



# Sapphire™

## Manual Configuration Settings

Software Revision 16.20 ,16.00



# Configuration Settings

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## Please set the authorization level to: "Technician"

Prior to configuring the pump, the authorized technician must read the Sapphire™ Infusion Pump Service Manual. Mode specific settings will only be visible when in that selected mode.

The pump configuration is set by the drug library, but local changes on the pump can be temporarily made.

**Note:** This advisory document does not replace the official Instructions for Use. Read the User Manual and any instructions accompanying disposables or accessories before operating the Sapphire device.



# Configuration Settings

## Pump Configuration | Alarms



### Alarms

Modes	Parameter	Options/Range	Default Setting	Facility Setting	Parameter Description
All	Occlusion Units	BAR, PSI, mmHg	BAR		The format of occlusion units.
All	Occlusion Pressure	0.1-1.2 (BAR) 1.5-17.4 (PSI) 75-900 (mmHg)	0.4 (BAR)		The minimum downstream pressure that triggers an occlusion alarm.
All	Pump Unattended	2 min, 5 min, 10 min	10 min		The number of consecutive minutes of no interaction with the pump after which a "Pump Unattended" alarm is triggered. <b>Note:</b> A "Pump Unattended" alarm is not triggered when the pump is in "Delayed Start" or "Standby".
All	Infusion Near End	1 min, 3 min, 5 min, 10 min, Off	10 min		The number of minutes before completion of an infusion at which an "Infusion Near End" alarm is generated.
All	Alarm Volume	Maximum, Minimum	Maximum		Sets the speaker volume for the auditory alarm signal. <b>Maximum:</b> Errors and alarms sound level is 68 dB, messages sound level is 59 dB. <b>Minimum:</b> Errors and alarms sound level is 65 dB, messages sound level is 45 dB.

### Audio Settings

Modes	Parameter	Options/Range	Default Setting	Facility Setting	Parameter Description
All	Keys Volume	Low, High, Off	High		Sets the speaker volume for the auditory signal generated when users select functions and press keys on the pump.
All	Alarm Volume	Maximum, Minimum	Maximum		Sets the speaker volume for the auditory alarm signal. <b>Maximum:</b> Errors and alarms sound level is 68 dB, messages sound level is 59 dB. <b>Minimum:</b> Errors and alarms sound level is 65 dB, messages sound level is 45 dB.
<u>PCA</u> <u>PCEA</u> <u>Intermittent</u>	Bolus Handle	Always On, When Bolusing	Always On		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.

# Configuration Settings

## Pump Configuration | General Settings



### General Settings

Modes	Parameter	Options/Range	Default Setting	Facility Setting	Parameter Description
All	Start Up Configuration: Repeat Last Infusion	On, Off	On		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.
All	Start Up Configuration: PreProgram	On, Off	Off		Allows the user to start an infusion using predefined parameters. When the option is enabled, the "PreSet Programs" button appears on the pump "Start Up" screen.
All	Authorization Level	Low, Medium, High, Tech (Technician)	NA		Sets the authorization lock level of the pump.
All	Allow Delayed Start	On, Off	Off		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".
All	Set Prime Volume	2-25 mL	20 mL		The amount of fluid used to prime the administration set when automatic priming is performed.
All	Backlight	On, Off, Partial	On		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.
All	Prime Reminder	On, Off	Off		Enables a reminder for the user to prime the administration set before starting an infusion.

### General Settings (Cont.)

Modes	Parameter	Options/Range	Default Setting	Facility Setting	Parameter Description
<u>Continuous</u>	Advanced Bolus	On, Off	Off		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.
<u>PCA</u> <u>PCEA</u> <u>Intermittent</u>	Bolus Reminder	On, Off	Off		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: <ul style="list-style-type: none"> <li>• Instructs to connect the bolus handle directly to the pump.</li> <li>• Checks functionality-bolus press is recognized by the pump.</li> </ul>
All	Auto Patient Lockout	On, Off	Off		Enables/disables patient lockout, a safety feature that requires password entry to make any parameter changes. When the option is enabled, patient lockout is activated automatically as the infusion begins, and automatically re-activated throughout the infusion.
All	Screen Saver	On, Off	Off		Enables/disables a far-view display of the main infusion parameters during a running infusion. The screen saver appears 30 seconds after the infusion program has started, and the pump has not been touched.

# Configuration Settings

## Pump Configuration | Regional



### Regional

Modes	Parameter	Options/Range	Default Setting	Facility Setting	Parameter Description
All	Date	dd/mm/yr mm/dd/yr*	mm/dd/yr		The regional menu controls date, time, language and US format settings.
All	Time	Current Time	12 hour clock		
All	Language	English	English		
All	US Format	On, Off	On		

\* When US format is enabled.



# Configuration Settings

## Mode Specific Options | PCA Options



### PCA Options

Modes	Parameter	Options/Range	Default Setting	Facility Setting	Parameter Description
<u>PCA</u>	Bolus Rate	1-600 mL/h	125 mL/h		The rate at which a bolus (patient bolus, clinician bolus and loading dose) is delivered.
	Allow Loading Dose	On, Off	On		Enables the user to program a loading dose (starting the infusion with a clinician bolus).
	Infusion Type	Bolus Only, Continuous Only, Continuous + Bolus	Continuous + Bolus		Defines the PCA infusion type that is available for the user.
	Limit Period	4 hours 1 hour	1 h(s)		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 maximum volume).

# Configuration Settings

## Mode Specific Options | PCEA Options



### Epidural PCEA Options

Modes	Parameter	Options/Range	Default Setting	Facility Setting	Parameter Description
<b>PCEA</b>	Bolus Rate	125 mL/h 200 mL/h 300 mL/h 400 mL/h 500 mL/h	125 mL/h		The rate at which a bolus (patient bolus, clinician bolus and loading dose) is delivered.
	Password Request	No, Yes	No		Enables a safety feature that requires a high authorization level password entry for programming and editing actions.
	Allow Loading Dose	On, Off	On		Enables the user to program a loading dose (starting the infusion with a clinician bolus).
	Infusion Type	Bolus Only, Continuous Only, Continuous + Bolus	Continuous + Bolus		Defines the PCEA infusion type that is available for the user.
	Limit Period	4 hours 1 hour	1 h(s)		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).

# Configuration Settings

## Mode Specific Options | Epidural Intermittent (Epi. Int) Options



### Epidural Intermittent Options

Modes	Parameter	Options/Range	Default Setting	Facility Setting	Parameter Description
<b>Epidural Intermittent</b>	Dose Rate	125 mL/h 200 mL/h 300 mL/h 400 mL/h 500 mL/h	125 mL/h		The rate at which an intermittent dose is delivered.
	Password Request	No, Yes	No		Enables a safety feature that requires a high authorization level password entry for programming and editing actions.
	Limit Period	4 hours 1 hour	1 h(s)		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*	On, Off	Off		Enables the user to program a PIEB infusion.

\*PIEB - Programmed Intermittent Epidural Bolus

# Configuration Settings

## Technician Options | Pump Settings | Set Hard Limits



### Set Hard Limits: Mode Specific

Modes	Parameter	Options/Range	Default Setting	Facility Setting	Parameter Description
<u>Continuous</u>	Primary VTBI	1-9,999 mL	9,999 mL		The total amount of fluid to be infused in a primary infusion.
	Primary Rate	0.1-999 mL/h	999 mL/h		The speed at which the fluid is infused in a primary infusion.
	Secondary VTBI	1-9,999 mL	9,999 mL		The total amount of fluid to be infused in a secondary infusion. In order to configure: "Set Secondary" must be turned "On" in the general menu.
	Secondary Rate	0.1-500 mL/h	500 mL/h		The speed at which the fluid is infused in a secondary infusion. In order to configure: "Set Secondary" must be turned "On" in the general menu.
<u>Intermittent</u>	VTBI	1-9,999 mL	9,999 mL		The total amount of fluid to be infused.
	Maximum Dose Time	00:01-96:00 h:min	96:00 h:min		The maximum period of time over which the intermittent dose is delivered.
	Intermittent Dose	0.1-999 mL/h	999 mL/h		The amount of each intermittent dose.

# Configuration Settings

## Technician Options | Pump Settings | Set Hard Limits



### Set Hard Limits: Mode Specific (Cont.)

Modes	Parameter	Options/Range	Default Setting	Facility Setting	Parameter Description
<u>Multi-step</u>	VTBI	1-9,999 mL	9,999 mL		The total amount of fluid to be infused.
	Rate	0.1-999 mL/h	999 mL/h		The speed at which the fluid is infused.
	Time	00:01-24:00 h:min	24:00 h:min		The period of time over which the fluid is infused. The range for the "Time value" varies according to the VTBI and "Rate".
<u>PCA</u>	VTBI	1-9,999 mL	9,999 mL		The total amount of fluid to be infused.
	Continuous Rate	0.1-99.9 mL/h	99.9 mL/h		The rate of the basal infusion.
	Demand Bolus	0.1-30 mL	20 mL		The amount of fluid infused in a single bolus. Changing the hard limits of the "Demand Bolus" parameter also applies to the "Clinician Bolus" parameter.
	Loading Dose	0.1-30 mL	20 mL		An optional feature that begins the infusion with a clinician bolus.
	Bolus Rate	1-600 mL/h	600 mL/h		The speed at which the bolus is infused.
	Minimum Bolus Lockout	00:01-24:00 h:min	00:01 h:min		The minimum time that must pass between the end of one bolus to the start of the next bolus.
	Maximum Bolus Lockout	00:01-24:00 h:min	24:00 h:min		The maximum time that is allowed between the end of one bolus to the start of the next bolus.

# Configuration Settings

## Technician Options | Pump Settings | Set Hard Limits



### Set Hard Limits: Mode Specific (Cont.)

Modes	Parameter	Options/Range	Default Setting	Facility Setting	Parameter Description
<u>TPN</u>	VTBI	1-9,999 mL	9,999 mL		The total amount of fluid to be infused.
	VTBI	1-9,999 mL	9,999 mL		The total amount of fluid to be infused.
<u>Epidural</u>	Continuous Rate	0.1-25 mL/h	25 mL/h		The speed at which the fluid is infused.
	Demand Bolus	0.1-30 mL	20 mL		The amount of fluid infused in a single bolus. Changing the hard limits of the "Demand Bolus" parameter also applies to the "Clinician Bolus" parameter.
	<u>PCEA</u> Loading Dose	0.1-30 mL	20 mL		An optional feature that begins the infusion with a clinician bolus.
	Minimum Bolus Lockout h:min	00:01-24:00 h:min	00:01 h:min		The minimum time that must pass between the end of one bolus to the start of the next bolus.
	Maximum Bolus Lockout h:min	00:01-24:00 h:min	24:00 h:min		The maximum time that is allowed between the end of one bolus to the start of the next bolus.

# Configuration Settings

## Technician Options | Pump Settings | Set Hard Limits



### Set Hard Limits: Mode Specific (Cont.)

Modes	Parameter	Options/Range	Default Setting	Facility Setting	Parameter Description
<b>Epidural</b> <b><u>Intermittent</u></b>	VTBI	1-9,999 mL	9,999 mL		The total amount of fluid to be infused.
	Intermittent Dose	0.1-30 mL/h	20 mL		The amount of each intermittent dose.
	Demand Bolus*	0.1-30 mL	20 mL		The amount of fluid infused in a single bolus. Changing the hard limits of the "Demand Bolus" parameter also applies to the "Clinician Bolus" parameter.
	Minimum Bolus Lockout*	00:01-24:00 h:min	00:01 h:min		The minimum time that must pass between the end of one bolus to the start of the next bolus.
	Maximum Bolus Lockout*	00:01-24:00 h:min	24:00 h:min		The maximum time that is allowed between the end of one bolus to the start of the next bolus.

\*Available when PIEB is enabled under Epidural Intermittent Options.

# Configuration Settings

## Technician Options | Pump Settings | Set KVO



### Set KVO

Modes	Options/Range	Default Setting	Facility Setting	Parameter Description
<u>Continuous</u>	0-20 mL/h	3 mL/h		The KVO screen of each delivery mode provides access to setting KVO* rates for all other delivery modes, with the exception of Intermittent and Epidural Intermittent. For Intermittent and Epidural Intermittent, KVO rate is programmed for every infusion.
<u>Multi-step</u>	0-20 mL/h	3 mL/h		
<u>PCA</u>	0-20 mL/h	0 mL/h		
<u>TPN</u>	0-20 mL/h	3 mL/h		
<u>Epidural</u>	0-20 mL/h	0 mL/h		

\* When the infusion is completed (entire programmed VTBI has been delivered), the pump automatically activates the KVO (the default or the infusion rate, the lower of the two)



# Configuration Settings

## Technician Options | Pump Settings | Set Air Detector



### Set Air Detector

Modes	Parameter	Options/Range	Default Setting	Facility Setting	Parameter Description
All	Single Air Detector	0.02 mL, 0.04 mL, 0.05 mL, 0.1 mL, 0.2 mL, 0.5 mL, Off	Off		In this mechanism, when a single bubble, equal to or larger than a user-selected size, passes through the detector, an alarm is triggered.
All	Accumulated Air Detector	0.02 mL, 0.04 mL, 0.05 mL, 0.1 mL, 0.2 mL, 0.5 mL	0.5 mL		In this mechanism, the user selects the values for both accumulated bubble size and the accumulated amount (threshold). Any single bubble equal to or larger than the selected accumulated bubble size is included in the counter of accumulated air. When the total amount of accumulated air reaches the selected accumulated threshold value in a 15 minute period, an alarm is triggered.
All	Accumulated Threshold	0.5 mL, 1 mL, Off	1 mL		
All Excluding Epidural	Air Detection	On, Off*	On		Determines whether the pump air detection is disabled (Off) or enabled (On) during infusion. This feature should be used when meeting the clinical practice and guidelines and coupled with an alternative method of eliminating air. When the air detection is disabled (Off) the user is prompted to use a set with an air-eliminating filter.

\* The "Off" option is available only for countries with MDR regulation.

# Configuration Settings

## Technician Options | Pump Settings | Reset System



### Reset System: Passwords

Modes	Parameter	Options/Range	Default Setting	Facility Setting	Parameter Description
All	High Level	1000-7000	****		<p>To help ensure patient safety, the Sapphire™ pump can be set to one of four authorization levels. Only a Technician authorization level may set the customized default setting.</p> <ul style="list-style-type: none"><li>• <b>Low:</b> All programming options are disabled, and no settings can be changed.</li><li>• <b>Medium:</b> Basic programming options, such as using shortcuts to start infusions, are enabled.</li><li>• <b>High:</b> All tasks and configuration settings are enabled, except for options limited to technician use.</li><li>• <b>Technician:</b> All settings are enabled. This level is restricted to technicians and developers only.</li></ul>
All	Medium Level	1000-7000	****		
All	Low Level	1000-7000	****		
All	PreProgram	1000-9999	****		

# Configuration Settings

## Technician Options | Pump Settings | General



### General: Mode Specific

Modes	Parameter	Options/Range	Default Setting	Facility Setting	Parameter Description
Delivery Modes (for Epidural Intermittent)	<u>Continuous</u>	On, Off	On		Determines the available delivery modes. Each mode can be turned off separately.
	<u>Multi-step</u>	On, Off	On		
	<u>Intermittent</u>	On, Off	On		
	<u>TPN</u>	On, Off	On		
	<u>PCA</u>	On, Off	On		
	<u>PCEA</u>	On, Off	On		
	<u>Epidural Intermittent</u>	On, Off	On		
All	New Patient	On, Off	Off		The Sapphire™ pump allows you to associate infusions to a specific patient. When "New Patient" feature is enabled, the "New Patient" screen appears. The pump calculates the accumulated volume infused and accumulated bolus history and zeroes them out when "New Patient" is identified during programming.

# Configuration Settings

## Technician Options | Pump Settings | General



### General: Mode Specific (Cont.)

Modes	Parameter	Options/Range	Default Setting	Facility Setting	Parameter Description
<u>Continuous</u>	Set Secondary (Piggyback)	On, Off	Off		Allows users to program a Secondary infusion.
	Allow Bolus	On, Off	Off		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.
	Bolus Rate	0.1-999 mL/h	125 mL/h		Specifies the rate of delivery of a fast dose, for rapid volume infusion.
	Secondary Bolus Rate	0.1-500 mL/h	125 mL/h		Specifies the rate of delivery of a fast dose for a Secondary (Piggyback) infusion.
All	Occlusion Auto-restart	On, Off	On		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.
All Excluding TPN	Calculate Concentration	On, Off	Off		Determines if the users enter final concentration or "Drug Amount" and "Diluent Volume".
All Excluding TPN	mL/h only	On, Off	Off		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.
All	Medium Titration	On, Off	Off		Allows users with medium authorization level to change rate during a running infusion.

# Configuration Settings

Technician Options | **Pump Settings** | General



## Sapphire™ PreSet Programs

Mode

Program Name

Content

Approver's Name

# Configuration Settings

Technician Options | **Pump Settings** | General



## Sapphire™ PreSet Programs

Mode

Program Name

Content

Approver's Name

# Configuration Settings

Technician Options | **Pump Settings** | General



## Sapphire™ Configuration Settings Defined And Agreed

Name

Date

Signature





[support@eitanmedical.com](mailto:support@eitanmedical.com) | [www.eitanmedical.com](http://www.eitanmedical.com)