



SAPPHIRE
by Eitan Group

Manual Configuration Settings

SAPPHIRE™ INFUSION PUMP

Software revision R15



Please set the authorization level to: "Technician"

Note: 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	0.4-1.2 (BAR) 5.8-17.4 (PSI) 300-900 (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. Note: 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. Note: The "Infusion Near End" alarm is triggered once each treatment.
All	Alarm Volume	Maximum, Minimum	Maximum		Sets the speaker volume for the auditory alarm signal. When the option is set to Minimum, messages are provided with a visual signal only. Alarm levels 1, 2 and 3, and the "Infusion Complete" message are provided with a visual signal and the lowest auditory signal permitted. Refer to the User Manual for Level 1, 2, 3 alarm details.

CONFIGURATION SETTINGS

Pump Configuration | Audio Settings

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. When the option is set to Minimum, messages are provided with a visual signal only. Alarm levels 1, 2 and 3, and the "Infusion Complete" message are provided with a visual signal and the lowest auditory signal permitted. Refer to the User Manual for Level 1, 2, 3 alarm details.
<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 in parameters. When the option is enabled, the PreSet Programs button appears on the pump Start Up screen.
All	Authorization Level	Low, Medium, High, 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.

CONFIGURATION SETTINGS

Pump Configuration | General Settings

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">• Instructs to connect the bolus handle directly to the pump.• Checks functionality - bolus press is recognized by the pump.
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 hr(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
	Bolus Rate	125 mL/h 200 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.
<u>PCEA</u>	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
Epidural <u>Intermittent</u>	Dose Rate	125 mL/h 200 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	1-9999 mL	9999 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	1-9999 mL	9999 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	1-9999 mL	9999 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	1-9999 mL	9999 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 acceptable range for time values vary according to the VTBI.
<u>PCA</u>	VTBI	1-9999 mL	9999 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	1-9999 mL	9999 mL		The total amount of fluid to be infused.
	VTBI	1-9999 mL	9999 mL		The total amount of fluid to be infused.
	Continuous Rate	0.1-25 mL/h	25 mL/h		The speed at which the fluid is infused.
Epidural	Demand Bolus	0.1-30 mL	20mL		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
Epidural <u>Intermittent</u>	VTBI	1-9999 mL	9999 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	20mL		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		
<u>Multi-step</u>	0-20 mL/h	3 mL/h		
<u>PCA</u>	0-20 mL/h	0 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>TPN</u>	0-20 mL/h	3 mL/h		
<u>Epidural</u>	0-20 mL/h	0 mL/h		

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, every time that 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.

* If an infusion is running at a rate of 1-4 mL/h or lower, the single air detector will automatically switch on to 0.5 mL. If an infusion is running at a rate lower than 1 mL/h, the single air detector will automatically switch on to 0.1 mL.

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	7770		
All	Medium Level	1000-7000	8880		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.
All	Low Level	1000-7000	9990		
All	PreProgram	1000-9999	7770		

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>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 restart the infusion automatically provided the occlusion was cleared within 40 seconds. An Occlusion Auto-restart can occur up to 5 times an hour.
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™ CONFIGURATION SETTINGS DEFINED AND AGREED

NAME

DATE

SIGNATURE



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