REF 15025-048-0027 Rev.01

SERVICE MANUAL - LEVEL 1

SAPPHIRE MULTI-THERAPY AND DEDICATED INFUSION PUMPS

Sapphire

Important Notice

The Sapphire Infusion Pump Service Manual is delivered subject to the conditions and restrictions listed in this section. Qualified service technicians should read the entire Service Manual, in addition to the Sapphire User Manual, prior to operating the pump, in order to fully understand the functionality and operating procedures of the pump and its accessories.

Service technicians and 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.

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 infusion 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 medication and parenteral nutrition. The instructions for use presented in this guide should in no way supersede established medical protocol concerning patient care.

Copyright, Trademark and Patent Information

Sapphire and Q Core (with or without logos) are trademarks of Q Core Medical Ltd.

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

Warning

Use only Q Core Medical Ltd. supplied administration sets and accessories with Q Core infusion pumps. 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.'s 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.

Technical Assistance

For technical questions, troubleshooting assistance and device problems, please contact your local agent/distributor. To locate authorized Hospira service centers near you, refer to Authorized Hospira Service Centers on page 211. You may also contact Q Core Medical Ltd. support via email to the following address: service@qcore.com

Chapter 1: Introduction

This *Sapphire Infusion Pump Service Manual* is a Level 1 support service manual that includes the technical information of all the available Sapphire pumps: Sapphire Multi-therapy, Sapphire Epidural, SapphireH100 and SapphirePlus. It is designed to assist trained technicians and support personnel to perform the service functions appropriate to their level of authorization.

A trained technician is a technician trained to complete maintenance actions according the Q Core Training Standard Operating Procedure.

The following sections describe the structure of the Service Manual, and provide a summary of safety information:

Manual Outline and Conventions

This manual describes the configuration settings available for trained technicians working with the Sapphire pump, and explains the procedures involved in servicing the Sapphire Multi-therapy and Sapphire Epidural (revisions 11 and lower), SapphireH100 (revision 11) and SapphirePlus (revision 13). The material provided in this manual supplements the material detailed in the Sapphire User Manual. It assumes familiarity with the information contained in the User Manual.

Before performing tasks or providing level 1 service support to the Sapphire pump, read and become familiar with the material in both the User Manual and the Service Manual.

This Service Manual is organized into the following chapters:

Chapter	Description
Common chapters for all Sapphire infusion pumps	
Introduction	The scope of the current manual and its target audience.
Managing Authorization Levels	The procedures for assigning authorization levels in the Sapphire pump, WiFi settings, WiFi configuration using the SXManager Software and testing the hard keys.
Maintenance and Storage	The proper cleaning, preventive maintenance, and storage procedures for the pump and the battery.
Performing Annual Certification Testing	The annual certification testing process for the Sapphire pump.
Upgrading Software Version	How to upgrade the software version in the Sapphire pump.
Downloading Event Log	How to download the Event Log from the Sapphire pump to a PC.
Replacing the Battery	How to replace the battery in the Sapphire pump.
Sapphire and SapphireH100	
Configuring Basic Pump Settings	How to view and update basic pump configuration settings, using the Options menu.
Using Technician Options	The configuration options available to users with a Technician authorization level code.
Alarms and Troubleshooting	The different types of alarms and messages that can be generated by the pump, and explanation on how to troubleshoot common programming issues.
Event Log Tables	Lists of the events that are recorded to the Event Log.
Upgrading Software Version	How to upgrade the pump software version.
SapphirePlus	
Configuring Basic Pump Settings	How to view and update basic pump configuration settings, using the Options menu.

Chapter	Description
Using Technician Options	The configuration options available to users with a Technician authorization level code.
Alarms and Troubleshooting	The different types of alarms and messages that can be generated by the pump, and explanation on how to troubleshoot common programming issues.
Event Log Tables	Lists of the events that are recorded to the Event Log.
Upgrading Software Version	How to upgrade the pump software version.

To obtain information about features or procedures not included in this manual, contact Q Core Medical by sending an email to the following address: service@qcore.com, or a local distributor at Hospira service center (refer to Authorized Hospira Service Centers on page 211).

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
BPOC	Barcode Point-Of-Care
CCA	Clinical Care Area
ECG	Electrocardiogram
eMAR	Electronic Medication Administration Record
EMC	Electromagnetic compatibility
EMI	Electromagnetic interference
FCC	Federal Communications Commission
H	Hour

Term/Abbreviation	Meaning
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
mUnits	Milliunits
M Units	Million Units
nanog	Nanograms
Occ.	Occlusion
PAV	Pressure Activated Valve
PDA	Personal Digital Assistant
PHY	Physical Layer
RF	Radio Frequency
TPN	Total Parenteral Nutrition
VI	Volume Infused
VTBI	Volume To Be Infused
Q Core	Q Core Medical Ltd.
QoS	Quality of Service
Sapphire pump	Q Core Sapphire infusion pump family
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. Cautions are also used to advise against unsafe practices.
	Notes provide additional information to help obtain optimal equipment performance.

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 Sapphire 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 Sapphire 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 WiFi.
- FCC: The Federal Communications Commission (FCC) regulates interstate and international communications by radio, television, wire, satellite and cable. The Sapphire pump complies with Part 15B, 15C, 15E of the FCC Rules.

Wireless Communication

The SapphirePlus pump 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 and enable the auto-programming feature over a wireless connection.

The pump's WiFi abilities have been tested and approved according to United States rules and regulations. Using the pump's WiFi 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 WiFi 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 Sapphire pump complies with Part 15B, 15C, 15E of the FCC Rules.

Operation is subject to the following two conditions:

1. This device may not cause interference.
2. 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 Wireless Sapphire 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 Sapphire 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 Sapphire pump meets the IP24 splash/dust standard according to IEC 60601-1-11. Protects from water which is sprayed at 10L/min at a pressure of 80-100kN/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 Sapphire pump:

- General Warnings and Precautions on page 17
- Proper Use of the Pump on page 21

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.

- Do not operate the pump with the safety door open.

Waste Disposal

Make sure 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 reservoir container, 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 Sapphire 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 Sapphire 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 separation between the equipment.
- Connect the equipment into 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's 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 802.11a/b/g/n device usage in the 5150-5250 MHz band is limited to indoor use to reduce potential for harmful interference to 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 may not cause interference, and (2) Pump operation must not be affected by any transmitted interference from other devices.

Data Transfer and Integrity

The SapphirePlus pump wireless system 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 (kilobyte per minute).

Data integrity is achieved in two levels:

- By WiFi 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 Sapphire WiFi module.
- Use roaming to ensure that the WiFi 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 administrator and based on the network configuration.

Proper Use of the Pump

Although the Sapphire 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 Sapphire 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, 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, and will not alarm under infiltration conditions.

	When using the pump, use only Q Core's 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 a trained 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 Sapphire pump has not been evaluated for compatibility with Extracorporeal Membrane Oxygenation (ECMO) systems.
- 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 emission 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 supplied administration sets with the Sapphire pump. Severe injury or death may result from using sets other than those indicated in Q Core's approved list of products.

For infection control purposes, consider the set change interval recommended by the local Centers for Disease Control and Prevention (CDC), your facility's 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 reservoir 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's 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 reservoir container is positioned at a height of 50 cm above the pump. There is no restriction on the location of the reservoir container in relation to the patient's heart.

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 to set the occlusion pressure 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).
- **Volume To Be Infused:** Do not enter a value greater than the amount of fluid available in the container.
- **Secondary Infusions:** When using the Piggyback infusion feature, verify that:
  - the medication/solution in the Secondary reservoir container is compatible with the medication/solution in the Primary reservoir container.
  - the Secondary administration set is connected to the appropriate injection site on the primary administration set.
  - 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 tubing is closed when Piggyback infusions are not running.

The following sections contain important safety information. All warnings and safety precautions should be read carefully before servicing the Sapphire pump.

 When working with the Sapphire pump, always adhere to the following instructions and safety guidelines:

- This equipment is not suitable for use in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide.
- The pump uses a Li-Ion battery, supplied by Q Core. Replace the battery only with the same type (Q Core issued battery). An explosion hazard exists if the battery is replaced by an incorrect type or not according to the instructions. Refer to Replacing the Battery on page 119.
- Do not short circuit the battery terminals. Do not disassemble or modify battery packs.
- Do not dispose of batteries or battery packs in fire.
- The packaging, the administration sets, the battery, and any other electronic components must not be disposed of as unsorted municipal waste, and must be collected separately in accordance with applicable environmental laws (such as the WEEE Directive for Waste Electrical and Electronic Equipment). Contact an authorized representative for information concerning the decommissioning of your equipment.
- Do not use a pump that has been dropped or that is visibly damaged. The pump must be inspected and repaired by a qualified service technician prior to further use.
- Do not test the pump if the room temperature is not in range (room temperature: 18° - 29° C).

- Use only Q Core approved administration sets. Use of any other sets will result in malfunction or inaccurate delivery. For a list of approved sets, refer to the Sapphire User Manual.

	Authorization level codes are provided in Managing Authorization Lock Levels on page 33. Do not leave this manual near unauthorized personnel or patients.

	Do not disclose the passwords of authorization levels to unauthorized users.

 When working with the pump, always adhere to the following precautionary guidelines:

- Federal (USA) law restricts this device to sale by or on the order of a physician or other licensed practitioner.
- Operate the pump only on the AC line voltage for which the AC Power Adaptor is marked.
- While the pump is in storage, recharge the battery at least every 12 months.
- Before servicing the pump, disconnect it from the AC power source.
- Routine cleaning and periodic maintenance is necessary to ensure that the pump remains safe and functional. For details, refer to Chapter 3: Maintenance and Storage on page 37.
- Solution spills should be wiped up as soon as possible, using a damp cloth or sponge. Dry the pump thoroughly before use.
- Static sensitive electronics used in the pump may be damaged by electrostatic discharge. Service technicians must follow proper ESD procedures when working on the pump.
- Do not use a pen or any other sharp object to press the hard keys or the buttons on the touch screen. Replace torn or punctured front panel immediately, to prevent damage to the front panel switch.

Default Configuration Settings of the Sapphire Pump

Feature	Default	For Details Refer To
Occlusion Units	BAR	Configuring General Settings
Occlusion Threshold	0.4 BAR	Configuring General Settings
Pump unattended	10 minutes	Configuring General Settings
Infusion near end	10 minutes	Configuring General Settings
Alarm Volume	Maximum	Configuring General Settings
Keys volume	High	Configuring General Settings
Authorization level	High	Configuring General Settings
Allow delayed start	Off	Configuring General Settings
Allow PreProgram	Off	Sapphire & SapphireH100: Configuring General Settings
PreProgram	Off	SapphirePlus: Configuring General Settings
Set Prime Volume	20 mL	Configuring General Settings
Backlight	On	Configuring General Settings
Prime Reminder	Off	SapphirePlus: Configuring General Settings
Bolus Handle	Always On	SapphirePlus: Configuring Basic Pump Settings
Language	English	Configuring General Settings
US Format	Off	Configuring General Settings
Single Air detector	Off	Using Technician Options
Accumulated Air detector	0.05 mL	Using Technician Options
Accumulated Threshold	1 mL	Using Technician Options
New Patient	Off	Using Technician Options
Continuous Bolus Rate	600 mL/h	Using Technician Options
Set Secondary (continuous delivery)	Off	Using Technician Options
PCA / PCEA infusion type	Continuous + Bolus	Sapphire & SapphireH100: Using Technician Options

Feature	Default	For Details Refer To
PCA/PCEA Max Bolus per	1 Hr	Sapphire & SapphireH100: Using Technician Options
WiFi	Off	SapphirePlus: Using Technician Options
Allow Loading Dose	On	User Manual (Using Special Mode Options)
Auto.P.Lockout	Off	User Manual (Using Special Mode Options)
Password request	No	User Manual (Using Special Mode Options)

The specific parameters ranges are listed in 'Using the Infusion Modes' chapter of the Sapphire User Manual.

FTP site

Q Core FTP site contains the latest version of the pump software, Pump Loader software, Annual Certification software, Event Log Viewer software, updated forms, work instructions and user manuals.

	The files located at the FTP Site are highly confidential. Keep your user name and password in a safe place and do not allow your browser to save them automatically.

> To access Q Core FTP Site:

	Accessing the Q Core FTP site requires your browser to access HTTPS://qcore.smartfile.com. HTTPS is an established standard for secure, encrypted web-based communications and operates via TCP/IP port 443.

1. Obtain username and password directly from Q Core Medical at service@qcore.com, or from a local distributor at Hospira service center

(refer to Authorized Hospira Service Centers on page 211).

2. Type https://qcore.smartfile.com in the browser address bar, and press **Enter**.
3. Enter your username and password, and then click **OK**.

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Chapter 2: Managing Authorization Levels

The following sections review the security passwords and levels of authorization and explain how to view and change the current authorization lock level:

Overview

To help ensure patient safety, the Sapphire pump can be set to one of four authorization levels. Authorization levels control access to the programming options available in the pump. Each level enables 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, in addition to 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 a technician or loaded with the Drug Library. For information regarding new security passwords definition by a technician, refer to To change the passwords: on page 40.

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
	Administer patient bolus
	Use the View menu
Medium	Stop the pump, and then start an 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 infusion mode (requires password re-entry)
	Clinician bolus (requires password re-entry)
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 level authorization lock level.
Verify that the pump is not in Technician mode before returning it to the user.

The default passwords are:

Level	Password
Low	9990
Medium	8880
High	7770
Technician	7772

Do not publish or email codes to unauthorized people. Do not give access of this publication to home users.

Managing Authorization Lock Levels

View and change the current authorization lock level as required.

Viewing Authorization Lock Levels

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 level 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 level 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**.

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.

Setting Technician Lock Level

Users with Technician authorization level have two options in setting the lock level for the Sapphire pump. The procedures vary, depending on how the pump is configured.

> If the pump is set on High or Technician lock level:

1. From the Options menu, select **Pump Configuration →General Settings**.
2. Select **Authorization Level**.
3. From the keypad, enter the Technician or High Level password.
4. Press **OK**.
5. Select the authorization level at which to lock the pump.

   The authorization level matching the entered password, as well as all levels below it, are listed on the Main Display.
6. Press **OK** to confirm.
7. Press **OK** to exit the Options menu.

> If the pump is set on Medium or Low lock level:

1. From the Options menu, select Pump Configuration.
2. From the keypad, enter the Technician or High Level password.
3. Press **OK**.
4. Press **OK** on the Attention screen.

The Sapphire pump allows you to override a lower authorization level by entering the High level password whenever a password request appears onscreen.

Password Re-entry

The Sapphire 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 you to re-enter your High level password before performing the following actions:

- Changing infusion mode
- Changing authorization level
- Entering a clinician bolus

	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.

Chapter 3: Maintenance and Storage

This chapter describes the proper cleaning, preventive maintenance, and storage procedures for the pump and the battery. It includes content from the corresponding chapter in the Sapphire User Manual with relevant material highlighted for trained technicians:

Cleaning and Disinfecting the Pump

Between use on different patients, the Sapphire 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, 15 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.
  - The pump is disconnected from a power supply.
- While cleaning/disinfecting the pump, do not allow fluid to enter the pump housing, speaker holes, or battery chamber.
- Do not use aggressive cleaning agents - these can damage the exterior surface of the pump.
- 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.

	Before using materials other than the products listed above for cleaning and disinfecting the Sapphire Infusion pump, the facility must have its cleaning and disinfection agents approved by Q Core Medical or its local representatives. Q Core or its local representative will let you know in writing if and when such additional materials will be validated for use.

	The pump must be completely dried out before connecting it to a power supply.

Cleaning and Disinfecting 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 Assiciates, Inc.

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 pump power socket.
2. Use the appropriate dilution ratio according to 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 should be completely dried out before connecting it to a power supply.

Disinfection Procedure

The following procedure explains how to disinfect the pump using the approved agents (see Cleaning and Disinfecting Procedure on page 39):

> 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 should 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 Finger	Clean the finger tip of the sensor using only a damp cloth or sponge.
• 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	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. **Note:** Swabbing should be applied in vertical or horizontal movement, where possible, while less accessible areas will be swabbed in a circular motion (at least 3 bi-directional rotations clockwise-counterclockwise).

Do not return the Sapphire pump to the patient if it is unclean or damaged.

Reprocessing the pump when used by a single patient multiple times

When the Sapphire 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 Disinfecting Procedure on page 39.

Preventative Maintenance

This section describes the following preventative maintenance topics:

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 Sapphire 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 hospital biomedical engineer, or a Q Core approved service technician.

The following equipment checks should be performed following each use of the pump, and as required:

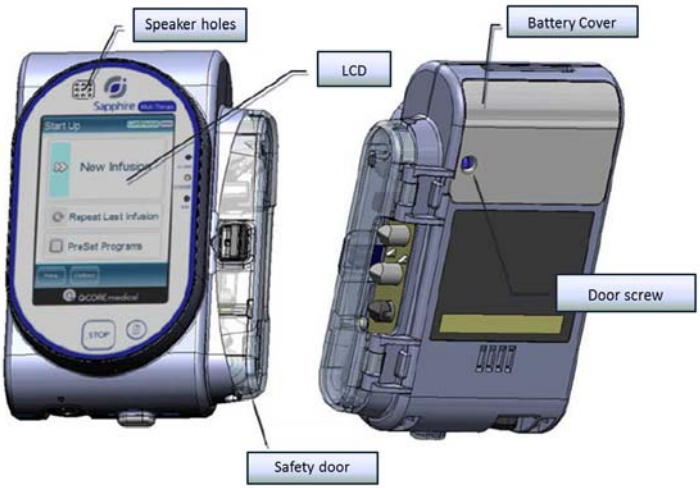
Pump Component	Action
Pump Housing	Check for cracks and dents.
Power Cord	Verify that the power cord is undamaged. Check the entire length of the cord, and the plug.

Additional instructions about cleaning the delicate parts of the pump are included below.

Thorough Visual Inspection

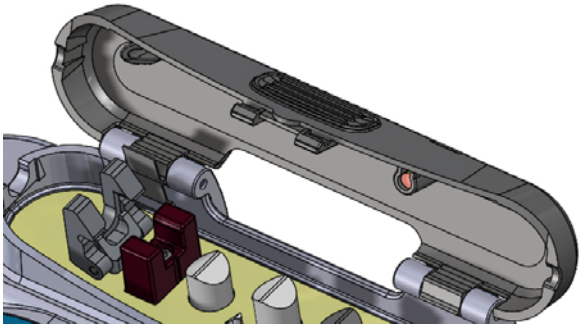
1. Check the pump plastic housing for cracks and broken parts. If parts are broken or cracked, the pump must be serviced.

Figure 3.1. Visual Inspection for Cracks



2. Verify that the safety door is functioning properly (Figure 3.2). The door must be free of cracks and the door latch should be intact. Check if the door is cleaned to transparency, so you can monitor that the cassette is properly located during set installation. If necessary, clean and dry the safety door with a dry cloth.

Figure 3.2. Visual Inspection of Safety Door



This figure displays the safety door design of SapphirePlus and Multi-Therapy pumps. SapphireH100 pump has a unique safety door design, see SapphireH100 Design on page 131.

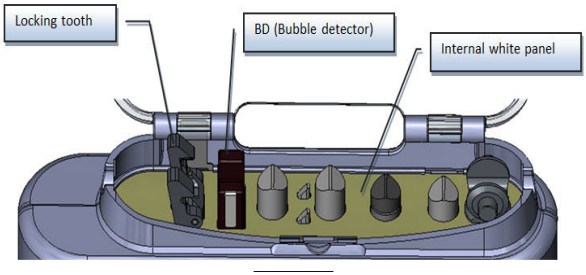
3. Check the cassette chamber, pumping mechanism and cassette locking mechanism for functionality and cleanness (Figure 3.3):

   a. The door latch should move to "cassette unlock position" freely and spring back to "lock position" without any resistance, otherwise return the pump for servicing.

   b. The internal white panel should be free of foreign materials and dirt. If necessary, use standard detergent solution to clean the connector or the Dispatch® (Caltech) ready-to-use towels. Pay particular attention to the area around the 4 fingers roots.

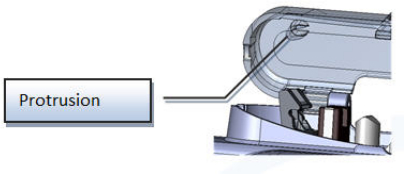
c. The Bubble Detector (BD) must be inspected for possible cracks, scratches or dirt. If the BD plastic shell is damaged, return the pump for servicing. A dirty BD cover can lead to improper functioning of the BD, creating false alarms. Verify that the BD plastic cover is clean of grease or other foreign materials.

Figure 3.3. Visual Inspection of Cassette Chamber



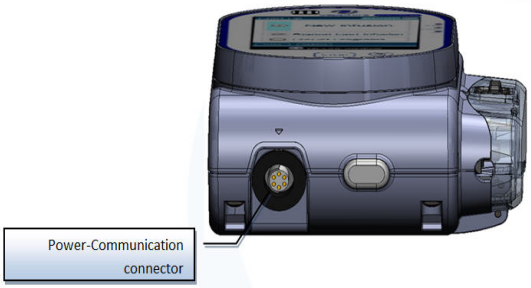
4. A properly functioning safety door must "click" itself into the open position, and must snap itself to a secure closed position. The door has an internal protrusion to assure correct locking of the cassette when the door is closed. Verify that the protrusion is not broken.

Figure 3.4. Visual Inspection of Safety Door



5. Check that the power-communication connector is free of foreign materials and dirt. If necessary, clean and dry with a dry cloth.

Figure 3.5. Visual Inspection of Power-Communication Connector

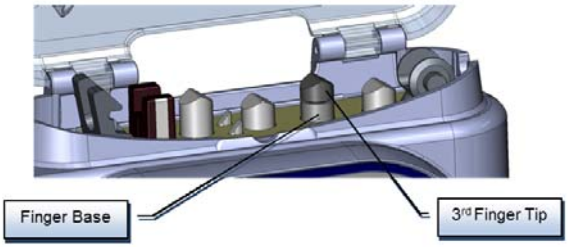


6. The pump has flat golden connectors (P2C) on the back of its plastic housing. Make sure that the connectors are not loose, broken, dirty or corroded. When cleaning the pads, take special care not to scratch its golden surfaces.

Figure 3.6. Visual Inspection of Connectors

7. The pump pressure sensor is located on the 3rd finger tip. This finger tip should move freely and the gap between the tip and the finger should be free of dirt, grease or foreign materials. Gently press the tip to verify that it is moving freely.

Figure 3.7. Visual Inspection of Pressure Sensor



Pump must be serviced:

- In any case of cracked, broken or deformed parts of the pump housing, the pump must be serviced. This includes the pump housing, cassette chamber door and battery door.
- In case of a cracked, broken or deformed BD plastic housing.
- Pumps suspected of being damaged must be tested for proper performance before being returned to patient use. This includes pumps that have been physically damaged, or those that have fluid intrusion.

Alarm Testing

It is recommended to perform manual testing of the following alarms at least yearly or per facility protocol.

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 collapsible bag of water 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, return the pump for service.

	The operator should stand 1 meter from the pump, and verify that the alarm can be seen and heard.

	For additional information about the Air in Line and Occlusion alarms, refer to Chapter 7: Level 3 Alarms on page 148.

Built-in Test

The pump performs automatic testing upon turning it on.

Once you start the pump by pressing on the start button, during startup the pump is performing two test sequences:

First test sequence

- Boot version validation
- Pump program version validation

Failure in one of the above tests will prompt one of the error screen set in the table below:

Error Code	Source of Failure
1	PMM Boot (Pump mechanism module) version
2	Program version
3	EEPROM (Electrically Erasable Programmable Read-Only Memory) version
4	Master grid error
5	Flow table error
6	Pump definitions error
7	Reset because of bus fault
8	Reset because of watchdog
9	Stack is out of range

Second sequence

- LCD Drivers version validation.
- GUI (Graphical User Interface) version validation.

At start of this sequence failure in the LCD Drivers version validation will cause the screen to remain inactive BLACK.

Failure in the GUI version will prompt a screen with colored lines. Test is done automatically upon turning the pump on.

Failure resolution

For any failure in the built-in test with one of the above source of failure notes: upgrade software version.

In case of malfunction alarm during built-in test, pump must be serviced.

Testing System Function

The Test system menu enables 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	• **On:** High volume auditory signal sounds. • **Off:** No auditory signal.
Speaker low	• **On:** Low volume auditory signal sounds. • **Off:** No auditory signal.
Alarm LED	• **On:** The red (Alarm) LED is lit. • **Off:** The red (Alarm) LED is not lit.
Charge LED	• **On:** The yellow (Charge) LED is lit. • **Off:** The yellow (Charge) LED is not lit.
Running LED	• **On:** The green (Run) LED is lit. • **Off:** The green (Run) LED is not lit.
Door sensor	• **Closed:** The safety door is closed. • **Opened:** The safety door is open.
Bolus handle	• **Released:** The handle is not pressed. • **Pressed:** The handle is pressed.

To test bolus handle functionality first connect the bolus handle to the Sapphire infusion pump. Do NOT connect bolus handle to mini cradle splitter.

Annual Certification Kit

The Annual Certification kit allows you to perform the tests described in the table below.

Name of Test	Procedure
Pressure (Occlusion) Sensor Test	This functional test involves creating pressure in the system by introducing specific amounts of air into the IV tubing, against a check valve. The air is inserted in a 3-step process.
Bubble (Air) Detector Test	This functional test involves introducing air into the IV tubing from above the administration cassette, and checking whether the pump detects air in the system.
Flow Accuracy Test	This functional test involves infusing a specific amount of fluid into a container, and checking whether the pump measures the correct volume infused.

All of the functional tests included in the Annual Certification process and their specific procedures are detailed in Chapter 4: Performing The Annual Certification Test on page 67.

Battery Care Information

The Sapphire pump can operate on battery power, enabling operation of the pump during an electrical power failure, during patient transport, or during ambulatory care.

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%

Number of Bars in Icon	Approximate Remaining Battery Capacity
2	25%
1	Low

You can also check the status of the battery using the **Options** menu. For details, refer to the Sapphire User Manual, Viewing System Parameters.

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 charge 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 Sapphire 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 a rechargeable Lithium Ion (Li-Ion) battery (supplied by Q Core Medical Ltd.) 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 any liquid.
- 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 of less than 85% RH.
- 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

The Sapphire pump should be used with a Q Core battery only.

Before initial use of the Sapphire 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 charger, ensure that the pump is attached securely to the charger, 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 charger whenever possible.

	Before charging the battery, ensure that the device is completely dry. Failure to do so may compromise patient safety.

	While connected to a power supply and charging, the Charge (yellow) LED blinks, and lights steadily when the battery is fully charged and the charger is connected. If the pump is turned off, the current time appears on the screen while the pump is charging.

> To charge the battery:

1. Plug the Q Core supplied power supply cord into the main power supply.
2. With the arrows facing up (arrows to arrow on the pump), plug the power cord into the Sapphire 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).
4. The battery is fully charged when the charge LED is steady On.

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 the battery

Splitter Assembly Instructions

Required parts and tools:

- Splitter kit (includes 2 screws)
- Mini cradle
- Screwdriver

Assembly process:

Insert the splitter to the mini cradle as described in Figure 3.8, and tighten using the 2 included screws.

Figure 3.8. Splitter Assembly

Sapphire Multi-Pump Mounting System

Read the directions before assembling or using the Sapphire Multi-Pump Mounting System.

Mounting System safety guidelines:

Before and during the use of the Mounting System, always adhere to the following safety precautions and guidelines:

Warnings:

- Verify 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 the IV pole is not moving, tilting or wavering when mounted with a Mounting System.
- Before using the Mounting System, make sure the Mounting System power supply and all cords are completely dry.
- 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.

Cautions:

- Use only Q Core approved AC input cord and power supply with the Mounting System.
- To avoid risk of electric shock, the mounting system power supply must be connected to a power outlet with protective earth.

- 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 bag hooks (not supplied by Q Core) when mounting more than two Mounting System on a single IV pole.

Overview

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 250 when mounted on the right-hand mini cradle among the three.

The Mounting System is compatible with the following infusion pumps: Sapphire Multi Therapy Infusion Pump, Sapphire PCA Infusion Pump, Sapphire TPN Infusion Pump, Sapphire Epidural Infusion Pump, SapphireH100 Infusion Pump, SapphirePlus Infusion Pump, and IVVET Infusion Pump.

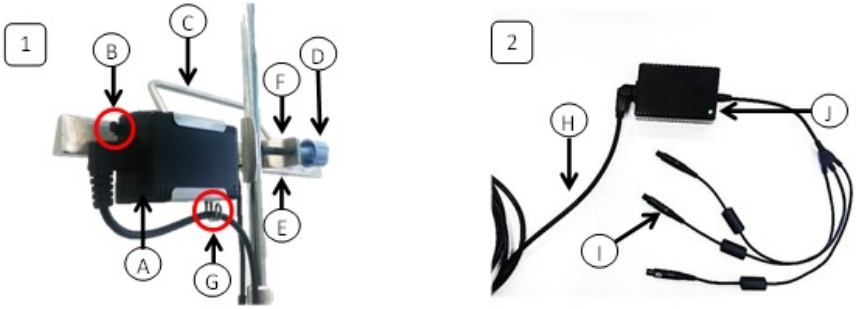
It is recommended to use mini cradles with a splitter in order to facilitate attachment and detachment of pumps.

Unpacking the Mounting System

When unpacking the Mounting System, inspect each item to confirm that it is undamaged. The following items should be included:

- Sapphire Multi-Pump Mounting System, P/N: 15171-120-0001-MEC
- Power supply with three DC output connectors
- AC input cord, compatible with the regional power outlet type
- Clamp knob key

Figure 3.9. Mounting system



A. Mounting System power supply
B. Latch
C. Carry handle
D. Clamp knob
E. Clips
F. Clamp
G. Cord hook
H. AC input cord
I. DC output connector
J. Power supply LED

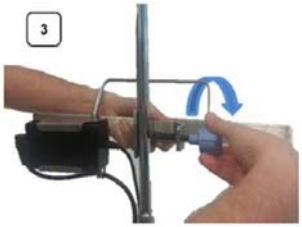
Mounting System setup instructions

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

Attaching the Mounting System to an IV pole

1. Loosen the clamp knob (Figure 3.9 D) by rotating it counter-clockwise.
2. Firmly hold the Mounting System and place the clamp (Figure 3.9 F) on an IV pole with the carry handle (Figure 3.9 C) facing upwards.
3. Tighten the clamp knob by rotating it clockwise (Figure 3.10).

Figure 3.10. Clamp knob

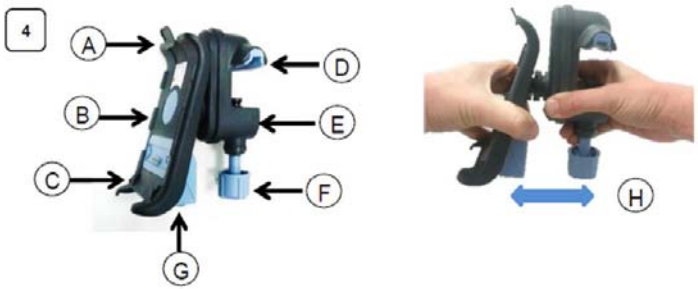


To prevent detaching from the IV pole, the Mounting System can be locked to the pole by removing the knob cap or knob key from the clamp knob.

Attaching a mini cradle to the Mounting System

1. Pull the pump holder (Figure 3.11 B) away from the base (Figure 3.11 E) and rotate it to a position where the mini cradle knob (Figure 3.11 F) points downward and the top hook (Figure 3.11 A) points upward.

Figure 3.11. Attaching the mini cradle

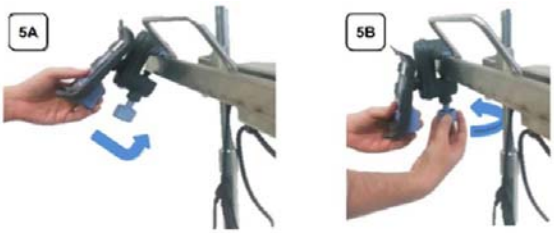


A. Top hook
B. Pump holder
C. Bottoms hooks
D. Mini cradle vise
E. Mini cradle base
F. Mini cradle knob
G. Splitter socket
H. Proper position

	Place the mini cradles according to the markings on the Mounting System, between the designated lines (Figure 3.13).

2. Loosen the mini cradle knob (Figure 3.11 F) to maximum extent by rotating it.
3. Tilt the mini cradle and place the open vise (Figure 3.11 D) on the top of the Mounting System (Figure 3.12 A). Align the cradle and tighten the knob by rotating it (Figure 3.12 B).

Figure 3.12. Tilting the mini cradle



4. Plug a DC output connector (Figure 3.9 I) to the mini cradle splitter (Figure 3.11 G).
5. Fasten the DC output cables to the clips located on the bottom of the Mounting System (Figure 3.9 E).
6. Plug the AC input cord (Figure 3.9 H) to the power outlet. Verify that the Mounting System power supply LED (Figure 3.10 J) is ON.

Figure 3.13. Fully assembled Mounting System

Attaching a pump to a mini cradle

1. First insert the pump into the bottom hooks of the mini cradle (Figure 3.11 C), and then click the pump into the top hook (Figure 3.11 A).
2. Verify that the charging connector is plugged into the splitter socket (Figure 3.11 G) or the pump socket.

Detaching a pump from a mini cradle

1. Before detaching the pump unplug the DC output cord from the pump socket (if connected).
2. Hold the pump and press the top hook (Figure 3.11 A) backwards.

When transporting 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.

Cleaning and disinfecting the Mounting System

	To clean the Mounting System thoroughly, remove the Mounting System power supply and all the mini cradles

Cleaning of the Mounting System involves wiping it with Dispatch® (Caltech) ready-to-use towels or with the following cleaning and disinfection agents:

- Virex® II 256
- Klor DeTM (Chlorine tablets)
- 70% Isopropyl alcohol

Mounting System power supply servicing

Remove the Mounting System power supply for maintenance or cleaning, by performing the following steps:

Disassemble the Mounting System power supply from the Mounting System:

1. Disconnect the AC input cord from the power outlet.
2. Unplug the DC output connectors from the mini cradles.
3. Push the latch and slide the Mounting System power supply out of its housing (Figure 3.14 A).
4. Take the AC input cord out of the cord hook (Figure 3.14 B).

Reassemble the Mounting System power supply to the Mounting System:

1. Place the AC input cord in the cord hook
2. Slide the Mounting System power supply back to its housing till the latch snaps into place (Figure 3.14 C).
3. Refer to the Mounting System setup instructions to reassemble the Mounting System and prepare it for use.

Figure 3.14. Reassemble the Mounting System power supply

Problem	Problem Cause	Solution
Pump is not charging while attached to the mini cradle on the Mounting System	Mounting System power supply is defective	Replace the Mounting System power supply with another Q Core approved Mounting System power supply.
	AC input cord plugged improperly or defective	Verify that the AC input cord is properly connected and that the Mounting System power supply LED is ON. Otherwise, replace it with another Q Core approved AC input cord.
	DC output connector plugged improperly or defective	Verify that the DC output connector is properly plugged to the splitter socket. Otherwise, replace the Mounting System power supply with another Q Core approved Mounting System power supply.
	Splitter socket is defective	Replace the splitter or the mini cradle or plug the DC output connector directly into the pump socket.

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 (see Charging the Battery on page 53).

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	70 kPa to 106 kPa (500 hPa to 1060 hPa)

Q Core Service for Sapphire Pumps

If pumps require service please contact Q Core Medical Ltd. or a local distributor at Hospira service center (refer to Authorized Hospira Service Centers on page 211).

Pumps will be serviced as follows:

- Directly by trained technical personnel for First Level Support for tasks they have been trained for.
- In local service centers authorized by Q Core Medical Ltd.
- Ship pumps to a Q Core Medical Ltd. International Service Center for servicing according to the instructions below.

Q Core Product Return Policy

Devices may be shipped to Q Core Medical for service or a local distributor at Hospira service center (refer to Authorized Hospira Service Centers on page 211). Please adhere to the following guidelines in order to ensure effective and quality processing of your claim(s) and refer to SAMA-5000, Returned Materials Policy on Q Core FTP site (https://qcore.smartfile.com). For information regarding the FTP site, refer to FTP site on page 28.

Devices will not be accepted as returned without a Return Material Authorization (RMA) number. Returns received without authorization will not be processed.

1. Request a RMA through one of the following methods:
   - Contact your Q Core account manager directly
   - Send a RMA request form to service@qcore.com or a local distributor at Hospira service center.
2. Provide a detailed description of problem encountered with the device.
3. The request will be reviewed within 24 hours; do not send your item until you have received an RMA Number.
4. A notification email will be sent to you when your RMA Request will be approved. Print the RMA form and Packing Slip and attach them to the returned device. The forms can be obtained from Q Core FTP site (https://qcore.smartfile.com).
5. Clean and disinfect the pump in accordance with Q Core's pump cleaning and disinfection guidelines prior packaging it for shipment, refer to Cleaning and Disinfecting the Pump on page 37.

Chapter 4: Performing The Annual Certification Test

The following sections detail the annual certification process for the Sapphire pump:

Annual Certification Overview

The annual certification process includes a sequence of maintenance checks that need to be performed annually on the Sapphire infusion pump. The annual certification procedures are briefly described in the following table.

Maintenance Check	Description
Visual inspection (including mechanical and electrical inspections)	Checking for pump integrity: cracks, loose parts, connectors, touch screen and other tests, as defined in Chapter 3: Maintenance and Storage on page 37.
Safety features testing	Checking speaker, LEDs, door sensor and bolus handle
Calibration verification	Performing tests that determine whether calibration is necessary.

The current chapter explains the annual certification process, with special emphasis on the calibration verification tests. The annual process is supported by Q Core's Annual Certification Kit and Software. The kit includes tools for performing the tests, as well as a PC program that provides trained technicians with step-by-step instructions for how to perform the tests.

Certification due date counting

Sapphire and SapphireH100

The starting condition for counting the certification date is the shorter of the two options:

10 working hours or 180 days from pump shipment day from Q Core warehouse. The date one of these conditions is met is defined as the start date.

- After the condition is met, the next certification date will be the start date + 380 days.
- Before the condition is met, the next certification date will be the release date (pump shipment date from Q-Core) + 380 days.

After preforming the certification process, the next certification due date will be the date of the PC that performed the test (start user usage date at pump's Eeprom)+ 380 days.

Tolerance = ±7 days.

SapphirePlus

The starting condition of counting certification date is the shorter of the two options:

10 working hours or 2 years from pump shipment day from Q Core warehouse (set as the certification date during Q Core FTP Lab process in EEPROM).

- After the condition is met, the next certification date is a dynamic value that will be calculated according to calibration days left from current date (calibration days = certification date + 380 – current date):
  - 10 hours condition: certification date is due after 10 working hours.
  - 2 years condition: certification date is set to the original certification date + 2 years
- Before the condition is met, the calibration days will be calculated as follows: Certification date + 2 years + 380 days – current date.

  The next certification date in view system will be calculated according to the calibration days that were left from the current date.

After preforming the certification process, the next certification due date in EEPROM is set to the date of the PC that performed the test.

Testing Rationale of the Annual Certification Process

The annual certification process involves visual and safety inspection and performing a series of tests on the pump, to determine whether or not the pump requires calibration. The tests need to be performed once a year by a trained technician.

The Sapphire pump saves the date of the last certification process, and automatically displays the following messages on the pump's Main Display as the next required testing date approaches:

- Annual certification due in 2 weeks. Please contact trained technician.
- Annual certification due in 2 days. Please contact trained technician.
- Annual certification date is overdue. Please contact trained technician.

The Calibration Verification Process

The heart of the annual certification process is the calibration verification which is made up of the following set of tests:

- Occlusion Sensor
- Air Detector
- Flow Accuracy

To facilitate the testing process, Q Core has developed a special testing kit referred to as "Annual Certification Kit" which supplies special tools necessary for testing 5 pumps. The kit is used with the Annual Certification Software. It enables you to perform testing with the pump connected to your PC and to receive immediate testing feedback via the Q Core server.

The software application provides step-by-step testing instructions with a summary version of the same instructions inscribed on the pump itself. The application allows you to test simultaneously 1-8 pumps, using a USB to 4-port serial RS232 adapter which can be purchased separately from Q Core.

A test can be simultaneously performed on up to 8 pumps. The tools provided in Annual Certification Kit can be used for 5 pumps, and only one pump at a time.
To test multiple pumps simultaneously, prepare number of kits as the number of pumps that will be tested.

Annual Certification Kit

The Annual Certification Kit is a pre-packaged kit provided by Q Core that contains all the special equipment necessary for performing certification testing. One kit can be used for testing 5 pumps. The Annual Certification Kit is designed to be used in conjunction with Q Core's Annual Certification Software. Testing with the software application is initiated by scanning the barcode of the Kit (found on the Directions for Use).

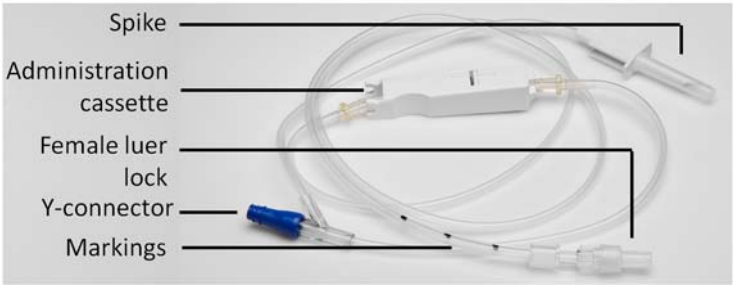
Q Core Medical has access to Event Log information and may use it for purposes such as back up, research, and statistical analysis. However, Q Core Medical does not collect, save, or disclose any personally identifiable information.

Kit Components

The components of the Annual Certification Kit are shown in the following illustrations. All components of the kit are listed and described in the table preceding the figures.

Component	Description	Used for
Administration set	1.5 meter tubing including 3 markings, with (i) spike, (ii) Y-connector, (iii) administration cassette, and (iv) male luer lock. (See Figure 4.1)	All tests
Extension set	5-8 cm tubing, with female luer lock and check valve (with female luer lock). (See Figure 4.2)	Occlusion Sensor test
Syringe	5 mL (no needle). (See Figure 4.3)	Occlusion Sensor and Air Detector tests
Flow Accuracy Container	Two bottles of 120 mL; one plastic cap, with (i) a metal hanger, (ii) a male luer lock port and (iii) a female luer lock port with a leading tube. (See Figure 4.4 and Figure 4.5)	Flow Accuracy test
Hydrophobic filters (6) **Note**: Only 5 are required; one extra is included.	3 micron hydrophobic filter. (See Figure 4.6)	Flow Accuracy test

Figure 4.1. Administration Set



⚠	The administration set used in the Annual Certification Process is not for human use. Do not use this Administration Set for any other purpose.

Figure 4.2. Extension Set

Figure 4.3. Syringe

Figure 4.4. Flow Accuracy Container

Figure 4.5. Flow Accuracy Container: cap

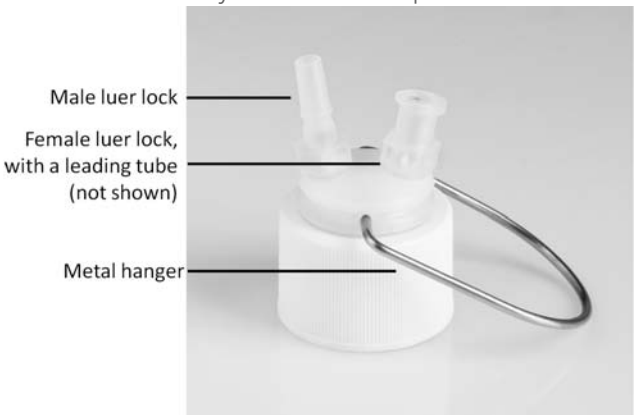


Figure 4.6. Hydrophobic filter (6)

Annual Certification Software

Q Core's Annual Certification Software streamlines the Annual Certification process by enabling you to test the pump while communicating with the Q Core server. Step-by-step instructions are provided onscreen (PC and Pump screens), and results are printed immediately following the testing process.

The following topics are covered:

Requirements

Before installing the software, verify that the following requirements are met:

- Operating System: Windows 7, Windows XP
- Screen Resolution: 1024:768 (minimum), 96 DPI
- Memory: 4 GB
- Internet Access

	Verify with your facility IT team that the internet connection has an open port TCP 5100 to host name: *applicationsserver.qcore.com* for communicating with Q Core server, and is not restricted by firewall.

Acquiring the Software

The Annual Certification Kit software can be obtained from Q Core FTP site (https://qcore.smartfile.com). For information regarding the FTP site, refer to FTP site on page 28.

Please note that only trained technicians registered with the company will be cleared to receive the software.

Logging In

The user is requested to insert the username and password provided by Q Core Medical. Contact Q Core for a new password or username if forgotten.

Figure 4.7. Login Screen

Station Setup

This section describes how to connect the pumps to the PC via COM ports. Each pump adequately connected, will immediately be presented as a station on the left pane of the screen. There might be a lag between the pump and computer screen, please wait for the PC and pump to synchronize and follow the instructions on the screen.

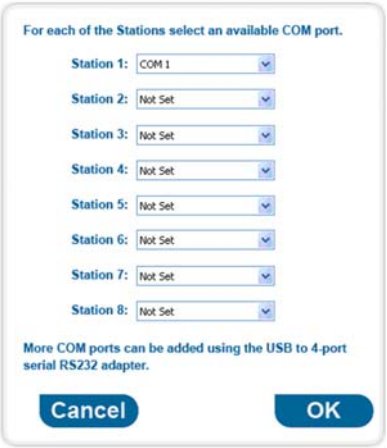
You can connect a single pump via serial port (see To connect via serial: on page 76); for configuring additional COM ports to your PC, use the USB to 4-port serial RS232 adapter, see the following explanation on page 77.

It is recommended to configure all COM ports to the PC application before starting a test. Configuring an additional COM port while a test is running is not possible.

> To connect via serial:

1. Open the Annual Certification program; log into the program.
2. Choose the Setup link at the upper right corner. The following window appears:

Figure 4.8. Stations Dialog Box



3. Choose a free COM for each station needed.

4. Confirm selection by clicking the **OK** button. Your selection will be saved for the next use of the software.

> To use the Q Core USB to 4-port serial RS232 adapter (for enabling additional COM ports):

The USB to 4-port serial RS232 adapter provides 4 external COM ports to your computer (P/N 15077-000-0001). Follow the DFU instructions for installation.

The Testing Screen

This section provides an overview of the structure and features of the Annual Certification Software screen.

Figure 4.9. Testing Screen

The main portion of each page of the application consists of a "main screen" which provides step-by-step instructions for performing the current stage of testing. The header of each page provides the number of the currently selected Station, the name of the test and the specific test-step being conducted (for example, Occlusion Sensor (Station 2): Prime).

The Station pane, at the left side of each page, provides information about the testing status of each Station. For details, refer to Working with the Station Pane on page 78.

The following links are available at the upper right corner of each page:

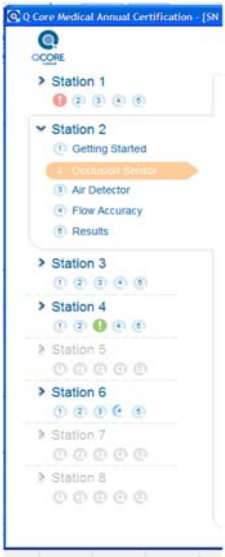
Name of Link	Function/Notes
Refresh active pump	Refreshes the display of the pump that connected to the active station. (See Working with the Station Pane on page 70).
Help	Provides more detailed information/ instructions about certification testing.
About	Provides information about the software version and corresponding pump versions.
Login/Logout	Enters/exits the application.
Setup	Configures stations to available COM ports. (See Working with the Station Pane on page 78.)
Close	Provides option to close the current/all tests, and to exit the program

Working with the Station Pane

After the pumps are connected to the computer and turned on (Launching the Annual Certification Process on page 82), the Station Pane becomes active. Each Station corresponds to a pump that is connected to the computer. Stations that have no pump connected to them (such as Station 3 in Figure 4.10) are disabled.

The Station pane provides a snapshot of the status of each pump throughout the testing process. Each Station has five numbered circles, corresponding to the stages of testing. The circle that is highlighted represents the stage that the pump is currently in. To help differentiate between the pumps, the numbers of each Station are coded in a different color. To help associate between the pump tested and its depiction on the screen, the pump's display is marked with a rectangle colored with the color code on the computer screen.

Figure 4.10. Station Panel



The five stages of testing (listed 1-5 on the pane) are:

Number of Testing Stage	Name of Testing Stage
1	Getting Started
2	Occlusion Sensor
3	Air Detector
4	Flow Accuracy
5	Results

Performing the Annual Certification Tests

The following sections explain how to perform the required Annual Certification tests using Q Core's software application:

The descriptions in this section elaborate on the directions in the software application.

The annual certification tests are designed in a way that each action is required in order to set the pump to a specific condition required for the tests. Follow each instruction fully in order to perform the tests adequately.

Getting Started

The following sections describe how to prepare the testing environment and begin the testing process.

Required Materials

The following equipment is required for certification testing:

- Q Core Annual Certification Kit(s).
- An infusion bag that is filled with at least 200 mL fluid - the bag should be a collapsible bag of water.
- RS232 COM ports, or Serial on USB (optional).
- Motorola LS2008 barcode reader (optional); you may use the barcode key manually instead.
- RS232 communication cable between pump and computer.

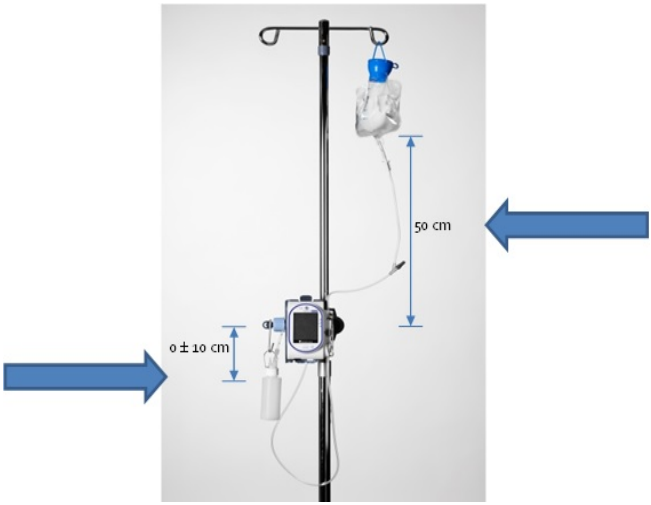
⚠	Before beginning the tests, make sure that the Annual Certification Kits contain all the original parts supplied by Q Core (Kit Components on page 71).

Testing Conditions

The following environmental conditions should be met during testing to help ensure accurate results. Deviation from the environmental conditions might affect the accuracy of the tests.

- Approximate time of the test (per pump) is 15 minutes; verify that your computer has adequate power supply to last for the duration of the test.
- Room temperature: 20° C ± 5° C
- Relative humidity: up to 70%
- Pump position: straight and vertical
- The required distance between the center of the pump and the bottom of the bag is 50 cm (Figure 4.11).
- The required distance between the center of the pump and the bottom of the container cap is 0 ±10 cm (Figure 4.11).

Figure 4.11. Station setup



Launching the Annual Certification Process

> To perform the Setup Sequence:

Carry out the following setup sequence for all the devices prior to connecting the pumps to the PC and starting the Annual Certification test.

	If the pumps were already connected to the PC, disconnect all the devices from the COM ports and wait for 30 seconds before performing the setup sequence.

	The Annual Certification software uses Continuous delivery mode for the tests, even if this mode is not configured on the Sapphire pump. When the certification tests are finished, make sure that the pump is at an allowed delivery mode.

1. From the Options menu, select **Pump configuration** → **General settings**. Select **Authorization level**. Then, using the keypad, enter the High level password → **OK**.
   (refer to Chapter 2: Managing Authorization Lock Levels on page 33).
2. Change the Occlusion Pressure to 1.2 BAR (17.4 PSI, 900 mmHg).
   Press **Options** from the Start screen →**Pump Configuration** → **Alarms** → **Occlusion Pressure**.
3. Programming a treatment:
   3.1 The following instructions are for pumps **without** a Drug Library installed.

   Multi Therapy pumps:

   a. Select Continuous delivery mode
   b. Configure treatment: Rate= 100ml/h, VTBI=100 ml
   c. Confirm the treatment by pressing **OK**
   d. Exit the treatment by pressing **Exit**
   e. Verify that the option Repeat Last Infusion is available (don't select it). If not, repeat steps b-d.

Proceed to the section To perform the Preliminary Inspections: on page 85.

Epidural only pumps:

a. Select PCEA delivery mode

b. Configure treatment: VTBI=100 ml, Rate=10 ml/h, Demand bolus=0mL, No loading Dose

c. Confirm the treatment by pressing **OK**

d. Exit the treatment by pressing **Exit**

e. Verify that the option Repeat Last Infusion is available (don't select it). If not, repeat steps b-d.

Proceed to the section To perform the Preliminary Inspections: on page 85.

3.2 The following instructions are for pumps **with** a Drug Library installed.

For pumps with Continuous delivery mode available:

a. Select Continuous delivery mode

b. Configure a treatment with Drug Name="General"

c. Configure treatment: Rate=100ml/h, VTBI=100ml

d. Confirm treatment by pressing **OK**

e. Exit the treatment by pressing **Exit**

f. Verify that the option Repeat Last Infusion is available (don't select it). If not, repeat steps b-e

Proceed to the section To perform the Preliminary Inspections: on page 85.

For pumps without Continuous delivery mode:

The Drug Library should be removed prior to the Annual Certification Test; For removing the Drug Library use the Pump Cleanup tool available at Q Core's FTP site (under the folder "Pump Cleanup Tool for Maintenance"). see FTP site on page 28.

The "Pump Cleanup Tool for Maintenance" FTP folder contains the Pump Cleanup tool, work instructions, and self-declaration training record. In order to receive credentials to use the Pump Cleanup Tool the following should be followed:

a. Download and read the work instructions and the self-declaration training record
b. Fill and sign the self-declaration training record
c. Send a scanned copy of the signed self-declaration training record to: service@qcore.com
d. User name and password will be sent to your e-mail by Q Core's service department.

Change the pump's settings back to factory default after the test is completed.

> To perform the Preliminary Inspections:

1. Perform Thorough Visual Inspection, as described in Thorough Visual Inspection on page 43. Check Pass or Fail in the box next to Visual inspections according to findings.
2. Perform Functional Tests, as described in Testing System Function on page 50. Check Pass or Fail on applicable boxes next to Functional Inspections according to findings.

	The Preliminary Inspections verify that the pump is in a proper condition before starting the certification. A pump that failed one of the inspections tests is considered as Failed and should be serviced. A Failed pump cannot proceed to the certification process. A pump that passed all of the inspections tests is marked as Pass, and can continue to the Calibration Verification process.

	By clicking **Next**, the user who is logged in confirm to be the one who performed the inspections tests.

> To begin the testing process:

1. Log in to the Q Core Annual Certification Software (Logging In on page 75).

> If this is the first time you run this program, you need to configure your stations and COM ports first. Verify that the driver installed successfully. The ACK software automatically recognizes the ports that successfully connected to the pumps (See Working with the Station Pane on page 78.)

2. Using the RS232 connector cable, connect each pump to the computer, and turn the pump(s) on.
3. Select a station by double clicking on its slot on the Navigation Pane.

> To perform the Kit Selection:

1. Using the barcode reader (or the keyboard), enter the barcode number of the Annual Certification Kit and verify the following:
   a. The barcode number has 28 characters
   b. The barcode number starts with "+M8261…"
   c. The PC language is set to English (some characters, such as "/" will be translated and won't reflect the actual serial number of the kit).

   The barcode reader can be found on the top left of the Directions for Use, found within the kit.

   After entering (or scanning), the barcode number will appears in the **Kit Serial Number** field.
2. Click **Check**. The Q Core server checks the validity of the kit.

> The kit is limited to 5 uses. Save the DFU for further eligible uses of the kit.

If the kit has not been fully used, a message appears listing the number of uses remaining. If the number of uses is exhausted or the kit is otherwise invalid, an appropriate error message appears.

	Ensure that all parts of an old kit are disposed of before using a new kit. Parts from an old kit should not be used under another kit number.

Use of the kit is deducted from the eligible uses once the results of the tests are sent to Q Core.

	Exiting the tests in the middle of the process will not deduct the number of uses remaining. However, you will have to start the process from the beginning. Results are not saved if you exit the process in the middle.

3. To start the first test (Occlusion Sensor), click **Start certification**.

Performing the Occlusion Sensor Test

This test involves creating pressure in the system by introducing specific amounts of air into the administration set, against a check valve. The air is inserted in a 3-step process.

> To perform the Occlusion Sensor test:

1. Prepare the infusion bag and the administration set:
   a. Fill the bag with at least 200 mL of tap water, and attach the administration set to the bag.
   b. Attach the administration set to the pump, and close the safety door.
2. Perform automatic priming on the pump, press **Prime**.

	For this test, automatic priming is required. Do not prime the administration set manually.

	During the Occlusion Sensor Test (Prime, Setup and Test), do not remove the administration cassette from the pump.

3. Verify effectiveness of the prime by visually inspecting the administration set and checking for air.

   If any air is present, on the pump, press **Prime**. Repeat automatic priming until the set is completely free of air.
4. When the administration set is fully primed, on the pump, press **Next**.
5. Attach the extension set to the administration set, with the check valve at the free end (Figure 4.2 on page 72). Then, fill the syringe with air.
6. On the pump, press **Next**.

	Steps 7-9 need to be completed within 30 seconds. Be exact in applying air! To start the test over for any reason, on the toolbar of the pump, press **Restart**.

7. Using the syringe, insert air into the administration set until the air reaches the first mark on the tubing (Figure 4.1 on page 72). Then, on the pump, press **Mark 1**.
8. Insert more air into the administration set, until the air reaches the second mark on the tubing. Then, on the pump, press **Mark 2**.
9. Insert more air into the administration set, until the air reaches the third mark on the tubing. Then, on the pump, press **Mark 3**.
10. To proceed to the next test (Air Detector), on the pump, press **Next**.

Performing the Air Detector Test

This test involves introducing air into the administration set from above the administration cassette, and checking whether the pump detects air in the system.

> To perform the Air Detector test:

1. Remove the extension set from the administration set.
2. Using the syringe, insert 1 mL of air into the administration set, via the Y-connector (Figure 4.1 on page 72), and disconnect the syringe. Then, on the pump, press **Start**.

   Infusion of fluid starts, and then (when the air is recognized) stops.
3. To proceed to the next test (Flow Accuracy), on the pump, press **Next**.

Performing the Flow Accuracy Test

This test involves infusing a specific amount of fluid into a container, and checking whether the pump measures the correct volume infused.

Prior to starting the test verify fluid container is completely dry. The kit is provided with two bottles in order to ensure that at least one of the bottles is dry at any given time. Starting the test with all components dry is critical to the success of the certification testing.

> To perform the Flow Accuracy test:

1. With the cap removed from the Flow Accuracy Container, attach a new hydrophobic filter to the male luer fitting on the cap of the Flow Accuracy Container. Do not reuse hydrophobic filters.

   Then, attach the end of the administration set to the female luer fitting. When finished, press **Next** on the pump.
2. Prime the administration set manually, as follows:
   - Remove the administration cassette from the pump, and perform manual priming by opening the AFFV on the cassette.
   - Verify the set and the leading tube of the cap are flushed.
   - Avoid getting the hydrophobic filter wet.

3. Verify effectiveness of the prime by visually inspecting the administration set and checking for air.

   If any air is present, repeat priming until the set is completely free of air.

4. When the administration set is fully primed, reinsert the cassette to the pump and close the door. Verify that all connections are tight. On the toolbar of the pump, press **Next**.

- Keep the positioning of the fluid container vertical during the test period.
- Once the flow accuracy container is full, the device detects the occlusion and stops the test. Drops may seem coming from the filter as the water in the container reaches the top, this is normal.

5. Make sure the cap and the Flow Accuracy Container are completely dry. Attach a completely dry container to the cap. A container from a different kit maybe used.

To ensure the container is completely dry, hang it upside down for at least 10 minutes prior to use.
You may verify the container dryness by weighing the container with a balance: the weight of a dry bottle should not exceed 13g. Weight above this value indicates that some water is present in the container.
Ensure the cap is dry by wiping it with a dry cloth. Verify there is no residual fluid in the inner areas of the bottle cap.

6. Make sure the connectors on the top are fully screwed into place prior to starting the test.

Figure 4.12. Flow Accuracy Container cap

7. Make sure the container is positioned upright and in the same height of the pump. Use the hanger on the cap if necessary.

⚠	10cm difference between the two is acceptable. Larger difference can cause back pressure that will jeopardize the credibility of the results.

8. Make sure the collapsible bag of water holds at least 150 mL of water. Then, press **Start** on the pump.
9. To complete the certification testing process and generate results, press **Finish**.
10. If the pump failed the Flow Accuracy test, perform the manual prime again as described in step 2 before repeating the Flow Accuracy test. This will not deduct from the number of kits available.

Viewing Results

When certification testing is finished, a PDF report is automatically generated and displayed on the computer monitor. The report includes the following information:

- Document number
- Pump serial number
- Kit serial number

- Testing results (successful or unsuccessful)

For the certification process to be successful, you must have the Preliminary Inspections confirmed and the pump passed all 3 tests. The report can be printed for further records. After printing, close the test's screen on the PC.

	At the end of the ACK test, turn the pump off and disconnect the pump from power supply and communication cable. Change Occlusion pressure back to original settings.

After the Test

After the device passes the ACK test, verify the following:

- The date and time are set to local date and time. Adjust as necessary.
- The new ACK date is more than 1 year from present date. The annual certification record can be printed if required before clicking "close" on the PC window. Once the window is closed, printing is unavailable.

	The next certification date may be inaccurate when the pump is checked right after passing ACK. This date will be updated to +380 days when the pump is put to use.

Disconnect the pump from the Annual Certification software and change the pump's settings to "Factory Settings".

From the toolbar of the Start Up screen, press **Options → Technician options → Pump settings → Reset system → Factory defaults**

Troubleshooting Certification Testing

The following sections explain how to troubleshoot common problems that may arise while performing certification testing:

Communication

The following issues can arise due to communication problems:

Problem	Management
The cable is connected and COM port is selected but the pump does not appear	There may be a delay, please wait until the pump appears.
Username and password were entered, yet the application couldn't connect to the Q Core server. An error message appears: "Failed to connect to the server"	Check that: • The PC is connected to the internet • The firewall allows communication to outer servers. Consult your IT department regarding security instructions in your facility before changing the firewall settings. • If the error message keeps appearing, contact service@qcore.com or a local Hospira service center.
The following error message appears: "Connection with the pump has lost (no samples in 4 seconds)".	• Verify the communication cable is properly attached to the pump and the PC • Restart the certification process If problem persists, replace communication cable

Login and Kit Entry

The following issues can arise due to login and kit entry problems:

Problem	Management
Username was entered, and the following error message appears: "Username should contain only letters and digits"	• Make sure to enter the correct username you were given. • To retrieve the username or to acquire a new one, contact service@qcore.com or a local Hospira service center.
Password was entered, and the following error message appears: "Password should contain only letters and digits"	• Make sure to enter the correct password you were given. • To retrieve the password or to acquire a new one, contact service@qcore.com or a local Hospira service center.
Username and password were entered, and the following error message appears: "Unknown User"	• Make sure to enter the correct username and password you were given. • To retrieve the username and password or to acquire new ones, contact service@qcore.com or a local Hospira service center.
A kit number that was not approved by Q Core Server was entered, the following error message appears: "Invalid Kit Number".	Check that: • The correct kit Serial number was entered. • The serial number matches the barcode number that is located on the kit DFU.

Occlusion Sensor Test

The following issues can arise during the Occlusion Sensor test:

Problem	Management
Reset of the Test	For any reason that the test needs to be restarted, you must disconnect the Extension Set first. After confirmation, the pump performs automatically priming. Repeat the test, starting from the Setup screen.
Test was not completed within 30 seconds after pressing **Mark 1** on the pump. An error message appears.	Perform Reset of the Test.
Test was performed incorrectly, and needs to be restarted.	On the toolbar of the pump, press **Restart**. Then, to confirm, press **Yes**. Perform Reset of the Test.
The pump does not detect rising pressure between marks. An error message appears.	Check that: • The administration set is not damaged • The Extension Set is connected correctly • Air was inserted If one of the conditions is not met, correct it, and then press **Restart**. Perform reset of the test. If the set is undamaged, and the test was performed properly, press **Confirm**. The program proceeds to the Air Detector test.

Air Detector Test

The following issue can arise during the Air Detector test:

Problem	Management
Air could not be detected within 30 seconds of pressing **Start**. An error message appears.	If air was not inserted into the administration set, press **Restart**. Then, repeat the test, starting at the Test screen. If air was inserted into the administration set, press **Confirm**. The program proceeds to the Flow Accuracy test.
Error message appears indicating "Cannot Start Pump"	Close the test software, reopen and ensure to carry out the "Setup" sequence, as described in Logging In on page 75.

Flow Accuracy Test

The following issues can arise during the Flow Accuracy test:

Problem	Management
Test is completed too quickly. An error message appears.	Verify that: • The Flow Accuracy Container is in an upright position • The hydrophobic filter is dry • The container is full If the conditions are not met, press **Restart**. Empty the Flow Accuracy Container and replace the filter. Position the Container upright, using the hanger. Then, press **Start**. The test begins again. If the conditions are met, press **Confirm**. The program proceeds to the Finish screen.
Test is not completed within the expected amount of time. An error message appears.	Verify that: • The administration set is connected to the Flow Accuracy Container • All connections are tight • There are no leaks in the Container or the cap If the conditions are not met, correct them, and then press **Restart**. Empty the Flow Accuracy Container and replace the filter. Position the Container upright, using the hanger. Then, press **Start**. The test begins again. If the conditions are met, press **Confirm**. The program proceeds to the Finish screen.
Pump has stopped even though no pressure was built. The test aborted and the pump switched to prime state.	Repeat the Flow Accuracy test

General

The following are general issues that can arise during certification testing:

Problem	Management
The ACK software stops during the test	Re-start the ACK software and begin the test from the start.
The ACK test failed	Repeat the ACK test only if you suspect that an incorrect technique may have been used, or there was faulty test equipment (e.g. loose cap on bottle, not enough back pressure introduced etc.)
Some of the graphic information was not transferred and is missing from the pump screen (title, text, and buttons).	On the PC, activate the station that the pump is connected to. Click the "Refresh active pump" link on the Status and Links bar. The display is reloaded into the pump screen.
The certificate printing process failed; information is printed without the certificate image background.	Perform one of the following options: 1.Use the "print screen" option and copy the certificate image to a suitable application to print. 2.Provide the pump S/N and certification date to service@qcore.com and the certificate will be emailed to you.
Station appears inactive although being properly configured	Verify there are no other active PC programs that use the same configured COM port
The user double-clicked a station that has no live pump attached to it, the following error message appears: "There is no pump attached to this station. Action Canceled"	Check that: • The pump is connected to the matching COM port • The pump is turned on or attached to a power supply
The user double clicked a station, but no user is logged in, the following error message appears: "No User Logged In. Login first, and then start the certification process"	Log into the software

Problem	Management
An alarm was triggered in the pump that is not related for the specific stage, the following error message appears: "Critical Alarm Occurred. Check pump. Certification is aborted"	• Refer to Alarms and Troubleshooting on page 144 and attend the alarm as instructed. • Restart the certification process.
Some of the graphic information was not transferred and is missing from the pump screen (title, text, buttons).	• If text or title is missing, they will appear on the PC screen. • If a button is missing, try to press its location. If only the image is missing, the function will work. If pressing on the button location doesn't work, close the current test and restart.

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Chapter 5: Downloading Event Log

The following sections explain how to download an Event Log from the Sapphire pump to a computer:

Overview

Event Log are downloaded to a PC using Event Viewer software, which can be obtained from Q Core FTP site (https://qcore.smartfile.com). For information regarding the FTP site, refer to FTP site on page 28.

- Make sure to use the most updated Event Viewer software version.
- Event Viewer software can only be used with Sapphire Rev11 software and above.

Event Viewer files have the following file name pattern:

Events Viewer RevXX vYY.exe, where:

- XX is the release number
- YY is the version number

Once an Event Log is downloaded, it can be saved in .csv format (Excel file) and sent to Q Core Medical for evaluation. Logs should be sent to Q Core in the following circumstances:

- The pump was involved in the injury or death of a patient.
- The pump was involved in an event that might have caused injury or death of a patient.
- The pump has caused or may have caused injury to the medical staff.

- The pump is not performing as expected.

For a complete list of events that are recorded in the Event Log, refer to Event Log Tables on page 106.

Prerequisites

Before beginning the download, verify that the following hardware and software requirements are met.

Hardware Requirements

- **PC**: Core 2 duo, 2 GB (or higher) RAM
- **Screen resolution**: 1280 x 1024 (minimum)
- Communication cable for the Sapphire pump (P/N 05020-110-0213)
- RS232 connectivity, in either of the following forms:
- An RS232 port in the PC

Figure 5.1. PC Connector

- A USB to RS232 adaptor and driver (can be purchased from Q Core Medical Ltd.) (P/N 15077-000-0001).

Figure 5.2. USB Adaptor and Driver

Software Requirements

- OS: Windows XP, Windows Vista, or Windows 7 (32 or 64 bit)
- MS Excel (2003 or higher)
- WinRar or other software for handling .zip files
- Event Viewer software (.exe file provided by Q Core)

Download Procedure

The following procedure explains how to download an Event Log from the pump to your PC.

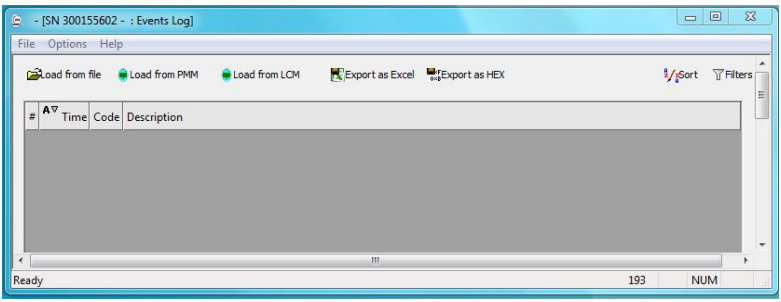
> To download a new software version:

1. Copy the Event Viewer file to the directory of your choice.
2. Turn on the Sapphire pump. Then, using the communication cable, connect the pump to the computer.
3. Open the Event Viewer file.

   The "Please Select the RS232 Communication Port" window appears on the monitor, with a list of available ports displayed.
4. Select a port from the list, and then click **OK**.

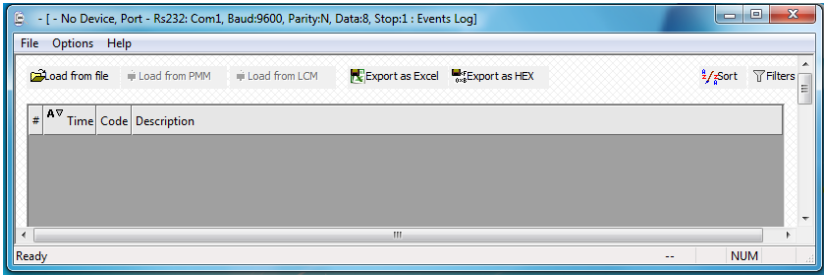
   The Event Viewer screen appears, displaying the serial number of the pump on the upper left corner of the window.

Figure 5.3. Event Viewer



If the pump wasn't identified properly by the Event Viewer, a "No Device" message will be displayed on the upper left corner of the window.

Figure 5.4. Event Viewer: No device

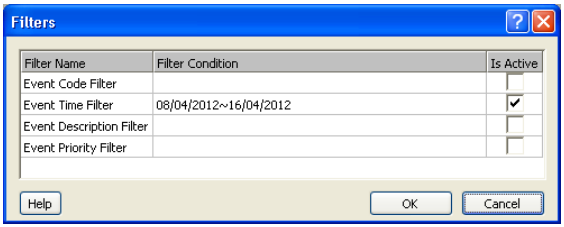


5. If required, filter the Event Log by selecting specific events to be downloaded:

   a. In the upper right corner of the Event Viewer screen, click **Filters**. The Filters dialog box opens.

   b. To select filters, in the relevant row, enter the required condition, and then check the Is Active checkbox. In the following example, only the events that occurred between April 8 and April 16, 2012, will be downloaded:

Figure 5.5. Event Viewer: Filters



Repeat in all necessary rows.

Filtering by priority is currently not supported.

c. Click **OK**. The Filters dialog box closes.

6. At the top of the Event Viewer screen, click either **Load from LCM** or **Load from PMM** (Liquid Crystal Module or Pump mechanism module). The caption of the button changes to **Stop loading**, and the download begins. As the download progresses, events are displayed on the Event Viewer screen.

By default the Event time filter is active for events of the prior 7 days.

7. After the download is complete, at the top of the Event Viewer screen, click **Export as Excel**, and then save the file in the directory of your choice.

   The file is automatically given the serial number of the pump and the date and time it was saved. It is recommended to give the file a relevant name that includes the institution name, serial number of the pump, date, etc. At the end of the file name, write PMM or LCM to identify the Event Log.

8. Send the file to Q Core Medical, by emailing it to service@qcore.com.

9. Disconnect the pump from the PC, and then exit the Event Viewer software.

Event Log Tables

The following tables list all Sapphire infusion pumps versions events that are recorded to the Event Log:

Power-on Events

The following events occur during the power-on period:

Event Code	Event Description	Text on Screen
2	End of battery life span	End of battery life
3	Watchdog reset	Built in test failure
111	Battery life expires	Battery life expires in 2 days
112	Battery life expires	Battery life expires in 2 weeks
117	Non authorized battery	Non authorized battery inserted
118	Software failure	Software failure. Code xx (1 – Program memory, 2 – Drug library, 3 – Icons, 4 - Fonts, 5 - Language 1, 6- Language 2, 7- Language 3)
119	External watchdog failure	External watchdog failure
140	Time changed to	Time changed to: <xx:xx> AM/PM
193	Battery usage	Battery usage error

Event Code	Event Description	Text on Screen
246	WiFi malfunction	WiFi module communication malfunction
250	System monitoring used to monitoring for unrecovered failures in client site	System monitoring

Pump Idle Time Events

The following events occur while the pump is idle (not during an infusion):

Event Code	Event Description	Text on Screen
18	Pump unattended	Pump unattended
248	Time synchronization	Difference of +/- xx days and xx:xx:xx h:min:sec Server time from displayed time
249	Auto program	Auto program was accepted by user
257	Auto program	Auto program was rejected by user

Pre-infusion and Intra-infusion Events

The following events occur before and during an infusion:

Event Code	Event Description	Text on Screen
5	Inconsistent flow/Pumping mechanism	Faulty pumping mechanism or inconsistent flow <xx>
7	Low input pressure	Upstream occlusion
9	Output Occlusion	Downstream occlusion
10	Administration set misplaced	No administration set loaded

Event Code	Event Description	Text on Screen
12	Air in Line	Air in line
13	Faulty air Detector	Air detector failure
14	*Battery depleted	Depleted battery
16	Door open	Door of administration cassette open
17	External Communication Error	External communication error
20	Certification due within 2 days	Calibration due in <xx> days.
21	Certification due now - Certification date arrived/ passed	Calibration due now
25	Certification due within 2 weeks	Next calibration due in 2 weeks.
26	Low battery voltage for high rates	Low battery for rate over 800 mL/h
28	Treatment near end	Treatment near end
29	Delayed KVO (may appear only when ADP/ EDHR is in control of a pump)	KVO during Delayed Start changed to: <xx.x> mL/h
31	Incorrect pressure value reading	Incorrect pressure value reading
36	Wireless network connection	Pump is connected to wireless network
40	Accumulated Air in Line	Accumulated air in line
42	VI Reset	VI Reset XXXX mL
82	Continuous rate, Soft limit override	Continuous rate, soft limit override: <xxx> mL/h
102	Pump Bolus key pressed	Pump bolus key pressed
103	Bolus handle key pressed	Bolus handle key pressed
127	Wireless network connection	Pump was disconnected from wireless network

Event Code	Event Description	Text on Screen
129	Check for Occlusion	Possible occlusion; infusion started with clamps closed
131	Auto-KVO changed	Auto-KVO changed to: <xx.x> mL/h
132	Unknown occlusion	Possible occlusion; infusion started with clamps closed
136	Secondary VI Reset	Secondary VI Reset XXXX mL
139	Infusion near end	Infusion near end alarm set to: <xx> min
169	Power save mode state	Power save mode state: <error code> (0 – Entering stop mode, 1 – Failed to enter stop mode, 2 – Exit stop mode On/Off button pressed, 3 – Exit stop mode Stop button pressed, 5 – Exit stop mode Pump request, 6 – Exit stop mode One Minute Before Step/ State Changed)
184	Automatic restart	Automatic restart after downstream occlusion
244	MedNet connection	Pump is connected to MedNet
245	MedNet connection	Pump was disconnected from MedNet
265	Accumulated VI Reset	Accumulated VI Reset XXXX mL

Operation-related Events

The following events occur during specific pump operations, such as priming, starting an infusion, delivering a bolus, etc.:

Event Code	Event Description	Text on Screen
24	Treatment completed	<Delivery mode> treatment completed
32	Bolus started Rate: XXX mL/h	Bolus started rate: <xxx> mL/h
33	Bolus stopped Volume infused: XX.X mL	Bolus stopped; volume infused: <xx.x> mL
34	Bolus finished Volume infused: XX.X mL	Bolus finished; volume infused: <xx.x> mL
41	Delayed start	Delayed start set to: <xx:xx:xx>
56	Power off	Power off
57	Power on	Power on
68	Clinician Bolus started	Clinician bolus started
71	Clinician Bolus complete. Volume infused: XX.X mL	Clinician Bolus complete. Volume infused: XX.X mL
73	New Infusion started	New infusion started
104	Bolus started	Bolus started
105	Demand Bolus Complete. Volume infused: XX.X mL	Demand Bolus complete. Volume infused: XX.X mL
108	Prime started	Prime started
109	Prime stopped	Prime stopped
110	Prime finished	Prime finished
122	Started from secondary bag	Started from secondary bag
124	Started from primary bag	Started from primary bag
130	Infusion Info	Infusion ended info: VTBI left = xxxx, VI=xxx, Time=xx:xx:xx, Rate=xxx.x (or last rate).
147	Infusion started with delay	Infusion started with delay (KVO = X mL/h)
159	Continued from primary bag	Continued from primary bag

Event Code	Event Description	Text on Screen
160	Continued from secondary bag	Continued from secondary bag
161	Secondary line added	Secondary line added
163	Power on (battery supply)	Power on (battery supply)
164	Demand Bolus quit prematurely. Volume infused: XX.X mL	Demand Bolus quit prematurely. Volume infused: XX.X mL
165	Clinician Bolus quit prematurely. Volume infused: XX.X mL	Clinician Bolus quit prematurely. Volume infused: XX.X mL
166	Demand Bolus paused	Demand Bolus paused
167	Clinician Bolus paused	Clinician Bolus paused
172	Certification succeeded	Pump passed certification
173	Certification failed	Pump failed certification
175	Pausing bolus was not confirmed	Pausing bolus administration was attempted but not confirmed
176	Pausing infusion was not confirmed	Pausing infusion was attempted but not confirmed
177	Turn off while running was not confirmed	Turn off while running was attempted but not confirmed
178	Turn off was not confirmed	Turn off was attempted but not confirmed
179	Unlock screen was not confirmed	Unlock screen was attempted but not confirmed
182	Continue infusion was not confirmed	Continue infusion was attempted but not confirmed
183	Continue bolus was not confirmed	Continue bolus administration was attempted but not confirmed
202	Repeat last infusion	Last treatment was repeated
209	Infusion started with delay	Infusion started with delay (No KVO)
210	KVO of x mL/h was ended	KVO of x mL/h was ended
219	Standby mode started	Standby mode started

Event Code	Event Description	Text on Screen
220	Standby mode ended	Standby mode ended
222	New treatment wizard initiated	New treatment wizard initiated
223	Bolus wizard initiated	Bolus wizard initiated
224	Prime wizard initiated	Prime wizard initiated
225	Secondary line wizard initiated	Secondary line wizard initiated
226	Programing was cancelled	Programing was cancelled
231	Delayed start finished	Delayed start finished

Settings and Options-related Events

The following events occur when pump configuration options are set:

Event Code	Event Description	Text on Screen
23	Backlight	Backlight set to: On/Off/Partial
35	Key volume	Keys volume set to: <x>
37	Allow delayed start	Allow Delayed start set to: On/Off
38	Bolus rate	Default bolus rate set to: <xxx> mL/h
39	Accumulated Threshold	Accumulated threshold set to: <xxx>
46	Programmed treatment	Allow load pre-programmed treatments set to: <xx>
48	Pump unattended	Pump unattended set to: <xx>
51	Delivery mode changed to: X	Delivery mode changed to: <x>
52	Occlusion level changed to: XX.X X	Occlusion level changed to XX.XX
53	Occlusion units set to: X	Occlusion units set to: <x>
54	Single Bubble set to: X	Single bubble set to: <x>

Event Code	Event Description	Text on Screen
55	Accumulated Bubble set to: X	Accumulated bubble set to: <x>
58	Authorization level set to: X	Authorization level set to: <x>
59	Alarm Volume set to: X	Alarm Volume set to: <x>
60	Speaker interval set to: X	Speaker interval set to: <x>
61	Reset system set to factory defaults	Reset system set to factory defaults
62	Language changed to: X	Language changed to: <x>
63	Time changed to: XX:XX	Time changed to: <xx:xx>
64	Date changed to: XX/XX/XX	Dated changed to: <xx/xx/xx>
65	New drug library	New drug library file uploaded: xxxxxx
67	Dose units changed to: X	Dose unit changed to: <x>
69	Clinician Bolus Amount set	Clinician bolus amount set to: <xx.xxx>
72	Bolus rate set to: XXX.X mL/h	Bolus rate set to: <xxx.x> mL/h
76	*VTBI set to: XXXX mL	VTBI set to: <xxxx> mL
77	*Rate set to: XXX mL/h	Rate set to: <xxx.x> mL/h
78	Dose set to: XXX	Dose set to: <xxx>
79	Interval set to: XX:XX h:min	Interval set to: <xx:xx> hr:min
81	Infusion Period set to: XX:XX h:min	Infusion period set to: <xx:xx> hr:min
83	KVO set to: XX.X mL/h	<Delivery mode> KVO set to: <xx.x> mL/h
84	KVO options set to XX.X [units] (for intermittent)	KVO options set to XX.X [units]
85	Taper Up set to: XX:XX h:min	Taper up set to: <xx:xx> hr:min
86	Taper Down set to: XX:XX h:min	Taper down set to: <xx:xx> hr:min
87	Plateau Rate calculated to: XXX.X mL/h	Plateau rate calculated to:< xxx.x> mL/h

Event Code	Event Description	Text on Screen
90	Concentration set to: XX.X X /mL	Concentration set to: <xx.xx> /mL
92	Patient Weight set to: XXX kg	Patient weight set to: <xxx> kg
95	Drug concentration selected to: XX.X X	Drug concentration selected to: <xx.xx>
96	Bolus Lockout set to: XX:XX h:min	Bolus lockout set to: <xx:xx> h:min
97	Max Bolus per hour set to: XXX	Max bolus per hour set to: <xxx>
98	Continuous rate set to: XXX.XX mL /h	Continuous rate set to: <xxx.xxx> /h
99	Demand Bolus set to: XXX.XX X	Demand bolus set to: <xx.xxx>
100	Demand Bolus calculated	Demand Bolus calculated to: <xxx.xx>
101	Rate calculated	Continuous rate calculated to: <xxx.xx>/h
120	Secondary VTBI set to: xxxx mL	Secondary VTBI set to: <xxxx> mL
121	Secondary rate set to: xxx.x mL/h	Secondary rate set to: <xxx.x> mL/h
125	Password changed	Password(s) were changed
134	Infusion type	Infusion type set to <x>
135	Max boluses per 1/4 hour	Max boluses set for: <x> hr(s)
137	Patient ID	Patient ID set to: xxxxxxxxxx *PATIENT for 'null' Patient ID
138	US format	US format set to: On/Off
141	Air detection has been set to Off	Air detection has been set to Off
142	New patient	New patient set to: On/Off
143	Loading dose	Loading dose set to: <xx>
144	Allow loading dose	Allow loading dose set to: <xx>

Event Code	Event Description	Text on Screen
145	Password request	Password request set to: Yes/No
146	Hard limits	Hard limit <delivery mode> <parameter> set to: <xxxxxx>
148	Hard Limit Multi-step step duration	Hard Limit Multi-step step duration set to: <xx:xx>
149	Bolus rate changed	Current bolus rate changed to XXX.X mL/h
153	Alarm disabled	Alarm <xx> was disabled
154	Alarm enabled	Alarm <xx> was enabled
155	Alarms enabled	All alarms were enabled
156	Alarms disabled	All alarms were disabled
162	Enable Secondary line set to: On/Off	Enable Secondary line set to: On/ Off
170	Secondary time set to: XX:XX:XX hh:mm:ss	Secondary time set to: XX:XX:XX hh:mm:ss
185	Secondary concentration set to: XX.X mcg or mg /mL	Secondary concentration set to: XX.X mcg or mg /mL
186	Secondary Dose Rate units changed to: X	Secondary Dose Rate units changed to: X
187	*Dose Rate set to: XXX	Secondary Dose Rate set to: XXX
188	Secondary Dose Rate set to:XXX.XX	Secondary Dose Rate set to:XXX.XX [Dose]/[Time]
189	Drug amount	Drug amount set to: xxx unit
190	Diluent Volume	Diluent Volume set to: xxx mL
191	Drug Name	Drug Name set to: xxxxxxxxxx
192	Secondary Drug Name	Secondary Drug Name set to: xxxxxxxxxx
194	Secondary Drug amount	Secondary Drug amount set to: xxx unit
195	Secondary Diluent Volume	Secondary Diluent Volume set to: xxx mL
196	Clinical care area	Clinical care area set to: xxxx

Event Code	Event Description	Text on Screen
197	Drug amount units	Drug amount units set to: xxx unit
198	Concentration units	Concentration units set to: xxx unit
199	Secondary Drug amount units	Secondary Drug amount units set to: xxx unit
200	Secondary Concentration units	Secondary Concentration units set to: xxx unit
201	Delivery mode turned On/Off	XXX delivery mode turned On/Off
203	General drug	General drug chosen
204	Secondary General drug	Secondary General drug chosen
205	Upper soft limit	[parameter] of xx [units] is above the upper soft limit
206	Lower soft limit	[parameter] of xx [units] is below the lower soft limit
207	Calculate concentration	Calculate concentration set to: On/Off
208	mL/h only	mL/h only set to On/Off
212	Advanced Bolus	Advanced Bolus programming set to On/Off
216	Bolus Handle sound	Bolus Handle sound set to: X
227	Screen Saver	Screen Saver set to On/Off
229	Prime Reminder	Prime Reminder set to On/Off
230	Secondary Bolus Rate	Default Secondary Bolus Rate set to: XXX mL/h
256	WiFi setting	WiFi set to On/Off

General Events

The following events are not associated with any specific periods or operations:

Event Code	Event Description	Text on Screen
1	Battery temperature	Battery temperature is out of range <xx>°C
4	Internal communication failure	Internal communication failure
6	Temperature of pump	System temperature is out of range <xx>°C
11	System error	System error <xxx>
15	Key stuck	Key stuck
17	SW Update (external communication error that is prompted for SW update)	SW update in process
19	Battery near depletion	Battery near depletion
22	*Charger failure	Charger error
43	Initializing software update(system error 3)	Initializing software update
44	Power on without enough battery voltage	Power on was initiated without enough battery voltage
45	Charger disconnected	Power supply disconnected
49	Automatic alarm cleared	Automatic alarm <xx> cleared
50	Confirmation of alarm	Confirmation of alarm <xxx>
70	Connection of power supply	Power supply connected
74	Pump started	Pump started
75	Pump stopped	Pump stopped
115	Battery replaced UID: <xxxxxxxx>	Battery replaced UID: <xxxxxxxx>

Event Code	Event Description	Text on Screen
123	Software uploaded XXXXXX XXXX X (the event will not pop up for PMM when uploading a software with the same change set)	Software uploaded rXX vXX CXXXX
133	Boot request	Boot request
247	Pump stopped	Pump stopped due to Alarm
258	Alarm was silenced	Alarm was silenced
259	Alarm was unsilenced	Alarm was unsilenced
260	Battery power change	Battery power changed to X%

Chapter 6: Replacing the Battery

The following sections describe how to replace the battery in the Sapphire pump:

Getting Started

The Sapphire pump uses Li-Ion batteries, which are supplied by Q Core Medical Ltd. Only qualified technicians should replace the batteries.

Before and during battery replacement, always adhere to the following safety precautions and guidelines:

- Make sure that the pump is turned off, and disconnected from an external power supply.
- Replace the battery only with the same type. An explosion hazard exists if the battery is replaced by an incorrect type or not according to the instructions.
- Do not short circuit the battery terminals. Do not disassemble or modify battery packs.
- Do not dispose of batteries or battery packs in fire.
- The packaging, the administration sets, the battery, and any other electronic components must not be disposed of as unsorted municipal waste, and must be collected separately in accordance with applicable environmental laws (such as the WEEE Directive for Waste Electrical and

Electronic Equipment). Contact an authorized representative for information concerning the decommissioning of your equipment.

Fill out the Customer Battery Replacement Form on page 124, scan the form and e-mail it to service@qcore.com.

Required Equipment

Before beginning the battery replacement procedure, verify that the following equipment is available:

- Li-Ion battery (supplied by Q Core)
- Number 3 flat screwdriver, or number 1 Phillips screwdriver

Replacing the Battery

The following procedure explains how to change the battery. Before beginning, it is recommended to disconnect the administration set from the pump, and clean/sterilize the pump. After replacing the battery it is required to set the date and the time.

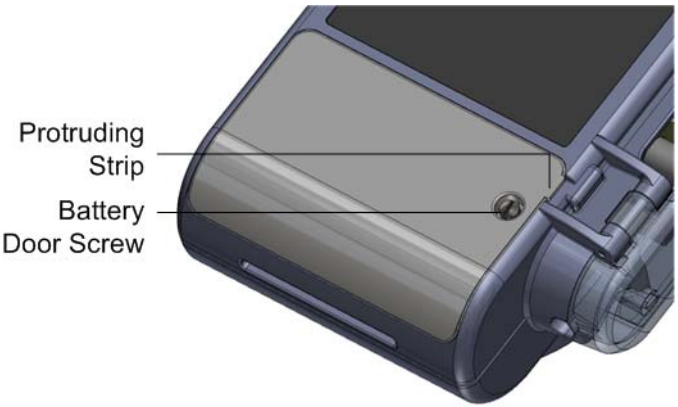
It is possible to set the date and time in the Pump Configuration menu. See Defining Regional Parameters on page 130 (Sapphire and SapphireH100) or Defining Regional Parameters on page 174 (SapphirePlus).

> To replace the battery:

1. Verify that the pump is turned off, and disconnected from an external power supply.
2. Using a number 3 flat screwdriver or number 1 Phillips screwdriver, unscrew the battery door screw, until the door is loose enough to remove.

3. Separate the battery door from the pump by inserting the screwdriver under the protruding strip near the door hinge. The battery door screw remains attached to the door.

Figure 6.1. Battery Door



4. Carefully remove the battery from the battery compartment, and disconnect it from the battery connector.

⚠	Never pull/push the wires to disconnect/connect the battery connector. Hold the connectors parts directly and pull/push them by hand.

5. Set the old battery aside, record the new battery's serial number on the Battery Replacement Form prior to connecting the new battery and Email the form to service@qcore.com.

ℹ	When the battery is connected, the pump automatically turns on.

6. Inspect the battery cable and chamber, and verify that:
   - The battery cable is in good condition
   - Wires are not exposed or disconnected

- The battery chamber is free of loose particles and dirt

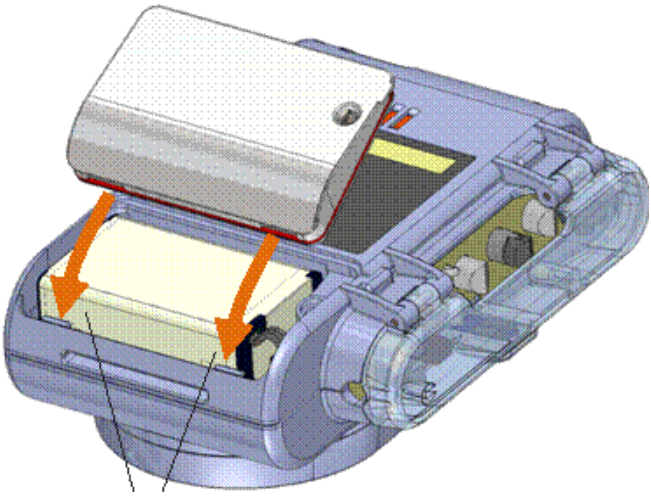
7. Position the battery on top of the connector inside the battery chamber so the battery door can be easily installed. Make sure the connector and wires are positioned to the side of the battery, and not on top of it

Figure 6.2. Battery Connector.

8. Installing the door:

   Starting at the side closer to the top of the pump, position the door by engaging it with the two hinges. Then, from the opposite side, carefully close the door until it snaps into place.

Figure 6.3. Installing the Battery Door



9. Tighten the battery door screw.

⚠	Avoid using extensive torques, as they may crack the plastic housing or harm the screw thread.

10. Inspect the battery door, and verify that:
    - The door is not raised
    - The door is aligned with the bottom shell of the pump
    - The O-Ring cannot be seen

Customer Battery Replacement Form

CUSTOMER BATTERY REPLACEMENT FORM

Fill the form in clear handwriting or typing and submit to: service@qcore.com

Customer:	**Site/Warehouse:**
Country:	**Battery replacement date (DD/MM/YYYY):**

Pump Serial Number	**Original Battery Serial Number**	**New Battery Serial Number**

Performed By			
Name	**Position**	**Signature**	**Date (DD/MM/YYYY)**

Chapter 7: Sapphire & SapphireH100

Configuring Basic Pump Settings

The following sections describe how to view and update basic pump configuration settings, using the Options menu:

For a description of all basic pump options, refer to the Sapphire User Manual.

Managing Alarm Settings

The Alarms menu enables you to view and modify alarm-related options.

> 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 pressure that triggers an Occlusion alarm. Acceptable ranges for Sapphire are: 0.4 – 1.2 Bar (5.8 – 17.4 PSI, 300-900 mmHg). Acceptable ranges for SapphireH100 are: 0.2 – 1.2 Bar (2.9 – 17.4 PSI, 150-900 mmHg). An alarm sounds when the pressure reaches the set value ± the sensor sensitivity level. If a value outside the permitted range is entered during programming, the range is displayed in red font, and the **OK** function key is disabled.	Select **Occlusion pressure**. Then, using the keypad, enter the required 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 while an infusion is running.	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. Options are **1**, **3**, **5**, or **10** minutes, disable the alarm by selecting **Off**. **Note:** The Infusion Near End alarm is triggered only once during treatment.	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	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. Level 1, 2, or 3 alarms are provided with visual and the lowest auditory signal permitted, according to IEC 60601-1-8. Maximum alarm volume is 70 dB. Minimum alarm volume is 56 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 Alarms and Troubleshooting on page 144.	Select **Alarm Volume**. Then, select **Maximum** or **Minimum**.

Local configuration changes made after the Drug Library is loaded, will be valid until the pump is turned off.
When resuming an infusion after pump shutdown, local configurations will remain until the end of the current infusion. For more details regarding Drug Library, refer to the Sapphire User Manual.

Configuring General Settings

The General settings menu enables you to view basic pump settings, and modify them according to clinical requirements.

> 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)
Keys Volume	Sets the speaker volume for the auditory signal generated when users select functions and press keys on the pump. **Note:** When keys volume is set to Off the bolus handle is silenced.	Select **Keys Alarm 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. Level 1, 2, or 3 alarms are provided with visual and the lowest auditory signal permitted, according to IEC 60601-1-8. Infusion Complete message is provided with a visual and auditory alarm signal, which will not be affected by the volume changes. For more information about messages and alarms, refer to Alarms and Troubleshooting on page 144.	Select **Alarm Volume**. Then, select **Maximum** or **Minimum**.
Authorization level	Sets the authorization lock level of the pump.	Select **Authorization level**. Then, enter a password and select **Low**, **Medium**, **High**, or **Tech**.

Option	Descriptions/Notes	To Modify Parameter (from the General settings screen)
Allow delayed start	Enables/disables programming of infusions that begin after a predefined period of time. When the option is enabled, the Set Delay frame appears on the Start screen. Note: This feature functions like a timer.	Select the Allow delayed start row, to toggle the option between **On** and **Off**.
Allow PreProgram	Enables/disables starting infusions using predefined infusion parameters. When the option is enabled, the PreSet Programs frame appears on the Start screen.	Select the Allow PreProgram 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. If a value outside the permitted range is entered during programming, the range is displayed in red font, and the **OK** function key is disabled.	Select **Set Prime Volume**. Then, using the keypad, enter the desired value → **OK**.
Backlight	Sets the degree of screen dimming while the pump is running. The Off and Partial options of this feature save power and promote longer battery life.	Select **Backlight**. Then, select **On**, **Off**, or **Partial**.

Defining Regional Parameters

The Regional menu controls date, time, and language settings.

> 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 row.
2. Using the keyboard, enter values (2 digits each) for the day, month, and year. (When U.S. 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 row.
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 to On.)
4. To confirm the new settings, press **OK**.

> To set the language:

1. Select the Language row.
2. Select the required language.

In some pumps, only the default language is listed.

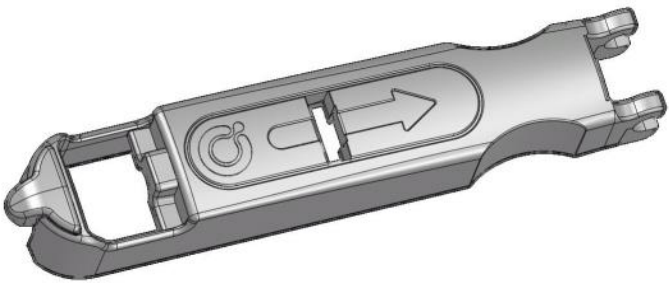
3. To confirm the new settings, press **OK**.

SapphireH100 Design

The new SapphireH100 safety door is designed to accommodate the dedicated SapphireH100 line of sets. If needed, regular Sapphire administration sets can be used with the SapphireH100 infusion pump as well.

Figure 7.1. SapphireH100 infusion pump

Figure 7.2. SapphireH100 infusion pump cassette



SapphireH100 Infusion Pump Functions

Delivery Modes

SapphireH100 infusion pump supports the following delivery modes:

- Continuous
- Multi-step
- Intermittent
- TPN

Pressure Settings

The SapphireH100 infusion pump pressure values are 0.2 – 1.2 Bar (2.9– 17.4 PSI, 150-900 mmHg), at increments of 0.1 bar (the increment in PSI is 0.1 PSI. The increment in mmHg is 1 mmHg).

Using Technician Options

The following sections describe the configuration options available to users with a Technician authorization code:

Overview

The Tech. options screen provides access for viewing and managing settings used for calibration, testing and maintenance purposes.

> To access the Tech. options screen:

1. From the toolbar of the Start Up screen, press **Options**.
   The Options screen appears.
2. Select **Technician options**.
   The Tech. options screen appears.

The Tech. options screen is accessible only when the pump is set to Technician authorization level. If the **Technician options** selection does not appear on the Options screen, change the authorization level to Technician and repeat the procedure. (For details refer to Setting Technician Lock Level on page 37.)

Alarms manager

This function is reserved for Q Core Medical's internal use only.

Managing Pump Settings

The pump settings screen provides access to pump configuration settings that can be managed only by a technician. The screen is accessed from the Tech. options screen by selecting **Pump settings**.

The following sections describe:

Setting Hard Limits

The hard limit is the acceptable range of a given parameter; the hard limit is displayed in the upper right corner of the main display while entering the parameter.

The Set hard limits screen provides access for viewing and modifying the upper limits of infusion parameter ranges. Parameter's hard limits and permitted ranges are mode-specific. Parameters of a given mode can be viewed and updated only when the pump is set to that delivery mode. Settings are not saved after turning off current delivery mode.

Hard Limit Parameters for Continuous and Multi-step Delivery Modes

Delivery Mode	VTBI	Rate	Time
Continuous	✓	✓	
Multi-step	✓	✓	✓

Hard Limit Parameters for Continuous, when Set Secondary is set to On (refer to To enable secondary settings: on page 142)

Delivery Mode	Primary VTBI	Primary Rate	Secondary VTBI	Secondary Rate
Continuous	✓	✓	✓	✓

Hard Limit Parameters for TPN, and Intermittent Delivery Modes

Delivery Mode	VTBI	Rate	Time	Dose Rate	Dose
TPN	✓				
Intermittent	✓			✓	✓

Hard Limit Parameters for PCA, PCEA and Epidural Intermittent Delivery Modes (Sapphire only)

Delivery Mode	VTBI	Continuous Rate	Demand Bolus	Loading Dose/ Dose	Bolus Rate	Bolus Lockout
PCA	✓	✓	✓	✓	✓	✓
PCEA	✓	✓	✓	✓		✓
Epi. Int	✓			✓		

> To update hard limits for a delivery mode:

1. From the Tech. options screen of the relevant delivery mode, select **Pump settings → Set hard limits**.
   The hard limit parameters for the current delivery mode are displayed.
2. Select the row of the parameter that you want to change. Using the keypad, enter the required value, and then press **OK**.

3. To exit the Set hard limits screen, from the toolbar, press either **OK** or **Exit**. The Start Up screen is displayed.

Setting KVO Rate

KVO is the rate of fluid that is delivered to the patient when the infusion program is completed, in order to prevent clotting in the infusion cannula. Separate KVO rates can be set for different delivery modes. The permitted range for the KVO rate parameter is 0-20 mL/h (for all delivery modes).

It is not necessary to change the delivery mode of the pump to program KVO rates for the different modes. The KVO screen of each delivery mode provides access to setting KVO rates for all other delivery modes, with the exception of intermittent and Epidural intermittent.
For intermittent and epidural intermittent KVO rate is programmed for every infusion.

> To set the default KVO rate for a delivery mode:

1. From the Tech. options screen, select **Pump settings → Set KVO**. The KVO screen appears, with a list of delivery modes displayed.
2. Select the delivery mode whose parameter is to be updated.

   The keypad is displayed.
3. Using the keypad, enter the value of the required KVO rate. Then, from the toolbar, press **OK**.

   The KVO rate for the selected delivery mode is set.
4. To set the KVO rate for an additional delivery mode, repeat Steps 2-3.
5. To exit the KVO screen, from the toolbar, press **Exit**. The Start Up screen is displayed.

Setting Air Detector Settings and Thresholds

The Air detector screen provides access for viewing and modifying the amount of air in the administration set that triggers an 'Air in Line' alarm. Air detector configuration is a general pump setting that needs to be set only once. Values configured for air detection in one delivery mode are automatically applied to all other delivery modes.

	In Epidural modes, both Single and Accumulated can be switched to Off. When changing the delivery mode to NON epidural - one of the setting will turn on.

The Sapphire pump has 2 mechanisms for triggering the Air In Line alarm:

- **Single air detector**: In this mechanism, every time that a single bubble equal to or larger than a user-selected size passes through the detector, an alarm is triggered.
- **Accumulated air detector**: In this mechanism, the user selects values for both accumulated bubble size and the accumulated amount (threshold). Any single bubble equal to or larger than the selected accumulated bubble size is included in the counter of accumulated air. When the total amount of accumulated air reaches the selected accumulated threshold value within a 15-minute period, an alarm is triggered.

There is an option to turn off the single air detector or the Accumulated air detector, but not both. In Epidural Mode, the option to turn both air detectors off will be available (Sapphire only).

> To set air detector settings:

1. From the Tech. options screen, select **Pump settings** → **Set air detector**.
   The Air detector screen appears.
2. Set the single air detector value:
   a. Select the Single Air Detector row.
      The Single bubble screen appears, with a list of values displayed.
   b. Select the required value. To deactivate this mechanism, select **Off**.
      The Air detector screen reappears.

3. Set the accumulated air values:
   a. Select the Accumulated Air Detector row.
      The Accum Bubble screen appears, with a list of values displayed.
   b. Select the required value. The Air detector screen reappears.
   c. Select the Accumulated Threshold row.
      The Accum Threshold screen appears, with a list of values displayed.
   d. Select the required value. To deactivate this mechanism, select **Off**.
      The Air detector screen reappears.
   e. To save changes in the system, from the toolbar, press **OK**.

	If the pump is not in Epidural delivery mode and both air detector mechanisms have been set to Off, an error message appears on the Attention screen, and you are prompted to reconfigure the values (Sapphire only).

The Start Up screen appears.

Air In Line Alarm

The Single air detector will automatically switch to On in the following conditions:

- The Single air detector was set to OFF
- The SapphireH100 infusion pump is operating on rate lower or equal to 4mL/h.

	Valid for rate, continuous rate, KVO rate and bolus rate.

- If the pump is operating on rates between 0.1mL/h to 0.9mL/h, the Single air detector automatically switch to On. If 0.1 mL air bubble was identified, the Air in line alarm will be activated.
- If the pump is operating on rates 1mL/h to 4mL/h , the Single air detector will automatically switch to On. If 0.5 mL air bubble was identified, the Air in line alarm will be activated.

If the pump is operating on a rate higher than 4mL/h, the Single air detector will automatically switch back to OFF.

Resetting the System

The Reset System option is used to revert all pump parameters and features to the factory default settings.
This option also allows defining of new security passwords.

Factory defaults

> To set pump parameters to factory default settings:

1. From the Tech. options screen, select **Pump settings** → **Reset system**.
   The Reset system screen appears.
2. Select **Factory defaults**.
   The Attention screen appears.
3. To confirm the reset, from the toolbar, press **OK**.
   Changes are saved in the system, and the Start Up screen appears.

Passwords

To help ensure patient safety, the Sapphire pump can be set to one of four authorization levels. For more information regarding the different authorization levels, refer to Configuring General Settings on page 128.

> To change the passwords:

1. From the Tech. options screen, select **Pump settings** → **Reset system**.
   The Reset system screen appears.
2. Select **Passwords**.
3. Select authorization level password to change.

4. Enter a 4-digit password in the specified range [1000 - 7000].

Passwords for each security level must be unique and in the specified range. The OK button will be disabled when entering the same password for more than one security level.

5. When finished, press **OK** to save the changes.

Configuring General Settings

The General screen provides access for viewing and modifying selected basic pump settings. Some of these settings are common to all delivery modes. Others are specific to certain delivery modes, and appear only when the pump is set to those modes.

> To access the General screen:

- From the Tech. options screen, select **Pump settings → General**.
  The General screen appears.

The following settings appear in all delivery modes. Changes made while the pump is in one delivery mode are automatically applied to all other delivery modes.

Setting	Description/Notes	Default Value
Delivery Mode	Determines the available delivery modes. Each mode can be turned off separately.	On
New patient	When this setting is On, the New Patient screen appears when new infusions are programmed, and users are prompted to specify whether the infusion is for a new patient.	Off
US format	When this setting is On, the date format is month/day/year, and a 12 hour time format.	Off

Setting	Description/Notes	Default Value
Occ. Auto-restart	Enables the pump to restart the infusion automatically provided the occlusion was cleared. If the occlusion was not cleared within 40 seconds, the downstream occlusion alarm is activated. An Occlusion Auto-restart can occur up to 5 times an hour.	On
Calculate Concentration	Determines if the users enter final concentration or Drug Amount and Diluent Volume. **Note**: appears in all delivery modes excluding TPN.	Off
Dose Calculation	Enables users to use units other than mL/h. If this option is disabled, programming will automatically default to mL/h. This feature is available in the absence of a Drug Library on the pump. **Note**: appears in all delivery modes excluding TPN.	On

The following settings appear only when the pump is in the Continuous delivery mode:

Setting	Description/Notes	Default Value
Bolus Rate	The rate of delivery of a fast dose, for rapid volume infusion.	600 mL/h
Set Secondary	Allows setting secondary infusion (piggyback) in continuous mode.	Off

Press **OK** to save the changes.

> To set the general settings:

1. From the General screen, select the row of the relevant option, to toggle the setting between **On** and **Off**.
2. After changing the setting(s), from the toolbar, press **OK**.
   Changes are saved in the system, and the Start Up screen appears.

> To set the bolus rate:

1. From the General screen, select the **Bolus Rate** row.
   The Bolus rate screen appears.
2. Using the keypad, enter the required rate. Then, from the toolbar, press **OK**.
   The General screen reappears.
3. After changing the setting(s), from the toolbar, press **OK**.
   Changes are saved in the system, and the Start Up screen appears.

> To enable secondary settings:

1. From the General screen, select the Set Secondary row, to toggle the setting between **On** and **Off**.
2. From the toolbar of the General screen, press **OK**.
   Changes are saved in the system, and the Start Up screen appears.

The following settings appear only when the pump is in the PCA or PCEA delivery mode (relevant for Sapphire only):

Setting	Description/Notes	Default Value
Max bolus per:	Specifies the time period relevant to the infusion parameter of **Boluses per <x> hr(s)**. Options are 1 hour or 4 hours.	1 h(s)

> To set the Max bolus per setting:

1. From the General screen, select the **Max bolus** per row.
   The Max Bolus screen appears, with the possible options displayed.

2. Select the required option.

   The General screen reappears.

3. From the toolbar of the General screen, press **OK**.

   Changes are saved in the system, and the Start Up screen appears.

Viewing General Info Parameters

This option is reserved for Q Core Medical's internal use only.

Calibrating the Screen

The Screen Calibration option enables you to calibrate the screen, to ensure that the values and options displayed on the screen match those that were entered or selected by the user.

> To calibrate the screen:

1. From the Tech. options screen, select **Screen calibration**.
2. Press the center of the Red "plus" sign. You may be prompted to repeat this several times.
3. When prompted, press the center of the Green Box icon to complete the calibration.

   When calibration is successfully completed, the Tech. options screen reappears.

Testing the Hard Keys

The Key test screen enables you to test the function of the **Stop** hard key and the **On/Off** hard key. The test can be performed in any delivery mode.

> To test the hard keys:

1. From the Tech. options screen, select **Key test**.

   The Key test screen appears.

2. Press the **Stop** hard key, and verify that the setting in the **Stop** button row changes from **Released** to **Pressed**.
3. Release the **Stop** hard key, and verify that the setting in the **Stop** button row changes from **Pressed** to **Released**.
4. Test the **On/Off** hard key, using the method described in Steps 2 and 3 above.

Alarms and Troubleshooting

The following sections describe the different types of alarms and messages that can be generated by the Sapphire pump from the perspective of the pump user. The material set out here offers the trained technician tips and specific corrective actions. The trained technician will find this material helpful in troubleshooting common programming issues.

Topics covered include:

Alarms Overview

The Sapphire 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 is on or blinking continuously, and an auditory alarm sounds continuously. These alarms require immediate attention.

The following sections provide details about each alarm type.

Tip for 1st level support: Start faulty pump examination by connecting the pump to power.

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 a trained service technician.

Alarm Title	Displayed Text
Battery Depleted	Pump will automatically shut down in 3 minutes. Please connect pump to power.
Internal 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 trained technicians only.

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

- **Mute:** Silences the auditory alarm for 2 minutes.
- **OK:** Displays the Paused screen.

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 Fault	The battery has been tampered with. Please contact trained technician to replace battery.

* Entering the code will give trained technician same or more information about the problem and possible solutions. In most instances, trained technician will be directed to return pump for service.

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, the caregiver may continue the infusion after the problem has been resolved. Instructions for resolution of the problem are displayed on the touch screen.

Figure 7.3. Sample Level 3 Alarm Screen

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

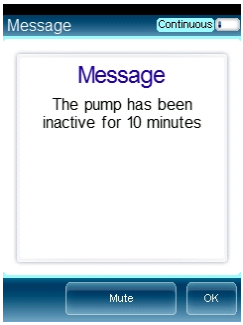
- **Mute:** Silences the auditory alarm for 2 minutes.
- **OK:** Displays the Paused screen. The infusion may then be resumed after the problem is resolved.
- **Prime:** Enables automatic priming. This key appears only during an Air in Line alarm.

Alarm Title	Displayed Text
Air in Line	Accumulated air in line is over the limit. Please prime administration set. Prime administration set. If problem reoccurs, remove and reinsert the cassette.
Cassette Misplaced	The administration cassette is not loaded or misplaced. Please reload the cassette. Reinsert cassette. Verify that both flanges are inside the safety door. If problem persists contact technician. Remove the administration cassette and make sure to correctly reinsert it. If alarm reoccurs please contact trained technician.
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.
Flow Error	Verify that the administration cassette is correctly positioned and battery is sufficiently charged. If alarm reoccurs contact trained technician.
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.
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 (with recommended actions, if relevant) is displayed on the touch screen.

Figure 7.4. 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.
- **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.

Message Title	Displayed Text
Low Battery	30 minutes left to battery depletion. Connect pump to power supply.
Battery Reminder	End of battery life, please contact trained technician to replace battery.
Message	Battery life will expire in 2 days. Please contact trained technician.
	The battery could not be fully charged - please check power supply.
	Annual certification due in 2 days. Please contact trained technician.
	Annual certification due in 2 weeks. Please contact trained technician.
	Annual certification date is overdue. Please contact trained technician. **Note:** The pump continues to function after the certification date; however, failure to perform annual certification impacts the pump's 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 alarm reoccurs please contact trained technician. Please Wait. Possible Downstream Occlusion. The pump is attempting to restart; press exit to cancel.

Guidance in Problem Solving

The Guidance in Problem Solving section provides practical tools for 1st level analysis of problems and resolution.

Alarms Description List

The alarm title is displayed in the Event Log. Reviewing the Event Log is an essential tool in the analysis of a problem.

Alarm Title	Description	Solution
Watchdog Timer Reset	The external watchdog has lost communication with the pump. This means there is no control over the main processing unit of the pump. The internal watchdog (a CPU) then commands the reset.	If this alarm appears return pump for service.
Battery Temperature out of range	Battery reached its critical temperature or exceeded it (60°c).	In case of reoccurring alarm replace battery. Refer to Chapter 6: Replacing the Battery on page 119.
System Temperature out of range	System reached its critical temperature and exited it (70°c).	If this alarm appears return pump for service.
External Watchdog	The external watchdog has lost communication with the internal watchdog (CPU).	If this alarm appears return pump for service.
Battery Depleted	Battery has depleted and can no longer supply sufficient power to the pump. The alarm is triggered by battery voltage below 6.8V.	Replace the battery.Refer to Chapter 6: Replacing the Battery on page 119.

Alarm Title	Description	Solution
PME	Pump Mechanism Error- This is a family of alarms related to problems with the actual mechanism.	If stated on screen, return pump to service. In all other cases, the pump set up or battery voltage was too low; therefore recharge the battery and test for reoccurrence. If the alarm doesn't appear again, this is not a pump failure.
End of Battery Life	Battery has exceeded its usage life (has been in use for more than 2 years or reached the max of 500 charges cycles) and needs to be replaced with a new one.	If this alarm occurs replace the battery. Refer to Chapter 6: Replacing the Battery on page 119.
Non-Authorized Battery	A battery that was not authorized by Q Core to be used with the pump.	If this alarm occurs replace the battery. Refer to Chapter 6: Replacing the Battery on page 119.
System Error	A group of system errors. In some cases, depends on the error cause, it is possible that the error will not be written to the Event Log.	If this alarms appears return pump for service.
Internal Communication Error	The pump has lost communication with the battery.	Disconnect and reconnect the battery. In case of reoccurring alarm replace battery. Refer to Chapter 6: Replacing the Battery on page 119.
External Communication Error	The pump CPU has lost communication with the LCM (Liquid Crystal Module) or the LCM lost communication with the CPU.	In case of reoccurrence return pump for service.

Alarm Title	Description	Solution
Air in Line	An air bubble, bigger or equal by size to the value defined by user was detected by the light sensor.	Normal course of operation. Not a pump malfunction.
Accumulated Air in line	The accumulated bubble volume has reached its limit (set by user) in 15 min (only bubbles that are bigger or equal by size to the user set value are counted).	Normal course of operation. Not a pump malfunction.
Downstream/ Upstream Occlusion	Downstream occlusion-Occlusions from the pump to the patient line. Upstream occlusion- Occlusions from the reservoir/bag to the pump.	Normal course of operation. Not a pump malfunction.
Possible Occlusion	An infusion was started with clamps closed. Not a pump malfunction.	Normal course of operation. Not a pump malfunction.
Unknown Occlusion	There is an occlusion but the pump is not able to determine if it is upstream or downstream. Alarm in normal course of operation.	Normal course of operation. Not a pump malfunction.
Check for Occlusion	This alarm occurs when an occlusion, either downstream or upstream, is detected at the beginning of treatment, while the pump is determining a reference.	Normal course of operation. Not a pump malfunction.
AS not loaded/ misplaced	Administration Cassette is not loaded successfully if at all. Alarm in normal course of operation.	Normal course of operation. Not a pump malfunction.

Alarm Title	Description	Solution
Low voltage for current rate	Detected when the pump cannot reach a current rate due to reaching PWM 140 when battery power is insufficient. Happens only when the pump is on battery power.	When pump is working on battery: Alarm in normal course of operation. Not a pump malfunction.
Inconsistent flow	Alarming when pump is not running in a stable flow rate.	If this alarm appears return pump for service.
Air detector Faulty	The air detector is unable to make correct readings.	Clean the air detector. If reoccurring alarm return pump to service.
Incorrect pressure value reading		If this alarm appears, return pump for service.
30 min to battery depletion	User has at least 30 min of pump use in current rate before the battery is depleted and pump is turned off.	Normal course of operation. Not a pump malfunction.
Treatment complete	Treatment is complete, VTBI is fully infused.	Normal course of operation. Not a pump malfunction.
Door opened	The administration set door is opened or not fully closed.	Normal course of operation. Not a pump malfunction.
Pump unattended	The pump has been idle for the set amount of time.	Normal course of operation. Not a pump malfunction.
Treatment near end	There are <xx> minutes before the end of treatment.	Normal course of operation. Not a pump malfunction.
Charge error	It is taking longer than usual to charge the pump. Alarm is triggered after 7 hours of charge time.	In case of reoccurring alarm replace charger and battery. If the alarm is periodically reoccurring, send pump for service.
Battery life expires 2 days	In 2 days the battery will reach its two years life time.	Replace the battery. Refer to Chapter 6: Replacing the Battery on page 119.

Alarm Title	Description	Solution
Calibration Due now	Working time or calendar time has ended. Calibration may be needed.	Perform Annual Certification.
Calibration Due 2 days	Working time or calendar time has ended and is due in 2 days. Calibration may be needed.	Perform Annual Certification.
Calibration Due 2 weeks	Working time or calendar time has ended and is due in 2 weeks. Calibration may be needed.	Perform Annual Certification.

Upgrading Software Version

The following sections explain how to upgrade the software version in the Sapphire pump:

Overview

New software revisions are downloaded to the pump using Q Core's Pump Loader software. The Pump Loader Software is a tool used to download new software revision (Revision) to the pump. Both the Pump Loader and Revision can be obtained from Q Core FTP site (https//qcore.smartfile.com). For information regarding the FTP site, refer to FTP site on page 28.

The current software version of the pump can be viewed using the Options menu.

> To view the current software version:

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

	A software update may erase some of the pump settings. It is recommended to keep a copy of the pump's current settings for your records before updating the pump software version.

	Prior to upgrading from software revision 9, erase all preset programs from the pump

	Pump software maybe be downgraded at the request of the customer. When downgrading the pump software version from revision 11, upload the software twice.

Prerequisites

Before beginning the upgrade process, verify that the following hardware and software requirements are met.

Hardware Requirements

- **PC**: Pentium 4, 1500 MHz CPU, 512 MB (or higher) RAM
- **Screen resolution**: 1280 x 1024 (minimum)
- Communication cable for the Sapphire pump (P/N 0520-110-0213-02)
- RS232 connectivity, in either of the following forms:
  - An RS232 port in the PC

Figure 7.5. PC Connector

  - A USB to RS232 adaptor + driver (can be purchased from Q Core Medical Ltd. (P/N 15077-000-0001).)

Figure 7.6. USB Adaptor and Driver

Software Requirements

- **OS**: Windows XP, Windows Vista, or Windows 7 (32 or 64 bit)
- WinRar or other software for handling .zip files
- Pump Loader software (.rar file provided by Q Core)
- Sapphire Pump Revision software (.qmf file provided by Q Core)

The Revision software files have the following file name pattern:
RevXvY AAA BBB.qmf, where:

- X and Y are the revision identification
- AAA is the pump type (Multi Therapy or dedicated)
- BBB is the language available on the pump

For example, the file **SWR Rev 11 US English Epidural Only (C5679).qmf** is software revision 11, for an Epidural pump configured in English.

Upgrade Procedure

The following procedure explains how to download a new software version to the Sapphire pump.

Before beginning the procedure:

- Verify that you have the correct Revision software file (Software Requirements on page 158).
- Connect the pump to power supply, otherwise verify the pump's battery is fully charged.
- When using a USB to RS232 adaptor, verify the adaptor's driver is installed before connecting the Sapphire pump.

Make sure to load the correct software to the correct pump. Do not upload All Delivery Modes software to a dedicated Sapphire pump (Epidural, PCA, TPN), and vice versa.

> To download a new software version:

1. Copy the Pump Loader file and the Sapphire Pump revision file to the directory of your choice.
2. Turn on the Sapphire pump.
3. Open the Pump Loader file. Then, using the communication cable, connect the pump to the computer.

   The "Please Select the RS232 Communication Port" window appears on the monitor, with a list of available ports displayed.
4. Select a port from the list, and then click **OK**.

The word **PUMP** appears next to the **Download** button.

If a **NO DEVICE** message appears next to the **Download** button, repeat Step 4 using another port, until the word **PUMP** appears.

5. Click **Download**. Then, navigate to the Sapphire Pump Revision file saved earlier, and click **OK**.

   The download begins automatically. Progress of the downloading process is reflected in the progress bar on the monitor.

Do not shut the pump off or disconnect it from the computer while downloading is in progress.

6. When the download is complete, exit the Pump Loader software, and then disconnect the pump from the PC.
7. If the software language is not as expected refer to Defining Regional Parameters on page 130.
8. Verify that the upgrade process was completed successfully, refer to To view the current software version: on page 157.

9. Inform Q Core or a local distributor at Hospira service center of every pump update with the Customer Software Update Form, found at the FTP site (refer to FTP site on page 13) and on the Service Manual at Appendix A: Customer Software Update Form on page 213

If the software upgrade has failed, retry. If upgrade continues to be unsuccessful please contact service@qcore.com or a local distributor at Hospira service center for further instructions.

Troubleshooting Software Upgrade

The following sections explain how to troubleshoot common problems that may arise while upgrading the software.

Problem	Probable Cause	Solution
The following message appears: "Software execution failure! Please re-install software"	Interference in the upgrade process	1. Close the pump loader software. 2. Disconnect the pump from the communication and the power supply. 3. Turn the pump off 4. Turn the pump on 5. Check if the software upgrade to rXvY was successful. 6. If the software revision is not the correct revision or if the pump displays again "Software execution failure! Please re-install software", repeat the upgrade process.
Error message prompted on screen	Software upgrade error	1. Close the pump loader software. 2. Approve the message. 3. Disconnect the pump from the communication and the power supply. 4. Wait 15 minutes 5. Verify that the software upgrade to rXvY was successful. 6. If the software revision is not the correct revision repeat the upgrade process.

Problem	Probable Cause	Solution
The header of the screen text appears in red	Incomplete upgrade. Communication error	1. Close the pump loader software. 2. Disconnect the pump from communication and the power supply. 3. Wait 15 minutes. 4. Repeat the upgrade process.
Pump Loader crash	Communication error	1. Disconnect the pump from the communication and the power supply. 2. Wait 15 minutes. 3. Repeat the upgrade process.

Problem	Probable Cause	Solution
Pump's screen doesn't turn on after the upgrade (black screen)	Software LCM update error	1. Close the pump loader software. 2. Turn the pump off. 3. Disconnect the pump from the communication and the power supply. 4. Disconnect the battery from the pump. 5. Wait a few seconds and reconnect the battery. 6. Connect the pump to the communication and to the power supply. 7. Open the pump loader software. In the pump loader bar go to: Option → write LCM program. 8. Select the software revision. The LCM downloading process will start automatically. 9. Repeat the regular upgrade process.

Problem	Probable Cause	Solution
After completing the upgrade process, turning the pump off and then on, the following can be observed: 1. The pump's fingers don't perform a cycle of movement upon start up. 2. The battery icon displays one line in red (although the battery isn't empty) when the pump is not connected to the power supply.  3. In the pump's View System menu (Options → View → View System), the pump's serial number is not displayed.		1. Insert an administration cassette. 2. Prime the pump for at least 20 seconds. 3. Turn the pump off. 4. To verify proper functionality turn on the pump.

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Chapter 8: SapphirePlus

Configuring Basic Pump Settings

The following sections describe how to view and update basic pump configuration settings, using the Options menu:

For a description of all basic pump options, refer to the Sapphire User Manual.

Managing Alarm Settings

The Alarms menu enables you to view and modify alarm-related options.

> 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 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 pressure reaches the set value ± the sensor sensitivity level. If a value outside the permitted range is entered during programming, the range is displayed in red font, and the **OK** function key is disabled.	Select **Occlusion pressure**. Then, using the keypad, enter the required 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 while an infusion is running.	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. Options are **1**, **3**, **5**, or **10** minutes, disable the alarm by selecting **Off**. **Note:** The Infusion Near End alarm is triggered only once during treatment.	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	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. Level 1, 2, or 3 alarms are provided with visual and the lowest auditory signal permitted, according to IEC 60601-1-8. Maximum alarm volume is 70 dB. Minimum alarm volume is 56 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 Alarms and Troubleshooting on page 190.	Select **Alarm Volume**. Then, select **Maximum** or **Minimum**.

	An **Occlusion Auto-restart** option exists and is available for configuration by trained technicians only. This option enables the pump to restart the infusion automatically provided the occlusion was cleared. If the occlusion was not cleared within 40 seconds, the downstream occlusion alarm is activated. An Occlusion Auto-restart can occur up to 5 times an hour.

	Local configuration changes made after the Drug Library is loaded, will be valid until the pump is turned off. When Resuming an infusion after pump shutdown, local configurations will remain until the end of the current infusion. For more details regarding Drug Library, refer to the Sapphire User Manual.

Configuring Audio Settings

The Audio settings menu enables you to define audio levels options.

> To access the Audio 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 Audio Settings screen)
Keys Volume	Sets the speaker volume for the auditory signal generated when users select functions and press keys on the pump. **Note:** When keys volume is set to Off, the bolus handle is silenced.	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. Level 1, 2, or 3 alarms are provided with visual and the lowest auditory signal permitted, according to IEC 60601-1-8. Infusion Complete message is provided with a visual and auditory alarm signal, which will not be affected by the volume changes. For more information about messages and alarms, refer to Alarms and Troubleshooting on page 190.	Select **Alarm Volume**. Then, select **Maximum** or **Minimum**.

Configuring General Settings

The General settings menu enables you to view basic pump settings, and modify them according to clinical requirements.

> 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	Sets the CCA currently used by the pump. Appears only when Drug Library is loaded. For more details regarding Drug Library, refer to the Sapphire User Manual.	Select **Current CCA**. Choose the appropriate CCA; then, from the Attention screen press **OK**.
Authorization level	Sets the authorization lock level of the pump.	Select **Authorization level**. Then, enter a password and select **Low**, **Medium**, **High**, or **Tech**. Refer to Managing Authorization Lock Levels on page 33.
Allow delayed start	Enables/disables programming of infusions that begin after a predefined period of time. When the option is enabled, the Set Delay frame appears on the Start screen. **Note:** This feature functions like a timer.	Select the **Allow delayed start** row, to toggle the option between **On** and **Off**.
Allow PreProgram	Enables/disables starting infusions using predefined infusion parameters. When the option is enabled, the PreSet Programs frame appears on the Start screen.	Select the Allow PreProgram row, to toggle the option between **On** and **Off**.

Option	Descriptions/Notes	To Modify Parameter (from the General settings screen)
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. If a value outside the permitted range is entered during programming, the range is displayed in red font, and the **OK** function key is disabled.	Select **Set Prime Volume**. Then, using the keypad, enter the required value → **OK**.
Backlight	Sets the degree of screen dimming while the pump is running. The Off and Partial options of this feature save power and promote longer battery life.	Select **Backlight**. Then, select **On**, **Off**, or **Partial**.
Prime Reminder	Enables/disables a prompt reminder message to the user that appears when Start was pressed and prime wasn't preformed.	Select **Prime Reminder** to toggle the option between **On** and **Off**.
Advanced Bolus	Enables/disables users to program a bolus by entering rate, amount and time. To enable this option select **Options → Technician options → Pump settings → General**, and set Allow Bolus to **On**. Note: This option is relevant to Continuous delivery mode only.	Select the Advanced Bolus row, to toggle the option between **On** and **Off**.
Auto P. Lockout	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 when an infusion begins.	Select **Auto P. Lockout** to toggle the option between **On** and **Off**.

Option	Descriptions/Notes	To Modify Parameter (from the General settings screen)
Screen Saver	Enables/disables a screen saver which appears after 30 seconds of the pump running an infusion, displaying the rate, drug name and soft limit icon. The screen saver will not appear during paused treatment, delayed start, bolus administration, infinite KVO, standby and view/edit screens. The screen saver setting is not dependent on backlight settings. Pressing Stop or On/Off hard keys, appearance of alarm message or simply touching the screen will stop the screen saver from running.	Press **Next** and select **Screen Saver** to toggle the option between **On** and **Off**.

Defining Regional Parameters

The Regional menu controls date, time, and language settings.

> 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 row.
2. Using the keyboard, enter values (2 digits each) for the day, month, and year. (When U.S. 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 row.
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 to On.)
4. To confirm the new settings, press **OK**.

> To set the language:

1. Select the Language row.
2. Select the required language.

In some pumps, only the default language is listed.

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

> To set the US Format:

1. Toggle the setting between **On** and **Off**.
2. To confirm the new settings, press **OK**.

Using Technician Options

The following sections describe the configuration options available to users with a Technician authorization code:

Overview

The Tech. options screen provides access for viewing and managing settings used for configuration, testing and maintenance purposes.

> To access the Tech. options screen:

1. From the toolbar of the Start Up screen, press **Options**.
   The Options screen appears.
2. Select **Technician options**.

The Tech. options screen appears.

The Tech. options screen is accessible only when the pump is set to Technician authorization level. If the **Technician options** selection does not appear on the Options screen, change the authorization level to Technician and repeat the procedure. (For details refer to Setting Technician Lock Level on page 59.)

Alarms manager

This function is reserved for Q Core Medical's internal use only.

Managing Pump Settings

The pump settings screen provides access to pump configuration settings that can be managed only by a technician. The screen is accessed from the Tech. options screen by selecting **Pump settings**.

The following sections describe:

Setting Hard Limits

The hard limit is the acceptable range of a given parameter; the hard limit is displayed in the upper right corner of the main display while entering the parameter.

The Set hard limits screen provides access for viewing and modifying the upper limits of infusion parameter ranges. Parameter's hard limits and permitted ranges are mode-specific. Parameters of a given mode can be viewed and updated only when the pump is set to that delivery mode. Settings are not saved after turning off current delivery mode.

Hard Limit Parameters for Continuous and Multi-step Delivery Modes

Delivery Mode	VTBI	Rate	Time
Continuous	✓	✓	
Multi-step	✓	✓	✓

Hard Limit Parameters for Continuous, when Set Secondary is set to On (refer to To enable secondary settings: on page 184)

Delivery Mode	Primary VTBI	Primary Rate	Secondary VTBI	Secondary Rate
Continuous	✓	✓	✓	✓

> To update hard limits for a delivery mode:

1. From the Tech. options screen of the relevant delivery mode, select **Pump settings → Set hard limits**.
   The hard limit parameters for the current delivery mode are displayed.
2. Select the row of the parameter that you want to change. Using the keypad, enter the required value, and then press **OK**.
3. To exit the Set hard limits screen, from the toolbar, press either **OK** or **Exit**. The Start Up screen is displayed.

Setting KVO Rate

KVO is the rate of fluid that is delivered to the patient when the infusion program is completed, in order to prevent clotting in the infusion cannula. Separate KVO rates can be set for different delivery modes. The permitted range for the KVO rate parameter is 0-20 mL/h (for all delivery modes).

It is not necessary to change the delivery mode of the pump to program KVO rates for the different modes. The KVO screen of each delivery mode provides access to setting KVO rates for all other delivery modes.

> To set the default KVO rate for a delivery mode:

1. From the Tech. options screen, select **Pump settings → Set KVO**. The KVO screen appears, with a list of delivery modes displayed.
2. Select the delivery mode whose parameter is to be updated.

   The keypad is displayed.
3. Using the keypad, enter the value of the required KVO rate. Then, from the toolbar, press **OK**.

   The KVO rate for the selected delivery mode is set.
4. To set the KVO rate for an additional delivery mode, repeat Steps 2-3.
5. To exit the KVO screen, from the toolbar, press **Exit**. The Start Up screen is displayed.

Setting Air Detector Settings and Thresholds

The Air detector screen provides access for viewing and modifying the amount of air in the administration set that triggers an 'Air in Line' alarm. Air detector configuration is a general pump setting that needs to be set only once. Values configured for air detection in one delivery mode are automatically applied to all other delivery modes.

The Sapphire pump has 2 mechanisms for triggering the Air In Line alarm:

- **Single air detector**: In this mechanism, every time that a single bubble equal to or larger than a user-selected size passes through the detector, an alarm is triggered.
- **Accumulated air detector**: In this mechanism, the user selects values for both accumulated bubble size and the accumulated amount (threshold). Any single bubble equal to or larger than the selected accumulated bubble size is included in the counter of accumulated air. When the total amount of accumulated air reaches the selected accumulated threshold value within a 15-minute period, an alarm is triggered.

There is an option to turn off the single air detector or the Accumulated air detector, but not both.

> To set air detector settings:

1. From the Tech. options screen, select **Pump settings** → **Set air detector**.
   The Air detector screen appears.
2. Set the single air detector value:
   a. Select the Single air detector row.
      The Single bubble screen appears, with a list of values displayed.
   b. Select the required value. To deactivate this mechanism, select **Off**.
      The Air detector screen reappears.
3. Set the accumulated air values:
   a. Select the Accumulated air detector row.
      The Accum bubble screen appears, with a list of values displayed.
   b. Select the required value. The Air detector screen reappears.
   c. Select the Accumulated Threshold row.
      The Accum threshold screen appears, with a list of values displayed.
   d. Select the required value. To deactivate this mechanism, select **Off**.
      The Air detector screen reappears.
   e. To save changes in the system, from the toolbar, press **OK**.

If both air detector mechanisms have been set to Off, an error message appears on the Attention screen, and you are prompted to reconfigure the values.

The Start Up screen appears.

Air In Line Alarm

The Single air detector will automatically switch to On in the following conditions:

- The Single air detector was set to OFF
- The SapphirePlus infusion pump is operating on rate lower or equal to 4mL/h.

	Valid for rate, continuous rate, KVO rate and bolus rate.

- If the pump is operating on rates between 0.1mL/h to 0.9mL/h, the Single air detector automatically switch to On. If 0.1 mL air bubble was identified, the Air in line alarm will be activated.
- If the pump is operating on rates 1mL/h to 4mL/h , the Single air detector will automatically switch to On. If 0.5 mL air bubble was identified, the Air in line alarm will be activated.

If the pump is operating on a rate higher than 4mL/h, the Single air detector will automatically switch back to OFF.

Resetting the System

The Reset System option is used to revert all pump parameters and features to the factory default settings.

This option also allows defining of new security passwords.

	Resetting the system to the factory default doesn't effect the On/Off definitions of US Format and WiFi.

Factory defaults

> To set pump parameters to factory default settings:

1. From the Tech. options screen, select **Pump settings** → **Reset system**.
   The Reset system screen appears.
2. Select **Factory defaults**.
   The Attention screen appears.
3. To confirm the reset, from the toolbar, press **OK**.
   Changes are saved in the system, and the Start Up screen appears.

Passwords

To help ensure patient safety, the Sapphire pump can be set to one of four authorization levels. For more information regarding the different authorization levels, refer to Configuring General Settings on page 171.

> To change the passwords:

1. From the Tech. options screen, select **Pump settings** → **Reset system**.
   The Reset system screen appears.
2. Select **Passwords**.
3. Select authorization level password to change.
4. Enter a 4-digit password in the specified range [1000 - 7000].
   The password range for PreProgram is 1000-9999.

> Passwords for each security level must be unique and in the specified range. The OK button will be disabled when entering the same password for more than one security level.

5. When finished, press **OK** to save the changes.

Configuring General Settings

The General screen provides access for viewing and modifying selected basic pump settings. Some of these settings are common to all delivery modes. Others are specific to certain delivery modes, and appear only when the pump is set to those modes.

> To access the General screen:

- From the Tech. options screen, select **Pump settings** → **General**.
  The General screen appears.

The following settings appear in all delivery modes. Changes made while the pump is in one delivery mode are automatically applied to all other delivery modes.

Setting	Description/Notes	Default Value
Delivery Mode	Determines the available delivery modes. Each mode can be turned off separately.	On
New patient	When this setting is On, the New Patient screen appears when new infusions are programmed, and users are prompted to specify whether the infusion is for a new patient.	Off
Occ. Auto-restart	Enables the pump to restart the infusion automatically provided the occlusion was cleared. If the occlusion was not cleared within 40 seconds, the downstream occlusion alarm is activated. An Occlusion Auto-restart can occur up to 5 times an hour.	On
Calculate Concentration	Determines if the users enter final concentration or Drug Amount and Diluent Volume.	Off

Setting	Description/Notes	Default Value
mL/h only	Disables 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.	Off
WiFi	Enable/disable wireless capability on the infusion pump.  If the WiFi interface is On and not connected to a WiFi network, a gray WiFi icon will appear in the top right corner of the screen. To connect the infusion pump to a WiFi network in order to receive data from MedNet™, see Configuring the WiFi Settings on page 185.  If the WiFi interface is On and connected to a WiFi network, a blue WiFi icon will appear in the top right corner of the screen.	On

The following settings appear only when the pump is in the Continuous delivery mode:

Setting	Description/Notes	Default Value
Set Secondary	Allows setting secondary infusion (piggyback) in continuous mode.	Off
Allow Bolus	Enable/disable the user to administer bolus in Continuous (including secondary) delivery mode by a soft key. This feature is available in the absence of a Drug Library on the pump.	Off
Bolus rate	The rate of delivery of a fast dose, for rapid volume infusion.	600 mL/h
Sec. Bolus Rate	The rate of delivery of a secondary fast dose, for rapid volume infusion.	500 mL/h

Press **OK** to save the changes.

> To set the general settings:

1. From the General screen, select the row of the relevant option, to toggle the setting between **On** and **Off**.
2. After changing the setting(s), from the toolbar, press **OK**.
   Changes are saved in the system, and the Start Up screen appears.

> To enable secondary settings:

1. From the General screen, select the Set Secondary row, to toggle the setting between **On** and **Off**.
2. From the toolbar of the General screen, press **OK**.

Changes are saved in the system, and the Start Up screen appears.

> To enable bolus delivery:

1. From the General screen, select the Allow Bolus row, to toggle the setting between **On** and **Off**.
2. From the toolbar of the General screen, press **OK**.

   Changes are saved in the system, and the Start Up screen appears.

> To set the bolus rate:

1. From the General screen, select the **Bolus rate** or **Sec. Bolus Rate** row.

   The Bolus rate screen appears.
2. Using the keypad, enter the required rate. Then, from the toolbar, press **OK**.

   The General screen reappears.
3. After changing the setting(s), from the toolbar, press **OK**.

   Changes are saved in the system, and the Start Up screen appears.

Viewing General Info Parameters

This option is reserved for Q Core Medical's internal use only.

Configuring the WiFi Settings

The WiFi Settings screen provides access to view the WiFi configuration parameters without modifying them, and to initiate the WiFi connectivity.

WiFi configuration is required in order to connect the infusion pump to MedNet™ drug library and for software upgrade, and can be managed only by a technician.

Verify that the Wi-Fi is enabled, see Configuring General Settings on page 182.

The screen is accessed from the Tech. options screen by selecting **WiFi Settings**.

The following sections describe:

	Acquire the WiFi settings information from the Hospital IT manager before the beginning of the configuration procedure.

	When all settings are configured correctly both the WiFi and MedNet™ connection icons will appear in blue on the indication bar, indicating a connection.

View Configuration

View the current WiFi configuration of the pump.

> To view the WiFi configuration:

- From the Tech. options screen, select **WiFi settings → View Configuration**.
  The WiFi Configuration screen appears, displaying the following information:

Setting	Description
Operating Mode	The Wireless Local Area Network (WLAN) operating mode. Since the communication with MedNet™ server is done through an access point, the pump's operating mode should always be Infrastructure mode.
IP Method	Dynamic IP or Static IP.

Setting	Description
SSID	SSID (Service Set Identifier) is an ID that distinguishes a wireless LAN network from others. For wireless devices to communicate with each other on a wireless network, they must share the same SSID. The SSID is a case sensitive field of alphanumeric characters. In a pump that is not configured, the SSID field will be empty. After connecting to the MedNet™ server, the SSID field will display "********".
Access Point MAC Address	The Access Point MAC Address is a unique identifier. It is permanent and cannot be changed.
MAC Address	The pump MAC Address unique identifier is permanent and cannot be changed.
IP Address	The pump IP is set by the router and cannot be manually changed. It may have different values upon each connection.
Device Name	The Device Name must be unique for each pump, as the MedNet™ server will not allow access to pumps with identical names. Device Name can be edited using the SXManager software. If the Device Name wasn't configured yet, this field will be empty.
Destination Address	MedNet™ server IP Address.
Destination Port	MedNet™ server Port number.
Radio Frequency	The pump's radio frequency protocol. Options are: 802.11 a-b-g-n, 802.11 b-g-n or 802.11 a-n.
Power Level	The pump's radio power level. Options are: High or Low.

Start Configuration

The WiFi configuration is performed using the external SxManager Software. Before entering the configuration definitions, a connection to QCore access point needs to be generated using the pump.

> To generate WiFi connection to QCore access point:

1. Set the Technician's PC to be connected to the SSID "QCoreSxConfiguration".
2. Restart the pump.
3. From the Tech. options screen, select **WiFi Settings → Start Configuration**.

   The Attention screen appears.
4. To confirm the connection, from the toolbar, press **OK**.

   Connection to QCore access point is generated in the system, and the WiFi Settings screen appears.

Configuration failure will be followed by an Attention screen

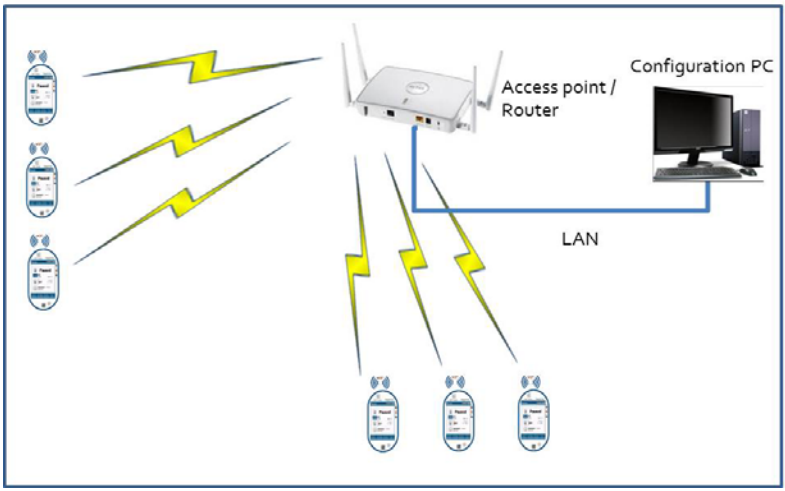
5. Allow 1-2 minutes to establish the connection, and wait until the SSID field will display: "********".
6. Attempt to connect to the pump using the SxManager Software, and configure the WiFi definitions.

SxManager

The SxManager Software enables configuring and editing of the Sapphire Pump WiFi connection.

The PC software allows to create a new general WiFi configuration file and upload the settings to a single pump.

Figure 8.1. WiFi Connectivity Diagram



For a description of SXManager software configuration and procedure, refer to the SxManager DFU P/N 16017-003-0001-DFU, and to SXManager website at: https://download.qcore.com/sxmanager.

Testing the Hard Keys

The Key test screen enables you to test the function of the **Stop** hard key and the **On/Off** hard key. The test can be performed in any delivery mode.

> To test the hard keys:

1. From the Tech. options screen, select **Key test**.
   The Key test screen appears.
2. Press the **Stop** hard key, and verify that the setting in the **Stop** button row changes from **Released** to **Pressed**.
3. Release the **Stop** hard key, and verify that the setting in the **Stop** button row changes from **Pressed** to **Released**.

4. Test the **On/Off** hard key, using the method described in Steps 2 and 3 above.

Alarms and Troubleshooting

The following sections describe the different types of alarms and messages that can be generated by the Sapphire pump from the perspective of the pump user. The material set out here offers the trained technician tips and specific corrective actions. The trained technician will find this material helpful in troubleshooting common programming issues.

Topics covered include:

Alarms Overview

The Sapphire 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 is on or blinking continuously, and an auditory alarm sounds continuously. These alarms require immediate attention.

The following sections provide details about each alarm type.

Tip for 1st level support: Start faulty pump examination by connecting the pump to power.

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 a trained service technician.

Alarm Title	Displayed Text
Battery Depleted	Pump will automatically shut down in 3 minutes. Please connect pump to power.
Internal 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 trained technicians only.

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

- **Mute:** Silences the auditory alarm for 2 minutes, and enables the **OK** soft key.
- **Unmute:** Reactivates the paused auditory alarm.
- **OK:** Displays the Paused screen.

If the issue has not been cleared after 2 minutes, the alarm sound will be resumed.

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 Fault	The battery has been tampered with. Please contact trained technician to replace battery.
Battery Reminder	End of battery life. Please contact trained technician to replace battery.

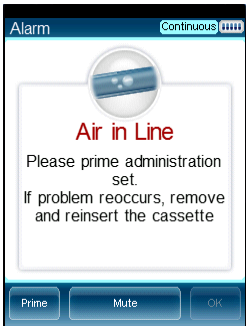
* Entering the code will give trained technician same or more information about the problem and possible solutions. In most instances, trained technician will be directed to return pump for service.

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, the caregiver may continue the infusion after the problem has been resolved. Instructions for resolution of the problem are displayed on the touch screen.

Figure 8.2. Sample Level 3 Alarm Screen



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

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

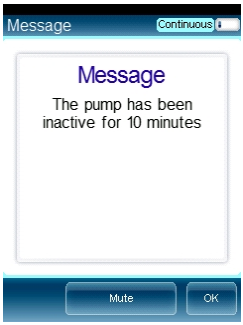
	If the issue has not been cleared after 2 minutes, the alarm sound will be resumed.

Alarm Title	Displayed Text
Air in Line	Accumulated air in line is over the limit. Please prime administration set. Prime administration set. If problem reoccurs, remove and reinsert the cassette.
Cassette Misplaced	The administration cassette is not loaded or misplaced. Please reload the cassette. Reinsert cassette. Verify that both flanges are inside the safety door. If problem persists contact technician. Remove the administration cassette and make sure to correctly reinsert it. If alarm reoccurs please contact trained technician.
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 **Mute** → **OK** to continue.
Flow Error	Verify that the administration cassette is correctly positioned and battery is sufficiently charged. If alarm reoccurs contact trained technician.
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 **Mute** → **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 **Mute** → **OK** to continue.
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 (with recommended actions, if relevant) is displayed on the touch screen.

Figure 8.3. 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, and enables the **OK** soft key.
- **Unmute:** Reactivates the paused 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.

	If the issue has not been cleared after 2 minutes, the alarm sound will be resumed. When the alarm volume is configured to minimum in the Alarms menu, the auditory alarm will not sound, and only the message will be displayed.

Message Title	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 trained technician.
	The battery could not be fully charged - please check power supply.
	Annual certification due in 2 days. Please contact trained technician.
	Annual certification date is overdue. Please contact trained technician. **Note:** The pump continues to function after the certification date; however, failure to perform annual certification impacts the pump's 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 alarm reoccurs please contact trained technician.
	Please Wait. Possible Downstream Occlusion. The pump is attempting to restart; press exit to cancel.
	WiFi communication problem. Press OK to continue without WiFi connection. **Note:** The pump continues to function when WiFi has a connectivity problem. Following this alarm, the WiFi icon turns gray.

Guidance in Problem Solving

The Guidance in Problem Solving section provides practical tools for 1st level analysis of problems and resolution.

Alarms Description List

The alarm title is displayed in the Event Log. Reviewing the Event Log is an essential tool in the analysis of a problem.

Alarm Title	Description	Solution
Watchdog Timer Reset	The external watchdog has lost communication with the pump. This means there is no control over the main processing unit of the pump. The internal watchdog (a CPU) then commands the reset.	If this alarm appears return pump for service.
Battery Temperature out of range	Battery reached its critical temperature or exceeded it (60°c).	In case of reoccurring alarm replace battery. Refer to Chapter 6: Replacing the Battery on page 119.
System Temperature out of range	System reached its critical temperature and exceeded it (70°c).	If this alarm appears return pump for service.
External Watchdog	The external watchdog has lost communication with the internal watchdog (CPU).	If this alarm appears return pump for service.
Battery Depleted	Battery has depleted and can no longer supply sufficient power to the pump. The alarm is triggered by battery voltage below 6.8V.	Replace the battery. Refer to Chapter 6: Replacing the Battery on page 119.

Alarm Title	Description	Solution
PME	Pump Mechanism Error- This is a family of alarms related to problems with the actual mechanism.	If stated on screen, return pump to service. In all other cases, the pump set up or battery voltage was too low; therefore recharge the battery and test for reoccurrence. If the alarm doesn't appear again, this is not a pump failure.
End of Battery Life	Battery has exceeded its usage life (has been in use for more than 2 years or reached the max of 500 charges cycles) and needs to be replaced with a new one.	If this alarm occurs replace the battery. Refer to Chapter 6: Replacing the Battery on page 119.
Non-Authorized Battery	A battery that was not authorized by Q Core to be used with the pump.	If this alarm occurs replace the battery. Refer to Chapter 6: Replacing the Battery on page 119.
System Error	A group of system errors. In some cases, depends on the error cause, it is possible that the error will not be written to the Event Log.	If this alarms appears, return pump for service.
Internal Communication Error	The pump has lost communication with the battery.	Disconnect and reconnect the battery. In case of reoccurring alarm replace battery. Refer to Chapter 6: Replacing the Battery on page 119.
External Communication Error	The pump CPU has lost communication with the LCM (Liquid Crystal Module) or the LCM lost communication with the CPU.	In case of reoccurrence return pump for service.

Alarm Title	Description	Solution
Air in Line	An air bubble, bigger or equal by size to the value defined by user was detected by the light sensor.	Normal course of operation. Not a pump malfunction.
Accumulated Air in line	The accumulated bubble volume has reached its limit (set by user) in 15 minutes (only bubbles that are bigger or equal by size to the user set value are counted).	Normal course of operation. Not a pump malfunction.
Downstream/ Upstream Occlusion	Downstream occlusion-Occlusions from the pump to the patient line. Upstream occlusion- Occlusions from the collapsible bag of water to the pump.	Normal course of operation. Not a pump malfunction.
Possible Occlusion	An infusion was started with clamps closed. Not a pump malfunction.	Normal course of operation. Not a pump malfunction.
Unknown Occlusion	There is an occlusion but the pump is not able to determine if it is upstream or downstream.	Normal course of operation. Not a pump malfunction.
Check for Occlusion	This alarm occurs when an occlusion, either downstream or upstream, is detected at the beginning of treatment, while the pump is determining a reference.	Normal course of operation. Not a pump malfunction.
AS not loaded/ misplaced	Administration Cassette is not loaded successfully if at all.	Normal course of operation. Not a pump malfunction.
Low voltage for current rate	Detected when the pump cannot reach a current rate due to reaching PWM 140 when battery power is insufficient. Happens only when the pump is on battery power.	When pump is working on battery: the alarm will sound. Not a pump malfunction.
Inconsistent flow	Alarming when pump is not running in a stable flow rate.	If this alarm appears return pump for service.

Alarm Title	Description	Solution
Air detector Faulty	The air detector is unable to make correct readings.	Clean the air detector. If alarm reoccurs, return pump to service.
Incorrect pressure value reading		If this alarm appears return pump for service.
30 min to battery depletion	User has at least 30 minutes of pump use in current rate before the battery is depleted and pump is turned off.	Normal course of operation. Not a pump malfunction.
Treatment complete	Treatment is complete, VTBI is fully infused.	Normal course of operation. Not a pump malfunction.
Door opened	The administration set door is opened or not fully closed.	Normal course of operation. Not a pump malfunction.
Pump unattended	The pump has been idle for the set amount of time.	Normal course of operation. Not a pump malfunction.
Treatment near end	There are <xx> minutes before the end of treatment.	Normal course of operation. Not a pump malfunction.
Charge error	It is taking longer than usual to charge the pump. Alarm is triggered after 7 hours of charge time.	In case of reoccurring alarm replace charger and battery. If the alarm is periodically reoccurring, send pump for service.
Battery life expires 2 days	In 2 days the battery will reach its two years life time.	Replace battery. Refer to Chapter 6: Replacing the Battery on page 119.
Calibration Due now	Working time or calendar time has ended. Calibration may be needed.	Perform Annual Certification.
Calibration Due 2 days	Working time or calendar time has ended and is due in 2 days. Calibration may be needed.	Perform Annual Certification.
Calibration Due 2 weeks	Working time or calendar time has ended and is due in 2 weeks. Calibration may be needed.	Perform Annual Certification.

Troubleshooting

This section contains some basic troubleshooting procedures.

Non-technical Troubleshooting

The troubleshooting table below provides basic problem-solving assistance.

Description of Problem	Solution
Pump can't be turned on	Connect pump to external power supply and charge for at least 4 hours. If pump still cannot be turned on return pump for service.
After I disconnect pump from an external power supply, the pump shuts down immediately without any warning	Connect pump to external power supply and charge for at least 4 hours. If problem recurs replace the battery. If the problem still persists, do not use pump and return it for service.
The pump cannot be turned off	Press the On/Off key for 5 seconds. If problem persists, do not use pump and return it for service.
Can't start treatment	Make sure that the treatment parameters are correct. Make sure pump is not in low lock level. Else, return pump for service
Stop button is not responding	Return pump for service.
On/Off hard key not responding	Return pump for service.
Touch screen not responding	Return pump for service
The screen has no back light	Make sure that the pump is not in lock screen or patient lockout state. If the pump is running with backlight off, press the off button once to turn the screen on. If backlight is not turned-on or the pump does not turn on, return pump for service.
Alarm LED is on	An alarm occurred. See information displayed on screen
Alarm LED Is blinking	An alarm occurred. See information displayed on screen

Description of Problem	Solution
Charging LED is on	Indicates battery is fully charged
Charging LED is blinking	Battery is charging
Run LED is blinking	Pump is in delivery mode
Door cannot be snapped closed after inserting the administration cassette	Verify that the administration cassette is placed properly in the cassette's housing.
Door cannot be snapped closed, without administration cassette	Return pump for service
I press the keys or the touch screen but no audible sound is heard	Verify that *"Keys Volume"* option under *Options* →*Pump Configuration* →*Audio settings* is not set to "Off". If "keys volume" is set to "On", don't use the pump and return it for service.
I see alarms displayed on the screen but no sound is heard	Verify that *"Alarm Volume"* option under *Options* → *Pump Configuration* → *Audio settings* is not *set* to "Off". If "alarm volume" is set to "On", do not use the pump and return it for service.
I press the bolus but the pump doesn't respond	• Verify that the current treatment allows to administrate boluses. • Make sure that the bolus handle is connected to the pump and not to the cradle. • Make sure that the bolus handle, cable and connector are not broken and properly connected to the pump. • Verify that *"Bolus available"* is written on the main screen, otherwise the time left for bolus administration should indicate the remained time. • Replace bolus handle if necessary.

Description of Problem	Solution
I cannot stop a treatment when I press the Stop button	Pump can be stopped either by pressing the PAUSE soft key or by pressing the stop key. In case both options are not working, open the cassette door and this will immediately stop the treatment. Return pump for service.
I get continuous air in line alarms when there are no visible air bubbles in the tube	Make sure the cassette is fitted well in its position and make sure that small bubbles are not stuck inside the cassette silicone tube. If problem persists, this may indicate that the pump was damaged. Return pump for service
I get occlusion alarms in situation where no occlusions exists.	Make sure the cassette is fitted well in its position. Replace the set and check if the problem reoccurs. Else, return pump for service.
WiFi icon is gray	Verify that there is an available network at the hospital.
MedNet icon is gray	Verify that the WiFi icon is blue and that the TCP/IP configuration under Tech. Options → WiFi Settings or via the SXManager Software were configured correctly. Otherwise, don't use the pump and return it for service.

Troubleshooting Programming Issues

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 Basic Pump Settings on page 167). Authorization level of High 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 Basic Pump Settings on page 167). Authorization level of High is required.
Pump is automatically locked whenever an infusion starts.	The Auto Patient Lockout feature is enabled.	Disable the **Auto P. lockout** setting (refer to 'Using the Infusion Modes' chapter of the Sapphire User Manual). Authorization level of High is required.

Problem	Probable Cause	Solution
The Bolus button does not appear in the toolbar during a Continuous infusion.	The Allow Bolus feature is not enabled.	• Enable the Allow Bolus setting. Technician Authorization level is required. For more information refer to Configuring General Settings on page 171. • The drug profile in the Drug Library was not configured to support a bolus.
Pump is not charging.	The charger is disconnected from the mini cradle or the main power supply, or the charger is not working.	Connect the charger to a different power supply, and reconnect it to the pump. If the charger is not functioning properly, replace it.
Recurring Air in Line alarms.	Treatment is near end, or the air detection settings are too sensitive.	Flush/prime 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.

Problem	Probable Cause	Solution
Recurring Occlusion alarms.	The occlusion issue has not been properly resolved.	• Flush/prime the set manually. • Replace the administration set. • Change the infusion site.
Screen saver doesn't appear.	• Screen saver option was not enabled. • Pump is not in an applicable state.	• Enable the Screen Saver option (refer to Configuring Basic Pump Settings on page 167). • If the pump is in one of the following states, the screen saver will not turn on: Paused, Delayed Infusion, end of treatment KVO, during alarm, when screen is touched, when key is pressed, or during bolus administration.

Upgrading Software Version

SapphirePlus pump software can be upgraded using the Pump Loader Software tool, as described in Upgrading Software Version on page 157, or using the WiFi connection.

The following section explains how to upgrade the software version in the SapphirePlus pump using the WiFi connection.

Upgrade Procedure

When a new software version is available and the infusion pump is connected to the hospital's wireless network, the software download will start automatically. When completed, the user is prompted to specify whether or not to update the software.

	Updating software should be conducted according to local facility procedures. Updating a new software version may take up to 1 hour, during which the pump is inactive. The user is advised to connect the pump to a charger 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 a new software version:

1. From the New Software screen, press **Yes**.
2. Enter the installation code, and press **OK**. The pump will start updating the software. At the end of the process the pump will enter charging mode.

	If the pump is not connected to a power charger, the pump will turn on in the end of the installation.

3. Press On/Off hard button to activate the pump.

The Start Up screen will appear.

	If the software update occurred when an infusion was running and the pump turned off to perform the update, the user will be asked first whether to continue the infusion or to "Exit". If the user presses the "Exit", the new software screen appears. If the user presses "Continue", the infusion will be continued. When the infusion (including the KVO, if defined) is completed, the New Software screen will appear.

> To view the current software version:

From the Options menu, select Technician Options → General Info → LCM Info. The **SW Version** parameter is displayed.

Inform Q Core or a local distributor at Hospira service center of every pump update with the Customer Software Update Form, found at the FTP site (refer to FTP site on page 28) and on the Service Manual at Appendix A: Customer Software Update Form on page 213

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Authorized Hospira Service Centers

For service related questions or repair please contact:
In the USA: supportservices@hospira.com
In Canada: CanadaPumpSupport@hospira.com
In Europe: custsi@hospira.com
In Asia Pacific: Servicedirect.au@hospira.com
To report a customer complaint please contact:
In the USA:
Phone: 1-800-441-4100 (8am-5pm CT, M-F)
Email: sapphireGCM@hospira.com
In Canada: productcomplaintsca@hospira.com
In EMEA (Europe): custserv@hospira.com
In Latin America: productcomplaintsla@hospira.com
In Asia Pacific: Australia.sme@hospira.com
To report a customer complaint via fax:
USA: 1-224 212 4080
Rest of World: 0 1 224 212 4080

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Customer Software Update Form

Fill the form in clear handwriting or typing and submit to: service@qcore.com

Customer:_____	Site/Warehouse: _____
Country: _____	Date of Upgrade (DD/MM/YYYY): _____

#	Pump Serial Number	Original Software Revision (RxxVyy)	New Software Revision Verified in Pump (RxxVyy)	Pump Type- MT/EPI/H100/SapphirePlus/IVVet/Other (MT=Multi Therapy, EPI=Epidural)					
				MT	EPI	H100	Plus	IVVet	Other
1				☐	☐	☐	☐	☐	☐
2				☐	☐	☐	☐	☐	☐
3				☐	☐	☐	☐	☐	☐
4				☐	☐	☐	☐	☐	☐
5				☐	☐	☐	☐	☐	☐
6				☐	☐	☐	☐	☐	☐
7				☐	☐	☐	☐	☐	☐
8				☐	☐	☐	☐	☐	☐
9				☐	☐	☐	☐	☐	☐
10				☐	☐	☐	☐	☐	☐
11				☐	☐	☐	☐	☐	☐
12				☐	☐	☐	☐	☐	☐
13				☐	☐	☐	☐	☐	☐
14				☐	☐	☐	☐	☐	☐
15				☐	☐	☐	☐	☐	☐
16				☐	☐	☐	☐	☐	☐

Performed By			
Name	Position	Signature	Date (DD/MM/YYYY):

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QCORE
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REF 15025-048-0027 Rev.01