USER MANUAL SAPPHIRE MULTI-THERAPY AND DEDICATED INFUSION PUMPS – ADDENDUM 3

15031-048-0060* (Rev 13 Ver01), Update to Sapphire SW 13.23.2 and clarification regarding administration sets of different manufacturers

**P/N 15031-048-0060 refers to User Manual for Sapphire Rev 13 Ver01 – English for US

Changes to Page 2: Clause 'Warning'

Update: The following sentences were added to the end of the first paragraph:

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.

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

Changes to Chapter 1: Introduction; Clause 'Product Overview and Indications'

Update: *The third paragraph was updated with an added intended use - air transportation*

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

Changes to Chapter 1: Introduction; Clause 'Safety and Compliance Information; Sub-clause 'Safety and compliance information'

Update: *An additional standard was added to the Compliance and Classification section*

IEC 60601-1-12 - Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment.

Changes to Chapter 1: Introduction; Clause 'Proper Use of the Pump'; Sub-clause 'Administration Sets

Update: The warning was replaced with the following:

Use Q Core standard administration sets listed here or 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 page 60.

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

Changes to Chapter 1: Introduction; Clause 'Basic Infusion Safety Information'
Update: The following sentences were added to the first paragraph:

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.

Changes to Chapter 1: Introduction; Clause 'Proper Use of the Pump'; Sub-clause 'Administering Infusions: General Safety Precautions'
Update: Three bullets were added to the warnings list:

- 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.

Changes to Chapter 1: Introduction; Clause 'Warnings and Safety Precautions'; Sub-clause 'Electromagnetic Compatibility'
Update: the Electromagnetic Compatibility sub-clause has been rephrased:

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

Changes to Chapter 2: Components, Accessories, and Administration Sets; Clause 'Using Pump Accessories'; Sub-clause 'Administration sets'

Update: *the following information was added to the first paragraph, after the first sentence:*

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.

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

Changes to Chapter 2: Components, Accessories, and Administration Sets; Clause 'Using Pump Accessories'; Sub-clause 'Q Core Approved Administration sets'

Update: *The warning was replaced with the following:*

Use Q Core standard administration sets listed here or 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.

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

Update: *the following information was added below the approved Q Core administration sets table:*

All filters used in Q Core approved administration sets are air eliminating filters.

Changes to Chapter 3: Fundamental Concepts and Operations; Clause ' Working with the Main Display'; Sub-clause 'Alphanumeric keypad'
Update: The first paragraph was updated:

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

Changes to Chapter 3: Fundamental Concepts and Operations; Clause 'Overview of Icons'
Update: An icon was added to the icons table:

Icon	Meaning	Notes

⌀	Air detection is disabled (OFF)	No Air in Line alarm is triggered when the pump air detection is disabled (OFF). A technician authorization code is required to enable or disable the air detection (this can only be set manually on the pump and not by the DLE). If air detection is disabled (OFF), use a set with an air-eliminating filter to prevent injury. Always ensure the administration set is primed before starting an infusion.

Changes to Chapter 3: Fundamental Concepts and Operations; Clause ' Enabling Special Features'; Sub-clause 'A technician authorization code is required to enable/disable the following additional features'

Update: The following replaces the New Patient feature in the table:

Feature	Delivery Mode(s)	Description/Notes
New Patient	All	Allow users to associate an infusion with a patient and reset the Accumulated VI (accumulated volume infused)

Update: The following was added to the features table:

Feature	Delivery Mode(s)	Description/Notes
Air Detection	All, except Epidural	Determines whether the pump air detection is disabled (OFF) or enabled (ON) during infusion. 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 (OFF) the user is prompted to use a set with an air-eliminating filter.

Changes to Chapter 4: Getting Started; Clause; 'Connecting the Infusion Container to the Administration Set'

Update: The '> To connect the container to the administration set:' workflow was updated:

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

Changes to Chapter 5: Using the Infusion Modes; Clause 'Continuous Mode'; Sub-clause 'To begin a continuous infusion without drug library'

Update: The following step was added after step #2:

3. If a warning that the air detection is disabled (OFF) appears, ensure that a set with an air-eliminating filter is used and press OK.

Changes to Chapter 5: Using the Infusion Modes; Clause 'Continuous Mode'; Sub-clause 'To begin a continuous infusion with a drug library'

Update: The following step was added after step #2:

3. If a warning that the air detection is disabled (OFF) appears, ensure that a set with an air-eliminating filter is used and press OK.

Changes to Chapter 5: Using the Infusion Modes; Clause 'Multi-step Mode'; Sub-clause 'To begin a Multi-step infusion without drug library'

Update: The following step was added after step #2:

3. If a warning that the air detection is disabled (OFF) appears, ensure that a set with an air-eliminating filter is used and press OK.

Changes to Chapter 5: Using the Infusion Modes; Clause 'Multi-step Mode'; Sub-clause 'To begin a Multi-step infusion with drug library'

Update: The following step was added after step #2:

3. If a warning that the air detection is disabled (OFF) appears, ensure that a set with an air-eliminating filter is used and press OK.

Changes to Chapter 5: Using the Infusion Modes; Clause 'TPN Mode'; Sub-clause 'To begin a TPN infusion'

Update: The following step was added after step #2:

3. If a warning that the air detection is disabled (OFF) appears, ensure that a set with an air-eliminating filter is used and press OK.

Changes to Chapter 5: Using the Infusion Modes; Clause 'Intermittent Mode'; Sub-clause 'To begin an Intermittent infusion without drug library'

Update: The following step was added after step #2:

3. If a warning that the air detection is disabled (OFF) appears, ensure that a set with an air-eliminating filter is used and press OK.

Changes to Chapter 5: Using the Infusion Modes; Clause 'Intermittent Mode'; Sub-clause 'To begin an Intermittent infusion with drug library'

Update: The following step was added after step #2:

3. If a warning that the air detection is disabled (OFF) appears, ensure that a set with an air-eliminating filter is used and press OK.

Changes to Chapter 5: Using the Infusion Modes; Clause 'PCA Mode'; Sub-clause; Infusion Parameters: PCA Mode

Update: the following replaces the Boluses per 1 h or Total dose per 1h in the table:

Parameter	Description
Bolus per 1h (or 4hrs) OR Total dose per 1hr (or 4hrs)	The maximum number of boluses OR the maximum dose that can be delivered during a 1 hour (or 4 hours) period. (User with high authorization codes can set the 1 hour or 4 hours parameters). The Total dose limit takes into account medication delivered via: Continuous rate Yes Demand Bolus Yes Loading Dose Yes Clinician bolus Yes All doses, including boluses given by clinician, are taken into account. When the Total dose limit is reached, the patient is locked out from activating additional boluses.

Changes to Chapter 5: Using the Infusion Modes; Clause 'PCA Mode'; Sub-clause 'To begin a PCA infusion without drug library'

Update: The following step was added after step #2:

3. If a warning that the air detection is disabled (OFF) appears, ensure that a set with an air-eliminating filter is used and press OK.

Changes to Chapter 5: Using the Infusion Modes; Clause 'PCA Mode'; Sub-clause 'To begin a PCA infusion with drug library'

Update: The following step was added after step #2:

3. If a warning that the air detection is disabled (OFF) appears, ensure that a set with an air-eliminating filter is used and press OK.

Changes to Chapter 5: Using the Infusion Modes; Clause 'PCA Mode'; Sub-clause; PCA Mode: Mid-infusion actions

Updates:

- The term Viewing Bolus History is replaced with the term Viewing Delivery History
- The following replaces the text in 'To update parameters using the View/edit function key' section, third bullet in step #5:
  Delivery History: Displays summary of medication delivery events. For more information, refer to Viewing Delivery History section.

Changes to Chapter 5: Using the Infusion Modes; Clause 'Epidural Mode'; Sub-clause 'Infusion Parameters: PCEA Mode'

Update: the following replaces the Boluses per 1 h or Total dose per 1h in the table:

Parameter	Description
Bolus per 1h (or 4hrs) OR Total	The maximum number of boluses OR the maximum dose that can be delivered during a 1 hour (or 4 hours) period. (User with high authorization codes can set

dose per 1hr (or 4hrs)	the 1 hour or 4 hours parameters). The Total dose limit takes into account medication delivered via: Continuous rate Yes Demand Bolus Yes Boluses given by a clinician, are not taken into account for the Total dose limit: Loading Dose No Clinician bolus No When the Total dose limit is reached, the patient is locked out from activating additional boluses.

Changes to Chapter 5: Using the Infusion Modes; Clause 'PCEA Mode'; Sub-clause; PCEA Mode: Mid-infusion actions

Updates:

- The term Viewing Bolus History is replaced with the term Viewing Delivery History
- The following replaces the text in 'To update parameters using the View/edit function key' section, third bullet in step #5:
  Delivery History: Displays summary of medication delivery events. For more information, refer to Viewing Delivery History section.

Changes to Chapter 5: Using the Infusion Modes; Clause 'Epidural Mode'; Sub-clause 'Infusion Parameters: Epidural Intermittent Mode'

Update: the following replaces the Boluses per 1 h or Total dose per 1h in the table:

Parameter	Description
Bolus per 1h (or 4hrs) OR Total dose per 1hr (or 4hrs)*	The maximum number of boluses OR the maximum dose that can be delivered during a 1 hour (or 4 hours) period. (User with high authorization codes can set the 1 hour or 4 hours parameters). The Total dose limit takes into account medication delivered via: Continuous rate Yes Intermittent dose Yes Demand Bolus Yes Boluses given by a clinician, are not taken into account for the Total dose limit: Clinician bolus No When the Total dose limit is reached, the patient is locked out from activating additional boluses.

Changes to Chapter 5: Using the Infusion Modes; Clause 'Epidural Mode'; Sub-clause 'Epidural Intermittent Mode: Mid-infusion Actions'

Updates:

- The term Viewing Bolus History is replaced with the term Viewing Delivery History
- The following replaces the text in 'To update parameters using the View/edit function key' section, third bullet in step #5:

Delivery History: Displays summary of medication delivery events. For more information, refer to Viewing Delivery History section. Applies only when Epidural Intermittent with PCEA infusion was programmed.

- The following replaces the first paragraph in 'Administering a Clinician Bolus' section
  A bolus of any amount (within the predefined range) can be delivered by clinicians who have a High authorization level code. A clinician bolus can be given only while the infusion is running. The lockout time is reset after delivering a clinician bolus.
  Clinician bolus is applicable only when programming Epidural Intermittent with PCEA.

Changes to Chapter 5: Using the Delivery Modes; Clause 'Epidural mode'; Sub-clause 'Epidural Intermittent Mode: Mid-infusion Action'; Sub-sub-clause 'Administering a Clinician Bolus'

Updates: the note at the end of the Sub-clause was replaced with the following note

The RATE of the Clinician Bolus, as all other boluses in PCEA mode is defined prior to programming the infusion. It can be set to 125 mL/h or 200 mL/h (for more information, refer to Epidural Mode Options Menu on page 205).

Changes to Chapter 6: Basic Infusion Operations; Clause 'Starting New Infusions: Shortcuts'; Sub-clause 'Repeating last infusion'

Updates:

- *The first note was replaced with the following note:*
  When using Repeat Last Infusion option, the Delivery History, Accumulated VI parameter and the remaining Lockout Time are not cleared; instead, they continue counting from the previous infusion. For more information about Accumulated VI, and Delivery History, refer to Using the New Patient feature chapter.
- '*To repeat the last infusion' section, the following step was added after step #1:*
  2. If a warning that the air detection is disabled (OFF) appears, ensure that a set with an air-eliminating filter is used and press OK.

Changes to Chapter 6: Basic Infusion Operations; Clause 'Starting New Infusions: Shortcuts'; Sub-clause 'Using a PreSet Program'

Update: 'To start an infusion using PreSet programs function' section, the following step was added after step #1:

2. If a warning that the air detection is disabled (OFF) appears, ensure that a set with an air-eliminating filter is used and press OK.

Changes to Chapter 6: Basic Infusion Operations; Clause 'Resuming Infusions After Pump Shutdown'

Update: 'To resume the infusion' section was updated:

To resume the infusion:

- On the Attention screen, press OK.
- If a warning that the air detection is disabled (OFF) appears, ensure that a set with an air-eliminating filter is used and press OK.
- The Paused infusion screen appears, press Request continue to resume the infusion.
- On the attention screen press OK to confirm.
- The running screen appears.

Changes to Chapter 7: Options Menu: Configuring, Viewing and Testing; Clause 'Main Options: Overview'

Update: the last sentence in the overview was replaced with the following sentence:

The screen also provides access to testing components and viewing pump (as opposed to infusion) parameters (e.g. System parameters, Event logs, and Delivery History)

Changes to Chapter 7: Options Menu: Configuring, Viewing and Testing; Clause 'Managing Configuration Settings'; Sub-clause 'View Menu'

1. *Update: View system parameters*

   (i) The description of Single Air detector, Accumulated Air detector and Accumulated Threshold has been updated

   These settings are associated with the amount of air that triggers an Air in Line alarm, when the air detection is enabled (ON). These settings can be modified by Technicians only. For more information, refer to the Service Manual. Note: While a non-epidural infusion is running at a rate of 4 mL/h or lower, the Single air detector switches automatically to ON.

   (ii) A setting was added below the accumulated threshold, "Air detection".

   This setting indicates the air detection is disabled (OFF), and it is displayed instead of the single and accumulated air settings mentioned above.

2. *Update: The bolus history category in the table was replaced with the following:*

Category	Description/Notes
Delivery History (PCA, PCEA and Epidural intermittent delivery modes only)	Provides a view of the boluses and the total amount of medication delivered during PCA, PCEA or PIEB infusion. The Delivery History is associated with a patient. For more information, refer to Viewing Delivery History section.

Changes to Chapter 7: Options Menu: Configuring, Viewing and Testing; Clause Managing Configuration settings; Sub-clause Managing Alarm Settings

Update: In the description of 'Infusion near end' option the note has been removed

Changes to Chapter 7: Options Menu: Configuring, Viewing and Testing; Clause Viewing Bolus History'

Update: Title and first paragraph were replaced with the following:

Viewing Delivery History

This screen, which appears only in PCA, PCEA and PIEB delivery modes, provides a summary of all bolus-related events that occurred during a specified time frame and the total amount of medication delivered throughout the treatment.

Note: To access the Delivery History during PCA, PIEB or PCEA infusions:

From the toolbar select View/edit, then, select Edit PCEA --> Delivery History.

When the pump is locked, the Delivery History can be accessed from the toolbar without unlocking the pump. Delivery History information includes:

Update: The Bolus History information table was updated:

1. Total Dose given parameter was added
2. History period parameter was replaced with the text below

Name of Value	Description/Notes
Total Dose given	The total amount of drug delivered to the patient during a treatment through Boluses, Loading dose, Continuous rate, KVO if applied and Intermittent doses. When using Repeat Last Infusion, this value accumulates from the previous infusion/s.
Bolus History Period	The number of hours over which the displayed boluses occurred. The default history period is 1 hour, and it can be set from 1 hour up to the number of hours that the infusion has been running. The setting can be modified by pressing >, entering a value using the keypad, and then pressing OK.

3. The note below the table was replaced with the following note
   When using the Repeat Last Infusion option (for the same patient), the Delivery History, accumulated VI and lockout time are not cleared, they continue counting from the previous infusion.

Changes to Chapter 8: Using Advanced Features; Clause 'Using the New Patient Feature'

Update: The entire clause was replaced with the following:

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

Note: The New Patient feature can be enabled/ disabled by technicians only.

When a New Patient is selected, entries associated with the patient can be tracked in the Event Log (Viewing the Event Log section). In addition, when Repeat Last Infusion is used the pump calculates the accumulated volume infused (Accumulated VI) for all infusions associated with the patient, and

the Delivery History. When a new patient is selected, the Accumulated VI and Delivery History are automatically cleared (for more information, refer to Monitoring the Accumulated Volume Infused (Shift's Total) section). The current accumulated Delivery history can be viewed via the Options menu. When an infusion is running, the Delivery History can be accessed via the View/Edit soft key in the toolbar (for more information, refer to the Viewing Delivery History section).
To select a new patient:
1. From the startup screen, select New Infusion or PreSet Programs
2. On the New Patient screen, select Yes.

Changes to Chapter 10: Alarms and Troubleshooting; Clause: 'Level 3 Alarms'

Update: Additional Alarms were added to the table.

Alarm Title	Displayed Text
Potential Air in Line	Press OK to test for air
Pump Stopped	Please quit and then restart the infusion

Changes to Chapter 11: Maintenance and Storage; Clause: 'Preventive Maintenance'; Sub-clause: 'Cleaning and Disinfecting the Pump'

Update: Cleaning and Disinfection: Safety Precautions

- *A safety precaution was added to the list:*

Do not clean the pump with Bleach (8.25% concentration, mixed at 1 part bleach in 10 parts water), as deterioration may occur.

- *The precaution note was replaced with the following precaution note:*

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's official approved list of materials (published at www.qcore.com)

Update: Cleaning and Disinfection Procedure - one cleaning agent was added to the table:

Cleaning/Disinfecting Solution	Manufacturer
Virox® AHP 5 RTU	Diversey

Changes to Chapter 11: Maintenance and Storage; Clause 'Preventive Maintenance'; Sub-clause 'Alarm Testing'

Updates:

- *The first paragraph was replaced with the following:*

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.
For the Sapphire Epidural pump manual alarm testing, refer to the testing protocols available for authorized technicians (for more information refer to the service manual).

- *A note was added to the Air in Line test:*

Note - To test the Air in Line alarm, ensure the air detection is enabled (ON) in the technician options. If the air detection disabled (OFF) icon is displayed and a warning message stating the air detection is disabled (OFF) appears when programing an infusion, the Air in Line alarm will not be triggered.

Changes to Chapter 11: Maintenance and Storage; Clause: 'Preventive Maintenance'; Sub-clause: 'Battery Care Information'

Update: The first paragraph (preceding the table) was replaced with the following:

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, on the upper right corner of the indicators bar, indicates remaining battery capacity. Check the status of the battery charge level icon regularly:

Changes to Chapter 12: Technical specification; Clause: 'Environmental specifications'; Sub-clause: ''Operating Conditions'

Update: Transient conditions were added to the Temperature and Humidity conditions:

Humidity : (15% to 90% at transient state)

Temperature: (-20°C to +50°C at transient state)