation.
- Transportable.

Date of Manufacture

See product label, the date after  symbol.

Near End of Infusion (NEOI) Alarm

The Near End of Infusion Alarm is only available when a Volume to Be Infused (VTBI) has been programmed on the Pump. **The Near End of Infusion Alarm** setting can be configured in the Medication Safeware, Data Set Profile: Range 1 to 240 minutes.

Special Functions

- Power supply mode switching: Pump automatically switches to battery mode in case of an AC power failure and automatically switches to AC power supply mode when the AC power recovers from the failure.
- Authority management: different authorities are granted to different users. For details, refer to 'Technical Service Mannual'.

Power Supply

- AC power supply: 100-240V AC, 50/60Hz.
- Input power: 45VA.

Battery Specifications

- Built-in lithium battery: 10.8V, 3000mAh; model: 18650-3S1P.
- Charge time of the lithium battery: no longer than four hours (the Pump is powered off during the charge).
- Charge mode of the lithium battery: The battery can be charged when AC input is available.
- When no AC power supply is available, the power supply mode of the Pump automatically switches to built-in battery mode.

Continuous operation duration of the lithium battery .

Infusion Rate	Continuous operation time
25ml/h	≥ 10 hours
125ml/h	≥ 8 hours
2000ml/h	≥ 5 hours

Note: Test conditions: A fully-charged brand new battery is used at room temperature, screen brightness is adjusted to the lowest level.

Dimensions

214 mm(W) x 75mm(H) x 142mm(D).

Weight

Approximately 1.4kg (including the battery).

Protection Against Fluid Ingress

IP33 – Protected against solid foreign objects of 2.5 mm and greater, Protected against spraying water.

Alarm Conditions

AC Power Fail	Air Bubble In Line	Attention
Battery Empty	Battery Low	Downstream Occlusion
Drop Sensor Disconnect	Hand Over Failed	KVO End
Step n Completed	Near End Of Infusion	No Battery
No Flow	Pressure Rise Alarm	Standby End
Titration Not Confirmed	Too Few Drops	Too Many Drops
Upstream Occlusion	VTBI Done (Continue)	VTBI Done (KVO)
VTBI Done (STOP)		

Environmental Specifications

Condition	**Acceptable Range**
Operating Temperature	5°C to 40°C
Operating Relative Humidity	15%RH to 95% RH, non-condensing
Operating Atmospheric Pressure	57kPa to 106kPa
Operating Altitude	Max:3000m
Transport and Storage Temperature	–20°C to +55°C
Transport and Storage Relative Humidity	10%RH to 95%RH, non-condensing
Transport and Storage Atmospheric Pressure	22kPa to 107.4kPa

Service Life

Ten years with routine maintenance and servicing every two years, as per Technical Service Manual.

Electrical/Mechanical Safety

IEC 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
IEC 60601-2-24 Medical electrical equipment – Part 2-24: Particular requirements for the basic safety and essential erformance of infusion pumps and controllers.

IEC60601-1-8 Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance -Collateral standard: General requirements ,tests and guidance for alarm systems in medical electrical equipment and medical electrical systems.

IEC 60601-1-2 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance –Collateral Standard : Electromagnetic disturbances –Requirements and tests.

Ports

- Drop Sensor port: Used to connect to the drop sensor.
- USB3.0 port: Used to connect to the nurse call button.
- USB2.0 port: Used to connect to infusion workstation for communication through the RS-232 protocol.
- RJ-45 network port: 10/100 Mbps self-adaptive Ethernet port.