eitan medical sapphire™

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# Sapphire™

## User Manual

### Multi-Therapy & Epidural Infusion Pumps

For use with
Sapphire Infusion Pump Software r16.20

# Important Notice

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

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

# Prescription Notice

Federal United States law restricts this device for sale by or on the order of a physician only {21 CFR 801.109(b) (1)}.
The Sapphire pump is for use at the direction of, or under the supervision of, licensed physicians and/or licensed healthcare professionals who are trained in the use of the pump and in the administration of blood, medication and parenteral nutrition. The instructions for use presented in this manual should in no way supersede established medical protocol concerning patient care.

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

# Disclaimer

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

# Warning

Use only Eitan Medical Ltd. supplied administration sets and accessories with the Sapphire pump. Use of administration sets other than Eitan 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.

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.

Eitan Medical Ltd. warranty on this device will be null and void and Eitan Medical Ltd. will assume no responsibility for incidents which may occur if the product is not used in accordance with product labeling. Refer to Warnings and Safety Precautions on page 25 for a complete list of warnings and cautions.

## Technical Assistance

For technical questions, troubleshooting assistance and reporting of unexpected events, please contact your local agent/distributor, and refer to Technical Support Contacts on page 330. You may also contact Eitan Medical Ltd. support via email to the following address: support@eitanmedical.com

## Serious Incident Reporting

Any serious incident that has occurred in relation to the device should be reported to complaints@eitanmedical.com and the local competent authority.

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# Chapter 1: Introduction

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


Product Overview and Indications ..... 10
Terms and Abbreviations ..... 14
Document Conventions ..... 16
Safety and Compliance Information ..... 16
Warnings and Safety Precautions ..... 25


## Product Overview and Indications

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

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

The pump is intended to be used by both licensed health care professionals and lay users. The pump is intended to be used in the following environments: clinical, ambulatory, pre-hospital, air and ground transportation and home.

The dedicated Eitan Medical Sapphire administration sets for the Sapphire Infusion Pump are intended for single-patient use and single-use only.

This user manual supports the use of Sapphire software version r16.20. Verify that the software version that appears on the Sapphire turn-on screen is r16.20. The version number can be viewed from **View system** as well (for more information, refer to View Menu on page 243).

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

## Clinical Benefits

The pump offers significant advantages over manual administration of fluids, including the ability to deliver fluids in very small volumes, and the ability to deliver fluids at precisely programmed rates or automated intervals, thus increasing patient safety.

These and other pump features result in the following benefits:

- Consistent medication flow rates within a stated accuracy range
- Reduction of medication treatment errors
- Simplification of treatment profiles (delivery modes)

## Contraindications

The pump has no contraindications.

## Dedicated Delivery Mode Configurations

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

| Pump Type | Delivery Modes Supported |
|---|---|
| Multi-therapy | 1 or more of the following:<br>• Continuous<br>• Intermittent<br>• TPN<br>• PCA<br>• Multi-step<br>• Epidural |
| Epidural | • PCEA<br>• Intermittent Epidural |

Each delivery mode is assigned a unique color that appears on the Indicators Bar, helping users to easily differentiate between the different modes (Figure 3.1 on page 105).

## Features

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

### Treatment-Related Features

- **Single platform device:** The delivery mode of the pump can be changed, according to the required type of infusion.
- **Priming alternatives:** Both manual priming (by gravity) and automatic priming (using the pump) are available.
- **Quick infusion titration (in most delivery modes):** Modification options allow updating of infusion parameters without stopping the infusion.
- **Delayed Infusion:** Allows users to program an infusion in advance, and set it to Standby for an unlimited time period, or to set it for a defined Delayed Period.
- **Repeat Last Infusion:** Automatically saves the parameters of the last infusion, and allows a quick-start infusion using these parameters.
- **Resume Infusion After Pump Shut Down:** Allows resuming an infusion after the pump has been shut down from a running or paused infusion.
- **PreSet Programs:** Allows saving the infusion parameters of commonly used protocols, and allows a quick-start infusion using these parameters.
- **Piggyback (Continuous delivery mode only):** Provides the ability to add a Secondary line to a running continuous infusion, without re-entering infusion parameters for the Primary line.
- **Flexible programming features (excluding TPN mode):**
  - Infusions can be programmed in a variety of dose rate units, including the following, per different time units: mL, mg, mcg, units, mUnits, Million Units, gram, nanogram, mmol, mEq.

- Infusion rate can be programmed as a weight based infusion (patient weight can range from 0.1- 500 Kg).
- PIEB – epidural infusion can support the combination of programmed intermittent doses with patient controlled boluses.

## Safety-Related Features

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

## Terms and Abbreviations

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

| Term/Abbreviation | Meaning |
|---|---|
| AFFV | Anti-Free-Flow-Valve |
| AC/DC | Alternating Current / Direct Current |
| Accum. | Accumulated |
| CCA | Clinical Care Area |
| CW | Continuous Wave |
| DFU | Directions for Use |
| EBP | External Battery Pack |
| ECG | Electrocardiogram |
| Eitan Medical Sapphire administration set | Sapphire administration set |
| EMC | Electromagnetic compatibility |
| EMI | Electromagnetic interference |
| Epi. Int | Epidural Intermittent |
| h | Hour |
| Kg | Kilograms |
| KVO | Keep Vein Open |
| mcg | Micrograms |
| mEq | Milliequivalents |
| min | Minutes |
| mg | Milligrams |
| mL | Milliliters |
| mmol | Millimoles |
| Mounting System | Sapphire Multi-Pump Mounting System |
| MRI | Magnetic Resonance Imaging |

| Term/Abbreviation | Meaning |
|---|---|
| mUnits | Milliunits |
| M Units | Million Units |
| nanog | Nanograms |
| Occ. | Occlusion |
| PAV | Pressure Activated Valve |
| PC | Personal Computer |
| PCA | Patient Controlled Analgesia |
| PCEA | Patient Controlled Epidural Analgesia |
| PIEB | Programmed Intermittent Epidural Bolus |
| Prim. | Primary |
| RFID | Radio Frequency Identification |
| Sec. | Secondary |
| TPN | Total Parenteral Nutrition |
| VI | Volume Infused |
| VTBI | Volume To Be Infused |
| Eitan Medical | Eitan Medical Ltd. |
| Sapphire pump | Eitan Sapphire infusion pump family |

## Document Conventions

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

| | |
|---|---|
| | **Warnings** indicate instructions for serious adverse reactions and potential safety hazards which, if not followed, may result in personal injury. |
| | **Cautions** indicate instructions which, if not followed, may result in damage to the equipment or to the quality of treatment. |
| | **Notes** provide additional information to help obtain optimal equipment performance. |

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

## Safety and Compliance Information

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


- Symbols and Labeling on page 17
- Compliance and Classification on page 23
- Biocompatibility on page 24
- Sterilization on page 24
- Degree of Protection Against Ingress of Water and Dust on page 24

## Symbols and Labeling

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

| Symbol | Description | Location |
|---|---|---|
| SN | Serial number. | Back of the pump casing, front of Sapphire Connect, all accessories, product box and on the back of the mini cradle. |
| CE | CE certification mark. | Back of the pump casing, back of the Sapphire Connect, back of the mini cradle, EBP, PCA Lockboxes 100, 250 and 500mL, and Mounting System. |
| MD | Medical Device. | Back of the Sapphire Connect, Sapphire Connect product box. |
| REF | Catalog Number. | Back of the pump casing, front of Sapphire Connect, all accessories, product box. |
| EC REP | Authorized representative in the European Community. | Back of the Sapphire Connect, Sapphire Connect product box. |
| LOT | Batch code. | Inside casing of the mini cradle, EBP, PCA Lockboxes 100, 250 and 500mL, and Mounting System. |

| Symbol | Description | Location |
|---|---|---|
| | Caution: Consult accompanying documents for safety instructions (service to be performed by qualified technician; consult Service Manual before removing cover). | Back of the pump casing cover, EBP, on the back of the mini cradle, and Mounting System. |
| | Storage temperature range. | Shipping package. |
| | Storage humidity range. | Shipping package. |
| | Storage atmospheric pressure range. | Shipping package. |
| | Consult instructions for use. | EBP, on the back of the mini cradle, and PCA Lockbox 500mL. |
| | Follow instructions for use. | Back of the pump casing, on the back of Sapphire Connect, PCA Lockbox 250mL, and Mounting System. |

| Symbol | Description | Location |
|---|---|---|
| C US | The C and US indicators adjacent to the CSA mark signify that the product has been evaluated to the applicable CSA and UL standards, for use in Canada and the United States. | Back of the pump casing and Mounting System. |
| | Date of manufacture (year). | Back of the pump casing. |
| | Name and address of the manufacturer. | Back of the pump casing, on the back of Sapphire Connect, on the back of the mini cradle, EBP, PCA Lockboxes 100, 250 and 500mL, and Mounting System. |
| | Identify defibrillation proof and degree of protection against electric shock. Equipment Type BF Applied Part. | Back of the pump casing. |
| | Input: 100-240 V; 50-60 Hz; Max. 120 VA<br>Output: 10V DC; Max. 4.7 A. | Mounting System. |
| IP24 | Dust and splash proof. | Back of the pump casing, and front of the Sapphire Connect. |
| IPX1 | Waterproof rating. | Mounting System. |
| IPX2 | Waterproof rating. | EBP. |

| Symbol | Description | Location |
|---|---|---|
| Rx Only | US federal law restricts this device to prescription only. | Back of the pump casing, on the back of the Sapphire Connect, on the back of the mini cradle, PCA Lockboxes 100, 250, and 500mL. |
| | Waste Electrical and Electronic Equipment (WEEE) Disposal. This symbol indicates that used batteries and electronic equipment must not be disposed of as unsorted municipal waste, and must be collected separately. Contact an authorized representative for information concerning the decommissioning of your equipment. | Back of the pump casing cover, on the back of Sapphire Connect, EBP, and on the back of the mini cradle. |
| ALARM | Alarm — LED, when lit, indicates an alarm situation in the operation of the pump. Refer to Hardware and Software Components on page 39. | Front casing of the pump, below the red LED. |
| CHARGE | Charge — LED, when lit, indicates that the battery is charging. Refer to Hardware and Software Components on page 39. | Front casing of the pump, below the yellow LED. |

| Symbol | Description | Location |
|---|---|---|
| RUN | Run — LED, when lit, indicates that the pump is infusing. Refer to Hardware and Software Components on page 39. | Front casing of the pump, below the green LED. |
| STOP | Stop — Allows you to temporarily stop the infusion. | Front casing of the pump, below the touch screen. |
| On/Off | On/Off — Turns pump On and Off. | Front casing of the pump, below the touch screen. |
| MR WARNING Projectile Hazard | MR Unsafe (Do not use in MR environment) | Back of the pump casing, and the back of Sapphire Connect. |
| | Connectivity — LED, indicates the communication status of the Sapphire Connect. Refer to Troubleshooting on page 71 | Side of Sapphire Connect, below the connectivity LED. |
| | Charge — LED, when lit, indicates that the Sapphire Connect battery is charging. | Side of Sapphire Connect, below the charging LED. |
| | Electromagnetic radiation from the device is below the limits specified by the Federal Communications Commission | Back of Sapphire Connect. |
| | Input current | Front of Sapphire Connect |

| Symbol | Description | Location |
|---|---|---|
| | Output current | Front of Sapphire Connect |
| | Direct current | Front of Sapphire Connect |
| UDI | Indicates a carrier that contains unique device identifier information. | Back of the pump casing, all Sapphire accessories. |
| | Do not use if package is damaged | On the products label or box |
| | Keep dry/Keep away from rain | On the products label or box |
| | Keep away from sunlight | On the products label or box |
| | Fragile; handle with care | On the products label or box |

## 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.

- UL 60601-1 and CAN/CSA C22.2 601.1-M90 medical electrical equipment, which classifies the Sapphire pump as:
  - Class II
  - Type BF
  - Continuous operation
  - IP24 dust and splash proof
  - Not suitable for use in the presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide
- IEC 60601-1-2: Electromagnetic compatibility.
- IEC 60601-2-24: Infusion pumps and controllers, which classifies the Sapphire pump as a Type 4 pump (continuous infusion flow, combined with bolus delivery).
- IEC 60601-1-11: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.
- IEC 60601-1-12: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services 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.

## 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 Eitan Medical 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 10 L/min at a pressure of 80-100 kN/m2 for 5 minutes at all angles, and protects from touch by objects greater than 12 millimeters such as fingers.

# Warnings and Safety Precautions

The following sections contain important safety information.

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


- General Warnings and Precautions on page 25
- Proper Use of the Pump on page 30


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 Eitan Medical Ltd. trained, qualified personnel only. |

- All service procedures, including certification, calibration, part replacement and modification of equipment, should be carried out only by a qualified service technician. Detailed instructions are available in the service manual.

| | |
|---|---|
| ⚠ | Eitan Medical Ltd. does not approve any changes or modifications to this device by the user. Any changes or modifications could void the user's authority to operate the equipment. |

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

## Security

- Do not disclose passwords for High Medium or Technician authorization to patients, home users or any other unauthorized personnel.
- Do not operate the pump in clinical use under the Technician mode. The pump must not be in the Technician mode when outside of the Service or Repair lab! If the pump is in clinical use, and the pump display indicates that it is in the Technician mode, **immediately** turn OFF the pump; then, turn it ON again, in order to log out of the Technician mode.
- Unless the pump is required to be connected to facility's wired data system, before using it for clinical use, pay attention to the following:
  - Unexpected message or icon concerning the pump being connected to the PC.
  - Any cable connected to the pump or to the cradle serial ports.

## Waste Disposal

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

### Waste Disposal Safety Warnings

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

## Explosion Hazard

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

## Electric Shock Hazards

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

### Electrical Safety Warnings

- 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 dedicated Sapphire power supply.

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

## Electromagnetic Compatibility

The Sapphire infusion system 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 infusion system, do not use the infusion system near sources of strong electric and magnetic interference (EMI), such as MRI, CT, diathermy, electromagnetic security systems (e.g metal detectors), radio frequency identification (RFID), electrosurgery devices, lithotripsy devices, 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 system and/or the operation of the Infusion system.

| | |
|---|---|
| | 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 infusion system to perform as intended without disturbing other equipment.
- Separate the infusion system from all other electronic equipment. If the infusion system must be used near other electrical equipment, monitor the equipment to ensure there is no electromagnetic interference.
- Infusion systems should not be used adjacent to or stacked with other equipment. If the infusion system must be used adjacent to or stacked with other equipment, monitor the infusion system to verify normal operation.

- If you identify or suspect that external RF sources or other equipment are influencing infusion system operation (from known or unknown sources), try to (as applicable) increase the infusion system's distance from the EMI source, re-orient the infusion system, relocate the infusion system, connect the infusion system to a 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, as defined by IEC 60601-1-2/EN 60601-1-2 (edition 4.1), are designed to provide reasonable protection against harmful interference in a typical medical installation.

Harmful interference" is defined in 47 CFR §2.122 by the FCC as follows: Interference which endangers the functioning of a radionavigation service or of other safety services or seriously degrades, obstructs, or repeatedly interrupts a radio communication service operating in accordance with the [ITU] Radio Regulations.

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

## Proper Use of the Pump

Using the pump not according to its labeling or intended use might result in the following side effects: pain, exacerbation of illness, injury or harm, stroke, electrocution, exsanguination trauma and death. 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. The administration route and infusion parameters are determined by the clinician, based on the needs of the patient.

When using the pump, periodic patient monitoring must be performed by healthcare providers, based on clinical practice, to ensure that the infusion is proceeding as expected. For home users in an ambulatory environment, monitoring may be provided by means of a visiting or an on-call nurse, training of patient or relative, or any other means specified by the provider of the devices, based on suitable clinical practice for said environment. The pump is capable of developing positive fluid pressures to overcome widely varying resistances to flow, such as resistance imposed by small-gauge catheters, ports, filters, or intra-arterial infusions. Although the pump is designed to stop fluid flow when an alarm occurs (High Priority alarm), it is neither

designed nor intended to detect infiltrations or extravasations, and such conditions will not trigger an alarm.

| | |
|---|---|
| ⚠ | When using the pump, use only Eitan Medical approved accessory equipment. |

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

## ⚠ Environmental Safety Precautions

- The pump has not been evaluated for use within magnetic resonance imaging (MRI) environments, or with other medical equipment that emits radiation for diagnostic or therapeutic purposes.
- The Sapphire pump has not been evaluated for compatibility with Extracorporeal Membrane Oxygenation (ECMO) systems.
- Use only Sapphire dedicated accessories and cables. The use of accessories and cables other than those specified in this manual, with the exception of cables sold by Eitan Medical Ltd. as replacement parts for internal components, may result in increased emissions or decreased immunity of the pump.

## Administration Sets

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

| | |
|---|---|
| ⚠ | Use Sapphire standard administration sets listed here or in Eitan Medical's approved list of products: https://eitanmedical.com/.<br>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.<br>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 Eitan Medical's approved list of products. For more information refer to Administration Sets section on page 95. |

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

### ⚠ Administration Sets: Safety Warnings

- Do not use a damaged administration set or damaged set components or packaging. Always refer to the instructions for use that are included.
- Sapphire 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 Sapphire administration cassette from the pump.
- Do not apply pressure or pressurized air to any outlet or tubing connected to the pump. Pressure may destroy sensitive elements.
- Do not pull or stretch the tubing in any section of the administration set when the pump is in use, nor apply pressure to the infusion container.

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

- The administration set and container should be replaced as needed to avoid fluid contamination problems.
- The administration set must be replaced according to the hospital policy of infection control and treatment protocol. Sapphire 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.
High Priority alarm conditions automatically stop the infusion and require immediate attention before the infusion can be restarted.
When clamping the administration set, ensure that the clamp is at least 20 cm (8 in) away from the pump, when possible.
Note that if the dose rate is beyond the pump resolution of 0.1mL/h increments, the pump will increase or decrease the rate by up to 0.05 mL/h. This flow rate (mL/h) is presented on the running screen during infusion.

### Administering Infusions: General Safety Warnings

- **Occlusion Pressure Alarm Settings:**
  - High pressure settings may affect the time for occlusion detection. Make sure that the occlusion pressure is set according to the clinical use case.
  - When using sets with a Pressure Activated Valve (PAV), detection may be offset by 0.3 BAR (4.35 PSI or 225 mmHg). (This offset is called PAV cracking pressure.)
- **Volume To Be Infused:** Do not enter a volume to be infused greater than the amount of fluid available in the container.
- **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.
- **Secondary Infusions:** When using the Piggyback infusion feature, verify that:
  - The medication/solution in the Secondary infusion container is compatible with the medication/solution in the Primary infusion container.
  - The Secondary administration set is connected to the appropriate injection site on the primary administration set (above the administration cassette).
  - Interruption of the Primary infusion is clinically appropriate for the duration of the Piggyback infusion.
  - The Secondary source container is positioned at least 8 inches (20 cm) higher than the Primary source fluid level.
  - The drip chamber on the set should be used to verify that the correct line is delivering and the other line is idle.
  - The clamp of the Secondary set is closed when Piggyback infusions are not running.
- Do not infuse non-epidural drugs in the Epidural Delivery mode.
- Epidural drugs must be infused in the Epidural Delivery mode.

- Use of the device in preterm neonates and those below normal birth-weight i.e., low birth weight (≤2,499 g); very low birth weight (< 1500 g) and extremely low birth weight (<1000g), has not been evaluated and therefore the clinician should assess whether to use the device for these neonatal subsets.

## PCA, PCEA, and Epidural Intermittent Delivery Mode

When using the Clinician Bolus and Patient Demand Bolus functions, special safety precautions need to be followed.

| | |
|---|---|
| ⚠ | Do not use the Remote Bolus Cord to pick up or carry the cradle or pump. Using the cord in this manner may damage the pump or cord.<br>To avoid damaging the connector or cord, do not use any excessive force or instruments to remove the Remote Bolus Cord from the cradle. |

Performing an infusion above 50 mL/h while using a catheter size of 24G or smaller may result in occlusion and delay of care.
In addition, adhere to all the warnings listed below.

### ⚠ PCA, PCEA, and Epidural Intermittent Delivery: Safety Warnings

- Do not place the Remote Bolus Cord where the button might accidentally be pushed. Accidentally pushing the button may deliver an inadvertent demand bolus.
- When using the Clinician Bolus function, pay close attention to the current treatment parameters, as well as to the amount of additional dosage being administered.
- Do not allow the patient to access the Clinician Bolus function. Do not reveal the Clinician code to the patient.
- The demand bolus option should be used only by the patient. Administration of a demand bolus by anyone other than the patient (especially if the patient is sleeping or sedated) incurs the risk of potentially fatal overdose.

## Epidural Delivery Mode

Epidural administration of anesthetics is limited to short term infusion (not to exceed 96 hours) with indwelling catheters specifically identified for short term anesthetic epidural drug delivery.

### Epidural Delivery: Safety Warnings

- Epidural administration of drugs other than those indicated for epidural use could result in serious injury to the patient.
- To prevent infusion of drugs not indicated for epidural use, do not use administration sets with injection ports during epidural delivery.
- Do not infuse non-epidural drugs in the Epidural Delivery mode.
- Epidural drugs must be infused in the Epidural Delivery mode.

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# Chapter 2: Components, Accessories, and Administration Sets

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

Unpacking the Pump ..... 38
Hardware and Software Components ..... 39
Using Pump Accessories ..... 42

## Unpacking the Pump

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

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

## Hardware and Software Components

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

Figure 2.1. Hardware Components

| Number | Component | Description/Notes |
|---|---|---|
| 1 | Safety door | Covers and protects the administration set and pumping mechanism. |
| 2 | Speaker | Delivers auditory alarm sounds. |
| 3 | Status LEDs | Colored indicators providing a summary of the pump current status:<br>• Red: An alarm is occurring.<br>• Yellow (blinking): The battery is charging.<br>• Yellow (steady on): The pump is connected to main power, and the battery is fully charged.<br>• Green: The pump is running. |
| 4 | On/Off button | Enables the user to turn the pump On and Off. |
| 5 | Stop button | Enables the user to temporarily stop an infusion. |

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

## Touch Screen

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

Figure 2.2. Touch Screen Areas

Sapphire without Drug Library

Sapphire with Drug Library

| Number | Component | Description/Notes |
|---|---|---|
| 1 | Indicators Bar | Displays the following essential status information:<br>• CCA name (appears above Screen title, across all screens when Drug Library is loaded).<br>• Soft Limit icon (appears above Battery status icon, when Drug Library is loaded and current infusion exceeds soft limit range).<br>• External battery icon (appears above the delivery mode header, when an EBP is connected to the pump).<br>• Screen title (Start Up, Running, Paused, drug name, etc.).<br>• Drug concentration (appears when applicable, under screen title).<br>• Running icon (appears while an infusion is running).<br>• Delivery mode (Continuous, Multi-step, etc.).<br>• Battery status icon. |
| 2 | Main Display | Displays infusion parameters and other pump settings, and serves as a work area in which most programming and configuration takes place. |
| 3 | Toolbar | Contains function keys that enable you to perform common operations, such as confirming settings, pausing infusions, locking the screen, etc. |

## Using Pump Accessories

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


Mini Cradle ..... 42
PCA Lockboxes ..... 46
PCA Lockbox 250mL ..... 50
PCA/PCEA/PIEB Bolus Handle ..... 55
Sapphire Connect (Version 1.0) ..... 56
Power Supply ..... 79
Integrated Power Supply ..... 79
USB-C Power Supply (Sapphire Connect power supply) ..... 81
External Battery Pack ..... 83
Multi-Pump Mounting System ..... 90
Administration Sets ..... 95


### Mini Cradle

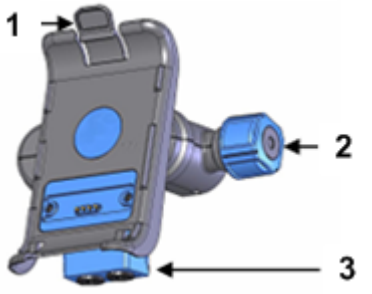
The small, easy to use bedside mini cradle offers flexible positioning of the pump at any angle or height. Eitan Medical's Mini Cradles are provided in one of the following configurations:

- With an optional connection splitter at the base (Figure 2.3, #3).
- With an optional Integrated Power Supply (IPS) at the base (Figure 2.4, #1). The IPS is an AC to DC power supply that is assembled to the Mini Cradle and is used to charge the pump battery.
- Without the optional connection splitter or the optional IPS at the base.

Identify your Mini Cradle configuration by turning the Mini Cradle bottom side up; Mini Cradles with a connection splitter will have two ports, as seen in Figure 2.3 #3. These are used for the RS-232 communication cable and power supply. Mini Cradles with IPS will have power cord connector covered by a power cord retainer, as seen in Figure 2.4, #2. This is used for Sapphire AC power cord.

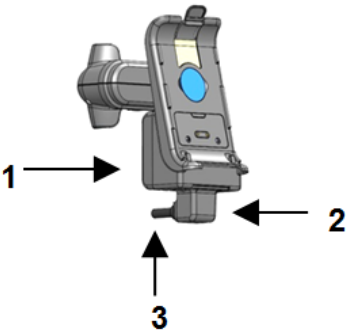
Components of the mini cradle are listed and described in the table following the figure.

Figure 2.3. Mini cradle




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

Figure 2.4. Mini-Cradle with Integrated Power Supply




| Number | Component | Description/Notes |
|---|---|---|
| 1 | Integrated Power Supply (optional) | Located on the base of the mini cradle. Used for power-supply connection. |
| 2 | Cord retainer | Located at the bottom of the integrated power supply. It holds the AC power cord in the IPS power socket. |
| 3 | AC Power Cord | Medical Grade AC Power Cord that connected the IPS to the wall socket. |

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

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

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

1. Attach the mini cradle to the IV pole by tightening the mini cradle knob on the right side (Figure 2.3, #2).
   To unlock the knob, make sure that the supplied key or pin is placed inside it.

> To attach several pumps to the IV pole, rotate the mini cradle to a horizontal position:
> Pull the pump holder and the base of the mini cradle away from each other, and rotate to the desired position.

2. To attach the pump to the mini cradle, insert the pump onto the bottom hooks of the mini cradle (Figure 2.5, #1), and then click it into the top hook (Figure 2.5, #2). Ensure that the pump is seated on both hooks.
3. To release the pump, press the pump hook located on the top of the pump holder (Figure 2.5, #2).
4. To open and release the mini cradle, rotate the knob.

Figure 2.5. Mini cradle Hooks

## PCA Lockboxes

PCA Lockboxes are designed to secure the IV bag, primarily for treatments involving narcotics or opioids, without interrupting the treatment workflow.

### PCA Lockbox 500mL

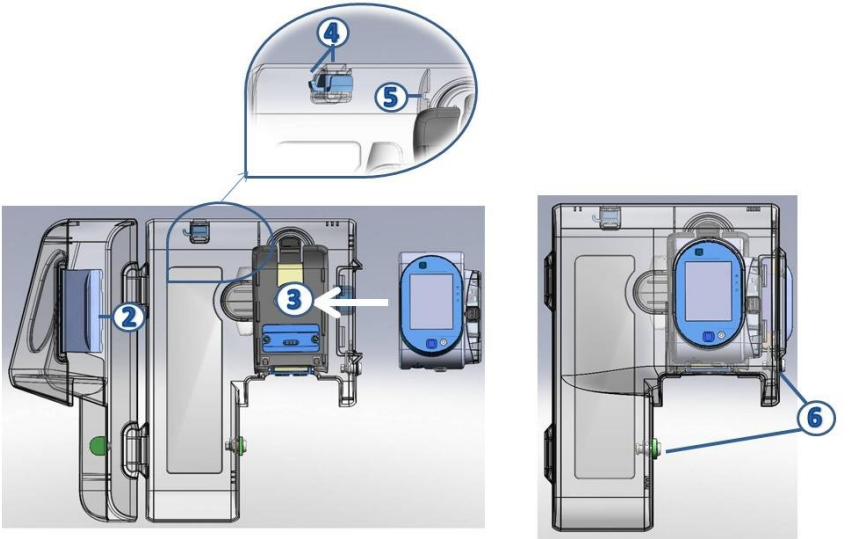
This Lockbox can accommodate IV bags of up to 500 mL.

Figure 2.6. PCA Lockbox 500mL and Mini cradle

The following steps explain the workflow of using the PCA Lockbox 500mL:

1. Using the mini cradle knob, attach the mini cradle to the IV pole (Figure 2.3 on page 43).
2. To open the Lockbox, swing the blue handle to the left (Figure 2.7, #2).

Figure 2.7. PCA Lockbox 500mL: Workflow

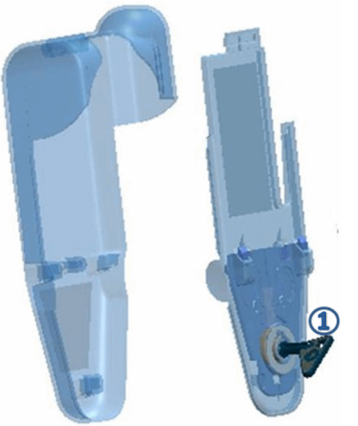



3. Attach the pump to the mini cradle (Figure 2.7, #3).
4. Hang the IV bag with the medication (Figure 2.7, #4) inside the PCA Lockbox.
5. Clamp the administration set, spike the bag, and attach the administration set to the pump.
6. Place the administration set through the hole on top of the pump (Figure 2.7, #5). Verify that there are no kinks in the administration set, so the infusion can run smoothly.
7. Unclamp the administration set. Then, close both locks of the Lockbox and lock it, using the supplied key (Figure 2.7, #6).

## PCA Lockbox 100mL

This Lockbox can accommodate IV bags of up to 100 mL.

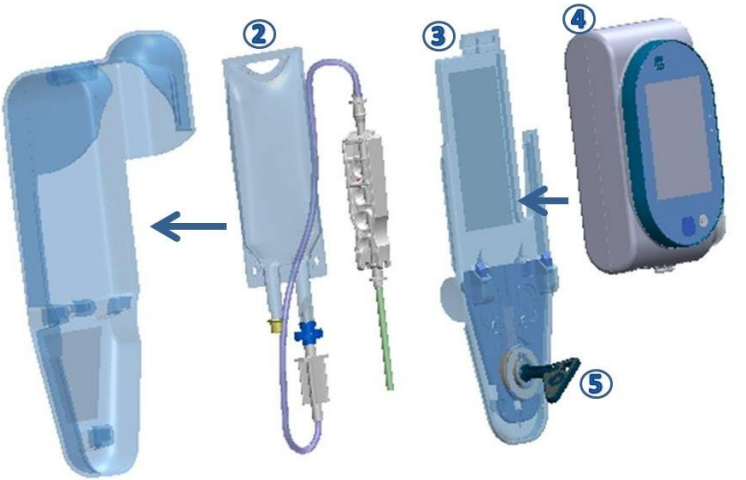
Figure 2.8. PCA Lockbox 100mL




The following steps explain the workflow of using the PCA Lockbox 100mL:

1. Using the key supplied with the Lockbox (Figure 2.8, #1), open the box and remove the plastic cover.
2. Close the clamps on the administration set, and spike the bag.
3. Block the administration set using the AFFV (for more information about the AFFV, refer to: Priming Manually on page 123), and then open the clamps.
4. Insert the container into the box, and wrap the tube around the inner walls of the box, in order to allow free flow and prevent kinks. Then, set the tube through the exit channel (Figure 2.9, #2).

Figure 2.9. Lockbox 100mL: Workflow




5. Connect the administration set to the pump.
6. Close the box by sliding back the plastic cover (Figure 2.9, #3).
7. Place the pump on the plastic cover (Figure 2.9, #4), and secure it by locking the box with the supplied key (Figure 2.9, #5).

## PCA Lockbox 250mL

### Attaching the Lockbox to the IV Pole

This Lockbox can accommodate IV bags of up to 250 mL.

- The Lockbox is used in an upright position only; it may be attached to an IV pole, carried by the carry handle, or carried by the shoulder strap.
- Do not use sets with drip chamber or burette with the Lockbox.
- Use the Lockbox with bags up to 250 mL IV that are smaller than 7 cm depth,10 cm width and 24 cm height.

Before setup, it is recommended to clamp the administration set and spike the IV bag.
Priming may be completed manually at this point, or with the pump after set is inserted to the pump.

The following steps explain the workflow for using the PCA Lockbox 250mL:

1. Attach the Lockbox to the mini cradle by inserting the pump compartment back side of the Lockbox onto the bottom hooks of the mini cradle (Figure 2.10A), and then click it into the top hook (Figure 2.10B). Make sure the Lockbox is secured to the mini cradle.

When using the Lockbox with Sapphire Connect, attach the entire unit via Sapphire Connect with the same bottom-to-top action. For more information about using Sapphire Connect, see Sapphire Connect (Version 1.0) on page 56.

Figure 2.10. Attaching the Lockbox to the Mini Cradle

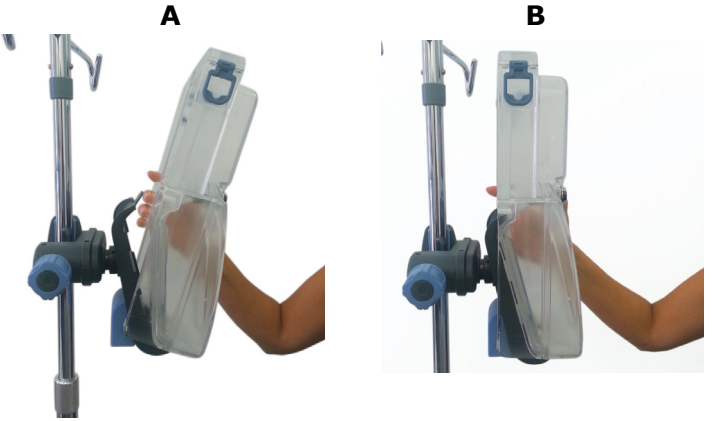
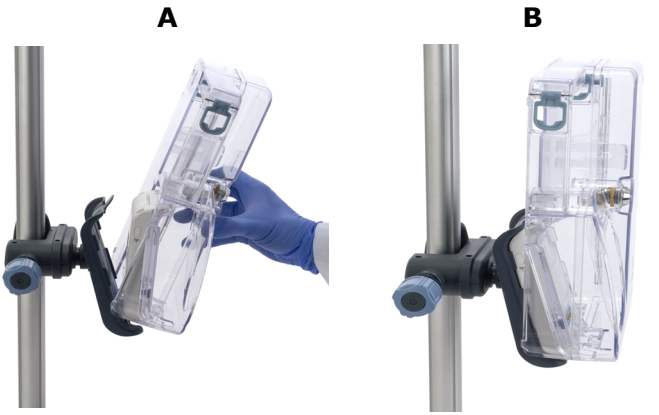



Figure 2.11. Attaching the Lockbox and Sapphire Connect to the Mini Cradle

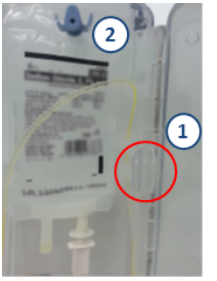


2. Unlock the Lockbox, and open the door.

> To lock and unlock the Lockbox the key must be first pressed inwards before turned.

3. Insert the pump onto the bottom hooks of the Lockbox, and then click it into the top hook.
4. Make sure the organizer is aligned with the inner Lockbox wall (Figure 2.12, #1); Hang the spiked IV bag on the hook inside the Lockbox (Figure 2.12, #2).

Figure 2.12. Placing the IV Bag and Set Inside the Lockbox




5. Attach the administration cassette to the pump.
6. Insert the set tubing between the IV bag and the pump into the organizer (Figure 2.12, #1).

> Make sure this segment of the set does not contain any additional components.
> Verify there are no kinks in the administration set.

7. Unclamp the administration set.
8. Close the Lockbox door and lock it using the supplied key. Note not to close the Lockbox door on the set itself.

9. Make sure the Lockbox is locked before removing the key.

| | |
|---|---|
| | Locking the Lockbox with attached mini cradle, locks in the mini cradle as well as the medication. To lock the Lockbox to the IV pole, the mini cradle must be locked to the IV pole. |

## Removing the Lockbox from the IV pole

1. Unlock the Lockbox using the supplied key. Then, open the door.
2. To release the Lockbox, press the top hook of the mini cradle. Secure the pump by holding it in the Lockbox while releasing the Lockbox from the mini cradle.
3. Lock the Lockbox using the supplied key.

Figure 2.13. Shoulder Strap

| | |
|---|---|
| | The Lockbox can be carried using the carry handle or the optional shoulder strap (Figure 2.13). The shoulder strap can be used with a pouch for storing the power supply when it is not plugged in. |

| | |
|---|---|
| | Do not grab the Lockbox by the handle when attached to an IV pole. |

Therapy Identification – to identify the therapy the Lockbox is used for, stick one of the supplied colored stickers to the upper inner side of the Lockbox door. The available sticker colors include: white, blue, red, yellow and green.

## Removing the Lockbox from the IV pole when using Sapphire Connect

When using with Sapphire Connect, remove the lockbox from the cradle by pulling the top hook of the mini cradle — secure the Lockbox by holding it while releasing.

Figure 2.14. Removing the Lockbox from IV pole when using with Sapphire Connect

## PCA/PCEA/PIEB Bolus Handle

The remote bolus handle enables patients to deliver boluses on demand (under clinician's programmed limits). The bolus is requested by pressing the button on the handle, eliminating the need for patient interaction with the function keys on the pump.

When pressing the bolus handle, an auditory signal will be generated. This option can be configured on the pump. For more information refer to Configuring Audio Settings on page 235.

Figure 2.15. Bolus Handle

Connect the bolus handle by attaching it to the socket at the bottom of the pump. Make sure that the white arrows or the red dot on the cable connector are facing up (arrows or dot on the bolus cable towards the arrow on the pump).

| | |
|---|---|
| | When using a mini cradle, the blue-buttoned bolus handle must be connected directly to the pump.<br>When using a gray-buttoned bolus handle, it may be connected to any port; but the Sapphire Connect or communication cable should not be connected simultaneously.<br>If a blue-buttoned bolus handle is switched to a gray-buttoned bolus handle the treatment must be re-started. |

## Sapphire Connect (Version 1.0)

Sapphire Connect is an accessory for the Sapphire infusion pump. It is intended for use in clinical, ambulatory, and home environments.

The Sapphire Connect snaps onto the Sapphire infusion pump to enable connectivity. Sapphire Connect's secure connection and wireless capabilities allow Sapphire Connect to transmit pump events and Sapphire Connect geolocation to the Insights Tool*. Sapphire Connect automatically establishes cellular communication when connected to a supported Sapphire Infusion Pump and requires no pre-use setup. Sapphire Connect supports wireless software updates to its own software, through the cellular network.

The Sapphire Connect is powered by an independent rechargeable Li-Ion battery, and can be charged via a dedicated USB-C type charger. When connected to a Sapphire pump, both the Sapphire Connect and Sapphire pump can be charged using a single power source.

Sapphire Connect supports seamless pump operation, including charging and the use of multiple Sapphire accessories.

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* The Insights Tool is a cloud-based platform that includes modules for pump fleet management and treatment monitoring, which are not covered in this user manual.

Sapphire Connect is compatible for use only with Sapphire Infusion Pumps with software version Rev16 or above that were manufactured during 2017 or later. The Sapphire Connect will not charge pumps that do not meet these criteria.

The pump manufacturing date can be found on the back of the pump casing:

General Safety Precautions

- Before using, make sure that Sapphire Connect and its power supply and cord are dry.
- While the Sapphire pump is attached to Sapphire Connect, do not connect the pump to a PC tool or a gray-buttoned bolus handle.
- Cleaning Sapphire Connect is restricted to the use of 70% Isopropyl alcohol (IPA) ONLY. For information about cleaning with IPA 70%, see Cleaning Sapphire Connect and Electric Connectors of Sapphire Accessories on page 295.
- For disposal information, see Waste Disposal on page 27.

## Components

Figure 2.16. Sapphire Connect Components

| # | Name | Description |
|---|---|---|
| 1 | Bottom hooks | Attaches to the Sapphire pump. |
| 2 | Top hook | when pressed, releases the pump. |
| 3 | Power button | When pressed, turns Sapphire Connect ON/OFF. |
| 4 | Communication LED | Indicates the communication status. |
| 5 | Charging LED | Indicates charging status. |
| 6 | USB-C port | For connection to the power supply. |

Table 2.1. **Sapphire Connect Communications LED Behavior**

| LED Color | LED Status | Meaning |
|---|---|---|
| Blue | Blinking | Self-test is in progress. |
| | Steady | Sapphire Connect is ON and communication is established. |
| | Flashing every second | Sapphire Connect is ON and in idle mode.<br>Sapphire Connect enters idle mode when it is operating on a battery, and not sending data or acquiring location. |
| Green | Steady | Self-test was successful, device is ready to be paired with Sapphire pump. |
| Purple | Steady | Sapphire Connect Software update is in progress. See Sapphire Connect Over-The-Air Software Update on page 63. |
| Red | Steady | Error was identified. See Troubleshooting on page 71. |
| | Blinking | No cellular connection was found. See Troubleshooting on page 71. |

Table 2.2. **Sapphire Connect Charging LED Behavior**

| LED Color | LED Status | Meaning |
|---|---|---|
| Yellow | Blinking | Sapphire Connect is charging. |
| | Steady | Sapphire Connect is fully charged. |

## Charging Sapphire Connect

Charge Sapphire Connect by connecting the Sapphire Connect power supply. The charging LED blinks during charging and steady when fully charged (for more information, see USB-C Power Supply (Sapphire Connect power supply) on page 81.

Figure 2.17. Charging Sapphire Connect

To preserve battery life, connect Sapphire Connect to a power supply whenever possible.

Sapphire Connect can also be charged via a power supply connected to a mini cradle with splitter or mini cradle with IPS (Figure 2.18).

Connecting a charger directly to the Sapphire pump will only charge the Sapphire pump battery and **will not** charge the Sapphire Connect.

Figure 2.18. Charging Sapphire Connect through Mini-Cradle

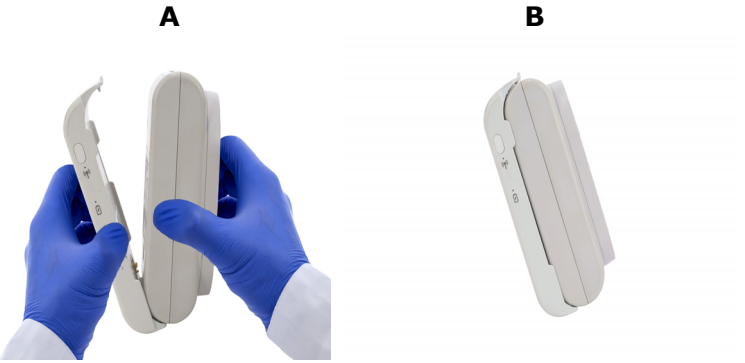
## Attaching Sapphire Connect to the Pump

1. Turn Sapphire Connect ON by pressing the power button once.
   The power-up sound is heard.
2. The Sapphire Connect will run a self-test and establish cellular communication. During this time, the communication LED should blink blue. When cellular communication is available, this process should take up to three minutes.
3. The communication LED turns steady green for 20 seconds, indicating that the self-test and cellular connection were successful (If not, see Troubleshooting on page 71).
4. The communication LED turns steady blue, indicating that Sapphire Connect is ON and that both the cellular connection process and self-test have completed successfully.

| | |
|---|---|
| i | Following a successful self-test, in case a Sapphire Connect Software update is available, Sapphire Connect software update will start automatically. For more details on Sapphire Connect Software updates refer to Sapphire Connect Over-The-Air Software Update on page 63. |

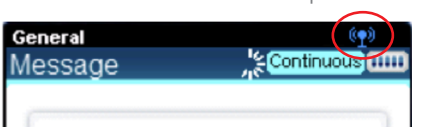
5. Attach Sapphire Connect to the pump by inserting the bottom of the pump onto the Sapphire Connect bottom hooks (Figure 2.19, A). Press the top of the pump back until it clicks into place on the top hook (Figure 2.19, B).

Figure 2.19. Attaching Sapphire Connect to Pump




6. The communication icon appears on the Sapphire pump screen (Figure 2.20) within one minute, indicating that the pump and Sapphire Connect have established communication.

Figure 2.20. Communication Icon on Pump Screen



## Sapphire Connect Over-The-Air Software Update

Sapphire Connect checks for updates to its own software every time it is turned On, and every 24 hours. If a Sapphire Connect Software update is available and Sapphire Connect has been configured accordingly (through the Insights Tool), Sapphire Connect will perform a Software update. While performing the update, the communication LED turns steady purple. When the Software update is complete, the Sapphire Connect performs an automatic restart. During this restart, the Sapphire Connect performs a self test, and the communication LED behaves as described in Attaching Sapphire Connect to the Pump on page 61.

| | |
|---|---|
| | During this Sapphire Connect Software upgrade, the communication icon does not appear on the pump screen. After the Sapphire Connect performs a restart and the communication LED turns blue again, the communication icon on the pump screen reappears, and communication with the pump resumes. If this does not happen, refer to page 287. |

| | |
|---|---|
| | Sapphire Connect Software update does not affect the pump Software. |

Removing Sapphire Connect

1. Hold the pump firmly.
2. Pull back on the top hook, until the pump is released (Figure 2.21).

Figure 2.21. Releasing Sapphire Connect from Sapphire Pump

3. To turn off Sapphire Connect, press and hold the power button for 5 seconds. The communication LED turns off, and the power-down sound is heard.

| | |
|---|---|
| | Sapphire Connect needs to be turned On to allow data transmission. |

4. 90 seconds after disconnecting Sapphire Connect from the pump, the communication icon will no longer be displayed on the pump screen.

## Using Sapphire Connect with Other Accessories

Sapphire Connect is designed to work with multiple Sapphire accessories such as Mini-cradle, Bolus Handle, and Lockbox 250mL, by supporting the same connection mechanisms.

Sapphire Connect cannot be used with the PCA Lockbox 100mL, External Battery Pack, or gray buttoned bolus handle.

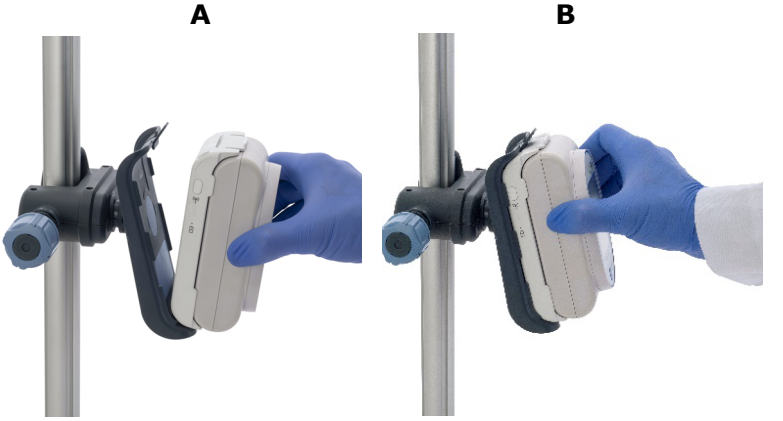
### Using Sapphire Connect with a Mini-Cradle

> When the pump is connected to Sapphire Connect, it can still be charged via a power enabled Mini-Cradle. For more information, see Power Supply on page 79.

**> To use with a mini cradle, assemble in this order:**

1. Make sure that the mini cradle is attached to the IV pole (see Mini Cradle on page 42).
2. Attach the pump to Sapphire Connect (see Attaching Sapphire Connect to the Pump on page 61).
3. Attach Sapphire Connect to the mini cradle, using the same bottom-to-top action (Figure 2.22). Make sure that the combined pump-Sapphire Connect unit is seated securely on both hooks of the mini cradle.

Figure 2.22. Attaching Sapphire Connect to Mini Cradle




**> To remove from the mini cradle:**

1. Hold the pump securely.
2. Push back on the top hook of the mini cradle until the combined pump-Sapphire Connect unit is released (Figure 2.23).

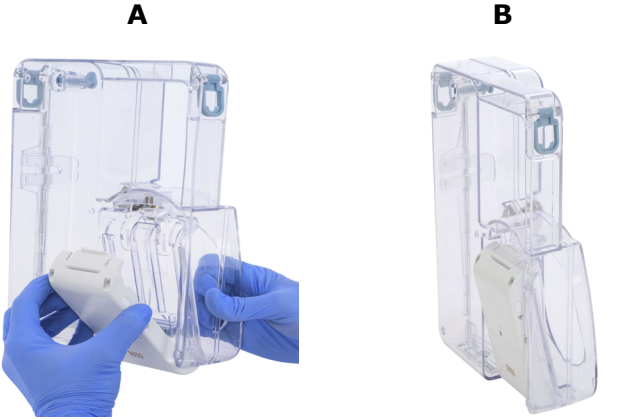
Figure 2.23. Disconnecting from Mini Cradle

## Sapphire Connect with Lockbox 250mL

Sapphire Connect can be used with the PCA Lockbox 250mL:

1. Attach Sapphire Connect to the back of the Lockbox (Figure 2.24), using the same bottom-to-top action. Make sure that the Lockbox is seated securely on both hooks of Sapphire Connect.

Figure 2.24. Attaching Sapphire Connect to Lockbox




2. If using with a mini cradle, attach the entire unit to the mini cradle via Sapphire Connect.

For more information about using the lockbox, see PCA Lockboxes on page 46.

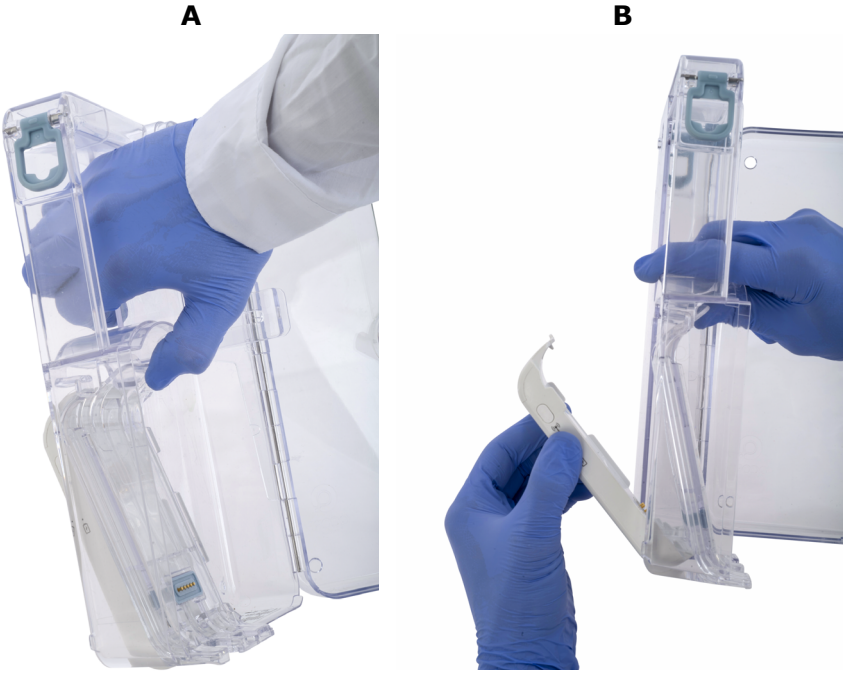
**> To remove Sapphire Connect from the Lockbox:**

1. When using a mini cradle, remove the Lockbox from the cradle as instructed in Removing the Lockbox from the IV pole when using Sapphire Connect on page 54.
2. Unlock the Lockbox.

Figure 2.25. Opening the Lockbox

3. Hold Sapphire Connect and the Lockbox securely.
4. From the inside of the Lockbox, press the top hook up and back to release Sapphire Connect (Figure 2.26).

Figure 2.26. Releasing Sapphire Connect from Lockbox



## Demand Bolus Handle (Blue Buttoned)

Sapphire Connect can be used with the blue buttoned bolus handle.
When using a bolus handle, connect the bolus handle by attaching it to the socket at the bottom of the pump. Make sure that the white arrow or red dot on the cable connector is facing up. For more information, see PCA/PCEA/PIEB Bolus Handle on page 55.

Figure 2.27. Connecting Blue-Buttoned Bolus Handle

When the Sapphire pump is attached to Sapphire Connect, do not connect the pump to a gray-buttoned bolus handle.

| Problem / Indication | Meaning | Probable Cause | Action |
|---|---|---|---|
| Communication LED is steady red. | Sapphire Connect has encountered an error. | • Temporary internal communication error.<br>• Hardware error. | Reset the Sapphire Connect by pressing the on/off button for 11 seconds. Then press the on/off button again to turn on the Sapphire Connect. If the error was resolved, the Sapphire Connect should pass the self test as described in Attaching Sapphire Connect to the Pump on page 61. If the problem persists, contact your local representative, or contact Eitan Medical at www.eitanmedical.com. |
| Communication LED is blinking red. | Self-test was successful, but no cellular connection was found.<br>The status should change to steady blue after 20 seconds. | Poor cellular reception or network problems. | Move to another location to find better reception. Try again later in case the problem was caused by the cellular network. |

| Problem / Indication | Meaning | Probable Cause | Action |
|---|---|---|---|
| Charging LED is off when the Sapphire Connect power supply is plugged in. | The Sapphire Connect is not charging. | • The USB-C connector is not properly connected.<br>• The power supply has become disconnected from the mains power supply.<br>• The power supply is not working.<br>• The USB-C inlet is damaged. | • Disconnect and reconnect the power supply to the Sapphire Connect.<br>• Verify the charger is properly connected to the mains power supply.<br>• Try charging the Sapphire Connect unit with another power supply.<br>• Try charging the Sapphire Connect unit with a powered mini-cradle (for more information on charging the Sapphire Connect, see page 60).<br>If the problem persists, contact your local representative, or contact Eitan Medical at www.eitanmedical.com. |
| Sapphire Connect cannot be turned on. | Sapphire Connect cannot be turned on. | • If this occurs right after power-off, Sapphire Connect may be in the process of shutting down.<br>• Sapphire Connect battery is depleted. | • After power-down, wait up to a minute and then press the On/Off button again.<br>• Charge the Sapphire Connect battery and try again after 1 hour (for more information on charging the Sapphire Connect, see page 60).<br>If the problem persists, contact your local representative, or contact Eitan Medical at www.eitanmedical.com. |

## Environmental Conditions

Sapphire Connect shall be stored, transported, and operated under the following conditions:

| | Environmental Conditions | | |
|---|---|---|---|
| Condition | Storage (> 72 hrs) | Transportation (< 72 hrs)* | Operating * |
| Temperature (°C) | -20°C to 40°C (-4°F to 104°F) | -40°C to 70°C (-40°F to 158°F) | 5°C to 40°C (41°F to 104°F) |
| Relative Humidity (% R.H) | 15% to 95% | 15% to 95% | 15% to 95% (15% to 90% at transient state) |
| Ambient Pressure (kPa) | 50 kPa to 106 kPa | 50 kPa to 106 kPa | 70 kPa to 106 kPa |

* These are the same environmental conditions as for the Sapphire infusion pump.

- Storage at low temperatures may affect initial battery performance.
- Storage at high temperatures may degrade battery performance.

Use the original packaging when transporting Sapphire Connect.

While Sapphire Connect is in storage, recharge the battery at least once every 12 months.

## Technical Specifications

| Parameter | Description |
|---|---|
| FCC ID | 2A3JW-SAPPHIRE |
| Dimensions | (H x W x D) 146.5 x 78.6 x 16 mm<br>(5.77 x 3.09 x 0.63 in) |
| Weight | 175 g (6.2 oz) with battery |
| Connectivity | Cellular, Cat M1 and 2G |
| Encryption Mode | AES128 + CBCIV with pre-shared key |
| Digital Privacy | Includes a 'do not track me' and a cellular communication disable function. Read Privacy policy at eitanmedical.com/privacy-policy/. |
| Power Inputs | USB-C; can also be charged using Sapphire mini cradle with splitter or IPS |
| Battery Type | Rechargeable Lithium-Ion battery (1 cell) |
| Battery Capacity | 850 mAh |
| Battery Output | 3.7V (nominal) |
| Battery Life | Charging 500 cycles at nominal conditions, 23°C (74°F) |
| Operating on Battery | 45 hours without being connected to an external power. |
| Communications with Pump | RS-232 Serial communication |
| Indicator LEDs | Power and communication, charging |
| IPX Rating | IP24 |
| SIM Type | Nano-SIM (Universal) |
| Geolocation | GPS, Cellular |
| Data Storage Memory | 2 MB |
| Firmware update | Automatic firmware updates |

| Communication Control | Frequency Band and Bandwidth |
|---|---|
| LTE-FDD | **Cat M1:** |
| | B1/B2/B3/B4/B5/B8/ |
| | B12/B13/B18/B19/ |
| | B20/B25/B26/B27/ |
| | B28/B66/B85 |
| GSM/EDGE | 850/900/ |
| | 1800/1900 MHz |
| GNSS | GPS/GLONASS/ |
| | BeiDou/Galileo/QZSS |

## Class B Warnings

**FCC Statement**

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 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, and if not installed in accordance with the instruction, may cause harmful interference to radio communications. However, there is nor 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 to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment to an outlet on a circuit different from that to which the receiver is connected.

- Consult the dealer or an experienced radio/TV technician.

**CAN ICES-003 (B)**
This Class B digital apparatus complies with Canadian ICES-003.

In order to maintain compliance with FCC regulations, shielded cables must be used with this equipment. Operation with non-approved equipment or unshielded cables is likely to result in interference to radio and TV reception.

## Modification Statements and FCC/ ISED Regulatory Notices

**FCC Warning**
Modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment under FCC Rules.

**ISED Warning**
**Interference statement (if it is not placed in the device)**
This device complies with Part 15 of the FCC Rules and Industry Canada licence-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

**Wireless notice**

This device complies with FCC/ISED radiation exposure limits set forth for an uncontrolled environment and meets the FCC radio frequency (RF) Exposure Guidelines and RSS-102 of the ISED radio frequency (RF) Exposure rules. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

## Portable Device RF Exposure Statement

RF Exposure - This device has been tested for compliance with FCC RF exposure limits in a portable configuration. At least 5 mm of separation distance between the Raptor device and the user's body must be maintained at all times. This device must not be used with any other antenna or transmitter that has not been approved to operate in conjunction with this device.

## RF Exposure Warnings - SAR

### RF Exposure Information (SAR)- FCC

This device meets the government's requirements for exposure to radio waves. This device is designed and manufactured not to exceed the emission limits for exposure to radio frequency (RF) energy set by the Federal Communications Commission of the U.S. Government.

The exposure standard employs a unit of measurement known as the Specific Absorption Rate, or SAR. The SAR limit set by the FCC is 1.6 W/kg. Tests for SAR are conducted using standard operating positions accepted by the FCC with the EUT transmitting at the specified power level in different channels.

The FCC has granted an Equipment Authorization for this device with all reported SAR levels evaluated as in compliance with the FCC RF exposure guidelines. SAR information on this device is on file with the FCC and can be found under the Display Grant section of www.fcc.gov/eot/ea/fccid after searching on FCC ID: 2A3JW-SAPPHIRE

To ensure that RF exposure levels remain at or below the tested levels, use a belt-clip, holster, or similar accessory that maintains a minimum separation distance of 5mm between your body and the device.

### RF Exposure Information (SAR)- IC

The radiated output power of the Wireless Device is below the Industry Canada (IC) radio frequency exposure limits. The Wireless Device should be used in such a manner such that the potential for human contact during normal operation is minimized.
This device has been evaluated for and shown compliant with the IC Specific Absorption Rate ("SAR") limits when operated in portable exposure conditions.

### RF Exposure information (SAR)- CE

This device meets the EU requirements (2014/53/EU) on the limitation of exposure of the general public to electromagnetic fields by way of health protection.

The limits are part of extensive recommendations for the protection of the general public. These recommendations have been developed and checked by independent scientific organizations through regular and thorough evaluations of scientific studies. The unit of measurement for the European Council's recommended limit for mobile devices is the "Specific Absorption Rate" (SAR), and the SAR limit is 2.0 W/Kg averaged over 10 grams of body tissue. It meets the requirements of the International Commission on Non-Ionizing Radiation Protection (ICNIRP).

For next-to-body operation, this device has been tested and meets the ICNRP exposure guidelines and the European Standard EN 62311 and EN 62209-2. SAR is measured with the device directly contacted to the body while transmitting at the highest certified output power level in all frequency bands of the mobile device.

## Power Supply

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

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

| | |
|---|---|
| ⚠ | To prevent entanglement, always secure the cable cord properly. |

| | |
|---|---|
| ⚠ | Always detach the Sapphire pump from the EBP, before connecting it to the power supply. |

**> To charge the battery:**

1. Plug the Sapphire power supply cord into the main power supply source.
2. With the white arrows or red dot facing up, slide the power cord into the Sapphire pump power socket or into the splitter connector without rotating the connector.
3. On the front of the pump, verify that the Charge LED status indicator is On (blinking yellow light).

For more information regarding charging the battery, refer to Charging the Battery on page 304.

**> To disconnect the power supply from the pump:**

Gently press on both sides of the power supply connector, and pull it straight out of the Sapphire pump power socket without rotating the connector.

## Integrated Power Supply

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 Sapphire 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 Sapphire AC Power Cord into the main power supply source.
2. On the back of the IPS, verify that the Power LED status indicator is On (blue light).
3. Mount the pump into the mini cradle.

> When using Sapphire Connect, mount the pump and the Sapphire Connect using the same bottom-to-top action.

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 Sapphire 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 Sapphire AC Power Cord from the IPS.

## USB-C Power Supply (Sapphire Connect power supply)

The Sapphire Connect power supply is used to charge both the Sapphire Connect and the Sapphire pump.
Specifications of the power supply contain the following options:

- Input voltage: 5 VDC
- Output voltage: 10 VDC

| | |
|---|---|
| ⚠ | The USB-C power supply is intended for use in the home environment. |

**> To charge the pump's battery:**

1. Attach Sapphire Connect to the pump (for more information on how to use the Sapphire Connect (Version 1.0) on page 56).
2. Plug the USB-C power cord into the USB-C inlet on the Sapphire Connect.
3. Verify that the Sapphire Connect charging LED is ON – blinking yellow light (Figure 2.28B).
4. On the front of the pump, verify that the Charge LED status indicator is ON – blinking yellow light (Figure 2.28A).

| | |
|---|---|
| ℹ | When charging the Sapphire pump via the pump's power socket, the Sapphire Connect will not charge. |

Figure 2.28. Charging Sapphire Pump via Sapphire Connect

**> To disconnect the USB-C Power Supply from the Sapphire Connect:**

Unplug the USB-C power cord from the Sapphire Connect, by pulling the USB-C connector.

## External Battery Pack

The EBP extends the pump's operation time with no need for additional charging.

### Warning EBP:

- Do not use the EBP if it is difficult to insert AA batteries or to attach it to the pump.
- Do not use the EBP if the black O-Ring is missing or not attached all around the AA batteries compartment lid.
- When using the strap to hang the EBP with the pump, make sure that the pump is safely secured to the EBP.
- Hang the EBP with the pump only on an IV pole, so that there is no risk of the pump falling.

### General Safety Precautions:

- Begin using the EBP before the pump shuts down due to battery depletion.
- When using the EBP with the pump, do not connect the power supply to the pump.

### AA Battery Safety Guidelines:

- AA Batteries with signs of rust, bad odor, overheating, and/or other irregularities should not be used in the EBP.
- Avoid any contact of the AA batteries with water.
- Use only valid (none-expired) AA batteries in the EBP.

---

It is recommended to use in the EBP fresh AA alkaline batteries manufactured by the brands listed below:

- Energizer
- Duracell

---

## General information

- The duration of operation time provided by the EBP, varies according to the pump's Internal Battery power status, infusion rate, backlight settings and AA batteries power status. Operation time of the pump with the EBP is presented in the following table:

| Pump Settings | Operation time duration (with fresh AA batteries of the specified brands) |
|---|---|
| • Infusion rate of 125 mL/h<br>• Backlight set to Off<br>• Internal Battery depleted | 15-20 hours |

It is recommended to turn the pump's backlight Off in order to extend its operation time. For details about configuring the backlight, refer to Backlight on page 237.

## Getting Ready to Use the EBP

The EBP requires six 1.5 V AA batteries (not included in package).

Figure 2.29. The EBP Components

| Number | Component |
|---|---|
| 1 | Small hooks |
| 2 | Large hook |
| 3 | Latch |
| 4 | Suspension hooks |
| 5 | EBP LED |

## Inserting AA Batteries into the EBP

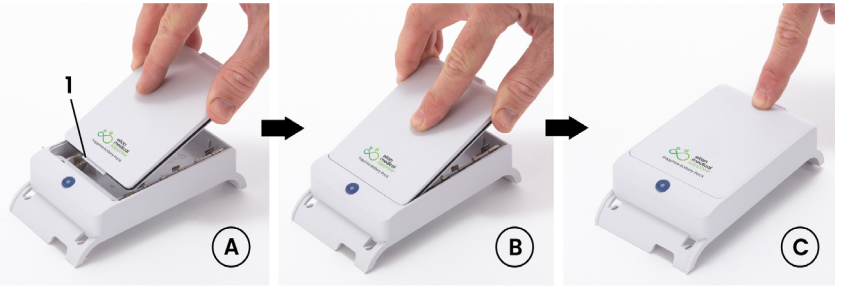
**> To insert AA batteries into the EBP:**

1. Make sure that the pump is detached from the EBP.
2. Open the AA batteries compartment lid, by pushing the latch up (Figure 2.29, #3).

Figure 2.30. Opening EBP Lid

3. Place the batteries in their slots by pressing the flat end (negative pole) of each battery to the flat metal plates (marked with "-"), and then fix the other end (positive pole) in place (marked with "+").
4. After all six batteries are in place, insert the protrusion at the bottom of the lid (Figure 2.31, #A1) to its slot in the EBP, and press the latch (Figure 2.29, #3) downwards until it clicks.

Figure 2.31. Closing EBP Lid




| | |
|---|---|
| ⚠ | To avoid damaging the product, open and close the batteries compartment lid only as instructed. Avoid using excessive force, as it may crack the plastic or damage the metal parts. |

## Strapping the EBP

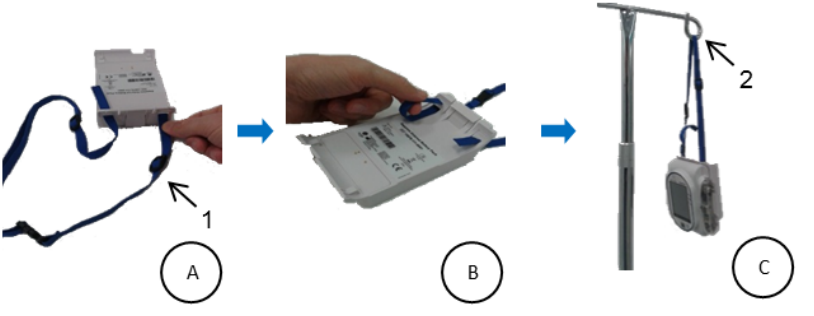
If the pump needs to be hung, thread the strap supplied with the EBP through the suspension hooks (Figure 2.29, #4).

**> To strap the EBP:**

> Thread the strap before attaching the Pump to the EBP.

1. Place the EBP with the cover facing down.
2. Thread both ends of the strap through the bottom notch of the suspension hooks (Figure 2.29, #4). Make sure that both buckles (Figure 2.32, #A1) of the strap are facing up.
3. Bend both ends of the strap to form a loop, and thread each end through the top notch of the suspension hooks (Figure 2.29, #4).
4. Thread each end through the buckle and stretch to adjust the length.
5. Attach the pump to the EBP, and hang on an IV pole (Figure 2.32, #C2). For attaching instructions, refer to the next section.

Figure 2.32. Attaching EBP Straps



## Attaching the Pump to the EBP

**> To attach the pump to the EBP:**

1. Insert the bottom of the pump onto the two small hooks (Figure 2.29, #1) at the bottom of the EBP, and then push it to click into the large hook (Figure 2.29, #2) at the top of the EBP.
   If the power supply is connected to the pump, disconnect it before attaching the EBP.
2. Check for all the indications of proper connection to the EBP:
   a. The pump turns On.
   b. The external battery icon appears.
   c. The LED at the bottom of the EBP (Figure 2.29, #5) turns On.

> If the LED at the bottom of the EBP doesn't light, blinks or turns off, replace the AA batteries in the EBP with new fresh AA batteries.

## Detaching the Pump from the EBP

Detach the EBP when treatment ends, AA batteries are depleted or stable power supply becomes available. Detach the pump from the EBP before turning the pump Off.

**> To detach the pump from the EBP:**

1. Hold the pump firmly when detaching it from the EBP.
2. Detach the pump from the EBP by gently pulling the large hook (Figure 2.29, #2), until the pump is released from grip. Make sure not to pull the suspension hooks (Figure 2.29, #4), because this prevents the detachment of the pump from the EBP.
3. Check for all the indications of proper detachment:
   a. An attention screen, indicating that the pump is operating on Internal Battery, appears.
   b. Press **OK** to continue working with the pump.
   c. The external battery icon disappears.
   d. The EBP LED turns Off.

| | |
|---|---|
| ⚠ | AA batteries may deplete when pump is turned off and still attached to the EBP. |

| | |
|---|---|
| ⚠ | If stable power supply is available, make sure to detach the Pump from the EBP before connecting the pump to a power supply. |

## EBP storage

| | |
|---|---|
| ℹ | It is recommended to remove the AA batteries from the EBP when not in use. |

## Cleaning the EBP

| | |
|---|---|
| ⚠ | Clean only exterior surfaces of the EBP. |

## Multi-Pump Mounting System

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

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

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

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

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

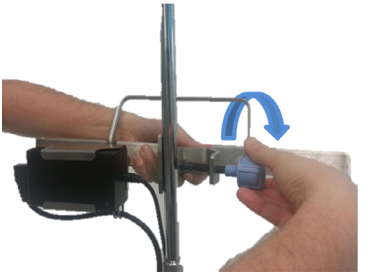
## Setup Instructions

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

**> To attach the Mounting System to an IV Pole:**

1. Loosen the clamp knob by rotating it counter-clockwise.
2. Firmly hold the Mounting System and place the clamp on an IV pole with the carry handle facing upwards.
3. Tighten the clamp knob by rotating it clockwise (Figure 2.33).

Figure 2.33. Mounting System on IV Pole



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

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

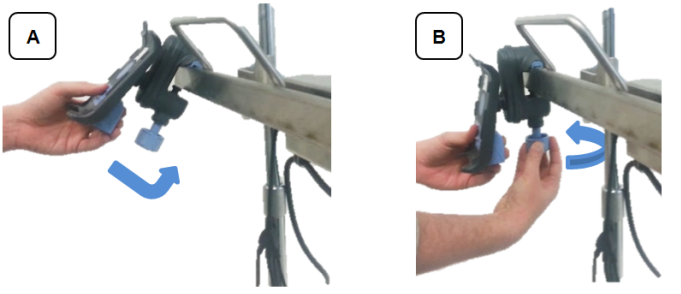
1. Rotate the mini cradle to a vertical position with the mini cradle knob pointing downward and the top hook pointing upward.

Figure 2.34. Attaching Mini Cradle to Mounting System

Place the mini cradles according to the markings on the Mounting System, between the designated lines (Figure 2.36).

2. Loosen the mini cradle knob to maximum extent by rotating it.
3. Tilt the mini cradle and place the open vice on the top of the Mounting System (Figure 2.35 Item A). Align the cradle and tighten the knob by rotating it (Figure 2.35 Item B).

Figure 2.35. Placing Mini Cradle on Mounting System




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

Figure 2.36. Fully Assembled Mounting System

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

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

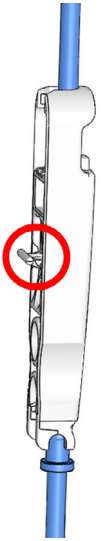
Always contact a certified technician in cases of Mounting System electrical and mechanical malfunctions.
When removing the Mounting System from the IV pole, avoid applying pressure on the power cable, connectors or cradles.

## Administration Sets

The Sapphire pump should be used with a Sapphire dedicated administration set, which includes the Sapphire administration cassette. 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.

This cassette includes a normally closed valve (three-state Anti-Free-Flow Valve) that provides automatic anti-free-flow protection. Opening the valve allows manual priming as well as transition of infusion to gravity induced.

Figure 2.37. Sapphire Administration Cassette and AFFV



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

For more information about priming the administration set and inserting it into the pump, refer to Priming Manually on page 123 and Inserting the Administration Cassette on page 117.

## Sapphire Approved Administration Sets

The Eitan Medical Ltd. approved list of administration sets to be used with the Sapphire pump is listed in the Eitan Medical Official Website at https://eitanmedical.com.

| | |
|---|---|
| ⚠ | Use Sapphire standard administration sets listed here or in Eitan Medical's approved list of products: https://eitanmedical.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. |

| | |
|---|---|
| ℹ | All filters in Sapphire approved administration sets are air eliminating filters. |

Other products available from Eitan Medical Ltd. are listed in the Eitan Medical Official Product List, at https://eitanmedical.com/

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# Chapter 3: Fundamental Concepts and Operations

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

Working with the Main Display ..... 98
Selecting Delivery Mode ..... 104
Enabling Special Features ..... 106

## Working with the Main Display

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

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

### Using the Keypad

#### Numeric keypad

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

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

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

## Alphanumeric keypad

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

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

## Overview of Toolbar Function Keys

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

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

The following function keys are available from the Running screen:

| Name of Key | Action | Notes |
|---|---|---|
| Lock | Locks the screen or the pump | For more information, refer to Locking the Screen on page 226 and Activating Patient Lockout on page 227. |
| Press to Unlock screen | Unlocks the screen | |
| Press to Unlock Patient | Unlocks the pump | Unlocking the screen requires a password. |

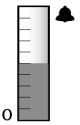
| Name of Key | Action | Notes |
|---|---|---|
| Request Pause/ Pause Bolus | Pauses an infusion or a bolus | For more information, refer to Pausing Infusions on page 224. |
| Request Continue/ Continue Bolus | Resumes a paused infusion or a bolus | |
| View/Edit | Displays a list of infusion parameters to be viewed or edited | |
| Bolus | Delivers a bolus during continuous, PCA and PCEA modes | |

## Overview of Icons

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

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

| Icon | Meaning | Notes |
|---|---|---|
| | Time remaining until the end of the infusion. | |
| | Indicates that an infusion is currently running. | |
| | Indicates status of battery charge. | For more information, refer to Battery Care Information on page 301. |
| | Indicates that the current infusion is above the upper soft limit range in at least one parameter. | For more information, refer to Soft Limit on page 273. |
| | Indicates that the current infusion is below the lower soft limit range in at least one parameter. | For more information, refer to Soft Limit on page 273. |
| | Indicates that the current infusion is exceeding both upper and lower soft limit ranges. | When more than one parameter is limited by the Drug Library – one of the parameters is programmed above the upper soft limit, and another parameter is programmed below the lower soft limit.<br><br>For more information, refer to Soft Limit on page 273. |
| | Indicates that the EBP is connected to the pump. | For more information, refer to External Battery Pack on page 83. |

| Icon | Meaning | Notes |
|---|---|---|
| | Updating data. | May appear when transitioning between lines. |
| | Pump connected to PC. | Indicates that the pump is connected to the PC. |
| | Air detection is disabled. | 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 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 that the administration set is primed before starting an infusion. |
| | Pump connected to Sapphire Connect. | Indicates that the pump is connected to Sapphire Connect. |
|   | Pressure display bar | Displays a bar on which the pressure alarm setting is represented by the bell on the top, the baseline downstream pressure is the bottom end represented by a "0", and the current relative downstream pressure is represented by the darker gray end of the bar. |

## Selecting Delivery Mode

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

> The delivery modes availability can be set by a technician

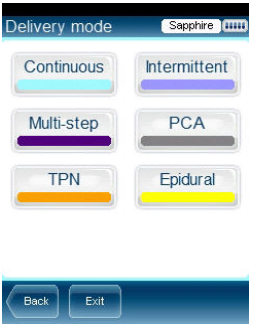
Possible delivery modes include:

| Mode | Description/Notes |
|---|---|
| Continuous | Delivers an infusion at a constant, programmed rate. This mode includes the option to add a Secondary (Piggyback) line. |
| Intermittent | Delivers infusions at intermittent programmed intervals. |
| TPN (Total Parenteral Nutrition) | Delivers an infusion at a constant rate, with optional tapering at the beginning and end of the infusion. |
| PCA (Patient Controlled Analgesia) | Delivers PCA boluses, either alone or in addition to a basal programmed rate. |
| Multi-step | Delivers the infusion in a set of 1 and up to 25 steps. |
| Epidural | **PCEA (Patient Controlled Epidural Analgesia):** Delivers epidural boluses, either alone or in addition to a basal programmed rate.<br>**Intermittent Epidural:** Delivers epidural infusions at intermittent pre-set intervals, with the option to add PCEA (refer to PIEB under Epidural Mode Options Menu **on page** 251). |

> The Epidural (PCEA and Epidural Intermittent) modes do not deliver IV infusions. They deliver epidural infusions, using a special catheter and all the required clinical procedures.

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

Figure 3.1. Indicators Bar: Delivery Mode




Changing the delivery mode is done using the Options menu. An authorization code of High is required to modify the delivery mode. For more information about how to change the delivery mode, refer to Setting Delivery Mode on page 231.

## Enabling Special Features

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

> Local configuration made after the Drug Library is loaded, will be valid until the user selects a CCA or turns the pump Off.
> When Resuming an infusion after pump shutdown, local configurations will remain until the end of the current infusion. For more information about Drug Library, refer to Chapter 9: Drug Library on page 266.
> When no Drug Library is loaded, all local changes made to any configuration will remain valid until reconfigured or until the pump is set to factory defaults.

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

| Feature | Delivery Mode(s) | Description/Notes |
|---|---|---|
| Allow delayed start | All | Enables users to start an infusion at a later time. The user may either define a specific delay period or set the pump to Standby.<br>For more information, refer to Using the Set Delay Feature on page 259. |
| Allow PreProgram | All | Allows users to start an infusion using predefined infusion parameters. When this option is enabled, the PreSet Programs button appears on the pump Start Up screen.<br>For more information, refer to Creating and Editing PreSet Programs on page 256. |

| Feature | Delivery Mode(s) | Description/Notes |
|---|---|---|
| Repeat last infusion | All | Allows the users to start infusions using the same infusion parameters for the same patient. When this option is enabled, the Repeat Last Infusion button appears on the pump Start Up screen.<br>For more information, refer to Repeating Last Infusion on page 220. |
| Limit Period | PCA<br>Epidural (PCEA and Epidural Intermittent) | 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). |
| Prime Reminder | All | Enables a reminder for the user to prime the administration set before starting an infusion.<br>For more information, refer to Automatic Priming Using the Pump on page 120 |
| Allow loading dose | PCA<br>PCEA<br>(Epidural) | Enables starting a PCA or PCEA infusion with a programmed initial clinician dose (bolus).<br>For more information about enabling the feature, refer to PCA Options Menu on page 250 or Epidural Mode Options Menu on page 251. |
| Password request | Epidural (PCEA and Epidural Intermittent) | A safety feature that requires password entry to make changes to important parameters.<br>For more information about enabling the feature, refer to Epidural Mode Options Menu on page 251. |
| Advanced Bolus | Continuous | Allows users to program a bolus by entering rate, amount and time.<br>For more information, refer to Administering a Bolus on page 143. |

| Feature | Delivery Mode(s) | Description/Notes |
|---|---|---|
| Bolus Reminder | PCA<br>Epidural (PCEA and Epidural intermittent) | Enables a reminder for the user to connect the bolus handle before starting a PCA, or PCEA or PIEB infusion that includes patient boluses. The reminder (i) instructs to connect the bolus handle directly to the pump (ii) Checks functionality – bolus press is recognized by the pump. For more information, refer to Bolus Reminder on page 238. |
| Auto P. Lockout | All | A safety feature that enables automatic locking of the screen. A password is required to unlock the screen in order to make changes to the infusion parameters or to start a new infusion. Activated first during a running infusion, and automatically re-activated throughout the infusion.<br>For more information about enabling the feature, refer to Configuring General Settings on page 236.<br>For more information about using the feature, refer to Activating Patient Lockout on page 227. |
| Screen Saver | All | Provides a distant view of the main parameters during a running infusion. Activated 30 seconds after the infusion starts. |

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

| Feature | Delivery Mode(s) | Description/Notes |
|---|---|---|
| Delivery modes | All | Determines the available delivery modes. Each mode can be turned Off separately. |
| New Patient | All | Allows users to associate an infusion with a patient, and reset the Accumulated VI (accumulated volume infused). |

| Feature | Delivery Mode(s) | Description/Notes |
|---|---|---|
| Set Secondary (Piggyback) | Continuous | Allows users to program a Secondary infusion. For more information about programming a Secondary infusion, refer to Adding a Secondary Line on page 148. |
| Allow Bolus | Continuous | Allows users to program a bolus during a Continuous infusion. When this feature is enabled, the Bolus button appears in the toolbar during the running infusion. For more information about administering a bolus, refer to Administering a Bolus on page 143. |
| Bolus Rate | Continuous | Specifies the rate of delivery of a fast dose, for rapid volume infusion. |
| Sec. Bolus Rate | Continuous | Specifies the rate of delivery of a fast dose for a Secondary (Piggyback) infusion. |
| Occ. Auto-restart | All | Enables the pump to automatically restart an infusion, up to 5 times an hour, if a downstream occlusion was detected and cleared within 40 seconds. |
| Calculate Concentration | All Excluding TPN | Determines if the user enters final concentration or Drug Amount and Diluent Volume. |
| mL/h Only | All Excluding TPN | Allows users to use units other than mL/h. If this option is enabled, programming will automatically default to mL/h. This feature is available in the absence of a Drug Library on the pump. |
| Med. Titration | All | Allows users with medium authorization level to change rate during a running infusion. |
| Air Detection | All Excluding 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 air detection is disabled (OFF), the user is prompted to use the set with an air-eliminating filter. |

## Setting KVO Rate

Allows users to set the default rate of fluid that is delivered when the infusion program is completed. The permitted range for the KVO rate parameter is 0-20 mL/h (for all delivery modes).

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# Chapter 4: Getting Started

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

Typical Workflow ..... 112
Connecting the Infusion Container to the Administration Set ..... 115
Opening the Safety Door ..... 116
Inserting the Administration Cassette ..... 117
Automatic Priming Using the Pump ..... 120

## Typical Workflow

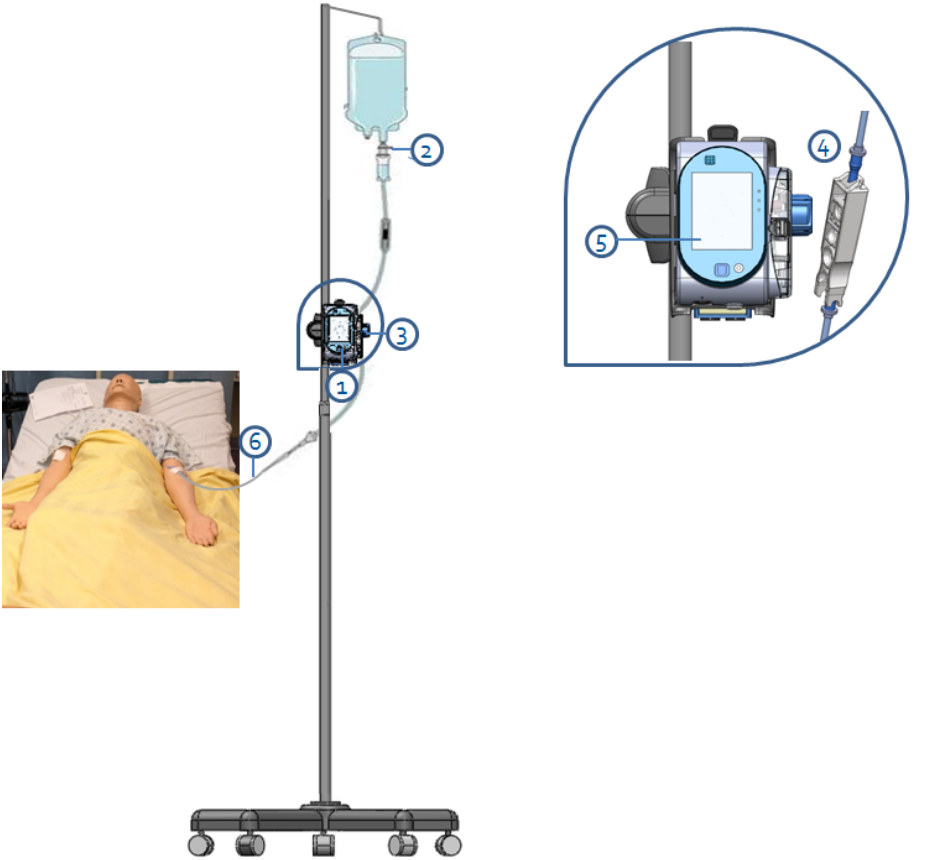
The recommended workflow for preparing the pump and administration set for an infusion comprises the following steps:

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

* It is recommended to prime the administration set using the pump. It is possible to prime the administration set manually. For more information, refer to Priming Manually on page 123.

The workflow sequence is illustrated in the following figure:

Figure 4.1. Recommended Workflow



## Turning the Pump On

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

When a Drug Library is loaded, a message is displayed asking to accept or change the current CCA. For more information about CCA, refer to Clinical Care Area (CCA) on page 267.

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

| | |
|---|---|
| ℹ | If a message regarding resuming previous infusion appears upon turning the pump On, refer to Resuming Infusions After Pump Shutdown on page 223. |

### Turning the Pump Off

Pressing the **On/Off** hard key for 5 consecutive seconds turns the pump Off. Alternatively, press the **On/Off** hard key, and then, from the Attention screen, press **Off**.

For more information about turning the pump Off during an infusion, refer to Aborting Infusions on page 225.

The pump enables resuming an infusion after pump shut down. For more information, refer to Resuming Infusions After Pump Shutdown on page 223.

## Connecting the Infusion Container to the Administration Set

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

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

**> To connect the container to the administration set:**

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

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

### Connecting the Infusion Container: Safety Warnings

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

## Opening the Safety Door

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

**> To open the safety door:**

1. Using your thumb, press the door outwards.

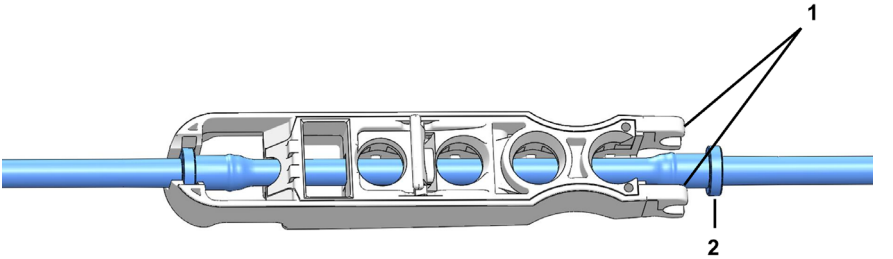
If gray latch is present, press the latch itself outwards.

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

## Inserting the Administration Cassette

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

Figure 4.2. Administration Cassette

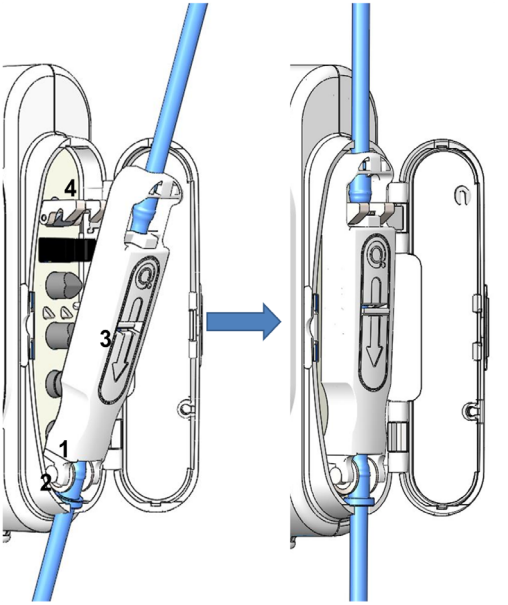



| | |
|---|---|
| ⚠ | It is recommended to make sure that the pump is turned On, and to verify that all clamps on the administration set are closed before inserting the administration cassette. |

**> To insert the Sapphire administration cassette:**

1. Open the safety door (Opening the Safety Door on page 116). Then, insert the administration cassette at an angle, by placing the saddle (Figure 4.3, #1) on the round metal anchor (#2) in the cassette's housing. Make sure that the arrow on the cassette (#3) is pointing toward the bottom of the pump, and the bottom flange is inside the cassette housing.

Figure 4.3. Insertion of Cassette




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

## Removing the Administration Cassette

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

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

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

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

**> To remove the Sapphire administration cassette:**

1. Close all clamps on the administration set.
2. Disconnect the patient from the administration set.
3. Open the safety door (Opening the Safety Door on page 116).
4. Loosen the cassette by raising the metal lock that secures it to the pump (#4 in Figure 4.3).
5. Pull out the cassette, and close the safety door.

## Automatic Priming Using the Pump

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

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

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

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

Before using the pump for priming, ensure that:

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

The Sapphire administration cassette is properly connected to the pump.

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

| | |
|---|---|
| ℹ | When priming a set with a filter – if the filter has an arrow drawn on it, make sure the arrow points up. |

| | |
|---|---|
| ℹ | When the Prime Reminder is enabled and the set has not yet been primed using the pump, a Prime Reminder will be displayed, enabling the user to press **Prime** in order to start priming or to press **Start** in order to proceed with the infusion (refer to Configuring General Settings, page 237). |

To prime the administration using the pump

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

   While the pump is priming, a progress circle appears on the screen, with a time countdown displayed. The default priming time is 2 minutes.
   When using administration sets that contain less than 20 mL, shorter priming times can be set. For more information, refer to Set prime volume on page 237.

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

The pump automatically indicates when priming is finished.
If priming is completed before the default priming time has elapsed, automatic priming can be discontinued.

**> To discontinue priming:**

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

If after priming, a patient is not connected to the administration set, close the clamp below the filter until patient is connected.

## Priming Manually

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

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

| | |
|---|---|
| | The following procedure explains how to prime the administration set manually, using gravity. However, it is recommended to prime the administration set using the pump. For more information, refer to Automatic Priming Using the Pump on page 120. |

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

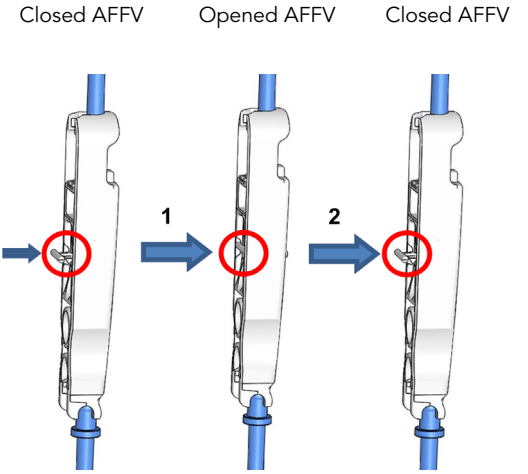
| | |
|---|---|
| | When priming a set with a filter – if the filter has an arrow printed on it, make sure the arrow points up. |

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

**> To prime the administration set manually:**

1. Open all the clamps on the administration set.
2. To allow free flow, open the AFFV by pushing it in and down, towards the center of the Sapphire administration cassette (#1 in Figure 4.4).
3. Fill the entire administration set with fluid, so that the fluid displaces all air in the administration set.
4. To block free flow, close the AFFV by pushing it up and away from the center of the cassette (#2 in Figure 4.4).

Figure 4.4. Opening and Closing the AFFV




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

To use as a gravity set, fix the AFFV in an open position as described in step 2 in To prime the administration set manually on page 123. Only administration sets that include a roller clamp and do not include pressure activated valves (PAV) can be used by gravity. For more information, refer to the Administration set's DFU.

If after priming, a patient is not connected to the administration set, close the clamp below the filter until patient is connected.

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# Chapter 5: Using the Delivery Modes

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


Continuous Mode ..... 126
Multi-step Mode ..... 156
Total Parenteral Nutrition (TPN) Mode ..... 165
Intermittent Mode ..... 172
Patient Controlled Analgesia (PCA) Mode ..... 182
Epidural Mode ..... 193

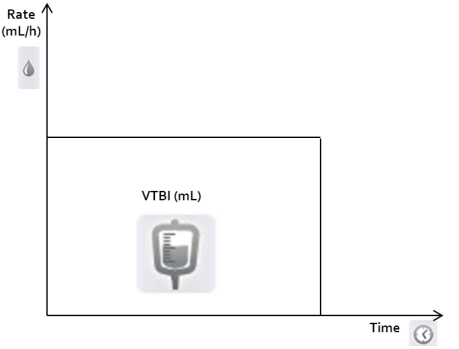

## Continuous Mode

The following sections will be reviewed:


Infusion Parameters: Continuous Mode ..... 129
Starting a Continuous Infusion ..... 129
Continuous Mode: Mid-infusion Actions ..... 141


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

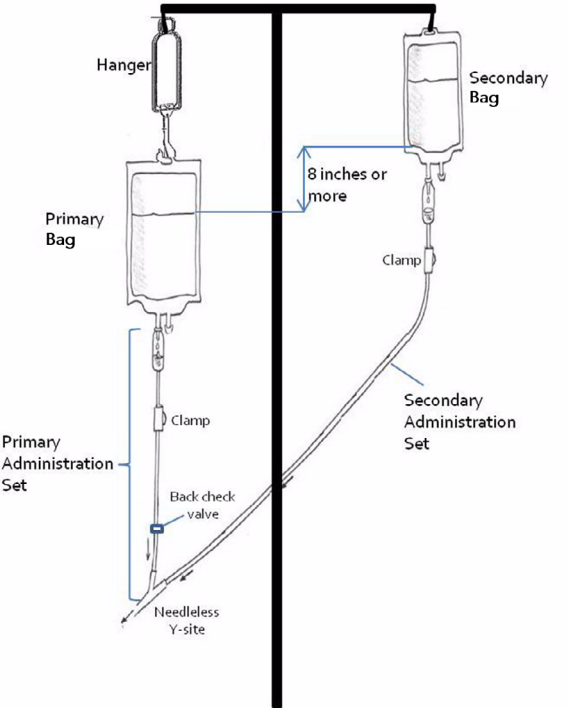
Figure 5.1. Continuous Flow Profile



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

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

Figure 5.2. Secondary Infusion Setup



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

- Immediately after programming the Primary infusion (Starting a Continuous Infusion Using the Secondary Function on page 135).
  OR
- While a Primary infusion is already running (Adding a Secondary Line on page 148).

### Piggyback Option: Safety Warnings

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

- Use only Sapphire administration sets designed for Piggyback infusions. (For more information, refer to Sapphire Approved Administration Sets on page 96.)
- Hang the Secondary solution container at least 8 inches above the Primary solution fluid level.
- Use the drip chamber on the set to verify that the correct line is delivering and the other line is idle.
- After the Secondary infusion is complete, clamp the Secondary administration set.

## Infusion Parameters: Continuous Mode

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

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

## Starting a Continuous Infusion

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

> If relevant, you may skip programming by using the Repeat Last Infusion or PreSet programs procedures to begin the infusion. For more information, refer to Starting New Infusions: Shortcuts on page 220.

**> To begin a new Continuous infusion without Drug Library:**

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

> For more information about changing delivery modes, refer to Selecting Delivery Mode on page 104.

2. From the Start Up screen, select **New Infusion**.
3. If a warning that air detection is set to Off appears, ensure that a set with an air-eliminating filter is used, and press **OK**.
4. If the Dosing method screen appears, select the appropriate option:
   - **mL:** Continue to Step 8.
   - **Dose calculation:** Continue to Step 5.

   Weight based units are available for both Dosing methods

   Otherwise, continue to Step 11.
5. From the Concentration units screen, select the appropriate drug units.

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

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

   If the selected drug unit is Million Units, continue to Step 10.
8. If the Patient Weight screen appears, specify whether the infusion is weight based:
   - **Yes**: Continue to Step 9.
   - **No**: Continue to Step 10.
9. From the Patient Weight screen, using the keypad, enter the Patient Weight → **OK**.
10. From the Dose Rate units screen, select the appropriate dose rate units.
11. From the Edit screen, program 2 of the following 3 parameters, by selecting the relevant rows:
    - **Rate:** Using the keypad, enter the value → **OK**.
    - **VTBI:** Using the keypad, enter the value → **OK**.

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

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

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

12. Review the parameters displayed on the Confirm screen.

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

Then, press **OK**.

> If the pump is configured to support Secondary infusions, Secondary infusion parameters can be programmed at this point. For detailed instructions, go to Step 3 on page 135 (To begin a new Continuous infusion using the Secondary option without Drug Library).

13. Make sure that the clamps on the administration set are open; then, press **Start**.

    The Running screen is displayed, and the infusion begins.

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

- **Drug Name:** The name of the selected drug. Displayed on the indicators bar, when working with a Drug Library.
- **Drug Concentration:** Drug concentration as entered by the user (Final concentration or Drug Amount / Diluent Volume). Displayed when applicable.

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

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

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

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

> For more information about changing delivery modes, refer to Selecting Delivery Mode on page 104

2. From the Start Up screen, select **New Infusion**.
3. If a warning that air detection is set to Off appears, ensure that a set with an air-eliminating filter is used, and press **OK**.
4. From the Drug Name screen:
   - Using the keypad, enter the drug name; then, press **Find** and proceed to Step 5.

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

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

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

From the Attention screen, confirm choosing General, and press **OK**.
Proceed to Step 4 on page 130 (To begin a new Continuous infusion without Drug Library) and continue programming from there.

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

| | |
|---|---|
| ℹ | To display additional drugs press **Next**. |

6. If a list of available drug profiles appears, select the appropriate drug profile and proceed according to the step directed to:
   - **No concentration**: proceed to Step 8 on page 130 (To begin a new Continuous infusion without Drug Library), and continue programming from there.
   - **Diluent only** (e.g., 10 mL): proceed to Step 8 on page 130 (To begin a new Continuous infusion without Drug Library), and continue programming from there.
   - **Custom/Partial concentration**: the Drug Amount and/or Diluent Volume are/is missing. The screen/s of the missing value/s will appear:
     - From the Drug Amount screen, using the keypad, enter the Drug Amount → **OK**.
     - From the Diluent Volume screen, using the keypad, enter the Diluent Volume → **OK**.

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

     Proceed to Step 8 on page 130 (To begin a new Continuous infusion without Drug Library), and continue programming from there.

- **Full concentration**:

  Proceed to Step 8 on page 130 (To begin a new Continuous infusion without Drug Library), and continue programming from there.

If a list of available drug profiles does not appear, continue to Step 11 on page 130 (To begin a new Continuous infusion without Drug Library), and continue programming from there.

For more information about the Drug Library, refer to Chapter 9: Drug Library on page 266.

## Starting a Continuous Infusion Using the Secondary Function

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

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

1. Verify that the pump is in Continuous mode, and then enter parameters for the Primary infusion (Step 2 on page 130 through Step 11 on page 130 in To begin a new Continuous infusion without Drug Library).

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

2. Review the parameters displayed on the Confirm screen.

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

   Then, press **OK**.

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

   Weight based units are available for both Dosing methods.

   Otherwise, continue to Step 11.
5. From the Concentration units screen, select the appropriate drug units.

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

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

   If the selected drug unit is Million Units, continue to Step 10.
8. If the Patient Weight screen appears, specify whether the infusion is weight based:
   - **Yes**: Continue to Step 9.
   - **No**: Continue to Step 10.
9. From the Patient Weight screen:

   If the patient weight was entered during the primary line programming, continue to Step 10.
   If the patient weight was not entered during the primary line programming, using the keypad, enter the Patient Weight → **OK**.
10. From the **Dose Rate units** screen, select the appropriate dose rate units.
11. Program 2 of the following 3 parameters, by selecting the relevant boxes:
    - **Rate (Secondary):** Using the keypad, enter the value → **OK**.
    - **VTBI (Secondary):** Using the keypad, enter the value → **OK**.
    - **Time (Secondary):** Using the keypad, enter the value → **OK**.

    The third (unprogrammed) parameter is then automatically calculated by the pump and displayed in the relevant box.
12. Review the parameters displayed on the Confirm screen.

| | |
|---|---|
| ⚠ | Verify that the parameters reflect the correct treatment according to the prescription. |

Then, press **OK**.

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

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

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

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

| | |
|---|---|
| | You can switch between the two infusions at any time. For more information, refer to Switching between Primary and Secondary Infusions on page 152. |

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

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

1. Verify that the pump is in Continuous mode, and then enter parameters for the Primary infusion (To begin a new Continuous infusion with a Drug Library Step 2 on page 132 to Step 6 on page 133).

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

2. Review the parameters displayed on the Confirm screen.

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

   Then, press **OK**.

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

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

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

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

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

From the Attention screen, confirm choosing General and press **OK**. Proceed to Step 4 on page 135 (To begin a new Continuous infusion using the Secondary option without Drug Library) and continue programming from there.

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

> To display additional drugs press **Next**.

6. If a list of available drug profiles appears, select the appropriate drug profile and proceed according to the step directed to:
   - **No concentration**: proceed to Step 8 on page 136 (To begin a new Continuous infusion using the Secondary option without Drug Library), and continue programming from there.
   - **Diluent only** (e.g., 10 mL): proceed to Step 8 on page 136 (To begin a new Continuous infusion using the Secondary option without Drug Library), and continue programming from there.
   - **Custom/Partial concentration**: the Drug Amount and/or Diluent Volume are/is missing. The screen/s of the missing value/s will appear:
     - From the Drug Amount screen, using the keypad, enter the Drug Amount → **OK**.
     - From the Diluent Volume screen, using the keypad, enter the Diluent Volume → **OK**.

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

Proceed to Step 8 on page 136 (To begin a new Continuous infusion using the Secondary option without Drug Library), and continue programming from there.

- **Full concentration**:

  Proceed to Step 8 on page 136 (To begin a new Continuous infusion using the Secondary option without Drug Library), and continue programming from there.

If a list of available drug profiles does not appear, continue to Step 11 on page 136 (To begin a new Continuous infusion using the Secondary option without Drug Library), and continue programming from there.

For more information about the Drug Library, refer to Chapter 9: Drug Library on page 266.

## Continuous Mode: Mid-infusion Actions

The following actions can be performed during Continuous infusions:


Updating Infusion Parameters ..... 141
Administering a Bolus ..... 143
Adding a Secondary Line ..... 148
Switching between Primary and Secondary Infusions ..... 152
Replacing the Current Secondary Line ..... 153
Pausing Infusions ..... 224
Aborting Infusions ..... 225
Locking the Screen ..... 226
Activating Patient Lockout ..... 227


### Updating Infusion Parameters

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

**> To update current parameters directly from the screen:**

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

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

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

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

- **Clear Accum. VI:** Resets the total volume infused via all infusions associated with the current patient to 0 mL. For more information, refer to Clearing Accumulated VI on page 265.
- **View system:** Displays various system and pump parameters. (Refer to View Menu on page 243.)
- **Edit Primary/Secondary Line:** Allows you to update infusion parameters of the infusion that is not currently running. The pump will prompt you to pause the infusion while updating these parameters.

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

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

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

## Administering a Bolus

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

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

**> To deliver a bolus:**

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

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

2. If the Patient Weight screen appears, using the keypad, enter the Patient Weight → **OK.**
3. According to configuration, one of the following screens will appear:
   - **Edit**:
     - **Amnt (Bolus)**: Using the keypad, enter the Bolus Amount → **OK** (the acceptable range varies, according to the current VTBI).

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

   Enter one of the following parameters, by selecting the relevant box:
   - **Rate (Bolus)**: Using the keypad, enter the Bolus Rate → **OK**.
   - **Time (Bolus)**: Using the keypad, enter the Bolus Time → **OK**.

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

Continue to Step 4.

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

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

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

| | |
|---|---|
| | When the bolus is programmed by amount only, the default bolus rate is 125 mL/h. This default can be modified using a Technician authorization code.<br>When the infusion rate is higher than 125 mL/h, the bolus rate will be 1 mL/h faster than the infusion rate.<br>During a bolus, some of the parameters can be updated from the Bolus delivery screen. For more information, refer to Updating Bolus Infusion Parameters on page 146. |

4. Review the parameters displayed on the Confirm screen.

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

Then, press **OK**.

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

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

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

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

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

## Mid-bolus Actions

The following actions can be performed during bolus delivery:

Updating Bolus Infusion Parameters ..... 146
Pausing a Bolus ..... 146
Aborting a Bolus ..... 147

### Updating Bolus Infusion Parameters

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

**> To update parameters from the Bolus delivery screen:**

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

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

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

   Updated parameters are displayed.

### Pausing a Bolus

When necessary, you can temporarily stop the bolus.

**> To pause a bolus:**

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

**> To resume a paused bolus:**

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

## Aborting a Bolus

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

**> To abort a bolus and quit all infusions:**

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

Resuming infusion after quitting will not be possible.

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

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

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

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

## Adding a Secondary Line

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

> If you have already programmed the Secondary infusion, and want to start it, refer to Switching between Primary and Secondary Infusions on page 152.

> Before programming a Secondary infusion, verify that the administration set you are using is appropriate for Secondary (Piggyback) infusions. For more information, refer to Sapphire Approved Administration Sets on page 96.

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

1. From the toolbar, press **View/Edit**.
2. Select **Add Sec. Line**.
3. If the Dosing method screen appears, select the appropriate option:
   - **mL:** Continue to Step 7.
   - **Dose calculation:** Continue to Step 4.

   Weight based units are available for both Dosing methods.

   Otherwise, continue to Step 10.
4. From the Concentration units screen, select the appropriate drug units.

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

5. According to pump configuration one of the following screens will appear:
   - **Concentration**: From the Concentration screen, using the keypad, enter the Concentration → **OK**. Then, continue to Step 7.
   - **Drug amount**: Using the keypad, enter the Drug Amount → **OK**. Then, using the keypad, enter the Diluent Volume → **OK**. Then, continue to Step 6.
6. From the Attention screen, confirm the concentration and press **OK**.
   If the selected drug unit is Million Units, continue to Step 9.

7. If the Patient Weight screen appears, specify whether the infusion is weight based:
   - **Yes**: Continue to Step 8.
   - **No**: Continue to Step 9.
8. From the Patient Weight screen:

   If the patient weight was entered during the primary line programming, continue to Step 9.
   If the patient weight was not entered during the primary line programming, using the keypad, enter the Patient Weight → **OK**.
9. From the Dose Rate units screen, select the appropriate dose rate units.
10. Program 2 of the following 3 parameters, by selecting the relevant boxes:
    - **Rate (Secondary):** Using the keypad, enter the value → **OK**.
    - **VTBI (Secondary):** Using the keypad, enter the value → **OK**.
    - **Time (Secondary):** Using the keypad, enter the value → **OK**.

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

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

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

    Then, press **OK**.

12. From the Start screen, select one of the following:
    - **Start secondary:** The Attention screen appears. After verifying that the clamps on the Secondary administration set are open, press **OK**. The Secondary screen appears, and the Secondary infusion begins. When the Secondary infusion is complete, the pump automatically continues with the Primary infusion.
    - **Continue primary:** The Primary screen appears, and the Primary infusion begins.
      For more information about switching from one infusion to the other, refer to Switching between Primary and Secondary Infusions on page 152.

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

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

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

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

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

    From the Attention screen, confirm choosing General and press **OK**.
    Proceed to Step 3 on page 148 (To add a Secondary line while a Primary line is running, without Drug Library), and continue programming from there.

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

> To display additional drugs press **Next**.

5. If a list of available drug profiles appears, select the appropriate drug profile and proceed according to the step directed to:
   - **No concentration**: proceed to Step 7 on page 149 (To add a Secondary line while a Primary line is running, without Drug Library), and continue programming from there.
   - **Diluent only** (e.g., 10 mL): proceed to Step 7 on page 149 (To add a Secondary line while a Primary line is running, without Drug Library), and continue programming from there.
   - **Custom/Partial concentration**: the Drug Amount and/or Diluent Volume are/is missing. The screen/s of the missing value/s will appear:
     - From the Drug Amount screen, using the keypad, enter the Drug Amount → **OK**.
     - From the Diluent Volume screen, using the keypad, enter the Diluent Volume → **OK**.

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

     Proceed to Step 7 on page 149 (To add a Secondary line while a Primary line is running, without Drug Library), and continue programming from there.
   - **Full concentration**:

     Proceed to Step 7 on page 149 (To add a Secondary line while a Primary line is running, without Drug Library), and continue programming from there.

   If a list of available drug profiles does not appear, continue to Step 7 on page 149 (To add a Secondary line while a Primary line is running, without Drug Library), and continue programming from there.

For more information about the Drug Library, refer to Chapter 9: Drug Library on page 266.

## Switching between Primary and Secondary Infusions

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

**> To switch from the Primary to the Secondary infusion:**

1. Pause the Primary infusion:

   From the toolbar of the Primary screen, press **Request Pause**. Then, from the Attention screen, press **OK**.

   Alternatively, press the **Stop** hard key.

2. From the toolbar of the Primary screen, select **Switch or Continue**.

3. From the Start screen, select **Start secondary**.

   The Attention screen appears. After verifying that the clamps on the Secondary administration set are open, press **OK**. The Secondary screen appears, and the Secondary infusion begins.

**> To switch from the Secondary to the Primary infusion:**

1. Pause the Secondary infusion:

   From the toolbar of the Secondary screen, press **Request Pause**. Then, from the Attention screen, press **OK**.

   Alternatively, press the **Stop** hard key.

2. From the toolbar of the Secondary screen, select **Switch or Continue**.

3. From the Start screen, select **Continue primary (or Start primary)**.

   The Attention screen appears. After verifying that the clamps on the Secondary administration set are closed, and that the clamps on the primary set are open, press **OK**. The Primary screen appears, and the Primary infusion begins.

## Replacing the Current Secondary Line

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

Deleting the Current Secondary Line and Moving to the Primary Infusion ..... 153
Replacing the Current Secondary Line with a New Secondary Line ..... 154

### Deleting the Current Secondary Line and Moving to the Primary Infusion

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

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

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

> If you want to program a new Secondary line, refer to Adding a Secondary Line on page 148.

## Replacing the Current Secondary Line with a New Secondary Line

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

> Before programming a Secondary infusion, verify that the administration set you are using is appropriate for Secondary (Piggyback) infusions. For more information, refer to Sapphire Approved Administration Sets on page 96.

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

1. Pause the Secondary infusion:
   From the toolbar of the Secondary screen, press **Request Pause**. Then, from the Attention screen, press **OK**.
   Alternatively, press the **Stop** hard key.
2. From the toolbar of the paused screen, press **View/Edit**.
3. On the View/Edit screen, select **Delete/Replace Sec. Line**.
4. On the Delete/Replace screen, select **Replace secondary**.
5. From the Attention screen press **OK** to delete the current secondary line and to program a different secondary infusion.
6. Proceed to Step 3 on page 148 (To add a Secondary line while a Primary line is running, without Drug Library).

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

1. Pause the Secondary infusion:
   From the toolbar of the Secondary screen, press **Request Pause**. Then, from the Attention screen, press **OK**.
   Alternatively, press the **Stop** hard key.
2. From the toolbar of the paused screen, press **View/Edit**.
3. On the View/Edit screen, select **Delete/Replace Sec. Line**.
4. On the Delete/Replace screen, select **Replace secondary**.
5. From the Attention screen press **OK** to delete the current secondary line and to program a different secondary infusion.
6. Proceed to Step 3 on page 150 (To add a Secondary line while a Primary line is running, with a Drug Library).

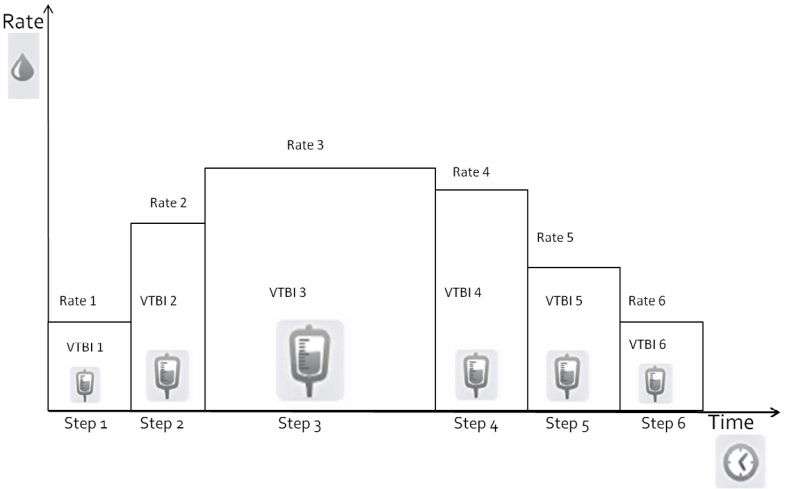
## Multi-step Mode

The following sections will be reviewed:

Infusion Parameters: Multi-step Mode ..... 157
Starting a Multi-step Infusion ..... 157
Multi-step Mode: Mid-infusion Actions ..... 163

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

Figure 5.3. Multi-step Flow Profile



## Infusion Parameters: Multi-step Mode

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

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

## Starting a Multi-step Infusion

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

> If relevant, you may skip programming by using the Repeat Last Infusion or PreSet programs procedures to begin the infusion. For more information, refer to Starting New Infusions: Shortcuts on page 220.

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

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

   > For more information about changing delivery modes, refer to Selecting Delivery Mode on page 104.

2. From the Start Up screen, select **New Infusion**.

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

   Weight based units are available for both Dosing methods.

   Otherwise, continue to Step 11.
5. From the Concentration units screen, select the appropriate drug units.

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

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

   If the selected drug unit is Million Units, continue to Step 10.
8. If the Patient Weight screen appears, specify whether the infusion is weight based:
   - **Yes**: Continue to Step 9.
   - **No**: Continue to Step 10.
9. From the Patient Weight screen, using the keypad, enter the Patient Weight → **OK**.
10. From the Dose Rate units screen, select the appropriate dose rate units.
11. Using the keypad, enter the number of Steps required for the infusion, and then press **OK**.
12. For the first Step, program 2 of the following 3 parameters, by selecting the relevant boxes (the digit refers to the number of the Step):
    - **Rate 1:** Using the keypad, enter the value → **OK**.

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

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

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

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

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

    Then, press **OK**.
16. Make sure that the clamps on the administration set are open; then, press **Start**.

    The Running screen is displayed, and the infusion begins.

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

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

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

> To view all programmed parameters of the current infusion, including the rate in mL/h, from the Running screen, press **View/ Edit → View system → Infusion values**.
> For more information, refer to Viewing System Parameters on page 244.

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

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

> For more information about changing delivery modes, refer to Selecting Delivery Mode on page 104.

2. From the Start Up screen, select **New Infusion**.
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**.
4. From the Drug Name screen:

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

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

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

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

From the Attention screen, confirm Choosing General, and press **OK**. Proceed to Step 4 on page 158 (To begin a new Multi-step infusion without Drug Library), and continue programming from there.

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

> To display additional drugs press **Next**.

6. If a list of available drug profiles appears, select the appropriate drug profile and proceed according to the step directed to:
   - **No concentration**: proceed to Step 8 on page 158 (To begin a new Multi-step infusion without Drug Library), and continue programming from there.
   - **Diluent only** (e.g., 10 mL): proceed to Step 8 on page 158 (To begin a new Multi-step infusion without Drug Library), and continue programming from there.
   - **Custom/Partial concentration**: the Drug Amount and/or Diluent Volume are/is missing. The screen/s of the missing value/s will appear:
     - From the Drug Amount screen, using the keypad, enter the Drug Amount → **OK**.
     - From the Diluent Volume screen, using the keypad, enter the Diluent Volume → **OK**.

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

Proceed to Step 8 on page 158 (To begin a new Multi-step infusion without Drug Library), and continue programming from there.

- **Full concentration**:

  Proceed to Step 8 on page 158 (To begin a new Multi-step infusion without Drug Library), and continue programming from there.

If a list of available drug profiles does not appear, continue to Step 8 on page 158 (To begin a new Multi-step infusion without Drug Library), and continue programming from there.

For more information about the Drug Library, refer to Chapter 9: Drug Library on page 266.

## Multi-step Mode: Mid-infusion Actions

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


Updating Step Parameters ..... 163
Pausing Infusions ..... 224
Aborting Infusions ..... 225
Locking the Screen ..... 226
Activating Patient Lockout ..... 227


### Updating Step Parameters

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

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

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

**> To update current Step parameters from the Running screen:**

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

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

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

   In addition to parameter changes, the following actions are also available:
   - **Clear Accum. VI:** Resets the total volume infused via all infusions associated with the current patient to 0 mL. For more information, refer to Clearing Accumulated VI on page 265.
   - **Next step:** Allows you to update infusion parameters of the Step following the current Step. (This box appears only if there is a Step following the current Step.)
   - **View system:** Displays various system and pump parameters.
5. To confirm and save changes, press **OK**.

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

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

## Total Parenteral Nutrition (TPN) Mode

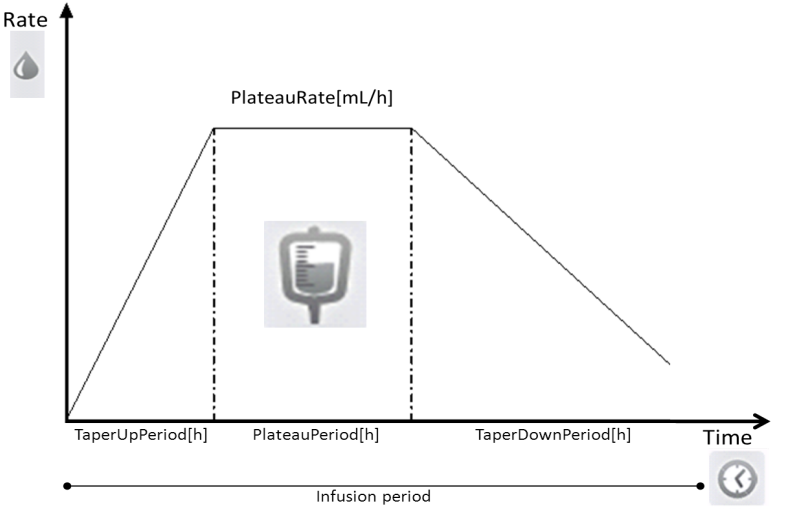
The following sections will be reviewed:


Infusion Parameters: TPN Mode ..... 166
Starting a TPN Infusion ..... 167
TPN Mode: Mid-infusion Actions ..... 169


Total Parenteral Nutrition, also known as Parenteral Nutrition or hyperalimentation, is used for patients who are unable to obtain adequate nutrients by oral or enteral routes. TPN solutions supply basic nutrients, including fluids, proteins, carbohydrates, electrolytes, fatty acids, vitamins, minerals, and trace elements directly to the patient's blood stream, bypassing the GI tract.

The TPN delivery mode permits high volume delivery of solutions, with optional tapering (ramping). When tapering is used, delivery rate is gradually increased/decreased (tapered-up/tapered-down) at the beginning and end of the infusion profile.

Figure 5.4. TPN Flow Profile




When not using tapers, the TPN infusion starts and ends at the Plateau Rate. In such cases, the Continuous delivery mode can be applied and is recommended.

## Infusion Parameters: TPN Mode

The infusion parameters that need to be set for a TPN infusion are listed in the following table. Based on the values that are programmed, the pump automatically calculates the rate (and the gradual increase and decrease) necessary to deliver the infusion.

| Parameter | Description/Notes |
|---|---|
| VTBI | The total amount of fluid to be infused. VTBI values can range from 0.1 to 9999 mL (with a tolerance of 0.2 mL). The remaining VTBI is displayed on the screen as the infusion progresses.<br>The pump calculates the Plateau Rate based on the VTBI, the infusion period, and the taper values. |
| Taper Up | The length of time over which the rate increases to the Plateau Rate. The Taper Up and Down period can be set to 0 minutes, or range from 10 minutes to 3 hours, for each Taper. |
| Taper Down | The length of time over which the rate decreases to the KVO rate (from the Plateau Rate). The Taper Up and Down period can be set to 0 minutes, or range from 10 minutes to 3 hours, for each Taper. |
| Infusion Period | The total time duration for delivering the VTBI (including tapers and plateau period).<br>The maximum Infusion Period is 96 hours. The minimum Infusion Period is determined by the sum of the taper periods plus 10 minutes (minimal Infusion Period between tapers). |

### TPN Mode: Safety Warnings

When working in TPN mode, adhere to the following safety precautions and procedures:

- Use only parenteral feeding solutions prescribed by the responsible doctor, registered dietician, nurse or other licensed medical practitioner.
- Check that the correct dosage has been programmed. While a TPN infusion is running or paused, infusion parameters cannot be changed.

- Prior to administration, verify the identity of the patient by using at least two identifiers, as well as the parenteral nutrition container label.
- The Air in Line detector working range when delivering fatty acids is 2%-20% lipids.

## Starting a TPN Infusion

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

> If relevant, you may skip programming by using the Repeat Last Infusion or PreSet programs procedures to begin the infusion. For more information, refer to Starting New Infusions: Shortcuts on page 220.

**> To begin a new TPN infusion:**

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

> For more information about changing delivery modes, refer to Selecting Delivery Mode on page 104.

2. From the **Start Up** screen, select **New Infusion**.
3. If a warning that air detection is set to Off appears, ensure that a set with an air-eliminating filter is used, and press **OK**.
4. Using the keypad, enter the **VTBI** value → **OK**.
5. Specify whether you want to use tapers: Select **Yes** or **No**.

   If you select **No**, proceed to Step 7.
6. Specify tapers:
   a. On the Taper Up screen, use the keypad to enter the Taper Up time → **OK**. The Taper Up time can be set to 0.
   b. On the Taper Down screen, use the keypad to enter the Taper Down time → **OK**. The Taper Down time can be set to 0.

7. Using the keypad, enter the infusion period → **OK**.
8. Review the parameters displayed on the Confirm screen.

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

Then, press **OK**.

9. To begin the infusion, make sure that the clamps on the administration set are open; then, press **Start**. The infusion begins.

Throughout the infusion, the following information appears on the Main Display:

- **Rate:** Current infusion rate. For all dose units other than mL/h, the calculated rate will be displayed in mL/h, both in the View system menu and in the Running screen.
- **VTBI:** Total volume left to be infused. As the infusion progresses, this value decreases.
- **VI / Total:** Total volume delivered in the current infusion(including KVO if applied during a delayed start period) / the total VTBI value programmed. As the infusion progresses, the VI increases, and the Total remains constant.
- **Time left:** Time remaining until the end of the infusion.

> ℹ All the parameters of the current infusion can be viewed from **View system** → **Infusion Values**.

## TPN Mode: Mid-infusion Actions

The following actions can be performed during TPN infusions:


Pausing Infusions ..... 169
Immediate Taper Down ..... 171
Aborting Infusions ..... 225
Locking the Screen ..... 226
Activating Patient Lockout ..... 227


In TPN mode, infusion parameters cannot be updated using the **View/Edit** function key. To modify the parameters, you need to quit the infusion, and reprogram a new infusion.

The **View/Edit** function key can be used to perform the following actions only:

- **Clear Accum. VI:** Resets the total volume infused for all infusions associated with a patient to 0 mL.
- **View system:** Displays various system and pump parameters. (Refer to View Menu on page 243.)

### Pausing Infusions

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

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

| | |
|---|---|
| i | During the plateau rate of a TPN infusion, the **Request Pause** function key is replaced with the **Taper down** key. Pausing the infusion remains available using the Taper down key (for more information, refer to Immediate Taper Down on page 171). |

### > To pause an infusion during the plateau rate using the Taper Down function key:

1. From the toolbar, press **Taper Down**.

> If the pump is set to a Low authorization level, with no Taper Down period programmed, the **Request Pause** key will be available, without the option to **Taper Down**.

2. From the Pause Options screen, select **Pause Infusion**; then, press **OK**.
3. The infusion is paused.

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

### > To pause an infusion during taper using the Request Pause function key:

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

   If the pump is set to the Low authorization level, with no Taper Down period programmed, the Request Pause key will be available, without the option to Taper down.

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

### > To resume a paused infusion:

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

## Immediate Taper Down

Immediate Taper Down can be used to end the infusion prematurely, utilizing taper down, to slow the infusion rate gradually before stopping. The option is available during the infusion's plateau period, provided there are more than 10 minutes before the infusion is complete. The taper down period is set to the time programmed originally for the infusion, and it can be modified when the pump is set to a Medium or higher authorization level.

Immediate Taper Down is available only in the following conditions:

- The pump is running.
- The pump is delivering at the plateau rate.
- The time left for the infusion is greater than 10 minutes.
- The pump is set to Medium or higher authorization level, in case no Taper period is programmed.

**> To immediately Taper Down an infusion:**

1. From the toolbar, press **Taper Down**.
2. From the Taper Down screen select **Immediate Taper Down**.

| | |
|---|---|
| i | If the pump is set to Low authorization level, the user will be prompted to acknowledge the preprogrammed Taper Down time value (skip step 3) without the ability to change it. |

| | |
|---|---|
| i | When using the immediate Taper option, the original values programmed for the infusion will be presented in the Infusion Values menu. |

3. From the Immediate Taper Down screen, accept the preprogrammed time settings, or enter the Taper Down time using the keypad → **OK**.

| | |
|---|---|
| i | Entering 00:00 hh:mm to Taper Down time frame will stop the infusion without tapering. |

4. From the Attention screen, press **OK** to begin the Taper Down.

   The Taper Down running screen appears.

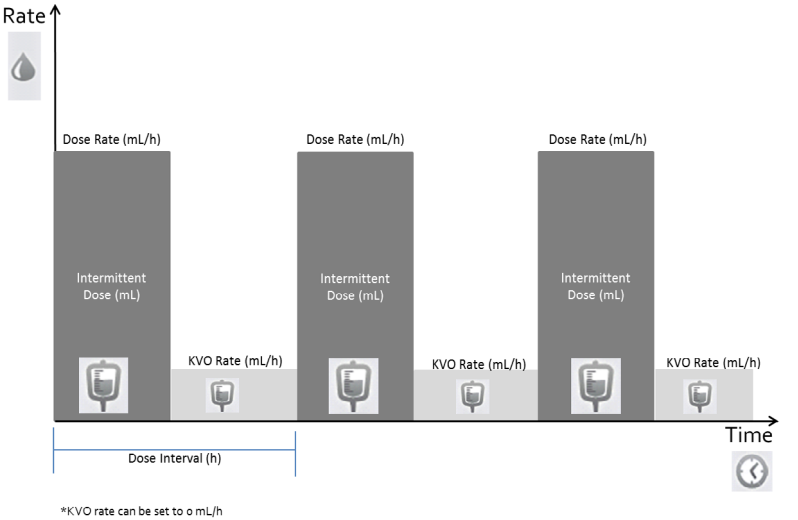
## Intermittent Mode

The following sections will be reviewed:

Infusion Parameters: Intermittent Mode ..... 173
Starting an Intermittent Infusion ..... 173
Intermittent Mode: Mid-infusion Actions ..... 180

This mode enables you to program a dose time and volume infusion to be repeated at regular intervals or cycles. The Dose Interval is the time frequency at which the dose is delivered. A KVO rate can be programmed to run between intermittent dose.

Figure 5.5. Intermittent Flow Profile



## Infusion Parameters: Intermittent Mode

The following infusion parameters need to be set for an Intermittent infusion:

| Parameter | Description/Notes |
|---|---|
| VTBI | The total amount of fluid to be infused. The remaining VTBI is displayed on the screen as the infusion progresses. VTBI values can range from 0.1 to 9999 mL. |
| Intermittent Dose | The amount of each Intermittent Dose. Values can range from 0.1 to 999 mL. |
| Dose Time | The period of time over which the intermittent dose is delivered. Values can range from 00:01 to 96:00 hh:mm. |
| Dose Interval | The frequency of intermittent dose delivery (Intermittent Dose + KVO). Intermittent doses can be given as frequently as 5 minutes apart. Therefore, the minimum programmable Dose Interval is the Dose time plus 5 minutes. This rule applies even when the KVO rate is set to 0. |
| KVO (Keep Vein Open) | The rate of fluids delivered between doses, to prevent clotting in the infusion cannula. The KVO rate can be set from 0 to 20 mL/h. |

## Starting an Intermittent Infusion

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

If relevant, you may skip programming by using the Repeat Last Infusion or PreSet programs procedures to begin the infusion. For more information, refer to Starting New Infusions: Shortcuts on page 220.

### > To begin a new Intermittent infusion without Drug Library:

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

> For more information about changing delivery modes, refer to Selecting Delivery Mode on page 104.

2. From the **Start Up** screen, select **New Infusion**.
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**.
4. If **Dosing method** screen appears, select the appropriate option:
   - **mL:** Continue to Step 8.
   - **Dose calculation:** Continue to Step 5.

   Weight based units are available for both Dosing methods

   Otherwise, continue to Step 11.
5. From the **Concentration units** screen, select the appropriate drug units.

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

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

   If the selected drug unit is Million Units, continue to Step 10.
8. If the **Patient Weight** screen appears, specify whether the infusion is weight based:
   - **Yes**: Continue to Step 9.
   - **No**: Continue to Step 10.

9. From the **Patient Weight** screen, using the keypad, enter the patient weight → **OK**.
10. From the **Dose Rate units** screen, select the appropriate dose rate units.
11. Using the keypad, enter the **VTBI** value → **OK**.
12. Using the keypad, enter the **Intermittent Dose** → **OK**.
13. Using the keypad, enter the **Dose Time** → **OK**.
14. Using the keypad, enter the **Dose Interval** → **OK**.
15. Using the keypad, enter the **KVO** rate → **OK**.

    The KVO rate may be set to zero.
16. Review the parameters displayed on the Confirm screen.

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

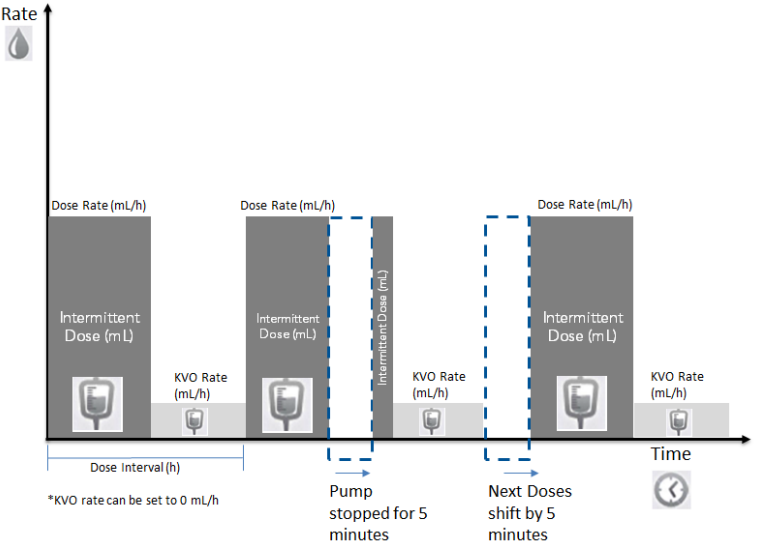
    Then, press **OK**.
17. To begin the infusion, make sure that the clamps on the administration set are open; then, press **Start**.

    The Intermittent Dose screen is displayed, and the infusion begins with the first dose.

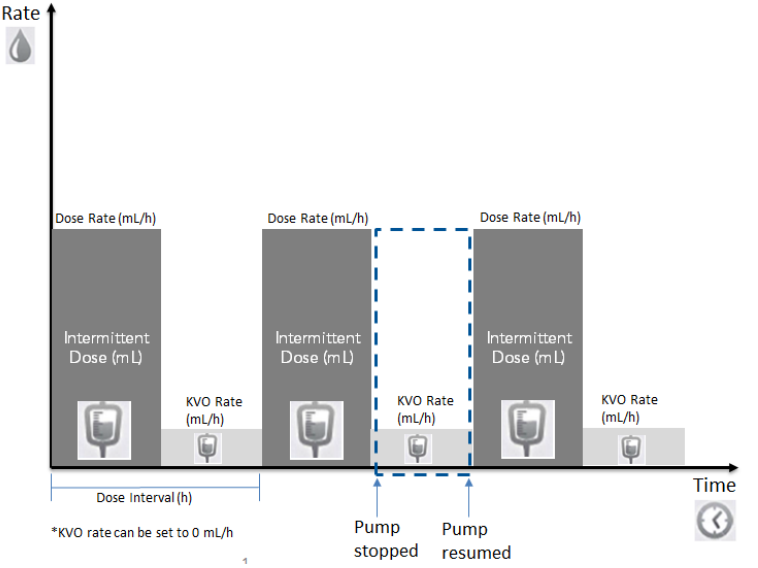
Throughout the infusion, the infusion phase (Intermittent Dose or KVO) is displayed on the Indicators Bar. In addition, the following information appears on the screen:

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

- **VI / Total:** Total volume delivered in the current infusion (including KVO if applied during a delayed start period) / the total VTBI value programmed. As the infusion progresses, the VI increases, and the Total remains constant.
- **Time to Dose:** Time remaining before the next dose starts (until the end of the current interval; Dose time left + KVO time).
  - **Pause During Dose**
    When the infusion is paused during Dose, the time to the next Intermittent Dose (Time to Dose) is paused and not displayed.



- **Pause During KVO**
  The pump can be switched off or paused between intermittent doses without impacting the dose schedule. The time to dose will be displayed, and the pump will also alert when dose schedule is due and infusion not started, reminding the user to resume the infusion.
  When the infusion is paused during KVO, the time to the next Intermittent Dose (Time to Dose) is displayed, and continues to count down.




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

---

To view all programmed parameters of the current infusion, including the rate in mL/h, from the Running screen, press **View/ Edit → View system → Infusion values**.
For more information, refer to Viewing System Parameters on page 244.

---

### > To begin a new Intermittent infusion with a Drug Library:

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

> For more information about changing delivery modes, refer to Selecting Delivery Mode on page 104.

2. From the **Start Up** screen, select **New Infusion**.
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**.
4. From the **Drug Name** screen:
   - Using the keypad, enter the drug name, then press **Find** and proceed to Step 5.

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

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

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

   From the Attention screen, confirm Choosing General and press **OK**. Proceed to Step 4 on page 174 (To begin a new Intermittent infusion without Drug Library), and continue programming from there.
5. From the **Drug List** screen, select the row of the relevant drug.

> To display additional drugs press **Next**.

6. If a list of available drug profiles appears, select the Appropriate drug profile and proceed according to the step directed to:
   - **No concentration**: proceed to Step 8 on page 174 (To begin a new Intermittent infusion without Drug Library), and continue programming from there.
   - **Diluent only** (e.g. 10 mL): proceed to Step 8 on page 174 (To begin a new Intermittent infusion without Drug Library), and continue programming from there.
   - **Custom/Partial concentration**: the Drug Amount and/or Diluent Volume are/is missing. The screen/s of the missing value/s will appear:
     - From the **Drug Amount** screen, using the keypad, enter the Drug Amount → **OK**.
     - From the **Diluent Volume** screen, using the keypad, enter the Diluent Volume → **OK**.

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

     Proceed to Step 8 on page 174 (To begin a new Intermittent infusion without Drug Library), and continue programming from there.
   - **Full concentration**:
     Proceed to Step 8 on page 174 (To begin a new Intermittent infusion without Drug Library), and continue programming from there.

   If a list of available drug profiles does not appear, continue to Step 8 on page 174 (To begin a new Intermittent infusion without Drug Library), and continue programming from there.

For more information about the Drug Library, refer to Chapter 9: Drug Library on page 266.

## Intermittent Mode: Mid-infusion Actions

The following actions can be performed during Intermittent infusions:

Updating Infusion Parameters ..... 180
Pausing Infusions ..... 224
Aborting Infusions ..... 225
Locking the Screen ..... 226
Activating Patient Lockout ..... 227

### Updating Infusion Parameters

Infusion parameters can be modified by using the **View/Edit** function key. In addition, the VTBI for the current phase (Intermittent Dose or KVO) can be modified directly from the Main Display.

**> To update parameters of the current phase from the Main Display:**

1. On the Main Display, select the **VTBI** relevant frame.
2. Using the keypad, enter the new VTBI → **OK**.
3. Review the parameter displayed on the Attention screen → **OK**.

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

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

1. From the toolbar, press **View/Edit**.
2. Select the box of the parameter to be modified.
3. Using the keypad, enter the new value of the parameter → **OK**.

> When changing Intermittent Dose or Dose Time, you will be prompted to enter the Dose interval.

4. To update additional parameters, repeat Steps 2-3.

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

   - **Clear Accum. VI:** Resets the total volume infused for all infusions associated with a patient to 0 mL.
   - **View system:** Displays various system and pump parameters. (Refer to View Menu on page 243.)

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

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

## Patient Controlled Analgesia (PCA) Mode

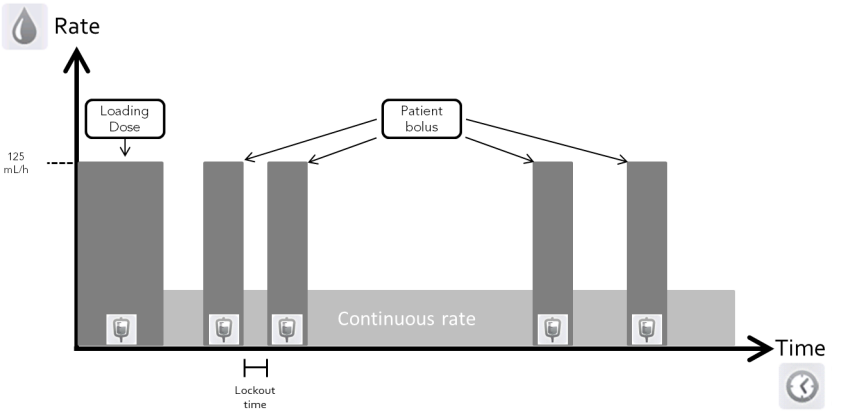
The following sections will be reviewed:


Infusion Parameters: PCA Mode ..... 183
Starting a PCA Infusion ..... 184
PCA Mode: Mid-infusion Actions ..... 190


The Patient Controlled Analgesia (PCA) mode allows the pump to deliver medication through the intravascular, subcutaneous, or perineural routes continuously, and or with boluses activated by the patient using the bolus handle or the on-screen key. Additional boluses can be administered by a clinician, using the appropriate authorization code. The administration route and infusion parameters are determined by the clinician, based on the needs of the patient.


For more information about the bolus handle, refer to PCA/PCEA/PIEB Bolus Handle on page 55.


Figure 5.6. PCA Flow Profile



## Infusion Parameters: PCA Mode

The following infusion parameters need to be set for a PCA infusion:

| Parameter | Description/Notes |
|---|---|
| Continuous Rate | The rate of the basal infusion. Continuous Rate values can range from 0.1 to 99.9 mL/h, or be equal to zero (Bolus Only infusion). |
| VTBI | The total amount of fluid to be infused. The remaining VTBI is displayed on the screen as the infusion progresses. VTBI values can range from 0.1 to 9999 mL. |
| Demand Bolus | The amount of fluid infused in a single bolus. Demand bolus values can range from 0.1 to 30 mL, or be equal to zero (Continuous Only infusion). |
| Bolus Lockout | The minimum time that must pass between the end of one bolus to the start of the next bolus. After a bolus delivery ends, the next bolus becomes available following the lockout time. |
| Dose Limit | The option to choose if patient boluses are limited by number or by volume. When choosing No Limits, the patient boluses are set to the maximum allowed volume, according to the other parameters defined for the infusion, including lockout time and demand bolus. |

| Parameter | Description/Notes |
|---|---|
| Boluses per 1h (or 4hrs)<br>OR<br>Total dose per 1h (or 4 hrs) | The maximum number of boluses OR the maximum dose that can be delivered during a 1 hour (or 4 hours) period. (Auser with High authorization codes can set the 1 hour or 4 hours parameters.)<br>The Total dose limit takes into account medication delivered via:<br>Continuous rate Yes<br>Demand Bolus Yes<br>Loading Dose Yes<br>Clinician bolus Yes<br>All doses, including boluses given by clinician, are taken into account.<br>When the Total dose limit is reached, the patient is locked out from activating additional boluses. |
| Loading Dose | An optional feature that begins the infusion with a clinician bolus. Loading dose values range from 0.1 to 30 mL.<br>To use this feature, it must be enabled. For more information, refer to PCA Options Menu on page 250. |

## Starting a PCA Infusion

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

> If relevant, you may skip programming by using the Repeat Last Infusion or PreSet programs procedures to begin the infusion. For more information, refer to Starting New Infusions: Shortcuts on page 220.

**> To begin a new PCA infusion without Drug Library:**

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

> For more information about changing delivery modes, refer to Selecting Delivery Mode on page 104.

2. From the Start Up screen, select **New Infusion**.

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

   Weight based units are available for both Dosing methods.
   Otherwise, continue to Step 11.
5. From the Concentration units screen, select the appropriate drug units.

---

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

---

6. According to pump configuration one of the following screens will appear:
   - **Concentration**: From concentration screen, using the keypad, enter the Concentration → **OK**. Then, continue to Step 8.
   - **Drug amount**: Using the keypad, enter the Drug Amount → **OK**. Then, using the keypad, enter the Diluent Volume → **OK**. Then, continue to Step 7.
7. From the Attention screen, confirm the concentration and press **OK**.
   If the selected drug unit is Million Units, continue to Step 10.
8. If the Patient Weight screen appears, specify whether the infusion is weight based:
   - **Yes**: Continue to Step 9.
   - **No**: Continue to Step 10.
9. From the Patient Weight screen, using the keypad, enter the patient weight → **OK**
10. From the Dose Rate units screen, select the appropriate dose rate units.
11. Using the keypad, enter the VTBI value → **OK**.
12. Using the keypad, enter the Continuous Rate value → **OK**.
    The Continuous Rate can be set to zero.
13. Using the keypad, enter the value for the Demand Bolus → **OK**.
14. Using the keypad, enter the value for the Bolus Lockout → **OK**.

15. From the Dose Limit Type screen, specify whether the boluses available for the patient should be limited:
    - **Yes**: Continue to Step 16.
    - **No**: Continue to Step 17.

> Choosing **No** on the Dose limit screen will set patient boluses to the maximum allowed, according to the other parameters defined for the infusion, including Lockout Time and Demand Bolus.

16. From the Dose Limit Type screen, select the type of limit to apply for the infusion, and proceed to the directed step:
    - **Number of Boluses**: Using the keypad, enter the maximum number of boluses that will be available for the patient within a one or four-hour period →**OK**. Continue to Step 17.
    - **Total Dose**: Using the keypad, enter the maximum amount of medication that may be delivered within a one or four-hour period →**OK**. Continue to Step 17.
17. If Add Loading Dose screen appears, specify whether to program a loading dose:
    - **Yes:** Using the keypad, enter the value for the Loading Dose → **OK**.
    - **No:** Proceed to Step 18.

    Otherwise, continue to Step 18.
18. Review the parameters displayed on the Confirm screen.

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

    Then, press **OK**.
19. To begin the infusion, make sure that the clamps on the administration set are open; then, press **Start**.

    The Running screen appears, and the infusion begins.

Throughout the infusion, the infusion phase (Loading Dose, Running, Bolus Delivery, or Clinician Bolus) is displayed on the Indicators Bar.
In addition, the following information appears on the screen:

- **Drug Name:** The name of the selected drug. Displayed on the indicators bar, when working with a Drug Library.
- **Drug Concentration:** Drug concentration as entered by the user (Final concentration or Drug Amount / Diluent Volume). Displayed when applicable.
- **Rate:** Current infusion rate. For all dose units other than mL/h, the calculated rate will be displayed in mL/h; both in the View system menu and in the Running screen.
- **VTBI:** Total volume left to be infused. As the infusion progresses, this value decreases.
- **VI / Total:** Total volume delivered in the current infusion (including KVO if applied during a delayed start period) / the total VTBI value programmed. As the infusion progresses, the VI increases, and the Total remains constant.
- **Lockout time:** Time remaining until the next bolus is available. After the lockout time elapses, this parameter changes to Bolus available (when a bolus is being given – loading dose, clinician bolus or patient bolus – this parameter does not appear).
- **Time left:** The maximum time remaining until the end of the entire infusion. If boluses are given, this time will be shortened.

To view all programmed parameters of the current infusion, including the rate in mL/h, from the Running screen, press **View/ Edit → View system → Infusion values**.
For more information, refer to Viewing System Parameters on page 244.

### > To begin a new PCA infusion with a Drug Library:

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

> For more information about changing delivery modes, refer to Selecting Delivery Mode on page 104.

2. From the **Start Up** screen, select **New Infusion**.
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**.
4. From the **Drug Name** screen:
   - Using the keypad, enter the drug name, then press **Find** and proceed to Step 5.

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

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

> 'Choose General' will bypass drug specific limits, the infusion will be programmed outside of the safe Drug Library environment.

   From the Attention screen, confirm Choosing General and press **OK**.
   Proceed to Step 4 on page 185 (To begin a new PCA infusion without Drug Library), and continue programming from there.
5. From the **Drug List** screen, select the row of the relevant drug.

> To display additional drugs press **Next**.

6. If a list of available drug profiles appears, select the appropriate drug profile and proceed according to the step directed to:
   - **No concentration**: proceed to Step 8 on page 185 (To begin a new PCA infusion without Drug Library), and continue programming from there.
   - **Diluent only** (e.g. 10 mL): proceed to Step 8 on page 185 (To begin a new PCA infusion without Drug Library), and continue programming from there.
   - **Custom/Partial concentration**: the Drug Amount and/or Diluent Volume are/is missing. The screen/s of the missing value/s will appear:
     - From the **Drug Amount** screen, using the keypad, enter the Drug Amount → **OK**.
     - From the **Diluent Volume** screen, using the keypad, enter the Diluent Volume → **OK**.

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

     Proceed to Step 8 on page 185 (To begin a new PCA infusion without Drug Library), and continue programming from there.
   - **Full concentration**:

     Proceed to Step 8 on page 185 (To begin a new PCA infusion without Drug Library), and continue programming from there.

   If a list of available drug profiles does not appear, continue to Step 8 on page 185 (To begin a new PCA infusion without Drug Library), and continue programming from there.

For more information about the Drug Library, refer to Chapter 9: Drug Library on page 266.

## PCA Mode: Mid-infusion Actions

The following actions can be performed during PCA infusions:


Updating Infusion Parameters ..... 190
Administering a Clinician Bolus ..... 192
Pausing Infusions ..... 224
Aborting Infusions ..... 225
Locking the Screen ..... 226
Activating Patient Lockout ..... 227
Viewing Delivery History ..... 248


### Updating Infusion Parameters

In PCA mode, the infusion must be paused before parameters can be updated. After the infusion is paused, infusion parameters can be modified by using the **View/Edit** function key. In addition, the Continuous Rate and VTBI for the current infusion phase can be updated directly from the Main Display. (During a bolus delivery, no parameter can be changed.)

**> To update parameters for the current phase (Basal/Bolus) from the Main Display:**

1. Pause the infusion (Pausing Infusions on page 224).
2. On the Main Display, select the relevant frame (**Continuous Rate** or **VTBI)**.
3. Using the keypad, enter the new Continuous Rate or VTBI → **OK**.
4. To confirm and save changes, press **OK**.
   To return to the Paused screen without saving changes, press **Back.** From the Continuous Rate of VTBI screen, press **Back**. Then, from the Attention screen, press **OK**.

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

1. Pause the infusion (Pausing Infusions on page 224).
2. From the toolbar, press **View/Edit**.
3. Select the box of the parameter to be modified.

4. Using the keypad, enter the new value of the parameter → **OK**.

> When modifying demand bolus limitations (volume or lockout time), the pump will prompt the user to confirm or adjust the other bolus limitations.

5. To update additional parameters, repeat Steps 3-4.

   In addition to parameter changes, the following functions are also available:
   - **Clear Accum. VI:** Resets the total volume infused for all infusions associated with a patient to 0 mL.
   - **View system:** Displays various system and pump parameters. (Refer to View Menu on page 243.)
   - **Delivery history:** Displays a summary of medication delivery events. For more information, refer to Viewing Delivery History on page 248.

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

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

## Administering a Clinician Bolus

During PCEA or PIEB infusions, 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.

**> To administer a clinician bolus:**

1. From the toolbar of the Running screen, press **View/Edit**.
2. Select **Clinician bolus**.
3. Using the keypad, enter the appropriate password → **OK**.
4. On the Clinician bolus screen, using the keypad, enter the bolus amount → **OK**.
5. To start the bolus, from the Attention screen, press **OK**.

   The Clinician bolus screen appears, and the bolus begins.

> The default clinician bolus infusion rate is 125 mL/h. This default can be modified using a Technician authorization code.

## Epidural Mode

This mode enables the pump to deliver epidural infusions. Epidural administration is limited to short term infusions (up to 96 hours), using indwelling catheters specifically identified for epidural drug delivery.

In Epidural delivery mode, the pump can operate in either of the following sub-modes:

- **PCEA (Patient Controlled Epidural Analgesia):** Delivers epidural boluses, either alone or in addition to a basal preset rate. Alternatively, only a basal infusion (without boluses) can be programmed.
- **Intermittent Epidural:** Delivers epidural infusions at intermittent programmed intervals. The Epidural Intermittent mode also enables the addition of PCEA, in order to allow patient boluses throughout the infusion (PIEB).

The features of the Epidural mode are designed to accommodate the special requirements of an epidural infusion, such as lower VTBI, lower infusion rate, and higher backpressure. In Epidural intermittent mode and in PCEA mode, bolus rate can be configured to 125 mL/h, 200 mL/h, 300 mL/h, 400 mL/h or 500 mL/h before starting infusion (for more information, refer to Epidural Mode Options Menu on page 251).

### Epidural Mode: Safety Warnings

When working with epidural infusions, adhere to the following safety procedures, guidelines and reminders:

- Before programming, always verify that the pump is in Epidural delivery mode.
- To prevent infusion of drugs not intended/labeled for epidural use, do not use administration sets with injection ports during epidural delivery.
- Use only yellow-marked administration sets for epidural infusions.
- Epidural administration of drugs other than those intended/labeled for epidural use could result in serious injury to the patient.
- Do not infuse non-epidural drugs in Epidural Delivery mode.
- Epidural drugs must be infused in Epidural Delivery mode.

## Patient Controlled Epidural Analgesia (PCEA) Mode

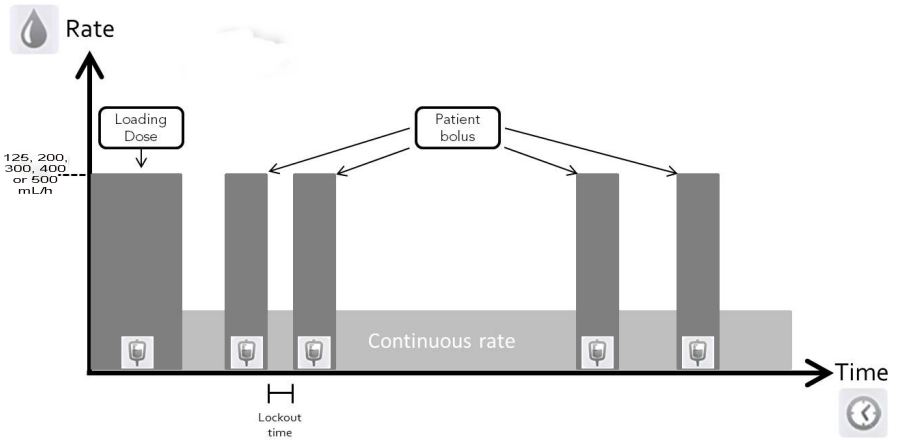
The following sections will be reviewed:


Infusion Parameters: PCEA Mode ..... 195
Starting a PCEA Infusion ..... 197
PCEA Mode: Mid-infusion Actions ..... 202


The PCEA mode allows the pump to deliver medication at a continuous rate (optional) and limited boluses activated by the patient (via screen key or bolus handle). Additional boluses can be provided by a clinician, using the appropriate authorization code.

> For more information about the bolus handle, refer to PCA/PCEA/PIEB Bolus Handle on page 55.

Figure 5.7. PCEA Flow Profile



## Infusion Parameters: PCEA Mode

The following infusion parameters need to be set for a PCEA infusion:

| Parameter | Description/Notes |
|---|---|
| Continuous Rate | The speed at which the fluid is infused. Continuous Rate values can range from 0.1 to 25 mL/h, or be equal to zero (Bolus Only infusion). |
| VTBI | The total amount of fluid to be infused. The remaining VTBI is displayed on the screen as the infusion progresses. VTBI values can range from 0.1 to 9999 mL. |
| Demand Bolus | The amount of fluid infused in a single bolus. Demand bolus values can range from 0.1 to 30 mL, or be equal to zero (Continuous Only infusion). |
| Bolus Lockout | The minimum time that must pass between the end of one bolus to the start of the next patient bolus. After a bolus delivery ends, the next patient bolus becomes available following the lockout time. |
| Dose Limit | The option to choose if patient boluses are limited by number or volume. When choosing No Limits, the patient boluses are set to the maximum allowed volume, according to the other parameters defined for the infusion, including Lockout Time and Demand Bolus. |

| Parameter | Description/Notes |
|---|---|
| Boluses per 1 h (or 4 hrs)<br>OR<br>Total dose per 1 h (or 4 hrs) | The maximum number of boluses OR the maximum dose that can be delivered during a 1 hour (or 4 hours) period. (Auser with High authorization codes can set the 1 hour or 4 hours parameters.)<br>The Total dose limit takes into account medication delivered via:<br>Continuous rate Yes<br>Demand Bolus Yes<br>Boluses given by a clinician, are not taken into account for the Total dose limit:<br>Loading Dose No<br>Clinician bolus No<br>When the Total dose limit is reached, the patient is locked out from activating additional boluses. |
| Loading Dose | An optional feature that begins the infusion with a clinician bolus. Loading dose values range from 0.1 to 30 mL.<br>To use this feature, it must be enabled. For more information, refer to Epidural Mode Options Menu on page 251. |

The bolus rate applies to all boluses delivered during the infusion, and is configured before programming starts. It can be set to 125 mL/h, 200 mL/h, 300 mL/h, 400 mL/h or 500 mL/h (for more information, refer to Epidural Mode Options Menu on page 251).

## Starting a PCEA Infusion

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

> If relevant, you may skip programming by using the Repeat Last Infusion or PreSet programs procedures to begin the infusion. For more information, refer to Starting New Infusions: Shortcuts on page 220.

**> To begin a new PCEA infusion without Drug Library:**

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

   > For more information about changing delivery modes, refer to Selecting Delivery Mode on page 104.

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

   Weight based units are available for both Dosing methods.
   Otherwise, continue to Step 10.
4. From the **Concentration units** screen, select the appropriate drug units.

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

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

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

   If the selected drug unit is Million Units, continue to Step 9.

7. If the **Patient Weight** screen appears, specify whether the infusion is weight based:
   - **Yes**: Continue to Step 8.
   - **No**: Continue to Step 9.

8. If the **Patient Weight** screen appears, using the keypad, enter the patient weight → **OK**.

9. From the **Dose Rate units** screen, select the appropriate dose rate units.

10. Using the keypad, enter the **VTBI** value → **OK**.

11. Using the keypad, enter the **Continuous Rate** value → **OK**.

    The Continuous Rate can be set to zero.

12. Using the keypad, enter the value for the Demand Bolus → **OK**.

13. Using the keypad, enter the value for the Bolus Lockout → **OK**.

14. From the Dose Limit Type screen, specify whether the infusion is according to dose limits:
    - **Yes**: Continue to Step 15.
    - **No**: Continue to Step 16.

> Choosing **No** on the Dose limit screen will set patient boluses to the maximum allowed, according to the other parameters defined for the infusion, including Lockout Time and Demand Bolus.

15. From the Dose Limit Type screen, select the appropriate Dose Limit type, and proceed to the directed step:
    - **Number of Boluses**: Using the keypad, enter the maximum number of boluses that will be available for the patient within a one or four-hour period →**OK**. Continue to Step 16.

- **Total Dose**: Using the keypad, enter the maximum amount of medication that may be delivered within a one or four-hour period →**OK**. Continue to Step 16.

16. If **Add Loading Dose** screen appears, specify whether to program a loading dose:
    - **Yes:** Using the keypad, enter the value for the Loading Dose → **OK**.
    - **No:** Proceed to Step 17.

    Otherwise, continue to Step 17.
17. Review the parameters displayed on the Confirm screen.

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

    Then, press **OK**.
18. To begin the infusion, make sure that the clamps on the administration set are open, then, press **Start**.

    The Running screen appears, and the infusion begins.

Throughout the infusion, the current infusion phase (Loading Dose, Running, Bolus Delivery or Clinician Bolus) is displayed on the Indicators Bar.
In addition, the following information appears on the screen:

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

- **Lockout time:** Time remaining until the next bolus is available. After the lockout time elapses, this parameter changes to **Bolus available**.

> When a bolus is being given (loading dose, clinician bolus or patient bolus), this parameter does not appear.

- **Time left:** The maximum time remaining until the end of the entire infusion. If boluses are given, this time will be shortened.

> To view all programmed parameters of the current infusion, including the rate in mL/h, from the Running screen, press **View/ Edit** → **View system** → **Infusion values**.
> For more information, refer to Viewing System Parameters on page 244.

### > To begin a new PCEA infusion with a Drug Library:

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

> For more information about changing delivery modes, refer to Selecting Delivery Mode on page 104.

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

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

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

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

From the Attention screen, confirm Choosing General and press **OK**.
Proceed to Step 3 on page 197 (To begin a new PCEA infusion without Drug Library), and continue programming from there.

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

| | |
|---|---|
| ℹ | To display additional drugs press **Next**. |

5. If a list of available drug profiles appears, select the appropriate drug profile and proceed according to the step directed to:
   - **No concentration**: proceed to Step 7 on page 198 (To begin a new PCEA infusion without Drug Library), and continue programming from there.
   - **Diluent only** (e.g. 10 mL): proceed to Step 7 on page 198 (To begin a new PCEA infusion without Drug Library), and continue programming from there.
   - **Custom/Partial concentration**: the Drug Amount and/or Diluent Volume are/is missing. The screen/s of the missing value/s will appear:
     - From the **Drug Amount** screen, using the keypad, enter the Drug Amount → **OK**.
     - From the **Diluent Volume** screen, using the keypad, enter the Diluent Volume → **OK**.

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

     Proceed to Step 7 on page 198 (To begin a new PCEA infusion without Drug Library), and continue programming from there
   - **Full concentration**:

     Proceed to Step 7 on page 198 (To begin a new PCEA infusion without Drug Library), and continue programming from there.

If a list of available drug profiles does not appear, continue to Step 7 on page 198 (To begin a new PCEA infusion without Drug Library), and continue programming from there.

For more information about the Drug Library, refer to Chapter 9: Drug Library on page 266.

## PCEA Mode: Mid-infusion Actions

The following actions can be performed during PCEA infusions:


Updating Infusion Parameters ..... 202
Administering a Clinician Bolus ..... 219
Pausing Infusions ..... 224
Aborting Infusions ..... 225
Locking the Screen ..... 226
Activating Patient Lockout ..... 227
Viewing Delivery History ..... 248


### Updating Infusion Parameters

In PCEA mode, the infusion must be paused before any parameter can be updated. Once the infusion is paused, infusion parameters can be modified by using the **View/Edit** function key. In addition, the continuous rate and VTBI for the current infusion phase can be modified directly from the Main Display. (During a bolus delivery, no parameters can be changed.)

**> To update parameters for the current phase (Basal/Bolus) from the Main Display:**

1. Pause the infusion (Pausing Infusions on page 224).
2. On the Main Display, select the relevant frame (**Continuous Rate** or **VTBI)**.
3. Using the keypad, enter the new Continuous Rate or VTBI → **OK**.
4. To confirm and save changes, press **OK**.
   To return to the Paused screen without saving changes, press **Back**. From the Continuous Rate of VTBI screen, press **Back**. Then, from the Attention screen, press **OK**.

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

1. Pause the infusion (Pausing Infusions on page 224).
2. From the toolbar, press **View/Edit**.
3. Select the box of the parameter to be modified.
4. Using the keypad, enter the new value of the parameter → **OK**.

> When modifying demand bolus limitations (volume or lockout time), the pump will prompt you to confirm or adjust the other bolus limitations.

5. To update additional parameters, repeat Steps 3-4.

   In addition to parameter changes, the following functions are also available:
   - **Clear Accum. VI:** Resets the total volume infused for all infusions associated with a patient to 0 mL.
   - **View system:** Displays various system and pump parameters. (Refer to View Menu on page 243.)
   - **Delivery history:** Displays a summary of medication delivery events. For more information, refer to Viewing Delivery History on page 248.
6. To confirm and save changes, press **OK**.

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

## Administering a Clinician Bolus

A bolus of any amount (within the predefined safe range) can be delivered by clinicians who have 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.

**> To administer a clinician bolus:**

1. From the toolbar of the Running screen, press **View/Edit**.
2. Select **Clinician bolus**.
3. Using the keypad, enter the appropriate password → **OK**.
4. Using the keypad, enter the bolus amount → **OK**.
5. To start the bolus, from the Attention screen, press **OK**.

   The Clinician bolus screen appears, and the bolus begins.

| | |
|---|---|
| | The rate of all boluses during PCEA is defined prior to programming the infusion. It can be set to 125 mL/h, 200 mL/h, 300 mL/h, 400 mL/h or 500 mL/h (for more information, refer to Epidural Mode Options Menu on page 251) |

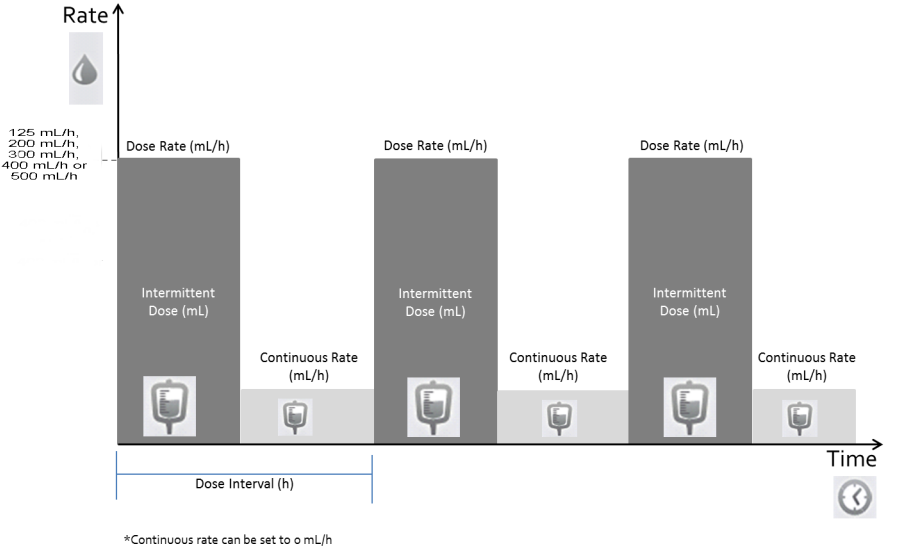
## Epidural Intermittent Mode

The following sections will be reviewed:


Infusion Parameters: Epidural Intermittent Mode ..... 207
Starting an Epidural Intermittent Infusion ..... 209
Epidural Intermittent Mode: Mid-infusion Actions ..... 217


This mode enables you to program epidural doses (boluses) that are given at a rate of 125 mL/h, 200 mL/h, 300 mL/h, 400 mL/h or 500 mL/h, and are repeated at regular intervals or cycles. The dose interval is the frequency at which the intermittent dose is delivered. A continuous rate can be programmed to run between intermittent doses.

Figure 5.8. Epidural Intermittent Flow Profile

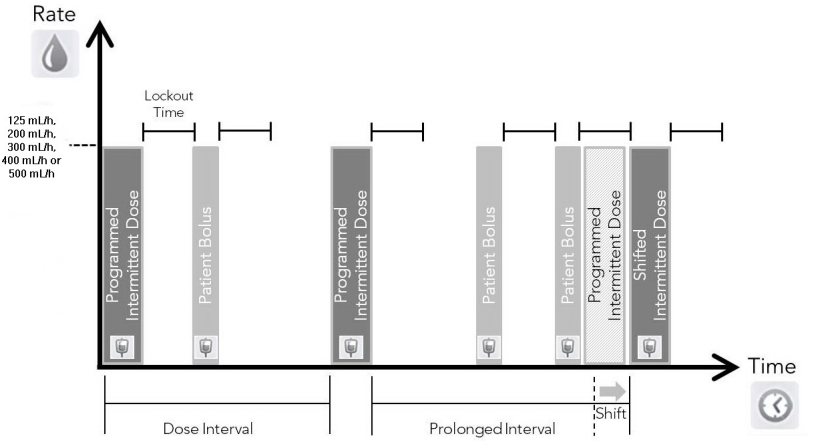


The Sapphire pump can also be configured to support PIEB (Programmed Intermittent Epidural Boluses). When enabled, the option to add PCEA is available on the Start screen. Note that in any case, an Epidural Intermittent infusion will start with an intermittent dose.

The patient will be able to activate a Patient Bolus between intermittent doses, except during the Lockout Time period immediately after an intermittent dose, or any other bolus. If the time remaining from the Patient Bolus to the next scheduled intermittent dose is shorter than the Lockout Time, the next intermittent dose will be delayed to accommodate the Lockout Time.

Unlike the Patient Bolus, the clinician will be able to administer a Clinician Bolus within the Lockout Time immediately after the intermittent dose.

Figure 5.9. Epidural Intermittent with PCEA Flow Profile




To use the PIEB option, the option must be enabled (requires high authorization code). Refer to Epidural Mode Options Menu on page 251.

For more information about the bolus handle, refer to PCA/PCEA/PIEB Bolus Handle on page 55.

When the PIEB option is enabled, you can set PCEA infusion parameters immediately after programming the Epidural Intermittent infusion (Starting a PIEB Infusion on page 214).

## Infusion Parameters: Epidural Intermittent Mode

The following infusion parameters need to be set for an Epidural Intermittent infusion:

| Parameter | Description/Notes |
|---|---|
| VTBI | The total amount of fluid to be infused. The remaining VTBI is displayed on the screen as the infusion progresses. VTBI values can range from 0.1 to 9999 mL. |
| Intermittent Dose | The amount of each intermittent dose. Values can range from 0.1 to 30 mL. |
| Dose Interval | The frequency of intermittent dose delivery (Intermittent Dose + Continuous Rate). Intermittent doses can be given as frequently as 5 minutes apart. Therefore, the minimum programmable Dose Interval is the Intermittent Dose time plus 5 minutes. This rule applies even when the continuous rate is set to 0. |
| Continuous Rate | The rate of fluids delivered between doses, to prevent clotting in the epidural catheter. The Continuous Rate can be set from 0 to 25 mL/h (the range varies according to the Intermittent Dose volume and the Dose Interval entered). |
| Demand Bolus* | The amount of fluid infused in a single bolus. Demand Bolus values can range from 0.1 to 30 mL. |
| Bolus Lockout* | The minimum time that must pass between the end of one Demand Bolus to the start of the next Demand Bolus. After a bolus delivery ends, the next Demand Bolus becomes available following the lockout time. |

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

* Applicable only when programming Epidural Intermittent with PCEA.

The bolus rate applies to all boluses delivered during the infusion. The bolus rate can be configured to 125mL/h, 200mL/h, 300 mL/h, 400 mL/h or 500 mL/h before programming the infusion (for more information, refer to Epidural Mode Options Menu on page 251).

## Starting an Epidural Intermittent Infusion

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

> If relevant, you may skip programming by using the Repeat Last Infusion or PreSet programs procedures to begin the infusion. For more information, refer to Starting New Infusions: Shortcuts on page 220.

**> To begin a new Epidural Intermittent infusion without Drug Library:**

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

> For more information about changing delivery modes, refer to Selecting Delivery Mode on page 104.

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

   Weight based units are available for both Dosing methods.
   Otherwise, continue to Step 10.
4. From the **Concentration units** screen, select the appropriate drug units.

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

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

   If the selected drug unit is Million Units, continue to Step 9.

7. If the Patient Weight screen appears, specify whether the infusion is weight based:
   - **Yes**: Continue to Step 8.
   - **No**: Continue to Step 9.
8. From the Patient Weight screen, using the keypad, enter the patient weight → **OK**.
9. From the Dose Rate units screen, select the appropriate dose rate units.
10. Using the keypad, enter the VTBI value → **OK**.
11. Using the keypad, enter the Intermittent Dose → **OK**.
12. Using the keypad, enter the Dose Interval → **OK**.
13. Using the keypad, enter the Continuous rate → **OK**.

    The Continuous rate may be set to zero.
14. Review the parameters displayed on the Confirm screen.

| | |
|---|---|
| ⚠ | Verify that the parameters reflect the correct treatment according to the prescription. |

Then, press **OK**.

| | |
|---|---|
| ℹ | If the pump is configured to support PIEB option, PCEA infusion parameters can be programmed at this point. For detailed instructions, go to To begin a new PIEB Infusion without Drug Library (Step 3 on page 214). |

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

    The Intermittent Dose screen is displayed, and the infusion begins with the first dose.

Throughout the infusion, the infusion phase (Intermittent Dose or Continuous Rate) is displayed on the Indicators Bar. In addition, the following information appears on the screen:

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

When the infusion is paused (Intermittent Dose or Continuous Rate), the time to next Intermittent Dose is paused and not displayed.

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

### > To begin a new Epidural Intermittent infusion with a Drug Library:

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

> For more information about changing delivery modes, refer to Selecting Delivery Mode on page 104.

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

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

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

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

   From the Attention screen, confirm Choosing General and press **OK**.
   Proceed to Step 3 on page 209 (To begin a new Epidural Intermittent infusion without Drug Library), and continue programming from there.
4. From the **Drug List** screen, select the row of the relevant drug.

> To display additional drugs press **Next**.

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

- **No concentration**: proceed to Step 7 on page 210 (To begin a new Epidural Intermittent infusion without Drug Library), and continue programming from there.
- **Diluent only** (e.g. 10 mL): proceed to Step 7 on page 210 (To begin a new Epidural Intermittent infusion without Drug Library), and continue programming from there.
- **Custom/Partial concentration**: the Drug Amount and/or Diluent Volume are/is missing. The screen/s of the missing value/s will appear:
  - From the **Drug Amount** screen, using the keypad, enter the Drug Amount → **OK**.
  - From the **Diluent Volume** screen, using the keypad, enter the Diluent Volume → **OK**.

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

  Proceed to Step 7 on page 210 (To begin a new Epidural Intermittent infusion without Drug Library), and continue programming from there.
- **Full concentration**:

  Proceed to Step 7 on page 210 (To begin a new Epidural Intermittent infusion without Drug Library), and continue programming from there.

If a list of available drug profiles does not appear, continue to Step 10 on page 210 (To begin a new Epidural Intermittent infusion without Drug Library), and continue programming from there.

For more information about the Drug Library, refer to Chapter 9: Drug Library on page 266.

## Starting a PIEB Infusion

The following procedure explains how to program an Epidural Intermittent with PCEA.

> If relevant, you may skip programming by using the Repeat Last Infusion or PreSet programs procedures to begin the infusion. For more information, refer to Starting New Infusions: Shortcuts on page 220.

**> To begin a new PIEB Infusion without Drug Library:**

1. Verify that the pump is in Epidural Intermittent mode, and then program the Epidural Intermittent infusion (Step 2 on page 209 through Step 13 on page 210 in To begin a new Epidural Intermittent infusion without Drug Library).
2. Review the parameters displayed on the Confirm screen.

   Then, press **OK**.
3. From the Start screen, select **Add PCEA**.
4. Using the keypad, enter the value for the Demand Bolus → **OK**.
5. Using the keypad, enter the value for the Bolus Lockout → **OK**.
6. From the Dose Limit Type screen, specify whether or not the patient boluses should be limited:
   - **Yes**: Continue to Step 7.
   - **No**: Continue to Step 8.

> Choosing **No** on the Dose limit screen will set patient boluses to the maximum allowed, according to the other parameters defined for the infusion, including Lockout Time and Demand Bolus.

7. From the Dose Limit Type screen, select the appropriate Dose Limit type, and proceed to the directed step:
   - **Number of Boluses**: Using the keypad, enter the maximum number of boluses that will be available for the patient within a one or four-hour period → **OK**. Continue to Step 8.

- **Total Dose**: Using the keypad, enter the maximum amount of medication that may be delivered within a one or four-hour period → **OK**. Continue to Step 8.

8. Review the parameters displayed on the Confirm screen.

   Then, press **OK**.

| | |
|---|---|
| ⚠ | Verify that the parameters reflect the correct treatment according to the prescription. |

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

   The Running screen appears, and the infusion begins.

Throughout the infusion, the infusion phase (Intermittent dose, continuous rate or bolus) is displayed on the Indicators Bar. In addition, the following information appears on the Main Display:

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

- **Time to Dose**: Time remaining before the next dose starts (until the end of the interval time: Dose Time left + Continuous Rate time).

| | |
|---|---|
| | When the infusion is paused (Intermittent Dose or Continuous Rate), the time to the next Intermittent Dose is paused and not displayed. |

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

### > To begin a new PIEB Infusion with a Drug Library:

1. Verify that the pump is in Epidural Intermittent mode, and then program the Epidural Intermittent infusion (Step 2 on page 212 through Step 5 on page 212 in To begin a new Epidural Intermittent infusion with a Drug Library).
2. Review the parameters displayed on the Confirm screen.

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

   Then, press **OK**.
3. From the Start screen, select **Add PCEA**.

Proceed to Step 4 on page 214 (To begin a new PIEB Infusion without Drug Library), and continue programming from there.

For more information about the Drug Library, refer to Chapter 9: Drug Library on page 266.

## Epidural Intermittent Mode: Mid-infusion Actions

The following actions can be performed during Epidural Intermittent infusions:


Updating Infusion Parameters ..... 217
Administering a Clinician Bolus ..... 219
Pausing Infusions ..... 224
Aborting Infusions ..... 225
Locking the Screen ..... 226
Activating Patient Lockout ..... 227
Viewing Delivery History ..... 248


### Updating Infusion Parameters

In the Epidural Intermittent mode, the infusion must be paused before any parameter can be updated. Once the infusion is paused, any infusion parameter can be modified, by using the **View/Edit** function key. In addition, the rate (Continuous Rate or Dose Rate) and VTBI for the Intermittent Dose phase can be modified directly from the Main Display (during a bolus delivery, no parameter can be changed).

**> To update parameters for the current phase (intermittent dose/Continuous rate) the Main Display:**

1. Pause the infusion (Pausing Infusions on page 224).
2. On the Main Display, select the relevant frame (Dose rate, Continuous rate or VTBI).
3. Using the keypad, enter the new Dose rate, Continuous rate or VTBI → **OK**.
4. To confirm and save changes, press **OK**.

   To return to the Paused screen without saving changes, press **Back**. From the Dose rate, Continuous rate or VTBI screen, press **Back**. Then, from the Attention screen, press **OK**.

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

1. Pause the infusion (Pausing Infusions on page 224).
2. From the toolbar, press **View/Edit**.

3. Select the box of the parameter to be modified.
4. Using the keypad, enter the new value of the parameter → **OK**.

| | |
|---|---|
| i | When changing the Intermittent Dose or Dose Rate, you will be prompted to confirm or adjust the dose interval. |

| | |
|---|---|
| i | When modifying demand bolus limitations (volume or lockout) the pump will prompt you to confirm or adjust the other bolus limitations. |

5. To update additional parameters, repeat Step 3 through Step 4.

   In addition to parameter changes, the following functions are also available:
   - **Clear Accum. VI:** Resets the total volume infused for all infusions associated with a patient to 0 mL.
   - **View system:** Displays various system and pump parameters. (Refer to View Menu on page 243.)
   - **Delivery History:** Displays a summary of medication delivery events. For more information, refer to Viewing Delivery History on page 248. Applies only when Epidural Intermittent with PCEA infusion was programmed.
6. To confirm and save changes, press **OK**.

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

## Administering a Clinician Bolus

A bolus of any amount (within the predefined range) can be delivered by clinicians who have 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.

**> To administer a clinician bolus:**

1. From the toolbar of the Running screen, press **View/Edit**.
2. Select **Clinician bolus**.
3. Using the keypad, enter the appropriate password → **OK**.
4. Using the keypad, enter the bolus amount → **OK**.
5. To start the bolus, from the Attention screen, press **OK**.

   The Clinician bolus screen appears, and the bolus begins.

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, 200 mL/h, 300 mL/h, 400 mL/h or 500 mL/h (for more information, refer to Epidural Mode Options Menu on page 251).

# Chapter 6: Basic Infusion Operations

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

Starting New Infusions: Shortcuts ..... 220
Resuming Infusions After Pump Shutdown ..... 223
Mid-infusion Actions ..... 224

## Starting New Infusions: Shortcuts

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

Repeating Last Infusion ..... 220
Using a PreSet Program ..... 222

### Repeating Last Infusion

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

When using the 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 on page 263.

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

| | |
|---|---|
| | Repeat Last Infusion is not available (grayed out) when the pump settings differ from those used for the previous infusion. For example: CCA, and PCA/PCEA infusion type. |

| | |
|---|---|
| | Repeat Last Infusion is not available (grayed out) when the pump time and date settings are updated by Sapphire Connect. These include the following delivery modes: PCA, PCEA, Intermittent, and Epidural intermittent. |

| | |
|---|---|
| | Repeat Last Infusion does not include a loading dose, even if one was programmed for the original infusion. If required, a clinician bolus can be given when the infusion starts. For more information refer to Administering a Clinician Bolus on page 192. |

### > To repeat the last infusion:

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

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

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

   The Running screen appears, and the infusion begins.

## Using a PreSet Program

The PreSet Programs function allows you to select an infusion with predefined parameters. Each delivery mode can support up to 25 PreSet programs. PreSet programs are available only in the delivery mode in which they were saved.

> For the PreSet Programs option to appear on the Start Up screen, the PreSet programs need to be enabled on the pump. For more information, refer to Configuring General Settings on page 236.

**> To start an infusion using the PreSet Programs function:**

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

> If no PreSet program was saved in the current delivery mode, a blank screen appears.
> For more information about adding or modifying a program, refer to Creating and Editing PreSet Programs on page 256.

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**.
3. Select the row of the desired program.

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

4. Review the parameters that are displayed.

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

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

   The Running screen appears, and the infusion begins.

## Resuming Infusions After Pump Shutdown

When the pump is turned Off during an active infusion (running or paused), the option to resume the previous infusion will be displayed after the pump is turned On. This option is applicable for all delivery modes.

**> To resume the infusion:**

1. In the Attention screen, press **OK**.
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**.

   The Paused infusion screen appears,
3. Press **Request continue** to resume the infusion.
4. On the Attention screen, press **OK** to confirm.
5. The Running screen appears.

| | |
|---|---|
| i | The option to resume will not be available if the pump was shut down due to an error alarm, or if the user quit the infusion. |

| | |
|---|---|
| i | When a Drug Library is loaded, Resume Infusion after pump shutdown will keep local configurations changes until the end of the treatment. |

**> To abort the previous infusion:**

- On the Attention screen, press **Exit**. The Start Up screen appears.

| | |
|---|---|
| i | When a Drug Library is loaded on the pump, the Clinical Care Area screen appears. The user can either accept or change the current CCA. For more information, refer to Clinical Care Area (CCA) on page 267. |

## Mid-infusion Actions

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

Pausing Infusions ..... 224
Aborting Infusions ..... 225
Locking the Screen ..... 226
Activating Patient Lockout ..... 227

### Pausing Infusions

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

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

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

**> To pause an infusion using the Stop hard key:**

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

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

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

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

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

### > To resume a paused infusion:

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

## Aborting Infusions

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

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

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

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

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

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

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

> Resuming infusion after quitting will not be possible.

> When a Drug Library is loaded on the pump, the Clinical Care Area screen appears. The user can either accept or change the current CCA. For more information, refer to Clinical Care Area (CCA) on page 267.

**> To turn Off the pump:**

1. At the bottom of the pump, press the **ON/OFF** hard key.
2. From the toolbar, press **Off**.

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

> In case of emergency, when Patient Lockout or Lock Screen is activated (Activating Patient Lockout on page 227), the user must press and hold **ON/OFF** for 5 seconds to turn the pump Off, or unlock the pump before turning it Off.

## Locking the Screen

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

**> To lock the screen:**

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

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

**> To unlock the screen:**

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

## Activating Patient Lockout

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

> During Patient Lockout or screen lock, the **Request Pause** function key is not available. Pause the infusion by pressing the **Stop** hard key. (Refer to To pause an infusion using the Stop hard key on page 224.)
> To turn the pump Off, press and hold the **ON/OFF** hard key for 5 consecutive seconds.

**> To activate Patient Lockout:**

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

**> To release Patient Lockout:**

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

# Ending Infusion

When the infusion is complete (entire programmed VTBI delivered), the pump automatically activates the KVO (the default or the infusion rate, the lower of the two) and displays the infusion summary:

- VI - volume infused (VI for the current completed infusion. If the Accumulated VI has been cleared during this infusion, VI presents the volume infused from that time on).

- Rate – the rate at which the infusion was delivered
- Total time – the total time of the infusion

> The default KVO can be set by an authorized technician.

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

**> To proceed with the KVO and view the KVO screen:**

- From the toolbar of the Message screen, press **OK**.

**> To discontinue the KVO:**

1. From the toolbar of the Message screen, press **OK**.
2. From the toolbar of the KVO screen, press **Quit**.

> When a Drug Library is loaded and CCA was changed during the previous running infusion, an Attention screen appears, asking to confirm the new CCA. For more information, refer to Clinical Care Area (CCA) on page 267.

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# Chapter 7: Options Menu: Configuring, Viewing and Testing

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

Main Options: Overview ..... 230
Setting Delivery Mode ..... 231
Managing Configuration Settings ..... 232
Using Special Mode Options ..... 250

## Main Options: Overview

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

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

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

## Setting Delivery Mode

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

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

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

**> To change the delivery mode:**

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

> To access the PCEA or Intermittent Epidural delivery modes, select **Epidural**. Then select the relevant Epidural delivery mode.

The Start Up screen of the selected mode appears.

## Managing Configuration Settings

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


Managing Alarm Settings ..... 232
Configuring Audio Settings ..... 235
Configuring General Settings ..... 236
Defining Regional Parameters ..... 240
Testing System Function ..... 242
View Menu ..... 243


When a drug library is loaded to the pump, local configurations made on the pump remain valid until the user selects a CCA or turns the pump Off. For more information refer to Chapter 9: Drug Library on page 266.

### Managing Alarm Settings

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

**> To access the Alarms menu:**

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

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

| Option | Descriptions/Notes | To Modify Parameter (from the Alarms screen) |
|---|---|---|
| Occlusion pressure | The minimum downstream pressure that triggers an Occlusion alarm. Acceptable ranges are 1.5 to 17.4 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. | Select **Occlusion pressure**. Then, using the keypad, enter the desired value → **OK**. |
| Pump unattended | The number of consecutive minutes of no interaction with the pump after which a Pump Unattended alarm is triggered. Options are **2**, **5** or **10** minutes.<br>**Note:** A Pump Unattended alarm is not triggered when the pump is in Delayed start or Standby. | Select **Pump unattended**. Then, select **2 min, 5 min** or **10 min**. |
| Infusion near end | The number of minutes before completion of an infusion at which an Infusion Near End alarm is generated. | Select **Infusion near end**. Then, select **1 min**, **3 min**, **5 min**, **10 min** or **Off**. |
| Alarm volume | Sets the speaker volume for the auditory alarm signal. Options are **Maximum** or **Minimum**.<br><br>**Maximum:**<br>Errors and alarms sound level is 68 dB, Messages sound level is 59 dB.<br>**Minimum:**<br>Errors and alarms sound level is 65 dB, Messages sound level is 45 dB.For more information about messages and alarms, refer to Chapter 10: Alarms and Troubleshooting on page 276. | Select **Alarm volume**. Then, select **Maximum** or **Minimum**. |

An Occlusion Auto-restart option exists and is available for configuration by authorized technicians only. This option allows the pump to restart the infusion automatically provided the occlusion was cleared.
If the occlusion is not cleared within 40 seconds, or the user chooses to exit the process, the downstream occlusion alarm is activated (appears within a few seconds). An Occlusion Auto-restart can occur up to 5 times in one hour.

## Configuring Audio Settings

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

**> To access the Audio settings menu:**

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

| Option | Descriptions/Notes | To Modify Parameter (from the General settings screen) |
|---|---|---|
| Keys volume | Sets the speaker volume for the auditory signal generated when users select functions and press keys on the pump. | Select **Keys volume**. Then, select **Low**, **High** or **Off**. |
| Alarm volume | Sets the speaker volume for the auditory alarm signal. Options are **Maximum** or **Minimum**.<br><br>**Maximum:**<br>Errors and alarms sound level is 68 dB, Messages sound level is 59 dB.<br>**Minimum:**<br>Errors and alarms sound level is 65 dB, Messages sound level is 45 dB.<br>For more information about messages and alarms, refer to Chapter 10: Alarms and Troubleshooting on page 276. | Select **Alarm volume**. Then, select **Maximum** or **Minimum**. |
| 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, when the bolus handle is pressed and bolus is available. | Select **Bolus Handle**. Then, select **Always On** or **When Bolusing**. |

## Configuring General Settings

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

**> To access the General settings menu:**

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

| Option | Descriptions/Notes | To Modify Parameter (from the General settings screen) |
|---|---|---|
| Current CCA | Used to select the CCA to which the pump should be set. Appears only when Drug Library is loaded.<br>For more information, refer to Clinical Care Area (CCA) on page 267. | 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. For more information, refer to Start Up Configuration Menu on page 240. | Refer to Start Up Configuration Menu on page 240. |
| Authorization level | Sets the authorization lock level of the pump. For more information, refer to Managing Authorization Levels on page 252. | Select **Authorization level**. Then, enter a password and select **Low**, **Medium**, **High** or **Tech**. |
| Allow delayed start | Enables users to start an infusion at a later time. The user may either define a specific delay period, or set the pump to Standby. For more information, refer to Using the Set Delay Feature on page 259. | 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) |
|---|---|---|
| Allow PreProgram | Enables/disables starting infusions using predefined infusion parameters. When the option is enabled, the PreSet Programs frame appears on the Start screen.<br>For more information, refer to Creating and Editing PreSet Programs on page 256. | Select the **Allow PreProgram** row, to toggle the option between **On** and **Off**. |
| Set prime volume | The amount of fluid used to prime the administration set when automatic priming is performed. The acceptable range is 2 to 25 mL. | Select **Set prime volume**. Then, using the keypad, enter the desired value → **OK**. |
| Backlight | Allows the user to set the degree of screen brightness for a running infusion. Backlight can also be modified during a running infusion. The Off and Partial options of this feature save power and promote longer battery life. | Select **Backlight**. Then, select **On**, **Off** or **Partial**. |
| Prime Reminder | Enables a reminder for the user to prime the administration set before starting an infusion.<br>For more information, refer to Automatic Priming Using the Pump on page 120. | Select the **Prime Reminder** row, to toggle the option between **On** and **Off**. |
| Advanced Bolus | Allows users to program a bolus by entering rate, amount and time. When this option is disabled, the bolus is programmed by amount only, and the rate is the default bolus rate. The option is available only when Allow Bolus is enabled (by a Technician authorization code). Applicable only for the Continuous delivery mode.<br>For more information, refer to Administering a Bolus on page 143. | 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:<br>• Instructs to connect the bolus handle directly to the pump.<br>• 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.<br>When the option is enabled, Patient Lockout is activated automatically as the infusion begins (Activating Patient Lockout on page 227). | 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 phase (dose, continuous rate etc., excluding the TPN delivery mode.).<br>The screen saver appears 30 seconds after the infusion program has started, and the pump has not been touched.<br>The screen saver will not appear in the following cases: Delayed start, end of infusion KVO, or during a Bolus delivery.<br>The screen saver will disappear in the following cases:<br>• Alarm – screen will revert to the alarm screen<br>• Touching the screen – screen will revert to the Running screen<br>• Infusion is paused – screen will revert to the Paused screen. | Select the **Screen Saver** row, to toggle the option between **On** and **Off**. |

## Start Up Configuration Menu

**> To access the Start Up Configuration menu:**

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

| Option | Descriptions/Notes | To Modify Parameter (from the General settings screen) |
|---|---|---|
| Repeat last infusion | Allows the user to start infusions, using the same infusion parameters for the same patient. When the option is enabled, the Repeat Last Infusion button appears on the pump Start screen.<br>For more information, refer to Repeating Last Infusion on page 220. | Select the **Repeat Last Infusion** row, to toggle the option between **On** and **Off**. |
| PreProgram | Allows the user to start an infusion using predefined infusion parameters. When the option is enabled, the PreSet Programs button appears on the pump Start Up screen.<br>For more information, refer to Creating and Editing PreSet Programs on page 256. | Select the **PreProgram** row, to toggle the option between **On** and **Off**. |

## Defining Regional Parameters

The Regional menu controls date, time, language and US format settings. Only users with authorization levels of High or Technician have access to this menu.

> When the Sapphire pump is connected to Sapphire Connect, the date and time are set automatically by the Sapphire Connect server. Date and/or time updates made manually on the pump remain valid until the next Sapphire Connect time update.
> For more information on Sapphire Connect, refer to Sapphire Connect (Version 1.0) on page 56.

### > To access the Regional menu:

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

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

### > To set the date:

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

### > To set the time:

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

> When using Sapphire Connect, date and/or time updates made manually on the pump remain valid until the next Sapphire Connect time update.

### > To set the language:

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

> In some pumps, only the default language is listed.

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

**> To set the US format:**

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

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

## Testing System Function

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

**> To access the Test system menu:**

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

| Option | Descriptions/Notes |
|---|---|
| Speaker high | • **On:** High volume auditory signal sounds.<br>• **Off:** No auditory signal. |
| Speaker low | • **On:** Low volume auditory signal sounds.<br>• **Off:** No auditory signal. |
| Alarm LED | • **On:** The red (Alarm) LED is lit.<br>• **Off:** The red (Alarm) LED is not lit. |
| Charge LED | • **On:** The yellow (Charge) LED is lit.<br>• **Off:** The yellow (Charge) LED is not lit. |
| Running LED | • **On:** The green (Run) LED is lit.<br>• **Off:** The green (Run) LED is not lit. |

| Option | Descriptions/Notes |
|---|---|
| Door sensor | • **Closed:** The safety door is closed.<br>• **Opened:** The safety door is open. |
| Bolus handle | • **Released:** The handle is not pressed.<br>• **Pressed:** The handle is pressed. |

## View Menu

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

| Category | Description/Notes |
|---|---|
| View system | Provides a view of the current system settings, and allows updating selected settings. For more information, refer to Viewing System Parameters on page 244. |
| Event log | Provides a view of the events recorded by the system; such as authorization level change, programming infusion parameters, activated alarms etc. For more information, refer to Viewing the Event Log on page 247. |
| 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 on page 248. |

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

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

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

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

## Viewing System Parameters

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

The following settings appear in all delivery modes:

| Setting | Description/Notes |
|---|---|
| Infusion Values | Displays all the programmed parameters of the current infusion, including rate in mL/h. Applicable only on an active infusion, or during Standby.<br>Pressing **>** displays the parameters. |
| Alarm volume | The volume of the auditory alarm signal (**Maximum** or **Minimum**). The setting can be modified by pressing **>**, and then selecting a setting. |
| Occlusion | The level of downstream pressure that triggers an occlusion alarm. For more information, refer to Managing Alarm Settings on page 232.<br>The setting can be modified by pressing **>**, entering a value using the keypad, and then pressing **OK**. |
| Authorization | Current authorization lock level. For more information, refer to Managing Authorization Levels on page 252.<br>The setting can be modified by pressing **>**, selecting a setting, and then pressing **OK.** Password entry is required to change the authorization. |
| Current CCA | The current CCA, as pre-selected by the user, and used for the current infusion. Appears only when Drug Library is loaded.<br>For more information, refer to Clinical Care Area (CCA) on page 267. |
| Next CCA | The next CCA appears only when the Drug Library is loaded, and the user changed the CCA during an infusion.<br>**Note:** The next CCA will apply only after the infusion has ended. Applicable only during an active infusion, or during Standby.<br>For more information refer to Clinical Care Area (CCA) on page 267. |

| Setting | Description/Notes |
|---|---|
| Backlight | Current backlight settings. For more information refer to Configuring General Settings on page 236.<br>The setting can be modified by pressing **>**; then selecting **On**, **Partial** or **Off**. |
| Accumulated VI | The cumulative volume infused (mL). The Accumulated VI can be cleared by pressing **>**. For more information, refer to Monitoring the Accumulated Volume Infused (Shift's Total) on page 264. |
| Accum. Prim. VI | The cumulative volume infused (mL) via the primary infusions. Appears in the View System menu only in the Continuous Delivery mode. For more information, refer to Monitoring the Accumulated Volume Infused (Shift's Total) on page 264. |
| Accum. Sec. VI | The cumulative volume infused (mL) via the secondary infusions. Appears in the View System menu only in the Continuous Delivery mode. For more information, refer to Monitoring the Accumulated Volume Infused (Shift's Total) on page 264. |
| VI cleared date<br>VI cleared time | The date and time in which the Accumulated VI was last cleared. For more information, refer to Monitoring the Accumulated Volume Infused (Shift's Total) on page 264. |
| Delivery mode | Current delivery mode. |
| Single Air detector<br>Accumulated Air detector<br>Accumulated Threshold | 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.<br>**Note**: While a non-epidural infusion is running at a rate of 4 mL/h or lower, the Single air detector switches automatically On. |
| Air detection | This setting indicates that air detection has been disabled (OFF) – it is displayed instead of the single and accumulated air settings mentioned above. |
| Date<br>Time | Current date and time. For more information, refer to Defining Regional Parameters on page 240. |
| Software version | The software version loaded on the pump. |

| Setting | Description/Notes |
|---|---|
| Drug Library name | The Drug Library name appears only if the pump is loaded with a Drug Library. For more information about the Drug Library, refer to Chapter 9: Drug Library on page 266. |
| Drug Library published date | The Drug Library published date appears only if the pump is loaded with a Drug Library. For more information about the Drug Library, refer to Chapter 9: Drug Library on page 266. |
| Serial number | Serial number of the pump. |
| Next Certification | Date that the pump is due for the next Certification. For more information refer to the Service Manual. |
| Set Prime Volume | The amount of fluid used to prime the administration set, when automatic priming is performed. The acceptable range is 2 to 25 mL. |
| Battery status | The approximate percentage of current battery charge. Possible values are **100%**, **75%**, **50%**, **25%**, and **Low Batt**. |
| KVO | The default KVO rate set for the current delivery mode. The parameter is not relevant to Intermittent or Epidural Intermittent mode (in which the KVO is equal to the KVO/continuous rate programmed for the infusion). |
| Bolus rate | The default bolus rate set for the current delivery mode. The parameter is not relevant to the Intermittent, TPN or Multi-step modes. In continuous mode, when the Advanced Bolus option is set to On, the bolus Amount, Rate and Time can be programmed by the user, and the bolus rate will not be displayed on the View System menu.<br>Default bolus rate can be modified by Technicians only. For more information, refer to the Service Manual. |
| Secondary bolus rate | The default secondary bolus rate. This parameter is relevant only for the Continuous Delivery mode. When the Advanced Bolus option is set to On, the bolus Amount, Rate and Time can be programmed by the user, and the secondary bolus rate will not be displayed on the View System menu.<br>Default bolus rate can be modified by Technicians only. For more information, refer to the Service Manual. |

## Viewing the Event Log

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

**> To view events that occurred on a specific day:**

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

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

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

   A list of events is displayed.

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

**> To view all events:**

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

   A list of events is displayed.

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

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

## 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.

To access the Delivery History during PCA, PCEA, or PIEB infusion: From the tool bar 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:

| 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.<br>The setting can be modified by pressing **>**, entering a value using the keypad, and then pressing **OK**. |

| Name of Value | Description/Notes |
|---|---|
| Patient bolus given/attempts | Total number of patient boluses delivered to the patient/ number of times that the patient requested a bolus (by pushing the button on the Bolus Handle, or by pressing the **Bolus** function key). |
| Patient Bolus given | Total amount of infusion (in mL, mg, mcg, mUnits, million Units, gram, nanogram, mmol, or mEq) given via demand boluses. |
| Clinician Bolus given | Total amount of infusion (in mL, mg, mcg, mUnits, million Units, gram, nanogram, mmol, or mEq) given via boluses administered by clinicians, including loading dose. |
| Total Bolus given | Total amount of infusion given to the patient via boluses (loading dose, clinician, patient) or intermittent doses (PIEB). |
| Intermittent Doses given | Total amount of intermittent doses (in mL, mg, mcg, mUnits, million Units, gram, nanogram, mmol, or mEq). Appears only when Epidural Intermittent with PCEA is programmed. |
| Intermittent doses Given/ Total | Total number of Intermittent doses actually given/number of Intermittent doses programmed to be administered. Appears only when Epidural Intermittent with PCEA is programmed. |

When using the **Repeat Last Infusion** option (for the same patient), the Delivery History, the accumulated VI, and the lockout time are not cleared; they continue counting from the previous infusion.

## Using Special Mode Options

The following sections describe options that are available only in PCA and Epidural delivery modes:

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### PCA Options Menu

The PCA options screen is accessed from the main Options menu, when the pump is in PCA delivery mode. It enables you to view and update the following parameters:

| Parameter | Description/Notes |
|---|---|
| Bolus rate | The rate at which a bolus (Patient bolus, Clinician bolus and Loading dose) is delivered. The bolus rate can be set from 1 and up to 600 mL/h; the default is 125 mL/h. |
| Allow loading dose | Enables the user to program a loading dose (starting the infusion with a clinician bolus).<br>Select the row to toggle the option between **On** and **Off**. |
| Infusion type | Defines the PCA infusion type that is available for the user:<br>• Continuous only – includes only a continuous rate without boluses (if enabled, a loading dose can be programmed)<br>• Bolus only – includes only patient boluses and no continuous rate (clinician and loading dose can be given)<br>• Continuous with Bolus – allows the user to program both continuous and patient boluses (either one of which is optional) |
| 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). |

**> To change the bolus rate from the PCA options screen:**:

1. Select the Bolus rate row.
2. Using the keypad, enter the value for the new bolus rate → **OK**.

3. To save the change in the system, press **OK**.

## Epidural Mode Options Menu

The PCEA options and Epi Int options screens are accessed by pressing the **Options** function key when the pump is in PCEA or Epidural Intermittent delivery modes, respectively. These screens enable you to view and update the following parameters:

| Parameter | Description/Notes |
|---|---|
| Bolus rate<br>(PCEA mode only) | The rate at which a bolus (Patient bolus, Clinician bolus and Loading dose) is delivered. Options are: 125mL/h, 200 mL/h, 300 mL/h, 400 mL/h or 500 mL/h; the default rate is 125 mL/h. |
| Password request | Enables a safety feature that requires a high authorization level password entry for programming and editing actions. |
| Allow loading dose<br>(PCEA mode only) | Enables the user to program a loading dose (starting the infusion with a clinician bolus).<br>Select the row to toggle the option between **On** and **Off**. |
| Infusion type<br>(PCEA mode only) | Defines the PCEA infusion type that is available for the user:<br>• Continuous only – includes only a continuous rate without boluses (if enabled, a loading dose can be programmed)<br>• Bolus only – includes only patient boluses and no continuous rate (clinician and loading dose can be given)<br>• Continuous with Bolus – allows the user to program both continuous and patient boluses (either one of which is optional) |
| Dose rate<br>(Epi. Int mode only) | The rate at which an Intermittent dose is delivered. Options are 125mL/h, 200 mL/h, 300 mL/h, 400 mL/h or 500 mL/h; the default rate is 125 mL/h. |
| Limit Period | Specifies the time period to which the dose limit type is applied (during the selected time, the delivered boluses are limited by either maximum number, or by maximum volume). |
| PIEB<br>(Epi. Int mode only) | Enables the user to program a PIEB infusion. |

# Chapter 8: Using Advanced Features

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


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Password Re-entry ..... 255
Creating and Editing PreSet Programs ..... 256
Using the Set Delay Feature ..... 259
Using the New Patient Feature ..... 263


## Managing Authorization Levels

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 allows users to access a different set of pump actions and programming options.

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

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

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

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

| Authorization Level | Allowed Actions |
|---|---|
| Low | Stop the pump, and then continue the infusion |
| | Power the pump On and Off |
| | 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 continue the 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 |
| High | Start infusions using the New Infusion feature |
| | View/Edit parameters |
| | Use the Pump Configuration menu |
| | Create/Edit PreSet programs (requires a unique password) |
| | Use of all PCA, PCEA and PIEB options |
| | Changing delivery mode (requires password re-entry) |
| | Clinician bolus |
| Technician | All |

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

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

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

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

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

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

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

## Setting Authorization Lock Levels

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

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

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

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

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

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

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

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

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

## Password Re-entry

The 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 the user to re-enter the High level password before performing the following actions:

- Changing delivery modes
- Changing authorization levels

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

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

## Creating and Editing PreSet Programs

The PreSet Programs feature allows users to start infusions using predefined infusion parameters, thus eliminating the need for programming. Each delivery mode can support its own set (of up to 25) predefined infusion programs. Only the infusion programs set for the currently selected delivery mode are displayed (a preset program is available for use and edit only when the pump is set to the delivery mode in which the program was saved).

> For the PreSet Programs function to appear in the Start Up screen, the pump needs to be configured to the PreProgram setting. For more information, refer to Start Up Configuration Menu on page 240.

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

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

A PreSet program will be available for creating, using and editing only when the program settings are consistent with the current pump settings, and drug availability in the current CCA (for example, when creating a PCA PreSet program while the pump is set to Continuous + Bolus infusion type, this program can be used only when the pump is configured to Continuous + Bolus and not when the pump is configured to Continuous only or Bolus only).

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

**> To create a new preset program:**

1. From the Indicators Bar, verify that the pump is in the desired delivery mode.
2. From the Start Up screen, select **PreSet Programs**.
3. From the toolbar, press **Create New**.
4. Using the keypad, enter the appropriate password; then, press **OK**.

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

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

| Delivery Mode | Refer to: |
|---|---|
| Continuous | Starting a Continuous Infusion on page 129 |
| Intermittent | Starting an Intermittent Infusion on page 173 |
| TPN | Starting a TPN Infusion on page 167 |
| Multi-step | Starting a Multi-step Infusion on page 157 |
| PCA | Starting a PCA Infusion on page 184 |
| Epidural | Starting a PCEA Infusion on page 197, Starting an Epidural Intermittent Infusion on page 209, or Starting a PIEB Infusion on page 214 |

7. Review the parameters displayed on the screen.

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

   Then, press **OK**. The program is saved.
8. To return to the PreSet programs screen, press **OK**.

### > To edit a preset program:

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

3. From the toolbar of the PreSet Programs screen, press **Edit**.
4. Using the keypad, enter the appropriate password; then, press **OK**.
5. From the list, select the program that you want to update.
6. Select the box of the parameter that you want to change. Using the keypad, enter the new parameter, and then press **OK**.

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

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

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

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

### > To delete a preset program:

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

   The program is deleted.

## Using the Set Delay Feature

The Set Delay feature allows users to program an infusion in advance. When the option is enabled, the Set Delay option appears on the Start screen. The users can then choose to set the infusion to Standby for an unlimited time period, or to set the infusion for a defined Delayed Period, after which one of the following occurs:

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

> For the Set Delay option to appear on the Start screen, the pump needs to be configured with the **Allow delayed start** setting enabled. For more information, refer to Configuring General Settings on page 236.

**> To program an infusion using the Standby option:**

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

| Delivery Mode | Refer to: |
|---|---|
| Continuous | Starting a Continuous Infusion on page 129 |
| Intermittent | Starting an Intermittent Infusion on page 173 |
| TPN | Starting a TPN Infusion on page 167 |
| Multi-step | Starting a Multi-step Infusion on page 157 |
| PCA | Starting a PCA Infusion on page 184 |
| Epidural | Starting a PCEA Infusion on page 197 or Starting an Epidural Intermittent Infusion on page 209 |

2. From the Start screen, select **Set Delay**.
3. From the Delayed Start screen, select **Standby**.
4. The Standby screen is displayed.

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

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

During Standby, Pump unattended message will not be active.

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

When in Standby, the pump can be turned Off without losing the infusion parameters. To resume infusion, refer to Resuming Infusions After Pump Shutdown on page 223.

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

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

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

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

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

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

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

| Delivery Mode | Refer to: |
|---|---|
| Continuous | Starting a Continuous Infusion on page 129 |
| Intermittent | Starting an Intermittent Infusion on page 173 |
| TPN | Starting a TPN Infusion on page 167 |
| Multi-step | Starting a Multi-step Infusion on page 157 |
| PCA | Starting a PCA Infusion on page 184 |
| Epidural | Starting a PCEA Infusion on page 197 or Starting an Epidural Intermittent Infusion on page 209 |

2. From the Start screen, select **Set Delay**.
3. From the Delayed Start screen, select **Delay Period**.
4. Using the keypad, enter the desired delay period (h:min); then, press **OK**.

5. Specify whether or not to run the infusion in a KVO, during the delay period:

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

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

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

- **Do not use KVO:**
  Press **No** → **Start with Delay**.
  On the Delayed Start screen, the words No KVO appear in the Rate frame, and a time countdown for the delay period is displayed in the Time frame.

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

When the delay period is over, a message (level 3, low priority alarm) is triggered.

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

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

## Using the New Patient Feature

The Sapphire pump allows you to associate infusions to a specific patient.
When the New Patient feature is enabled, and either a New Infusion or a PreSet program is selected, the pump prompts 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 does not appear, and the pump indicates that the infusion to be repeated will be used for the last patient selected.

> 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 on page 247). 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) on page 264). 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 Viewing Delivery History on page 248).

**> To select a New Patient:**

1. From the Start Up screen, select **New Infusion** or **PreSet Programs**.
2. On the New Patient screen, select **Yes**.

## Monitoring the Accumulated Volume Infused (Shift's Total)

The Sapphire pump calculates the Accumulated Volume Infused (Accumulated VI) for all infusions associated with a specific patient.

The accumulated VI includes the volume infused to a specific patient via infusions (including primary, secondary etc.), Boluses and KVO (if applied during delayed Start or post infusion). This allows the clinical staff to monitor the total volume infused to a specific patient. The Accumulated VI can be cleared during infusion or before starting another infusion (for more information, refer to Clearing Accumulated VI on page 265). The date and time in which the Accumulated VI was cleared is also captured.

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

### Viewing Accumulated VI

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

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

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

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

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

The Accumulated VI value is presented in the Clear Accum. VI box.

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

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

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

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

## Clearing Accumulated VI

The Accumulated VI value is cleared in the following cases:

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

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

**> To clear the Accumulated VI value during infusion:**

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

# Chapter 9: Drug Library

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


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Clinical Care Area (CCA) ..... 267
Programming a New Infusion with the Drug Library ..... 271
Soft Limit ..... 273
Update a New Drug Library Version ..... 274


## Overview

The Drug Library contains information about customized groups of drugs and Clinical Care Areas (CCA) that were approved and saved by qualified and authorized local hospital personnel, using the Eitan Medical Drug Library Editor.

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

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

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

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

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

The complete detailed information about the Drug Library is available in the Drug Library Editor Software. For more information refer to Drug Library Editor user manual.

## Clinical Care Area (CCA)

The Drug Library accommodates of up to 40 CCAs, and up to 8,500 unique drug profiles. Each CCA can accommodate up to 1000 drug profiles, and each unique drug profile can be assigned to more than one CCA, i.e. up to a total of 40,000 medications. The CCA unique configuration is set by the Drug Library. Local configuration made when a Drug Library is loaded remains valid until the user selects a CCA or turns the pump Off.

| | |
|---|---|
| i | CCA settings do not include TPN specific settings; TPN hard limits and KVO can be set locally by a technician only. |

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

### Changing a CCA

CCA selection is available in the following cases:

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

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

#### Selecting a CCA when pump is turned On

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

**> To accept or change a CCA:**

1. Turn the pump On.
2. From the Clinical Care Area screen select whether to **Accept** or **Change** the current clinical care area:

- To accept the current CCA, press **Accept**.
  The Start Up screen appears.
- To change the current CCA, press **Change**.
  a. From the Choose CCA screen, select the relevant CCA.

> To display additional CCAs press **Next**.

  b. From the Attention screen, press **OK**.

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

  The Start Up screen appears.

> CCA selection should be selected according to local facility procedures.

> If a message regarding resuming previous infusion appears upon turning the pump On, refer to Resuming Infusions After Pump Shutdown on page 223.

## Selecting a CCA from the General Settings

**> To change the current CCA:**

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

> To display additional CCAs press **Next**.

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

The Start Up screen appears.

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

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

## Changing a CCA during a running infusion

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

**> To change a CCA during a running infusion:**

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

| | |
|---|---|
| | To display additional CCAs press **Next**. |

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

The View/Edit screen is displayed.

To view or change the Next CCA:

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

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

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

## Programming a New Infusion with the Drug Library

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

### Drug Name

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

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

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

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

### Drugs List

The filtered drugs are displayed in the Drugs List screen.
The Drugs List screen displays only drugs that are available in the current CCA and delivery mode. When there are more than 4 available drugs, use the **Next** key to display additional drugs.

---

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

## Drug Profiles

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

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

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

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

To begin a new Continuous infusion with a Drug Library on page 132
To begin a new Multi-step infusion with a Drug Library on page 160
To begin a new Intermittent infusion with a Drug Library on page 178
To begin a new PCA infusion with a Drug Library on page 188
To begin a new PCEA infusion with a Drug Library on page 200
To begin a new Epidural Intermittent infusion with a Drug Library on page 212

## Soft Limit

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

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

Figure 9.1. Soft Limit Icon

Current infusion is above upper soft limit

Current infusion is below lower soft limit

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

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

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

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

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

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

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

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

## Update a New Drug Library Version

Following a Drug Library update, when the pump is turned On, the user is prompted to specify whether or not to update the Drug Library with the new available version.

> Updating Drug Library should be conducted according to local facility procedures.
> Updating a new Drug Library version may take a few minutes, during which the pump is inactive.

**> To update a new Drug Library version:**

From the Update screen, press **Yes**. The pump will start updating the Drug Library. At the end of the process the pump will restart and the user will be prompted to specify the CCA;

- If the last active CCA is available in the new Drug Library, the Clinical Care Area screen will appear. Press **Accept** and the Start Up screen will appear.
- If the last active CCA is not available in the new Drug Library, the Choose CCA screen will appear.

  a. Select the relevant CCA.

  b. To confirm the changed CCA, press **OK**.

  The Start Up screen will appear.

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

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# Chapter 10: Alarms and Troubleshooting

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


Alarms Overview ..... 276
Error – Level 1, High Priority Alarms ..... 277
Alarm – Level 2, High Priority Alarms ..... 278
Messages – Level 3, Low Priority Alarms ..... 281
Troubleshooting ..... 283


## Alarms Overview

The Sapphire pump generates three different types of alarms. The alarm types are categorized according to the urgency of the needed response ("Immediate response" or "Awareness needed"). 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 |
|---|---|
| Error – Level 1, high priority alarm | Immediate response required. Pump will shut down after 3 minutes. |
| Alarm – Level 2, high priority alarm | Immediate response required. Infusion stops, but may be resumed. |
| Message – Level 3, low priority alarm | User Awareness is required. Infusion is not interrupted. |

The following sections provide details about each alarm type. Alarms related to battery problems can be prevented by adhering to the recommended guidelines for battery care (Battery Care Information on page 301).

## Error – Level 1, High Priority Alarms

This type of alarm requires Immediate user attention.

When initiated, an auditory alarm sounds, the alarm LED blinks, and the recommended action is displayed on the screen. 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 resumed.

**Exception:** 'Battery depleted' alarm (placed in this category because it will lead to pump shutdown within 3 minutes) can be resolved and dismissed (infusion can continue) by connecting a power supply to the pump.

The following soft keys are available during an error alarm:

- **Mute**: Silences the auditory signal (pause audio).
- **Shutdown**: Turns Off the pump immediately.

When a Battery Depleted alarm occurs, connect the pump to an AC power supply. When an error alarm is triggered, please contact an authorized technician.

| Alarm Title | Screen Header | Displayed Text |
|---|---|---|
| Battery Depleted | Error | Pump will automatically shut down in 3 minutes. Please connect pump to power. |
| Internal Error | Error | Pump will automatically shut down in 3 minutes. Please contact an authorized technician. |

## Alarm – Level 2, High Priority Alarms

This alarm type requires immediate user response.

When triggered, an auditory alarm sounds, the alarm LED blinks, and the condition that triggered the alarm (and recommended actions, if relevant) is displayed on the screen.

If the alarm occurs during an infusion, the infusion automatically stops. However, you may continue the infusion after the problem has been resolved. Instructions for resolution of the problem are displayed on the touch screen.

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

**Exception:** 'Battery Near Depletion' alarm (placed in this category because it is considered a high priority alarm, although it does not lead to infusion automatic stop) can be resolved and dismissed by connecting a power supply to the pump.

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

Figure 10.1. Alarm – Level 2, High Priority Alarm Screen

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

- **Mute:** Silences the auditory signal for 2 minutes (pause audio).

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

| Alarm Title | Screen Header | Displayed Text |
|---|---|---|
| Infusion Complete | Alarm | VI: xxx mL<br>Rate: xxx.x mL/h<br>Total Time: xx:xx:xx h:min:sec |
| Air in Line | Alarm | Accumulated air in line is over the limit. Please prime administration set. If problem reoccurs, remove and reinsert the cassette.<br>Please prime administration set. If problem reoccurs, remove and reinsert the cassette.<br>Possible excessive environmental light.<br>Please reduce exposure and check if priming is required. |
| Potential Air in Line | Alarm | Press OK to test for air. |
| Cassette Misplaced | Alarm | The administration cassette is not loaded or misplaced. Please reload the cassette.<br>Reinsert cassette. Verify both flanges inside safety door. If problem persists contact technician.<br>Remove the administration cassette, verify cassette chamber is clean, and correctly reinsert it. If alarm reoccurs please contact authorized technician. |
| Downstream Occlusion | Alarm | 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. |

| Alarm Title | Screen Header | Displayed Text |
|---|---|---|
| Flow Error | Alarm | 1. Remove and reinsert administration cassette; 2. Connect pump to a power supply. If alarm reoccurs contact authorized technician. |
| Occlusion | Alarm | To clear occlusions verify: 1. Clamps are open; 2. Administration cassette is properly positioned; 3. Line is not kinked; 4. No occlusion at the input and output connections. If all occlusions were cleared press OK to continue. |
| Upstream Occlusion | Alarm | 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 | Alarm | Low battery voltage for current rate. Please connect pump to power supply. |
| Battery Near Depletion | Alarm | Less than 10 minutes to Battery Depletion. Connect pump to power supply.* |

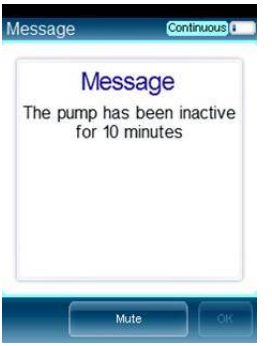
* If the alarm condition still exists after pressing **OK**, the message will be prompted again after 3 minutes (paused alarm).

## Messages – Level 3, Low Priority Alarms

A Message is an alarm that requires user awareness as soon as possible. When triggered, an auditory alarm sounds, the alarm LED is steady on, and the condition that triggered the alarm (and recommended actions, if relevant) is displayed on the touch screen.

To silence the alarm's auditory signal, press the **Mute** soft key. This silences the alarm auditory signal for 2 minutes. If the issue has not been cleared after 2 minutes, the auditory signal will be resumed.

Figure 10.2. Sample Message Screen




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

- **Mute:** Silences the auditory signal for 2 minutes (pause audio).
- **Unmute:** Returns the auditory signal.
- **OK:** Confirms the message, and returns the display to the previous screen. If the infusion is complete, the pump returns to the Start Up screen. This soft key is enabled after **Mute** is pressed.

  The Message (Level 3- low priority alarm) display includes the following fields:

| Alarm Title | Screen Header | Displayed Text |
|---|---|---|
| Low Battery | Message | 30 minutes left to battery depletion. Connect pump to power supply*. |
| Battery Reminder | Message | End of battery life. Please contact authorized technician to replace battery. |
| Battery life expires in 2 weeks | Message | Battery life will expire in 2 weeks, Please contact authorized technician. |
| Check Battery Charge | Message | The battery could not be fully charged, Please check power supply. |
| Pump failed annual certification | Message | Pump failed annual certification. Please return to service. |
| Battery life expires in 2 days | Message | Battery life will expire in 2 days. Please contact authorized technician. |
| | | The battery could not be fully charged - please check power supply. |
| Door Open | Message | Door open. Check administration cassette position and close the safety door*. |
| Infusion Near End | Message | Infusion near end. |
| Pump Inactive | Message | The pump has been inactive for <xx> minutes. |
| System Temperature out of range | Message | System temperature is out of range. If the alarm reoccurs please contact authorized technician*. |
| Key Stuck | Message | Key Stuck. Please release the key. |
| Delayed Start Over | Message | Delayed period is over. |

* If the alarm condition still exists after pressing **OK**, the message will be prompted again after 2 minutes (paused alarm).

## Troubleshooting

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

| Problem | Probable Cause | Solution |
|---|---|---|
| Programming cannot be completed. The **OK** function key is disabled, and the parameter range is in red font. | The parameter entered is outside of the safety range calculated by the pump. | Verify the prescription, and obtain a new one if necessary. Enter infusion parameters within the permitted ranges. |
| The Set Delay option does not appear on the Start screen. | The option is not enabled. | Enable the Allow delayed start setting (Configuring General Settings on page 236). High Authorization level is required. |
| The PreSet Programs option does not appear on the Start Up screen in any mode. | The option is not enabled. | Enable the Allow PreProgram setting (Configuring General Settings on page 236). High Authorization level is required. |
| The Repeat last infusion option does not appear on the Start Up screen in any mode. | The option is not enabled. | Enable Repeat Last infusion setting (Start Up Configuration Menu on page 240). High Authorization level is required. |
| Loading dose cannot be programmed in PCA or PCEA mode. | The option is not enabled. | Enable the Allow loading dose setting (PCA Options Menu on page 250 or Epidural Mode Options Menu on page 251). Authorization level of High is required. |
| Pump becomes locked whenever an infusion starts. | The Auto Patient Lockout feature is enabled. | Disable the Auto P. Lockout option (Configuring General Settings, page 238). High Authorization level is required. |

| Problem | Probable Cause | Solution |
|---|---|---|
| A password needs to be entered to change any parameter in Epidural mode. | The Password Request feature is enabled. | Disable the **Password request** setting (Epidural Mode Options Menu on page 251). Authorization level of High is required. |
| Gray-buttoned bolus handle is not responding. | • The gray-buttoned bolus handle has become disconnected from the pump<br>• The gray-buttoned bolus handle is connected to the mini cradle together with a communication cable, or with Sapphire Connect. | • Reconnect the bolus handle to the pump.<br>• Disconnect the communication cable from the mini cradle, or the Sapphire Connect from the Sapphire pump. |
| Blue-buttoned bolus handle is not responding. | The handle has become disconnected from the pump, or the blue-buttoned bolus handle is being used, and is connected to the mini cradle instead of to the pump. | Reconnect the bolus handle to the pump. |
| 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 the Service Manual.<br>• The drug profile in the Drug Library was not configured to support a bolus. |
| Communication error while pressing the bolus handle button. | The Bolus handle button was pressed during pump start up. | Disconnect the bolus handle from the pump, turn the pump off, and reconnect the bolus handle after turning the pump On. |

| Problem | Probable Cause | Solution |
| --- | --- | --- |
| Pump is not charging. | • The power supply has become disconnected from the mini cradle, or from Sapphire Connect.<br>• The power supply was connected to the pump during pump turn-off.<br>• The power supply is not working. | • Verify that the power supply is connected to the mini cradle splitter, or to the Sapphire Connect USB-C port.<br>• Disconnect and reconnect the power supply to the pump.<br>• If a Sapphire Connect is used for charging, disconnect and reconnect the power supply from the Sapphire Connect USB-C port.<br>• If the power supply is not functioning properly, replace it. |
| Recurring Air in Line alarms. | Treatment is near end, or the air detection settings are too sensitive. | Close clamps, remove administration cassette from pump and prime (flush) the set manually.<br>If the issue is not resolved, replace the administration set.<br>If the issue is still not resolved, have a technician review and adjust the air detection settings. |
| Recurring Occlusion alarms. | The occlusion issue has not been properly resolved. | • Close clamps, remove administration cassette from pump, disconnect patient and prime (flush) the set manually.<br>• Replace the administration set.<br>• Change the infusion site. |
| Occlusion alarm is triggered immediately after the infusion or bolus starts, or rate is increased. | 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. |

| Problem | Probable Cause | Solution |
|---|---|---|
| Screen saver does not appear. | • Screen saver option was not enabled.<br>• Pump is not in an applicable state. | • Enable the Screen Saver option (refer to Configuring General Settings on page 236)<br>• The screen saver will not appear if the pump is in one of the following states: Paused, Delayed Infusion, end of treatment KVO, during alarm, when screen is touched, when key is pressed, or during a Bolus delivery |
| The pump pauses when programming a secondary. | The pump is not connected to an AC outlet, and currently the battery power is insufficient to support both the primary line rate and the secondary line programming. | Connect the pump to an AC outlet, and select to continue the primary or start the secondary. |
| Fast depletion of AA batteries. | Power Supply is connected to the Pump, and not to electricity, while EBP is attached to the pump. | Disconnect power supply from the Pump. |
| Pump doesn't turn on when attached to the EBP. | Internal battery is below the required voltage level for the pump to turn on. | • If stable power supply is available, connect the power supply to the pump.<br>• Contact an authorized technician to replace the internal battery. |

| Problem | Probable Cause | Solution |
|---|---|---|
| Pump does not show indications of connection when attached to the EBP. | • EBP was not properly attached. | • Detach the EBP and re-attach it exactly as instructed. |
| | • AA batteries were misplaced in compartment. | • Detach the EBP, make sure the AA batteries inserted properly and re-attach it exactly as instructed. |
| | • AA batteries are depleted. | • Detach the EBP and replace the AA batteries with fresh AA batteries and re-attach it exactly as instructed. |
| Pump does not show indications of connection when attached to Sapphire Connect. | • Sapphire Connect was not properly attached. | • Detach the Sapphire Connect and re-attach it exactly as instructed (refer to Removing Sapphire Connect on page 64 and Attaching Sapphire Connect to the Pump on page 61). |
| | • The electrical connectors are not clean. | • Clean the Sapphire Connect electrical components (refer to Cleaning Sapphire Connect and Electric Connectors of Sapphire Accessories on page 295) and the pump P to C connectors (refer to Guidelines for cleaning/disinfecting specific pump components on page 294). |

| Problem | Probable Cause | Solution |
| --- | --- | --- |
| Pump does not show indications of connection when attached to Sapphire Connect (Cont'd). | • The software version on the Sapphire pump is not compatible with Sapphire Connect. | • Contact your local representative, or contact Eitan Medical at www.eitanmedical.com in order to upgrade the pump software to Rev16 or later.<br>Sapphire Connect is compatible for use only with Sapphire Rev16 (or above) pumps manufactured in 2017 or later. |
| | • Sapphire Connect is currently in the process of updating its software, and therefore cannot connect to the pump. In this case, the communication LED on the Sapphire Connect will turn purple (refer to Sapphire Connect Over-The-Air Software Update on page 63). | • Wait for the Sapphire Connect software update to complete (refer to Sapphire Connect Over-The-Air Software Update on page 63).<br><br>If the problem persist, contact your local representative, or contact Eitan Medical at www.eitanmedical.com |

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# Chapter 11: Maintenance and Storage

The following sections describe the proper cleaning, preventive maintenance, and storage procedures for the pump and the battery:

Cleaning and Disinfecting the Pump ..... 290
Cleaning Sapphire Connect and Electric Connectors of Sapphire Accessories ..... 295
Preventive Maintenance ..... 298
Battery Care Information ..... 301
Transport and Storage ..... 305

## Cleaning and Disinfecting the Pump

Between use on different patients, the Sapphire pump and all of its components need to be first thoroughly 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.

Additional Cleaning and Disinfection Agents:

- Virex® II 256
- Virox® AHP 5 RTU, Diversey
- Klor De™ (Chlorine tablets)
- 70% Isopropyl alcohol

## Cleaning and Disinfection: Safety Precautions

Before and during cleaning, adhere to the following safety guidelines and recommendations:

- Only people who are trained in the maintenance of this type of medical device should clean the infusion pump
- Before cleaning/disinfecting the pump, verify that:
  - The pump is disconnected from the patient.
  - The pump is disconnected from all connections, sets, and accessories.
  - The pump is turned Off.
- While cleaning/disinfecting the pump, do not allow fluid to enter the pump housing, speaker holes or battery chamber.
- Do not steam autoclave, ethylene oxide sterilize or immerse any part of the pump in fluid.
- Do not use spray or aerosol cleaners.
- Dispose of all cleaning/disinfectant materials per laws and regulations for infectious waste disposal.
- Do not clean or disinfect the pump using liquid household Bleach.

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

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

## Cleaning and Disinfection Procedure

| Cleaning/Disinfecting Solution | Manufacturer |
|---|---|
| Dispatch® (Caltech) ready-to-use towels | Caltech |
| Virex® II 256 | Diversey |
| Virox® AHP 5 RTU | Diversey |
| Klor DeTM (Chlorine tablets) | Concept |
| 70% Isopropyl alcohol | Veltek Associates, Inc. |

### Cleaning Procedure

The following procedure explains how to thoroughly 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 Sapphire pump power socket.
2. Use the appropriate dilution ratio per the manufacturer's instructions.
3. When the solution is ready, apply the solution on a cloth or sponge, then squeeze so it won't drip.
4. Wipe the exterior planes areas in back and forth motions, vertically and horizontally (mainly on the pump housing).
5. The wiping should be applied with normal force, few times on the same locations (at least twice) verifying complete coverage of the areas to be thoroughly cleaned.
6. Guidelines for cleaning specific pump components are listed in the table below.
7. After the thorough cleaning process is completed, the pump should be dried out for 10 minutes.
8. Wipe the pump with a clean dry cloth.

9. Inspect the device for any visible soil after the cleaning steps (but before the disinfection steps) to ensure that the device is cleaned between uses prior to disinfection. If the device has remaining visible soil following cleaning, repeat the cleaning steps (1 through 8 above).

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

## Disinfecting Procedure

The following procedure explains how to disinfect the pump using the approved agents (listed in Cleaning and Disinfection Procedure on page 292):

**> 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) five more times (a total of six cycles). Each area should be cleaned for at least five seconds.
3. After the disinfection process is completed, the pump should be dried out for 15 minutes.
4. Wipe the pump with a clean dry cloth.

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

### Guidelines for cleaning/disinfecting specific pump components

Guidelines for cleaning/disinfecting specific pump components are listed in the following table:

| Component | Cleaning Recommendations |
|---|---|
| LCD Screen | Wipe thoroughly with a squeezed sponge. Avoid scratching the LCD panel. Ensure that no fluid enters the speaker holes at the top of the panel. |
| Sensor Fingers | Thoroughly clean the finger tip of the sensor using only a damp cloth or sponge. |
| • Internal White Panel<br>• Bubble Detector (on the internal white panel)<br>• Anchor (on the internal white panel)<br>• Locking tooth (on the internal white panel)<br>• 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 thoroughly 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.<br><br>**Note**: Swabbing should be applied in vertical or horizontal movement, where possible, while less accessible areas should be swabbed in a circular motion (at least 3 bi-directional rotations clockwise-counterclockwise). |

## 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 Disinfection Procedure on page 292.

## Cleaning Sapphire Connect and Electric Connectors of Sapphire Accessories

| | |
|---|---|
| ⚠ | Before cleaning/disinfecting the Sapphire Connect, verify that it is OFF and disconnected from the power supply. |

Cleaning Sapphire Connect and the electrical connectors of all accessories is restricted to the use of 70% Isopropyl alcohol (IPA) ONLY.
Between use on different patients, the Sapphire Connect and accessories need to be first thoroughly cleaned, and then disinfected, per hospital/medical provider protocol for multiple patient use.

**> To clean the Sapphire Connect and accessories:**

1. Place the Sapphire Connect or 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 that it would not drip on the accessory to be cleaned.
4. Wipe the exterior planes areas in back and forth motions, vertically and horizontally (mainly on the accessory housing).
5. The wiping should be applied with normal force, a few times on the same locations (at least twice), verifying complete coverage of the areas to be thoroughly cleaned.
6. For hard-to-reach areas and electrical connectors, swab in a rotational manner for at least 3 bi-directional rotations (clockwise-counterclockwise)*.

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

Figure 11.1. Cleaning Electric Connectors

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

The user is required to clean and disinfect the Sapphire Connect in the following conditions (the earlier of the three):

- Every time it is visibly not clean.
- Once a week.
- After storage at the patient's home – even if not used.

### > To disinfect the Sapphire Connect and accessories :

1. To disinfect the Sapphire Connect or accessory, replace cloth or sponge and repeat steps 2-6 in the cleaning process above five more times (a total of six cycles). Each area should be cleaned for at least five seconds.
2. After the disinfection process is complete, the Sapphire Connect or accessory should be dried out for 15 minutes.

| | |
|---|---|
| ⚠ | The Sapphire Connect must be completely dried out before connecting it to a power supply, pump or any other accessories. |

# Preventive Maintenance

The following sections describe:

Routine Inspection and Maintenance Tasks ..... 298
Alarm Testing ..... 299
Certification ..... 300

## 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 facility biomedical engineer or a Eitan Medical approved service technician.

### Post-use Procedures

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

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

## Alarm Testing

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

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

| Name of Test | Procedure |
|---|---|
| Air in Line Alarm | Connect a new Sapphire administration set to the pump without connecting it to the infusion container. Start an infusion at a rate of 100 mL/h. An Air in Line alarm should occur.<br>**Note**: To test the Air in Line alarm, ensure that air detection is enabled (ON) in the Technician options. If air detection has been disabled (OFF), the icon is displayed, and a warning message stating that air detection has been disabled (OFF) appears when programming an infusion. The Air in Line alarm will not be triggered. |
| 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.<br>Test the Downstream Occlusion alarm by repeating the above test, but closing the clamp or pinching the tubing downstream while the pump is running. |

If an alarm is not generated, contact your local representative or authorized technician.

The operator should stand 1 meter from the pump, and verify that he/she can hear and see the alarm.

For more information about the Air in Line and Occlusion alarms, refer to Alarm – Level 2, High Priority Alarms on page 278.

## Certification

To ensure proper fluid delivery, the pump should be checked by an authorized service provider at least once a year, to perform yearly certification. For more information on yearly maintenance procedures to be performed by technicians or certified service providers, refer to the Sapphire Infusion Pump Service Manual.

## 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 the main power supply) the battery charge level icon, at the upper right corner of the Indicators Bar, indicates remaining battery capacity. Check the status of the battery charge level icon regularly:

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

You can also check the status of the battery using the **Options** menu. For more information, refer to Viewing System Parameters on page 244.

Battery operation time is dependent upon the condition of the battery, which varies according to temperature conditions, and the extent of prior use of the battery.

For optimal performance, use the device (with battery) at Room Temperature (25°C).

An alarm is triggered when there are 30 minutes left until battery depletion, and again when there are 10 minutes left. 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. Make sure to test the batteries at least once a year, and replace the batteries every 2 years or every 500 charging cycles, whichever comes first.

## 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 Eitan Medical's rechargeable Lithium Ion (Li-Ion) battery is used.
- In case of rust, bad odor, overheating, and/or other irregularities when using the battery pack for the first time, return it to your local representative.
- Avoid any contact with water. Do not immerse the battery pack in water.
- Do not open the battery casing.
- Store batteries in a closed carton.
- Short term storage temperature should be below 35°C (95°F).
- Avoid battery exposure to direct sunlight.

## 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 (recommended up to 50% 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

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 once every 12 months.
The pump can operate while it is being charged.

| | |
|---|---|
| ⚠ | When using the pump while connected to the power supply, ensure that the pump is attached securely to the power supply, the mini cradle is attached securely to an IV pole, and the power cord is secure, to prevent entanglements that might cause strangulation. |

To preserve battery life, connect the pump to the main power supply using the power supply whenever possible.

| | |
|---|---|
| ℹ | While connected to a power supply and charging, the Charge (yellow) LED blinks, and stops blinking when the battery is fully charged.<br>If the pump is turned Off, the company logo appears on the screen while the pump is charging. |

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

**> To charge the battery:**

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

## Battery Maintenance

To promote maximum battery life, the following procedures should be performed at regular intervals.

| Frequency | Action |
|---|---|
| Following each use of the pump | Check the status of battery charge, and recharge as necessary. |
| Every 2 years or every 500 charging cycles | Replace batteries. |

# Transport and Storage

The pump should always be transported in a protective case internally padded with cushioning material. It is best to use the original packaging. During handling and transport, protect the pump and the case from water, excessive humidity, and heat sources.

To safeguard the pump against prolonged exposure to dust and moisture, the pump must be stored in a clean and dry environment. It is recommended that the pump remain plugged in during storage, in order to maintain the battery at full charge. If the pump is disconnected from the power supply, or is in storage without being connected to power for several months, check the battery level, and recharge the battery before using the pump (Charging the Battery on page 304).

For any storage period, make sure that the Sapphire administration cassette is disconnected from the pump, and that the safety door over the pump mechanism is closed. Specific recommendations for long term storage conditions are listed in the following table.

| Condition | Parameters |
|---|---|
| Temperature | -40°C (-40°F) to +70°C (+158°F) |
| Relative humidity | 15% RH to 95% RH |
| Atmospheric pressure | 50 kPa to 106 kPa (500 hPa to 1060 hPa) |

# Chapter 12: Technical Specifications

The following sections present technical specifications for the pump and its components:

Pump Accuracy ..... 306
Pump Specifications ..... 314
Average Bolus Volume After Occlusion ..... 316
Environmental Specifications ..... 317
Electromagnetic Compatibility Statement ..... 319

## Pump Accuracy

The following graphs and curves were derived from the pump accuracy testing procedures described in the IEC60601-2-24 standard. Testing was performed under normal conditions at room temperature (25°C, 72°F).
Normal conditions to ensure optimal accuracy of ±2.5%:

- Fluid level should be 50 cm above the pump
- No back pressure due to catheter size or difference in height of pump and infusion site
- Room temperature (25°C; 30-60% RH)
- Barometric pressure of sea level altitude (101kPa)
- IV medication with water like fluid characteristics

A tiered flow rate accuracy information is presented below with practical information of the pump accuracy under nominal and boundary conditions according to the pump specifications:

## Tiered Flow Rate Accuracy Specifications

Accuracy behavior in a wide range of practical use cases.

### Impact of Treatment-Related Parameters on Flow Rate Accuracy at Normal Environmental Conditions

| | Ranges | | |
|---|---|---|---|
| | Low | Nominal | High |
| Rates (mL/h)* | 0.1 | 0.1 up to 999 | 999 |
| Accuracy | ±2.5% for all three ranges | | |

* Testing is reported only for the 2nd and 96th hours

| Boluses | Rate: 10 mL/h<br>Volume: 0.1mL | Rate:125mL/h<br>Volume: 1mL | Rate: 600mL/h<br>Volume: 20mL | Rate: 999mL/h<br>Volume: 30 mL |
|---|---|---|---|---|
| Accuracy | ±2.5% for all three ranges | | | |

## Impact of External/Environmental Parameters on Flow Rate Accuracy

| Temperature (°C)* | 5-15 | 15-30 | 30-40 |
|---|---|---|---|
| Accuracy | Up to -3.6% | ±2.5% | Up to +3.5% |
| Altitude (Ft)† | -978 (Dead Sea) up to sea level | Sea level to 3600 | 3600 - 10,000 (e.g., some cities in Colorado state) |
| Accuracy | Within 2.5% for all three ranges | | |
| Backpressure (bar) | -0.133 up to 0 (requires combination of extreme parameters, e.g., patient is more than 1.5m below the pump while using a narrow catheter) | 0-0.2 | 0.2-0.5‡ |
| Accuracy | ±2.5% | ±2.5% | ±5% |
| Head Height (m) | -0.5 | -0.5 up to +0.5 | 0.5 |
| Accuracy | ±2.5% for all three ranges** | | |

* Testing was only performed at 600 mL/h.

† Testing was only performed at 25 mL/h.

‡ Higher backpressures (e.g. from use of thin catheters, backcheck valves, filters) will result in additional deviations: every increase of 0.05 bar will result in deviation of -3% in accuracy.

** When using accessories (e.g., PCA Lockboxes, Homecare Large Backpack and External Battery) where the container height deviates more than 50cm above or below the pump, there may be deviations in pump accuracy. A head height change (change in the fluid level above or below the pump) of ±25cm above the stated values may result in deviation in accuracy of ±1%.

### Impact of Viscosity

The table below shows the flow rates required to maintain the delivery accuracy at a worst case viscosity of 10.8cP.

| | Flow Rate (mL/h) | | | | |
|---|---|---|---|---|---|
| | 25 | 125 | 300 | 600 | 999 |
| Average | -1.13% | -3.47% | -3.10% | -5.43% | -11.49% |
| STDev | 0.82% | 1.12% | 2.48% | 1.98% | 0.32% |

## Start-up and Trumpet Graphs

The start-up graphs represent startup flow versus operating time for the first two hours from the start of the infusion. They exhibit the stability of delivery due to mechanical compliance and provide a visual representation of uniformity. Start-up graphs were performed according to the IEC 60601-2-24 standard.

In the Sapphire pump, as in all infusion systems, the action of the pumping mechanism and variations or external factors may cause fluctuations in rate accuracy. Conditions that can cause flow fluctuations include:

- Position of the infusion container
- Fluid density
- Positive and negative pressure
- Environmental temperature
- Operation of the pump beyond the recommended operating limits

Trumpet curves are named for their characteristic /shape, and are developed in accordance with IEC 60601-2-24. They display the percent flow rate deviation from the programmed rate over time. The horizontal axis represents the observation time intervals.

Over long observation windows, short-term fluctuation has little effect on accuracy, as represented by the flat part of the curve. As the observation window is reduced, short-term fluctuations have a greater effect, as represented by the "mouth" of the trumpet.

Figure 12.1. Delivery Startup Graph, First 2 Hours of Test Period, 1 mL/h

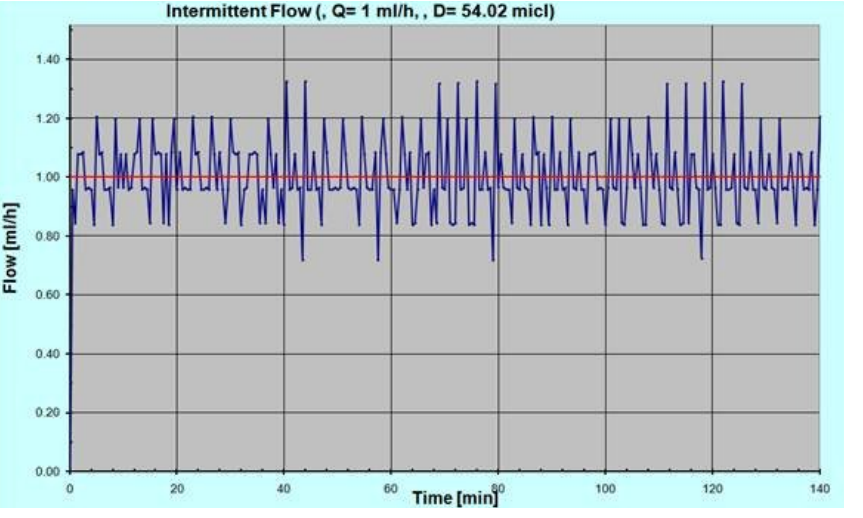


Figure 12.2. Trumpet Graph, Second Hour of Delivery, 1 mL/h

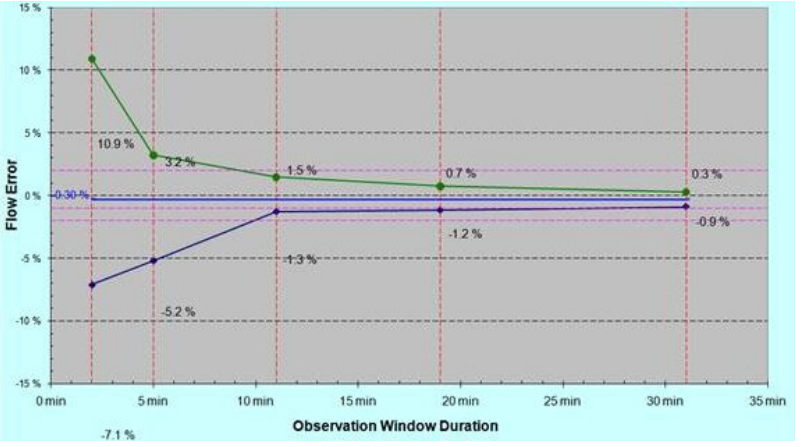



Figure 12.3. Trumpet Graph, 24th (Last) Hour of Delivery, 1 mL/h

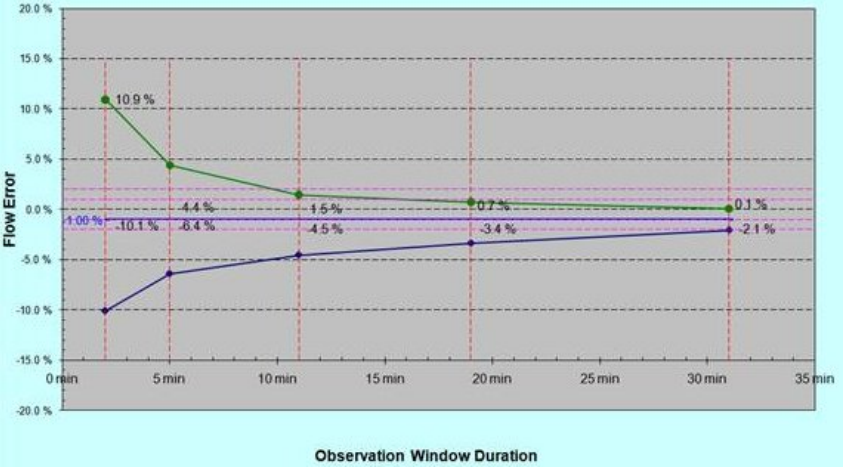


Figure 12.4. Delivery Startup Graph, First 2 Hours of Test Period, 25 mL/h

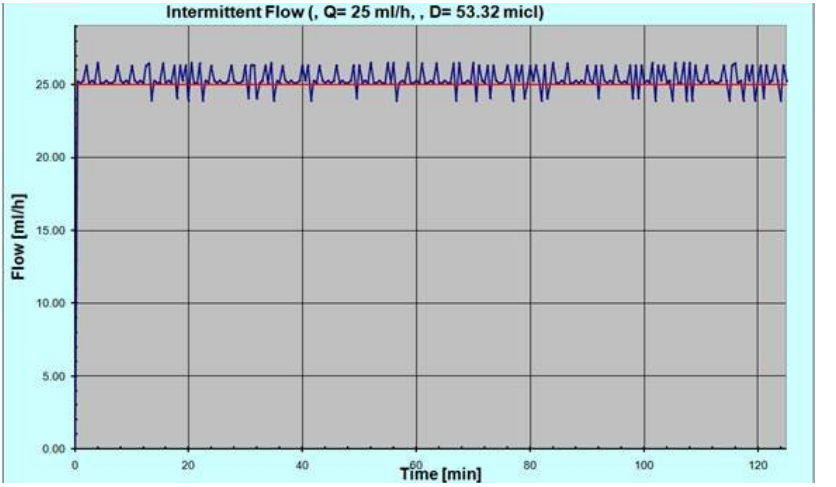


Figure 12.5. Trumpet Graph, Second Hour of Delivery, 25 mL/h

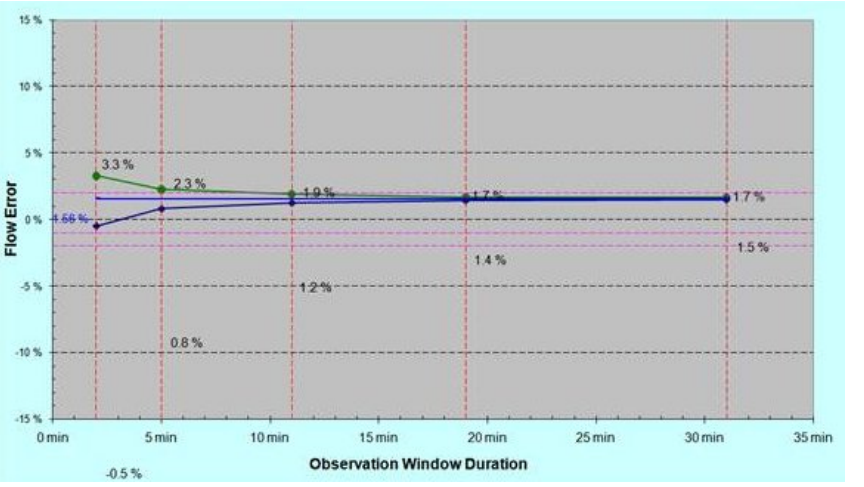
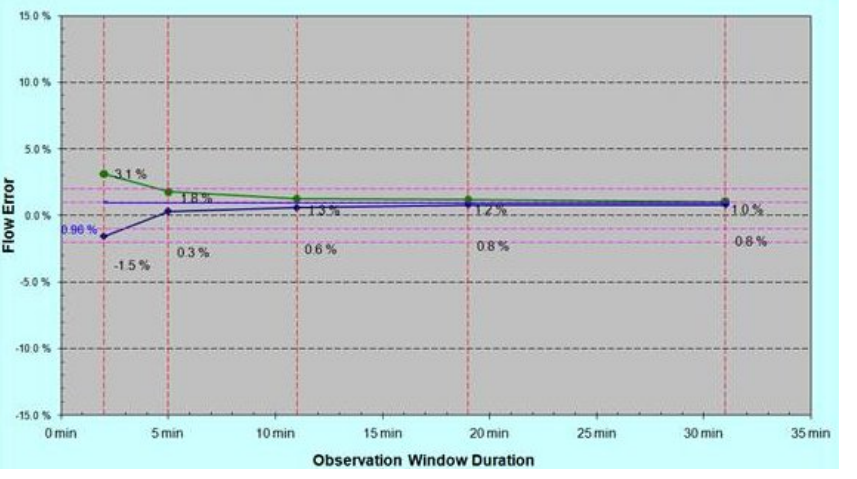



Figure 12.6. Trumpet Graph, 24th (Last) Hour of Delivery, 25 mL/h



## Pump Specifications

The following table lists and describes pump specifications.

| Parameter | Description |
|---|---|
| Dimensions | 143 x 96 x 49 mm (5.63 x 3.78 x 1.93 in.) (H x W x D) |
| Weight (excluding batteries) | 418 g (14.7 oz.) |
| Pumping mechanism | Single channel volumetric, with integral pressure sensor |
| Infusion delivery modes | Continuous (with and without a Secondary line), PCA, Intermittent, Multi-step, TPN, Epidural (PCEA, Epidural Intermittent) |
| KVO rate | Up to 20 mL/h in increments of 0.1 mL/h |
| Accuracy | ±2.5% (Subject to external conditions such as tubing, pressure, container position relative to the pump, barometric pressure, humidity and temperature) |
| Defibrillation proof - recovery time | Max 1 sec |
| Flow rate | 0.1 - 99.9 mL/h in increments of 0.1 mL/h<br>100 - 999 mL/h in increments of 1 mL/h |
| Volume (VTBI) | 0.1 - 9999 mL in increments of 0.1 mL |
| Infusion device | Volumetric, peristaltic |
| External power supply | 100 - 240V 50-60 Hz, 0.6A |
| Battery | • Rechargeable Li-Ion battery 7.4V, 1960 mA/h<br>• 24 hrs @ 125 mL/h (with a fully charged battery, and backlight Off)*<br>• Recharge time: up to 6 hrs (when pump is not in operation) |
| Adaptor | AC Adaptor 10 VDC/2.0A |
| Downstream occlusion | Up to 17.4 PSI (1.2 bar or 900 mmHg) |
| Operating temperature | +5° (41°F) to 40°C (104°F) |

| Parameter | Description |
| --- | --- |
| Alarms | Refer to full list of alarms in Chapter 10: Alarms and Troubleshooting on page 276. |
| Prime | Manual or automatic priming (600 mL/h, or from air in line alarm 900 mL/h). |
| Sensors | • **Air in line sensor:** Detects both single and accumulated bubbles sized 0.02-0.5 mL. The desired size range of each option can be selected by the technician.<br>• Upstream/Downstream occlusion sensor<br>• Door open sensor<br>• Temperature sensor |

* The specification of 24 hours @ 125 mL/h was tested at an ambient temperature, with a medication/fluid with viscosity of 1cP (water like). Test results support operational time of at least 24 hours (based on 90% reliability and 95% confidence level). The impact of worst-case (i) Rate, (ii) Temperature and (iii) viscosity parameters on battery operational time were evaluated separately (with a fully charged battery and backlight Off):

- At Rate of 800 mL/h – operational time will decrease to 18 hours
- At Temperature of 5°C – no reduction below 24 hours will occur
- At Viscosity of 10.8 Cp – no reduction below 24 hours will occur

## Average Bolus Volume After Occlusion

The following table presents the average time to a downstream occlusion alarm, and the bolus volume after occlusion, at a rate of 25 mL/h.

| Parameter | Pressure | |
|---|---|---|
| | **0.1 bar** | **1.2 bar** |
| Average bolus volume following downstream occlusion | 0.133 mL | 0.75 mL* |
| Average time to downstream occlusion alarm | 36 sec | 3 min |

* Under single fault condition

The following table presents the average time to a downstream occlusion alarm at a rate of 0.1 mL/h.

| Parameter | Pressure | |
|---|---|---|
| | **0.1 bar** | **1.2 bar** |
| Average time to downstream occlusion alarm | 01:14 hours | 12:30 hours |

In case of an occlusion (upstream or downstream), clear the occlusion by disconnecting the set from the patient and priming the administration set. When priming manually, close clamps and disconnect the patient from the administration set prior to detaching the administration cassette from the pump.

## Environmental Specifications

The pump should be operated within the temperature and humidity ranges specified below. To avoid damage to the pump or battery, do not store the pump or the administration set outside these temperature and humidity ranges. Do not store the pump for prolonged periods with the battery installed.

### Operating Conditions

Adhere to the following operating conditions:

| Condition | Details/Range |
|---|---|
| Operating mode | Long term infusion usage |
| Humidity | 15% to 95% (15% to 90% at transient state) |
| Temperature | +5°C to 40°C (41°F to 104°F)<br>(-20°C to +50°C at transient state) |
| Atmospheric pressure | 70 kpa to 106 kpa |

### Environmental Conditions for Transport and Storage

When transporting or storing the pump, adhere to the following conditions:

| Condition | Details/Range |
|---|---|
| Atmospheric pressure | 50 kPa to 106 kPa (500 hPa to 1060 hPa) |
| Relative humidity | 15% to 95% |
| Temperature | -40°C to +70°C (-40°F to 158°F) |

Do not disassemble the portion of the Sapphire pump that houses the pump mechanism and the electronics. This should be done by authorized personnel only; Eitan Medical Ltd. will not be obligated to provide technical service in such a case.

When storing batteries separately from the pump, maintain the following storage temperature ranges:

| Type of Storage | Temperature Range |
|---|---|
| Short term | <40°C (<95°F) |
| Long term | -20°C (-4°F) to +35°C (+95°F)<br>Recommended: 23° ±3°C (73° ±5°F) |

Storage at low temperatures may affect initial battery performance.
Storage at high temperatures may degrade battery performance.

The following list provides guidelines about environmental conditions and situations to be avoided when working with or storing the pump:

- Avoid locations where there is inadequate ventilation.
- Avoid locations where sudden impact or vibration may occur.
- Avoid damp locations, or locations where moisture level may increase considerably.
- Avoid locations with large temperature fluctuations.
- Avoid locations exposed to direct sunlight.
- Avoid locations near an electrical heating apparatus.
- Avoid locations exposed to chemicals or explosive gases.

# Electromagnetic Compatibility Statement

The following sections provide information about testing of and recommendations for:

Electromagnetic Emission ..... 319
Electromagnetic Immunity ..... 320
Recommended Separation Distances from Mobile RF Communication Equipment ..... 324

## Electromagnetic Emission

The infusion system is intended for use in the electromagnetic environment specified below. The customer or the user of the infusion system should ensure that it is used in such an environment.

### Declaration - Electromagnetic Emissions

| Emission Test | Compliance | Electromagnetic Environment Guidance |
|---|---|---|
| RF emission CISPR 11 | Group 1 Class B | The infusion system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. |
| Harmonic emissions IEC 610003-3-2 | Class B | The infusion system is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| Voltage fluctuations /and Flicker emissions IEC 61000-3-3:2013 | Complies | |

## Electromagnetic Immunity

The infusion system is intended for use in the electromagnetic environment specified below. The customer or the user of the infusion system should ensure that it is used in such an environment.

### Table 12.1. **Declaration - Electromagnetic Immunity**

| Immunity Test | IEC 60601 Test Level | Compliance Level | Electromagnetic Environment Guidance |
|---|---|---|---|
| Electrostatic discharge (ESD) IEC 61000-4-2 | 2,4,8 kV contact<br>2, 4, 8, 15kV air | 2,4,8 kV contact<br>2, 4, 8, 15kV air | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %. |
| Electrical fast transient/burst IEC 61000-4-4 | 2 kV for power supply lines<br>1 kV for input/ output lines | 2 kV for power supply lines<br>N/A | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge IEC 61000-4-5 | 1 kV line(s) to line(s)<br>2 kV line(s) to earth<br>2 kV Signal input/ output) to earth | 1 kV line(s) to line(s)<br>2 kV line(s) to earth<br>N/A | Mains power quality should be that of a typical commercial or hospital environment. |
| Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 | 0% UT*; 0.5cycle at 0°, 45°, 90°, 135°,180°, 225°, 270° and 315°<br>0% UT; 1cycle and 70% UT; 25/30 cycles<br>Single phase at 0°<br>0% UT; 250/300 cycle | 0% UT; 0.5cycle at 0°, 45°, 90°, 135°,180°, 225°, 270° and 315°<br>0% UT; 1cycle and 70% UT; 25/30 cycles<br>Single phase at 0°<br>0% UT; 250/300 cycle | Mains power quality should be that of a typical commercial or hospital environment. If the user of the infusion system requires continued operation during power mains interruptions, it is recommended that the infusion system be powered from an uninterruptible power supply or a battery. |

| Immunity Test | IEC 60601 Test Level | Compliance Level | Electromagnetic Environment Guidance |
|---|---|---|---|
| Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 | 30 (A/m) | 30 (A/m) | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |

* UT is the A.C. mains voltage prior to application of the test level.

## Electromagnetic Immunity for Life-supporting Equipment and Systems

The infusion system is intended for use in the electromagnetic environment specified below. The customer or the user of the infusion system should ensure that it is used in such an environment.

Portable and mobile RF communications equipment should be used no closer to any part of the infusion system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.

Interference may occur in the vicinity of equipment marked with the symbol.

## Table 12.2. **Declaration - Electromagnetic Immunity**

| Immunity Test | IEC 60601 Test Level | Compliance Level | Electromagnetic Environment Guidance* |
|---|---|---|---|
| Conducted RF IEC 61000-4-6 | 3 Vrms 0,15 MHz - 80 MHz 6 Vrms in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz | 3 Vrms 0,15 MHz - 80 MHz 6 Vrms in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz | Portable and mobile RF communications equipment should be used no closer to any part of the infusion system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$ $d = \left[\frac{12}{V_2}\right]\sqrt{P}$ $d = \left[\frac{12}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{23}{E_1}\right]\sqrt{P}$ 800 MHz to 2.5 GHz |

| Immunity Test | IEC 60601 Test Level | Compliance Level | Electromagnetic Environment Guidance* |
|---|---|---|---|
| Radiated RF IEC 61000-4-3 | 10V/m, 80MHz to 2.7GHz, 80% AM at 1kHz | 10V/m, 80MHz to 2.7GHz, 80% AM at 1kHz | where **p** is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer, and **d** is the recommended separation distance in meters (m).<br>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.<br>D Interference may occur in the vicinity of equipment marked with the following symbol:<br> |
| Proximity magnetic fields IEC 61000-4-39 | 8 A/m (30 kHz, CW)<br><br>65 A/m (134.2 kHz, pulse modulation 2.1 kHz)<br><br>7.5 A/m (13.56 MHz, pulse modulation 50 kHz) | 8 A/m (30 kHz, CW)<br><br>65 A/m (134.2 kHz, pulse modulation 2.1 kHz)<br><br>7.5 A/m (13.56 MHz, pulse modulation 50 kHz) | Infusion System containing magnetically sensitive components or circuitry where a separation distance of those components or circuitry of at least 0,15 m from the field sources specified in table below is ensured by the ENCLOSURE or by the physical design of an attached ACCESSORY during INTENDED USE need not be evaluated further for IMMUNITY to proximity magnetic fields in the frequency range 9 kHz to 13,56 MHz. |

* These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Notes

1. The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.
2. The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.
   For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.
3. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Sapphire infusion system is used exceeds the applicable RF compliance level above, the infusion system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the infusion system. Electromagnetic disturbances may result in alarms and pump stoppage.
4. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

## Recommended Separation Distances from Mobile RF Communication Equipment

The infusion system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer/infusion system user can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the infusion system, according to the maximum output power of the communications equipment. The following table provides recommended separation distances between portable and mobile RF communication equipment and the infusion system (for life-supporting equipment and systems).

For transmitters rated at a maximum output power not listed in the table, the recommended separation distance *d* in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where *p* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

## Table 12.3. **Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Infusion System**

| Rated Maximum Output Power of Transmitter (W) | Separation Distance According to Frequency of Transmitter (m) | | | |
|---|---|---|---|---|
| **Rated Maximum Output Power of Transmitter (W)** | **150 kHz to 80 MHz outside ISM Bands** | **150 kHz to 80 MHz in ISM Bands** | **80 MHz to 800 MHz** | **800 MHz to 2.5 GHz** |
| | $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$ | $d = \left[\frac{12}{V_2}\right]\sqrt{P}$ | $d = \left[\frac{12}{E_1}\right]\sqrt{P}$ | $d = \left[\frac{23}{E_1}\right]\sqrt{P}$ |
| 0.01 | 0.12 | 0.20 | 0.40 | 1 |
| 0.1 | 0.37 | 1.64 | 1.30 | 2.6 |
| 1 | 1.17 | 2.00 | 4.0 | 8 |
| 10 | 3.7 | 6.4 | 13.0 | 26 |
| 100 | 11.7 | 20.00 | 40 | 80 |

Table 12.4. **Test Specifications for ENCLOSURE PORT IMMUNITY to RF Wireless Communications Equipment**

| Test Freq. (MHz) | Band (MHz) | Service | Modulation | Immunity Test Level (V/m) |
|---|---|---|---|---|
| 385 | 380 -390 | TETRA 400 | Pulse modulation 18 Hz | 27 |
| 450 | 430 - 470 | GMRS 460, FRS 460 | FM ±5 kHz deviation 1 kHz sine | 28 |
| 710 | 704 - 787 | LTE Band 13, 17 | Pulse modulation 217 Hz | 9 |
| 745 | | | | |
| 780 | | | | |
| 810 | 800 - 960 | GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5 | Pulse modulation 18 Hz | 28 |
| 870 | | | | |
| 930 | | | | |
| 1720 | 1 700 - 1 990 | GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS | Pulse modulation 217 Hz | 28 |
| 1845 | | | | |
| 1970 | | | | |
| 2450 | 2 400 - 2 570 | Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7 | Pulse modulation 217 Hz | 28 |
| 5240 | 5 100 - 5 800 | WLAN 802.11 a/n | Pulse modulation 217 Hz | 9 |
| 5500 | | | | |
| 5785 | | | | |

## Table 12.5. **Test specifications for ENCLOSURE PORT IMMUNITY to Proximity Magnetic Fields**

| Test Frequency | Modulation | Immunity Test Level (A/m) |
|---|---|---|
| 30 kHz | CW | 8 |
| 134,2 kHz | Pulse modulation 2.1 kHz | 65 |
| 13,56 MHz | Pulse modulation 50 kHz | 7.5 |

Notes

1. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
2. At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
3. The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.
4. An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz.
   This decreases the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

# Chapter 13: Limited Warranty

Eitan Medical Ltd. (the "**Manufacturer**") warrants to the buyer who purchased the Sapphire directly from the Manufacturer (the "**Initial Buyer**") that the Sapphire Infusion Pump ("**Sapphire**"), shall be free from defects in materials and workmanship under normal use, if used in accordance with this User Manual, for a period of 2 years from the actual date of sale to the Initial Buyer (the "**Warranty Period**"). The Warranty Period provided with respect to the Sapphire Connect shall be 6 months from the actual date of sale to the Initial Buyer. OTHER THAN AS EXPLICITLY SET FORTH HEREIN, NO OTHER WARRANTIES ARE BEING PROVIDED.

This warranty does not cover normal wear and tear and maintenance items, (such as the Yearly Certification Kit), and specifically excludes batteries, administration sets, extension sets or any other accessory items or equipment used with the Sapphire.

Subject to the conditions of and upon compliance with this Limited Warranty, the Manufacturer will repair or replace at its option without charge (except for a nominal charge for postage and handling) any defective Sapphire or Sapphire Connect, as the case may be, provided a claim is made during the applicable Warranty Period.

The following conditions, procedures, and limitations apply to the Manufacturer's obligation under this warranty:

A. **Parties Covered by this Warranty**: This Warranty extends only to the Initial Buyer of the Sapphire or Sapphire Connect, as the case may be.

**Warranty Performance Procedure**: Notice of the claimed defect must be made by Initial Buyer in writing to the Manufacturer as follows:

Eitan Medical Ltd., 29 Yad Haruzim St., P.O. Box 8639, Netanya, 4250529, Israel. Initial Buyer should send mail to support@eitanmedical.com or contact the account manager. Notice to the Manufacturer must include date of purchase, serial number, and a description of the claimed defect in sufficient detail to allow the Manufacturer to determine and facilitate any repairs which may be necessary. AUTHORIZATION MUST BE OBTAINED PRIOR TO RETURNING THE SAPPHIRE OR SAPPHIRE CONNECT, as the case may be. If authorized, the Sapphire or Sapphire Connect, as the case may be, must be properly and carefully cleaned, packaged and returned to the Manufacturer. Any loss or damage during shipment is at the risk of the sender.

B. **Conditions of Warranty**: The warranty is void if the Sapphire or Sapphire Connect, as the case may be, has been

1) repaired by someone other than the Manufacturer or its authorized agent

2) altered so its stability or reliability is affected

3) misused or

4) damaged by negligence or accident. Misuse includes, but is not limited to, use not in compliance with the User Manual or use with non-approved accessories. Removal or damage to the Sapphire's or Sapphire Connect serial number, as the case may be, will invalidate this warranty.

C. **Limitations and Exclusions**: Repair or replacement of the Sapphire or Sapphire Connect, as the case may be, or any component part therefore is the EXCLUSIVE remedy offered by Manufacturer. The following exclusions and limitations shall apply:

1. No agent, representative, or employee of the Manufacturer has authority to bind the Manufacturer to any representation or warranty, expressed or implied.

2. THERE IS NO WARRANTY OF MERCHANTABILITY OR FITNESS OR USE OF THE SAPPHIRE OR SAPPHIRE CONNECT, as the case may be, FOR ANY PARTICULAR PURPOSE.

3. The Sapphire or Sapphire Connect, as the case may be, can only be used under the instruction of medical personnel whose skill and judgment determine the suitability of the Sapphire for any particular medical treatment.

4. All recommendations, information, and descriptive literature supplied by the Manufacturer or its agents are believed to be accurate and reliable, but do not constitute warranties.

The Manufacturer disclaims responsibility for the suitability of the Sapphire for any particular medical treatment or for any medical complications resulting from the use of the Sapphire. The Manufacturer shall not be responsible for any incidental damage or consequential damages to property, loss of profits, or loss of use caused by any defect or malfunction of the Sapphire or Sapphire Connect, as the case may be.

Notwithstanding the foregoing, it is acknowledged that the warranty terms set forth above are subject to and governed by any applicable law.

## Service Information

While under Eitan Medical warranty, the Sapphire pump must not be opened by unauthorized personnel.

Use only an authorized Eitan Medical service provider for service and repair. In the event that your pump needs to be returned for service, contact your local representative, or obtain a Return Authorization by filling an inquire form through the Eitan Medical website. The pump must be packed in a suitable container that will provide adequate protection during shipment. To ensure prompt return, a Eitan Medical authorized service representative must be notified before shipping any pump for repair. When calling for service, please be prepared to provide the serial number of the pump and software version details. A brief written description of the problem should be attached to the pump when it is returned for service.

Eitan Medical Ltd. will not be responsible for unauthorized returns or for pumps damaged in shipment due to improper packing. The Sapphire pump service life is 7 years from the date of manufacture.

## Technical Support Contacts

For technical assistance, contact your local representative, or contact Eitan Medical by filling an inquire form through the Eitan Medical website https://eitanmedical.com/.

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