REF 15025-048-0027 Rev.06

SERVICE MANUAL - LEVEL 1

SAPPHIRE MULTI-THERAPY AND DEDICATED INFUSION PUMPS

SAPPHIRE
by Eitan Group

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

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.

Alternatively, administration sets from different manufacturers that are regulatory cleared and labeled for use with the Sapphire infusion system, can be used as well. The list of regulatory cleared sets needs to be obtained from the official manufacturer's publication such as manufacturer's website, catalog or any other formally published document.

Using anything other than administration sets regulatory cleared and labeled for use with Sapphire infusion system, may result in operation that is not within the constraints and parameters of the device.

The use of Administration sets manufactured by ICU Medical is approved for sale through March, 2023.

Technical Assistance

For technical questions, troubleshooting assistance and device problems, please contact your local agent/distributor, and refer to page 268. You may also contact Q Core Medical Ltd. support via email to the following address: service@qcore.com.

Registered technicians can submit a call via the personal profile drop down menu in the Service Portal at the following address

https://service.qcore.com/Main.aspx.

Contents

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 and explains the procedures involved in servicing Sapphire pumps (Sapphire Multi Therapy, Sapphire Epidural, ShapphireH100 and SapphirePlus). 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. Q Core Medical is not responsible for any action performed by users that is not described in the Service Manual or in its Addendum.

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.
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.

Chapter	Description
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.
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.
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.
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. For more information refer to page 268.

Terms and Abbreviations

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

Term/Abbreviation	Meaning
AC/DC	Alternating Current / Direct Current
ACT	Annual Certification Test
AFFV	Anti-Free-Flow-Valve
BOH	Bill Of Health

Term/Abbreviation	Meaning
BPOC	Barcode Point-Of-Care
CCA	Clinical Care Area
DFU	Directions for Use
ECG	Electrocardiogram
eMAR	Electronic Medication Administration Record
EMC	Electromagnetic compatibility
EMI	Electromagnetic interference
FasTest PM	FasTest Preventive Maintenance
FCC	Federal Communications Commission
H	Hour
HIS	Hospital Information System
Kg	Kilograms
KVO	Keep Vein Open
LE-LAN	License-Exempt Local Area Network
M Units	Million Units
MAC	Media Access Control
mcg	Micrograms
mEq	Milliequivalents
mg	Milligrams
min	Minutes
mL	Milliliters
mmol	Millimoles
mUnits	Milliunits
nanog	Nanograms
Occ.	Occlusion
PAV	Pressure Activated Valve
PDA	Personal Digital Assistant
PHY	Physical Layer
Q Core	Q Core Medical Ltd.

Term/Abbreviation	Meaning
QoS	Quality of Service
RF	Radio Frequency
Sapphire pump	Q Core Sapphire infusion pump family
Service Portal	Q Core Medical Service Portal
SCM	Sapphire Configuration Manager
TPN	Total Parenteral Nutrition
VI	Volume Infused
VTBI	Volume To Be Infused
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 60601-1-12 - Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment.
- 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.

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 18
- Proper Use of the Pump on page 23

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 MRI, CT, diathermy (deep heat treatment), electromagnetic security systems (e.g. metal detectors) and large electric motors.

Portable and mobile RF communications equipment, such as RF emitters, 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.

Some of these EMI sources (mostly RF emitters) may not be visible and the device can potentially be exposed to fields from these EMI sources without the user's awareness.

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
- 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 identify or suspect external RF sources or other equipment are influencing device operation (from known or unknown source), try to (as applicable) increase the pump's distance from the EMI source, re-orient the device, relocate the device, connecting device to different outlet, contact the biomedical engineering department for additional guidelines concerning electromagnetic immunity or decrease emitting device output power (to 30 dBm).
- Contact the biomedical engineering department for additional information in the service manual concerning operating devices near RF sources.

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

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

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 Q Core standard administration sets listed in Q Core's approved list of products: http://www.qcore.com/. Alternatively, administration sets from different manufacturers that are regulatory cleared and labeled for use with the Sapphire infusion system, can be used as well. The list of regulatory cleared sets needs to be obtained from the official manufacturer's publication such as manufacturer's website, catalog or any other formally published document.

Using anything other than administration sets regulatory cleared and labeled for use with Sapphire infusion system, may result in operation that is not within the constraints and parameters of the device. Severe injury or death may result from using sets other than those indicated in Q Core's approved list of products. For more information refer to Administration Sets on User Manual, 15025-048-0095 page 63.

The use of Administration sets manufactured by ICU Medical is approved for sale through March, 2023.

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 infusion container is positioned at a height of 50 cm above the pump. There is no restriction on the location of the infusion container in relation to the patient's heart.

Alarm conditions automatically stop the infusion and require immediate attention before the infusion can be restarted. When clamping the administration set, ensure the clamp is at least 20 cm (8 in) away from the pump, when possible. Note that if the dose rate is beyond the pump resolution of 0.1mL/h increments, the pump will increase or decrease the rate by up to 0.05mL/h. This flow rate (mL/h) is presented on the running screen during infusion.

⚠ Administering Infusions: General Safety Precautions

- **Air detection (in software versions that support the disabling of Air detection):**
  - Air detection is an important safety feature of the Sapphire pump. If the air detection is disabled (Off), use a set with an air-eliminating filter to prevent injury to the patient due to an air embolus.

    - Air detection serves as a safety component. Disabling the air detection hinders the pump's ability to alert on hazardous situations.
    - Always ensure that the administration set is primed before starting an infusion.
    - The air detector working range when delivering fatty acids is 2%-20% lipids.
- **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. For more information refer to Replacing the Battery on page 154.
- 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 37. 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 42.
- 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	125 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
Limit Period	1 Hr	User Manual (Using Special Mode Options). The feature is available only in the PCA/PCEA/Epi. Int options menu
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, BOH software, 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. • It is recommended to use Google Chrome.

1. Obtain username and password directly from Q Core Medical at service@qcore.com, or a local distributor. For more information refer to page 268.
2. Type https://qcore.smartfile.com in the browser address bar, and press **Enter**.
3. Enter your username and password, and then click **Login**.

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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 180, or page 237.

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
	Activate immediate taper-down during TPN infusion, using the taper-down period defined by the clinician
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
	Edit Rate during running infusion (the option must be enabled prior to the infusion by an authorized Technician)
	View bolus rate (PCA options)
	Activate immediate taper-down during TPN infusion, and set the time for it
	Use the set delay feature
High	Start infusions using the New Infusion feature
	View/Edit parameters
	Use the Pump Configuration menu
	Create/Edit PreSet programs (requires a unique password)
	Changing delivery mode (requires password re-entry)
	Clinician bolus (requires password re-entry)
	Use of all PCA, PCEA and PIEB options
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.

	It is recommended to change the authorization level passwords from the factory defaults, to avoid unauthorized users from accessing the pump. To change a password see To change the passwords: on page 180.

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. 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**.

	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 delivery mode
- Changing authorization level
- Programming 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.

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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.

Cleaning/Disinfecting Solution	Manufacturer
Dispatch® (Caltech) ready-to-use towels	Caltech
Virex® II 256	Diversey
Virox® AHP 5 RTU	Diversey
Klor DeTM (Chlorine tablets)	Concept
70% Isopropyl alcohol	Generic (any brand containing 70% Isopropyl alcohol diluted in water)

⚠ 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.
- Do not clean or disinfect the pump using liquid household Bleach, as deterioration may occur.
- 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, make sure they are listed in Q Core Medical's official approved list of materials (published at http://www.qcore.com).

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

Cleaning and Disinfecting Procedure

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.

Disinfection Procedure

The following procedure explains how to disinfect the pump using the approved agents (see Cleaning and Disinfecting Procedure on page 44):

> 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.

Before using materials other than the products listed above for cleaning and disinfecting the Sapphire Infusion pump, make sure they are listed in Q Core Medical's official approved list of materials (published at www.qcore.com)

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.
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 44.

Cleaning Electrical Connectors of Sapphire Accessories

Cleaning the electrical connectors of all accessories is restricted to the use of 70% Isopropyl alcohol (IPA) ONLY.

1. Place the accessory on a clean and stable surface.
2. Apply IPA 70% lightly to a cloth or sponge.
3. Squeeze the cloth / sponge before cleaning, so it won't drip on the accessory to be cleaned.
4. Swab in a rotational manner for at least 3 bi-directional rotations (clockwise-counterclockwise).[1]

Figure 3.1. Cleaning Electrical Connectors

5. Take caution and avoid dripping the reagent into the pins or pores of the electrical connector.
6. Allow the IPA to air dry for at least 3 minutes before connecting to power.

1. Be careful not to apply excessive pressure on the connector during swabbing.

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.

Post-use Procedures

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

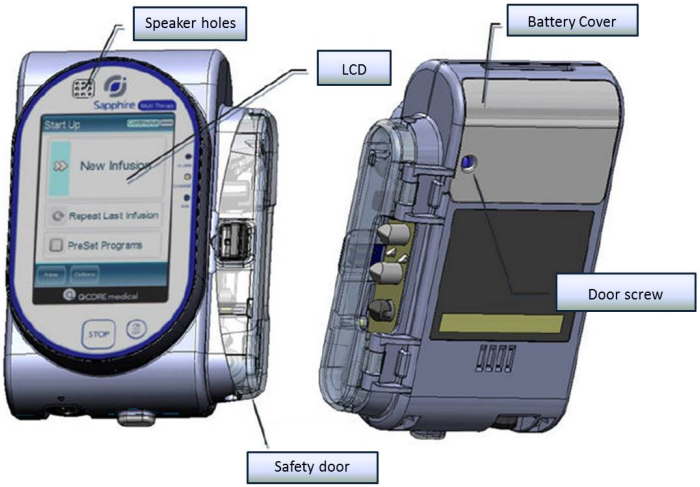
Pump Component	Action
Pump Housing	Check for cracks and dents.
Power Cord	Verify that the power cord is undamaged. Check the entire length of the cord, and the plug.

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

Thorough Visual Inspection

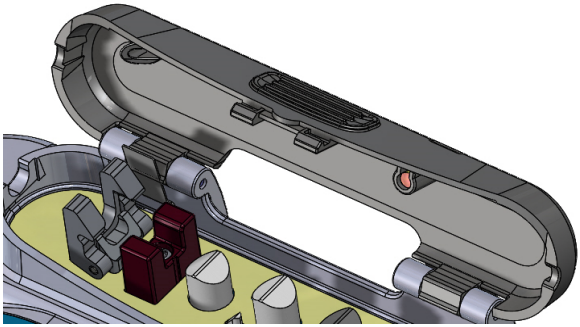
1. Check the pump plastic housing for cracks and broken parts. If parts are broken or cracked, the pump must be serviced.

Figure 3.2. Visual Inspection for Cracks



2. Verify that the safety door is functioning properly (Figure 3.3). 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 3.3. 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 171.

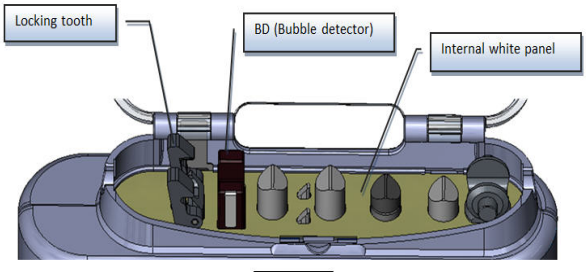
3. Check the cassette chamber, pumping mechanism and cassette locking mechanism for functionality and cleanness (Figure 3.4):

   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.

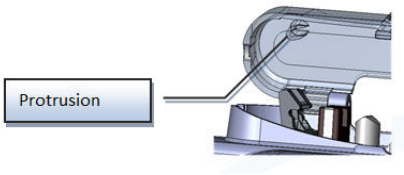
c. The Bubble Detector (BD) must be inspected for possible cracks, scratches or dirt. If the BD plastic shell is damaged, return the pump for servicing. A dirty BD cover can lead to improper functioning of the BD, creating false alarms. Verify that the BD plastic cover is clean of grease or other foreign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

Figure 3.4. Visual Inspection of Cassette Chamber



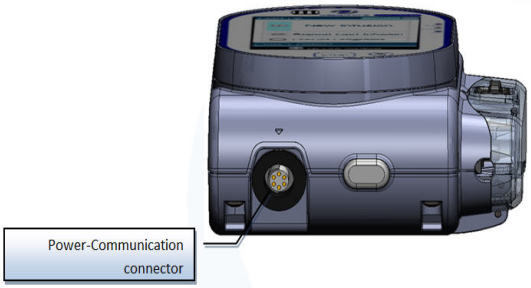
4. A properly functioning safety door must "click" itself into the open position, and must snap itself to a secure closed position. The door has an internal protrusion to assure correct locking of the cassette when the door is closed. Verify that the protrusion is not broken.

Figure 3.5. Visual Inspection of Safety Door



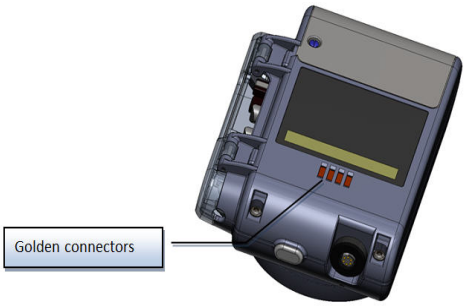
5. Check that the power-communication connector is free of foreign materials and dirt. If necessary, clean and dry with a dry cloth.

Figure 3.6. Visual Inspection of Power-Communication Connector



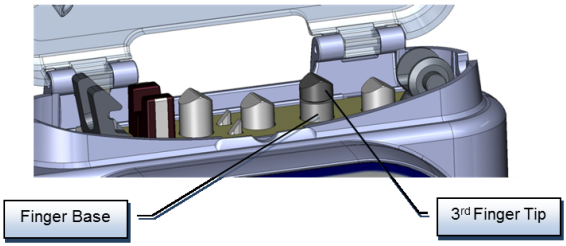
6. The pump has flat golden connectors (P2C) on the back of its plastic housing. Make sure that the connectors are not loose, broken, dirty or corroded. When cleaning the pads, take special care not to scratch its golden surfaces.

Figure 3.7. 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 3.8. 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

Sapphire Pumps

It is recommended to perform manual testing of the following alarms at least once a year. Alarm testing can be conducted as part of the yearly certification.

Before testing the alarms, make sure to disconnect the set from the patient.

Name of Test	Procedure
Air in Line Alarm	Connect a new Q Core administration set to the pump without connecting it to the 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 6: Level 3 Alarms on page 192.

	In software versions that support the disabling of Air detection, please ensure that air detection is enabled (On) in the technician options. If the air detection disabled (Off) icon is displayed and a warning stating the air detection is disabled (Off) appears when programming an infusion, the Air in Line alarm will not be triggered.

Sapphire Epidural Pumps

To perform the manual testing of the Air in Line alarm and Occlusion alarm in Sapphire Epidural pumps refer to the 'Field Air Detector Test for Sapphire, SapphireH100 and SapphirePlus Infusion Pumps' (P/N 15025-042-0057) and 'Field Occlusion Test for Sapphire SapphireH100 and SapphirePlus Infusion Pumps' (P/N 15020-042-0006).

The Testing Protocols can be found on the Service Portal, https://service.qcore.com/

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

For any failure in the built-in test, contact Q Core Medical via the Service Portal or contact the local distributor service center.

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.

	Sapphire Plus devices do not have the option for Patient Bolus, therefore, if a bolus handle is not available for this test, mark Pass and proceed.

Air Detection, Occlusion Sensor and Accuracy Tests

There are two methods for checking the pump's air detection, occlusion sensor and accuracy:

We recommend using the FasTest PM Test Method.

The FasTest PM method allows you to perform the tests described in the table below.

Name of Test	Procedure
Air Detector & Accuracy	This test involves introducing a pre-specified amount of air into the administration set. The application checks if the pump detected air in the system, and whether the measured infused volume is correct (checks it versus the expected volume).
Occlusion Sensor	This test involves delivering a known volume of fluid; then, creating pressure in the system – caused by introducing a specific amount of air into the administration set against a closed clamp.

All of the functional tests included in the FasTest PM process and their specific procedures are detailed in FasTest PM Test Method on page 100.

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.

When working on battery power (disconnected from main power supply) the battery charge level icon, at the upper right corner of the indicators bar, indicates remaining battery capacity. Check the status of the battery charge level icon regularly.

Number of Bars in Icon	Approximate Remaining Battery Capacity
5	100%
4	75%
3	50%
2	25%
1	Low

You can also check the status of the battery using the **Options** menu. For 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.

ℹ	While connected to a power supply and charging, the Charge (yellow) LED blinks.
	If the pump is turned off, the following information is displayed:
	• Status (Charging or Battery fully charged)
	• For Rev 14.5 SW only:
	  • Pump serial number
	  • Software version
	  • Drug library number
	  • Days to pump checkup
	The Charge (yellow) LED stops blinking when the battery is fully charged.

> To charge the battery:

1. Plug the Q Core supplied power supply cord into the main power supply.
2. Plug the power cord into the pump power socket or into the splitter connector, with the white arrows or red dot facing up.

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

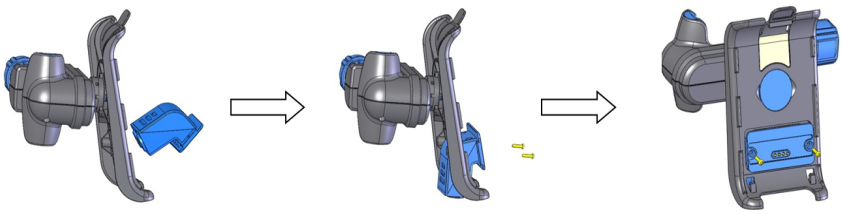
Required parts and tools:

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

Assembly process:

Insert the splitter to the mini cradle as described in Figure 3.9, and tighten using the 2 included screws.

Figure 3.9. 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.

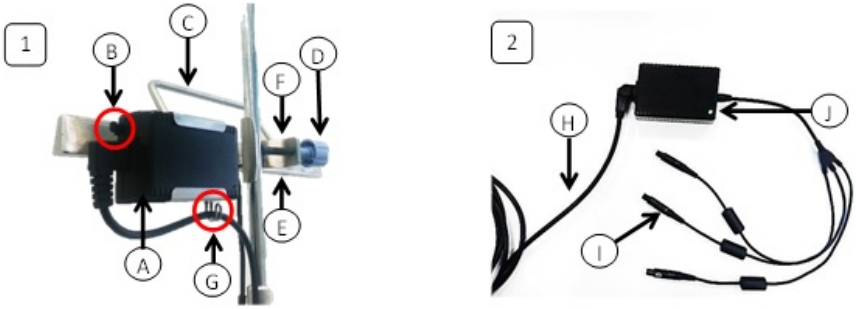
It is recommended to use mini cradles with a splitter in order to facilitate attachment and detachment of pumps.

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 3.10. 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

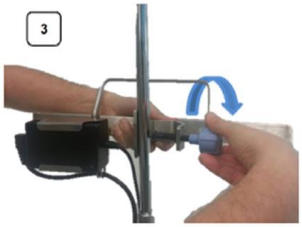
Mounting System setup instructions

i	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 3.10 D) by rotating it counter-clockwise.
2. Firmly hold the Mounting System and place the clamp (Figure 3.10 F) on an IV pole with the carry handle (Figure 3.10 C) facing upwards.
3. Tighten the clamp knob by rotating it clockwise (Figure 3.11).

Figure 3.11. Clamp knob

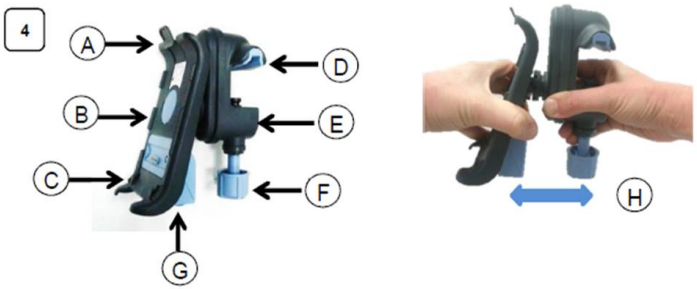


	To prevent detaching from the IV pole, the Mounting System can be locked to the pole by removing the knob cap or knob key from the clamp knob.

Attaching a mini cradle to the Mounting System

1. Pull the pump holder (Figure 3.12 B) away from the base (Figure 3.12 E) and rotate it to a position where the mini cradle knob (Figure 3.12 F) points downward and the top hook (Figure 3.12 A) points upward.

Figure 3.12. Attaching the mini cradle

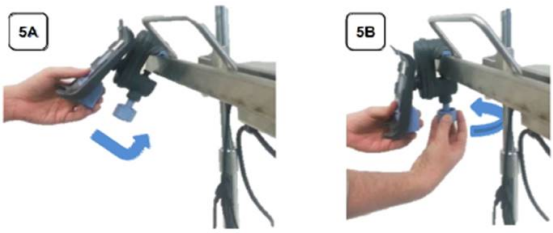


A. Top hook
B. Pump holder
C. Bottoms hooks
D. Mini cradle vise
E. Mini cradle base
F. Mini cradle knob
G. Splitter socket
H. Proper position

	Place the mini cradles according to the markings on the Mounting System, between the designated lines (Figure 3.14).

2. Loosen the mini cradle knob (Figure 3.12 F) to maximum extent by rotating it.
3. Tilt the mini cradle and place the open vise (Figure 3.12 D) on the top of the Mounting System (Figure 3.13 A). Align the cradle and tighten the knob by rotating it (Figure 3.13 B).

Figure 3.13. Tilting the mini cradle



4. Plug a DC output connector (Figure 3.10 I) to the mini cradle splitter (Figure 3.12 G).
5. Fasten the DC output cables to the clips located on the bottom of the Mounting System (Figure 3.10 E).
6. Plug the AC input cord (Figure 3.10 H) to the power outlet. Verify that the Mounting System power supply LED (Figure 3.11 J) is ON.

Figure 3.14. 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 3.12 C), and then click the pump into the top hook (Figure 3.12 A).
2. Verify that the charging connector is plugged into the splitter socket (Figure 3.12 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 3.12 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:

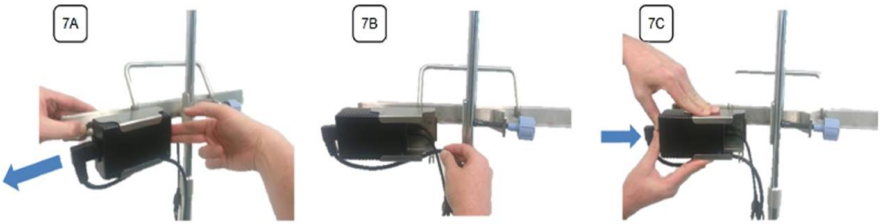
Disassemble the Mounting System power supply from the Mounting System:

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 3.15 A).
4. Take the AC input cord out of the cord hook (Figure 3.15 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 3.15 C).
3. Refer to the Mounting System setup instructions to reassemble the Mounting System and prepare it for use.

Figure 3.15. 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.

Integrated Power Supply (IPS)

The Integrated Power Supply (IPS) is a power supply that is assembled into the Mini Cradle to supply power to the pump. Specifications of the power supply include:

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

> To connect the AC Power Cord to the IPS:

1. Connect the Q Core AC Power Cord to the IPS.
2. Connect the Cord Retainer to the IPS, using a Philips head screwdriver.

> The cord retainer is an integral part of the IPS, and must be connected prior to initial use.

> To charge the battery:

1. Plug the Q Core AC Power Cord into the main power supply source.
2. On the back of the IPS B, verify that the Power LED status indicator is On (blue light).
3. Mount the pump into the mini cradle.
4. On the front of the pump, verify that the Charge LED status indicator is On (blinking yellow light).

> To disconnect the AC Power Cord from the IPS:

1. Unplug the Q Core AC Power Cord from the main power supply source.
2. Disconnect the Cord Retainer from the IPS, using a Philips head screwdriver.
3. Remove the Q Core AC Power Cord from the IPS.

Sapphire Multi-Pump Mounting System Compatible with IPS B

Safety Guidelines

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

Warnings:

- Verify the mini cradles with IPS are securely attached to the Mounting System Compatible with IPS B and that the Mounting System Compatible with IPS B is securely attached to the IV pole before attaching the pumps.
- Do not transport the Mounting System Compatible with IPS B 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 Compatible with IPS B.
- Before using the Mounting System Compatible with IPS B, make sure all the Mounting System Compatible with IPS B cords are completely dry.
- To avoid risk of electric shock the Trident AC power cord must be connected to a power outlet with protective earth.

Cautions:

- Use only Q Core approved Trident AC power cord with the Mounting System Compatible with IPS B.
- 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 Compatible with IPS B on a single IV pole.

Product overview

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

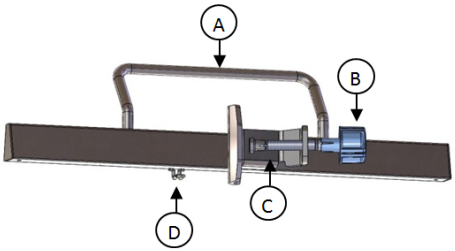
The Mounting System Compatible with IPS B is compatible with the following infusion pumps: Sapphire Multi Therapy Infusion Pump, Sapphire PCA Infusion Pump, Sapphire TPN Infusion Pump, Sapphire Epidural Infusion Pump, SapphireH100 Infusion Pump, SapphirePlus Infusion Pump, and IVVET Infusion Pump.

Unpacking the Mounting System Compatible with IPS B

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

- Sapphire Multi-Pump Mounting System Compatible with IPS B
- Trident AC Power cord
- Clamp knob key

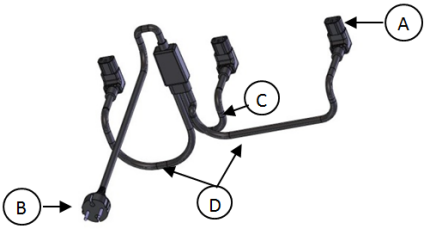
Figure 3.16. Mounting System Compatible with IPS B



Item	Description
A	Carry Handle
B	Clamp knob

Item	Description
C	Clamp
D	Cord Hook

Figure 3.17. Mounting System Compatible with IPS B Trident Power Cord



Item	Description
A	Power cord connector
B	Power cord plug
C	Short cord
D	Long cords

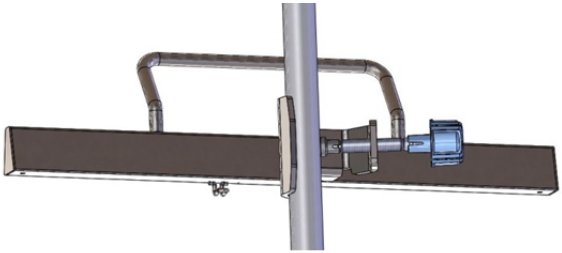
Mounting Instructions

It is recommended to first attach the Mounting System Compatible with IPS B to the IV pole before attaching the mini cradles with IPS to the Mounting System Compatible with IPS B.

Attaching to an IV Pole

1. Loosen the clamp knob (Figure 3.16, Item #B) by rotating it counter-clockwise.
2. Firmly hold the Mounting System Compatible with IPS B and place the clamp (Figure 3.16, Item #C) on an IV pole with the carry handle (Figure 3.16, Item #A) facing upwards.
3. Tighten the clamp knob by rotating it clockwise (Figure 3.18).

Figure 3.18. Attachment to an IV Pole

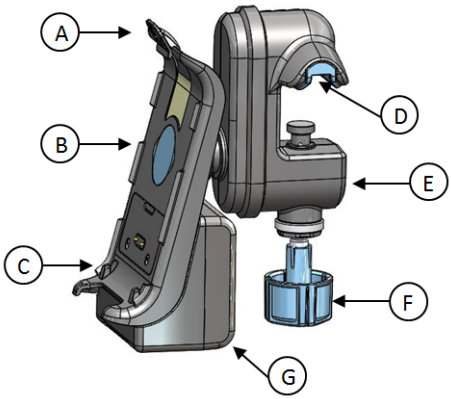


To prevent detaching from the IV pole, the Mounting System Compatible with IPS B can be locked to the pole by removing the knob cap or knob key from the clamp knob.

Attaching a Mini Cradle with IPS to the Mounting System Compatible with IPS B

1. Pull the pump holder (Figure 3.19, Item #B) away from the base (Figure 3.19, Item #E) and rotate it to a position where the mini cradle knob (Figure 3.19, Item #F) points downward and the top hook (Figure 3.19, Item #A) points upward.

Figure 3.19. Mini Cradle with IPS Parts

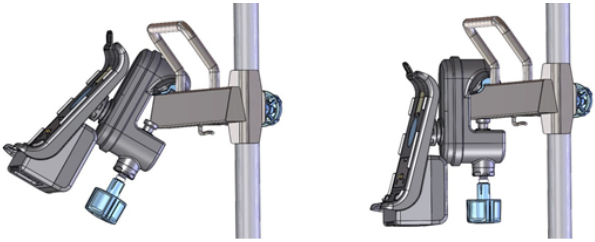


Item	Description
A	Top hook
B	Pump holder
C	Bottoms hooks
D	Mini cradle vise
E	Mini cradle base
F	Mini cradle knob
G	IPS

Place the mini cradles with IPS according to the markings on the Mounting System Compatible with IPS B, between the designated lines (Figure 8).

2. Loosen the mini cradle knob (Figure 3.19, Item #F) to maximum extent by rotating it.
3. Tilt the mini cradle and place the open vise (Figure 3.19, Item #D) on the top of the Mounting System Compatible with IPS B (Figure 3.20, Item #A). Align the cradle and tighten the knob by rotating it (Figure 3.20, Item #B).

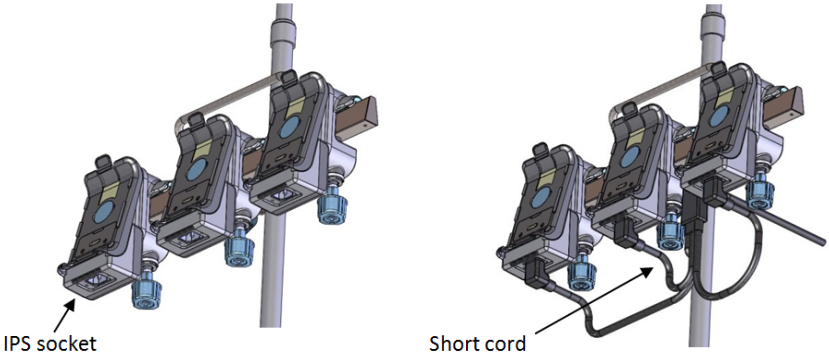
Figure 3.20. Mounted Cradle



A B

4. Plug each of the Trident AC Power cord connectors (Figure 3.17, Item #A) to the IPS sockets (Figure 3.21) of the mini cradles (the Trident AC power short cord should be connected to the middle Mini Cradle).

Figure 3.21. Connected by Trident AC



5. Connect the cord retainers to each IPS using a Philips head screwdriver (Figure 3.22).

   The cord retainer is an integral part of the IPS and must be connected prior to initial use.

6. Place the Trident AC Power Cord in the Mounting System Compatible with IPS B cord hook (Figure 3.16, Item #D).
7. Plug the Trident AC Power cord (Figure 3.17, Item #B) to the power outlet. Verify that the LEDs on the back of the IPSs are on.

Figure 3.22. Using the Cord Retainer

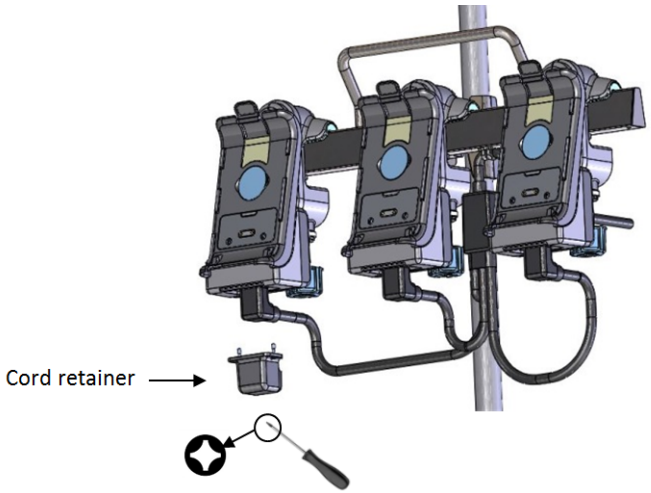
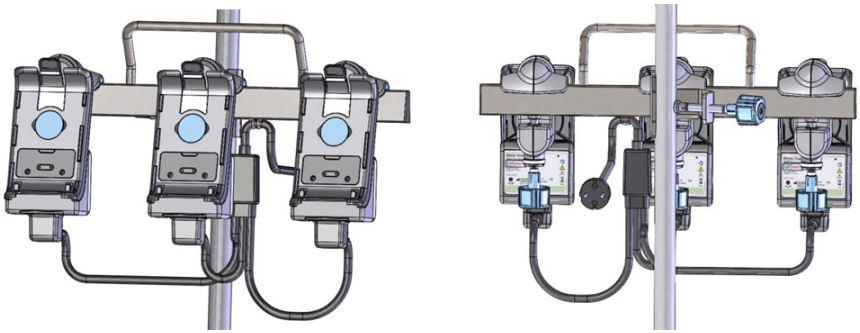


Figure 3.23. Fully Assembled Mounting System with IPS B



Attaching a pump to a mini cradle with IPS

First insert the pump into the bottom hooks of the mini cradle (Figure 3.19, Item #C), and then click the pump into the top hook (Figure 3.19, Item #A).

Detaching a pump from a mini cradle with IPS

Hold the pump and press the top hook (Figure 3.19, Item #A) backwards.

Detaching a pump from an IV Pole

When transporting the Mounting System Compatible with IPS B, detach it from the IV pole:

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

	To clean the Mounting System Compatible with IPS B thoroughly, remove all the mini cradles. Refer to Cleaning and Disinfecting Procedure on page 44 for more information about the cleaning process and approved cleaning materials.

	Always contact a certified technician in cases of Mounting System Compatible with IPS B electrical and mechanical malfunctions.

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 60).

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. For more information refer to page 268.

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 or to a local distributor for service. For more information refer to page 268. Please adhere to the following guidelines in order to ensure effective and quality processing of your claim(s) and refer to COMP-5000-0000034, Returned Materials Policy on Q Core MedicalService Portal (https://service.qcore.com/). For more information regarding the Service Portal, refer to Service Portal Work Instructions, 16019-049-0001-SRV.

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 to a local distributor. For more information refer to page 268.
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 43.

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Chapter 4: Performing Pump Certification Test

There are two options for performing the Certification Test:

We recommend using the FasTest PM Test Method.

Introduction

Pump Certification Test Overview

The certification process contains a sequence of maintenance checks that need to be performed annually on the Sapphire infusion pump. The 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 42.
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 certification process is supported by Q Core's FasTest PM or 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

When a certification process is completed, the next certification date is automatically set on the pump to 380 days from the date shown on the PC that is used to perform the test (Tolerance ±7 days).

Sapphire Multi–Therapy, Sapphire Epidural, SapphireH100 & SapphirePlus

The start date in cases where Certification has not yet been performed – for example, Unused Infusion Pump – will be the shorter period of the following options:

- 10 working hours.
- 2 years from shipment or manufacturing date (for SapphireH100 – 180 days).

SapphirePlus Software 14.50.0

- The next certification date on SapphirePlus SW rev 14.50.0 is referred to as Next Checkup. The Next Checkup date is displayed on the pump: **Options → View → View system → Next checkup**.
- After burning software 14.50.0, the next checkup date will be extended by two years from the last certification.
- If the FasTest PM/ACT was performed and passed on a SapphirePlus pump with software 14.50.0, the next checkup date will be two years from the date the FasTest PM/ACT was performed.

The certificate provided at the end of the certification will display the date of the next checkup as one year from the day the certification was performed.

Testing Rationale of the Certification Process

The certification process involves a visual and safety inspection, and 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, indicating that the next required testing date is approaching:

- 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.

In Sapphire Multi-therapy and Sapphire Epidural Rev 15 these messages are not displayed.

Shared Certification Notes

The instructions in this section are shared to both the FasTest PM and the ACT certification methods.

System Requirements

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

- Operating System: Windows 7, Windows 10 (for ACT only: Windows 8)
- .NET Framework 4.0
- FasTest PM/ACT setup file: an ".msi" or ".exe" file
- Screen Resolution: 1024:768 (minimum), 96 DPI
- Memory: 4 GB
- Internet Access

Acquiring the Software

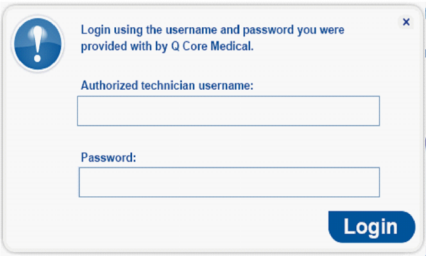
The Certification PC tool software can be obtained from Q Core FTP site (https://qcore.smartfile.com).For information regarding the FTP site, refer to FTP site on page 32.

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 at service@qcore.com for a new password, or if username or password have been forgotten.

Figure 4.1. Login Screen



FasTest PM is available for rev15 users and licensed Service Centers.

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.

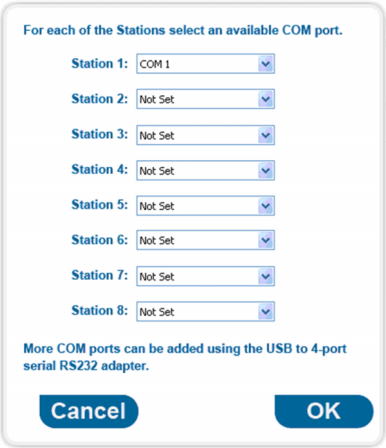
You can connect a single pump via serial port (see To connect via a Serial Port: on page 88); for configuring additional COM ports to your PC, use the USB to 4-port serial RS232 adapter, see the following explanation on page 88.

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 a Serial Port:

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 4.2. 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.

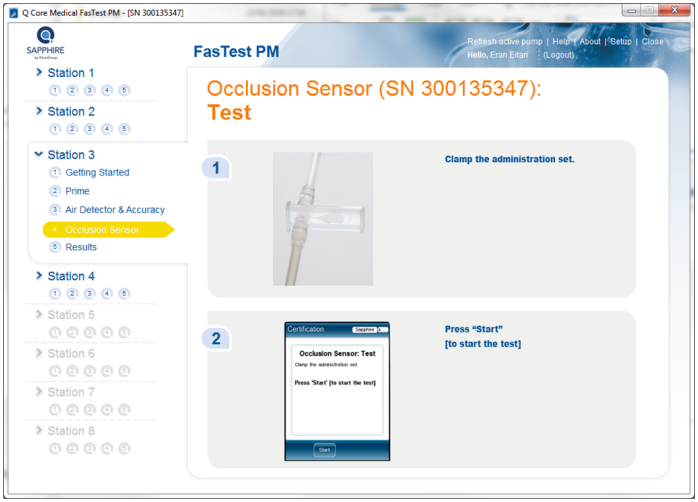
> To use the Q Core USB to 4-port serial RS232 adapter (for enabling additional COM ports):

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 4.3. 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 3): Clamp the administration set; then, press **Start** to start the test).

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 90.

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 is connected to the active station (see Working with the Station Pane on page 90).
Help	Provides more detailed information/ instructions about certification testing.
About	Provides information about the software version and corresponding pump versions.
Setup	Configures stations to available COM ports. (See Working with the Station Pane on page 90.)
Close	Provides option to close the current/all tests, and to exit the program.
Login/Logout	Enters/exits the application.

Additionally, name of the user that logged in is also displayed before the Logout link.

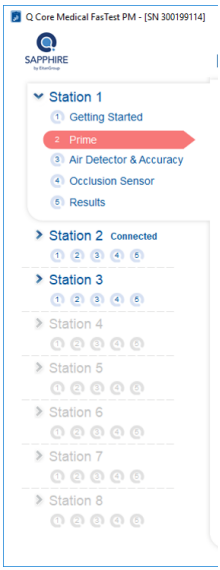
Working with the Station Pane

After the pumps are connected to the computer and turned on (Launching the Annual Certification Process on page 135), 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 4.4) 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.

	In Rev. 15, when the pump is connect to the PC the following icon will be displayed at the top right corner of the pump's screen: 

Figure 4.4. Station Pane

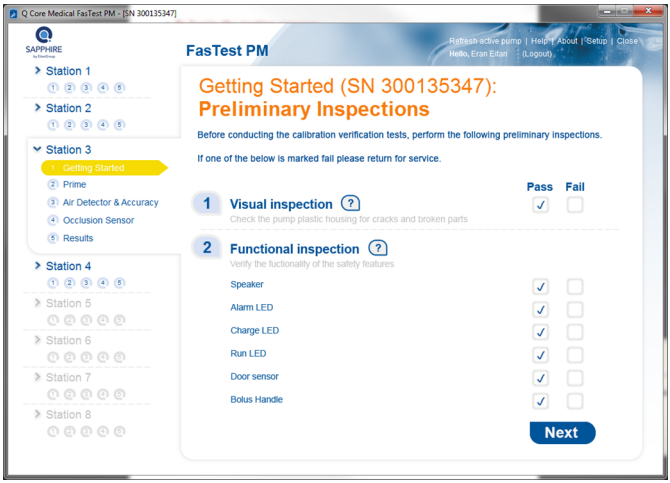


> To perform the Preliminary Inspections:

1. Perform Thorough Visual Inspection, as described in Thorough Visual Inspection on page 49. 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 56. Check Pass or Fail on applicable boxes next to Functional Inspections according to findings.
3. When using an SC bolus handle (bolus handle with a grey button), test the bolus handle prior to connecting the pump to the computer.

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

Figure 4.5. Getting Started Screen



Shared Troubleshooting

Communication

The following issues can arise due to communication problems in either the FasTest PM or the ACT certification methods:

Problem	Management
The following message appears after trying to install the certification Software: Service 'Q Core Logger Server' (QCoreLoggerSrv) failed to start. Verify that you have sufficient privileges to start system services.	Contact your IT department – re-install the software as an Administrator.
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 distributor. Refer to page 268.
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 distributor. Refer to page 268.
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 distributor. Refer to page 268.
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 distributor. Refer to page 268.
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.

General

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

Problem	Management
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 with an attached pump that is not live; 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.
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 189 and attend the alarm as instructed. • Restart the certification process.

Problem	Management
Some of the graphic information was not transferred and is missing from the pump screen (title, text, buttons).	• If text or title is missing, or a button is missing, or an image is missing, from the PC, select the active pump; then, press the **Refresh Active Pump** link at the top-right. The display on the selected pump will be refreshed. • 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 the process.
The next certification due date, as it appears in the certification provided at the end of the certification process, is different than the next certification due date in the **View system** menu on the pump.	• The next certification due date as it appears in the certification is the correct one. • The next certification due date in the **View system** menu will be updated with the correct date as it appears in the certification, after the pump has been operating for one second. • There may be a difference of one day between the dates that appear as the next certification due date in the **Certification**, and in the **View system** menu.

The certification process will prompt a message in the following cases:

Case	Message Displayed	Solution
Unauthorized pump software version.	The software version installed on this pump is obsolete! Please update the software to an authorized version before proceeding with the process. Authorized software versions are available for download from Q Core FTP site at https://qcore.smartfile.com/. A valid username and password is required to access the website.	Update the pump software to an approved version before proceeding. Approved pump software versions are available for download on the Q Core Medical FTP site at https://qcore.smartfile.com/. Valid username and password are required in order to access the website.
Obsolete certification software version.	The certification software version you are using is out of date. A new version of the certification software is available for download from Q Core FTP site at https://qcore.smartfile.com/. A valid username and password is required to access the website.	Install the most updated certification software.

Case	Message Displayed	Solution
Incompatible display settings – Windows 7 and Windows 8.	FasTest PM and Annual certifications are designed to work with a screen resolution of 96 DPI (Dots Per Inch) only. Please change your display settings and reopen the application.	1. Right-click on an empty area on your desktop and select Display. 2. Change the size of text to 100% and exit settings. **Note:** if "Change the size of text" option is grayed out, log out of Windows; then, log in again. 3. Reopen Q Core PC tool, and verify that the PC tool works.

Case	Message Displayed	Solution
Incompatible display settings – Windows 10	FasTest PM and Annual Certification are designed to work with a screen resolution of 96 DPI (Dots Per Inch) only. Please change your display settings and reopen the application.	**Change DPI Scaling for the entire PC** 1. Open **Settings**, and click System **Start** → **Settings** → **View** Or Right-click on an empty area on your desktop and select **Display Settings**. 2. In the System Settings screen, click the **Display** option. 3. Change the size of text to 100% and exit the settings. **Note:** If **Change the size of text** option is grayed out, log out of Windows; then, log in again. 4. Reopen Q Core PC tool and verify that PC tool works. **Change DPI Scaling for Q CORE Apps Only** 1. Right-click **FasTest PM**/ **Annual Certification Test** → **Price Properties**. 2. In the **Computably** tab; then, click **Settings** → Change high DPI settings → Select check box, setting to fix scaling problems for these programs instead of the one in settings.

FasTest PM Test Method

The following sections detail the FasTest PM certification process for the Sapphire pump:

FasTest PM Certification Overview

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

The five stages of testing are:

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

Each station in the navigation pane corresponds to a pump (see Figure 4.6).

- Stations that are not configured are disabled and appear in gray
- Stations that are configured but have no pump connected to them appear in blue
- Stations that are configured and have a pump connected to them appear in blue with the icon "Connected" next to them.

Figure 4.6. Station Status

FasTest PM Calibration Verification Process

The heart of the FasTest PM process is the calibration verification, which is made up of the following set of tests:

- Air Detection
- Flow Accuracy
- Occlusion Sensing

To facilitate the testing process, Q Core has developed a special testing application. The software application provides step-by-step testing instructions with a summarized version of the same instructions displayed on the pump itself. The application allows you to simultaneously test up to eight pumps, using a USB to 4-port serial RS232 adapter, which can be purchased separately from Q Core.

FasTest PM Certification Kit

The FasTest PM 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 up to 30 pumps. The FasTest PM Kit is designed to be used in conjunction with Q Core's FasTest PM 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 FasTest PM 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	1800 mm tubing, with (i) spike, (ii) Syringe (iii) back check valve (iv) Y-connector (v) T-connector (vi) administration cassette, (vii) slide clamp, (viii) Sleeve, (ix) Fluid bag cap (See Figure 4.7)	All tests
Fluid bag	Plastic bag that can hold up to 500 mL (See Figure 4.8).	All tests

Figure 4.7. Administration Set

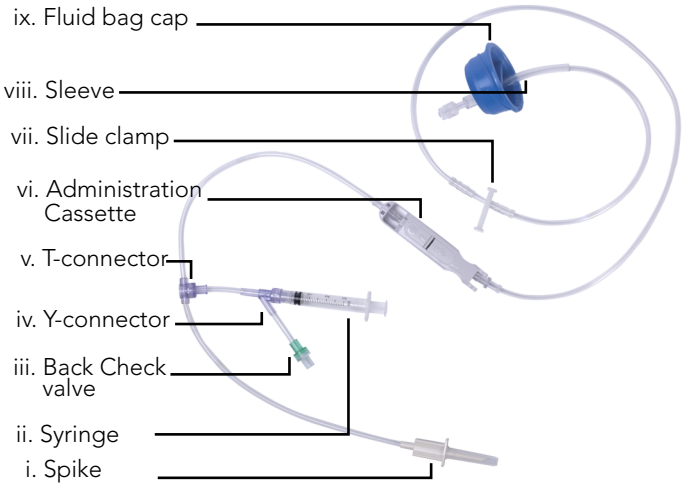


Figure 4.8. Fluid Bag

FasTest PM Certification Software

> To install the FasTest PM software:

1. Download the FasTest PM Setup file (.exe file) from the Q Core Medical FTP site to a directory of your choice.
2. Double-click the FasTest PM Setup file to start the installation process; then, click **Next**.
3. Review the license agreement details, and select the relevant checkbox to accept.
4. To create a shortcut to the FasTest PM software, select/unselect the relevant checkbox as desired.
5. Click **Install**.
6. After the installation process is completed, click **Finish**.

	In order to install the SW together with RS232 driver, it is reuqired to execute the "FasTest PM Setup.exe" as an administrator – from the cmd line.

FasTest PM Certification Test

Overview

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

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

	The FasTest PM 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 to perform the FasTest PM procedure:

- Q Core FasTest PM Kit(s).
- At least 100 mL water for each kit (the infusion bag is supplied with the kit).
- RS232 COM ports, or Serial on USB (optional).
- Motorola LS2008 barcode reader (optional); you may enter the barcode key manually instead.
- RS232 communication cable between pump and computer.

Before beginning the tests, make sure that the FasTest PM Kits contain all the original parts supplied by Q Core (Kit Components on page 128).

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.

- Room temperature: 20° C ± 5° C
- Relative humidity: up to 70%
- Pump position: straight and vertical
- Tubes are not kinked, and the clamp is set to open.
- The required distance between the center of the pump and the bottom of water level in the bag is 50 cm above the pump (page 110).

> 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 FasTest PM test.

1. Set pump authorization level to **High**.
2. Select **Options →Pump Configuration →General settings →Authorization level** and select **High.** Press **Next** and then **OK**.

> After clicking a station to start the test, if the pump is not set to High Authorization level, a stating to set the pump to High Authorization level will appear on screen.

> To begin the testing process:

1. Log in to the Q Core FasTest PM Software (Logging In on page 87).

> If this is the first time you run this program, you need to configure your stations and COM ports first. Verify that the driver has been installed successfully. The FasTest PM software automatically recognizes the ports that successfully connected to the pumps (See Working with the Station Pane on page 90.)

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

> To perform the Preliminary Steps:

1. Visually inspect the station to verify that all the parts have been correctly installed and connected.
2. Perform the preliminary inspection of the pump, according to To perform the Preliminary Inspections: on page 92, and fill the Preliminary Inspections result via the FasTest PM Software.

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

> To perform the Kit Selection:

1. Using the barcode reader (or the keyboard), enter the barcode number of the FasTest PM Kit and verify that the barcode number has 7 characters, and that the PC language is set to English (some characters, such as "/" will be translated and will not reflect the actual serial number of the kit).

   The barcode can be found on the Directions for Use. The same barcode is also located on the fluid bag.

   After entering (or scanning) the barcode number, it appears in the **Kit Serial Number** field.

After the certification test is completed on the pump, the user can press the **Reuse Barcode** button to reuse the kit's 7-character barcode for running the FasTest PM on the next pump, without needing to rescan or retype the barcode. Closing the FasTest PM Software will cancel this function, and require the user to re-enter (or rescan) the barcode.

Figure 4.9. The Reuse Barcode Button

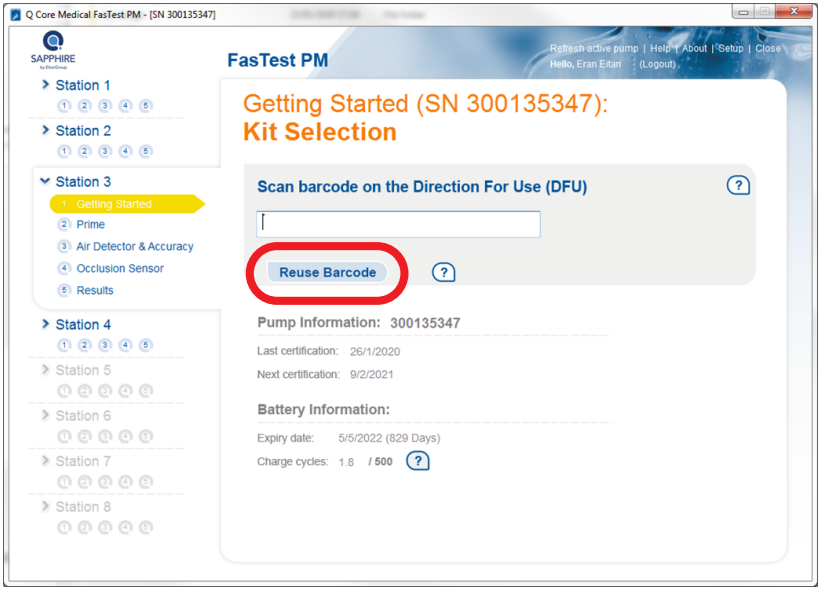
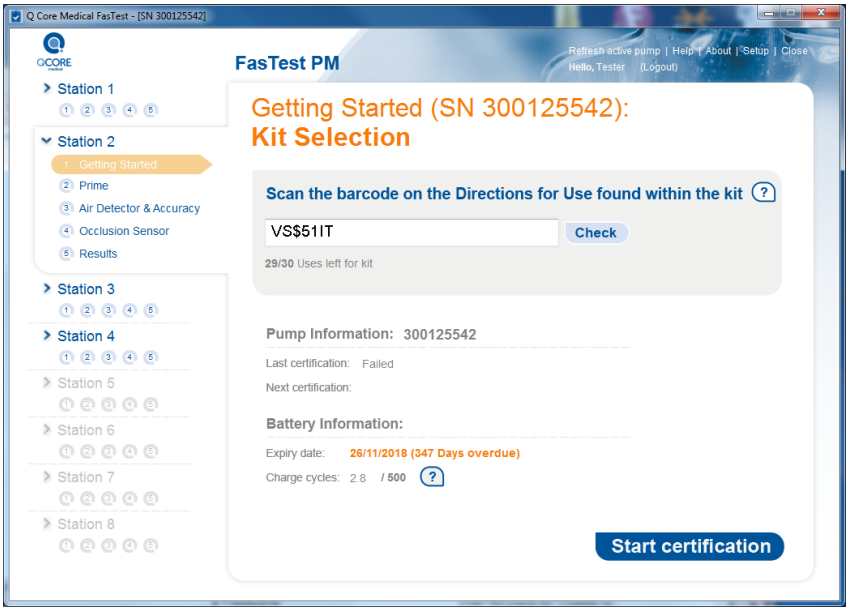


Figure 4.10. Battery information on the Kit selection screen



The battery information contains:

- **Expiry date** displays the expiry date and number of days left to or overdue from that date.
- **Charge cycles** displayed as "x / 500".

One charging cycle is defined as the cycle of the battery charging from depletion to full charge. Partial cycle is defined as the fraction of a full cycle.

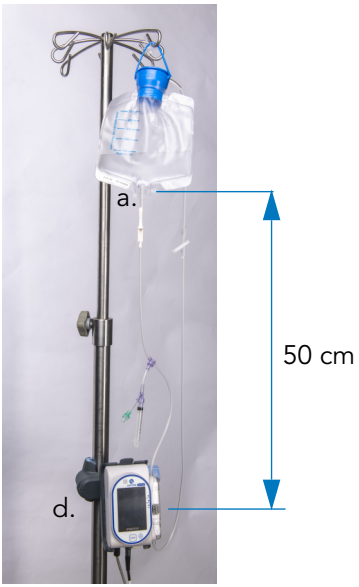
2. Click **Check**. The Q Core server checks the validity of the kit.

The kit is limited to 30 uses. Save the DFU for further eligible uses of the kit.

3. To start the first stage (Prime), click **Start certification**.

4. Set up the FasTest PM according to the following instructions:

   a. Insert the administration set spike into the bottom of the bag.
   b. Fill the bag with water (>100 mL) and close the cap.
   c. Hang the bag on an IV pole.
   d. Position the pump on the Mini Cradle in an upright vertical position, and make sure it is turned on.
   e. Insert the administration cassette into the pump and close the door.
   f. Adjust the bag height so that the water level in the bag is 50 cm above the pump.



During the test, it is recommended to connect the pump to a power supply.

> When the pump is connected to a power supply, the battery icon (on the pump indication bar) displays one bar, although the pump is recharging. The indication for the pump being charged can be obtain via the "Charge" LED on the pump.

5. On the pump, press **Next** to proceed to the Prime step.

For each of the tests (Air Detector & Accuracy and Occlusion Sensor) there are two retries available. Failing the two retries on any of these tests counts the entire certification test, and renders it FAILED. Operational errors, such as forgetting to insert air or clamping the set, will not be counted as retries. Each kit is limited to 30 certification tests.

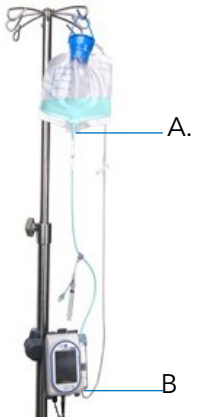
At any stage of the test, the user may re-start it, by pressing on the "Stop" hard key below the pump screen, or the "Quit" button on the pump screen. The test returns to the "Prime" step – stopped tests will not be counted as retries.

Performing the Prime Step

This is an optional stage. It is necessary only in the following cases:

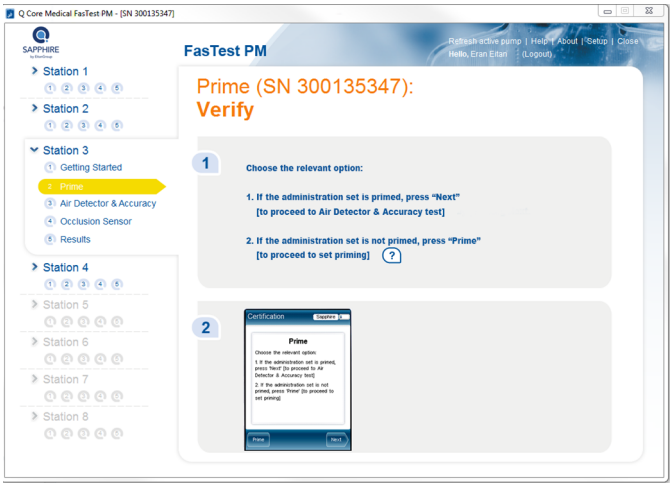
- When using a new FasTest PM Kit
- The upstream segment between the spike (A) and the bottom of the administration cassette (B) contains air.

When certifying subsequent pumps, priming is not required – as long as the upstream segment of the set is primed.



Note that as of this stage, the procedure is operated via the pump.

Figure 4.11. Priming Screen



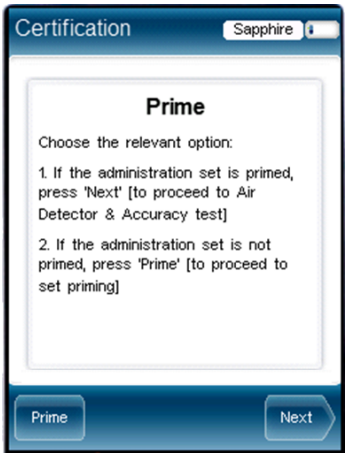
> To perform Priming:

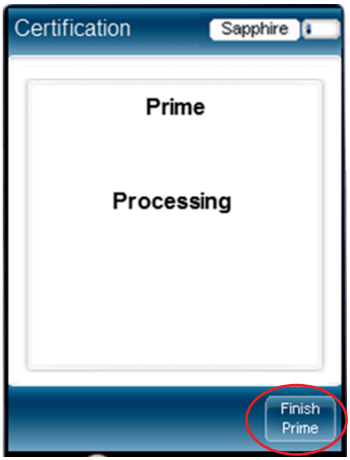
1. Prepare the infusion bag and the administration set:
   a. Fill the bag with at least 100 mL of tap water, and attach the administration set to the bag.
   b. Adjust the bag height, so that the water level in the bag is 50 cm above the pump.
   c. Attach the administration set to the pump, and close the safety door.

2. If required, press **Prime**.

The priming process can be finished at any time by pressing **Finish Prime**. This option can be used if the user observes that there is no air in the tube (between the spike and the bottom of the administration cassette – see page 111).

If not required, press **Next**.





Wait for the pump and software to synchronize.

3. Press "Next" to proceed to the Air Detector & Accuracy test.

Performing the Air Detector & Accuracy Process

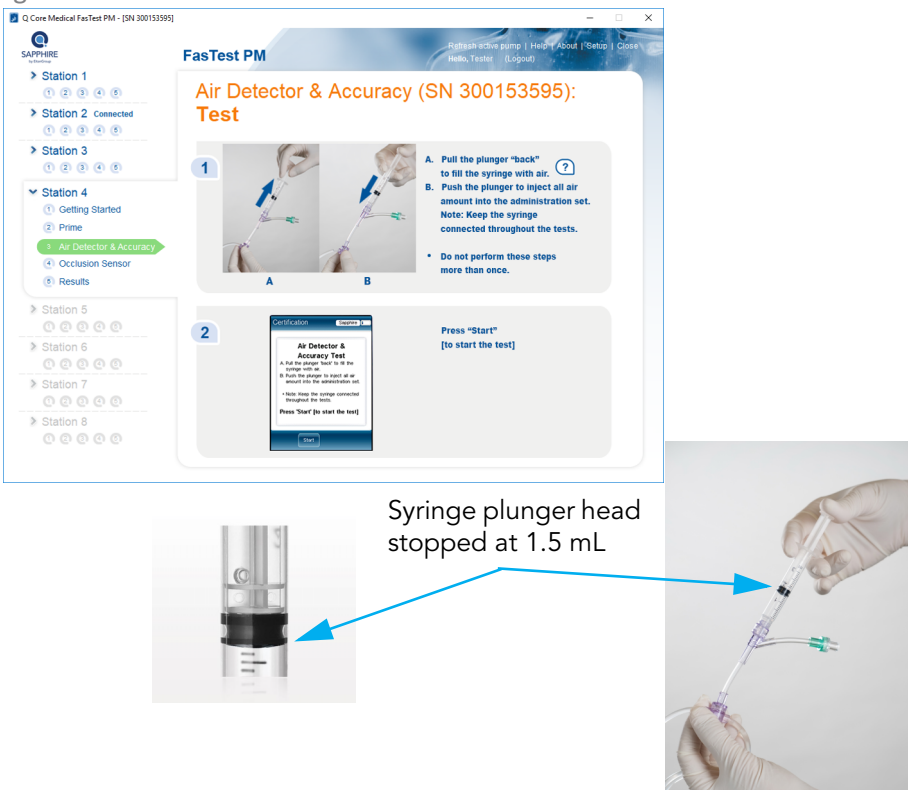
This test involves introducing a pre-specifiied amount of air into the administration set.

The application checks if the pump detected air in the system, and whether the measured infused volume is correct (checks it versus the expected volume).

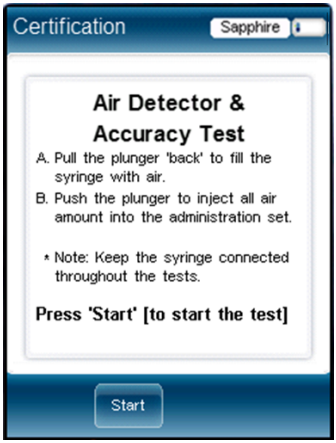
> To perform the Air Detector & Accuracy test:

1. Continuing from the previous stage, without disconnecting the syringe, pull the plunger back all the way to the 1.5 mL stopper; then, push in all the way to the Y-connector (Figure 4.12 on page 114).

Figure 4.12. Air Detector Test

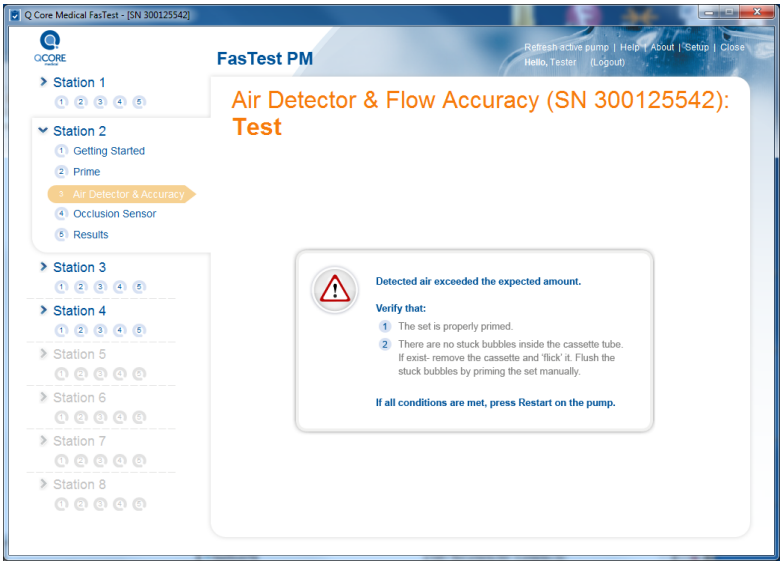


2. This inserts 1.5 mL of air into the administration set, via the Y-connector; then, on the pump, press **Start**.

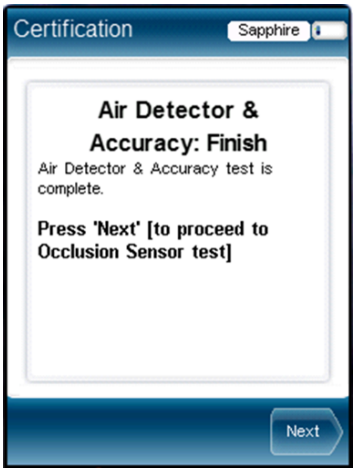


The pump starts delivering the water. When the stage is completed, the pump stops.

If a fault was detected, an error message is displayed with recommended corrective actions (see example below).



3. To proceed to the next test (Occlusion Sensor), on the pump, press **Next**.



Performing the Occlusion Sensor Test

This test involves delivering a known volume of fluid; then, creating pressure in the system – caused by introducing a specific amount of air into the administration set against a closed clamp.

> To perform the Occlusion Sensor test:

1. Set the administration clamp to CLOSED (clamp the administration set).

	During the FasTest PM process, do not remove the administration cassette from the pump.

Figure 4.13. Operating the Clamp

OPEN (Unclamped)

CLOSED (Clamped)

2. On the pump, press **Start**.

3. When the test is completed, set the administration clamp to OPEN (unclamp the administration set); then, on the pump, press **Next**.

4. On the pump, press **Next**.

Viewing Results

1. To complete the certification testing process and generate results, on the pump, press **Finish**.

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

- The field Device SW version displays the pump software version. Verify the pump software matches the pump type. For example, make sure All modes software designated for Multi Therapy pumps is not installed on an Epidural pump (yellow Lexan). Upgrade the software if applicable to ensure the correct software is installed on the pump per latest Labeling and Software Revision Table, 15000-004-0002-SM or Labeling & SW Revisions Table for Q Core Service Providers, 15000-004-0003-SM.
- The Occlusion sensor test and Accuracy test results are displayed on scales

- The Occlusion sensor test result is displayed on a scale in Bar units. An arrow and a number below it indicate the result. Any result within the limits is defined as "Pass" (see Figure 4.14).
- The Accuracy test result is displayed on a scale in percentage. An arrow and a number below it indicate the result. Any result within the limits is defined as "Pass" (see Figure 4.14).
- The certification can be printed or saved on the computer in soft copy (see icons on the top right corner in the figure below). When pressing the save icon, wait for the dialog box to appear and select the desired destination of the saved file.

	The Next certification date in the pump's View system menu will be updated after the pump has been operating for one second (That is, one second of treatment or of priming).

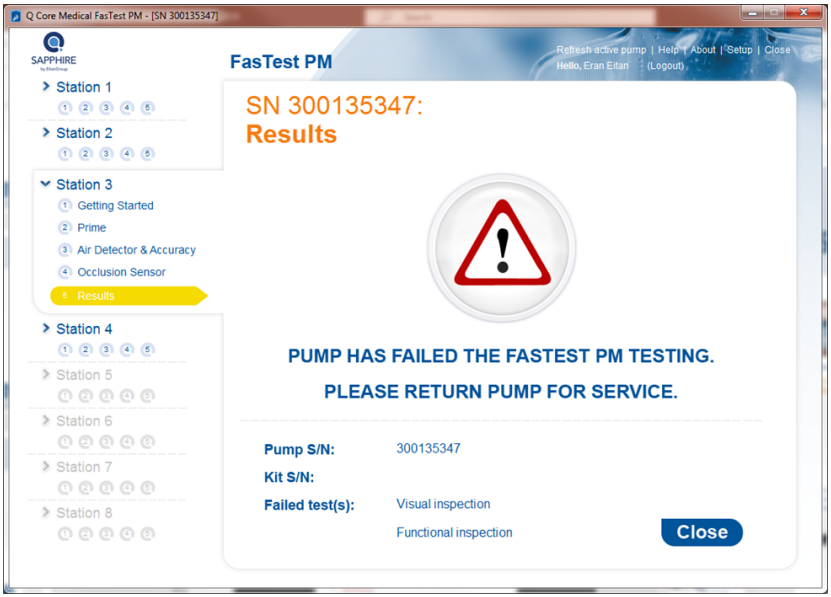
Figure 4.14. FasTest PM Results – Passed

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.

In case of failure in the Preliminary Inspections, the reason(s) for the failure will be either one (or both) of the following (see Figure 4.15):

- Visual inspection
- Functional inspection

Figure 4.15. FasTest PM Results – Failure

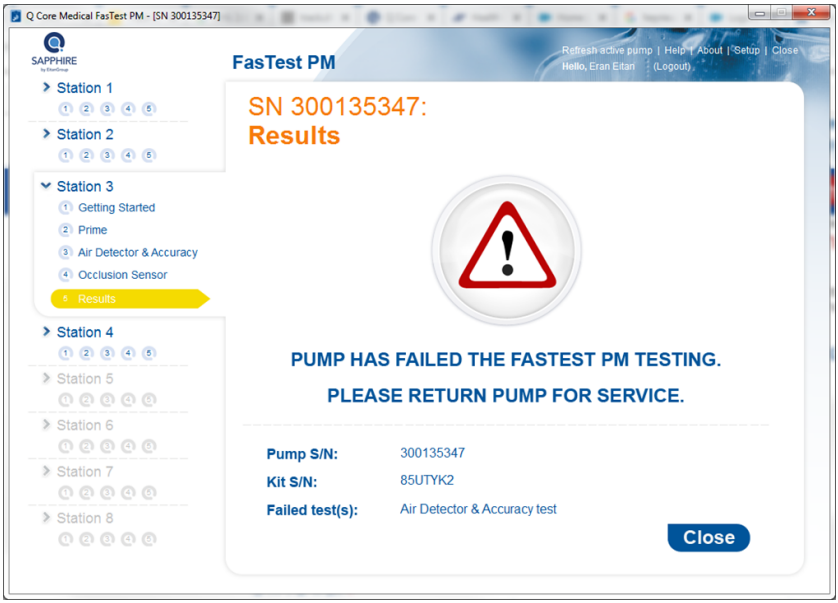


In case of failure in the calibration verification tests, the reason(s) for the failure will be one (or more) of the following (see figure below):

- Occlusion Sensor
- Air Detector
- Flow Accuracy

Only the results of failed tests will be displayed. If the Occlusion sensor test or the Accuracy test fails, the arrow and the number below it will be displayed outside the scale, on the relevant side of it (see figure below).

Figure 4.16. FasTest PM Failure – Calibration Verification



Please note that failed pumps have to be returned for service.

FasTest PM – Following the Certification

After the device passes the FasTest PM test, verify the following:

- The date and time are set to local date and time. Adjust as necessary.
- The new FasTest PM 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 FasTest PM. This date will be updated to +380 days when the pump is put to use.

Disconnect the pump from the FasTest PM software.

In case the FasTest PM terminated unexpectedly, or pump became disconnected during the test, make sure the following pump parameters are set as required:

- Accumulated Bubble Size
- Single Bubble Size
- Accumulated Threshold

In the event that the FasTest PM terminates unexpectedly, it is recommended to set the pump to factory defaults.

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

	In REV 14.50.0 after test completion, the pump displays the "Infusion completed" screen, and not the Main screen ("New Infusion screen")

FasTest PM Troubleshooting

The following sections explain how to troubleshoot common problems that may arise while performing the FasTest PM certification process:

Air Detector & Flow Accuracy Test

The following issues can arise during the Air Detector & Flow test:

Problem	Management
Occlusion alarm alert appears during the Air Detector & Flow Accuracy test.	Verify that the administration clamp is set to OPEN; then, perform Reset of the Test (see Occlusion Sensor Test on page 124).
The user forgot to introduce air into the set.	Repeat the Air Detector & Flow Accuracy Test. Pay attention to follow the instructions as they are displayed.
Air could not be detected by the Air Detector.	Verify the following: 1. Air has been appropriately inserted to the set. 2. Cassette chamber is clean. To verify cassette chamber is clean: a. Remove the administration cassette from the pump. b. Verify that the light sensor, located above the pump fingers in the cassette chamber, is clean. (Figure 3.4 on page 51). To clean, see Chapter 3: Maintenance and Storage on page 42. c. Reinsert the administration cassette.

Problem	Management
Detected air exceeded the expected amount.	Check the following: 1. The set is properly primed. 2. There are no stuck bubbles inside the cassette tube. If there are, remove the cassette and "flick" it. Flush the stuck bubbles by priming the set manually: a. Remove the administration cassette from the pump. b. Open the Anti Free Flow Valve (AFFV) on the administration cassette. c. Prime the set. Make sure that all air has been removed.
Accuracy could not be verified.	Verify the following: 1. The set is properly primed. 2. The fluid bag is not empty. 3. There are no kinks along the administration set.

Occlusion Sensor Test

The following issues can arise during the Occlusion Sensor test:

Problem	Management
Reset of the Test.	At any failure of the Occlusion Test, repeat the **Air Detector Test** and/or the **Flow Accuracy Test**, as detailed by the FasTest PM software.
An error message appears.	Perform Reset of the Test.
Test was performed incorrectly, and needs to be restarted.	Perform Reset of the Test.
Occlusion sensor could not detect the expected increase in pressure.	Verify the following: 1. The administration set is not damaged. 2. The administration set was clamped.

FasTest PM General

For issues common to both ACT and FasTest, see also General on page 95

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

Problem	Management
Unauthorized Pump message appears.	The pump is running a software that is not rev. 15. Upgrade the software – contact the support team for further instructions.
The FasTest PM software stops during the test.	Re-start the FasTest PM software and begin the test from the start.
The certificate printing process failed; information is printed without the certificate image background.	Perform one of the following options: 1. Go to the service portal https://service.qcore.com/; and search for the Device; then, from the Maintenance tab, download the certificate. 2. Provide the pump S/N and certification date to service@qcore.com and the certificate will be emailed to you. 3. Use the "print screen" option and copy the certificate image to a suitable application to print.
During the FasTest PM installation, the following is prompted: "This application requires .NET Framework 4.0 full, please install the .NET Framework and then run the installer again."	• Click **OK** to cancel the installation. • On the computer: Go to **Start →All Programs →Windows Update.** • Select Optional Updates and then select **.NET Framework 4.0**. • Follow the online instructions to complete the update. • Double-click the FasTest PM Setup file to start the installation again.
Error message: "Battery Issue".	Contact Q Core Service department for more information.

Problem	Management
Test failure.	• Check the administration set, to see if there are any residues in the water. If there are visible residues, replace with fresh water. • Check if the clamp area is occluded. If it is, replace the set.

Annual Certification Test (ACT) Method

The following sections detail the Annual Certification Test (ACT) process for the Sapphire pump:

ACT 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.

ACT Kit

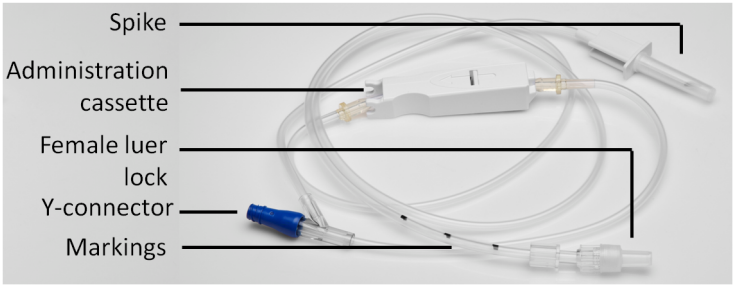
The Annual Certification Kit is a pre-packaged kit provided by Q Core, which contains all the special equipment necessary for performing certification testing. One kit can be used for testing 5 pumps. The Annual Certification Kit is designed to be used in conjunction with Q Core's Annual Certification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

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 4.17)	All tests
Extension set	5-8 cm tubing, with female luer lock and check valve (with female luer lock). (See Figure 4.18)	Occlusion Sensor test
Syringe	5 mL (no needle). (See Figure 4.19)	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 4.20 and Figure 4.21)	Flow Accuracy test
Hydrophobic filters (6) **Note**: Only 5 are required; one extra is included.	3 micron hydrophobic filter. (See Figure 4.22)	Flow Accuracy test

Figure 4.17. 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 4.18. Extension Set

Figure 4.19. Syringe

Figure 4.20. Flow Accuracy Container

Figure 4.21. Flow Accuracy Container: cap

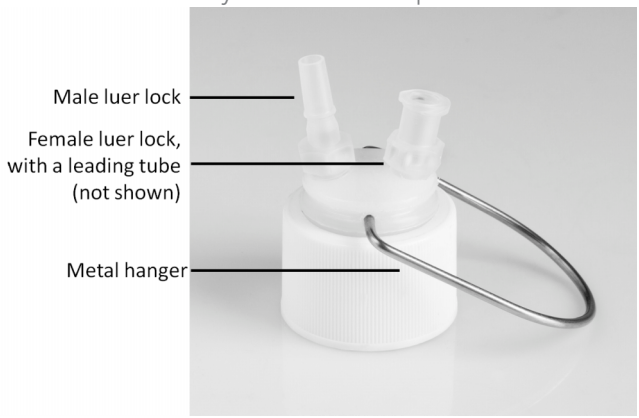


Figure 4.22. Hydrophobic filter (6)

ACT 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:

ACT Software Installation Process

1. Download the setup file **ACT Setup** (.msi or .exe file) from the Q Core Medical FTP site to a directory of your choice.
2. Double-click the **ACT Setup** file to start the installation process and click **Next**.
3. Review the license agreement details and check the relevant checkbox to accept.
4. To create a shortcut to the ACT software check/uncheck the relevant checkbox, as desired.

5. Click **Install**.
6. After the installation is completed click **Finish**.

The Station Pane

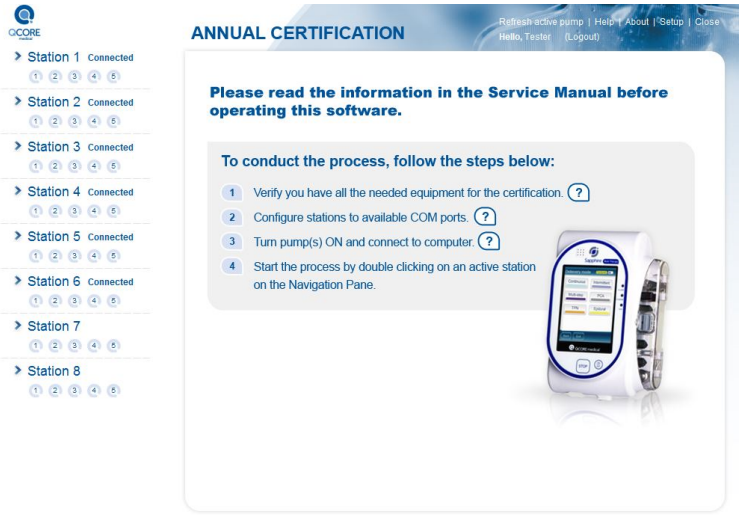
The five stages of testing (listed 1-5 on the pane) are:

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

Each station in the navigation pane corresponds to a pump (see figure below).

- Stations that are not configured are disabled and appear in gray
- Stations that are configured but have no pump connected to them appear in blue
- Stations that are configured and have a pump connected to them appear in blue with the icon "Connected" next to them.

Figure 4.23. Station Status



ACT Certification Tests

The following sections explain how to perform the required Annual Certification Tests (ACT) 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.

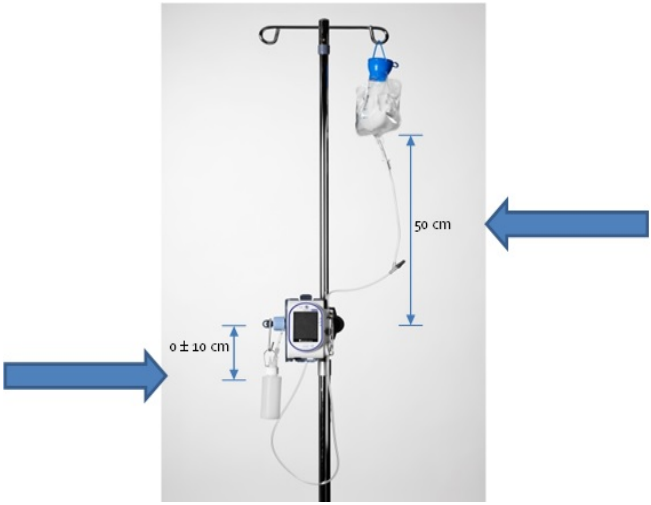
Before beginning the tests, make sure that the Annual Certification Kits contain all the original parts supplied by Q Core (Kit Components on page 128).

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 4.24).
- The required distance between the center of the pump and the bottom of the container cap is 0 ±10 cm (Figure 4.24).

Figure 4.24. 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. In software versions that support the disabling of Air detection:
   a. If the Air Detection disabled icon,  , appears on the indicators bar, enable the Air Detection (On). If pump is connected to mini cradle, disconnect it from mini cradle Select: **Options →Technician options →Pump settings →Set air detector →Air Detection**. Toggle the setting to **On** and press **OK**.
   b. For Epidural Devices, this icon  will not be displayed if air detectors are disabled. The air detectors are disabled if both Single Air Detector and Accumulated Threshold are set to OFF. To turn air detector on change the Accumulated Threshold to 1 mL disconnect pump from mini cradle. **Options →Technician options →Pump settings →Air Detector →Accumulated Threshold** and select **1 mL**. If the device has a drug library and both detector Single Air Detector and Accumulated Threshold are set to OFF, disconnect pump from mini cradle, set the Accumulated Threshold to 1 mL. These changes will be in effect when the device is on, once device is turned off, the values will revert back to drug library settings.
   c. From the **Start** menu, select **Options →Pump Configuration → General settings →Authorization level** and choose **High.** Press **Next** and then **OK**.

	After clicking a station to start the test, if the pump is not set to High Authorization level, a stating to set the pump to High Authorization level will appear on screen.

2. Perform the preliminary inspection according to To perform the Preliminary Inspections: on page 92.

	By clicking **Next**, the user who is logged in confirms 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 87).

> 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 90.)

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.

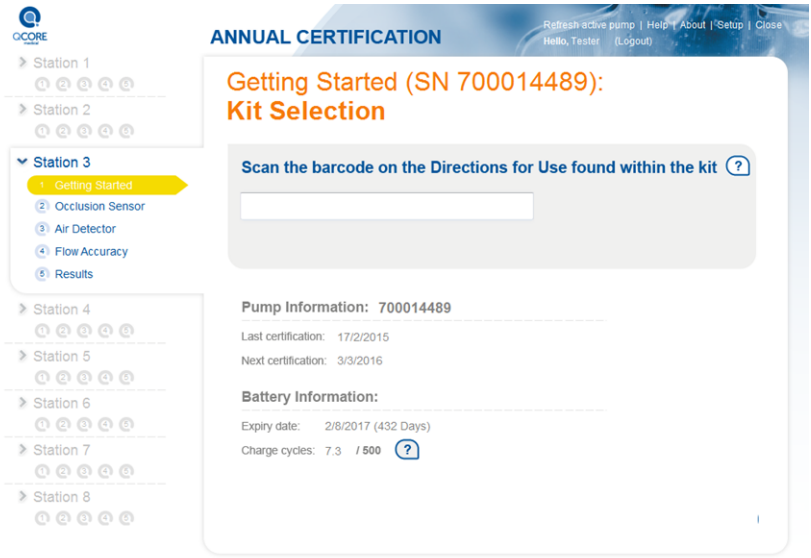
> To perform the Kit Selection:

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.

Figure 4.25. Battery information on the Kit selection screen



The battery information includes:

- Battery expiry date.
- Charge cycles displayed as "x / 500".

One charging cycle is defined as the cycle of the battery charging from depletion to full charge.

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 4.18 on page 129); then, fill the syringe with air, and connect it to the check valve at the free end of the extension set.
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 4.17 on page 129). 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 syringe from the extension set and then remove the extension set from the administration set.
2. Connect the syringeto the Y-connector (Figure 4.17 on page 129). Using the syringe, insert 1 mL of air into the administration set, via the Y-connector and disconnect the syringe. Then, on the pump, press **Start**.

   Infusion of fluid starts, and then (when the air is detected) 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 4.26. 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:

- The Occlusion sensor test and the Accuracy test results are displayed on a scale. An arrow and a number below it indicate the result. Any result within the limits is defined as "Pass" (see Figure 4.27).
- The certification can be printed or saved on the computer in soft copy (see icons on the top right corner in the figure below). When pressing the

save icon, wait for the dialog box to appear and select the desired destination of the saved file.

	The certification can also be found in the Portal.

	The Next certification date in the pump's View system menu will be updated after the pump has been operated for one second (That is, one second of treatment or of priming).

Figure 4.27. ACT Results

For the certification process to be successful, you must have the Preliminary Inspections confirmed and the pump passed all 3 tests. After verifying that all tests have passed, close the AnnualCertification 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.

In case of failure in the Preliminary Inspections, the reason(s) for the failure will be either one (or both) of the following (see Figure 4.28):

- Visual inspection
- Functional inspection

Figure 4.28. ACT Failure – Preliminary

In case the ACT has terminated unexpectedly, the following pump parameters may change:

- KVO in Continuous delivery mode
- Set Prime Volume
- Accumulated Air detector

In the event that the ACT terminates unexpectedly, we recommend that you set the pump to factory defaults.

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

In case of failure in the calibration verification tests, the reason(s) for the failure will be one (or more) of the following (see figure below):

- Occlusion Sensor
- Air Detector
- Flow Accuracy

Only the results of failed tests will be displayed. If the Occlusion sensor test or the Accuracy test fails, the arrow and the number below it will be displayed outside the scale, on the relevant side of it (see figure below).

Figure 4.29. ACT Failure – Calibration Verification

Please note that failed pumps have to be returned for service.

ACT – Following the Certification

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

- The date and time are set to local date and time. Adjust as necessary.

The new ACT 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 ACT. This date will be updated to +380 days when the pump is put to use.

Disconnect the pump from the Annual Certification software.

ACT Troubleshooting

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

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 87.

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

ACT General

For issues common to both ACT and FasTest PM, see also General on page 95

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

Problem	Management
The ACT software stops during the test	Re-start the ACT software and begin the test from the start.
The ACT test failed	Repeat the ACT 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.)
The certificate printing process failed; information is printed without the certificate image background.	Perform one of the following options: 1.Go to the service portal https://service.qcore.com/; and search for the Device; then, from the Maintenance tab, download the certificate.2.Provide the pump S/N and certification date to service@qcore.com and the certificate will be emailed to you. 3.Use the "print screen" option and copy the certificate image to a suitable application to print.
During the ACT installation the following is prompted: "This application requires .NET Framework 4.0 full, please install the .NET Framework and then run the installer again."	• Click **OK** to cancel the installation. • On the computer: Go to **Start →All Programs →Windows Update.** • Select Optional Updates and then select **.NET Framework 4.0**. • Follow the online instructions to complete the update. • Double-click the ACT Setup file to start the installation again.

Problem	Management
During the ACT installation the following is prompted: "This application is supported on Windows XP, Windows 7 and higher."	• Use a computer with the appropriate operating system.

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Chapter 5: 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.

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

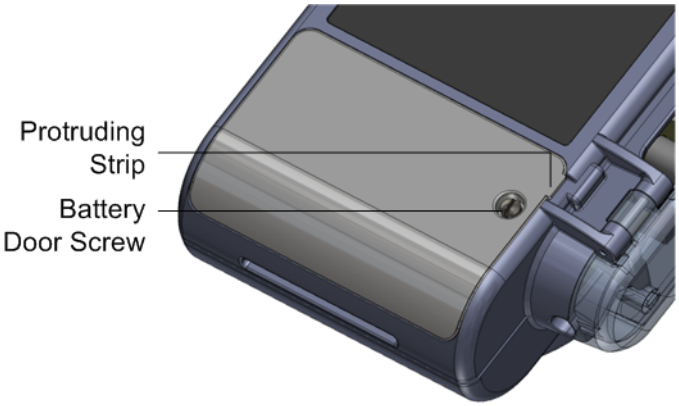
The following procedure explains how to change the battery. Before beginning, it is recommended to disconnect the administration set from the pump, and clean/sterilize the pump. After replacing the battery it is required to set the date and the time.

It is possible to set the date and time in the Pump Configuration menu. See Defining Regional Parameters on page 170 (Sapphire and SapphireH100) or Defining Regional Parameters on page 230 (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 5.1. 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.

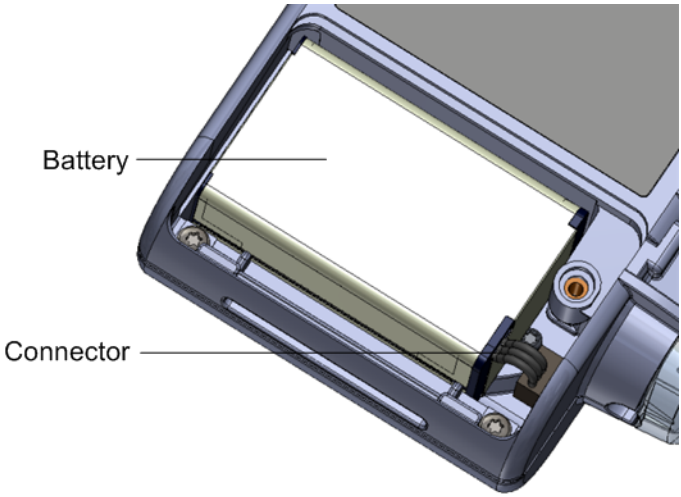
5. Set the old battery aside, record the new battery's serial number prior to installing it in the device. Report the battery's serial number in the Service Portal.

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

	<u>Reporting on battery replacement in the Service Portal:</u> • Go to the Service portal in the following address https://service.qcore.com/Main.aspx. • Login using your credentials. • In the Service Portal Home Page click **Battery Replacement**. • Fill in the details of the device and the replaced battery. Proceed to the **Battery Replacement Report** and **Checkout**. For more information on the Service Portal refer to the Service Portal Work Instructions, 16019-049-0001-SRV.

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

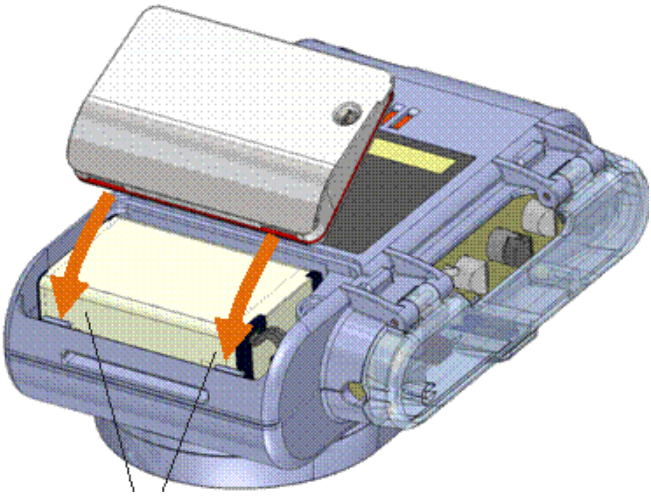
Figure 5.2. Battery Connector.



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 5.3. Installing the Battery Door



New battery cover

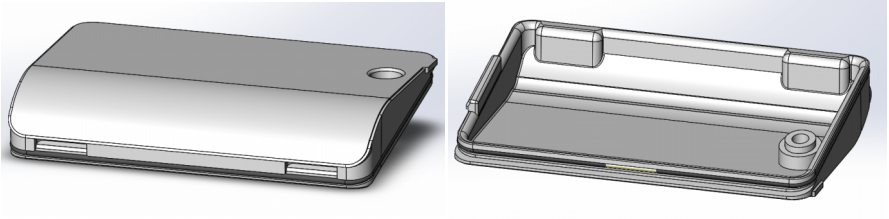
The new battery cover includes a white over-mold seal instead of the previous black one.

For pumps with the black O-ring seal on the battery cover, verify that the O-ring cannot be seen after closing the battery cover.

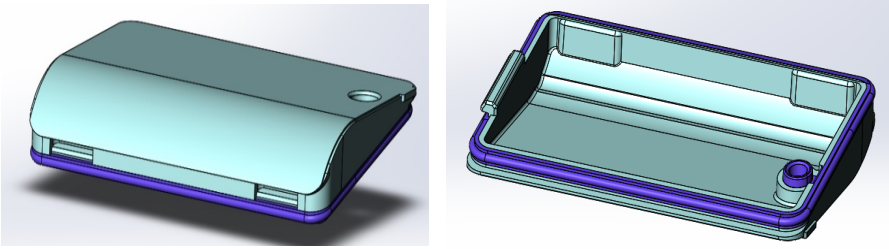
For pumps with the white over-mold seal on the battery cover, verify that the over-mold is not pinched, and that it cannot be seen after closing the battery cover.

Figure 5.4. Battery Covers Comparison

Current Battery Cover



New Battery Cover



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

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Chapter 6: 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	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	To Modify Parameter (from the Alarms screen)
Occlusion Alarm	The minimum downstream pressure that triggers an Occlusion alarm. Acceptable ranges are 1.5 to17.4 PSI, 0.1 to 1.2 BAR or 75 to 900 mmHg. An alarm sounds when the downstream pressure reaches the set value ± the sensor sensitivity level. During infusion, the current downstream pressure is displayed on the Pressure display screen (for more information refer to the SapphireH100 User Manual) and on the screen saver.	Select **Occlusion Alarm**. Then, using the keypad, enter the desired valueand press **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**.	Select **Infusion near end**. Then, select **1 min**, **3 min**, **5 min**, **10 min**, or **Off**.

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**.
- To save changes press **Next** and then **OK**.

Option	Descriptions/Notes	To Modify Parameter (from the General settings screen)
Current CCA	Used to select the CCA to which the pump should be set. Appears only when a Drug Library is loaded.	Select **Current CCA**. Choose the appropriate CCA; then, from the Attention screen press **OK**.
Start Up Config.	Set the configuration of the **Start Up** screen. Includes Repeat Last Infusion and PreProgram options. When the Repeat Last Infusion option is enabled, the Repeat Last Infusion frame appears on the Start Up screen.	See the User Manual
Authorization level	Sets the authorization lock level of the pump.	Select **Authorization level**. Then, enter a password and select **Low**, **Medium**, **High** or **Tech**.
Allow delayed start	Enables/disables programming of infusions that begin after a predefined period of time (or after standby). When the option is enabled, the Set Delay frame appears on the Start screen.	Select the **Allow delayed start** 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 OK function key is disabled.	Select **Set prime volume**. Then, using the keypad, enter the desired value and press **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 a reminder for the user to prime the administration set before starting an infusion.	Select the **Prime Reminder** row, to toggle the option between **On** and **Off**.
Advanced Bolus	Allows users to program a bolus by entering rate, amount and time. When this option is disabled, the bolus is programmed by amount only, and the rate is the default bolus rate. The option is available only when Allow Bolus is enabled (under Technician options). Applicable only for the Continuous delivery mode.	Select the **Advanced Bolus** row, to toggle the option between **On** and **Off**.

Option	Descriptions/Notes	To Modify Parameter (from the General settings screen)
Bolus Reminder	Enables a reminder for the user to connect the bolus handle before starting a PCA, PCEA or PIEB infusion that includes patient boluses. The reminder: • Instructs to connect the bolus handle directly to the pump. • Checks functionality - bolus press is recognized by the pump.	Select the **Bolus Reminder** 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 the **Auto P. Lockout** row, to toggle the option between **On** and **Off**.

Option	Descriptions/Notes	To Modify Parameter (from the General settings screen)
Screen Saver	Enables/disables a far-view display of the main infusion parameters during a running infusion. These include drug information, delivery mode (color indication), infusion rate and the current phase (dose, continuous rate, etc.). In SapphireH100, software 13.22.3, the pressure bar will also be displayed. The screen saver appears 30 seconds after the infusion program has started, and the pump has not been touched. The screen saver will not appear in the following cases: Delayed start, end of infusion KVO, or during a Bolus delivery. The screen saver will disappear in the following cases: • Alarm - screen will revert to the alarm screen • Touching the screen - screen will revert to the Running screen • Infusion is paused - screen will revert to the Paused screen.	Select the **Screen Saver** row, to toggle the option between **On** and **Off**.
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**.

Option	Descriptions/Notes	To Modify Parameter (from the General settings 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. 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 189.	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**.
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 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:

1. From the toolbar of the Start Up screen, select **Options**. Then, select **Pump configuration** → **Regional**.
2. Select the **US format** row to toggle the option between **On** and **Off**.

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.

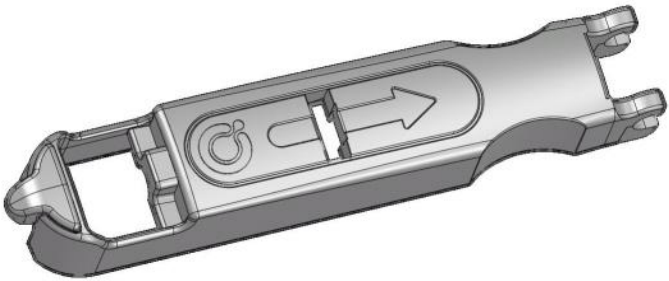
3. To confirm the new settings, press **OK**.

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 6.1. SapphireH100 infusion pump

Figure 6.2. 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 38.)

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 (for more information refer to To enable secondary settings: on page 186)

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

Hard Limit Parameters for TPN, and Intermittent Delivery Modes

Delivery Mode	VTBI	Max Dose Time	Int. Dose
TPN	✓		
Intermittent	✓	✓	✓

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

Delivery Mode	VTBI	Int. Dose	Cont. Rate	Demand Bolus*	Loading Dose	Bolus Rate	Min. Bolus Lockout	Max. Bolus Lockout
PCA	✓		✓	✓	✓	✓	✓	✓
PCEA	✓		✓	✓	✓		✓	✓
Epi. Int	✓	✓		✓**	✓		✓**	✓**

*. Changing the hard limits of the **Demand Bolus** parameter also applies to the **Clinician Bolus** parameter.

. The hard limits of this option can be only changed when PIEB is set to **On (in the **Epi. Int.** menu).

> 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.

In most software versions it is possible to turn off either the Single Air Detection or the Accumulated Air Detection but not both – Epidural Mode (Sapphire only) is the exception to this.

> 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**.
      The Start Up screen appears.

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).

Only in software versions that support disabling of the Air Detection

A technician authorization code is required to enable or disable the Air Detection setting (this can only be set manually on the pump and not with the Drug Library Editor).

To set the Air Detection setting select: **Options→ Technician options→ Pump settings→ Set air detector→ Air Detection**.

Toggle the setting to Off to disable the pump air detection during infusion. If the Air Detection setting is disabled, the icon  will appear at the right side of the indicators bar. Toggle the setting to On to enable air detection during infusion.

No Air in Line alarm is triggered when the pump air detection is disabled. This feature should be used when meeting the clinical practice and guidelines and coupled with an alternative method of eliminating air. When the Air Detection is disabled, use a set with an air-eliminating filter to prevent injury. Always ensure the administration set is primed before starting an infusion.

The Air Detection setting is available on all delivery modes, except Epidural. Disabling air detection in Epidural mode can be done manually, or via the Drug Library Editor, by switching both Single and Accumulated Air Detector settings to Off. This functionality remains the same as in previously available Sapphire Multi Therapy Infusion Pumps software versions.

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

- Reset all pump parameters and features to the factory defaults settings.
- Define new security passwords.
- Remove the Drug Library.
- Remove the PrePrograms.

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 164.

> 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,or **PreProgram** password, to change.

4. In **PreProgram** enter a 4-digit password in the specified range [1000 - 9999]. In an authorization level, 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.

The **PreProgram** password can be identical to an authorization level password, yet there is no connection between the options the authorization level enables and the **PreProgram** option.

5. Press **OK** to save the changes.

Remove Drug Library

The Drug Library can only be removed by users with Technician authorization level. This option will be hidden if there is no Drug Library on the pump. When the user removes the Drug Library all pump parameters are set to factory defaults.

1. From the Tech. options screen, select **Pump settings** → **Reset system**. The Reset system screen appears.
2. Select **Remove Drug Library**.
3. Press **OK** to confirm. The Start Up screen will appear.

SapphirePlus, software revision 14, the WiFi resets after the users confirms Drug Library removal.

Remove PreProgram

Enables the removal of all preset programs configured on the pump (in all delivery modes).

1. From the Tech. options screen, select **Pump settings** → **Reset system**. The Reset system screen appears.
2. Select **Remove PrePrograms**.

3. Press **OK** to confirm. The Start Up screen will appear.

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	Allows users to associate an infusion with a patient and reset the **Accumulated VI** (accumulated volume infused).	Off
Occ. Auto-restart	Enables the pump to automatically restart an infusion, up to 5 times an hour, if a downstream occlusion was detected and cleared within 40 seconds.	On
Calculate Concentration	Determines if the user enters final concentration or **Drug Amount** and **Diluent Volume**.	Off

Setting	Description/Notes	Default Value
mL/h only	Enables the user 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.	Off
Med. Titration	Allows users with medium authorization level to change rate during a running infusion.	Off

The following settings appear in the Audio Settings menu:

Setting	Description/Notes	Default Value
Keys Volume	Sets the speaker volume for the auditory signal generated when the user selects functions and presses keys on the pump.	High

Setting	Description/Notes	Default Value
Alarm Volume	Sets the speaker volume for the auditory alarm signal. Options are **Maximum** or **Minimum**. When the option is set to **Minimum**, s are provided with a visual signal only. Alarm levels 1, 2 and 3, and the "Infusion Complete" are provided with a visual signal 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.	Maximum
Bolus Handle	Sets the Bolus auditory signal generated when the bolus handle is pressed. When the option is set to Always On, an auditory signal is generated each time the bolus handle is pressed. When set to When Bolusing, an auditory signal is generated upon pressing of the bolus handle only when bolus is available.	On

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

Setting	Description/Notes	Default Value
Set Secondary (Piggyback)	Allows users to program a Secondary infusion.	Off
Allow Bolus	Allows users to program a bolus during a Continuous infusion. When this feature is enabled, the **Bolus** button appears in the toolbar during the running infusion.	Off
Bolus Rate	Specifies the rate of delivery of a fast dose, for rapid volume infusion.	125 mL/h
Sec. Bolus Rate	Specifies the rate of delivery of a fast dose for a Secondary (Piggyback) infusion.	125 mL/h

To save changes press **Next** and then **OK**.

> 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, PCEA and Epi. int Options menu (relevant for Sapphire only):

Setting	Description/Notes	Default Value
Limit Period	Specifies the time period to which the dose limit type is applied (during the selected time, the delivered boluses will be limited by either maximum number, or by maximum volume). Options are 1 hour or 4 hours.	1 h(s)

> To set the Limit Period:

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 isrecommended 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.*

* 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 6.3. Sample Level 3 Alarm Screen

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

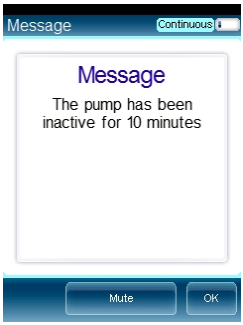
- **Mute:** Silences the auditory alarm for 2 minutes.
- **Unmute:** Returns the auditory alarm. This soft key is enabled after **Mute** is pressed.
- **OK:** Displays the Paused screen. The infusion may then be resumed after the problem is resolved.
- **Prime:** Enables automatic priming. This key appears 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. Possible excessive environmental light. Please reduce exposure and check if priming is required.
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 verify that the cassette chamber clean; then, 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.
Pump Stopped	Please quit and then restart the infusion.
Potential Air in Line	Press **OK** to test for air.
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 6.4. 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.

Screen Header	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.
	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.
	Key stuck. Please release the key

Guidance in Problem Solving

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

For troubleshooting in Sapphire and SapphireH100 refer to the Troubleshooting Software Upgrade section on page 211.

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. For more information refer to Chapter 5: Replacing the Battery on page 154.
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. For more information refer to Chapter 5: Replacing the Battery on page 154.

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. For more information refer to Chapter 5: Replacing the Battery on page 154.
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. For more information refer to Chapter 5: Replacing the Battery on page 154.
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. For more information refer to Chapter 5: Replacing the Battery on page 154.
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.
	Excessive environmental light, in addition to the regular Air in Line conditions, was detected	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. For more information refer to Chapter 5: Replacing the Battery on page 154.

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.

*. In Sapphire Multi-therapy and Sapphire Epidural Rev. 15 these messages are not displayed

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 32.

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.

Prerequisites

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

Hardware Requirements

- PC: Pentium 4, 1500MHz CPU, 512 RAM (or higher)
- Screen resolution 1280x1024 (minimum)
- Communication cable for the Sapphire pump (P/N 05020-110-0213)
- RS232 connectivity in either of the following forms:
  - RS232 port in the computer

Figure 6.5. PC Connector

  - USB to RS232 adaptor + driver (P/N 15077-000-0001)

Figure 6.6. USB Adaptor and Driver

- Internet connection.

Software Requirements

- OS: Win XP 32 / 64 bit, Win 7 32/64 bit, Win 8.1 32/64 bit, Win 10 64 bit
- .Net framework 4.0
- 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)

Upgrade Procedure

Use the most updated version of the Pump Loader. The most updated version of the Pump Loader can be found on the Q Core Medical FTP site (https://qcore.smartfile.com/).

The Pump Loader is compatible with all approved pump software revisions.

SapphirePlus pump software can be updated using the Pump Loader software or using the Wi-Fi connection (see the Chapter 7: SapphirePlus on page 222).

Up to 8 Pump Loader instances can be used simultaneously on one computer.

The Pump Loader requires communication with the Q Core Medical server. In case of communication problems refer to Troubleshooting Software Upgrade on page 211.

Informing Q Core Medical on Pump Software Update

For SapphirePlus pumps, if the Wi-Fi is used (MedNet) for the software update, it is required to fill in and submit the Pump Software Update Using MedNet form (15038-049-0001) as provided on the Service Portal. This form should be submitted electronically (soft copy) to service@qcore.com.

- In software versions that support disabling of the Air detection, to maintain the air detector settings values following software update, set the **Air Detection** setting to On prior to the software update. If the **Air Detection** setting is set to Off, following software update the air detector settings are set to factory defaults.
- Following the pump's software update additional pump settings may be added (according to the software updated). If additional settings are added they are set to factory defaults.
- Following the pump's software update, the **Occlusion Alarm** setting value configured on the pump may change. To maintain pump configuration, record the **Occlusion Alarm** value before the pump software update. After the software update has completed, configure the pump with the original **Occlusion Alarm** value.

> To install the Pump Loader software:

1. Download the setup file **Pump Loader Setup** (.msi or .exe file) from the Q Core Medical FTP site to a directory of your choice.
2. Double-click the **Pump Loader Setup** file to start the installation process and click **Next**.
3. Review the license agreement details and check the relevant checkbox to accept.
4. It is possible to create shortcuts to the Pump Loader software; Check/uncheck the relevant checkbox, as desired.
5. Click **Install**.
6. After the installation has completed, click **Finish**.

Prior to starting the software update

Prior to starting the software update process perform the following:

1. Connect the pump to the power supply. Otherwise, verify the pump's battery is fully charged.
2. If using the USB-to-RS232 adaptor, verify that the adaptor driver is installed on the computer prior to connecting the pump to the computer.
3. Verify that the software to be updated on the pump is compatible with the pump according to latest Labeling and Software Revision Table, 15000-004-0002-SM or Labeling & SW Revisions Table for Q Core Service Providers, 15000-004-0003-SM. Make sure you select the software designated for each pump type.
   For example, do not install All modes software designated for Multi Therapy pumps on an Epidural pump (yellow lexan).
   - All modes software: installed on Sapphire Multi-Therapy pumps ONLY
   - Epidural only software: installed on Sapphire Epidural pumps
   - SapphireH100 software: installed on SapphireH100 pumps
   - SapphirePlus software: installed on SapphirePlus pumps
4. Verify the computer is connected to the internet.
5. Disable the sleep mode on the computer; failing to do so may result in update failure.

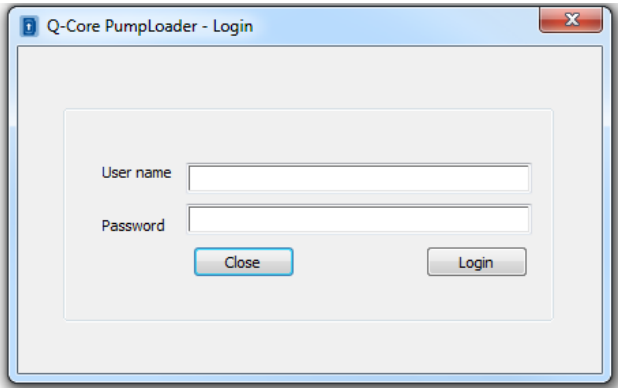
Software Update Process

> To update the software:

1. Turn the pump on. Connect the pump to the computer using the communication cable. You may also use the USB-to-RS232 adaptor.
2. Open the Pump Loader software by double-clicking the Pump Loader icon.

   The window Pump Loader Login opens.

Figure 6.7. Pump Loader Login Prompt

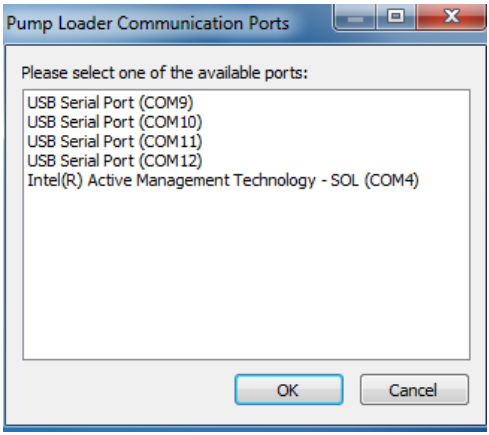


3. Enter the credentials; then, click **Login**.

	The credentials to the Pump loader software are the same on all Sapphire PC tools. The credentials are retained as long as you remain logged in to the Windows account. You will not be prompted to log in again, as long as you remain logged in to the Windows account. In case the software is installed on a computer that is used by different personnel in your facility, please remember to log off, or lock your Windows account to prevent the use of the Pump Loader SW by uncertified personal, using your credentials.

4. The window Pump Loader Communication Ports opens. Select the suitable COM port, and then click **OK**.

Figure 6.8. Pump Loader Communication Ports Window

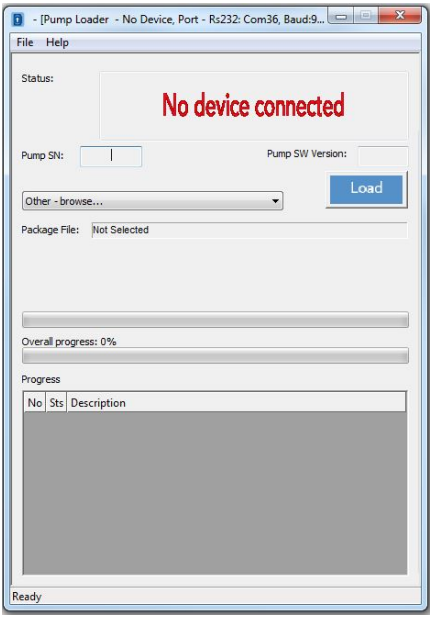


5. The main screen of the Pump Loader appears. After a few seconds the **Status** field should indicate **Pump connected**. If the status field indicates **No device connected** verify that the pump is connected properly to the computer via the correct COM port.

   In case of communication problems refer to Troubleshooting Software Upgrade on page 211.

   The main screen of the Pump Loader includes the following fields (see figure below):

Figure 6.9. Pump Loader Screen



Field Name	Function
File menu	The Exit option is used to exit the Pump Loader
Help menu	Includes the options Show Instructions (Hide Instructions after Show is selected) and About. The Show Instructions option shortly explains how to upload software on the pump. The About option displays the Pump Loader version information.
Status	Indicates if the pump is connected to the computer and the status of the upload process
Pump SN	Displays the serial number of the pump
Pump SW Version	Displays the current software version of the pump
Load button	Allows the selection of the software to upload to the pump
Package File	Displays the software that is being uploaded to the pump

Field Name	Function
Two progress bars	Indicating the progress of the upload. The bottom progress bar indicates the status of the overall progress
Progress	A table displaying the actions performed by the Pump Loader

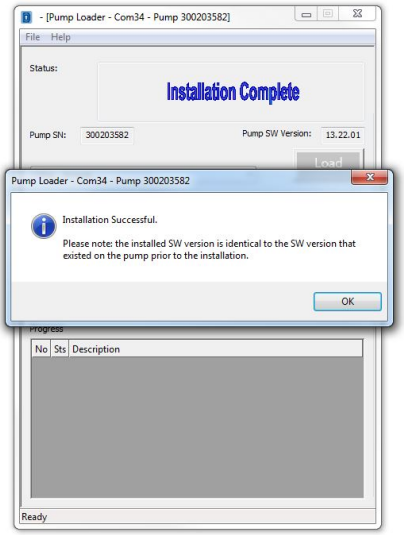
6. Click **Load**. Select the software to upload to the pump by double-clicking on the software file. The upload will start automatically.

	Do not turn the pump off or disconnect it from the computer while the update is in progress.

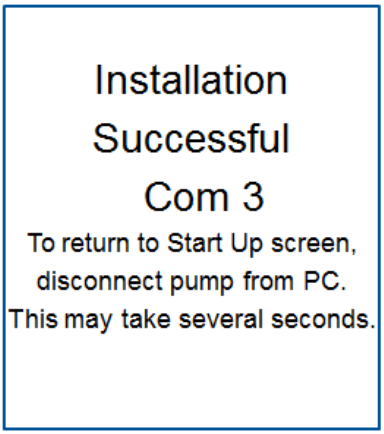
7. The pump software update is completed when a message The update was completed successfully is displayed on the computer and on the pump. See Figure 6.10.

	Do not disconnect the pump from the computer before the s of successful update appear both on the computer and on the pump. Pay attention to the relevant COM port.

Figure 6.10. Software update completed



Computer Screen



Pump Screen

8. After the software update has completed, press **OK** on the computer, close the Pump Loader and disconnect the pump from the computer. Wait until the "Installation Successful" screen has disappeared and the pump has returned to the Start Up screen. Restart the pump.
9. If the pump software language is not as required, refer to the Defining Regional Parameters section on page 170.
10. Verify that the desired software was uploaded on the pump. On the pump, go to: **Options → View → View system**. Click **Next** until the Software version field is displayed. Verify that the software version displayed matches the pump type, refer to the SW Revisions Table for Q Core Service Providers, 15000-004-0003-SM or Labeling and Software Revision Table, 15000-004-0002-SM.

In any case that the software was not updated successfully it is required to close the Pump Loader, restart it and repeat the software update process.

After verifying that the software was uploaded successfully, change the mL/h only setting: if it is set to **On** change it to **Off**; If it is set to **Off** change it to **On**:

1. Enter the menu: **Options** → **Technician options** → **Pump settings** → **General**. Press **Next**.
2. Toggle the mL/h only setting as described above.

Only relevant when upgrading from Rev. 11 to Rev. 13, or from Rev. 11 to Rev. 15. For more information refer to Troubleshooting Software Upgrade on page 211.

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 screen header appears in red	Incomplete upgrade. Communication error	1. Close the Pump Loader . 2. Disconnect the pump from communication and the power supply. 3. Wait 15 minutes. 4. Repeat the upgrade process. Even if the status field indicates **No device connected**, click **Load** to select the software to upload to the pump. **Note:** If the following is prompted: "Application did not recognize any attached device. If you are sure that the device is attached, please select it manually", click Pump.
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.
Installation Failed was prompted on the pump and/or the computer.		1. Close the Pump Loader. 2. Disconnect the pump from the computer. Wait for the Start Up screen to appear. 3. Restart the pump. 4. Repeat the software update process.
Prime button on Start Up screen is disabled after software upload.		1. Move to another screen or restart the pump. The **Prime** button will be enabled.

Problem	Probable Cause	Solution
After upgrading from revision 11 to revision 13 or 15, the Dose calculation option does not appear in the Dosing method window, although it was available in revision 11 before the software upgrade.		1. Go to the menu: **Options → Technician options → Pump settings → General**. Press **Next**. 2. Verify that the **mL/h only** setting is set to Off.
During the Pump Loader installation the following is prompted on the computer: "This application requires .NET Framework 4.0 full, please install the .NET Framework and then run the installer again."		1. Click **OK** to cancel the installation. 2. On the computer: Go to **Start → All Programs → Windows Update.** 3. Select **Optional Updates** and then select **.NET Framework 4.0**. 4. Follow the online instructions. 5. Double-click the **Pump Loader Setup** file to start the installation.
During the Pump Loader installation the following is prompted on the computer: "This application is supported on Windows XP, Windows 7 and higher."		1. Use a computer with the appropriate operating system.

Problem	Probable Cause	Solution
The following is prompted on the computer after the Pump Loader main screen appears: "Automatic connection of the Pump Loader Software to the Q Core server has failed. Contact your system administrator to verify internet connection and firewall configurations, and press Retry below. For further information, refer to the Troubleshooting section In the service manual. Press Cancel to exit Pump Loader."		1. Verify the computer is connected to the internet. 2. If the error keeps appearing submit a call via the personal profile drop down menu in the Q Core Medical Service Portal.

Problem	Probable Cause	Solution
The following is prompted on the computer after selecting **Yes** to exit the Pump Loader: "Process logs saved locally, and will be automatically uploaded to the Q Core Servers during the next connection with Pump Loader. No further action is required, Press OK to exit Pump Loader"		1. The was prompted due to a loss of communication with the Q Core Medical server. Process logs will be uploaded to the Q Core Medical server during the next use of the Pump Loader and establishing communication with the Q Core Medical server. 2. It is recommended to reconnect to the internet, open the Pump Loader, choose a COM port and close the Pump Loader after one minute.
The following error was prompted on the pump: "Version error Code: 7 Please contact an authorized Technician"		1. Repeat the software update process. 2. If the error keeps appearing submit a call via the personal profile drop down menu in the Q Core Medical Service Portal.
The following error was prompted on the computer:" The software version you are trying to install is incompatible with your device hardware. Please contact your local distributor. For further information, refer to the service manual"		1. Repeat the software update process. 2. Contact service@qcore.com or submit a call via the personal profile drop down menu in the Q Core Medical Service Portal.

Problem	Probable Cause	Solution
Installation failed appears on the pump screen before the software update process started.		1. Close the Pump Loader. 2. Disconnect the pump from the computer. Wait for the Start Up screen to appear. 3. Restart the pump. 4. Repeat the software update process.
The "Please Wait" screen is displayed on the pump while a failure is displayed on the computer.		1. Close the Pump Loader. 2. Disconnect the pump from the computer. Wait for the Start Up screen to appear. 3. Restart the pump. 4. Repeat the software update process.
"Software execution failure! Please re-install software" appears on the pump screen.		1. Close the Pump Loader. 2. Disconnect the pump from the computer. Wait for the Start Up screen to appear. 3. Restart the pump. 4. Repeat the software update process.

Problem	Probable Cause	Solution
After the software update process has completed the pump turns on with a black screen.		1. Close the Pump Loader. 2. Turn the pump off. 3. Disconnect the pump from the communication cable 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 cable and to the power supply. 7. Repeat the update process. Even if the status field indicates No device connected, click Load to select the software to upload to the pump. **Note:** If the following is prompted: "Application did not recognize any attached device. If you are sure that the device is attached, please select it manually", click **Pump**.
No communication between the pump and the computer.		1. Verify the communication cable is properly connected. 2. If using the USB-to-RS232 adaptor, verify that the adaptor driver is installed on the computer and that it is properly connected. 3. If the problem persists contact service@qcore.com or submit a call via the personal profile drop down menu in the Q Core Medical Service Portal.

Problem	Probable Cause	Solution
The computer entered sleep mode and the software update failed.		1. Close the Pump Loader. 2. Disconnect the pump from the computer. Wait for the Start Up screen to appear. 3. Restart the pump. 4. Verify the sleep mode on the computer is disabled. 5. Repeat the software update process.
During software update "Error Code 7" appears briefly on the pump's screen.		1. No action is required. 2. "Error Code 7" may appear briefly on the pump's screen during software update.
In pump software 14.50.0: a stating the Wi-Fi is disconnected and firmware update is required, is displayed on the pump.		1. Use the Pump Loader to burn software 14.50.0 on the pump. Do not burn the software via the MedNet.

Problem	Probable Cause	Solution
Pump software update failed. "Please Wait" screen is displayed on the pump.		1. Disconnect the pump from the computer. 2. Reconnect the pump to the computer. 3. "Select Device" appears on the computer. 4. Click "**Pump**". 5. Update the software. If software update keeps failing: 1. Remove the battery from the pump for 30 seconds. 2. Reinstall the battery. 3. Update the software.

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.

Chapter 7: 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 Alarm	The minimum pressure that triggers an Occlusion alarm. Acceptable ranges are 1.5 to 17.4 PSI, 0.1 to 1.2 BAR or 75 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 Alarm**. 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. **Note:** A Pump Unattended alarm is not triggered while an infusion is running.	Select **Pump unattended**. Then, select **30 seconds, 2 min, 5 min**, or **10 min**.
Infusion near end	The number of minutes before completion of an infusion at which an Infusion Near End alarm is generated.	Select **Infusion near end**. Then, select **1 min**, **3 min**, **5 min**, **10 min, 30 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 246.	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 246.	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**. For more information refer to Managing Authorization Lock Levels on page 37.
Allow delayed start (Set Delay*)	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** (**Set Delay***) row, to toggle the option between **On** and **Off**.
Allow PreProgram (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** (**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**.

Option	Descriptions/Notes	To Modify Parameter (from the General settings screen)
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. **Note:** In Sapphire Multi-therapy and Sapphire Epidural Rev. 15 and SapphirePlus Rev. 14.5, the Auto P. Lockout is automatically reactivated throughout the infusion.	Select **Auto P. Lockout** to toggle the option between **On** and **Off**.
Post Infusion Rate	Sets the rate that is applied at the end of infusion to KVO, or to continue at the current infusion rate. When KVO is selected, the rate applied is the default KVO rate set by an Authorized technician. **Note:** Applicable only for Sapphire software ver. **14.00.0** and **14.50.0**.	Select **Post Infusion Rate** and then KVO or Rate.

Option	Descriptions/Notes	To Modify Parameter (from the General settings screen)
Screen Saver	Enables/disables a far-view display of the main infusion parameters during Standby or a running infusion. These can include drug information, delivery mode (color indication), infusion rate, and the phase (dose, continuous rate etc.). The screen saver appears 30 seconds after the infusion program has started, and the pump has not been touched. Infusion parameters and display time are configurable via ICU MEDICAL MedNet™ per CCA. When a Drug Library is not installed on the pump, infusion rate will be displayed. The screen saver will not appear in the following cases: Delayed start, Post Infusion, or during a Bolus delivery. The screen saver will disappear in the following cases: • Alarm - screen will revert to the alarm screen • Touching the screen - screen will revert to the Running screen • Infusion is paused - screen will revert to the Paused screen.	Press **Next** and select **Screen Saver** to toggle the option between **On** and **Off**.

*. in Ver. 14.00.0 and 14.50.0

Defining Regional Parameters

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

> To access the Regional menu:

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

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

> To set the time format:

1. Toggle the 12 hour clock to On - the time display will be set to the AM/PM format (for example 02:00 PM).

   Or

2. Toggle the 12 hour clock to Off - the time display will be set to the 24 hour military style format (for example 14:00).
3. To confirm the new settings, press **OK**.

> To set the date format:

1. Toggle the US date format to On - the date display will be set to the US format – MM/DD/YY (for example 05/21/17).

   Or

2. Toggle the US date format to Off - the date display will be set to the European format – DD/MM/YY (for example 21/05/17).
3. To confirm the new settings, press **OK**.

> 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 frame.
2. Using the keyboard, enter values (2 digits each) for the hour and the minute.
3. If necessary, switch the time units from AM to PM, or vice versa, by pressing the **AM/PM** function key. (This step is relevant only when the12 hour clock format is set to On.)
4. To confirm the new settings, press **OK**.

> To set the language:

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

In some pumps, only the default language is listed.

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

> To set the US Format:

1. 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 38.)

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 (for more information refer to To enable secondary settings: on page 240)

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 226.

> 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	Allows users to associate an infusion with a patient and reset the Accumulated VI (accumulated volume infused)	Off

Setting	Description/Notes	Default Value
Med Titration	Allows users with medium authorization level to change rate during a running infusion.	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
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 241.  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.	N/A

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.	125 mL/h
Sec. Bolus Rate	The rate of delivery of a secondary fast dose, for rapid volume infusion.	125 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 238.

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.
WiFi Firmware Version	WiFi Firmware Version.

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

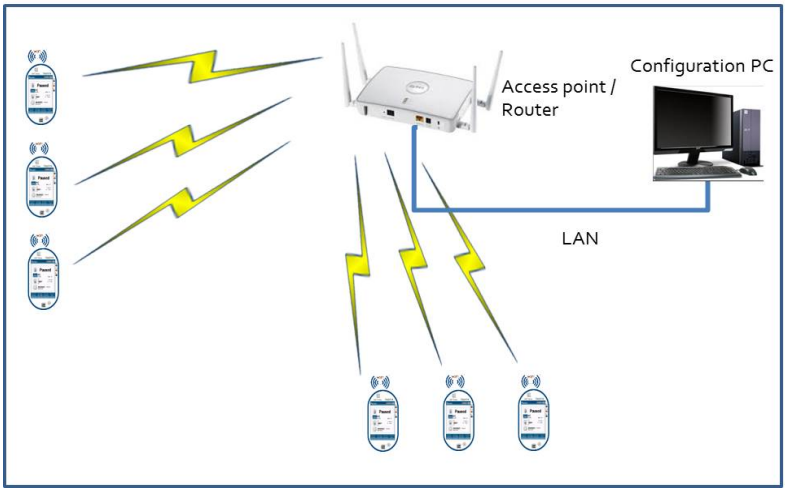
5. Allow 1-2 minutes to establish the connection, and wait until the SSID field will display: "********".
6. Attempt to connect to the pump using the SxManager Software, and configure the WiFi definitions.

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 7.1. 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 Reminder	End of battery life. Please contact trained technician to replace battery.

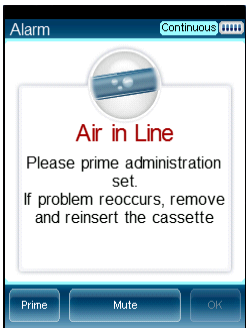
* Entering the code will give trained technician same or more information about the problem and possible solutions. In most instances, trained technician will be directed to return pump for service.

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 7.2. 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.

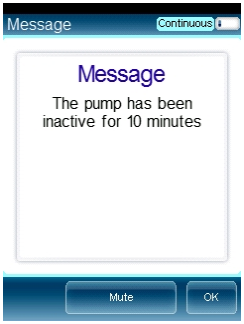
Alarm Title	Displayed Text
Air in Line	Accumulated air in line is over the limit. Please prime administration set. Prime administration set. If problem reoccurs, remove and reinsert the cassette. Please prime administration set. If problem reoccurs, remove and reinsert the cassette. Possible excessive environmental light. Please reduce exposure and check if priming is required.
Potential Air in Line	Press OK to test for air.
Pump Stopped	Please quit and then restart the infusion.
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.

Alarm Title	Displayed Text
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 7.3. 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.

Screen Header	Displayed Text
Low Battery	30 minutes left to battery depletion. Connect pump to power supply.
Message	Battery life will expire in 2 days. Please contact 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.

Screen Header	Displayed Text
	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.
	Key stuck. Please release the key.
	WiFi disconnected. To reconnect WiFi, connect pump to power supply.
	WiFi disconnected. Please contact authorized technician. Press OK to continue without WiFi.
	Battery Charging Error. Ensure power supply remains connected.
	The battery could not be fully charged. Please check power supply.

*. In SapphirePlus Rev14.50 these messages are not displayed.

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. For more information refer to Chapter 5: Replacing the Battery on page 154.
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. For more information refer to Chapter 5: Replacing the Battery on page 154.

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. For more information refer to Chapter 5: Replacing the Battery on page 154.
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. For more information refer to Chapter 5: Replacing the Battery on page 154.
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. For more information refer to Chapter 5: Replacing the Battery on page 154.
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.
	Excessive environmental light, in addition to the regular Air in Line conditions, was detected.	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.

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: 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.
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. For more information refer to Chapter 5: Replacing the Battery on page 154.

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.

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.
Occlusion alarm is triggered immediately after the infusion or bolus starts, or rate is increased.	In cases where the backpressure caused by the catheter used for the treatment, at the programmed rate, is too high- reduce the backpressure by either replacing the catheter or by decreasing the infusion rate.
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 **Set Delay** setting (Configuring Basic Pump Settings on page 222). 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 **PreProgram** setting (Configuring Basic Pump Settings on page 222). 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 (for more information 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 226. • 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 (for more information refer to Configuring Basic Pump Settings on page 222). • 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 200, 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 (may be indicated by green arrow at the top of the screen), the user is prompted to specify whether or not to update the software. This will be prompted only after entering Technician mode and turning the pump off. Note that updating the pump software removes the Drug Library if it has become incompatible.

In SapphirePlus software 14.50.0, downloading software or Drug Library from MedNet is possible also if the pump is turned on and not connected to power supply, and if the pump is not infusing.

Updating software should be conducted according to local facility procedures. Updating a new software version may take a few minutes, during which the pump is inactive. The user is advised to connect the pump to a power supply during the update process. If the pump is turned off, a 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 **Upload**.
2. Enter the installation code 12345, and press **OK**. The pump will start updating the software. At the end of the process the pump will shut down.

> To view the current software version:

1. From the **Options** menu, select **View g ViewSystem**.
2. On the toolbar, press **Next**, until the SW Version parameter is displayed. When the pump is turned off and connected to power supply, the current software version is displayed on the screen.

For SapphirePlus pumps, if the Wi-Fi is used (MedNet) for the software update, it is required to fill in and submit the Pump Software Update Using MedNet form (15038-049-0001) as provided on the Q Core Medical FTP site (for more information refer to FTP site on page 32). The form should be submitted electronically (soft copy) to service@qcore.com

Technical Support Contacts

For technical assistance, contact your local representative, or contact Q Core Medical Ltd. support by sending an email to Service@qcore.com or submitting a call via the personal profile drop down menu in the Service Portal at the following address https://service.qcore.com/Main.aspx.

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Chapter 8: Sapphire Configuration Manager (SCM)

The following sections explain how to transfer one pump's configuration to up to eight pumps simultaneously using the Sapphire Configuration Manager:

Overview

Multiple pumps can be configured simultaneously using Q Core's Sapphire Configuration Manager. The Sapphire Configuration Manager copies the settings, preset programs, and drug library (if installed) from a source pump and creates a Configuration File. The Configuration File can then be used to configure up to eight pumps running the same software version, same pump type (Multi-Therapy or Epidural) and same language, simultaneously with the same settings, preset programs, and drug library. The Sapphire Configuration Manager can be obtained from Q Core's FTP site (https://qcore.smartfile.com).

Prerequisites

Before using the Sapphire Configuration Manager, verify that the following hardware and software requirements are met.

Hardware Requirements

- PC: Pentium 4, 1500MHz CPU, 512 RAM (or higher)
- Screen resolution 1280x1024 (minimum)
- Communication cable for the Sapphire pump (P/N 05020-110-0213)
- RS232 connectivity in either of the following forms:
  - RS232 port in the computer
  - USB to RS232 adaptor + driver (P/N 15077-000-0001)
- Internet connection

Software Requirements

- OS: Win 7, Win 10
- .Net framework 4.0
- SCM software (.exe file from Q Core)

All pumps being configured must have the same software version, same pump type (Multi-Therapy or Epidural) and same language as the source pump.

The Sapphire Configuration Manager is compatible with the following software versions:

- Sapphire MultiTherapy 13.22.01
- Sapphire MultiTherapy 13.23.02
- Sapphire MultiTherapy 15.00.00

- Sapphire Epidural 13.22.01
- Sapphire Epidural 13.23.02
- Sapphire Epidural 15.00.00

For information regarding the FTP site, refer to FTP site on page 32.

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

Acquiring the Software

Use the most updated version of the Sapphire Configuration Manager. The most updated version can be found on the Q Core Medical FTP site (https://qcore.smartfile.com/). For information regarding the FTP site, refer to FTP site on page 32. Please note that only trained technicians registered with the company will be cleared to receive the software.

The Sapphire Configuration Manager requires communication with the Q Core Medical server. In case of communication problems refer to SCM Troubleshooting on page 285.

> To install the Sapphire Configuration Manager:

1. Download the setup file **SCM Setup** (.exe file) from the Q Core Medical FTP site to a directory of your choice.
2. Double-click the **SCM Setup** file to start the installation process and click **Next**.
3. Review the license agreement details and select the relevant checkbox to accept.

4. It is possible to create shortcuts to the Sapphire Configuration Tool; select/unselect the relevant checkboxes, as desired.
5. Click **Install**.
6. After the installation has completed, click **Finish**.

Prior to using the SCM

Prior to using the Sapphire Configuration Manager perform the following:

1. Configure one pump manually – it will serve as the source pump. Make sure to review all settings, preset programs, and drug library if applicable, and confirm that they are correct. Refer to Configuring Basic Pump Settings on page 162.
2. Connect the pump to the power supply.
3. If using the USB-to-RS232 adaptor, verify that the adaptor driver is installed on the computer prior to connecting the pump to the computer.
4. Verify that the computer is connected to the internet.

Create Configuration File

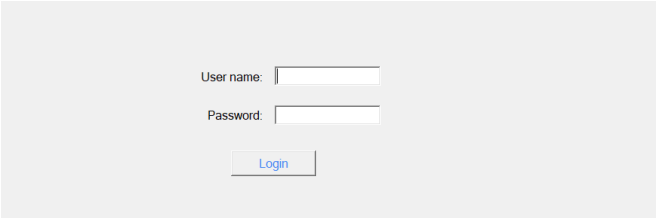
> To create a Configuration File:

1. Connect the pump to the power supply.
2. Turn the pump On. Connect the pump to the computer using the communication cable. You may also use the USB-to-RS232 adaptor.
3. Confirm that the Start-Up Screen is shown on the pump's display (check the top left corner on pump's display).

4. Open the Sapphire Configuration Manager by double-clicking the SCM icon  .

   The SCM login window is displayed.

Figure 8.1. SCM Login

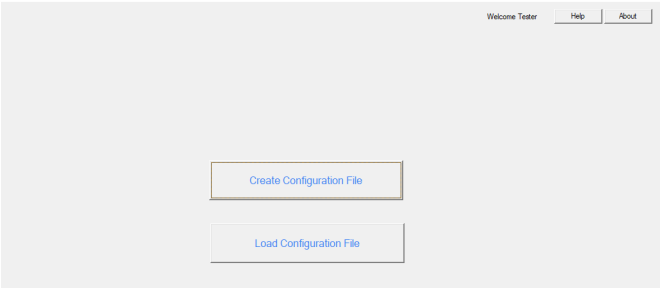


5. Enter the credentials; then, click **Login**.

The credentials to the SCM are the same as for all Sapphire PC tools.

   The mode selection window is displayed.

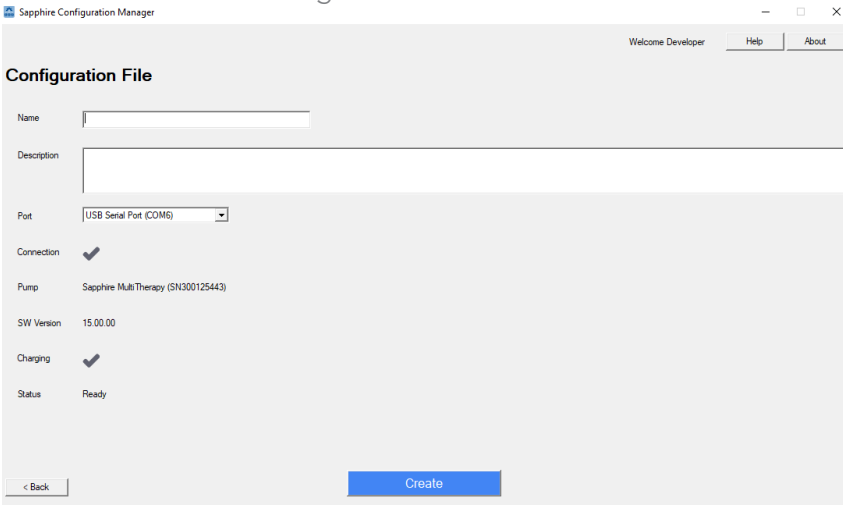
Figure 8.2. Mode Selection



6. Click **Create Configuration File**.

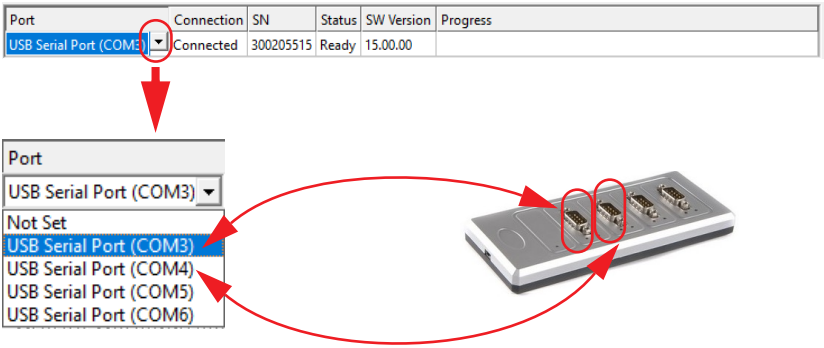
   The Create Configuration File window opens.

Figure 8.3. Create Configuration File Window



7. Type in the file name in the File Name field. This field is mandatory and supports uppercase/lowercase letter, numbers, underscores, and spaces only.
8. If desired, in the File Description field, type a short description. The information entered will help choose the appropriate Configuration File when configuring pumps.
9. Double-click the **Port** selection tool; then, from the drop-down list, select the suitable COM port.

Only one pump can be selected as the source pump.



Choosing a port: The lowest COM number available, is always assigned to the port that is nearest to the USB connection on the RS 232 splitter. The highest COM number is the farthest.

10. After a few seconds the Connection field should indicate that the pump is Connected (communication). If the connection field states that the pump is Disconnected, verify that the pump is connected properly to the computer via the correct COM port. If the connection field states **Busy**, make sure that there are no other applications using this port, or select a different one. In case of communication problems, refer to SCM Troubleshooting on page 285.

	After the pump is connected to the PC, any last-minute changes to the pump configuration (in **Settings** or **Preset Programs**) will not take affect. Make sure to have the required pump configuration settings ready before connecting it to the PC.

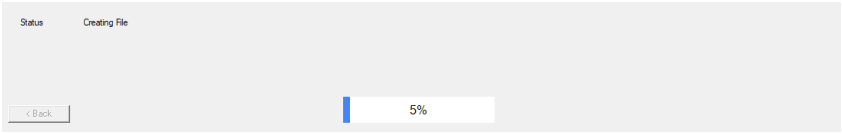
	If the Create Configuration File screen is left inactive for over an hour, return to the main window before attempting to connect a pump.

11. Wait until the status changes from **Syncing** to **Ready** and the SW Version is displayed. If the Status field states: **Power Supply required**, verify that the pump is connected properly to the power supply.

12. Click **Create Configuration File**.

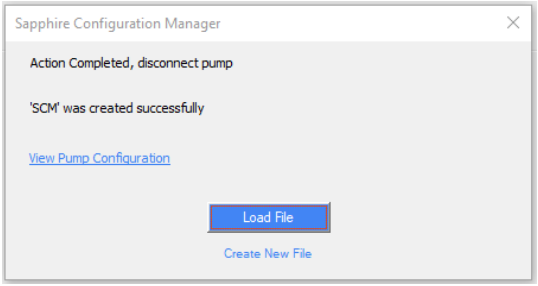
After the process begins it cannot be canceled; all buttons in the program and on the pump become disabled, and the pump screen displays the message "Connected to Sapphire Configuration Manager".

13. The Status changes to **Creating File**, and the progress can be seen in the progress bar. The pump enters the boot mode and may restart a few times.



Do not disconnect the pump during boot mode. If the pump is disconnected before the loading process of a configuration file is completed, the SCM automatically shuts down. In this case the SCM must be re-opened and the loading process repeated.

14. After the Configuration file is successfully created, a message appears on the computer screen. At this point the pump can be disconnected.



If any pumps fail, please refer to SCM Troubleshooting on page 285.

15. If you wish to view the settings, the present programs, and the drug library of the file that you have just created, click **View Pump Configuration**.

If you wish to immediately upload the file you created on other pumps, click **Load File** and proceed to the next section.

If the creation of the configuration file failed, please refer to SCM Troubleshooting on page 285.

Load Configuration File

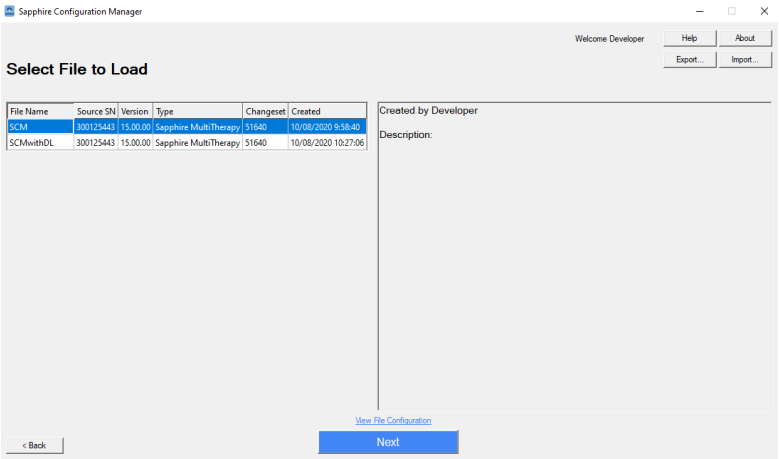
> To load a configuration file:

1. If you have just finished creating a Configuration File, and haven't closed the window, skip to Step 4.
2. Open the Sapphire Configuration Manager by double-clicking the SCM icon. The SCM login window is displayed.
3. Enter the credentials; then, click **Login** – the credentials to the SCM are the same as those used for all Sapphire PC tools.

   The mode selection window is displayed.
4. Select **Load Configuration File**.

   The Select Configuration File window is displayed (Figure 8.4).

Figure 8.4. Select Configuration File Window



5. Select the configuration file.
   When performing this step after creating a configuration file, that file will automatically be selected. The selected file will be highlighted; and the file description will be displayed on the right.

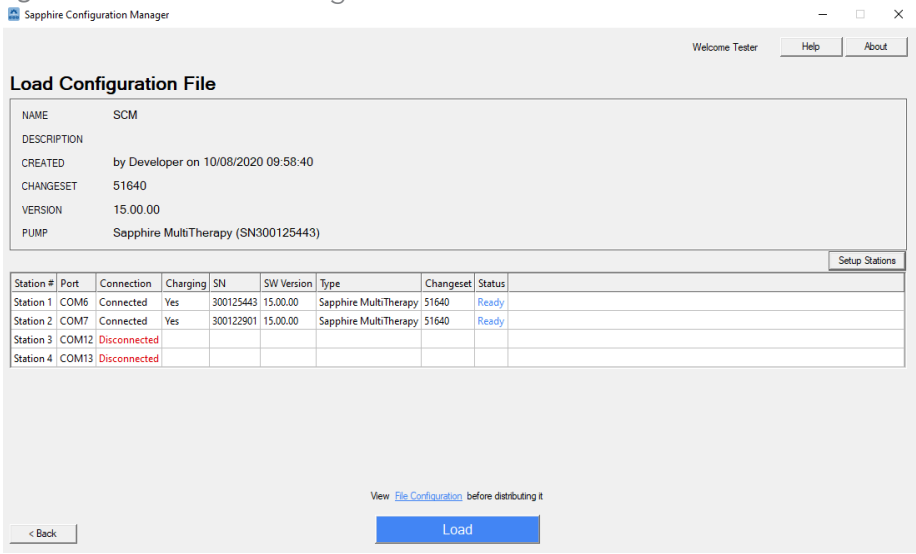
   If you wish to view the details of a configuration file, click **View File Configuration**.

   If you wish to save a configuration file on your computer, select the file you wish to save; then, click **Export…** , choose the location where the file will be saved and click **Save**.

   If have a configuration file saved on your computer and you wish to add it to the list of available files, click **Import…**; then, find the location where your file is saved and click **Open**.
6. Click **Next**.

   The Load Configuration File window is displayed.

Figure 8.5. Load Configuration File Window



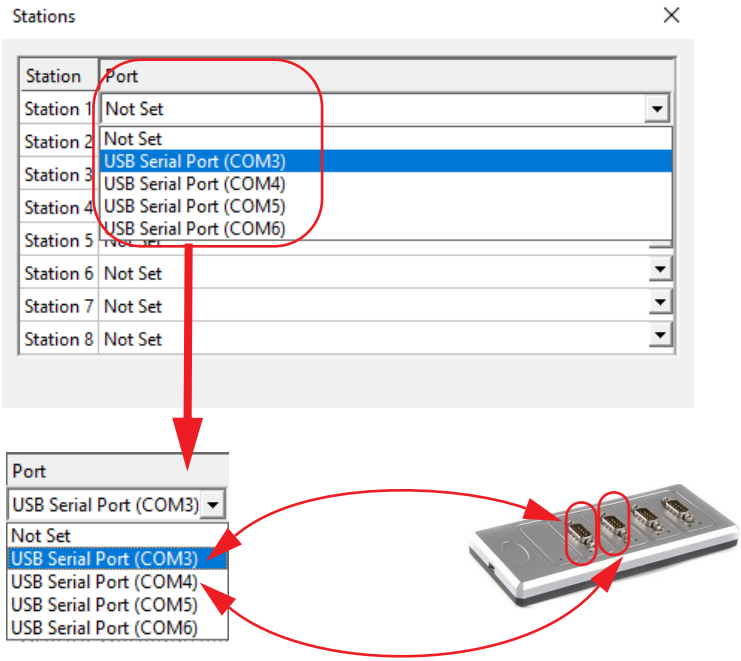
7. Upon first use, press **Setup Stations** to enter the Stations Setup menu. If the stations are already configured, skip to Step 11.

8. In the Station Setup window, choose a free COM for each station needed; then, click **OK** to confirm the selection.

   The configured setup is saved.

> If the configuration file description includes several lines, only the first line is displayed in the Load Configuration File screen.

Figure 8.6. Station Setup Window



Choosing a port: The lowest COM number available, is always assigned to the port that is nearest to the USB connection on the RS 232 splitter. The highest COM number is the farthest.

9. Connect 1 to 8 pumps, and confirm that the Start-Up Screen is shown on the pump's display (check top left corner on pump's display).
10. Connect the pumps to a power supply.

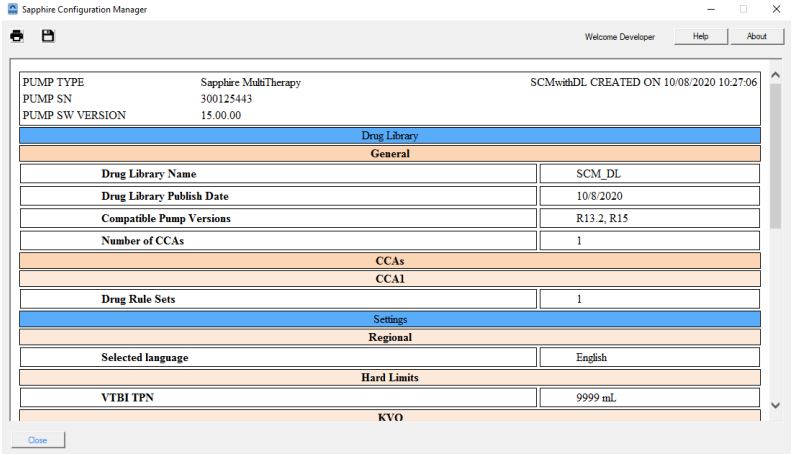
11. Wait until the **Status** for each pump changes from **Syncing** to **Ready**. If the Status field states: **Power Supply required**, verify that the pump is properly connected to a power supply.

> Pumps with software versions differing from the source pump will not receive the Configuration file.

12. At the bottom of the **Load Configuration File** window (Figure 8.5), click **Load**.

    A confirmation window is displayed.

Figure 8.7. Confirmation Window



> When the Configuration File includes a Drug Library, the confirmation window displays the Preset Program and the Drug Library. Otherwise, the confirmation window displays the Preset Program and the pump's settings.

When the Configuration File includes a TPN Preset Program, the Plateau Rate is calculated automatically, as detailed on page 134 of the Sapphire User Manual: "Infusion Parameters: TPN Mode". The confirmation window will display the Plateau Rate as "calculated". To view the Plateau Rate in units, review the Preset Program on the pump.

When the Configuration File includes a Continuous Preset Program, one of the 3 treatment parameters (Rate, VTBI or Time) is calculated automatically, as detailed on page 97 of the Sapphire User Manual: "Infusion Parameters: Continuous Mode". The confirmation window will display the calculated treatment parameter as "calculated". To view the treatment parameter in units, review the Preset Program on the pump.

13. Verify that the information is correct; then, select the **I've read the file preview** check-box at the bottom-right corner, and click **Confirm**.

    The status changes to Loading file, and the progress can be followed in the progress bar for each pump.

    Do not disconnect pumps during the boot mode.

    If the pump is disconnected before the loading process of a configuration file is completed, the SCM automatically shuts down. In this case the SCM must be re-opened and the loading process repeated.

14. Wait for the process to complete.

If any pumps fail, please refer to SCM Troubleshooting on page 285.

When uploading a configuration file with a Drug Library, a confirmation message is prompted on the pump screen during the loading process. Do not confirm this message until the uploading process is completed.

15. After Loading is completed, the Status field is updated according to the loading results:

    Following are the Status options:

    - For stations that the loading was completed:
      - **Success**

        Make sure to disconnect all completed pumps.

        For stations where the loading failed, the status appears with a red information icon. Clicking the red icon displays the details of the failure.
      - **Loading Failure**

        In any case of a loading failure, the pump will not be operable until loading is completed.

        A pump with loading failure prompts the following error:

        "Version error Code: 7 Please contact an authorized Technician"

        Repeat the loading process. After the process is completed, the error is removed, and the status changes to **Success**.
      - **Pump SW not compatible**

        Pump SW version must match the configuration file SW version. Update pump SW version as required (see Upgrading Software Version on page 266, or Upgrading Software Version on page 200).

- **Pump type is not compatible**

  Pump type (MultiTherapy or Epidural) must match the configuration file pump type. Please select a compatible pump type.
- **Pump language is not compatible**

  Pump language must match the configuration file pump type. Make sure that the SW version supports the language of the configuration file. The supported languages can be found in the regional settings.

For more information please refer to the SCM Troubleshooting on page 285.

SCM Troubleshooting

The troubleshooting tables below provides basic problem-solving assistance. The following subjects are covered:

Error Messages

The following table lists common error messages, and explains how to solve them.

Error Message	Description	Solution
The username or password is incorrect.	The username and/or password do not match.	Verify that the username and password were entered correctly. If the error message keeps appearing, contact service@qcore.com or contact your local agent/ distributor, and refer to page 268.
Service 'Q Core Logger Server' (QCoreLoggerSrv) failed to start.	The message appears after trying to install the Software, due to insufficient privileges.	Verify that you have sufficient privileges to start system services. Contact your IT department - re-install the software as an Administrator.

Error Message	Description	Solution
Failed to connect to the server.	Username and password were entered, yet the application couldn't connect to the Q Core server.	Check the following: • 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 contact your local agent/ distributor, and refer to page 268.
Connection with the pump has lost (no samples in 4 seconds)	Communication cable is either not properly connected or faulty.	Verify that the communication cable is properly attached to the pump and the PC. • Restart the process. • If problem persists, replace communication cable.
The Sapphire Configuration Manager version you are using is out of date.	The SCM version installed on your PC is not the most up to date version.	The most recent version of the Sapphire Configuration Manager is available for download from Q Core's FTP site at https://qcore.smartfile.com.
File name required	The file name field is empty.	Make sure that the file name was typed into the appropriate field.

Error Message	Description	Solution
File name supports uppercase/lowercase letters, numbers, underscores and spaces only	A character not supported by the SCM was used in the file name.	Update the file name to include uppercase/lowercase letters, numbers, underscores and/or spaces only.
Corrupt File	Configuration file is corrupted.	Create a new Configuration File with the source pump, or select an alternate file.
Loading failed	Failed to load configuration file to all connected pumps.	• Repeat the loading process. • If loading failed after repeating the process, contact service@qcore.com or contact your local agent/ distributor, and refer to page 268.

Create Configuration File Error Messages

The following table lists common error messages in the Configuration File creation process, and explains how to solve them.

Status	Error Message / Cause	Solution
File Failed	• Pump SN X Pump disconnected during file creating process Create Configuration File again and make sure the pump is connected throughout the process	Confirm that the communication cable is properly attached to the pump, and that the computer or RS-232. Replace any faulty equipment. Re-create the Configuration File, and make sure that the pump is connected throughout the process.

Status	Error Message / Cause	Solution
	• Pump SN X Pump disconnected from the power supply during file creating process. Create Configuration File again and make sure the pump is connected to a power supply throughout the process	Confirm that the pump is properly attached to a power supply. Re-create the Configuration File, and make sure that the pump is connected to a power supply throughout the process.
	• Configuration File failed Retry Create Configuration File	Re-create the Configuration File.
	• Configuration File failed Pump "SN X" has a new Drug Library that is pending upload. Upload the Drug Library on the pump and repeat the Configuration File Creating process	Upload the Drug Library on source pump by pressing **Yes** at the following prompt: **A more recent drug library is available. Upload now?** After the Drug Library is uploaded to the source pump, re-create the Configuration File (Create Configuration File on page 273).
Pump SW not compatible	The pump software version is not supported by the SCM. For further information, contact your local representative, or contact Q Core.	The Sapphire Configuration Manager only supports Multitherapy Pumps running Rev 15. Use Q Core's Pump Loader to upgrade to software version 15.

Load Configuration File Error Messages

The following table lists common error messages in the Configuration File loading process, and explains how to solve them

Status	Error Message	Solution
Loading Failure	Station X, Pump SN X Pump disconnected during loading process. Repeat the loading process and make sure the pump is connected until loading is completed Pump will not be operable until loading is completed.	Confirm that the communication cable is properly attached to the pump, and to the computer via RS-232. Replace any faulty equipment. Repeat the loading process and make sure the pump is connected until loading is completed.
	Station X, Pump SN X Pump disconnected from the power supply during loading process. Repeat the loading process and make sure pump is connected to a power supply until loading is completed Pump will not be operable until loading is completed.	Confirm that the pump is properly attached to a power supply. Repeat the loading process and make sure the pump is connected to a power supply until loading is completed.

Status	Error Message	Solution
	Station X, Pump SN X Loading failed Repeat loading process Pump will not be operable until loading is completed.	Repeat loading process.
	Station X, Pump SN X Pump disconnected during loading process. Repeat the loading process and make sure the pump is connected until loading is completed Do not use the pump until loading is completed.	Confirm that the communication cable is properly attached to the pump, and to the computer via RS-232. Replace any faulty equipment. Repeat the loading process and make sure that the pump is connected until loading is completed.
Pump SW not compatible	Station X, Pump SN X Pump SW version must match the configuration file SW version	Pump SW version must match the Version described in the Configuration File. Using Q Core Pump Loader, update all pumps to the same software version as that of the source pump.

General Issues

The following table lists some common faults, and explains how to solve them.

Description of Problem	Solution
Failed to create configuration.	Try to create the configuration file again. If unsuccessful, contact Q Core Support. Contact information can be found by pressing Help in the top right corner of the SCM.
The pump is disconnected before the loading process of a configuration file is complete. The SCM automatically shuts down.	Re-open the SCM and re-load the configuration file.
Cannot connect to COM when setting up stations.	Confirm that the COM port is configured for a different station or that it is used by another application.
Loading failed.	Restart the loading process. If unsuccessful, contact Q Core Support. Contact information can be found by pressing **Help** at the top-right corner of the SCM.
The cable is connected and a COM port is selected, but the pump does not appear in the list.	There may be a delay, please wait until the pump appears in the list.
Could not log in with username and password.	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 contact your local agent/distributor, and refer to page 268.
After loading the configuration file to the pump, the pump prompts the following error: **Version error Code: 7 Please contact an authorized Technician**	Repeat the loading process. After it is completed, the error is removed and the pump returns to be operable.

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REF 15025-048-0027 Rev.06 | 10/2020