



USER MANUAL

SapphirePlus INFUSION PUMP

For use with SapphirePlus Infusion Pump Software 14



SapphirePlus

Important Notice

The Sapphire Infusion Pump User Manual is delivered subject to the conditions and restrictions listed in this section. Clinicians, qualified hospital staff, and home users should read the entire User Manual prior to operating the Sapphire pump in order to fully understand the functionality and operating procedures of the pump and its accessories.

- Healthcare professionals should not disclose to the patient the pump's security codes, Lock levels, or any other information that may allow the patient access to all programming and operating functions.
- Improper programming may cause injury to the patient.
- Home users of the Sapphire pump should be instructed by a certified home healthcare provider or clinician on the proper use of this pump.

Prescription Notice

Federal United States law restricts this device for sale by or on the order of a physician only {21 CFR 801.109(b) (1)}.

The Sapphire pump is for use at the direction of, or under the supervision of, licensed physicians and/or licensed healthcare professionals who are trained in the use of the pump and in the administration of blood, medication and parenteral nutrition. The instructions for use presented in this manual should in no way supersede established medical protocol concerning patient care.

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The design, pumping mechanism and other features of the Sapphire pump are protected under one or more US and Foreign Patents.

Disclaimer

The information in this manual has been carefully examined and is believed to be reliable. No responsibility is assumed for any inadvertent inaccuracies. Q Core Medical Ltd. reserves the right to make changes to any of its products in order to improve reliability, design and performance. The instructions presented in this manual should in no way supersede established medical protocol concerning patient care. The text and drawings herein are for the purposes of illustration and reference only; the specifications on which they are based are subject to change without notice.

Warning

Use only Q Core Medical Ltd. supplied administration sets and accessories with the Sapphire pump. Use of administration sets other than Q Core Medical Ltd. supplied sets may impair the operation of the pump and the accuracy and flow rate of the infusion, and may generate hazardous fluid pressures which may activate occlusion alarms at unpredictable pressures.

Q Core Medical Ltd. warranty on this device will be null and void and Q Core Medical Ltd. will assume no responsibility for incidents which may occur if the product is not used in accordance with product labeling. Refer to [Warnings and Safety Precautions](#) on page 24 for a complete list of warnings and cautions.

Technical Assistance

For technical questions, troubleshooting assistance and reporting of unexpected events, please contact your local agent/distributor, and refer to page 221. You may also contact Q Core Medical Ltd. support via email to the following address:

support@Qcore.com

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Contents

1. INTRODUCTION10

Product Overview and Indications	10
Dedicated Delivery Mode Configurations	11
Features	12
Terms and Abbreviations.....	14
Document Conventions	16
Safety and Compliance Information.....	16
Symbols and Labeling	17
Compliance and Classification	21
Wireless Communication	22
FCC Information.....	22
Biocompatibility	23
Sterilization	23
Degree of Protection Against Ingress of Water and Dust	23
Warnings and Safety Precautions.....	24
General Warnings and Precautions	24
Proper Use of the Pump	29

2. COMPONENTS, ACCESSORIES, AND ADMINISTRATION SETS.....34

Unpacking the Pump.....	34
Hardware and Software Components	35
Touch Screen	36
Using Pump Accessories	38
Mini Cradle	38
Power Supply.....	40
Multi-Pump Mounting System	42
Administration Sets.....	47

3. FUNDAMENTAL CONCEPTS AND OPERATIONS50

Working with the Main Display	50
Using the Keypad.....	50
Overview of Toolbar Function Keys.....	52
Overview of Icons.....	53
Selecting Delivery Mode.....	56
Enabling Special Features.....	58
Setting KVO rate	61

4. GETTING STARTED.....62

Typical Workflow	62
Turning the Pump On.....	64
Turning the Pump Off.....	65
Connecting the Infusion Container to the Administration Set.....	65
Opening the Safety Door.....	66
Inserting the Administration Cassette.....	68
Removing the Administration Cassette	70
Automatic Priming Using the Pump.....	71
Priming Manually.....	73

5. USING THE DELIVERY MODES76

Continuous Mode	76
Infusion Parameters: Continuous Mode	79
Starting a Continuous Infusion	79
Continuous Mode: Mid-infusion Actions.....	91
Multi-step Mode.....	105
Infusion Parameters: Multi-step Mode.....	106
Starting a Multi-step Infusion.....	106
Multi-step Mode: Mid-infusion Actions	112

6. BASIC INFUSION OPERATIONS..... 114

Starting New Infusions: Shortcuts.....	114
Repeating Last Infusion.....	114
Using a PreSet Program	115
Resuming Infusions After Pump Shutdown	117
Mid- and Post Infusion Actions.....	118
Pausing Infusions	118
Infusion Standby	119
Aborting Infusions	120
Locking the Screen	122
Activating Patient Lockout.....	122
Ending an Infusion	123
Restarting the Infusion during the Post Infusion State	124

7. OPTIONS MENU: CONFIGURING, VIEWING AND TESTING 126

Main Options: Overview	126
Setting Delivery Mode.....	127
Managing Configuration Settings.....	128
Managing Alarm Settings	128
Configuring Audio Settings.....	131
Configuring General Settings.....	132
Defining Regional Parameters.....	135
Testing System Function	137
View Menu.....	138

8. USING ADVANCED FEATURES 144

Managing Authorization Levels	144
Setting Authorization Lock Levels	146
Password Re-entry	147
Creating and Editing PreSet Programs	148
Using the Set Delay Feature	151

Using the New Patient Feature	155
Viewing Accumulated VI.....	156
Clearing Accumulated VI.....	157
Updating to a New Pump Software Version.....	158

9. DRUG LIBRARY.....160

Overview	160
Clinical Care Area (CCA)	161
Changing a CCA	161
Programming a New Infusion with the Drug Library	165
Drug Name	165
Drugs List.....	165
Drug Profiles.....	166
Soft Limit	166
Update a New Drug Library Version	168

10. ALARMS AND TROUBLESHOOTING170

Alarms Overview	170
Level 1 Alarms.....	171
Level 2 Alarms.....	172
Level 3 Alarms.....	173
Messages	175
Troubleshooting	177

11. MAINTENANCE AND STORAGE180

Cleaning and Disinfecting the Pump	180
Cleaning and Disinfection Procedure	182
Reprocessing the pump when used by a single patient multiple times	184
Preventive Maintenance.....	185
Routine Inspection and Maintenance Tasks	185
Alarm Testing.....	186

Certification.....	186
Battery Care Information	187
Battery Classification	187
Battery Safety Information	188
Charging the Battery	190
Battery Maintenance	191
Transport and Storage	191

12. TECHNICAL SPECIFICATIONS..... 192

Pump Accuracy	192
Start-up and Trumpet Graphs.....	194
Pump Specifications	198
Wireless Upgrade Module.....	199
Average Bolus Volume After Occlusion.....	201
Environmental Specifications.....	202
Operating Conditions	202
Environmental Conditions for Transport and Storage.....	202
Electromagnetic Compatibility Statement.....	204
Electromagnetic Emission	204
Electromagnetic Immunity.....	205

13. LIMITED WARRANTY 210

APPENDIX A. SAPPHIREPLUS CONFIGURATION SETTINGS ... 214

User Options – Alarm and Audio Settings.....	214
User Options – General Pump Settings.....	215
User Options – Hard Limits and KVO Settings	218
User Options – Air Settings	219

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Chapter 1: Introduction

The following sections describe the functions and features of the Sapphire pump, and provide a summary of safety and regulatory information:

Product Overview and Indications	10
Terms and Abbreviations	14
Document Conventions	16
Safety and Compliance Information	16
Warnings and Safety Precautions	24

Product Overview and Indications

The Q Core Sapphire infusion pump is intended for controlled delivery through intravascular, subcutaneous, intra-arterial and epidural routes. The pump is designed to deliver saline, Total Parenteral Nutrition (TPN), lipids, IV medication, epidural medication, blood and blood products.

The Sapphire pump includes the following infusion modes for all intended uses: Continuous, Intermittent, TPN, PCA, Multi-step, and Epidural.

The pump is intended to be used by both licensed health care professionals in a clinical environment, and home users in an ambulatory environment and in pre-hospital medical ground transportation.

The dedicated Q Core administration sets for the Sapphire pump are intended for single-patient use and single-use only.

This user manual supports the use of Sapphire software version r14. Verify that the software version that appears on the Sapphire turn-on screen is r14. The version number can be viewed from **View system** as well (for more information, refer to [View Menu](#) on page 138).



This software version is intended for use only in the US.

Dedicated Delivery Mode Configurations

To promote safety and convenience of use in different environments, the Sapphire pump can be preconfigured to support only certain delivery modes. The different types of configurations available on various pump types, are described in the following table.

Pump Type	Delivery Modes Supported
PCA	<ul style="list-style-type: none">• PCA• Continuous
Epidural	<ul style="list-style-type: none">• PCEA• Intermittent Epidural
TPN	<ul style="list-style-type: none">• TPN• Continuous
Multi-therapy	1 or more of the following: <ul style="list-style-type: none">• Continuous• Intermittent• TPN• PCA• Multi-step• Epidural
SapphirePlus	<ul style="list-style-type: none">• Continuous• Multi-step
SapphireH100	1 or more of the following: <ul style="list-style-type: none">• Continuous• Intermittent• TPN• Multi-step

Each delivery mode is assigned a unique color that appears on the Indicators Bar, helping users to easily differentiate between the different modes ([Figure 3.1](#) on page 56).

Features

The features of the SapphirePlus pump are designed to simplify treatment and ensure patient safety.

Treatment-Related Features

- **Single platform device:** The delivery mode of the pump can be changed, according to the required type of infusion.
- **Priming alternatives:** Both manual priming (by gravity) and automatic priming (using the pump) are available.
- **Quick infusion titration (in most delivery modes):** Modification options allow updating of infusion parameters without stopping the infusion.
- **Incomplete action notification:** The pump – which has been left untouched for a defined time – notifies the user if an action was initiated but not confirmed.
- **Resume Infusion After Pump Shut Down:** Allows resuming an infusion after the pump has been shut down from a running or paused infusion.
- **PreSet Programs:** Allows saving the infusion parameters of commonly used protocols, and allows a quick-start infusion using these parameters.
- **Piggyback (Continuous delivery mode only):** Provides the ability to add a Secondary line to a running continuous infusion, without re-entering infusion parameters for the Primary line.
- **Flexible programming features:**
 - Infusions can be programmed in a variety of dose rate units, including the following, per different time units: mL, mg, mcg, units, mUnits, Million Units, gram, nanogram, mmol, mEq.
 - Infusion rate can be programmed as a weight based infusion (patient weight can range from 0.1- 500 Kg).
- **Wireless Networked Communication:** Enables communication between the pump and the facility network, using the facility Wi-Fi.

Safety-Related Features

- **Lock Screen:** Avoids inadvertently activating screen functions by locking the screen when the infusion is running.
- **Patient Lockout:** Prevents unauthorized tampering with the pump by locking pump functions. Password entry is required to reactivate the screen. This option can be configured to automatically activate once an infusion begins.
- **Authorization lock level:** Allows access to only those pump functions for which the user has authorization. Authorization levels (Low, Medium, High, Technician) are password-controlled.
- **Range parameter safety check:** Prevents entering infusion parameters that are outside of a precalculated safety range. The permitted ranges vary according to the parameters already entered by the user, or by the limits defined in the Drug Library, if one is installed on the pump.
- **Easy alarm troubleshooting:** Alarm screens display specific instructions about how to manage the alarm or resolve the problem.
- **Drug Library:** Enables safer practice according to clinical care area. Programming is done with drug specific name, profile, hard limits and recommended (soft) limits.

Terms and Abbreviations

The following table defines common terms and abbreviations used in this manual.

Term/Abbreviation	Meaning
AFFV	Anti-Free-Flow-Valve
AC/DC	Alternating Current / Direct Current
Accum.	Accumulated
CCA	Clinical Care Area
DFU	Directions for Use
ECG	Electrocardiogram
EMC	Electromagnetic compatibility
EMI	Electromagnetic interference
FCC	Federal Communications Commission
h	Hour
HIS	Hospital Information System
Kg	Kilograms
KVO	Keep Vein Open
LE-LAN	License-Exempt Local Area Network
MAC	Media Access Control
mcg	Micrograms
mEq	Milliequivalents
min	Minutes
mg	Milligrams
mL	Milliliters
mmol	Millimoles
Mounting System	Sapphire Multi-Pump Mounting System
MRI	Magnetic Resonance Imaging

Term/Abbreviation	Meaning
mUnits	Milliunits
M Units	Million Units
nanog	Nanograms
Occ.	Occlusion
PAV	Pressure Activated Valve
PCA	Patient Controlled Analgesia
PCEA	Patient Controlled Epidural Analgesia
PDA	Personal Digital Assistant
PHY	Physical Layer
Prim.	Primary
RF	Radio Frequency
Sec.	Secondary
TPN	Total Parenteral Nutrition
VI	Volume Infused
VTBI	Volume To Be Infused
Q Core	Q Core Medical Ltd.
Sapphire pump	Q Core Sapphire infusion pump family
SapphirePlus pump	Q Core SapphirePlus infusion pump
SapphireH100 pump	Q Core SapphireH100 infusion pump
WLAN	Wireless Local Area Network

Document Conventions

The following messages in this manual prompt readers to pay special attention to specific points:



Warnings indicate precautions and instructions which, if not followed, may result in personal injury.



Cautions indicate instructions which, if not followed, may result in damage to the equipment or to the quality of treatment.



Notes provide additional information to help obtain optimal equipment performance.

The parameters ranges described in this manual reflect their factory default settings. These ranges may be configured by an authorized technician.




Safety and Compliance Information








The following section presents important labeling, safety and compliance information:




- [Symbols and Labeling](#) on page 17
- [Compliance and Classification](#) on page 21
- [Biocompatibility](#) on page 23
- [Sterilization](#) on page 23
- [Degree of Protection Against Ingress of Water and Dust](#) on page 23



Symbols and Labeling

The following table describes the labels and symbols that appear on the Sapphire pumps and their components, and identifies their locations on the equipment.

Symbol	Description	Location
SN	Serial number.	Back of the pump casing and on the back of the mini cradle.
REF	Catalog Number.	Back of the pump casing, on the back of the mini cradle, EBP*, PCA Lockboxes 100*, 250* and 500mL*, and Mounting System.
LOT	Batch code.	Inside casing of the mini cradle, EBP, PCA Lockboxes 100*, 250* and 500mL*, and Mounting System.
	Caution: Consult accompanying documents for safety instructions (service to be performed by qualified technician; consult Service Manual before removing cover).	Back of the pump casing cover, EBP*, on the back of the mini cradle, and Mounting System.
	Storage temperature range.	Shipping package.
	Storage humidity range.	Shipping package.

Symbol	Description	Location
	Storage atmospheric pressure range.	Shipping package.
	Consult instructions for use.	EBP, on the back of the mini cradle, and PCA Lockbox 500mL*.
	Follow instructions for use.	Back of the pump casing, PCA Lockbox 250mL*, and Mounting System.
	The C and US indicators adjacent to the CSA mark signify that the product has been evaluated to the applicable CSA and UL standards, for use in Canada and the United States.	Back of the pump casing and Mounting System.
	Date of manufacture (year).	Back of the pump casing.
	Name of manufacturer.	Back of the pump casing, on the back of the mini cradle, EBP*, PCA Lockboxes 100*, 250* and 500mL*, and Mounting System.
	Identify defibrillation proof and degree of protection against electric shock. Equipment Type BF Applied Part.	Back of the pump casing.

Symbol	Description	Location
	Input: 100-240 V; 50-60 Hz; Max. 120 VA Output: 10V DC; Max. 4.7 A.	Mounting System.
IP24	Dust and splash proof.	Back of the pump casing.
IPX1	Waterproof rating.	Mounting System.
IPX2	Waterproof rating.	EBP*.
Rx Only	US federal law restricts this device to prescription only.	Back of the pump casing, on the back of the mini cradle, PCA Lockboxes 100*, 250*, and 500mL*.
 	Waste Electrical and Electronic Equipment (WEEE) Disposal. This symbol indicates that used batteries and electronic equipment must not be disposed of as unsorted municipal waste, and must be collected separately. Contact an authorized representative for information concerning the decommissioning of your equipment.	Back of the pump casing cover, EBP, and on the back of the mini cradle.
ALARM	Alarm — LED, when lit, indicates an alarm situation in the operation of the pump. Refer to Hardware and Software Components on page 35.	Front casing of the pump, below the red LED.
CHARGE	Charge — LED, when lit, indicates that the battery is charging. Refer to Hardware and Software Components on page 35.	Front casing of the pump, below the yellow LED.
RUN	Run — LED, when lit, indicates that the pump is infusing. Refer to Hardware and Software Components on page 35.	Front casing of the pump, below the green LED.
STOP	Stop — Allows you to temporarily stop the infusion.	Front casing of the pump, below the touch screen.

Symbol	Description	Location
On/Off	On/Off — Turns pump On and Off.	Front casing of the pump, below the touch screen.
	Complies with limits for Class B digital device established by FCC Rules, Part 15.	Back of the pump casing.
	Wi-Fi enabled. Complies with IEEE 802.11 a/b/g/n.	Back of the pump casing.

* PCA Lockboxes 100, 250 and 500mL, and External battery pack are available for use with Sapphire Multi-Therapy, PCA and Epidural pumps.

Compliance and Classification

This manual has been written in conjunction with the requirements in the International Standard, IEC 60601-2-24 for Medical Electrical Equipment - Part 2-24: Particular Requirements for Safety of Infusion Pumps and Controllers. Data presented in the Technical Specification section reflect specific test conditions defined in this standard. Other external factors, such as varying back pressure, temperature, head height, set usage, fluid restrictions, solution viscosity, or combinations of these factors may result in deviations from the performance data presented.

- IEC 60601-1, UL 60601-1 and CAN/CSA C22.2 601.1-M90 medical electrical equipment, which classifies the SapphirePlus pump as:
 - Class II
 - Type BF
 - Continuous operation
 - IP24 dust and splash proof
 - Not suitable for use in the presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide
- IEC 60601-1-2: Electromagnetic compatibility.
- IEC 60601-2-24: Infusion pumps and controllers, which classifies the SapphirePlus pump as a Type 4 pump (continuous infusion flow, combined with bolus delivery).
- IEC 60601-1-11: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.
- IEC 60601-1-8: Requirements for alarm systems in medical electrical equipment and medical electrical systems.
- Defibrillator compliance statement: Equipment Type BF Applied Part.
- IEEE 802.11 a/b/g/n: Requirements for wireless local area network (WLAN) computer communication – synonymous with Wi-Fi.
- FCC: The Federal Communications Commission (FCC) regulates interstate and international communications by radio, television, wire, satellite and cable. The SapphirePlus pump complies with Part 15B, 15C, 15E of the FCC Rules.

Wireless Communication

The SapphirePlus wireless device contains a Connectivity Module that allows for implementing Wireless Local Area Network (WLAN) networking capabilities. This allows the application software to download drug libraries and software updates to the infusion pump over a wireless connection.

The pump Wi-Fi abilities have been tested and approved according to United States rules and regulations. Using the pump Wi-Fi abilities outside of the United States where allocations and technical parameters may be different, may result in the violation of government regulations and possibly affect the functionality of the Wi-Fi module.

FCC Information

US FCC (FEDERAL COMMUNICATIONS COMMISSION) STATEMENT



The Federal Communications Commission (FCC) regulates interstate and international communications by radio, television, wire, satellite and cable. The SapphirePlus wireless device complies with Part 15B, 15C, 15E of the FCC Rules. Operation is subject to the following two conditions:

- This device may not cause interference.
- Pump operation must not be affected by any transmitted interference from other devices.

FCC INTERFERENCE STATEMENT

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15B, 15C, 15E of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy. If not installed and used in accordance with the instructions, it may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment Off and On, the user is encouraged to try and correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the distance between the equipment and the receiver.

- Connect the equipment to an outlet on a circuit other than the one to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

RADIO FREQUENCY EXPOSURE STATEMENT

- The Wireless LAN radio device in the connectivity module peripheral board of this infusion device has been evaluated and found compliant to the requirements of the following Radio Frequency exposure standards:
 - Federal Communications Commission, OET Bulletin 65 (Edition 97-01), Supplement C (Edition 01-01), Evaluating Compliance with FCC Guidelines for Human Exposure to Radio frequency Electromagnetic Fields, July 2001.
 - EN 50360 and EN62311
- The radiated output power of this wireless device is far below the FCC radio frequency exposure limits. The SapphirePlus wireless device has been evaluated at 0.2 inches away from a human body, and found to be compliant with FCC RF exposure limits.

Biocompatibility

All materials in components of the administration sets that are in the fluid pathway have been tested for biocompatibility, and are in compliance with applicable international standards ISO 10993-1 for biocompatibility.

Sterilization

Administration sets that are manufactured by Q Core for the SapphirePlus pump, are sterilized with ethylene oxide (EO), according to the sterilization requirements of ISO 11135-1.

Degree of Protection Against Ingress of Water and Dust

The SapphirePlus pump meets the IP24 splash/dust standard according to IEC 60601-1-11. Protects from water which is sprayed at 10 L/min at a pressure of 80-100 kN/m² for 5 minutes at all angles, and protects from touch by objects greater than 12 millimeters such as fingers.

Warnings and Safety Precautions

The following sections contain important safety information.

All warnings and safety precautions should be read carefully before operating the SapphirePlus pump:

- [General Warnings and Precautions](#) on page 24
- [Proper Use of the Pump](#) on page 29

Safety information specific to particular pump functions appears in the relevant sections of this manual.

General Warnings and Precautions

To ensure safety and proper operation, read the User Manual and any instructions accompanying disposables or accessories before operating this device. In addition, adhere to the following safety guidelines:



Avoid placing the administration set or power cord on the floor, or any other location where it can accidentally be damaged or provide a risk of strangulation, particularly due to excessive length.

- To avoid damage to the pump and its accessories, keep the equipment away from unattended children and pets.
- Do not clean, disinfect or sterilize any part of the pump by autoclaving, or with ethylene oxide gas. Doing so may damage the pump and void the warranty. Only external parts of the pump should be disinfected.



If the pump is dropped or appears to be damaged, it should be taken out of service and inspected by Q Core Medical Ltd. trained, qualified personnel only.

- All service procedures, including certification, calibration, part replacement and modification of equipment, should be carried out only by a qualified service technician. Detailed instructions are available in the service manual.
- Do not operate the pump with the safety door open.

Waste Disposal

Take care to dispose of the packaging, the administration sets, the battery, and any other electronic components in accordance with applicable environmental laws (such as the WEEE Directive for Waste Electrical and Electronic Equipment). Contact your local authority to determine the proper method of disposal.



Waste Disposal Safety Precautions

- Keep used plastic infusion containers, packaging and tubing out of the reach of children.
- Administration sets should be disposed of in a proper manner, considering the nature of residual fluid that may be contained within, in accordance with hospital disposal practices.
- Do not dispose of the battery in or near fire.

Explosion Hazard

The equipment is not suitable for use in the presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide.

Electric Shock Hazards

To promote safety, always adhere to the warnings listed below.



Electrical Safety Precautions

- Access to any internal part of the SapphirePlus pump and the performance of any service procedures should be carried out only by a qualified service technician, fully trained in the operation of the infusion pump.
- Disconnect the power supply before servicing.
- Disconnect the battery prior to opening the pump casing. Voltage present on internal components may cause severe shock or death on contact.
- Connect AC power to the pump only via a Q Core supplied power adapter.

- Do not touch the pump to cradle (P2C) connection in the back on the pump.

Electromagnetic Compatibility

The SapphirePlus pump is designed to conform with electromagnetic compatibility (EMC) standard IEC 60601-1-2 and to operate accurately in conjunction with other medical equipment which also meets the requirements of this standard. To avoid electromagnetic interference that may affect the operation of the pump, do not use the pump near sources of strong electric and magnetic interference (EMI), such as large electric motors.

- Manage the electromagnetic environment to permit the device to perform as intended without disturbing other equipment.
- Separate the device from all other electronic equipment. If the device must be used near other electrical equipment, monitor the equipment to ensure there is no electromagnetic interference.
- Devices should not be used adjacent to or stacked with other equipment. If the device must be used adjacent to or stacked with other equipment, monitor the device to verify normal operation.
- If you suspect external RF sources or other equipment are influencing device operation, contact the biomedical engineering department for additional guidelines concerning electromagnetic immunity.
- Contact the biomedical engineering department for additional information in the service manual concerning operating devices near RF sources.

The EMC limits for the Medical Device Directive 93/42/EEC (EN301489-1/-17 IEC/EN 60601-1-2:2007) are designed to provide reasonable protection against harmful interference in a typical medical installation. The equipment generates uses and can radiate radio frequency energy, and if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference with other devices, which can be determined by turning the equipment Off and On, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device

- Increase the distance separating between the equipment parts
- Connect the equipment to an outlet on a circuit different from that to which the other device(s) is connected
- Consult the manufacturer or field service technician for help

Portable and mobile RF communications equipment, such as cellular telephones, 2-way radios, Bluetooth™ devices, microwave ovens in close proximity to this device may affect wireless communications with the Infusion pump and/or the operation of the Infusion pump. Special precautions need to be exercised regarding EMC. These include:

- Maintaining a minimum separation distance of 2 ½ ft (¾ m) between the Infusion pump system and portable/mobile RF communications equipment



Electromagnetic Safety Precautions

- Do not expose the pump to therapeutic levels of ionizing radiation, as permanent damage to the pump electronic circuitry may occur. It is preferable to remove the pump from the patient during therapeutic radiation sessions.
- Do not use the pump in the vicinity of magnetic resonance imaging (MRI) equipment, as magnetic fields may adversely affect the operation of the pump. Remove the pump from the patient during MRI procedures, and keep it at a safe distance from magnetic energy.

Wireless Compatibility

To promote safety, always adhere to the precautions listed below.



Wireless Device Precautions

- The wireless 802.11 a/b/g/n device usage in the 5150-5250 MHz band is limited to indoor use in order to reduce potential for harmful interference with co-channel mobile satellite systems.

- In the 5250-5350 MHz and 5650-5850 MHz frequency bands, high power radars are allocated as primary users and these radars could cause interference and/or damage to LE-LAN devices.
- Operation is subject to the following two conditions: (1) the wireless device will not cause interference, and (2) Pump operation must not be affected by any transmitted interference from other devices.

Data Transfer and Integrity

The SapphirePlus wireless device is capable of operating at a full bandwidth of 802.11 a/b/g/n.

For network planning purposes, each pump transfers no more than 10 KB/min (kilobytes per minute).

Data integrity is achieved in two levels:

- By Wi-Fi TCP/IP protocol
- By the software of the pump

Wireless Quality of Service

Quality of Service is primarily the responsibility of the network and the networking equipment. It may be achieved by improving several network aspects:

- Use networking devices that support QoS infrastructure
- Use a dual-band access point so that if one of the bands is too crowded, the second band can be used. This is supported by the SapphirePlus wireless module.
- Use roaming to ensure that the wireless device will be assigned to the access point where the radio signal received from the pump is the strongest one.



The level of cyber security is the responsibility of the network and based on the network configuration.

Proper Use of the Pump

Although the SapphirePlus pump has been designed and manufactured to exacting specifications, it is not intended to replace trained personnel in the monitoring of infusions.



Home users must be trained by their medical provider before using the SapphirePlus pump.



Clinicians are advised to verify the proper route of delivery, and the patency of the infusion site.

When using the pump, periodic patient monitoring must be performed to ensure that the infusion is proceeding as expected. The pump is capable of developing positive fluid pressures to overcome widely varying resistances to flow, such as resistance imposed by small-gauge catheters, ports, filters, or intra-arterial infusions. Although the pump is designed to stop fluid flow when an alarm occurs, it is neither designed nor intended to detect infiltrations or extravasations, and such conditions will not trigger an alarm.



When using the pump, use only Q Core approved accessory equipment.



If auditory and/or visual signals do not perform according to settings, or if the hard keys do not perform as expected, do not use the pump, and contact an authorized technician.



Environmental Safety Precautions

- The pump has not been evaluated for use within magnetic resonance imaging (MRI) environments, or with other medical equipment that emits radiation for diagnostic or therapeutic purposes.
- The SapphirePlus pump has not been evaluated for compatibility with Extracorporeal Membrane Oxygenation (ECMO) systems.

- Use only Q Core supplied accessories and cables. The use of accessories and cables other than those specified in this manual, with the exception of cables sold by Q Core Medical Ltd. as replacement parts for internal components, may result in increased emissions or decreased immunity of the pump.

Administration Sets

Before using administration sets, always read and follow the instructions in the User Manual, and the instructions accompanying the administration set and source container. Carefully follow any label copy instructions for loading, removing, and reloading the set, as well as the recommended set change interval.



Use only valid Q Core approved administration sets with the SapphirePlus pump. Severe injury or death may result from using sets other than those indicated in Q Core's approved list of products. For more information refer to [Administration Sets](#) on page 47.

For infection control purposes, consider the set change interval recommended by the local Centers for Disease Control and Prevention (CDC), your facility guidelines, and the instructions provided with the administration set.



Administration Sets: Safety Precautions

- Do not use a damaged administration set or damaged set components or packaging. Always refer to the instructions for use that are included.
- Q Core administration sets are for **single patient use only**, and should not be sterilized or cleaned for re-use.
- **Do not connect the administration set to the patient while priming.**
- Do not use force when connecting the administration set to the patient.
- Always use the clamps on the administration set to occlude the administration set prior to removing the Q Core administration cassette from the pump.

- Do not apply pressure or pressurized air to any outlet or tubing connected to the pump. Pressure may destroy sensitive elements.
- Do not pull or stretch the tubing in any section of the administration set when the pump is in use, nor apply pressure to the infusion container.



The minimum pull force applied on the administration set which is capable of disengaging the administration set from the pump is 2.855 Kg.

- The administration set and container should be replaced as needed to avoid fluid contamination problems.
- The administration set must be replaced according to the hospital policy of infection control and treatment protocol. Q Core sets allow accurate delivery up to 96 hours. If you program rate, dose or bolus combinations which exceed a 96-hour schedule, make sure that you replace the administration set on time.

Basic Infusion Safety Information

To obtain maximum accuracy of the pump when used in a hospital or clinical environment, verify that the infusion container is positioned at a height of 50 cm above the pump. There is no restriction on the location of the infusion container in relation to the patient's heart.

When clamping the administration set, ensure that the clamp is at least 20 cm (8 in) away from the pump, when possible.

Note that if the dose rate is beyond the pump resolution of 0.1mL/h increments, the pump will increase or decrease the rate by up to 0.05mL/h. This flow rate (mL/h) is presented on the running screen during infusion.

For example, if the dose rate entered is 20 mg/h, which is equivalent to 3.64ml/h, the pump will decrease the rate to 3.6 ml/h and display it on the running screen.

Alarm conditions automatically stop the infusion and require immediate attention before the infusion can be restarted.



Administering Infusions: General Safety Precautions

- **Occlusion Pressure Alarm Settings:**
 - High pressure settings may affect the time for occlusion detection. Make sure that the occlusion pressure is set according to the clinical use case.
 - When using sets with a Pressure Activated Valve (PAV), detection may be offset by 0.3 BAR (4.35 PSI or 225 mmHg). (This offset is called PAV cracking pressure.)
- **Volume To Be Infused:**
 - Do not enter a volume to be infused greater than the amount of fluid available in the container.
 - When post infusion is not 0 mL/h, note that the pump continues to infuse until stopped by the user, or until the container is empty. To avoid over-delivery, use containers that match the volume to be infused.
- **Secondary Infusions:** When using the Piggyback infusion feature, verify that:
 - The medication/solution in the Secondary infusion container is compatible with the medication/solution in the Primary infusion container.
 - The Secondary administration set is connected to the appropriate injection site on the primary administration set (above the administration cassette).
 - Interruption of the Primary infusion is clinically appropriate for the duration of the Piggyback infusion.
 - The Secondary source container is positioned at least 8 inches (20 cm) higher than the Primary source fluid level.
 - The drip chamber on the set should be used to verify that the correct line is delivering and the other line is idle.
 - The clamp of the Secondary set is closed when Piggyback infusions are not running.
- **Air Detection:** The Air in Line detector working range when delivering fatty acids is 2%-20% lipids. Delivering fatty acids with different lipids concentrations may trigger the Air in Line alarm.

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Chapter 2: Components, Accessories, and Administration Sets

The following sections present a high level overview of the SapphirePlus pump components and accessories:

Unpacking the Pump	34
Hardware and Software Components	35
Using Pump Accessories	38

Unpacking the Pump

When unpacking the Sapphire pump, inspect each item to ensure that it is undamaged. The following items should be included:

- SapphirePlus pump (with Li-Ion Battery enclosed)
- AC/DC power adaptor for pump
- User Manual
- Mini cradle, with key (to lock) and pin (to allow open/close without the key)
- Other optional items:
 - Demand bolus handle *
 - Splitter for mini cradle
 - Communication cable
 - PCA Lockbox 100mL *
 - PCA Lockbox 250mL *
 - PCA Lockbox 500mL *
 - Infusion Pouch 500 mL
 - Home Large Backpack (5 liter)
 - Travel Case
 - External Battery Pack *
 - Mounting System

* Available for use with Sapphire Multi-Therapy, PCA and Epidural pumps.

Hardware and Software Components

The pump includes both hardware (control unit) and software (touch screen) components. Hardware components are shown in the figure below. The parts of the control unit are listed and described in the table following the figure.

Figure 2.1. Hardware Components



Number	Component	Description/Notes
1	Safety door	Covers and protects the administration set and pumping mechanism.
2	Speaker	Delivers auditory alarm sounds.
3	Status LEDs	Colored indicators providing a summary of the pump current status: <ul style="list-style-type: none">• Red: An alarm is occurring.• Yellow (blinking): The battery is charging.• Yellow (steady on): The pump is connected to main power, and the battery is fully charged.• Green: The pump is running.
4	On/Off button	Enables the user to turn the pump On and Off.
5	Stop button	Enables the user to temporarily stop an infusion.

Number	Component	Description/Notes
6	Power socket	Enables you to charge the battery using the power adaptor, connect a communication cable or a bolus handle.
N/A	Battery compartment	Houses the battery. (Located on the back of the pump.)

Touch Screen

The touch screen is used to configure and operate the pump. The main areas of the screen are listed and described in the table following the figure.

Figure 2.2. Touch Screen Areas

SapphirePlus without Drug Library



SapphirePlus with Drug Library



Number	Component	Description/Notes
1	Indicators Bar	<p>Displays the following essential status information:</p> <ul style="list-style-type: none"> • CCA name (appears above Screen title, across all screens when Drug Library is loaded). • ICU Medical MedNet™ Connectivity icon (appears next to the Wi-Fi icon across all screens on Sapphire-Plus pumps. Displayed in blue when connected; displayed in gray when not connected). • Wi-Fi icon (appears next to the ICU Medical Med-Net™ Connectivity icon across all screens on Sap-phirePlus. Displayed in blue when connected; displayed in gray when not connected). • Soft Limit icon (appears above Battery status icon, when Drug Library is loaded and current infusion exceeds soft limit range). • Screen title (Start Up, Running, Paused, drug name, etc.). • Drug concentration (appears when applicable, under screen title). • Running icon (appears while an infusion is running). • Delivery mode (Continuous, Multi-step). • Battery status icon.
2	Main Display	Displays infusion parameters and other pump settings, and serves as a work area in which most programming and configuration takes place.
3	Toolbar	Contains function keys that enable you to perform common operations, such as confirming settings, pausing infusions, locking the screen, etc.

Using Pump Accessories

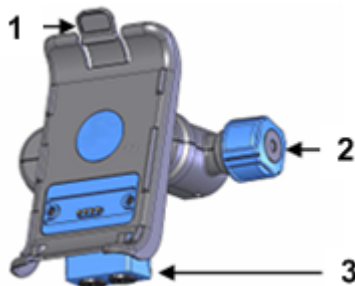
This section explains how to set up the following pump accessories:

Mini Cradle	38
Power Supply	40
Administration Sets	47

Mini Cradle

The small, easy to use bedside mini cradle offers flexible positioning of the pump at any angle or height. Components of the mini cradle are listed and described in the table following the figure.

Figure 2.3. Mini cradle



Number	Component Name	Description/Notes
1	Pump hook	Located on the pump holder. Press the hook to release the pump from the mini cradle.
2	Mini cradle knob	Located on the base of the mini cradle. Twist the knob to connect or release the mini cradle from an IV pole. To unlock the knob, use the supplied key or pin.
3	Connection splitter (optional)	Located on the base of the mini cradle. Used for the RS-232 communication cable (optional) and power-supply connections.

To operate the pump from an IV pole set, attach the pump to the mini cradle. This enables easy access to the screen without the risk of changing the settings through accidental contact. In the mini cradle, you can also charge the pump.



Make sure the cradle is securely attached to the IV pole before attaching the pump.

The following steps explain the workflow of attaching the mini cradle to the IV pole, attaching and releasing the pump, and releasing the mini cradle from the pole:

1. Attach the mini cradle to the IV pole by tightening the mini cradle knob on the right side (Figure 2.3, #2).

To unlock the knob, make sure that the supplied key or pin is placed inside it.

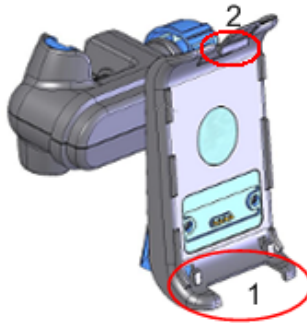


To attach several pumps to the IV pole, rotate the mini cradle to a horizontal position:

Pull the pump holder and the base of the mini cradle away from each other, and rotate to the desired position.

2. To attach the pump to the mini cradle, insert the pump onto the bottom hooks of the mini cradle (Figure 2.4, #1), and then click it into the top hook (Figure 2.4, #2). Ensure that the pump is seated on both hooks.
3. To release the pump, press the pump hook located on the top of the pump holder (Figure 2.4, #2).
4. To open and release the mini cradle, rotate the knob.

Figure 2.4. Mini cradle Hooks



Power Supply

The pump power supply is used to charge the battery. Specifications of the power supply include:

- **Input voltage:** 100-240 VAC
- **Output voltage:** 10 VDC



To prevent entanglement, always secure the cable cord properly.

> To charge the battery:

1. Plug the Q Core supplied power supply cord into the main power supply source.
2. With the white arrows facing up, plug the power cord into the SapphirePlus pump power socket or into the splitter connector.
3. On the front of the pump, verify that the Charge LED status indicator is On (blinking yellow light).

For more information regarding charging the battery, refer to [Charging the Battery](#) on page 190.

> To disconnect the power supply from the pump:

Gently press on both sides of the power supply connector, and pull it out of the SapphirePlus pump power socket.

Multi-Pump Mounting System

The Mounting System is designed to facilitate the use of multiple pumps while saving valuable bed-side space and providing power consolidation. The Mounting System is designed to accommodate three mini cradles, and charge three pumps via a single power outlet, all attached to an IV pole via a single clamp. The Mounting System can also accommodate the use of a single PCA Lockbox 250mL when mounted on the right-hand mini cradle among the three.



It is recommended to use mini cradles with a splitter in order to facilitate attachment and detachment of pumps.



- Verify that the mini cradles are securely attached to the Mounting System, and that the Mounting System is securely attached to the IV pole before attaching the pumps.
 - Do not transport the Mounting System while mounted on an IV pole. Detach and carry using the handle.
 - Verify that the IV pole is not moving, tilting or wavering when mounted with a Mounting System.
 - Before using the Mounting System, make sure that the Mounting System power supply and all cords are completely dry.
 - To avoid risk of electric shock the mounting system power supply must be connected to a power outlet with protective earth.
 - Always connect the AC input cord to the Mounting System power supply, before connecting it to a power outlet.
 - Make sure that the AC input cord is fully inserted into the Mounting System power supply socket and into the power outlet.
 - Always disconnect the AC input cord from the power outlet before disconnecting it from the Mounting System power supply.
-



- Use only Q Core approved AC input cord and power supply with the Mounting System.
 - To avoid entanglement of lines and cords, do not mount more than 4 Mounting Systems on a single IV pole.
-



It is recommended to use additional IV container hooks (not supplied by Q Core) when mounting more than two Mounting System on a single IV pole.

Setup Instructions

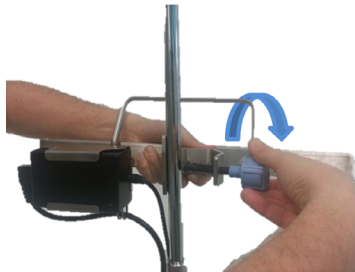


It is recommended to first attach the Mounting System to the IV pole before attaching the mini cradles to the Mounting System

> To attach the Mounting System to an IV Pole:

1. Loosen the clamp knob by rotating it counter-clockwise.
2. Firmly hold the Mounting System and place the clamp on an IV pole with the carry handle facing upwards.
3. Tighten the clamp knob by rotating it clockwise (Figure 2.5).

Figure 2.5. Mounting System on IV Pole



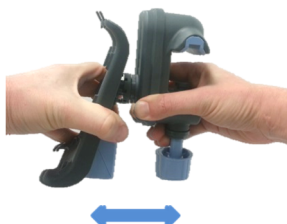


To prevent detaching from the IV pole, the Mounting System can be locked to the pole by removing the knob cap or knob key from the clamp knob.

> **To attach a mini cradle to the Mounting System:**

1. Rotate the mini cradle to a vertical position with the mini cradle knob pointing downward and the top hook pointing upward.

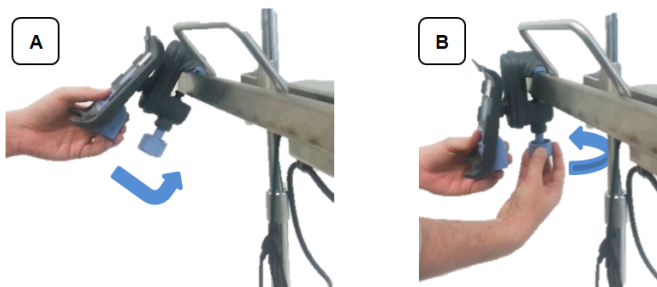
Figure 2.6. Attaching Mini Cradle to Mounting System



Place the mini cradles according to the markings on the Mounting System, between the designated lines ([Figure 2.8](#)).

2. Loosen the mini cradle knob to maximum extent by rotating it.
3. Tilt the mini cradle and place the open vice on the top of the Mounting System ([Figure 2.7](#) Item A). Align the cradle and tighten the knob by rotating it ([Figure 2.7](#) Item B).

Figure 2.7. Placing Mini Cradle on Mounting System



4. Plug a DC output connector to the mini cradle splitter.
5. Fasten the DC output cables to the clips located on the bottom of the Mounting System.
6. Plug the AC input cord to the power outlet. Verify that the Mounting System power supply LED is ON.

Figure 2.8. Fully Assembled Mounting System



> To transport the Mounting System, detach it from the IV pole:

1. Unplug the AC input cord from the power outlet.
2. Firmly hold the Mounting System and rotate the clamp knob counter-clockwise, until the Mounting System is loose.
3. To carry the Mounting System always use the dedicated carry handle.

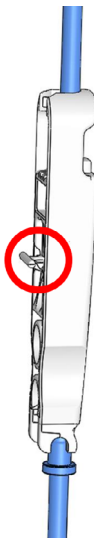


Always contact a certified technician in cases of Mounting System electrical and mechanical malfunctions.
When removing the Mounting System from the IV pole, avoid applying pressure on the power cable, connectors or cradles.

Administration Sets

The SapphirePlus pump should be used with a Q Core approved administration set, which includes the Q Core administration cassette. This cassette includes a normally closed valve (three-state Anti-Free-Flow Valve) that provides automatic anti-free-flow protection. Opening the valve allows manual priming as well as transition of infusion to gravity induced.

Figure 2.9. Sapphire Administration Cassette and AFFV



Only administration sets that include a roller clamp and do not include pressure activated valves (PAV) can be used by gravity. For more information, refer to the Directions for Use of each set.

For more information about priming the administration set and inserting it into the pump, refer to [Priming Manually](#) on page 73 and [Inserting the Administration Cassette](#) on page 68.

Q Core Approved Administration Sets

This section provides a list of administration sets approved by Q Core Medical Ltd. to be used with the SapphirePlus pump.



Use only administration sets listed here or in Q Core's approved list of products:
<http://www.qcore.com/>
Using anything other than Q Core approved administration sets with the pump may result in operation that is not within the constraints and parameters of the device.

Name of Set	Part Number
AP231-01 Infusion set with vented/non-vented drip chamber, back check valve, needleless y-site, 0.2µ filter and needleless y-site	12003-000-0027
AP232-01 Microbore with vented/non-vented drip chamber, back check valve, needleless y-site, 0.2µ filter and needleless y-site	12003-000-0028
AP233-01 Infusion set with vented/non-vented drip chamber, 1.2µ filter and needleless y-site	12000-000-0026
AP431-01 Infusion set with vented/non-vented drip chamber, back check valve and 2 needleless y-sites	12000-000-0027
AP432-01 Infusion set with vented/non-vented drip chamber, back check valve and 3 needleless y-sites	12000-000-0028
AP433-01 Infusion set with vented/non-vented drip chamber and needleless y-site	12000-000-0029
AP434-01 Infusion set with vented/non-vented drip chamber	12000-000-0030
SH348 Non PVC UV Resistant Infusion Set With Vented/ Non-Vented Spike, Drip Chamber Floating Ball With 4 Needleless Y-Site, 15µm Filter And Needleless Y-Site	12007-000-0014

Other products available from Q Core Medical Ltd. are listed in Q Core Official Product List, at <http://www.qcore.com/>

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Chapter 3: Fundamental Concepts and Operations

The following sections explain the structure and function of the Main Display and the toolbar, provide an overview of the delivery modes, and describe special features that can be enabled and disabled, according to user requirements:

Working with the Main Display	50
Selecting Delivery Mode	56
Enabling Special Features	58

Working with the Main Display

The Main Display is a touch screen that serves as a work area for programming infusion parameters, and choosing from lists of possible selections. While an infusion is running, selected infusion parameters and other relevant information (such as time left until completion of the infusion) appear on the Main Display.

The following sections describe how to use the keypads, and provide an overview of the main function keys and icons that appear on the Main Display.

Using the Keypad

Numeric keypad

The keypad is used for entering digits, to specify parameters for volumes, rates and times, and typing drugs names when searching the Drug Library. As you press the relevant digits, they are displayed in the frame at the top of the Main Display, replacing the name of the parameter. Pressing **Clr**, at the lower left corner of the keypad, clears all entered digits and lets you re-enter the value.



The acceptable range of a given parameter is displayed in the upper right corner of the Main Display. When you enter a value that is outside of a permitted range, the range values stay red, and the **OK** function key is disabled. The values of a range are dynamic, and change according to other parameters that have already been programmed.

When entering time, the pump allows you to enter minutes up to the value of **59**. Infusion time of over 59 minutes must be expressed in hours and minutes. For example, 90 minutes must be entered as **1:30** (h:min).

Alphanumeric keypad

In some instances, for example, defining a new PreSet program, or entering a drug name, the keypad displays letters and symbols in addition to numbers.

The Alphanumeric keypad displays uppercase letters with numbers, and lowercase letters with symbols. Uppercase letters and numbers are the default state. Switch the default keypad from uppercase and numbers to lowercase and symbols by pressing the 'abc sym' key on the toolbar and back to default by pressing 'ABC 123' key.

Overview of Toolbar Function Keys

The function keys are located in the toolbar, and enable user actions. The function keys that appear vary according to the screen or program that is currently selected.

Function keys enabling basic actions are described in the following table.

Name of Key	Action	Notes
OK	Confirms a selection or an entered parameter	If the selection involves parameters that are out of the permitted range, the OK key is disabled.
Prime	Initiates priming	Appears in the Attention screen, after the Prime function has been selected.
Mute/Unmute	Silences/unsilences the speaker	Appears when any alarm is triggered. The speaker unmutes automatically after 2 minutes.
Back	Displays the previous screen	
Exit	Returns to either the Start Up screen, or to the screen displaying current infusion parameters	In situations when the Back key and the Exit key will take users to the same screen, only the Exit key is displayed.



The following function keys are available from the Running screen:







Name of Key	Action	Notes
Lock	Locks the screen or the pump	For more information, refer to Locking the Screen on page 122 and Activating Patient Lockout on page 122.
Press to Unlock screen	Unlocks the screen	
Press to Unlock Patient	Unlocks the pump	Unlocking the screen requires a password.





Name of Key	Action	Notes
Request Pause/ Pause Bolus	Pauses an infusion or a bolus	For more information, refer to Pausing Infusions on page 118.
Request Continue/ Continue Bolus	Resumes a paused infusion or a bolus	
View/Edit	Displays a list of infusion parameters to be viewed or edited. Provides access for putting the infusion on Standby, when applicable.	For more information, refer to Infusion Standby on page 119.
Bolus	Delivers a bolus during continuous mode	

Overview of Icons

Icons that frequently appear on the Indicators Bar and the Main Display are described in the following table. In addition, some alarms appear with their own icons.

Icon	Meaning	Notes
>	Indicates that the parameter immediately adjacent to the icon can be viewed and updated directly from the Main Display.	To initiate the update, touch the box in which the icon appears.
	Rate of the infusion.	
	Volume to be infused.	

Icon	Meaning	Notes
	Time remaining until the end of the infusion.	
	Indicates that an infusion is currently running.	
	Indicates status of battery charge.	For more information, refer to Battery Care Information on page 187.
	Indicates that the current infusion is above the upper soft limit range in at least one parameter.	For more information, refer to Soft Limit on page 166.
	Indicates that the current infusion is below the lower soft limit range in at least one parameter.	For more information, refer to Soft Limit on page 166.
	Indicates that the current infusion is exceeding both upper and lower soft limit ranges.	<p>When more than one parameter is limited by the Drug Library – one of the parameters is programmed above the upper soft limit, and another parameter is programmed below the lower soft limit.</p> <p>For more information, refer to Soft Limit on page 166.</p>

Icon	Meaning	Notes
	Indicates that the pump is connected to the hospital network by Wi-Fi.	<p>The icon is displayed on the Indicator bar only when the Wi-Fi option is enabled.</p> <p>Displayed in blue when the device is receiving a wireless signal, displayed in gray when the device is not receiving a wireless signal.</p> <p>For more information, refer to page 37.</p>
	Indicates that the pump is connected to ICU Medical MedNet™ by Wi-Fi.	<p>The icon is displayed on the Indicator bar only when the Wi-Fi option is enabled.</p> <p>Displayed in blue when the device is connected to ICU Medical MedNet™, displayed in gray when device is not connected to ICU Medical MedNet™. For more information, refer to page 37.</p>
	Updating data.	May appear when transitioning between lines.
	Software updates available.	<p>Drug library or pump software updates are available for installation.</p> <p>Note: The option to install these updates is available when turning off an idle pump (not during a paused or running infusion).</p>

Selecting Delivery Mode

The SapphirePlus pump is a multi-platform device that has the ability to operate in several different delivery modes.



The delivery modes availability can be set by a technician

Possible delivery modes include:

Mode	Description/Notes
Continuous	Delivers an infusion at a constant, programmed rate. This mode includes the option to add a Secondary (Piggyback) line.
Multi-step	Delivers the infusion in a set of 1 and up to 25 steps.

Each delivery mode features its own unique options. The current mode is displayed at the right side of the Indicators Bar on some of the screens. On screens that are not mode related, such as **Delivery mode** selections screen below, the name "Sapphire" is displayed instead.

Figure 3.1. Indicators Bar: Delivery Mode



Changing the delivery mode is done using the Options menu. An authorization code of High is required to modify the delivery mode. For more information about how to change the delivery mode, refer to [Setting Delivery Mode](#) on page 127.

Enabling Special Features

Depending on the needs of a specific clinical care area or institution, the SapphirePlus pump can be enabled to perform special functions. An authorization code is required to enable/disable these functions.



After Drug Library is loaded, local changes to configurations controlled by the Drug Library will remain valid until the user selects a CCA or turns the pump Off.
Local changes made to configurations not controlled by the Drug Library will remain valid until reconfigured or pump is set to factory defaults.
When Resuming an infusion after pump shutdown, local configurations will remain until the end of the current infusion.
For more information about configuration settings, refer to [Appendix A: SapphirePlus Configuration Settings](#) on page 214.
When no Drug Library is loaded, all local changes made to any configuration will remain valid until reconfigured or until the pump is set to factory defaults.

The following features can be enabled/disabled by users who have an authorization code of High:

Feature	Delivery Mode(s)	Description/Notes
Set delay	All	Enables users to start or continue an infusion at a later time. The user may either define a specific delay period or set the pump to Standby. For more information, refer to Using the Set Delay Feature on page 151.
Post Infusion Rate	All	Sets the rate that is applied at the end of infusion to KVO or to continue at the current infusion rate. For more information refer to Ending an Infusion on page 123.

Feature	Delivery Mode(s)	Description/Notes
PreProgram	All	<p>Allows users to start an infusion using predefined infusion parameters. When this option is enabled, the PreSet Programs button appears on the pump Start Up screen.</p> <p>For more information, refer to Creating and Editing PreSet Programs on page 148.</p>
Prime Reminder	All	<p>Enables a reminder for the user to prime the administration set before starting an infusion.</p> <p>For more information, refer to Automatic Priming Using the Pump on page 71</p>
Advanced Bolus	Continuous	<p>Allows users to program a bolus by entering rate, amount and time.</p> <p>For more information, refer to Administering a Bolus on page 92.</p>
Auto P. Lockout	All	<p>A safety feature that enables automatic locking of the screen. A password is required to unlock the screen in order to make changes to the infusion parameters or to start a new infusion. Activated first during a running infusion.</p> <p>For more information about enabling the feature, refer to Configuring General Settings on page 132.</p> <p>For more information about using the feature, refer to Activating Patient Lockout on page 122.</p>
Screen Saver	All	<p>Provides a distant view of the main parameters during a running infusion. Activated 30 seconds after the infusion starts.</p>

A Technician authorization code is required to enable/disable the following additional features:

Feature	Delivery Mode(s)	Description/Notes
Delivery modes	All	Determines the available delivery modes. Each mode can be turned Off separately.
New Patient	All	Allows users to associate an infusion with a patient, and reset the Accumulated VI (accumulated volume infused).
Set Secondary (Piggyback)	Continuous	Allows users to program a Secondary infusion. For more information about programming a Secondary infusion, refer to Adding a Secondary Line on page 97.
Allow Bolus	Continuous	Allows users to program a bolus during a Continuous infusion. When this feature is enabled, the Bolus button appears in the toolbar during the running infusion. For more information about administering a bolus, refer to Administering a Bolus on page 92.
Bolus Rate	Continuous	Specifies the rate of delivery of a fast dose, for rapid volume infusion.
Sec. Bolus Rate	Continuous	Specifies the rate of delivery of a fast dose for a Secondary (Piggyback) infusion.
Occ. Auto-restart	All	Enables the pump to automatically restart an infusion, up to 5 times an hour, if a downstream occlusion was detected and cleared within 40 seconds.
Calculate Concentration	All	Determines if the user enters final concentration or Drug Amount and Diluent Volume.

Feature	Delivery Mode(s)	Description/Notes
mL/h Only	All	Allows users to use units other than mL/h. If this option is enabled, programming will automatically default to mL/h. This feature is available in the absence of a Drug Library on the pump.
Wi-Fi	All	Allows users to connect to the hospital network via wireless communication. This option is available after the Wi-Fi module has been installed and configured.

Setting KVO rate

Sets the default rate applied when the Post Infusion Rate is set to KVO. The permitted range for the KVO rate parameter is 0-20 mL/h (for all delivery modes).

Chapter 4: Getting Started

The following sections explain the sequence of actions necessary to prepare the pump and the administration set for an infusion:

Typical Workflow	62
Connecting the Infusion Container to the Administration Set	65
Opening the Safety Door	66
Inserting the Administration Cassette	68
Automatic Priming Using the Pump	71

Typical Workflow

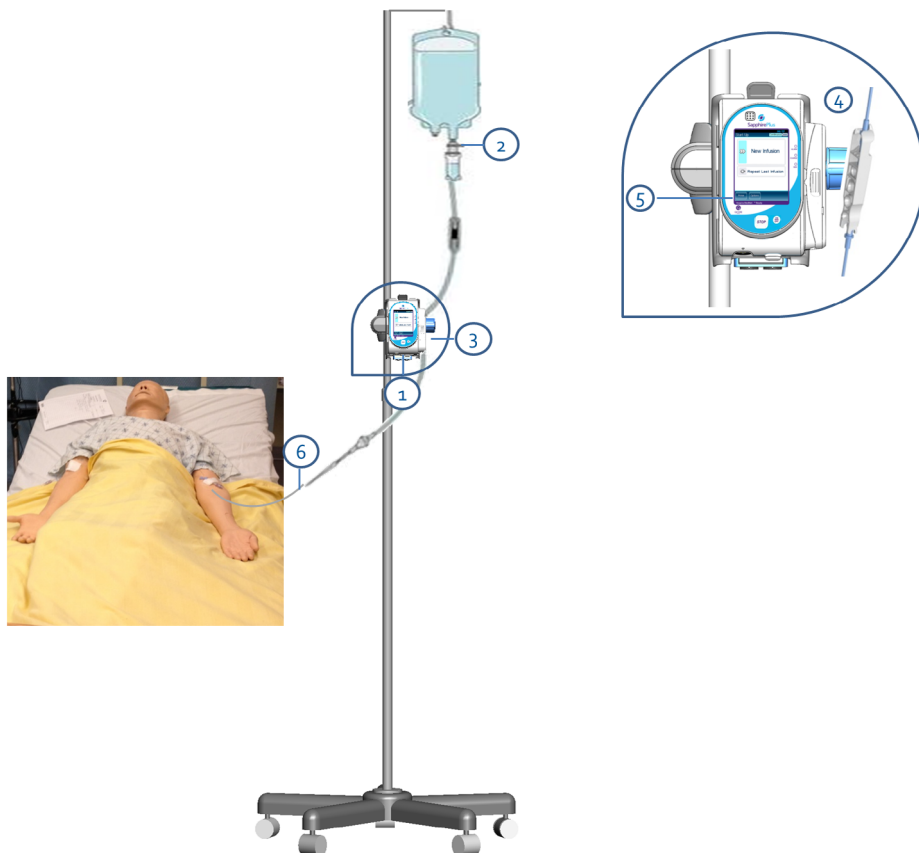
The recommended workflow for preparing the pump and administration set for an infusion comprises the following steps:

1. Turn the pump On.
2. Connect the infusion container to the administration set.
3. Open the safety door.
4. Insert the cassette.
5. Prime the administration set using the pump.*
6. Connect the administration set to the patient. When using an administration set with a filter, place the filter under the patient's IV infusion site.

* It is recommended to prime the administration set using the pump. It is possible to prime the administration set manually. For more information, refer to [Priming Manually](#) on page 73.

The workflow sequence is illustrated in the following figure:

Figure 4.1. Recommended Workflow



Turning the Pump On

The pump is turned On by pressing the **On/Off** hard key, at the lower right corner of the pump.

When a Drug Library is loaded, a message is displayed asking to accept or change the current CCA. For more information about CCA, refer to [Clinical Care Area \(CCA\)](#) on page 161.



While the pump turns On, a system check is performed. If you do not hear a sound from the speaker, or if items on the screen do not display properly, do not use the pump.



If a message regarding resuming previous infusion appears upon turning the pump On, refer to [Resuming Infusions After Pump Shutdown](#) on page 117.

Turning the Pump Off

Pressing the **On/Off** hard key for 5 consecutive seconds turns the pump Off. Alternatively, press the **On/Off** hard key, and then, from the Attention screen, press **Off**. If a drug library update, or software update is available for installation, the user is prompted with the option to install when turning off the pump. Note that installing a new pump software removes the Drug Library if it has become incompatible.



After operating the pump with <1 mL/h flow rate, you will be prompted to remove the administration cassette before turning Off the pump.

For more information about turning the pump Off during an infusion, refer to [Aborting Infusions](#) on page 120.

The pump enables resuming an infusion after pump shut down. For more information, refer to [Resuming Infusions After Pump Shutdown](#) on page 117.

Connecting the Infusion Container to the Administration Set

This section explains how to connect the infusion container to the administration set.



Before setting up the infusion, verify that the container, administration set and administration set package are undamaged.

> To connect the container to the administration set:

1. Open the sterilized administration set package.
2. Close the clamps and the AFFV to block the administration set. Make sure that the clamp is located at least 20 cm (8 in) from the pump, when possible.
3. Spike the administration set into the container.



Verify that the arrow on the administration cassette is pointing toward the same direction of the fluid flow (down).



Connecting the Infusion Container: Safety Precautions

- Make sure there is no leakage from the container, and that the spike is firmly attached to the container.
- Verify that the set components are positioned correctly. The arrows on the administration cassette and the filter must point toward the direction of the flow (from the container to the patient).
- When using a filter, maintain the filter level below the vascular access site.

Opening the Safety Door

Opening the safety door involves pressing it down while simultaneously pulling the safety door open.

> To open the safety door:

1. Using your thumb, press the door outwards.



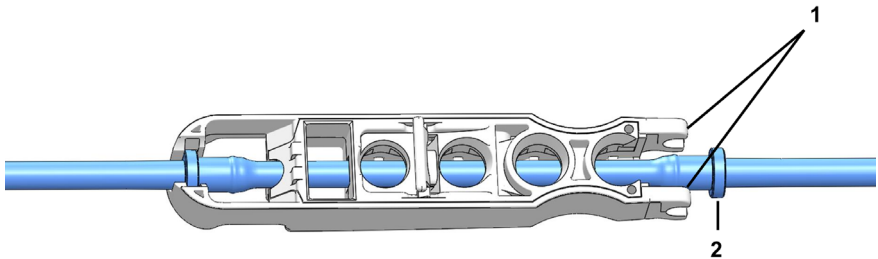
2. While maintaining pressure, swing the safety door outwards.



Inserting the Administration Cassette

Inserting the administration cassette into the pump involves positioning the cassette in the proper direction, and ensuring that all portions of the cassette including the flange, are secured inside the administration cassette's housing. In [Figure 4.2](#), the flange is represented by #2, and the saddle is represented by #1.

Figure 4.2. Administration Cassette

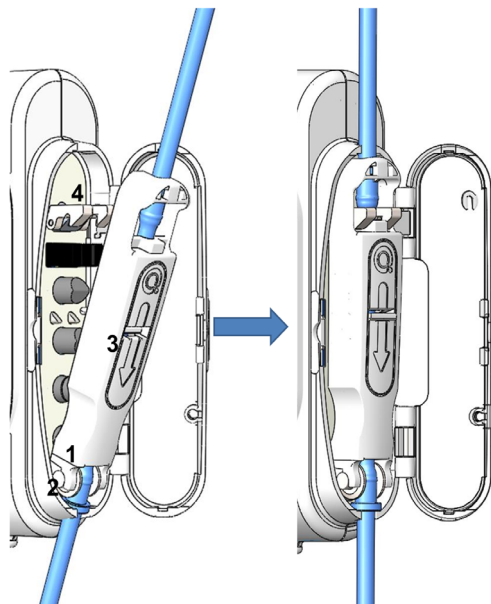


It is recommended to make sure that the pump is turned On, and to verify that all clamps on the administration set are closed before inserting the administration cassette.

> To insert the Q Core administration cassette:

1. Open the safety door ([Opening the Safety Door](#) on page 66). Then, insert the administration cassette at an angle, by placing the saddle ([Figure 4.3](#), #1) on the round metal anchor (#2) in the cassette's housing. Make sure that the arrow on the cassette (#3) is pointing toward the bottom of the pump, and the bottom flange is inside the cassette housing.

Figure 4.3. Insertion of Cassette



2. Clip the upper end of the administration cassette into the metal lock (Figure 4.3, #4).
3. Close the safety door over the administration cassette. Ensure that the safety door clicks upon closure.

Removing the Administration Cassette

When the infusion is complete, close the clamps, disconnect the administration set from the patient, and disconnect the administration cassette.

In case of emergency, you can stop pump operation by opening the safety door, closing the clamps, removing the administration cassette from the pump and disconnecting the administration set from the patient.

The following procedure describes how to remove the cassette from the pump.



Although the AFFV offers automatic free flow protection, a small amount of fluid (up to 0.09 mL) may be expelled when the administration cassette is detached. In order to ensure full protection, disconnect the patient from the administration set before detaching the cassette from the pump.

> To remove the Q Core administration cassette:

1. Close all clamps on the administration set.
2. Disconnect the patient from the administration set.
3. Open the safety door ([Opening the Safety Door](#) on page 66).
4. Loosen the cassette by raising the metal lock that secures it to the pump (#4 in [Figure 4.3](#)).
5. Pull out the cassette, and close the safety door.

Automatic Priming Using the Pump

Before commencing infusion setup, the administration set needs to be primed. Priming expels all the air from the administration set, and fills it with the infusion liquid. A fully primed administration set is a set filled with infusion liquid (from which all the air was removed).



It is recommended to prime the administration set using the pump.

Priming with the pump can be initiated from the following screens:

- Start Up
- Start
- Paused (infusion or bolus)
- Air in Line Alarm

Before using the pump for priming, ensure that:

- The administration set clamp is open.
- The safety door is closed.

The Q Core administration cassette is properly connected to the pump.



Before priming, verify that the administration set is disconnected from the patient.



When the Prime Reminder is enabled and the set has not yet been primed using the pump, a Prime Reminder will be displayed, enabling the user to press **Prime** in order to start priming or to press **Start** in order to proceed with the infusion (refer to [Configuring General Settings](#), page 133).

- To prime the administration using the pump

1. Position the pump in an upright position using one of the following methods:
 - Attach the pump to the cradle base.
 - Attach the pump to an IV pole using the mini cradle.
2. From the toolbar of the Start Up, Start, Air in Line Alarm, or Paused screen, press **Prime**.
3. **Verify that the administration set is disconnected from the patient.** Then, from the Attention screen, press **Prime**. Priming begins.

While the pump is priming, a progress circle appears on the screen, with a time countdown displayed. The default priming time is 2 minutes.

When using administration sets that contain less than 20 mL, shorter priming times can be set. For more information, refer to [Set prime volume](#) on page 132.



During priming with the pump, the Air in line alarm is disabled. When priming, check that all clamps are opened and that there is no occlusion. Ensure that liquid, not air, enters the administration set during priming.

The pump automatically indicates when priming is finished.

If priming is completed before the default priming time has elapsed, automatic priming can be discontinued.

> To discontinue priming:

1. From the toolbar, press **Finish Prime**. Alternatively, at the bottom of the pump, press the **Stop** hard key.
2. From the toolbar, press **OK**

Priming Manually

The Q Core administration set can also be used as a gravity set, and the Anti-Free-Flow Valve (AFFV) can be used manually.

Before commencing infusion setup, the administration set needs to be primed. Priming expels all the air from the administration set, and fills it with the infusion liquid. A fully primed set is a set filled with infusion liquid (from which all the air was removed).



The following procedure explains how to prime the administration set manually, using gravity. However, it is recommended to prime the administration set using the pump. For more information, refer to [Automatic Priming Using the Pump](#) on page 71.



A set with a Pressure Activated Valve (PAV) can not be primed manually.
For more information, refer to the Direction for Use for each set.

> To prime the administration set manually:

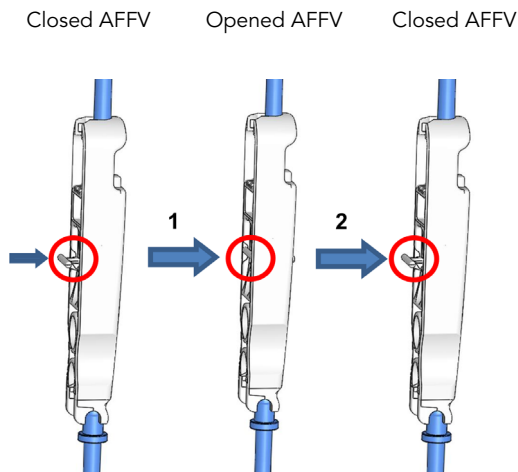
1. Open all the clamps on the administration set.
2. To allow free flow, open the AFFV by pushing it in and down, towards the center of the Q Core administration cassette (#1 in [Figure 4.4](#)).
3. Fill the entire administration set with fluid, so that the fluid displaces all air in the administration set.



When priming a set with a filter; the filter must remain lower than the patient line.

4. To block free flow, close the AFFV by pushing it up and away from the center of the cassette (#2 in [Figure 4.4](#)).

Figure 4.4. Opening and Closing the AFFV



Although the AFFV offers automatic free flow protection, a small amount of fluid (up to 0.12 mL) may be expelled when the administration cassette is attached. In order to ensure full protection, insert the administration cassette to the pump housing before connecting the set to the patient.



To use as a gravity set, fix the AFFV in an open position as described in step 2 in [To prime the administration set manually](#) on page 73. Only administration sets that include a roller clamp and do not include pressure activated valves (PAV) can be used by gravity. For more information, refer to the Administration set's DFU.

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Chapter 5: Using the Delivery Modes

The following sections explain how to operate the pump in the different delivery modes. After setting up the pump and the infusion, always check the battery status to ensure it is sufficient for the desired infusion program.

Continuous Mode	76
Multi-step Mode	105

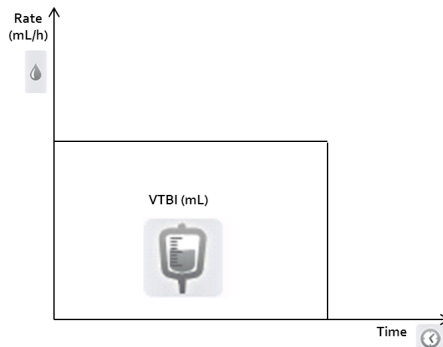
Continuous Mode

The following sections will be reviewed:

Infusion Parameters: Continuous Mode	79
Starting a Continuous Infusion	79
Continuous Mode: Mid-infusion Actions	91

In this mode, the pump infuses fluid at a constant, programmed rate.

Figure 5.1. Continuous Flow Profile

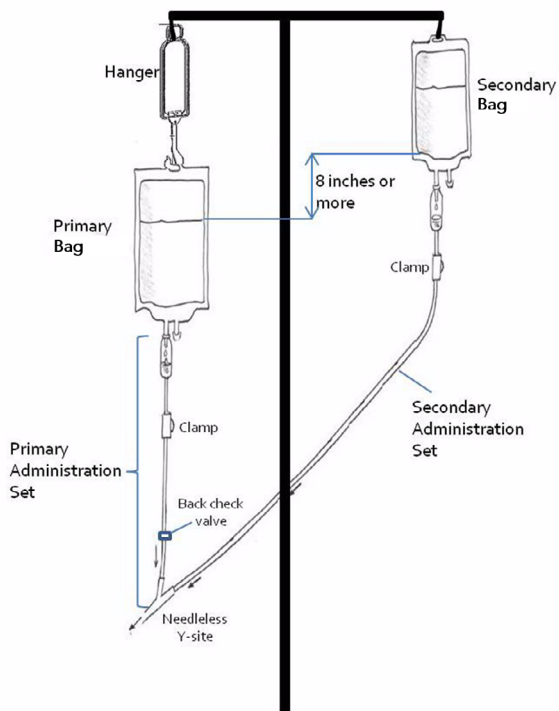


The SapphirePlus pump can also be configured to support Secondary (Piggyback) infusions. The Secondary option is used when two medications are administered from two different containers; The user may either alternate between the containers or administer them sequentially.



To use the Secondary option, the option must be enabled (requires Technician authorization code).

Figure 5.2. Secondary Infusion Setup



When the Secondary option is enabled, you can set Secondary infusion parameters:

- Immediately after programming the Primary infusion ([Starting a Continuous Infusion Using the Secondary Function](#) on page 85).
OR
- While a Primary infusion is already running ([Adding a Secondary Line](#) on page 97).



Piggyback Option: Safety Precautions

When working with Secondary infusions, adhere to the following instructions and guidelines:

- Use only Q Core administration sets designed for Piggyback infusions. (For more information, refer to [Q Core Approved Administration Sets](#) on page 48.)
- Hang the Secondary solution container at least 8 inches above the Primary solution fluid level.
- Use the drip chamber on the set to verify that the correct line is delivering and the other line is idle.
- After the Secondary infusion is complete, clamp the Secondary administration set.

Infusion Parameters: Continuous Mode

The following infusion parameters are relevant for a Continuous infusion. When programming the infusion, it is necessary to specify two of the parameters. The third parameter is then automatically calculated by the pump.

Parameter	Description/Notes
Rate	The speed at which the fluid is infused. Rate values can range from 0.1 to 999 mL/h. Note: When selecting units that are not from the mL/h family, the word Rate is replaced with Dose Rate .
VTBI	The total amount of fluid to be infused. VTBI values can range from 0.1 to 9999 mL. The remaining VTBI is displayed on the screen as the infusion progresses.
Time	The period of time over which the fluid is infused. The range for the Time value varies according to the VTBI and Rate. The upper limit of the Time value is 99 hours and 59 minutes.

Starting a Continuous Infusion

The following procedure explains how to program the pump to start a new Continuous infusion.



If relevant, you may skip programming by using the Repeat Last Infusion or PreSet programs procedures to begin the infusion. For more information, refer to [Starting New Infusions: Shortcuts](#) on page 114. To restart the infusion by adding VTBI during Post Infusion state, refer to [Restarting the Infusion during the Post Infusion State](#) on page 124.

> To begin a new Continuous infusion without Drug Library:

1. From the Indicators Bar, verify that the pump is in Continuous mode.



For more information about changing delivery modes, refer to [Selecting Delivery Mode](#) on page 56.

2. From the Start Up screen, select **New Infusion**.
3. If the Dosing method screen appears, select the appropriate option:
 - **mL:** Continue to Step 7.
 - **Dose calculation:** Continue to Step 4.

Weight based units are available for both Dosing methods

Otherwise, continue to Step 10.

4. From the Concentration units screen, select the appropriate drug units.



To display additional concentration units press **Next**.

5. According to the pump configuration one of the following screens will appear:
 - **Concentration:** From the Concentration screen, using the keypad, enter the Concentration → **OK**; then, continue to Step 7.
 - **Drug amount:** Using the keypad, enter the Drug Amount → **OK**. Then, using the keypad, enter the Diluent Volume → **OK**; then, continue to Step 6.
6. From the Attention screen, confirm the concentration and press **OK**.
If the selected drug unit is Million Units, continue to Step 9.
7. If the Patient Weight screen appears, specify whether the infusion is weight based:
 - **Yes:** Continue to Step 8.
 - **No:** Continue to Step 9.
8. From the Patient Weight screen, using the keypad, enter the Patient Weight → **OK**.
9. From the Dose Rate units screen, select the appropriate dose rate units.

10. From the Edit screen, program 2 of the following 3 parameters, by selecting the relevant rows:

- **Rate:** Using the keypad, enter the value → **OK**.
- **VTBI:** Using the keypad, enter the value → **OK**.
- **Time:** Using the keypad, enter the value → **OK**.

The third (unprogrammed) parameter is then automatically calculated by the pump and displayed in the relevant box.



If the calculated rate is beyond the pump resolution (0.1 mL/h increments), the pump decreases the rate by 0.1 mL/h during the infusion to achieve accurate delivery of the volume in the specified time. The rate reduction is always 0.1 mL/h, and is presented on the Running screen (when selecting dose calculation, the equivalent change to 0.1 mL/h applies).

11. Review the parameters displayed on the Confirm screen.



Verify that the parameters reflect the correct treatment according to the prescription.

Then, press **OK**.



If the pump is configured to support Secondary infusions, Secondary infusion parameters can be programmed at this point. For detailed instructions, go to Step 3 on page 85 ([To begin a new Continuous infusion using the Secondary option without Drug Library](#)).

12. Make sure that the clamps on the administration set are open; then, press **Start**.
The Running screen is displayed, and the infusion begins.

Throughout the infusion, the following information is displayed on the screen:

- **Drug Name:** The name of the selected drug. Displayed on the indicators bar, when working with a Drug Library.

- **Drug Concentration:** Drug concentration as entered by the user (Final concentration or Drug Amount / Diluent Volume). Displayed when applicable.
- **Rate:** Current infusion rate. For all dose units other than mL/h, the calculated rate will be displayed in mL/h, both in the View system menu and in the Running screen.
- **VTBI:** Total volume left to be infused during the current infusion. As the infusion progresses, this value decreases.
- **VI / Total:** Total volume (including KVO if applied during a delayed start period) / the VTBI value programmed. As the infusion progresses, the VI increases, and the Total remains constant.
- **Time left:** Time remaining until the end of the current infusion.



When the remaining VTBI is 0.1mL or less, the time left displayed on the screen may deviate up to a few minutes from the actual time remaining.

If the calculated rate is beyond the pump resolution (0.1 mL/h increments), the pump decreases the rate by 0.1mL/h during the infusion, in order to achieve accurate delivery of the volume in the specified time. The rate reduction is always of 0.1mL/h and is presented on the running screen (when selecting dose calculation, the equivalent change to 0.1mL/h applies).



To view all programmed parameters of the current infusion, including the rate in mL/h, from the Running screen, press **View/Edit → View system → Infusion values**.

> **To begin a new Continuous infusion with a Drug Library:**

1. From the Indicators Bar, verify that the pump is in Continuous mode.



For more information about changing delivery modes, refer to [Selecting Delivery Mode](#) on page 56

2. From the Start Up screen, select **New Infusion**.
3. From the Drug Name screen:
 - Using the keypad, enter the drug name; then, press **Find** and proceed to Step 4.



The **Find** key can be used to display all available drugs without entering any characters (letters, numbers or symbols), or filter drug names according to the characters entered.

- When the required drug is not found in the Drug Library, press **Choose General** key on the toolbar:



'Choose General' will bypass specific drug limits, and the infusion will be programmed without Drug Library limits.

From the Attention screen, confirm choosing General, and press **OK**. Proceed to Step 3 on page 80 ([To begin a new Continuous infusion without Drug Library](#)) and continue programming from there.

4. From the Drug List screen, select the row of the relevant drug.



To display additional drugs press **Next**.

5. If a list of available drug profiles appears, select the appropriate drug profile and proceed according to the step directed to:
- **No concentration:** proceed to Step 7 on page 80 ([To begin a new Continuous infusion without Drug Library](#)), and continue programming from there.
 - **Diluent only** (e.g., 10 mL): proceed to Step 7 on page 80 ([To begin a new Continuous infusion without Drug Library](#)), and continue programming from there.
 - **Partial concentration:** the Drug Amount and/or Diluent Volume are/is missing. The screen/s of the missing value/s will appear:
 - From the Drug Amount screen, using the keypad, enter the Drug Amount → **OK**.
 - From the Diluent Volume screen, using the keypad, enter the Diluent Volume → **OK**.From the Attention screen, confirm the concentration and press **OK**. Proceed to Step 7 on page 80 ([To begin a new Continuous infusion without Drug Library](#)), and continue programming from there.
 - **Full concentration:**
Proceed to Step 7 on page 80 ([To begin a new Continuous infusion without Drug Library](#)), and continue programming from there.
- If a list of available drug profiles does not appear, continue to Step 10 on page 81 ([To begin a new Continuous infusion without Drug Library](#)), and continue programming from there.
- For more information about the Drug Library, refer to [Chapter 9: Drug Library](#) on page 160.

Starting a Continuous Infusion Using the Secondary Function

The following procedure explains how to program a Continuous infusion using both Primary and Secondary lines.

> To begin a new Continuous infusion using the Secondary option without Drug Library:

1. Verify that the pump is in Continuous mode, and then enter parameters for the Primary infusion (Step 2 on page 80 through Step 10 on page 81 in [To begin a new Continuous infusion without Drug Library](#)).
2. Review the parameters displayed on the Confirm screen.



Verify that the parameters reflect the correct treatment according to the prescription.

Then, press **OK**.

3. From the Start screen, select **Set Secondary**.
4. If the Dosing method screen appears, select the appropriate option:
 - **mL:** Continue to Step 8.
 - **Dose calculation:** Continue to Step 5.

Weight based units are available for both Dosing methods.

Otherwise, continue to Step 11.

5. From the Concentration units screen, select the appropriate drug units.



To display additional concentration units press **Next**.

6. According to pump configuration one of the following screens will appear:
 - **Concentration:** From the Concentration screen, using the keypad, enter the Concentration → **OK**. Then, continue to Step 8.
 - **Drug amount:** Using the keypad, enter the Drug Amount → **OK**. Then, using the keypad, enter the Diluent Volume → **OK**. Then, continue to Step 7.

7. From the Attention screen, confirm the Concentration and press **OK**.
If the selected drug unit is Million Units, continue to Step 10.
8. If the Patient Weight screen appears, specify whether the infusion is weight based:
 - **Yes:** Continue to Step 9.
 - **No:** Continue to Step 10.
9. From the Patient Weight screen:
If the patient weight was entered during the primary line programming, continue to Step 10.
If the patient weight was not entered during the primary line programming, using the keypad, enter the Patient Weight → **OK**.
10. From the **Dose Rate units** screen, select the appropriate dose rate units.
11. Program 2 of the following 3 parameters, by selecting the relevant boxes:
 - **Rate (Secondary):** Using the keypad, enter the value → **OK**.
 - **VTBI (Secondary):** Using the keypad, enter the value → **OK**.
 - **Time (Secondary):** Using the keypad, enter the value → **OK**.The third (unprogrammed) parameter is then automatically calculated by the pump and displayed in the relevant box.



If the dose rate is beyond the pump resolution of 0.1 mL/h increments, the pump will increase or decrease the rate by up to 0.05 mL/h. This flow rate (mL/h) is presented on the running screen during infusion. For example, if the dose rate entered is 20 mg/h, which is equivalent to 3.64 mL/h, the pump will decrease the rate to 3.6 mL/h and display it on the running screen.

12. Review the parameters displayed on the Confirm screen.



Verify that the parameters reflect the correct treatment according to the prescription.

Then, press **OK**.

13. From the Start screen, select one of the following:

- **Start secondary:** The Attention screen appears. After verifying that the clamps on the Secondary administration set are open, press **OK**. The Secondary screen appears, and the Secondary infusion begins. When the Secondary infusion is complete, the pump automatically continues with the Primary infusion.
- **Start primary:** The Attention screen appears. After closing the clamp on the Secondary administration set, make sure that the clamps on the primary administration set are open; then, press **OK**. The Primary screen appears, and the Primary infusion begins.

Throughout the infusion, the Indicators Bar displays information regarding the current infusion (Primary, Secondary or the name of the drug infused). After the secondary infusion is completed, the pump automatically switches to the primary line, and beeps to notify the user. The following information is displayed on the Primary/Secondary screen:

- **Drug Name:** The name of the selected drug. Displayed on the indicators bar, when working with a Drug Library.
- **Drug Concentration:** Drug concentration as entered by the user (Final concentration or Drug Amount / Diluent Volume). Displayed when applicable.
- **Rate:** Current infusion rate. For all dose units other than mL/h, the calculated rate will be displayed in mL/h, both in the View system menu and in the Running screen.
- **VTBI:** Total volume left (in the current infusion) to be infused. As the infusion progresses, this value decreases.
- **VI / Total:** Total volume (including KVO if applied during a delayed start period) / the VTBI value programmed. As the infusion progresses, the VI increases, and the Total remains constant.

- **Time left:** Time remaining until the end of the current infusion.



When the remaining VTBI is 0.1 mL or less, the time left displayed on the screen may deviate up to a few minutes from the actual time remaining.



You can switch between the two infusions at any time. For more information, refer to [Switching between Primary and Secondary Infusions](#) on page 101.



To view all programmed parameters of the current infusion, including the rate in mL/h, from the Running screen, press **View/Edit → View system → Infusion values**.
For all dose units other than mL/h, the calculated rate will be displayed in mL/h, both in the View system menu and in the Running screen.

> To begin a new Continuous infusion using the Secondary option with a Drug Library:

1. Verify that the pump is in Continuous mode, and then enter parameters for the Primary infusion ([To begin a new Continuous infusion with a Drug Library](#) Step 2 on page 83 to Step 5 on page 84).
2. Review the parameters displayed on the Confirm screen.



Verify that the parameters reflect the correct treatment according to the prescription.

Then, press **OK**.

3. From the Start screen, select **Set Secondary**.
4. From the Drug Name screen:

- Using the keypad, enter the drug name, then press **Find** and proceed to Step 5.



The **Find** key can be used to display all available drugs without entering any characters (letters, numbers or symbols), or filter drug names according to the characters entered.

- When the required drug is not found in the Drug Library, press **Choose General** key on the toolbar:



'Choose General' will bypass specific drug limits, and the infusion will be programmed without Drug Library limits.

From the Attention screen, confirm choosing General and press **OK**.

Proceed to Step 4 on page 85 (To begin a new Continuous infusion using the Secondary option without Drug Library) and continue programming from there.

5. From the Drug List screen, select the row of the relevant drug.



To display additional drugs press **Next**.

6. If a list of available drug profiles appears, select the appropriate drug profile and proceed according to the step directed to:

- **No concentration:** proceed to Step 8 on page 86 (To begin a new Continuous infusion using the Secondary option without Drug Library), and continue programming from there.
- **Diluent only** (e.g., 10 mL): proceed to Step 8 on page 86 (To begin a new Continuous infusion using the Secondary option without Drug Library), and continue programming from there.
- **Partial concentration:** the Drug Amount and/or Diluent Volume are/is missing. The screen/s of the missing value/s will appear:
 - From the Drug Amount screen, using the keypad, enter the Drug Amount → **OK**.
 - From the Diluent Volume screen, using the keypad, enter the Diluent Volume → **OK**.

From the Attention screen, confirm the concentration and press **OK**.

Proceed to Step 8 on page 86 ([To begin a new Continuous infusion using the Secondary option without Drug Library](#)), and continue programming from there.

- **Full concentration:**

Proceed to Step 8 on page 86 ([To begin a new Continuous infusion using the Secondary option without Drug Library](#)), and continue programming from there.

If a list of available drug profiles does not appear, continue to Step 11 on page 86 ([To begin a new Continuous infusion using the Secondary option without Drug Library](#)), and continue programming from there.

For more information about the Drug Library, refer to [Chapter 9: Drug Library](#) on page 160.

Continuous Mode: Mid-infusion Actions

The following actions can be performed during Continuous infusions:

Updating Infusion Parameters	91
Administering a Bolus	92
Adding a Secondary Line	97
Switching between Primary and Secondary Infusions	101
Replacing the Current Secondary Line	102
Pausing Infusions	118
Infusion Standby	119
Aborting Infusions	120
Locking the Screen	122
Activating Patient Lockout	122

Updating Infusion Parameters

Infusion parameters can be modified by using the **View/Edit** function key. In addition, you can modify the rate, VTBI, and time left directly from the Running, Primary or Secondary screen.

> To update current parameters directly from the screen:

1. On the Main Display, select the relevant parameter (**Rate**, **VTBI** or **Time left**).
2. Using the keypad, enter the new value of the parameter → **OK**.
3. To confirm and save changes, press **OK**.
To return to the original infusion screen without saving changes, press **Back**.

> To update parameters using the View/Edit function key:

1. From the toolbar, press **View/Edit**.
2. Select the box of the parameter to be updated.
3. Using the keypad, enter the new value of the parameter → **OK**.
4. To update other parameters, repeat Steps 2-3.

In addition to parameter changes, the following actions are also available:

- **Clear Accum. VI:** Resets the total volume infused via all infusions associated with the current patient to 0 mL. For more information, refer to [Clearing Accumulated VI](#) on page 157.
- **View system:** Displays various system and pump parameters. (Refer to [View Menu](#) on page 138.)
- **Edit Primary/Secondary Line:** Allows you to update infusion parameters of the infusion that is not currently running. The pump will prompt you to pause the infusion while updating these parameters.

5. To confirm and save changes, press **OK**.

To return to the original infusion screen without saving changes, press **Back**. Then, from the Attention screen, press **OK**.



If the dose rate is beyond the pump resolution of 0.1 mL/h increments, the pump will increase or decrease the rate by up to 0.05 mL/h. This flow rate (mL/h) is presented on the running screen during infusion.

Administering a Bolus

The Bolus feature enables administration of a fast dose, when rapid volume infusion in the Continuous mode is necessary.



Bolus delivery allows infusion at high rates. Only certified medical personnel should use this feature.

> To deliver a bolus:

1. From the toolbar of the Running, Primary or Secondary screen, press **Bolus**.



For the **Bolus** button to appear on a Continuous running infusion, the pump needs to be configured to the Allow Bolus setting. The Allow Bolus setting can be modified by Technicians only. For more information, refer to the Service Manual. If a Drug Library is installed on the pump, the Bolus button will appear only if the option was enabled for a specific drug, or an entire CCA.

2. If the Patient Weight screen appears, using the keypad, enter the Patient Weight → **OK**.
3. According to configuration, one of the following screens will appear:



When using the ICU Medical MedNet™ Drug Library, bolus programming is only done via the Edit option.

- **Edit:**
 - **Amnt (Bolus):** Using the keypad, enter the Bolus Amount → **OK** (the acceptable range varies, according to the current VTBI).



Trying to enter one of the unavailable (grayed out) boxes, triggers a message requesting to enter the Bolus amount first.

Enter one of the following parameters, by selecting the relevant box:

- **Rate (Bolus):** Using the keypad, enter the Bolus Rate → **OK**.
- **Time (Bolus):** Using the keypad, enter the Bolus Time → **OK**.

The third (unprogrammed) parameter is then automatically calculated by the pump and displayed in the relevant box.

Continue to Step 4.

- **Bolus Amount:** Using the keypad, enter the Bolus Amount → **OK** (the acceptable range varies according to the current VTBI). Then, continue to Step 5.



When trying to exit programming before its completion, a message is displayed stating that the data entered has not been saved.



Bolus units used may differ from the units used by the infusion, due to their pre-configuration in the Drug Library.



When the bolus is programmed by amount only, the default bolus rate is 125 mL/h. This default can be modified using a Technician authorization code.

When the infusion rate is higher than 125 mL/h, the bolus rate will be 1 mL/h faster than the infusion rate.

During a bolus, some of the parameters can be updated from the Bolus delivery screen. For more information, refer to [Updating Bolus Infusion Parameters](#) on page 95.

4. Review the parameters displayed on the Confirm screen.



Verify that the parameters reflect the correct treatment according to the prescription.

Then, press **OK**.

5. To start the bolus, from the Attention screen, press **OK**.

The Bolus delivery screen is displayed, and the bolus begins.

Throughout the bolus, the following information is displayed on the screen:

- **Drug Name:** The name of the selected drug. Displayed on the indicators bar, when working with a Drug Library.

- **Drug Concentration:** Drug concentration as entered by the user (Final concentration or Drug Amount / Diluent Volume). Displayed when applicable.
- **Bolus Rate:** Current infusion rate.
- **Bolus VTBI:** Total bolus amount left to be infused. As the bolus progresses, this value decreases.
- **Bolus VI / Total:** Total bolus amount that has been infused during the current infusion / the total bolus amount programmed. As the infusion progresses, the Bolus VI increases, and the Total remains constant.
- **Time left:** Time remaining until the end of the bolus.

When the bolus is complete, a message appears on the Main Display.

Mid-bolus Actions

The following actions can be performed during bolus delivery:

Updating Bolus Infusion Parameters	95
Pausing a Bolus	96
Aborting a Bolus	96

Updating Bolus Infusion Parameters

Bolus infusion parameters are updated directly from the Bolus delivery screen.

> To update parameters from the Bolus delivery screen:

1. On the Main Display, select the relevant frame (Bolus Rate, Bolus VTBI or Time Left).



The Time Left parameter is not configurable, when the bolus was programmed by amount only.

2. Using the keypad, enter the new Rate, VTBI or Time left → **OK**.
3. From the Attention screen, press **OK**.
Updated parameters are displayed.

Pausing a Bolus

When necessary, you can temporarily stop the bolus.

> To pause a bolus:

- From the toolbar of the bolus delivery screen, press **Pause Bolus**. Then, from the Attention screen, press **OK**.
Alternatively, press the **Stop** hard key.
All volume delivery stops.

> To resume a paused bolus:

1. From the toolbar of the bolus delivery screen, press **Continue Bolus**.
2. From the Attention screen, press **OK**.

Aborting a Bolus

The following procedures involve pausing and then permanently quitting the bolus, with the option to quit the entire infusion.

> To abort a bolus and quit all infusions:

1. Press the **Stop** hard key. Alternatively, press the **Pause Bolus**, then press **OK**.
The bolus is paused.
2. From the toolbar, press **Quit Bolus**.
3. From the toolbar of the Paused screen, press **Quit**.
4. From the Attention screen, press **Quit infusion**.



Resuming infusion after quitting will not be possible.

> To abort a bolus and continue the infusion (Secondary option not in use):

1. Press the **Stop** hard key. Alternatively, press the **Pause Bolus**, then press **OK**.
The bolus is paused.
2. From the toolbar, press **Quit Bolus**.

3. From the toolbar of the Paused screen, press **Request Continue**.
4. From the Attention screen, press **OK**.

> **To abort a bolus and continue the infusion (Secondary option in use):**

1. Press the **Stop** hard key. Alternatively, press the **Pause Bolus**, then press **OK**. The bolus is paused.
2. From the toolbar, press **Quit Bolus**.
3. From the toolbar of the Paused screen, press **Switch or Continue**.
4. From the Start screen, press **Primary** or **Secondary**.
5. From the Attention screen, press **OK**.

Adding a Secondary Line

The following procedure explains how to add a Secondary line while a Primary infusion is already running.



If you have already programmed the Secondary infusion, and want to start it, refer to [Switching between Primary and Secondary Infusions](#) on page 101.



Before programming a Secondary infusion, verify that the administration set you are using is appropriate for Secondary (Piggyback) infusions. For more information, refer to [Q Core Approved Administration Sets](#) on page 48.

> **To add a Secondary line while a Primary line is running, without Drug Library:**

1. From the toolbar, press **View/Edit**.
2. Select **Add Sec. Line**.
3. If the Dosing method screen appears, select the appropriate option:
 - **mL:** Continue to Step 7.

- **Dose calculation:** Continue to Step 4.

Weight based units are available for both Dosing methods.

Otherwise, continue to Step 10.

4. From the Concentration units screen, select the appropriate drug units.



To display additional concentration units press **Next**.

5. According to pump configuration one of the following screens will appear:
 - **Concentration:** From the Concentration screen, using the keypad, enter the Concentration → **OK**. Then, continue to Step 7.
 - **Drug amount:** Using the keypad, enter the Drug Amount → **OK**. Then, using the keypad, enter the Diluent Volume → **OK**. Then, continue to Step 6.
6. From the Attention screen, confirm the concentration and press **OK**.
If the selected drug unit is Million Units, continue to Step 9.
7. If the Patient Weight screen appears, specify whether the infusion is weight based:
 - **Yes:** Continue to Step 8.
 - **No:** Continue to Step 9.
8. From the Patient Weight screen:
If the patient weight was entered during the primary line programming, continue to Step 9.
If the patient weight was not entered during the primary line programming, using the keypad, enter the Patient Weight → **OK**.
9. From the Dose Rate units screen, select the appropriate dose rate units.
10. Program 2 of the following 3 parameters, by selecting the relevant boxes:
 - **Rate (Secondary):** Using the keypad, enter the value → **OK**.
 - **VTBI (Secondary):** Using the keypad, enter the value → **OK**.
 - **Time (Secondary):** Using the keypad, enter the value → **OK**.

The third (unprogrammed) parameter is then automatically calculated by the pump and displayed in the relevant box.



If the dose rate is beyond the pump resolution of 0.1 mL/h increments, the pump will increase or decrease the rate by up to 0.05 mL/h. This flow rate (mL/h) is presented on the running screen during infusion.

11. Review the parameters displayed on the Confirm screen.



Verify that the parameters reflect the correct treatment according to the prescription.

Then, press **OK**.

12. From the Start screen, select one of the following:

- **Start secondary:** The Attention screen appears. After verifying that the clamps on the Secondary administration set are open, press **OK**. The Secondary screen appears, and the Secondary infusion begins. When the Secondary infusion is complete, the pump automatically continues with the Primary infusion.
- **Continue primary:** The Primary screen appears, and the Primary infusion begins.

For more information about switching from one infusion to the other, refer to [Switching between Primary and Secondary Infusions](#) on page 101.

> **To add a Secondary line while a Primary line is running, with a Drug Library:**

1. From the toolbar, press **View/Edit**.
2. Select **Add Sec. Line**.
3. From the Drug Name screen:
 - Using the keypad, enter the drug name, then press **Find** and proceed to Step 4.



The **Find** key can be used to display all available drugs when not entering any characters (letters, numbers or symbols), or filter drug names according to the characters entered.

- When the required drug is not found in the Drug Library, press the **Choose General** key on the toolbar:



'Choose General' will bypass specific drug limits, and the infusion will be programmed without Drug Library limits.

From the Attention screen, confirm choosing General and press **OK**.

Proceed to Step 3 on page 97 (To add a Secondary line while a Primary line is running, without Drug Library), and continue programming from there.

4. From the Drug List screen, select the row of the relevant drug.



To display additional drugs press **Next**.

5. If a list of available drug profiles appears, select the appropriate drug profile and proceed according to the step directed to:

- **No concentration:** proceed to Step 7 on page 98 (To add a Secondary line while a Primary line is running, without Drug Library), and continue programming from there.
- **Diluent only** (e.g., 10 mL): proceed to Step 7 on page 98 (To add a Secondary line while a Primary line is running, without Drug Library), and continue programming from there.
- **Partial concentration:** the Drug Amount and/or Diluent Volume are/is missing. The screen/s of the missing value/s will appear:
 - From the Drug Amount screen, using the keypad, enter the Drug Amount → **OK**.
 - From the Diluent Volume screen, using the keypad, enter the Diluent Volume → **OK**.

From the Attention screen, confirm the concentration and press **OK**.

Proceed to Step 7 on page 98 (To add a Secondary line while a Primary line is running, without Drug Library), and continue programming from there.

- **Full concentration:**

Proceed to Step 7 on page 98 (To add a Secondary line while a Primary line is running, without Drug Library), and continue programming from there.

If a list of available drug profiles does not appear, continue to Step 7 on page 98 (To add a Secondary line while a Primary line is running, without Drug Library), and continue programming from there.

For more information about the Drug Library, refer to [Chapter 9: Drug Library](#) on page 160.

Switching between Primary and Secondary Infusions

Switching between infusions involves pausing the infusion that is currently running, and then starting or continuing the other infusion.

> To switch from the Primary to the Secondary infusion:

1. Pause the Primary infusion:
From the toolbar of the Primary screen, press **Request Pause**. Then, from the Attention screen, press **OK**.
Alternatively, press the **Stop** hard key.
2. From the toolbar of the Primary screen, select **Switch or Continue**.
3. From the Start screen, select **Start secondary**.
The Attention screen appears. After verifying that the clamps on the Secondary administration set are open, press **OK**. The Secondary screen appears, and the Secondary infusion begins.

> To switch from the Secondary to the Primary infusion:

1. Pause the Secondary infusion:
From the toolbar of the Secondary screen, press **Request Pause**. Then, from the Attention screen, press **OK**.
Alternatively, press the **Stop** hard key.
2. From the toolbar of the Secondary screen, select **Switch or Continue**.
3. From the Start screen, select **Continue primary (or Start primary)**.
The Attention screen appears. After verifying that the clamps on the Secondary administration set are closed, and that the clamps on the primary set are open, press **OK**. The Primary screen appears, and the Primary infusion begins.

Replacing the Current Secondary Line

During a running secondary infusion, the secondary line can be replaced by using one of the following methods:

Deleting the Current Secondary Line and Moving to the Primary Infusion	102
Replacing the Current Secondary Line with a New Secondary Line	103

Deleting the Current Secondary Line and Moving to the Primary Infusion

The following procedure explains how to delete the running secondary line and move to the primary infusion.

> To delete the secondary line and move to the primary infusion:

1. Pause the Secondary infusion:
From the toolbar of the Secondary screen, press **Request Pause**. Then, from the Attention screen, press **OK**.
Alternatively, press the **Stop** hard key.
2. From the toolbar of the paused screen, press **View/Edit**.
3. On the View/Edit screen, select **Delete/Replace Sec. Line**.
4. On the Delete/Replace screen, select **Delete and move to primary**.
5. The Attention screen appears. After verifying that the clamps on the Secondary administration set are closed, and that the clamps on the primary set are open, press **OK**. This will delete the current programmed secondary line.
The paused Primary screen appears.
6. From the toolbar of the paused Primary screen, select **Request Continue**.
Then, from the Attention screen, press **OK**.



If you want to program a new Secondary line, refer to [Adding a Secondary Line](#) on page 97.

Replacing the Current Secondary Line with a New Secondary Line

The following procedure explains how to replace the current secondary line with a different secondary infusion.



Before programming a Secondary infusion, verify that the administration set you are using is appropriate for Secondary (Piggyback) infusions. For more information, refer to [Q Core Approved Administration Sets](#) on page 48.

> To replace the running secondary line with a different secondary line without Drug Library:

1. Pause the Secondary infusion:
From the toolbar of the Secondary screen, press **Request Pause**. Then, from the Attention screen, press **OK**.
Alternatively, press the **Stop** hard key.
2. From the toolbar of the paused screen, press **View/Edit**.
3. On the View/Edit screen, select **Delete/Replace Sec. Line**.
4. On the Delete/Replace screen, select **Replace secondary**.
5. From the Attention screen press **OK** to delete the current secondary line and to program a different secondary infusion.
6. Proceed to Step 3 on page 97 ([To add a Secondary line while a Primary line is running, without Drug Library](#)).

> To replace the running secondary line with a different secondary line with Drug Library:

1. Pause the Secondary infusion:
From the toolbar of the Secondary screen, press **Request Pause**. Then, from the Attention screen, press **OK**.
Alternatively, press the **Stop** hard key.
2. From the toolbar of the paused screen, press **View/Edit**.
3. On the View/Edit screen, select **Delete/Replace Sec. Line**.
4. On the Delete/Replace screen, select **Replace secondary**.
5. From the Attention screen press **OK** to delete the current secondary line and to program a different secondary infusion.
6. Proceed to Step 3 on page 99 (To add a Secondary line while a Primary line is running, with a Drug Library).

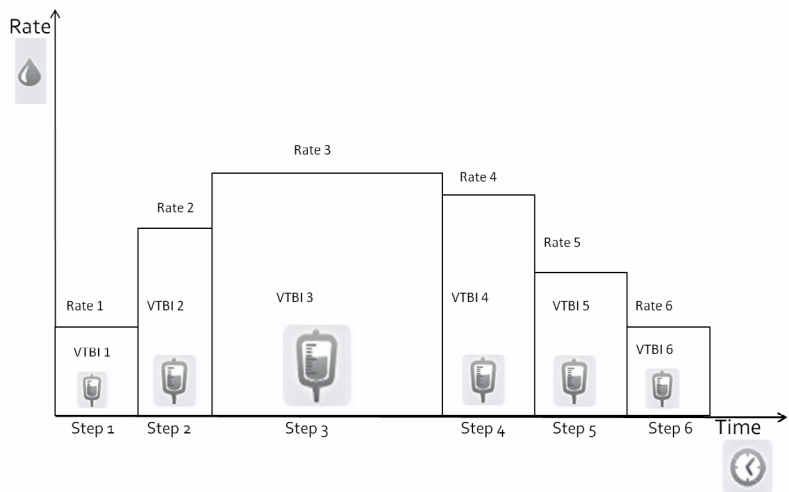
Multi-step Mode

The following sections will be reviewed:

Infusion Parameters: Multi-step Mode	106
Starting a Multi-step Infusion	106
Multi-step Mode: Mid-infusion Actions	112

This mode allows the pump to deliver a series of up to 25 consecutive infusion Steps from the same infusion container. Each Step is delivered as a Continuous infusion, at its own pre-programmed parameters. Although the infusion rates of each Step can differ, the rate within a single Step does not vary (constant, continuous infusion).

Figure 5.3. Multi-step Flow Profile



Infusion Parameters: Multi-step Mode

When programming a Multi-step infusion, the number of Steps must be specified. Infusion parameters relevant to each Step are listed in the following table. During programming, it is necessary to specify two of the three parameters. The remaining parameter is then automatically calculated by the pump.

Parameter	Description/Notes
Rate	The speed at which the fluid is infused. Rate values can range from 0.1 to 999 mL/h. Note: When selecting units that are not from the mL/h family, the word Rate is replaced with Dose Rate .
VTBI	The total amount of fluid to be infused. The remaining VTBI is displayed on the screen as the infusion progresses. VTBI values can range from 0.1 to 9999 mL.
Time	The period of time over which the fluid is infused. The acceptable range for time values vary according to the VTBI. The maximum Step time is 24 hours.

Starting a Multi-step Infusion

The following procedure explains how to program the pump to start a new Multi-step infusion.



If relevant, you may skip programming by using the Repeat Last Infusion or PreSet programs procedures to begin the infusion. For more information, refer to [Starting New Infusions: Shortcuts](#) on page 114. To restart infusion by adding VTBI during post infusion, refer to [Restarting the Infusion during the Post Infusion State](#) on page 124.

> To begin a new Multi-step infusion without Drug Library:

1. From the Indicators Bar, verify that the pump is in Multi-step mode.



For more information about changing delivery modes, refer to [Selecting Delivery Mode](#) on page 56.

2. From the Start Up screen, select **New Infusion**.
3. If the Dosing method screen appears, select the appropriate option:
 - **mL:** Continue to Step 7.
 - **Dose calculation:** Continue to Step 4.Weight based units are available for both Dosing methods.
Otherwise, continue to Step 10.
4. From the Concentration units screen, select the appropriate drug units.



To display additional concentration units press **Next**.

5. According to pump configuration one of the following screens will appear:
 - **Concentration:** From the Concentration screen, using the keypad, enter the Concentration → **OK**. Then, continue to Step 7.
 - **Drug amount:** Using the keypad, enter the Drug Amount → **OK**. Then, using the keypad, enter the Diluent Volume → **OK**. Then, continue to Step 6.
6. From the Attention screen, confirm the concentration and press **OK**.
If the selected drug unit is Million Units, continue to Step 9.
7. If the Patient Weight screen appears, specify whether the infusion is weight based:
 - **Yes:** Continue to Step 8.
 - **No:** Continue to Step 9.
8. From the Patient Weight screen, using the keypad, enter the Patient Weight → **OK**.
9. From the Dose Rate units screen, select the appropriate dose rate units.
10. Using the keypad, enter the number of Steps required for the infusion, and then press **OK**.
11. For the first Step, program 2 of the following 3 parameters, by selecting the relevant boxes (the digit refers to the number of the Step):
 - **Rate 1:** Using the keypad, enter the value → **OK**.
 - **VTBI 1:** Using the keypad, enter the value → **OK**.

- **Time 1:** Using the keypad, enter the value → **OK**.

The unprogrammed parameter is then automatically calculated by the pump, and displayed in the relevant box.



If the dose rate is beyond the pump resolution of 0.1 mL/h increments, the pump will increase or decrease the rate by up to 0.05 mL/h. This flow rate (mL/h) is presented on the running screen during infusion.

12. After reviewing the infusion parameters for the current Step (as displayed on the Indicators Bar), press **OK** to proceed and program the next Step.
13. To program parameters for the remaining Steps of the infusion, repeat Step 11 through Step 12 of this procedure.

After the final Step is programmed, the Confirm screen appears, displaying the following parameters:

- **Total VTBI:** Amount of fluid to be delivered during the entire infusion.
- **Total time:** Time period of the entire infusion.
- **Number of steps:** Number of Steps making up the total infusion.
- **Review Steps details:** Selecting this option displays the parameters of all programmed Steps, screen by screen (with each step displayed in its own screen).

14. Review the parameters displayed on the Confirm screen.



Verify that the parameters reflect the correct treatment according to the prescription.

Then, press **OK**.

15. Make sure that the clamps on the administration set are open; then, press **Start**.
The Running screen is displayed, and the infusion begins.

Throughout the infusion, the current Step number is displayed on the Indicators Bar (e.g., Running 1/6) and next to parameter on main display (Rate 1, VTBI 1 and Time 1). The transition between steps is accompanied by a beep. In addition, the following information appears on the screen:

- **Drug Name:** The name of the selected drug. Displayed on the indicators bar, instead of the step number, when working with a Drug Library.
- **Drug Concentration:** Drug concentration as entered by the user (Final concentration or Drug Amount / Diluent Volume). Displayed when applicable.
- **Rate:** Current infusion rate. For all dose units other than mL/h, the calculated rate will be displayed in mL/h, both in the View System menu and in the Running screen.
- **VTBI:** Total volume left to be infused during the current Step.
- **VI / Total:** Total volume (including KVO if applied during a delayed start period) / the total VTBI (for the entire infusion). As the infusion progresses, the VI increases, and the Total remains constant.
- **Time left:** Time remaining until the end of the entire infusion.
- **Step Time:** Time remaining until the end of the current Step.



When the remaining VTBI is 0.1 mL or less, the time left displayed on the screen may deviate up to a few minutes from the actual time remaining.



To view all programmed parameters of the current infusion, including the rate in mL/h, from the Running screen, press **View/Edit → View system → Infusion values**.
For more information, refer to [Viewing System Parameters](#) on page 139.

> **To begin a new Multi-step infusion with a Drug Library:**

1. From the Indicators Bar, verify that the pump is in Multi-step delivery mode.



For more information about changing delivery modes, refer to [Selecting Delivery Mode](#) on page 56.

2. From the Start Up screen, select **New Infusion**.
3. From the Drug Name screen:
 - Using the keypad, enter the drug name, then press **Find** and proceed to Step 4.



The **Find** key can be used to display all available drugs when not entering any characters (letters, numbers or symbols), or filter drug names according to the characters entered.

- When the required drug is not found in the Drug Library, press **Choose General** key on the toolbar:



'Choose General' will bypass specific drug limits, and the infusion will be programmed without Drug Library limits.

From the Attention screen, confirm Choosing General, and press **OK**. Proceed to Step 3 on page 107 ([To begin a new Multi-step infusion without Drug Library](#)), and continue programming from there.

4. From the Drug List screen, select the row of the relevant drug.



To display additional drugs press **Next**.

5. If a list of available drug profiles appears, select the appropriate drug profile and proceed according to the step directed to:
- **No concentration:** proceed to Step 7 on page 107 (To begin a new Multi-step infusion without Drug Library), and continue programming from there.
 - **Diluent only** (e.g., 10 mL): proceed to Step 7 on page 107 (To begin a new Multi-step infusion without Drug Library), and continue programming from there.
 - **Partial concentration:** the Drug Amount and/or Diluent Volume are/is missing. The screen for the missing value will appear:
 - From the Drug Amount screen, using the keypad, enter the Drug Amount → **OK**.
 - From the Diluent Volume screen, using the keypad, enter the Diluent Volume → **OK**.

From the Attention screen, confirm the concentration and press **OK**.

Proceed to Step 7 on page 107 (To begin a new Multi-step infusion without Drug Library), and continue programming from there.

- **Full concentration:**

Proceed to Step 7 on page 107 (To begin a new Multi-step infusion without Drug Library), and continue programming from there.

If a list of available drug profiles does not appear, continue to Step 7 on page 107 (To begin a new Multi-step infusion without Drug Library), and continue programming from there.

For more information about the Drug Library, refer to [Chapter 9: Drug Library](#) on page 160.

Multi-step Mode: Mid-infusion Actions

The following actions can be performed during Multi-step infusions:

Updating Step Parameters	112
Pausing Infusions	118
Aborting Infusions	120
Locking the Screen	122
Activating Patient Lockout	122

Updating Step Parameters

Infusion parameters for the current Step can be modified directly from the Running screen. In addition, infusion parameters for the current Step and the following Step can be updated by using the **View/Edit** function key.



Parameters for only the current Step and the Step immediately following it can be modified.



If the step being updated ends before the change is made or confirmed, the change will not be made and an Attention screen will appear.

> To update current Step parameters from the Running screen:

1. Select the frame of the parameter that you want to update (Rate, VTBI or Step Time).
2. Using the keypad, enter the new rate, VTBI (during the Step), or time remaining until the end of the Step → **OK**.
3. To confirm and save changes, press **OK**.
To return to the original infusion screen without saving changes, press **Back**.

> To update parameters of the current or next Step using the View/Edit function key:

1. From the toolbar, press **View/Edit**.
2. Select the box of the relevant parameter.
3. Using the keypad, enter the new value of the parameter → **OK**.
4. To update other parameters, repeat Steps 2-3.

In addition to parameter changes, the following actions are also available:

- **Clear Accum. VI:** Resets the total volume infused via all infusions associated with the current patient to 0 mL. For more information, refer to [Clearing Accumulated VI](#) on page 157.
- **Next step:** Allows you to update infusion parameters of the Step following the current Step. (This box appears only if there is a Step following the current Step.)
- **View system:** Displays various system and pump parameters.

5. To confirm and save changes, press **OK**.

To return to the Running screen without saving changes, press **Back**.
Then, from the Attention screen, press **OK**.



If the dose rate is beyond the pump resolution of 0.1mL/h increments, the pump will increase or decrease the rate by up to 0.05mL/h. This flow rate (mL/h) is presented on the running screen during infusion.

Chapter 6: Basic Infusion Operations

The following sections explain procedures and actions that are commonly performed in all delivery modes to start and manage infusions:

Starting New Infusions: Shortcuts	114
Resuming Infusions After Pump Shutdown	117
Mid- and Post Infusion Actions	118

Starting New Infusions: Shortcuts

The following shortcut operations allow you to begin an infusion without the need to enter required parameters:

Repeating Last Infusion	114
Using a PreSet Program	115

Repeating Last Infusion

Repeat Last Infusion is a quick method to continue the infusion with a new IV bag, after the first one has been emptied or discontinued (the same infusion parameters used for the same patient). The pump automatically saves all the parameters programmed, excluding secondary line, for the last infusion performed in that delivery mode. If a parameter is updated while an infusion is running, the updated parameter is saved. The Last Infusion settings are saved even if the last infusion was not completed or the pump has been turned Off. The Repeat Last Infusion option may be available only if it is enabled on the pump.



When using the Repeat Last Infusion option, the **Accumulated VI** parameter and the remaining **Lockout Time** are not cleared; instead they continue counting from the previous infusion. For more information about Accumulated VI, refer to [Using the New Patient Feature](#) on page 155.



Information about Secondary (Piggyback) infusions is not saved. This option is not relevant to Secondary infusions.



Repeat Last Infusion is not available (grayed out) when the pump settings differ from those used for the previous infusion. These include: CCA, regional settings, and the flow rate of the previous infusion exceeding the current hard limit. Additionally, it is not available for an infusion in which Add VTBI was used.

> To repeat the last infusion:

1. From the Start Up screen, select **Repeat Last Infusion**.
2. Review the parameters displayed on the Confirm screen.



Verify that the parameters reflect the correct treatment according to the prescription.

Then, press **OK**.

3. To begin the infusion, make sure that the clamps on the administration set are open, and press **Start**.

The Running screen appears, and the infusion begins.

Using a PreSet Program

The PreSet Programs function allows you to select an infusion with predefined parameters. Each delivery mode can support up to 10 PreSet programs. PreSet programs are available only in the delivery mode in which they were saved.



This feature is available when the ICU Medical MedNet™ Drug Library is not used. When not under the ICU Medical MedNet™ Drug Library, in order for the PreSet Programs function to appear in the Start Up screen, the pump needs to be configured to the Allow PreProgram setting. For more information, refer to [Configuring General Settings](#) on page 132.

> To start an infusion using the PreSet Programs function:

1. From the Start Up screen, select **PreSet Programs**.



If no PreSet program was saved in the current delivery mode, a blank screen appears.
For more information about adding or modifying a program, refer to [Creating and Editing PreSet Programs](#) on page 148.

2. Select the row of the desired program.



To display additional programs, press **Next**.

3. Review the parameters that are displayed.



Verify that the parameters reflect the correct treatment according to the prescription.

Then, press **OK**.

4. To begin the infusion, make sure that the clamps on the administration set are open, and press **Start**.

The Running screen appears, and the infusion begins.

Resuming Infusions After Pump Shutdown

When the pump is turned Off during an active infusion (running or paused), the option to resume the previous infusion will be displayed after the pump is turned On:

- **To resume the infusion:** on the Attention screen, press **OK**. The running screen appears.



The option to resume will not be available if the pump was shut down due to a critical alarm, or if the infusion was quit.

- **To abort the previous infusion:** on the Attention screen, press **Exit**. The Start Up screen appears.



When a Drug Library is loaded on the pump, the Clinical Care Area screen appears. The user can either accept or change the current CCA. For more information, refer to [Clinical Care Area \(CCA\)](#) on page 161.

Mid- and Post Infusion Actions

The following sections describe procedures that are commonly performed during an infusion:

Pausing Infusions	118
Infusion Standby	119
Aborting Infusions	120
Locking the Screen	122
Activating Patient Lockout	122
Ending an Infusion	123
Restarting the Infusion during the Post Infusion State	124

Pausing Infusions

The Pause function allows you to temporarily stop an infusion. Infusions can be paused using either the **Request Pause** function key, or, in an emergency, the **Stop** hard key. A message stating that the infusion has been paused appears 30 seconds after pausing the infusion (audible and visual).



Pressing the **Stop** hard key stops the infusion immediately, bypassing the need for confirmation of the Pause action. In an emergency, it is recommended to pause the infusion using the **Stop** hard key. In routine situations, using the **Request Pause** function key is recommended.



Turning the pump Off after pausing the infusion allows the user to resume this infusion after turning the pump back on.

> To pause an infusion using the Stop hard key:

- At the bottom of the pump, press **Stop**. The infusion is paused.



When the Patient Lockout or Lock Screen features are activated, it is necessary to confirm pausing from the Attention screen, by pressing **OK**.

> **To pause an infusion using the Request Pause function key:**

1. From the toolbar, press **Request Pause**.
2. From the toolbar of the Attention screen, press **OK**.
3. The infusion is paused.



If you do not press **OK** within 30 seconds, the infusion is not paused, and the Running screen reappears.

> **To resume a paused infusion:**

1. From the toolbar, press **Request Continue**.
2. From the toolbar of the Attention screen, press **OK**.

Infusion Standby

The Standby function allows you to temporarily stop the current infusion without being alerted for pump inactivity (up to 72 hours). The Standby option is available from the View/Edit menu during an active (running or paused) infusion.

Infusion parameters may be edited during Standby.

> **To enter the Standby mode during an infusion:**

1. From the toolbar of the infusion screen, press **View/Edit**.
2. From the toolbar of the View/Edit screen, press **Standby**.
3. From the toolbar of the Attention screen, press **OK**.
The infusion is paused, until it is resumed manually (see [To resume a paused infusion](#) above).



If the pump is turned Off during Standby for less than 72 hours, when it is turned On again, the option to resume the infusion will be available. For more information, refer to [Resuming Infusions After Pump Shutdown](#) on page 117.

> **To continue infusion from standby mode:**

1. From the toolbar press **End Standby**.
The Pause screen appears.
2. To continue infusion, press **Request continue**.
3. From the Attention screen, press **OK**.

> **To abort infusion from the Standby mode:**

1. From the toolbar, press **End Standby**.
The Pause screen appears.
2. From the toolbar, press **Quit**.
3. In the Attention screen, press **Quit Infusion**.

Aborting Infusions

Aborting an infusion is performed using one of the following methods:

- **Pausing and then quitting the infusion:** Returns the pump to the Start Up screen. Resuming the infusion after quitting is impossible.
- **Turning off the pump:** Turns the pump Off mid-infusion, using the **On/Off** hard key.

When the pump is turned Off mid-infusion, the infusion parameters are saved. When the pump is turned back On, the user is prompted to indicate whether or not to continue the stopped infusion.



In an emergency situation, it is recommended to press and hold the **ON/OFF** hard key for 5 consecutive seconds. This turns the pump Off, bypassing the need to confirm the action.

> **To pause and then quit an infusion:**

1. At the bottom of the pump, press the **Stop** hard key.
2. From the toolbar, press **Quit**.

3. From the toolbar of the Attention screen, press **Quit Infusion**.



Resuming infusion after quitting will not be possible.



When a Drug Library is loaded on the pump, the Clinical Care Area screen appears. The user can either accept or change the current CCA. For more information, refer to [Clinical Care Area \(CCA\)](#) on page 161.

> To turn Off the pump:

1. At the bottom of the pump, press the **ON/OFF** hard key.



If a rate of <1 mL/h was used, the pump will prompt the user to take the administration cassette out of the pump before turning the pump Off.

2. From the toolbar, press **Off**.

Pressing and holding the **ON/OFF** hard key for 5 consecutive seconds turns the pump Off (bypassing the need for confirmation).



If a Drug Library update or a Software update is available for installation, the user is prompted to update or turn Off the pump without updating.



In case of emergency, when Patient Lockout or Lock Screen is activated ([Activating Patient Lockout](#) on page 122), the user must press and hold **ON/OFF** for 5 seconds to turn the pump Off, or unlock the pump before turning it Off.

Locking the Screen

Locking the display screen prevents inadvertent and unintentional changes to settings, by disabling the functionality of the touch screen. For safety, it is recommended to lock the screen while an infusion is running.

> To lock the screen:

1. From the toolbar of the Running screen, press **Lock**.
2. On the Lock options screen, select **Lock Screen**.

The > icons on the Main Display and the toolbar function keys disappear. Only the **Press to Unlock Screen** function key appears on the toolbar.

> To unlock the screen:

1. From the toolbar, press **Press to Unlock Screen**.
2. From the toolbar of the Attention screen, press **OK**.

Activating Patient Lockout

The Patient Lockout feature prevents unauthorized personnel from modifying pump and infusion settings. In this state, only limited features are available. A password is required to unlock the pump.



During Patient Lockout or screen lock, the **Request Pause** function key is not available. Pause the infusion by pressing the **Stop** hard key. (Refer to [To pause an infusion using the Stop hard key](#) on page 118.)

To turn the pump Off, press and hold the **ON/OFF** hard key for 5 consecutive seconds.

> To activate Patient Lockout:

1. From the toolbar of the Running screen, press **Lock**.
2. On the Lock options screen, select **Patient lockout**.

> To release Patient Lockout:

1. From the toolbar, press **Press to Unlock Patient**.
2. Using the keypad, enter the relevant password and press **OK**.

Ending an Infusion

When the infusion is complete (entire programmed VTBI delivered), the pump automatically applies the post infusion rate – KVO or Rate – and displays the infusion summary:

- **VI** – Volume Infused for the currently completed infusion. If the Accumulated VI has been cleared during this infusion, VI presents the volume infused from that time on.
- **Rate** – the rate at which the infusion was delivered.
- **Total time** – the total time of the infusion.

The Post Infusion Rate is either KVO or Rate, according to the pump setting. The default KVO is set by an Authorized technician. When KVO is applied, the pump delivers at the KVO default rate, or the current infusion rate, the lower of the two. If Post Infusion Rate is not 0 mL/h. the Post Infusion screen will be displayed once the message is dismissed.

> To view the Post Infusion screen:

1. From the toolbar of the Message screen, press **Mute → OK**.

> To discontinue the Post Infusion and the infusion:

1. From the toolbar of the Message screen, press **Mute → OK**.
2. From the toolbar of the Post Infusion screen, press **Quit**.



When a Drug Library is loaded and CCA was changed during the previous running infusion, an Attention screen appears, asking to confirm the new CCA. For more information, refer to [Clinical Care Area \(CCA\)](#) on page 161.

Restarting the Infusion during the Post Infusion State

During Post Infusion, it is possible to restart the same infusion by adding VTBI, or by quitting and selecting Repeat Last Infusion. Note that using the Add VTBI option during a Post Infusion will disable the Repeat Last Infusion option.

> To add VTBI directly from the Post Infusion screen:

1. On the Main Display, select **VTBI**.
2. Using the keypad, enter the new **VTBI** → **OK**.



The infusion rate is automatically retained from the current infusion.

3. To update another parameter, select it from the View/edit and update its value using the keypad.
4. Review all infusion parameters and press **OK** to confirm the infusion program. The Running screen appears.

> To add VTBI using the View/Edit function key:

1. From the toolbar, press **View/Edit**.
2. Select **Add VTBI**.
3. Using the keypad, enter the new value of the **VTBI** → **OK**.



The infusion rate is automatically retained from the current infusion.

4. To update another parameter, select it from the View/edit and update its value using the keypad.
5. Review all infusion parameters and press **OK** to confirm the infusion program. The Running screen appears.

> To restart the infusion from the Start Up screen:

1. From the Start Up screen, select **Repeat Last Infusion**.
2. Review the parameters displayed on the confirmation screen.



Verify that the parameters reflect the correct treatment according to the prescription.

Then, press **OK**.

3. To begin infusion, make sure the clamps on the administration set are open, and press **Start**.

The running screen appears, and the infusion begins.

Chapter 7: Options Menu: Configuring, Viewing and Testing

The following sections describe configuring settings, testing elements, and viewing system data using the Options menu:

Main Options: Overview	126
Setting Delivery Mode	127
Managing Configuration Settings	128

Main Options: Overview

The Options screen provides access to configurable pump settings, testing modes, and system data. The screen is displayed by pressing the **Options** function key, on the toolbar of the Start Up screen.

The Options screen allows access to all configurations and settings of the SapphirePlus pump (as opposed to settings relevant to a specific infusion). The screen also provides access to testing components and viewing pump (as opposed to infusion) parameters (e.g., System parameters Event logs).



The Options function key is not available during an infusion. Some of the configuration and information accessed from the Options menu is also accessible during infusion via the ViewSystem menu.

Setting Delivery Mode

The SapphirePlus pump is a multi-platform device that has the ability to operate in several different modes. Each delivery mode features its own unique options. The current mode is displayed at the right side of the Indicators Bar.

Setting the delivery mode is done using the Options menu. An authorization code of High or Technician is required to modify the delivery mode.



When you change the delivery mode, the pump reverts to the default values for the newly selected mode.

> To change the delivery mode:

1. From the toolbar, press **Options**.
2. From the Options screen, select **Delivery mode**.
3. Using the keypad, enter the required password, and then press **OK**.
4. Select the relevant delivery mode.

The Start Up screen of the selected mode appears.

Managing Configuration Settings

The following sections describe how to view and update pump configuration settings:

Managing Alarm Settings	128
Configuring Audio Settings	131
Configuring General Settings	132
Defining Regional Parameters	135
Testing System Function	137
View Menu	138



When a drug library is loaded to the pump, local configurations made on the pump remain valid until the user selects a CCA or turns the pump Off. For more information refer to [Chapter 9: Drug Library](#) on page 160.

Managing Alarm Settings


The Alarms menu allows you to view and modify alarm-related options. Only users with authorization levels of High or Technician have access to this menu.

> **To access the Alarms menu:**

- From the toolbar of the Start Up screen, select **Options**. Then, select **Pump configuration** → **Alarms**.

Option	Descriptions/Notes	To Modify Parameter (from the Alarms screen)
Occlusion units	The format of occlusion units (BAR, PSI or mmHg).	Select Occlusion units . Then, select BAR, PSI or mmHg .

Option	Descriptions/Notes	To Modify Parameter (from the Alarms screen)
Occlusion pressure	The minimum downstream pressure that triggers an Occlusion alarm. Acceptable ranges are 5.8 to 17.4 PSI, 0.4 to 1.2 BAR or 300 to 900 mmHg. An alarm sounds when the downstream pressure reaches the set value \pm the sensor sensitivity level.	Select Occlusion pressure . Then, using the keypad, enter the desired value → OK .
Pump unattended	The number of consecutive minutes of no interaction with the pump after which a Pump Unattended alarm is triggered. Options are 2, 5 or 10 minutes. Note: A Pump Unattended alarm is not triggered when the pump is in Delayed start or Standby.	Select Pump unattended . Then, select 2 min, 5 min or 10 min .
Infusion near end	The number of minutes before completion of an infusion at which an Infusion Near End alarm is generated.	Select Infusion near end . Then, select 1 min, 3 min, 5 min, 10 min or Off .

Option	Descriptions/Notes	To Modify Parameter (from the Alarms screen)
Alarm volume	<p>Sets the speaker volume for the auditory alarm signal. Options are Maximum or Minimum.</p> <p>When the option is set to Minimum, messages are provided with a visual signal only. Alarm levels 1, 2 and 3, and the 'Infusion Complete' message are provided with a visual signal and the lowest auditory signal permitted, according to IEC 60601-1-8.</p> <p>Maximum alarm volume is 65 dB.</p> <p>Minimum alarm volume is 45 dB.</p> <p>Note: Auditory alarm signal sound levels, which are less than ambient levels, can impede operator recognition of alarm conditions.</p> <p>For more information about messages and alarms, refer to Chapter 10: Alarms and Troubleshooting on page 170.</p>	<p>Select Alarm volume. Then, select Maximum or Minimum.</p>
	<p>An Occlusion Auto-restart option exists and is available for configuration by authorized technicians only. This option allows the pump to restart the infusion automatically provided the occlusion was cleared.</p> <p>If the occlusion is not cleared within 40 seconds, or the user chooses to exit the process, or the user chose to exit the process, the downstream occlusion alarm is activated (appears within a few seconds). (appears within a few seconds) An Occlusion Auto-restart can occur up to 5 times in one hour.</p>	

Configuring Audio Settings

The Audio settings menu allows you to view and modify audio-related pump settings. Only users with authorization levels of High or Technician have access to this menu.

> To access the Audio settings menu:

- From the toolbar of the Start Up screen, select **Options**. Then, select **Pump configuration** → **Audio settings**.

Option	Descriptions/Notes	To Modify Parameter (from the General settings screen)
Keys volume	Sets the speaker volume for the auditory signal generated when users select functions and press keys on the pump.	Select Keys volume . Then, select Low , High or Off .
Alarm volume	Sets the speaker volume for the auditory alarm signal. Options are Maximum or Minimum. When the option is set to Minimum, messages are provided with a visual signal only. Alarm levels 1, 2 and 3, and the 'Infusion Complete' message are provided with a visual signal and the lowest auditory signal permitted, according to IEC 60601-1-8. Maximum alarm volume is 65 dB. Minimum alarm volume is 45 dB. Note: Auditory alarm signal sound levels, which are less than ambient levels, can impede operator recognition of alarm conditions. For more information about messages and alarms, refer to Chapter 10: Alarms and Troubleshooting on page 170.	Select Alarm volume . Then, select Maximum or Minimum .

Configuring General Settings

The General settings menu allows you to view basic pump settings, and modify them according to clinical requirements. Only users with authorization levels of High or Technician have access to this menu.

> To access the General settings menu:

- From the toolbar of the Start Up screen, select **Options**. Then, select **Pump configuration** → **General settings**.

Option	Descriptions/Notes	To Modify Parameter (from the General settings screen)
Current CCA	Used to select the CCA to which the pump should be set. Appears only when Drug Library is loaded. For more information, refer to Clinical Care Area (CCA) on page 161.	Select Current CCA . Choose the appropriate CCA; then, from the Attention screen press OK .
Start Up config.	Sets the configuration of the Start Up screen. For more information, refer to Start Up Configuration Menu on page 135.	Refer to Start Up Configuration Menu on page 135.
Authorization level	Sets the authorization lock level of the pump. For more information, refer to Managing Authorization Levels on page 144.	Select Authorization level . Then, enter a password and select Low , Medium , High or Tech .
Set Delay	Enables users to start or continue an infusion at a later time. The user may either define a specific delay period, or set the pump to Standby. For more information, refer to Using the Set Delay Feature on page 151.	Select the Set Delay row, to toggle the option between On and Off .
Set prime volume	The amount of fluid used to prime the administration set when automatic priming is performed. The acceptable range is 2 to 25 mL.	Select Set prime volume . Then, using the keypad, enter the desired value → OK .

Option	Descriptions/Notes	To Modify Parameter (from the General settings screen)
Backlight	Allows the user to set the degree of screen brightness for a running infusion. Backlight can also be modified during a running infusion. The Off and Partial options of this feature save power and promote longer battery life.	Select Backlight . Then, select On , Off or Partial .
Post Infusion Rate	Sets the rate that is applied at the end of infusion to KVO, or to continue at the current infusion rate. When KVO is selected, the rate applied is the default KVO rate set by an Authorized technician.	Select the Post Infusion Rate row. Then, select KVO or Rate .
Prime Reminder	Enables a reminder for the user to prime the administration set before starting an infusion. For more information, refer to Automatic Priming Using the Pump on page 71.	Select the Prime Reminder row, to toggle the option between On and Off .
Advanced Bolus	Allows users to program a bolus by entering rate, amount and time. When this option is disabled, the bolus is programmed by amount only, and the rate is the default bolus rate. The option is available only when Allow Bolus is enabled (by a Technician authorization code). Applicable only for the Continuous delivery mode. For more information, refer to Administering a Bolus on page 92.	Select the Advanced Bolus row, to toggle the option between On and Off .

Option	Descriptions/Notes	To Modify Parameter (from the General settings screen)
Auto P. lockout	<p>Enables/disables Patient Lockout, a safety feature that requires password entry to make any parameter changes. When the option is enabled, Patient Lockout is activated automatically as the infusion begins (Activating Patient Lockout on page 122).</p>	<p>Select the Auto P. Lockout row, to toggle the option between On and Off.</p>
Screen Saver	<p>Enables/disables a far-view display of the main infusion parameters during Standby or a running infusion. These include drug information, delivery mode (color indication), infusion rate, and the phase (dose, continuous rate etc.). The screen saver appears 30 seconds after the infusion program has started, and the pump has not been touched.</p> <p>The screen saver will not appear in the following cases: Delayed start, Post Infusion, or during a Bolus delivery. The screen saver will disappear in the following cases:</p> <ul style="list-style-type: none"> • Alarm – screen will revert to the alarm screen • Touching the screen – screen will revert to the Running screen • Infusion is paused – screen will revert to the Paused screen. 	<p>Select the Screen Saver row, to toggle the option between On and Off.</p>

Start Up Configuration Menu

> To access the Start Up Configuration menu:

1. From the toolbar of the Start Up screen, select **Options**. Then, select **Pump configuration** → **General settings** → **Start Up Config**

Option	Descriptions/Notes	To Modify Parameter (from the StartUp Config. screen)
Repeat last infusion	Allows the user to start infusions, using the same infusion parameters for the same patient. When the option is enabled, the Repeat Last Infusion button appears on the pump Start screen. For more information, refer to Repeating Last Infusion on page 114.	Select the Repeat Last Infusion row, to toggle the option between On and Off .
PreProgram	Allows the user to start an infusion using predefined infusion parameters. When the option is enabled, the PreSet Programs button appears on the pump Start Up screen. For more information, refer to Creating and Editing PreSet Programs on page 148.	Select the PreProgram row, to toggle the option between On and Off .

Defining Regional Parameters

The Regional menu controls date, time, language and US format settings. Only users with authorization levels of High or Technician have access to this menu. When SapphirePlus is connected to ICU Medical MedNet™, the date and time are set by the ICU Medical MedNet™ server and can't be changed manually on the pump.

> To access the Regional menu:

- From the toolbar of the Start Up screen, select **Options**. Then, select **Pump configuration** → **Regional**.

The following procedures explain how to configure settings from the Regional menu.

> **To set the date:**

1. Select the **Date** frame.
2. Using the keyboard, enter values (2 digits each) for the day, month, and year. (When US format is set, the order is month, day, and year.)
3. To confirm the new settings, press **OK**.

> **To set the time:**

1. Select the **Time** frame.
2. Using the keyboard, enter values (2 digits each) for the hour and the minute.
3. If necessary, switch the time units from AM to PM or vice versa, by pressing the **AM/PM** function key. (This step is relevant only when U.S. format is set.)
4. To confirm the new settings, press **OK**.

> **To set the language:**

1. Select the **Language** frame.
2. Select the desired language.



In some pumps, only the default language is listed.

3. To confirm the new settings, press **OK**.

> **To set the US format:**

1. Select the **US format** frame.
2. Toggle the settings between **On** and **Off**
3. To confirm the new settings, press **OK**.



The date will appear in month/day/year format and time will appear 12 hour format (am/pm) when this setting is toggled On.

Testing System Function

The Test system menu allows you to test basic system functionalities. Only users with authorization levels of High or Technician have access to this menu.

> To access the Test system menu:

- From the toolbar of the Start Up screen, select **Options**. Then, select **Pump configuration** → **Test system**.

Option	Descriptions/Notes
Speaker high	<ul style="list-style-type: none">• On: High volume auditory signal sounds.• Off: No auditory signal.
Speaker low	<ul style="list-style-type: none">• On: Low volume auditory signal sounds.• Off: No auditory signal.
Alarm LED	<ul style="list-style-type: none">• On: The red (Alarm) LED is lit.• Off: The red (Alarm) LED is not lit.
Charge LED	<ul style="list-style-type: none">• On: The yellow (Charge) LED is lit.• Off: The yellow (Charge) LED is not lit.
Running LED	<ul style="list-style-type: none">• On: The green (Run) LED is lit.• Off: The green (Run) LED is not lit.
Door sensor	<ul style="list-style-type: none">• Closed: The safety door is closed.• Opened: The safety door is open.

View Menu

The View menu provides access to current pump settings and lists of events that are audited by the system. The main categories are:

Category	Description/Notes
View system	Provides a view of the current system settings, and allows updating selected settings. For more information, refer to Viewing System Parameters on page 139.
Event log	Provides a view of the events recorded by the system; such as authorization level change, programming infusion parameters, activated alarms etc. For more information, refer to Viewing the Event Log on page 142.

> To access the View menu from the Start Up screen:

1. From the toolbar of the Start Up screen, select **Options**.
2. On the Options screen, select **View**.

> To access the View system screen from the Running screen:

1. From the toolbar of the Running screen, select **View/Edit**.
2. From the toolbar of the View/Edit screen, select **View system**.

Viewing System Parameters

The View system screen allows you to view current system settings and infusion parameters, and update selected settings. You can navigate through the pages of settings, by pressing the **Next** and the **Back** function keys.

The following settings appear in all delivery modes:

Setting	Description/Notes
Infusion Values	Displays all the programmed parameters of the current infusion, including rate in mL/h. Applicable only on an active infusion, or during Standby. Pressing > displays the parameters.
Post Infusion	The rate applied when the infusion ends; KVO or Rate. The setting can be modified before infusion ends, when no drug library is used or no drug has been selected, by pressing >, and then selecting KVO or Rate. Within a drug library each drug is set with a specific post infusion option, which can only be viewed during a running infusion.
Alarm volume	The volume of the auditory alarm signal (Maximum or Minimum). The setting can be modified by pressing >, and then selecting a setting.
Occlusion	The level of downstream pressure that triggers an occlusion alarm. For more information, refer to Managing Alarm Settings on page 128. The setting can be modified by pressing >, entering a value using the keypad, and then pressing OK .
Authorization	Current authorization lock level. For more information, refer to Managing Authorization Levels on page 144. The setting can be modified by pressing >, selecting a setting, and then pressing OK . Password entry is required to change the authorization.
Current CCA	The current CCA, as pre-selected by the user, and used for the current infusion. Appears only when Drug Library is loaded. For more information, refer to Clinical Care Area (CCA) on page 161.

Setting	Description/Notes
Next CCA	<p>The next CCA appears only when the Drug Library is loaded, and the user changed the CCA during an infusion.</p> <p>Note: The next CCA will apply only after the infusion has ended. Applicable only during an active infusion, or during Standby. For more information refer to Clinical Care Area (CCA) on page 161.</p>
Backlight	<p>Current backlight settings. For more information refer to Configuring General Settings on page 132.</p> <p>The setting can be modified by pressing >; then selecting On, Partial or Off.</p>
Accumulated VI	<p>The cumulative volume infused (mL). The Accumulated VI can be cleared by pressing >. For more information, refer to Monitoring the Accumulated Volume Infused (Shift's Total) on page 156.</p>
Accum. Prim. VI	<p>The cumulative volume infused (mL) via the primary infusions. Appears in the View System menu only in the Continuous Delivery mode. For more information, refer to Monitoring the Accumulated Volume Infused (Shift's Total) on page 156.</p>
Accum. Sec. VI	<p>The cumulative volume infused (mL) via the secondary infusions. Appears in the View System menu only in the Continuous Delivery mode. For more information, refer to Monitoring the Accumulated Volume Infused (Shift's Total) on page 156.</p>
VI cleared date	<p>The date and time in which the Accumulated VI was last cleared. For more information, refer to Monitoring the Accumulated Volume Infused (Shift's Total) on page 156.</p>
VI cleared time	
Delivery mode	Current delivery mode.
Single Air detector	<p>These settings are associated with the amount of air that triggers an Air in Line alarm. These settings can be modified by Technicians only. For more information, refer to the Service Manual.</p> <p>Note: While a non-epidural infusion is running at a rate of 4 mL/h or lower, the Single air detector switches automatically On.</p>
Accumulated Air detector	
Accumulated Threshold	
Date	<p>Current date and time. For more information, refer to Defining Regional Parameters on page 135.</p>
Time	

Setting	Description/Notes
Software version	The software version loaded on the pump.
Drug Library name	The Drug Library name appears only if the pump is loaded with a Drug Library. For more information about the Drug Library, refer to Chapter 9: Drug Library on page 160.
Drug Library published date	The Drug Library published date appears only if the pump is loaded with a Drug Library. For more information about the Drug Library, refer to Chapter 9: Drug Library on page 160.
Serial number	Serial number of the pump.
Next Certification	Date that the pump is due for the next Certification. For more information refer to the Service Manual.
Set Prime Volume	The amount of fluid used to prime the administration set, when automatic priming is performed. The acceptable range is 2 to 25 mL.
Battery status	The approximate percentage of current battery charge. Possible values are 100%, 75%, 50%, 25%, and Low Batt.
KVO	The default KVO rate set for the current delivery mode. The parameter is not relevant to Intermittent or Epidural Intermittent mode (in which the KVO is equal to the KVO/continuous rate programmed for the infusion).
Bolus rate	The default bolus rate set for the current delivery mode. The parameter is not relevant to the Multi-step modes. In continuous mode, when the Advanced Bolus option is set to On, the bolus Amount, Rate and Time can be programmed by the user, and the bolus rate will not be displayed on the View System menu. Default bolus rate can be modified by Technicians only. For more information, refer to the Service Manual.
Secondary bolus rate	The default secondary bolus rate. This parameter is relevant only for the Continuous Delivery mode. When the Advanced Bolus option is set to On, the bolus Amount, Rate and Time can be programmed by the user, and the secondary bolus rate will not be displayed on the View System menu. Default bolus rate can be modified by Technicians only. For more information, refer to the Service Manual.

Viewing the Event Log

The Event log screen allows you to view a record of all events audited by the system. You can view a list of all events or only the events that occurred on a specific day.

> To view events that occurred on a specific day:

1. From the Options menu, select **View**.
2. On the View screen, select **Event log**.
3. On the Event log screen, select **By date**.
4. Using the keypad, enter values for the day (2 digits), the month (2 digits), and the year (2 digits). (When U.S. format is set, the order is month, day, and year.)



To navigate directly to a component of the date (e.g., day), press the component.

5. On the toolbar, press **OK**.

A list of events is displayed.



If no events occurred on the selected day, a blank screen is displayed.

> To view all events:

1. From the Options menu, select **View**.
2. On the View screen, select **Event log**.
3. On the Event log screen, select **All events**.

A list of events is displayed.

The Event log is sorted according to time, with the most recent event listed first. Each event is assigned a specific code. (For example, the code for the Pump Unattended alarm is 18.) The code appears in the Event log next to the time of the event.

When the row of an event is selected, the Event details frame displays the complete timestamp of the event (date and exact time), and a brief description of the event. When the pump is turned Off, or a power failure occurs, the pump shut-down is registered as an event (with a time stamp), and the event log is saved. When the number of events in the Event Log exceeds the maximum capacity, the earlier half of the event log will be cleared, in order to allow logging of new events.

Chapter 8: Using Advanced Features

This chapter explains how to work with less frequently used pump features. The following options are generally reserved for more advanced pump users:

Managing Authorization Levels	144
Password Re-entry	147
Creating and Editing PreSet Programs	148
Using the Set Delay Feature	151
Using the New Patient Feature	155
Updating to a New Pump Software Version	158

Managing Authorization Levels

To help ensure patient safety, the SapphirePlus pump can be set to one of four authorization levels. Authorization levels control access to the programming options available in the pump. Each level allows users to access a different set of pump actions and programming options.

Authorization levels are modular. Therefore, users with a given authorization level can access actions available to their level, plus all actions available to users with lower authorization levels. The levels are:

- **Low:** All programming options are disabled, and no settings can be changed.
- **Medium:** Basic programming options, such as using shortcuts to start infusions, are enabled.
- **High:** All tasks and configuration settings are enabled, except for options limited to technician use.
- **Technician:** All settings are enabled. This level is restricted to technicians and developers only.



Passwords are defined by technician or loaded with the Drug Library.

Specific actions allowed in each of the authorization levels are listed in the following table.

Authorization Level	Allowed Actions
Low	Stop the pump, and then continue the infusion Power the pump On and Off Use the View menu
Medium	Stop the pump, and then continue the infusion Start infusions using the PreSet Programs feature Start infusions using the Repeat Last Infusion feature Priming with the pump
High	Start infusions using the New Infusion feature View/Edit parameters Use the Pump Configuration menu Create/Edit PreSet programs (requires a unique password) Changing delivery mode (requires password re-entry) Clinician bolus
Technician	All

When the pump is turned Off, the authorization lock level setting is saved. Therefore, the lock level set most recently is maintained when the pump is turned back On.



If the pump is turned Off in Technician mode, the pump turns back On in a High authorization level.

The current authorization lock level can be viewed via the Options menu. When an infusion is running, the lock level can be accessed via the Running screen.

> **To view the current authorization lock level from the Options menu:**

- From the Options menu, select **View → View system**.
The Authorization parameter is displayed.

> **To view the current authorization lock level via the Running screen:**

1. From the toolbar of the Running screen, press **View/Edit**.
2. From the View/Edit screen, select **View system**.
The Authorization parameter is displayed.

Setting Authorization Lock Levels

Users with an authorization level of High can reset the authorization lock level of the pump.

> **To change authorization level from a lock level of High:**

1. From the Options menu, select **Pump configuration → General settings**.
2. Select **Authorization level**. Then, using the keypad, enter the High level password → **OK**.



Because only High and Tech authorization levels can change the authorization level on the pump, a high or technician password is required to access this setting. Entering a Medium or Low level password generates an error message.

The authorization level matching the entered password, as well as all levels below it, are listed on the Main Display.

3. Select the authorization level at which you want to lock the pump. Then, from the Attention screen, press **OK**.
4. To exit the Options menu, press **OK**.

> **To change authorization level from a lock level of Medium or Low:**

1. From the Options menu, select **Pump configuration**.
2. On the Password screen, using the keypad, enter the High level authorization password. Then, from the toolbar, press **OK**.
3. From the toolbar of the Attention screen, press **OK**.
4. To exit the Options menu, press **Exit**.



Do not disclose the passwords of authorization levels Medium, High or Technician to patients, home users or any other unauthorized user.

Password Re-entry

The SapphirePlus pump is designed to prevent inadvertent parameter changes, or actions other than those permitted by the currently set authorization level. As a safety measure, the pump will prompt the user to re-enter the High level password before performing the following actions:

- Changing delivery modes
- Changing authorization levels



Entering a High level authorization password allows access to these actions, even if the pump is set at a Medium or Low authorization lockout level.

A password entry is also required to unlock the screen when the Auto Patient Lockout feature is enabled. The authorization level of the password entered sets the authorization lockout level of the pump.

Creating and Editing PreSet Programs

The PreSet Programs feature allows users to start infusions using predefined infusion parameters, thus eliminating the need for programming. Each delivery mode can support its own set (of up to 10) predefined infusion programs. Only the infusion programs set for the currently selected delivery mode are displayed (a preset program is available for use and edit only when the pump is set to the delivery mode in which the program was saved) .



This feature is available when the ICU Medical MedNet™ Drug Library is not used.
When not under the ICU Medical MedNet™ Drug Library, in order for the PreSet Programs function to appear in the Start Up screen, the pump needs to be configured to the Allow PreProgram setting. For more information, refer to [Configuring General Settings](#) on page 132.

The following procedures explain how to create, edit and delete preset programs.



Creating and Editing preset programs can be done only by High and Technician authorization levels, and in addition require a unique password.

A PreSet program will be available for creating, using and editing only when the program settings are consistent with the current pump settings, and drug availability in the current CCA (for example, if the flow rate of a certain PreSet program exceeds the current hard limit, the program will not be available for use).



Exception: a PreSet program created with Drug amount and Diluent volume, will be available for creating, using and editing, regardless of Calculate concentration setting.

> To create a new preset program:

1. From the Indicators Bar, verify that the pump is in the desired delivery mode.
2. From the Start Up screen, select **PreSet Programs**.
3. From the toolbar, press **Create New**.

4. Using the keypad, enter the appropriate password; then, press **OK**.
5. Using the keypad, enter a relevant name for the new program.
 - To enter the second character that appears on a key, press the key twice. (Press 3 times to enter the third character, etc.)
 - To enter a space, press the **0** (zero) key once.
 - To clear the most recently entered character, press the backspace key (left arrow key at the lower right corner of the keypad).
 - To clear all entered characters, press **Clr**.

After entering the name, press **OK**.
6. Set the relevant infusion parameters. Refer to the following table for more information about setting parameters in each mode.

Delivery Mode	Refer to:
Continuous	Starting a Continuous Infusion on page 79
Multi-step	Starting a Multi-step Infusion on page 106

7. Review the parameters displayed on the screen.



Verify that the parameters reflect the correct treatment according to the prescription.

Then, press **OK**. The program is saved.

8. To return to the PreSet programs screen, press **OK**.

> To edit a preset program:

1. From the Indicators Bar, verify that the pump is in the desired delivery mode.
2. From the Start Up screen, select **PreSet Programs**.
3. From the toolbar of the PreSet Programs screen, press **Edit**.
4. Using the keypad, enter the appropriate password; then, press **OK**.
5. From the list, select the program that you want to update.

6. Select the box of the parameter that you want to change. Using the keypad, enter the new parameter, and then press **OK**.



If relevant, the pump will prompt you to confirm or update other parameters that may need to be modified, based on the change made. The name of the program, drug name, drug concentration and patient weight cannot be modified.

7. Repeat Step 6 , until all relevant parameters are updated as required.
8. Review the parameters displayed on the screen.



Verify that the parameters reflect the correct treatment according to the prescription.

Then, press **OK**. The program is saved.

> To delete a preset program:

1. From the Indicators Bar, verify that the pump is in the desired delivery mode.
2. From the Start Up screen, select **PreSet Programs**.
3. From the toolbar of the PreSet Programs screen, press **Edit**.
4. Using the keypad, enter the appropriate password; then, press **OK**.
5. From the list, select the program that you want to delete.
6. From the toolbar, press **Delete**.
7. From the toolbar of the Attention screen, press **OK**.
The program is deleted.

Using the Set Delay Feature

The Set Delay feature allows users to program an infusion in advance, or put an active infusion on Standby.

Before starting an infusion – When the option is enabled, the Set Delay option appears on the Start screen. The users can then choose to set the infusion to Standby for a time period not greater than 72 hrs, or to set the infusion for a defined Delayed Period, after which one of the following occurs:

- If the KVO was used during the delay period, the pump starts the infusion automatically.
- If the KVO was not used during the delay period, the alarm for the clinician sounds to start the infusion.



For the Set Delay option to appear on the Start screen, the pump needs to be configured with the **Allow delayed start** setting enabled. For more information, refer to [Configuring General Settings](#) on page 132.



Alternatively, it is possible to initialize a Standby Period during an infusion. For more information, refer to [Infusion Standby](#) on page 119.

> To program an infusion using the Standby option:

1. Set the relevant infusion parameters. Refer to the following table for more information about setting parameters in each mode.

Delivery Mode	Refer to:
Continuous	Starting a Continuous Infusion on page 79
Multi-step	Starting a Multi-step Infusion on page 106

2. From the Start screen, select **Set Delay**.
3. From the Delayed Start screen, select **Standby**.

4. The Standby screen is displayed.

Throughout the Standby period, the following information appears on the screen:

- **Drug Name:** The name of the selected drug. Displayed on the indicators bar, when working with a Drug Library.
- **Concentration:** Drug concentration as entered by the user (Final concentration or Drug Amount / Diluent Volume). Displayed when applicable.
- **Rate:** Programmed infusion rate. For all dose units other than mL/h, the calculated rate will be displayed in mL/h, both in the View system menu and in the Running screen.
- **VTBI:** Total volume left to be infused. This parameter remains constant throughout the Standby period.
- **VI / Total:** Total volume that has been infused in the current infusion / the VTBI value programmed. These parameters remain constant throughout the Standby period.
- **Time left:** Time remaining until the end of the current infusion. This parameter remains constant throughout the Standby period.



During Standby, Pump unattended alarm will not be active.



To view all of the current infusion programmed parameters, from the Standby screen, press **View/Edit** → **View system** → **Infusion Values**.



When in Standby, the pump can be turned Off without losing the infusion parameters. To resume infusion, refer to [Resuming Infusions After Pump Shutdown](#) on page 117.



To abort Standby and the infusion, from the toolbar, press **End Standby**; then, from the Confirm screen, press **Exit**. The Start Up screen will appear.

> **To start an infusion from the Standby state:**

1. Press **End Standby**.
2. Review the parameters displayed on the Confirm screen.



Verify that the parameters reflect the correct treatment according to the prescription.

Then, press **OK**.

3. Make sure that the clamps on the administration set are open; then, press **Start**. The Running screen is displayed, and the infusion begins.

> **To program an infusion using the Delay Period option:**

1. Set the relevant infusion parameters. Refer to the following table for more information about setting parameters in each mode.

Delivery Mode	Refer to:
Continuous	Starting a Continuous Infusion on page 79
Multi-step	Starting a Multi-step Infusion on page 106

2. From the Start screen, select **Set Delay**.
3. From the Delayed Start screen, select **Delay Period**.
4. Using the keypad, enter the desired delay period (h:min); then, press **OK**.
5. Specify whether or not to run the infusion in a KVO, during the delay period:



If KVO rate is pre-configured to 0 mL/h for the delivery mode, from the Start screen, select **Start with Delay**. (Refer to [Do not use KVO: below](#))

- **Use KVO:**

Press **Yes** → **Start with Delay**. The infusion begins with a KVO rate. When the delay period is over, the programmed infusion begins immediately.



Pressing **Start** during the delay period begins the infusion immediately (overriding the delay period).

- **Do not use KVO:**

Press **No** → **Start with Delay**.

On the Delayed Start screen, the words No KVO appear in the Rate frame, and a time countdown for the delay period is displayed in the Time frame.



To override the delay period, from the toolbar, press **Skip delay**. Then, from the Start screen, press **Start**.

When the delay period is over, an alarm sounds.

6. To begin the infusion, verify that the clamps on the administration set are open, and press **OK**; then, press **Start**.



When a KVO rate is not used during the delay period, the infusion does not begin automatically when the delay period is over. You need to begin the infusion manually, by pressing **Start**.

During an active infusion – When the option is enabled, the Standby option appears on the View/Edit toolbar.

For more information about using the standby option, refer to [Infusion Standby](#) on page 119.

Using the New Patient Feature

When the New Patient feature is enabled, and either a New Infusion or a PreSet program is selected, the pump will prompt you to indicate whether or not the infusion to be programmed is for a new patient. When selecting Repeat Last Infusion the New Patient screen will not appear, and the pump will indicate that the infusion to be repeated will be used for the last patient selected.

When a New Patient is selected, entries associated with the patient can be tracked in the Event Log (see [Viewing the Event Log](#) on page 142). In addition, the pump calculates the accumulated volume infused (Accumulated VI) for all infusions associated with the patient. When a new patient is selected, the Accumulated VI is automatically cleared (for more information, refer to [Monitoring the Accumulated Volume Infused \(Shift's Total\)](#) on page 156.

> To select a new patient:

1. From the Startup screen select **New Infusion** or **PreSet Programs**.
2. In the New Patient screen, select **Yes**.



When under ICU Medical MedNet™ Drug Library, the new patient feature is enabled (refer to [Appendix A: SapphirePlus Configuration Settings](#) on page 214)

When not under the ICU Medical MedNet™ Drug Library, this feature can be enabled/disabled by technicians only

> **Monitoring the Accumulated Volume Infused (Shift's Total):**The SapphirePlus pump calculates the Accumulated Volume Infused (Accumulated VI) for all infusions associated with a specific patient.

The accumulated VI includes the volume infused to a specific patient via infusions (including primary, secondary etc.), Boluses, KVO and Post Infusion rate. This allows the clinical staff to monitor the total volume infused to a specific patient. The Accumulated VI can be cleared by a clinician (for more information, refer to [Clearing Accumulated VI](#) on page 157). The date and time in which the Accumulated VI was cleared is also captured.

The SapphirePlus pump also provides the volume infused in the current running infusion (VI), including KVO if applied, during a delayed start period. This VI is presented on the running screen as well as in the message given at the end of the infusion. Clearing the Accumulated VI automatically clears the VI.

Viewing Accumulated VI

The Accumulated VI value can be viewed before programming an infusion via the Options menu, or during an infusion via the View/Edit and View System menus.

> **To view the current Accumulated VI value from the Options menu:**

1. From the **Options** menu, select **View → View system**.
2. From the toolbar of the View system screen, press **Next** until the Accumulated VI parameter is displayed.

> **To view the current Accumulated VI value via the View/Edit menu:**

1. From the toolbar of the Running screen, press **View/Edit**.
- The Accumulated VI value is presented in the Clear Accum. VI box.

> **To view the current Accumulated VI value via the View System menu:**

1. From the toolbar of the Running screen, press **View/Edit**.
2. From the View/Edit screen, select **View system**.

3. From the toolbar of the View system screen, press **Next** until the Accumulated VI parameter is displayed.



The View system captures the date and time in which the accumulated VI was last cleared. In addition to the Accumulated VI value, when using the Continuous delivery mode, the View System screen also presents the Accumulated Volume Infused via the primary line (Accum. Prim. VI) and the Accumulated Volume Infused via the secondary line (Accu. Sec. VI).

Clearing Accumulated VI

The Accumulated VI value is cleared in the following cases:

- The pump clears the Accumulated VI automatically
 - If the New Patient feature is disabled – Each time a New Infusion or a PreSet Programs is confirmed (**Note:** Repeating the last infusion won't clear the Accumulated VI).
 - If the New Patient feature is enabled – Each time a new patient is identified (**Note:** Repeat Last Infusion is intended for the same patient; this means that a new patient can't be identified when using the Repeat Last Infusion shortcut).
- The user clears the Accumulated VI
 - During infusion via the View/Edit or View System screen. This will reset the total volume infused for all infusions associated with a specific patient to 0 mL.



The date and time in which the accumulated VI was cleared is captured and can be viewed in the View System menu.

> To clear the Accumulated VI value during infusion:

1. From the toolbar of the Running screen, press **View/Edit**.
2. From the View/Edit screen, press **Clear Accum. VI**.
3. From the Clear Accum. VI screen, press **Yes** to clear the Accumulated VI.

> **To clear the Accumulated VI value before or after infusion:**

1. From the toolbar of the Start up screen, press **Options**.
2. From the Options menu, select **View**.
3. From the View menu, select **View system**.
4. From the view system, select the **Accumulated VI** row by pressing the **>**.
5. From the Clear Accum. VI screen, press **Yes** to clear the Accumulated VI.

Updating to a New Pump Software Version

When a new software version is available, the user is prompted to specify whether or not to update the software. Note that updating the pump software removes the Drug Library if it has become incompatible.



Updating software should be conducted according to local facility procedures.

Updating a new software version may take a few minutes, during which the pump is inactive.

The user is advised to connect the pump to a power supply during the update process. If the pump is turned Off, a message appears at the top of the screen, indicating the software download status.

> **To update to a new software version:**

1. From the New Software screen, press **Upload**.
2. Enter the installation code, and press **OK**. The pump will start updating the software. At the end of the process the pump will shut down.

> **To view the current software version:**

1. From the Options menu, select **View** → **View System**.
2. On the toolbar, press **Next**, until the **SW Version** parameter is displayed.

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Chapter 9: Drug Library

The following sections explain about the Drug Library unique features, and describe how to operate the pump in the different delivery modes using the Drug Library:

Overview	160
Clinical Care Area (CCA)	161
Programming a New Infusion with the Drug Library	165
Soft Limit	166
Update a New Drug Library Version	168

Overview

The Drug Library contains information about customized groups of drugs and Clinical Care Areas (CCA) that were approved and saved by qualified and authorized local hospital personnel, using the ICU Medical MedNet™ Meds™ 6.21 Software and above (per ICU Medical MedNet™ Meds™ user manuals).

The Drug Library is identified by a Drug Library name and publish date, both displayed on the View system menu. The Drug Library name is also displayed on the SapphirePlus when the pump turns On.

The Drug Library functions as an error-reduction tool, thus enabling safer practice.

The Drug Library displays for each drug its available concentrations and allowed range (hard limits) of various infusion parameters, such as continuous rate and bolus amount. In addition, it contains the recommended range (soft limits) of these infusion parameters.

The information about customized groups of drugs may be specific to a CCA, or may apply to an entire institution.

The limits set in the Drug Library create a guiding range, thus reducing infusion errors. The pump alerts users when the programmed values exceed the recommended range (soft limits), and prohibits programming of values that exceed the allowed range (hard limits).

For more information refer to ICU Medical MedNet™ Meds™ 6.21 Software and above (per ICU Medical MedNet™ Meds™ user manuals).

Clinical Care Area (CCA)

The Drug Library accommodates of up to 40 CCAs, each with a unique configuration setting and up to 3400 drug profiles. A complete Drug Library may contain up to 11,150 drug profiles. The CCA unique configuration is set by the Drug Library. Local configuration made when a Drug Library is loaded remains valid until the user selects a CCA or turns the pump Off. For more information about configuration settings, refer to [Appendix A: SapphirePlus Configuration Settings](#) on page 214.



When Resuming an infusion after pump shutdown, local configurations will remain until the end of the current infusion.

Changing a CCA

CCA selection is available in the following cases:

- When the pump is turned On
- When the pump is idle, from the General Settings menu
- During a running infusion (the selected CCA will apply after the infusion has completed)

The name of the selected CCA is displayed on the Indicators Bar above the screen title.

Selecting a CCA when pump is turned On

When a Drug Library is loaded, a message is displayed, asking to accept or change the current CCA.

> To accept or change a CCA:

1. Turn the pump On.
2. From the Clinical Care Area screen select whether to **Accept** or **Change** the current clinical care area:
 - To accept the current CCA, press **Accept**.
The Start Up screen appears.

- To change the current CCA, press **Change**.
 - From the Choose CCA screen, select the relevant CCA.



To display additional CCAs press **Next**.

- a. From the Attention screen, press **OK**.



In case the current delivery mode is unavailable in the selected CCA, the pump will prompt the user to change the delivery mode.

The Start Up screen appears.



CCA selection should be selected according to local facility procedures.



If a message regarding resuming previous infusion appears upon turning the pump On, refer to [Resuming Infusions After Pump Shutdown](#) on page 117.

Selecting a CCA from the General Settings

> To change the current CCA:

1. From the toolbar of the Start Up screen, press **Options**; then, select **Pump** → **configuration** → **General Settings**.
2. Select the **Current CCA** row.
3. From the Choose CCA screen, press the row of the relevant CCA.



To display additional CCAs press **Next**.

4. To confirm the selected CCA, press **OK**.

The Start Up screen appears.



Selecting a CCA should be conducted according to local facility procedures.



The Repeat Last Infusion option will be unavailable (grayed out) after the CCA is changed.

Changing a CCA during a running infusion



When changing the CCA during a running infusion, the CCA will change only after the infusion has completed.
The selected CCA name will appear in the indicators bar, two arrows on either side.

> To change a CCA during a running infusion:

1. From the Running screen press **View/Edit**.
2. From the View/Edit screen, select **View system**.
3. Select the **Current CCA** row.
4. From the Choose CCA screen, select the row of the relevant CCA.



To display additional CCAs press **Next**.

5. From the Attention screen, confirm the selected CCA, and press **OK**.

The View/Edit screen is displayed.



To view or change the Next CCA:

- From the View/Edit screen, press **View System**.
 - Press **Next CCA**.
 - Select CCA from list.
Note: To display additional CCAs press **Next**.
 - From the Attention screen, press **OK**.
-



The Repeat Last Infusion option will be unavailable (grayed out) after the CCA is changed.

6. To return to the running infusion, press **OK**.

Programming a New Infusion with the Drug Library

When the SapphirePlus pump is loaded with a Drug Library, the programming flow includes additional related steps: Drug name entry, Drug list and Drug profile. Following the drug profile selection, the user is required to enter the infusion parameters according to the delivery mode.

Drug Name

After starting a **New Infusion**, the pump displays the Drug name screen. From the Drug name screen, using the keypad, the user enters the drug name then presses **Find***.



Drug name search is not sensitive to uppercase or lowercase letters.

When the required drug is not found in the Drug Library, the user can program an infusion without a defined drug by using the **Choose General** key on the toolbar.



'Choose General' will bypass the specific drug profile limits, and the infusion will be programmed under the CCA limitations only.

Drugs List

The filtered drugs are displayed in the Drugs List screen.

The Drugs List screen displays only drugs that are available in the current CCA and delivery mode. When there are several available drugs, use the **Next** key to display additional drugs.

* The **Find** key can be used to display all available drugs when no characters have been entered (letters, numbers or symbols), or to filter drug names according to the characters entered. The number of matching drugs found is displayed at the top right corner of the main display.

Drug Profiles

The pump displays the available profiles for the selected drug. The drug profile includes concentration and defines hard limits and soft limits. Each available drug is defined by the CCA and the delivery mode to which it was assigned; a drug profile may be available in more than one delivery mode.

Each drug profile is defined by one of the following types:

1. **No concentration:** The drug concentration or diluent volume are not needed. Available drug units are: mL/h, mL/min, mL/kg/h and mL/kg/min.
2. **Diluent only:** Solutions where medication amount is not required (e.g., 100 mL). Available drug units are: mL/h, mL/min, mL/kg/h and mL/kg/min.
3. **Partial concentration:**
 - **Without Drug Amount** Only Diluent Volume is defined. The user will be asked to enter Drug Amount (e.g., __ mg/100 mL).
 - **Without Diluent Volume** Only the Drug Amount is defined. The user will be asked to enter Diluent Volume (e.g., 10 mg/ __ mL).
 - **Without Drug amount and without Diluent Volume** (e.g., __mg/ __mL): No Drug Amount and no Diluent Volume were defined. The user will be asked to enter Drug Amount and Diluent Volume.
4. **Full concentration:** Both Drug Amount and Diluent Volume are defined.

For more information about programming a new infusion with Drug Library, according to the chosen delivery mode, refer to:

[To begin a new Continuous infusion with a Drug Library on page 83](#)

[To begin a new Multi-step infusion with a Drug Library on page 110](#)

Soft Limit

The limits set in the Drug Library create a guiding range, thus reducing infusion errors. When programming values that exceed the recommended range (soft limits), an Attention screen is displayed, showing the applicable soft limit icon, with the details of the exceeded parameter. The user can either:

- Acknowledge the message and continue with the entered value.
- Go back and enter a new value instead of the entered value.

Figure 9.1. Soft Limit Icon



Current infusion is
above upper soft
limit



Current infusion is
below lower soft
limit



Current infusion is exceeding
both upper and lower soft limits
of various parameter

> **To acknowledge the message and continue with the entered value:**

From the Attention screen, press **OK** and continue programming.



When a soft limit has been exceeded, an applicable Soft Limits icon will be shown on the Sapphire pump indicators bar during infusion.

> **To enter a new value instead of the entered value:**

From the Attention screen, press **Back**.

Then, using the keypad, enter a new value and press **OK**.



Soft limits Attention screen and icon are applicable only when soft limits are defined in the Drug Library.

Update a New Drug Library Version

When a drug library update is available for installation, an icon is displayed on the top header, The option to install the update is provided when turning off an idle pump.



Updating Drug Library should be conducted according to local facility procedures.

Updating a new Drug Library version may take a few minutes, during which the pump is inactive.

> To update a new Drug Library version:

From the New Drug Library screen, press **Upload**. The pump will start updating the Drug Library. At the end of the process the pump will power Off automatically.



If the user chooses not to update the Drug Library upon pump turn-off, the Update screen will be prompted the next time the pump is turned Off.

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Chapter 10: Alarms and Troubleshooting

The following sections describe the different types of alarms and messages that can be generated by the pump, and explain how to troubleshoot common programming issues:

Alarms Overview	170
Level 1 Alarms	171
Level 2 Alarms	172
Level 3 Alarms	173
Messages	175
Troubleshooting	177

Alarms Overview

The SapphirePlus pump generates four different types of alarms. The alarm types are categorized according to their effect on the infusion. In all alarm types, instructions about how to proceed (and, if relevant, to solve the problem) are displayed on the touch screen.

Alarm Type	Effect on Infusion
Level 1	Pump shuts down.
Level 2	Infusion stops and cannot be reactivated.
Level 3	Infusion stops, but may be reactivated.
Message	Infusion is not interrupted.

When Level 1, 2, and 3 alarms occur, the red Alarm LED stays On continuously, and an auditory alarm sounds continuously. These alarms require immediate attention.

The following sections provide details about each alarm type. In the lists of alarms, messages and alarms related to battery issues are shaded. Alarms related to battery problems can be prevented by adhering to the recommended guidelines for battery care ([Battery Care Information](#) on page 187).

Level 1 Alarms

This type of alarm is the highest severity alarm category. If the pump is running when the alarm occurs, the infusion stops immediately, and the pump automatically shuts down within 3 minutes. The infusion cannot be restarted or continued.

The following soft keys are available during a Level 1 alarm:

- **Mute:** Silences the auditory alarm.
- **Shutdown:** Turns Off the pump immediately.

When a Battery Depleted alarm occurs, connect the pump to an AC power supply. A pump with an Internal Error alarm needs to be evaluated by an authorized service technician.

Alarm Title	Screen Header	Displayed Text
Battery Depleted	Battery	Pump will automatically shut down in 3 minutes. Please connect pump to power.
Internal Error	Error	Pump will automatically shut down in 3 minutes. Please send the pump for service.

Level 2 Alarms

This alarm type is a high severity category. If the pump is running when a Level 2 alarm occurs, the infusion automatically stops.

The pump can be reactivated by a technician (using a technician authorization code) to retrieve infusion data and/or manage a battery problem. Pumps with Level 2 alarms need to be sent for servicing. Screen instructions are directed to technicians only.

To silence the audio signal of an alarm, press the **Mute** soft key. This silences the alarm sound for 2 minutes. If the issue has not been cleared after 2 minutes, the alarm sound will be resumed.

The following soft keys are available during a Level 2 alarm:

- **Mute:** Silences the auditory alarm for 2 minutes.
- **Unmute:** Returns the auditory alarm.
- **OK:** Displays the Paused screen. This soft key is enabled after **Mute** is pressed.

Alarm Title	Displayed Text
Mechanism Error	A pump fault has occurred. Please enter technician code to proceed.
Pump Fault	A pump fault has occurred. Please enter technician code to proceed.
Battery Reminder	End of battery life. Please contact authorized technician to replace battery.

Level 3 Alarms

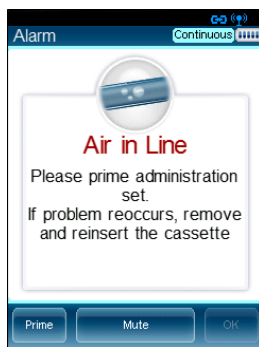
This alarm type is a medium severity category that requires immediate attention. If the alarm occurs during an infusion, the infusion automatically stops. However, you may continue the infusion after the problem has been resolved. Instructions for resolution of the problem are displayed on the touch screen.

To silence the audio signal of an alarm, press the **Mute** soft key. This silences the alarm sound for 2 minutes. If the issue has not been cleared after 2 minutes, the alarm sound will be resumed.



Resolving these alarms will lead to the Paused Infusion screen. If the alarm occurs while programming a mid-infusion action, the programming process needs to be re-initiate.

Figure 10.1. Sample Level 3 Alarm Screen



The following soft keys are available during a Level 3 alarm:

- **Mute:** Silences the auditory alarm for 2 minutes.
- **Unmute:** Returns the auditory alarm.
- **OK:** Displays the Paused screen. The infusion may then be resumed after the problem is resolved. This soft key is enabled after **Mute** is pressed.
- **Prime:** Enables automatic priming. This key appears only during an Air in Line alarm.

Alarm Title	Displayed Text
Air in Line	<p>Accumulated air in line is over the limit. Please prime administration set. If problem reoccurs, remove and reinsert the cassette.</p> <p>Please prime administration set. If problem reoccurs, remove and reinsert the cassette.</p> <p>Possible excessive environmental light.</p> <p>Please reduce exposure and check if priming is required.</p>
Potential Air in Line	Press OK to resolve.
Cassette Misplaced	<p>The administration cassette is not loaded or misplaced. Please reload the cassette.</p> <p>Reinsert cassette. Verify both flanges inside safety door. If problem persists contact technician.</p> <p>Remove the administration cassette and make sure to correctly reinsert it. If alarm reoccurs please contact authorized technician.</p>
Check for Occlusion	Please verify clamps are open and set is not occluded.
Downstream Occlusion	To clear occlusions verify: 1. Clamps are open; 2. Administration cassette is properly positioned; 3. Line is not kinked; 4. No occlusion at the output connection. If all occlusions were cleared press OK to continue.
Pump Stopped	Please quit and restart the infusion.
Occlusion	To clear occlusions verify: 1. Clamps are open; 2. Administration cassette is properly positioned; 3. Line is not kinked; 4. No occlusion at the output connection. If all occlusions were cleared press OK to continue.
Upstream Occlusion	To clear occlusions verify: 1. Clamps are open; 2. Administration cassette is properly positioned; 3. Line is not kinked; 4. No occlusion at the output connection. If all occlusions were cleared press OK to continue.
Flow Error	Verify that the administration cassette is correctly positioned and battery is sufficiently charged. If alarm reoccurs contact authorized technician.

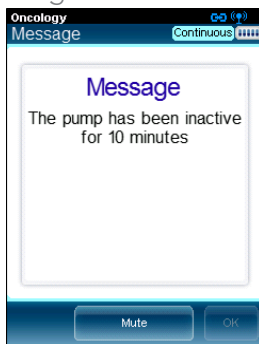
Alarm Title	Displayed Text
Insufficient Battery	Low battery voltage for current rate. Please connect pump to power supply.

Messages

A Message indicates a condition of medium severity that you should attend to as soon as possible. When a Message occurs, an auditory alarm sounds, and the condition that triggered the message (and recommended actions, if relevant) is displayed on the touch screen.

To silence the audio sound of a message, press the **Mute** soft key. This silences the message sound for 2 minutes. If the issue has not been cleared after 2 minutes, the alarm sound will be resumed.

Figure 10.2. Sample Message Screen



If a message is displayed during infusion, the infusion continues, and the system continues to operate. The following soft keys are available:

- **Mute:** Silences the auditory alarm for 2 minutes.
- **Unmute:** Returns the auditory alarm.

- **OK:** Confirms the message, and returns the display to the previous screen. If the infusion is complete, the pump returns to the Start Up screen. This soft key is enabled after **Mute** is pressed.

If the alarm volume is configured to minimum in the Alarms menu, the OK soft key will always be enabled.

Screen Header	Displayed Text
Low Battery	30 minutes left to battery depletion. Connect pump to power supply.
Message	Battery life will expire in 2 days. Please contact authorized technician.
	The battery could not be fully charged - please check power supply.
	Annual certification due in 2 days. Please contact authorized technician.
	Annual certification date is overdue. Please contact authorized technician.
	Note: The pump continues to function after the certification date; however, failure to perform annual certification impacts the pump warranty.
	Door open. Check administration cassette position and close the safety door.
	Infusion complete.
	Infusion near end.
	The pump has been inactive for <xx> minutes.
	System temperature is out of range. If the alarm reoccurs please contact authorized technician.
	Please Wait. Possible Downstream Occlusion. The pump is attempting to restart; press exit to cancel.
	WiFi disconnected. To reconnect WiFi, connect pump to power supply.
	WiFi disconnected. Please contact authorized technician. Press OK to continue without WiFi .
	Note: The pump continues to function when Wi-Fi has a connectivity problem. Following this alarm, the Wi-Fi icon turns gray.

Troubleshooting

The following table lists some common programming issues, and explains how to solve them.

Problem	Probable Cause	Solution
Programming cannot be completed. The OK function key is disabled, and the parameter range is in red font.	The parameter entered is outside of the safety range calculated by the pump.	Verify the prescription, and obtain a new one if necessary. Enter infusion parameters within the permitted ranges.
The Set Delay option does not appear on the Start screen.	The option is not enabled.	Enable the Allow delayed start setting (Configuring General Settings on page 132). High Authorization level is required.
The PreSet Programs option does not appear on the Start Up screen in any mode.	The option is not enabled.	Enable the Allow PreProgram setting (Configuring General Settings on page 132). High Authorization level is required.
Pump becomes locked whenever an infusion starts.	The Auto Patient Lockout feature is enabled.	Disable the Auto P. Lockout option (Configuring General Settings , page 134). High Authorization level is required.
Pump is not charging.	<ul style="list-style-type: none"> • The power supply has become disconnected from the mini cradle. • The power supply was connected to the pump during pump turn-off. • The power supply is not working. 	<ul style="list-style-type: none"> • Verify the power supply is connected to the mini cradle splitter. • Disconnect and reconnect the power supply to the pump. • If the power supply is not functioning properly, replace it.

Problem	Probable Cause	Solution
Recurring Air in Line alarms.	Treatment is near end, or the air detection settings are too sensitive.	Close clamps, remove administration cassette from pump and prime (flush) the set manually. If the issue is not resolved, replace the administration set. If the issue is still not resolved, have a technician review and adjust the air detection settings.
Recurring Occlusion alarms.	The occlusion issue has not been properly resolved.	<ul style="list-style-type: none"> • Close clamps, remove administration cassette from pump, disconnect patient and prime (flush) the set manually. • Replace the administration set. • Change the infusion site.
Occlusion alarm is triggered immediately after the infusion starts.	The backpressure caused by the catheter used for the treatment, at the programmed rate, is too high.	Reduce the backpressure by either replacing the catheter or by decreasing the infusion rate.
Screen saver does not appear.	<ul style="list-style-type: none"> • Screen saver option was not enabled. • Pump is not in an applicable state. 	<ul style="list-style-type: none"> • Enable the Screen Saver option (refer to Configuring General Settings on page 132) • The screen saver will not appear if the pump is in one of the following states: Paused, Delayed Infusion, Post Infusion Rate, during alarm, when screen is touched, when key is pressed, or during a Bolus delivery

Problem	Probable Cause	Solution
The pump pauses when programming a secondary.	The pump is not connected to an AC outlet, and currently the battery power is insufficient to support both the primary line rate and the secondary line programming.	Connect the pump to an AC outlet, and select to continue the primary or start the secondary.

Chapter 11: Maintenance and Storage

The following sections describe the proper cleaning, preventive maintenance, and storage procedures for the pump and the battery:

Cleaning and Disinfecting the Pump	180
Preventive Maintenance	185
Battery Care Information	187
Transport and Storage	191

Cleaning and Disinfecting the Pump

Between use on different patients, the SapphirePlus pump and all of its components need to be first cleaned, and then disinfected, per hospital/medical provider protocol for multiple patient use.

Cleaning and disinfecting the pump involves wiping it with Dispatch[®] (Caltech) ready-to-use towels.



For cleaning, one minute waiting time.
For disinfecting, ten minute waiting time.

Additional Cleaning and Disinfection Agents:

- Virex[®] II 256
- Klor De[™] (Chlorine tablets)
- 70% Isopropyl alcohol



Cleaning and Disinfection: Safety Precautions

Before and during cleaning, adhere to the following safety guidelines and recommendations:

- Only people who are trained in the maintenance of this type of medical device should clean the infusion pump
- Before cleaning/disinfecting the pump, verify that:
 - The pump is disconnected from the patient.
 - The pump is disconnected from all connections, sets, and accessories.
 - The pump is turned Off.
- While cleaning/disinfecting the pump, do not allow fluid to enter the pump housing, speaker holes or battery chamber.
- Do not steam autoclave, ethylene oxide sterilize or immerse any part of the pump in fluid.
- Do not use spray or aerosol cleaners.
- Dispose of all cleaning/disinfectant materials per laws and regulations for infectious waste disposal.
- Do not clean the pump with Bleach (8.25% concentration, mixed at 1 part bleach in 10 parts water), as deterioration may occur.



Before using materials other than the products listed above for cleaning and disinfecting the SapphirePlus Infusion pump, make sure that they are listed in Q Core's official approved list of materials (published at www.qcore.com) .



The pump must be completely dried out before connecting it to a power supply.

Cleaning and Disinfection Procedure

Cleaning/Disinfecting Solution	Manufacturer
Dispatch® (Caltech) ready-to-use towels	Caltech
Virex® II 256	Diversey
Klor DeTM (Chlorine tablets)	Concept
70% Isopropyl alcohol	Veltek Associates, Inc.
Virox® AHP 5 RTU	Diversey

Cleaning Procedure

The following procedure explains how to clean the pump using the approved agents (listed above):

> To clean the pump:

1. Turn the pump Off and unplug the power cord from the SapphirePlus pump power socket.
2. Use the appropriate dilution ratio per the manufacturer's instructions.
3. When the solution is ready, apply the solution on a cloth or sponge, then squeeze so it won't drip.
4. Wipe the exterior planes areas in back and forth motions, vertically and horizontally (mainly on the pump housing).
5. The wiping should be applied with normal force, few times on the same locations (at least twice) verifying complete coverage of the areas to be cleaned.
6. Guidelines for cleaning specific pump components are listed in the table below.
7. After the cleaning process is completed, the pump should be dried out for 10 minutes.

8. Wipe the pump with a clean dry cloth.



The pump must be completely dried out before connecting it to a power supply.

Disinfecting Procedure

The following procedure explains how to disinfect the pump using the approved agents (listed in [Cleaning and Disinfection Procedure](#) on page 182):

> To disinfect the pump:

1. Perform steps 1-6 specified in the cleaning process above.
2. Replace the cloth or sponge with a new one and repeat steps 3-5 (specified in the cleaning process above) two more times (a total of 3 cycles).
3. After the disinfection process is completed, the pump should be dried out for 15 minutes.
4. Wipe the pump with a clean dry cloth.



The pump must be completely dried out before connecting it to a power supply.

Guidelines for cleaning/disinfecting specific pump components

Guidelines for cleaning/disinfecting specific pump components are listed in the following table:

Component	Cleaning Recommendations
LCD Screen	Wipe thoroughly with a squeezed sponge. Avoid scratching the LCD panel. Ensure that no fluid enters the speaker holes at the top of the panel.

Component	Cleaning Recommendations
Sensor Fingers	Clean the finger tip of the sensor using only a damp cloth or sponge.
<ul style="list-style-type: none"> Internal White Panel Bubble Detector (on the internal white panel) Anchor (on the internal white panel) Locking tooth (on the internal white panel) P to C connector, Power communication connector 	<p>This part should be kept free from foreign materials and dirt. If necessary, use foam swab moistened with the detergent solution to clean the connector, particularly around the 4 fingers roots by applying normal finger force, assuring that the swab reaches all areas, at least twice.</p> <p>Note: Swabbing should be applied in vertical or horizontal movement, where possible, while less accessible areas should be swabbed in a circular motion (at least 3 bi-directional rotations clockwise-counterclockwise).</p>

Reprocessing the pump when used by a single patient multiple times

When the SapphirePlus pump is used by a single patient for multiple times, the pump and all of its components need to be cleaned first, and then disinfected using 70% Isopropyl alcohol.

The user is required to clean and disinfect the pump in the following conditions (the earlier of the three):

- Every time there is visibly soiled.
- Once a week.
- After storage at the patient's home; even if not used.

Cleaning and disinfection instructions are identical to [Cleaning and Disinfection Procedure](#) on page 182.

Preventive Maintenance

The following sections describe:

Routine Inspection and Maintenance Tasks	185
Alarm Testing	186
Certification	186

Routine Inspection and Maintenance Tasks

The following sections provide guidelines about inspecting and caring for the pump before and after use.



Take care not to drop the pump. If the pump is dropped or appears to be damaged, cracked or dented, return it to your local representative for inspection.



Preliminary Inspection

Before using the SapphirePlus pump and its accessories, check the pump for signs of any mechanical damage.



Do not use the pump if you identify anything which may indicate impaired functioning of the system. In such a case, contact the facility biomedical engineer or a Q Core approved service technician.

Post-use Procedures

The following equipment checks should be performed following each use of the pump, and as required:

Pump Component	Action
Pump housing	Check for cracks and dents.
Power cord	Verify that the power cord is undamaged. Check the entire length of the cord, and the plug.

Alarm Testing

It is recommended to perform manual testing of the following alarms at least once a year. Alarm testing can be conducted as part of the yearly certification.



Before testing the alarms, make sure to disconnect the set from the patient.

Name of Test	Procedure
Air in Line Alarm	Connect a new Q Core administration set to the pump without connecting it to the infusion container. Start an infusion at a rate of 100 mL/h. An Air in Line alarm should occur.
Occlusion Alarm	Start an infusion at a rate of 600 mL/h over 5 minutes. While the pump is running, close the upstream clamp. An Upstream Occlusion alarm should occur. Test the Downstream Occlusion alarm by repeating the above test, but closing the clamp or pinching the tubing downstream while the pump is running.

If an alarm is not generated, contact your local representative or authorized technician.



The operator should stand 1 meter from the pump, and verify that he/she can hear and see the alarm.



For more information about the Air in Line and Occlusion alarms, refer to [Level 3 Alarms](#) on page 173.

Certification

To ensure proper fluid delivery, the pump should be checked by an authorized service provider at least once a year, to perform yearly certification. For more information on yearly maintenance procedures to be performed by technicians or certified service providers, refer to the SapphirePlus Infusion Pump Service Manual.

Battery Care Information

The SapphirePlus pump can operate on battery power, enabling operation of the pump during an electrical power failure, during patient transport or during ambulatory care. When working on battery power (disconnected from the main power supply), the battery charge level icon, at the upper right corner of the Indicators Bar, indicates remaining battery capacity. Check the status of the battery charge level icon regularly:

Number of Bars in Icon	Approximate Remaining Battery Capacity
5	100%
4	75%
3	50%
2	25%
1	Low



You can also check the status of the battery using the **Options** menu. For more information, refer to [Viewing System Parameters](#) on page 139.

Battery operation time is dependent upon the condition of the battery, which varies according to temperature conditions, battery age, frequency of charging, and conditions of storage and use.

An alarm is triggered when there are 30 minutes left until battery depletion. This time may depend on the delivery rate, the frequency of pressing keys, and whether the backlight is On. When the Battery Depletion alarm sounds or following long periods of storage, connect the pump to the power supply.

Notification messages begin appearing on the Main Display of the pump 2 weeks before battery life expiration. When the battery life expires, the pump allows you to finish the current infusion and then turns Off. Make sure to test the batteries at least once a year, and replace the batteries every 2 years or every 500 charging cycles.

Battery Classification

The UL 1642 Standard for Lithium batteries classifies the Lithium-Ion battery used in the SapphirePlus pump as follows:

- Secondary battery (rechargeable)
- Technician replaceable

Battery Safety Information

When working with the battery, adhere to the safety precautions and recommendations listed below.



Battery Safety Guidelines

- Ensure that only Q Core Medical's rechargeable Lithium Ion (Li-Ion) battery is used.
- In case of rust, bad odor, overheating, and/or other irregularities when using the battery pack for the first time, return it to your local representative.
- Avoid any contact with water. Do not immerse the battery pack in water.
- Do not open the battery casing.
- Store batteries in a closed carton.
- Short term storage temperature should be below 35°C (95°F).

Long Term Battery Storage

When you store batteries for extended periods of time, ensure the following conditions:

- Well-ventilated facility, free of a corrosive gas atmosphere
- Low humidity environment
- Storage temperature should be between -20°C (-4°F) to +35°C (+95°F). The recommended temperature is 23° ±3°C (73° ±5°F).



Storage at low temperatures may affect initial battery performance.
Storage at high temperatures may degrade battery performance.

Charging the Battery

Before initial use of the SapphirePlus pump, the battery must be charged for at least 6 hours. The battery must also be charged if it has been disconnected from the pump unit for more than 6 months. While the pump is in storage, recharge the battery at least every 12 months.

The pump can operate while it is being charged.



When using the pump while connected to the power supply, ensure that the pump is attached securely to the power supply, the mini cradle is attached securely to an IV pole, and the power cord is secure, to prevent entanglements that might cause strangulation.

To preserve battery life, connect the pump to the main power supply using the power supply whenever possible.



While connected to a power supply and charging, the Charge (yellow) LED blinks, and stops blinking when the battery is fully charged.

If the pump is turned Off, the Q Core logo appears on the screen while the pump is charging.



Before charging the battery, ensure that the device is completely dry. Failure to do so may compromise patient safety.

> To charge the battery:

1. Plug the Q Core supplied power supply cord into the main power supply.
2. With the white arrows facing up, plug the power cord into the SapphirePlus pump power socket or into the splitter connector.
3. On the front of the pump, verify that the Charge LED status indicator is On (blinking yellow light).

Battery Maintenance

To promote maximum battery life, the following procedures should be performed at regular intervals.

Frequency	Action
Following each use of the pump	Check the status of battery charge, and recharge as necessary.
Every 2 years or every 500 charging cycles	Replace batteries.

Transport and Storage

The pump should always be transported in a protective case internally padded with cushioning material. It is best to use the original packaging. During handling and transport, protect the pump and the case from water, excessive humidity, and heat sources.

To safeguard the pump against prolonged exposure to dust and moisture, the pump must be stored in a clean and dry environment. It is recommended that the pump remain plugged in during storage, in order to maintain the battery at full charge. If the pump is disconnected from the power supply, or is in storage without being connected to power for several months, check the battery level, and recharge the battery before using the pump ([Charging the Battery](#) on page 190).

For any storage period, make sure that the Q Core administration cassette is disconnected from the pump, and that the safety door over the pump mechanism is closed. Specific recommendations for long term storage conditions are listed in the following table.

Condition	Parameters
Temperature	-40°C (-40°F) to +70°C (+158°F)
Relative humidity	15% RH to 95% RH
Atmospheric pressure	50 kPa to 106 kPa (500 hPa to 1060 hPa)

Chapter 12: Technical Specifications

The following sections present technical specifications for the pump and its components:

Pump Accuracy	192
Pump Specifications	198
Average Bolus Volume After Occlusion	201
Environmental Specifications	202
Electromagnetic Compatibility Statement	204

Pump Accuracy

The following graphs and curves were derived from the pump accuracy testing procedures described in the IEC60601-2-24 standard. Testing was performed under normal conditions (specified in IEC60601-2-24 standard) at room temperature (25°C, 72°F).

Normal conditions to ensure optimal accuracy of $\pm 2.5\%$:

- Fluid level should be 50 cm above the pump
- No back pressure due to catheter size or difference in height of pump and infusion site
- Room temperature (25°C)
- Barometric pressure of sea level altitude (101kPa)
- IV medication with water like fluid characteristics

Infusion under high backpressure conditions (for example, when using catheters, or other restricting administration set components) may cause the accuracy of the pump flow delivery to deviate from the accuracy stated for normal conditions.

The pump is designed to accommodate the delivery of infusions under backpressure conditions with an expected deviation in accuracy of +5% to -5% (Note: In high backpressure conditions, such as with a 26G PICC line infusing at 100mL/h, additional under delivery may occur).

In the SapphirePlus pump, as in all infusion systems, external factors may cause fluctuations in rate accuracy. Conditions that can cause flow fluctuations include:

- Position of the infusion container height (any deviation from 50 cm above the pump)
- Fluid characteristics that deviate from water-like characteristics, such as density, viscosity and homogeneity
- Positive and negative pressure, including back pressure
- Environmental temperature above or below 25°C
- Barometric pressure above or below 101kPa

For example:

- A change of ± 25 cm in the fluid level above the pump may result in deviation in accuracy of $\pm 1\%$
- Using sets with PAV may result in deviation in accuracy of -6%



When using accessories where the container height deviates from 50 cm above the pump, there may be deviations in pump accuracy (e.g., Homecare Large Backpack).

Start-up and Trumpet Graphs

The start-up graphs represent startup flow versus operating time for the first two hours from the start of the infusion. They exhibit the stability of delivery due to mechanical compliance and provide a visual representation of uniformity. Start-up graphs were performed according to the IEC 60601-2-24 standard.

In the SapphirePlus pump, as in all infusion systems, the action of the pumping mechanism and variations or external factors may cause fluctuations in rate accuracy. Conditions that can cause flow fluctuations include:

- Position of the infusion container
- Fluid density
- Positive and negative pressure
- Environmental temperature
- Operation of the pump beyond the recommended operating limits

Trumpet curves are named for their characteristic /shape, and are developed in accordance with IEC 60601-2-24. They display the percent flow rate deviation from the programmed rate over time. The horizontal axis represents the observation time intervals.

Over long observation windows, short-term fluctuation has little effect on accuracy, as represented by the flat part of the curve. As the observation window is reduced, short-term fluctuations have a greater effect, as represented by the "mouth" of the trumpet.

Figure 12.1. Delivery Startup Graph, First 2 Hours of Test Period, 1 mL/h

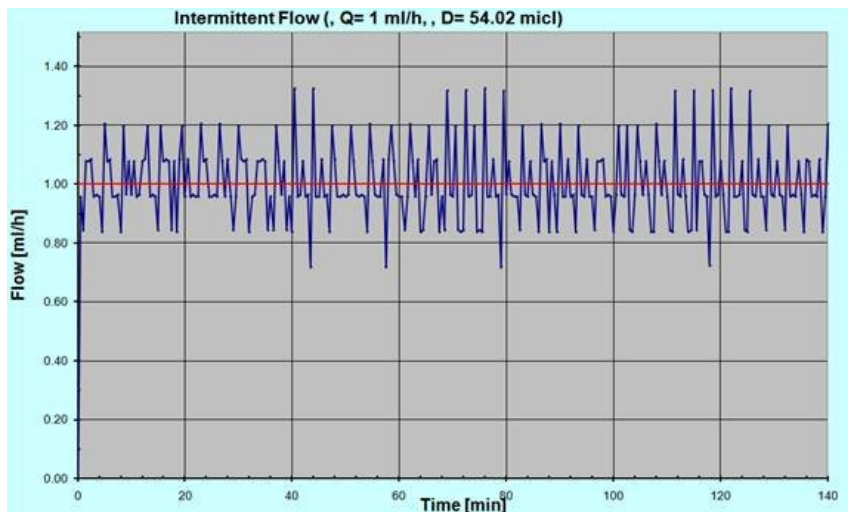


Figure 12.2. Trumpet Graph, Second Hour of Delivery, 1 mL/h

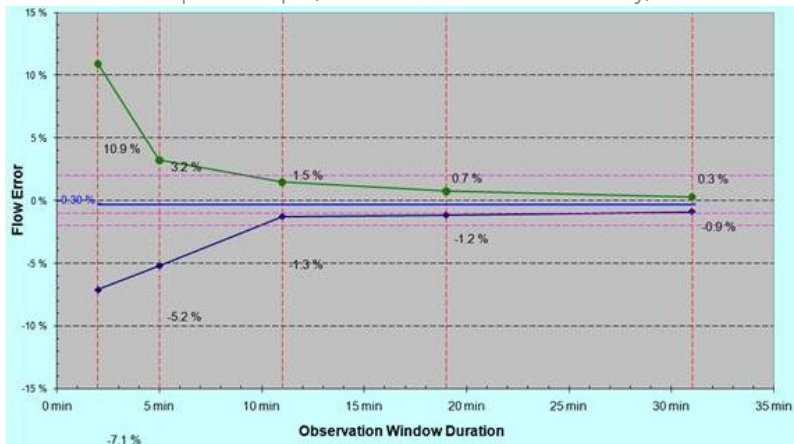


Figure 12.3. Trumpet Graph, 24th (Last) Hour of Delivery, 1 mL/h

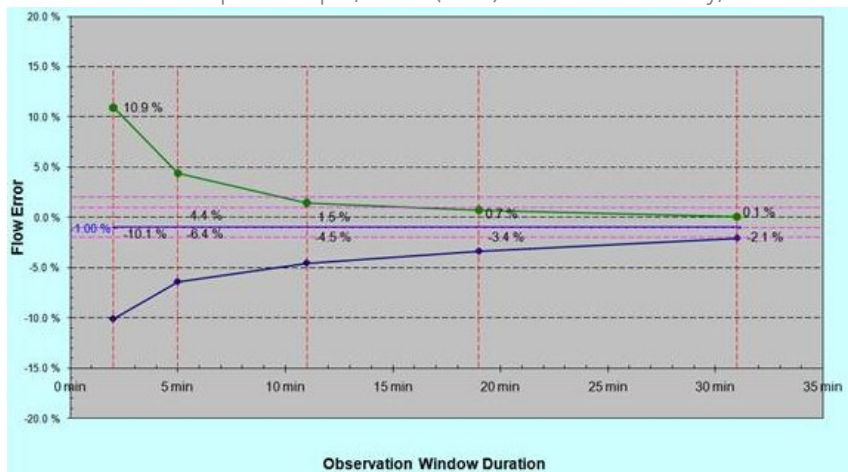


Figure 12.4. Delivery Startup Graph, First 2 Hours of Test Period, 25 mL/h

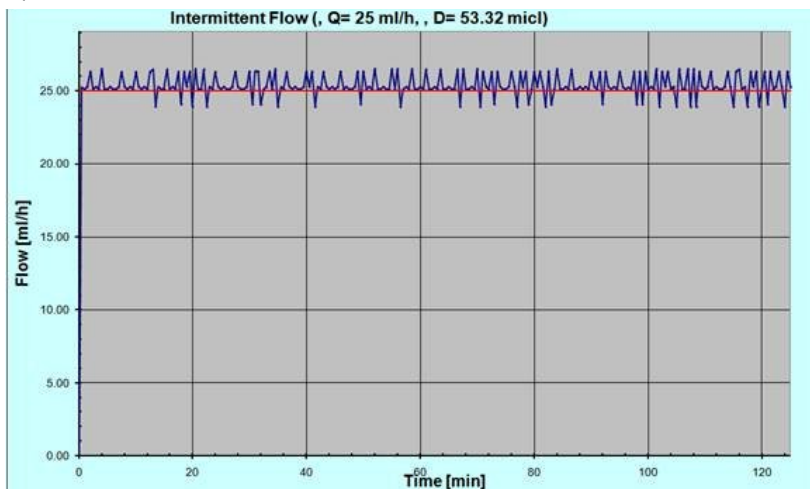


Figure 12.5. Trumpet Graph, Second Hour of Delivery, 25 mL/h

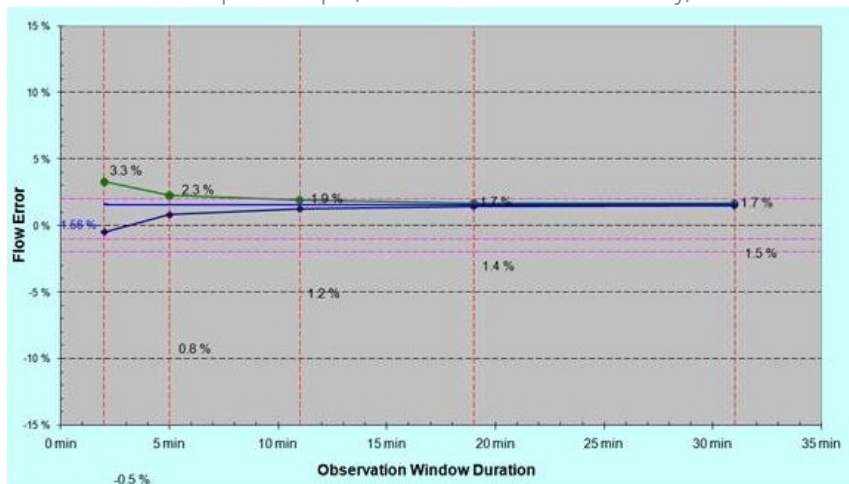
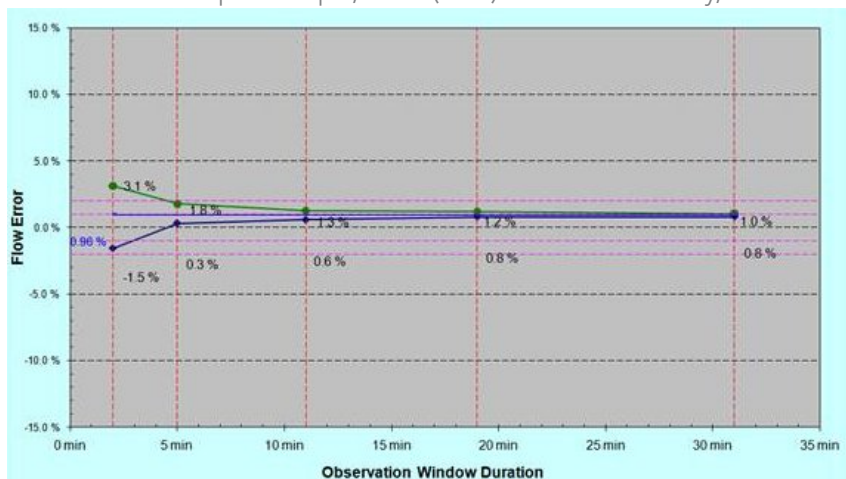


Figure 12.6. Trumpet Graph, 24th (Last) Hour of Delivery, 25 mL/h



Pump Specifications

The following table lists and describes pump specifications.

Parameter	Description
Dimensions	143 x 96 x 49 mm (5.63 x 3.78 x 1.93 in.) (H x W x D)
Weight (excluding batteries)	Sapphire* – 418 g (14.7 oz.) SapphirePlus – 433 g (15.3 oz.)
Pumping mechanism	Single channel volumetric, with integral pressure sensor
Infusion delivery modes	Continuous (with and without a Secondary line), PCA, Intermittent, Multi-step, TPN, Epidural (PCEA, Epidural Intermittent)**
KVO rate	Up to 20 mL/h in increments of 0.1 mL/h
Accuracy	±2.5% (Subject to external conditions such as tubing, pressure, container position relative to the pump, barometric pressure, humidity and temperature)
Defibrillation proof - recovery time	Max 1 sec
Flow rate	0.1 - 99.9 mL/h in increments of 0.1 mL/h 100 - 999 mL/h in increments of 1 mL/h
Volume (VTBI)	0.1 - 99.9 mL in increments of 0.1 mL 100 - 9999 mL in increments of 1 mL
Infusion device	Volumetric, peristaltic
External power supply	100 - 240V 50-60 Hz, 0.6A
Battery	<ul style="list-style-type: none"> • Rechargeable Li-Ion battery 7.4V, 1960 mA/h • 24 hrs @ 125 mL/h (with a fully charged battery, and backlight Off) • Recharge time: up to 6 hrs (when pump is not in operation) • When connected to Wi-Fi, 5 hrs @125 mL/h (with a fully charged battery, and backlight Off)

Parameter	Description
Adaptor	AC Adaptor 10 VDC/2.0A
Fuse rating	T1.6A, 250V
Downstream occlusion	Up to 17.4 PSI (1.2 bar or 900 mmHg)
Operating temperature	+5° (41°F) to 40°C (104°F)
Alarms	Refer to full list of alarms in Chapter 10: Alarms and Troubleshooting on page 170.
Prime	Manual or automatic priming (600 mL/h, or from air in line alarm 900 mL/h)
Sensors	<ul style="list-style-type: none"> • Air in line sensor: Detects both single and accumulated bubbles sized 0.02-0.5 mL. The desired size range of each option can be selected by the technician. • Upstream/Downstream occlusion sensor • Door open sensor • Temperature sensor

* Relevant for Sapphire Multi-therapy, Sapphire PCA, Sapphire Epidural, Sapphire TPN and SapphireH100.

** PCA, TPN, Intermittent, PCEA and Epidural intermittent modes are available in Sapphire Multi-Therapy pumps only.

Wireless Upgrade Module

The following table lists the wireless module specifications:

Parameter	Description
Device Name	QC-580 802.11 a/b/g/n Wireless (Upgrade) Module
Standards	IEEE 802.11 a/b/g/n
Transmit Power	802.11 b/g - 15 dBm 802.11 a/n - 16 dBm

Parameter	Description
Antenna	Two dual band antennas each operating at 2.4GHz and 5GHz bands
Certifications	FCC Part 15 (Subpart C, Subpart E) IC RSS (210, Gen)
This Device contains	FCC ID: N6C-SDMAN IC: 4908B-SDMAN Model: QC-580
Wireless Security	<ul style="list-style-type: none"> • WPA Personal <ul style="list-style-type: none"> • Authentication: PSK • Encryption: TKIP, AUTO • WPA2 Personal <ul style="list-style-type: none"> • Authentication: PSK • Encryption: AES • WPA Enterprise <ul style="list-style-type: none"> • Authentication: EAP-TLS, EAP-TTLS, PEAP, EAP-FAST • Encryption: TKIP, AUTO • WPA2 Enterprise <ul style="list-style-type: none"> • Authentication: EAP-TLS, EAP-TTLS, PEAP, EAP-FAST • Encryption: AES


Average Bolus Volume After Occlusion

The following table presents the average time to a downstream occlusion alarm, and the bolus volume after occlusion, at a rate of 25 mL/h.

Parameter	Pressure	
	0.4 bar	1.2 bar
Average bolus volume following downstream occlusion	0.135 mL	0.75 mL*
Average time to downstream occlusion alarm	38 sec	3 min
* Under single fault condition		

The following table presents the average time to a downstream occlusion alarm at a rate of 0.1 mL/h.

Parameter	Pressure	
	0.4 bar	1.2 bar
Average time to downstream occlusion alarm	2:30 hours	12:30 hours



In case of an occlusion (upstream or downstream), clear the occlusion by disconnecting the set from the patient and priming the administration set. When priming manually, close clamps and disconnect the patient from the administration set prior to detaching the administration cassette from the pump.

Environmental Specifications

The pump should be operated within the temperature and humidity ranges specified below. To avoid damage to the pump or battery, do not store the pump or the administration set outside these temperature and humidity ranges. Do not store the pump for prolonged periods with the battery installed.

Operating Conditions

Adhere to the following operating conditions:

Condition	Details/Range
Operating mode	Long term infusion usage
Humidity	15% to 95%
Temperature	+5°C to 40°C (41°F to 104°F)
Atmospheric pressure	70 kpa to 106 kpa

Environmental Conditions for Transport and Storage

When transporting or storing the pump, adhere to the following conditions:

Condition	Details/Range
Atmospheric pressure	50 kPa to 106 kPa (500 hPa to 1060 hPa)
Relative humidity	15% to 95%
Temperature	-40°C to +70°C (-40°F to 158°F)



Do not disassemble the portion of the SapphirePlus pump that houses the pump mechanism and the electronics. This should be done by authorized personnel only; Q Core Medical Ltd. will not be obligated to provide technical service in such a case.

When storing batteries separately from the pump, maintain the following storage temperature ranges:

Type of Storage	Temperature Range
Short term	<40°C (<95°F)
Long term	-20°C (-4°F) to +35°C (+95°F) Recommended: 23° ±3°C (73° ±5°F)



Storage at low temperatures may affect initial battery performance.
Storage at high temperatures may degrade battery performance.

The following list provides guidelines about environmental conditions and situations to be avoided when working with or storing the pump:

- Avoid locations where there is inadequate ventilation.
- Avoid locations where sudden impact or vibration may occur.
- Avoid damp locations, or locations where moisture level may increase considerably.
- Avoid locations with large temperature fluctuations.
- Avoid locations exposed to direct sunlight.
- Avoid locations near an electrical heating apparatus.
- Avoid locations exposed to chemicals or explosive gases.

Electromagnetic Compatibility Statement

The following sections provide information about testing of and recommendations for:

Electromagnetic Emission 204

Electromagnetic Immunity 205

Recommended Separation Distances from Mobile RF Communication Equipment 208

Electromagnetic Emission

The pump is intended for use in the electromagnetic environment specified below. The customer or the user of the pump should ensure that it is used in such an environment.

Emission Test	Compliance	Electromagnetic Environment Guidance
RF emission CISPR 11	Group 1	The pump uses RF energy for its internal function only. Therefore, RF emissions are very low and are not likely to cause any interference with nearby electronic equipment.
RF emission CISPR 11	Class B	The pump is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 610003-3-2	Class B	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Electromagnetic Immunity

The pump is intended for use in the electromagnetic environment specified below. The customer or the user of the pump should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±8 kV contact ±15 kV air*	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode	±1 kV at 110 & 230 VAC	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycles 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 s	<5% UT (>95% dip in UT) for 0.5 cycles 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the pump requires continued operation during power mains interruptions, it is recommended that the pump be powered from an uninterruptible power supply or a battery.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

* The pump was tested to the EMC requirements of **IEC 60601-1-2 (third edition)** and **IEC 60601-2-24 (second edition)**.

Electromagnetic Immunity for Life-supporting Equipment and Systems

The pump is intended for use in the electromagnetic environment specified below. The customer or the user of the pump should ensure that it is used in such an environment. Portable and mobile RF communications equipment should be used no closer to any part of the pump, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.



Interference may occur in the vicinity of equipment marked with the symbol.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance*
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 10 Vrms 150 kHz to 80 MHz	3 Vrms 3 Vrms**	Recommended separation distance (RSD) $d = 1.2\sqrt{p}$ RSD $d = 4\sqrt{p}$

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance *
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	10 V/m 80 MHz – 2.5 GHz 80% AM, 2 Hz 80 MHz – 2.5 GHz 80% AM, 1 KHz	<p>where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer, and d is the recommended separation distance in meters (m).</p> <p>Recommended separation distances:</p> <ul style="list-style-type: none"> 80 MHz to 800 MHz: $d = 4\sqrt{p}$ 800 MHz to 2.5 GHz: $d = 7.7\sqrt{p}$ <p>At 80 MHz and 800 MHz, the higher frequency range applies.</p>

* These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

** The pump was tested to the EMC requirements of **IEC 60601-1-2 (third edition)** and **IEC 60601-2-24 (second edition)**.

Notes

1. The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.
2. The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.
For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.

3. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the SapphirePlus pump is used exceeds the applicable RF compliance level above, the pump should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the pump.
4. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended Separation Distances from Mobile RF Communication Equipment

The pump is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer/pump user can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the pump, according to the maximum output power of the communications equipment.

The following table provides recommended separation distances between portable and mobile RF communication equipment and the pump (for life-supporting equipment and systems).

For transmitters rated at a maximum output power not listed in the table, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Rated Maximum Output Power of Transmitter (W)	Separation Distance According to Frequency of Transmitter (m)			
	150 kHz to 80 MHz outside ISM bands	150 kHz to 80 MHz in ISM bands	80 MHz to 800 MHz	800 MHz to 2.5 GHz
	$d = 1.2\sqrt{p}$	$d = 4\sqrt{p}$	$d = 1.2\sqrt{p}$	$d = 2.3\sqrt{p}$
0.01	0.12	0.40	0.12	0.23
0.1	0.38	1.3	0.38	0.72
1	1.2	4.00	1.2	2.3
10	3.8	13	3.8	7.27
100	12	4.00	12	23

Notes

1. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
2. At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
3. The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.
4. An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz.
This decreases the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.



Chapter 13: Limited Warranty

Q Core Medical Ltd. (the "Manufacturer") warrants to the buyer who purchased the SapphirePlus directly from the manufacturer (Initial Buyer) that the SapphirePlus Infusion Pump ("SapphirePlus"), not including accessories, shall be free from defects in materials and workmanship under normal use, if used in accordance with this User Manual, for a period of one year from the actual date of sale to the Initial Buyer. THERE ARE NO OTHER WARRANTIES. Extended warranty can be separately purchased following the end of the one year period.

This warranty does not cover normal wear and tear and maintenance items, (such as the Yearly Certification Kit), and specifically excludes batteries, administration sets, extension sets or any other accessory items or equipment used with the SapphirePlus. Subject to the conditions of and upon compliance with this Limited Warranty, the Manufacturer will repair or replace at its option without charge (except for a nominal charge for postage and handling) any defective SapphirePlus provided a claim is made during such one year period.

The following conditions, procedures, and limitations apply to the Manufacturer's obligation under this warranty:

A. Parties Covered by this Warranty: This Warranty extends only to the Initial Buyer of the SapphirePlus.

Warranty Performance Procedure: Notice of the claimed defect must be made by Initial Buyer in writing to the Manufacturer as follows:

Q Core Medical Ltd., 29 Yad Haruzim St., P.O. Box 8639, Netanya, 4250529, Israel.

Initial Buyer should send mail to support@qcore.com or contact the account manager.

Notice to the Manufacturer must include date of purchase, serial number, and a description of the claimed defect in sufficient detail to allow the Manufacturer to determine and facilitate any repairs which may be necessary. AUTHORIZATION MUST BE OBTAINED PRIOR TO RETURNING THE SAPPHIREPLUS. If authorized, the Sapphire must be properly and carefully cleaned, packaged and returned to the Manufacturer. Any loss or damage during shipment is at the risk of the sender.

The SapphirePlus service life is 7 years from the date of manufacture.

B. Conditions of Warranty: The warranty is void if the SapphirePlus has been
1) repaired by someone other than the Manufacturer or its authorized agent
2) altered so its stability or reliability is affected 3) misused or 4) damaged by negligence or accident. Misuse includes, but is not limited to, use not in compliance with the User Manual or use with non-approved accessories. Removal or damage to the SapphirePlus's serial number will invalidate this warranty.

C. Limitations and Exclusions: Repair or replacement of the SapphirePlus or any component part therefore is the EXCLUSIVE remedy offered by Manufacturer. The following exclusions and limitations shall apply:

1. No agent, representative, or employee of the Manufacturer has authority to bind the Manufacturer to any representation or warranty, expressed or implied.
2. THERE IS NO WARRANTY OF MERCHANTABILITY OR FITNESS OR USE OF THE SAPPHIREPLUS FOR ANY PARTICULAR PURPOSE.
3. The SapphirePlus can only be used under the instruction of medical personnel whose skill and judgment determine the suitability of the SapphirePlus for any particular medical treatment.
4. All recommendations, information, and descriptive literature supplied by the Manufacturer or its agents are believed to be accurate and reliable, but do not constitute warranties.

The Manufacturer disclaims responsibility for the suitability of the SapphirePlus for any particular medical treatment or for any medical complications resulting from the use of the SapphirePlus. The Manufacturer shall not be responsible for any incidental damage or consequential damages to property, loss of profits, or loss of use caused by any defect or malfunction of the SapphirePlus.

Service Information

While under Q Core warranty, the SapphirePlus pump must not be opened by unauthorized personnel.

Use only an authorized Q Core service provider for service and repair. In the event that your pump needs to be returned for service, obtain a Return Authorization by sending mail to support@qcore.com, or contact your account manager. The pump must be packed in a suitable container that will provide adequate protection during shipment.

To ensure prompt return, a

Q Core authorized service representative must be notified before shipping any pump for repair. When calling for service, please be prepared to provide the serial number of the pump and software version details. A brief written description of the problem should be attached to the pump when it is returned for service.

Q Core Medical Ltd. will not be responsible for unauthorized returns or for pumps damaged in shipment due to improper packing.

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Appendix A: SapphirePlus Configuration Settings

The following sections present the SapphirePlus pump configuration settings:

User Options – Alarm and Audio Settings	214
User Options – General Pump Settings	215
User Options – Hard Limits and KVO Settings	218
User Options – Air Settings	219

User Options – Alarm and Audio Settings

Parameter	Pump Options	Default Factory Setting (without drug library)	Controlled by Drug Library	ICU Medical MedNet™ Meds™ Configuration Options Notes	Authorization Level
Occlusion Units	PSI BAR mmHg	BAR	Yes		High
Occlusion Pressure	PSI: 5.8-17.4 in increments of 0.1 BAR: 0.4-1.2 in increments of 0.1 mmHg: 300 - 900 in increments of 1	0.4 BAR	Yes		High
Pump Unattended	2, 5, 10 min	10 min	Yes		High
Infusion Near End	Off, 1, 3, 5, 10 min	10 min	Yes		High

Parameter	Pump Options	Default Factory Setting (without drug library)	Controlled by Drug Library	ICU Medical MedNet™ Meds™ Configuration Options Notes	Authorization Level
Alarm Volume	Maximum, Minimum	Maximum	Yes		High
Keys Volume	Low, High, Off	High	Yes		High

User Options – General Pump Settings

Parameters	Pump Options	Default Factory Setting (without drug library)	Controlled by Drug Library	ICU Medical MedNet™ Meds™ Configuration Options Notes	Authorization level
Set Delay	On, Off	Off	Yes		High
Post Infusion Rate	KVO, Rate	KVO	Yes	Rule Set – configurable General Drug – controlled by CCA setting	
Pre-Program	On, Off	Off	Yes		High
Repeat Last	On, Off	On	Yes		High
Set Prime Volume	2 – 25 mL in increments of 1 mL	20 mL	Yes		High
Backlight Options	On, Partial, Off	On	Yes		High
Prime reminder	On, Off	Off	Yes		High

Parameters	Pump Options	Default Factory Setting (without drug library)	Controlled by Drug Library	ICU Medical MedNet™ Meds™ Configuration Options Notes	Authorization level
Advanced Bolus	On, Off	Off	Yes	Rule set – Not configurable; option set to On General drug – controlled by CCA settings	High
Auto Patient Lockout	On, Off	Off	Yes		High
Screen saver	On, Off	Off	Yes		High
US Format**	On, Off	Off	Yes		High
New Patient	On, Off	Off	Yes		Technician
Set Secondary	On, Off	Off	Yes	Rule set – configurable via ICU Medical MedNet™. Applied for primary and secondary bolus. General drug – controlled by CCA settings.	Technician
Allow bolus	On, Off	Off	Yes		Technician
Bolus Rate Continuous	0.1 - 99.9 mL/h in increments of 0.1 mL/h 100 - 999 mL/h in increments of 1 mL/h	125 mL/h	Yes		Technician

Parameters	Pump Options	Default Factory Setting (without drug library)	Controlled by Drug Library	ICU Medical MedNet™ Meds™ Configuration Options Notes	Authorization level
Secondary Bolus Rate (Continuous*)	0.1 - 99.9 mL/h in increments of 0.1 mL/h 100 - 500 mL/h in increments of 1 mL/h	125 mL/h	Yes	Rule set – configurable via ICU Medical MedNet™. Applied for primary and secondary bolus. General drug – controlled by Primary bolus rate in CCA settings.	Technician
Occlusion Auto-Restart	On, Off	On	Yes		Technician
Calculate concentration mL/h only	On, Off On, Off	Off Off	Yes No – appears Only in the absence of drug library on the pump.	Not configurable; option set to Off	Technician Technician
Wi-Fi**	On, Off	Off	No		Technician

*. Available when Set secondary is enabled.

**. Wi-Fi configuration is configured locally on the pump, but does not revert to default in any event.

User Options – Hard Limits and KVO Settings

Parameters	Pump Options	Default Factory Setting (without drug library)	Controlled by Drug Library	ICU Medical MedNet™ Meds™ Configuration Options Notes	Authorization level
Hard Limits Continuous VTBI	1 – 9999 mL in increments of 1 mL	9999 mL	Yes		Technician
Hard Limits Continuous Rate	0.1 – 99.9 mL/h in increments of 0.1 mL/h 100 – 999 mL/h in increments of 1 mL/h	999 mL/h	Yes		Technician
Hard Limits Continuous Secondary VTBI*	1 – 9999 mL in increments of 1 mL	9999 mL	Yes		Technician
Hard Limits Continuous Secondary Rate*	0.1 – 99.9 mL/h in increments of 0.1 mL/h 100 – 500 mL/h in increments of 1 mL/h	500 mL/h	Yes		Technician
Hard Limits Multistep VTBI	1 – 9999 mL in increments of 1 mL	9999 mL	Yes		Technician
Hard Limits Multistep Rate	0.1 – 99.9 mL/h in increments of 0.1 mL/h 100 – 999 mL/h in increments of 1 mL/h	999 mL/h	Yes		Technician

Parameters	Pump Options	Default Factory Setting (without drug library)	Controlled by Drug Library	ICU Medical MedNet™ Meds™ Configuration Options Notes	Authorization level
Hard Limits Multistep Time	00:01 – 24:00 hh:mm	24:00 hh:mm	Yes		Technician
KVO Continuous	0 – 20 mL in increments of 0.1 mL	3 mL/h	Yes		Technician
KVO Multistep	0 – 20 mL in increments of 0.1 mL	3 mL/h	Yes	Not configurable; option set to the configured Continuous KVO	Technician

*. Available when Set secondary is enabled

User Options – Air Settings

Parameters	Pump Options	Default Factory Setting (without drug library)	Controlled by Drug Library	ICU Medical MedNet™ Meds™ Configuration Options Notes	Authorization level
Single Air Detector	Off, 20, 40, 50, 100, 200, 500 mcl	Off	Yes		Technician
Accumulated Air Detector	20, 40, 50, 100, 200, 500 mcl	500 mcl	Yes		Technician
Accumulated Threshold	Off, 500, 1000 mcl	1000 mcl	Yes		Technician

Legend:

Controlled by Drug Library = Yes:

Users are able to change the settings temporarily on the pump (these are considered as local changes). The temporary settings revert to CCA defaults, when turning the pump Off or when selecting a CCA.

When choosing **Reset to Factory defaults**, changed settings will revert to pump factory defaults. This change is considered as a local change and will revert to CCA defaults, when turning the pump Off or when selecting a CCA.

Wi-Fi configuration is configured locally on the pump, but does not revert to default in any event.

Technical Support Contacts

US Phone: 1-800-241-4002



Manufacturer



Q Core Medical Ltd
29 Yad Haruzim St.
P.O. Box 8639
Netanya 4250529, ISRAEL

Product of Israel



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