# **Avoset Programming Tool**

**User Manual** 



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Serious Incident Reporting	Any serious incident that has occurred in relation to the device should be reported to <u>complaints@eitanmedical.com</u> and to the local competent authority.
Bluetooth License	Avoset is qualified under Bluetooth SIG and has licensee right to use the Bluetooth trademarks.
CE Mark	The CE symbol represents adherence to the Medical Device Regulation 2017/745 of the European Communities concerning medical devices.
0123	The electromagnetic compatibility (EMC) requirements are part of the General Safety and Performance Requirements of the Medical Device Regulation.

#### **Terms and Conditions**

The Avoset Programming Tool User Manual is applicable to the version 2.0 of the Programming Tool. This manual is delivered subject to the conditions and restrictions listed in this section. Clinicians and qualified hospital staff should read the entire User Manual prior to programming the Avoset Infusion Pump.

Contact your local agent/distributor as needed.

#### **Prescription Notice**

Federal United States law restricts this device for sale by or on the order of a physician only {21CFR 801.109(b) (1)}.

The Avoset Programming Tool is intended for use exclusively with Avoset Infusion Pumps, which are 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 parenteral and enteral infusions. (Contact Eitan Medical or your local agent/distributor for information about training.)

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# **Chapter 1: Introduction**

## **Product Description**

The Avoset Programming Tool is a software application designed to program the Avoset pump from a PC.

The clinician uses the Programming Tool to set up a pump for an infusion treatment for a patient. Working on a PC's large screen size provides a convenient and efficient way to define a treatment program and pump settings. The treatment program and the pump settings are then transferred (downloaded) to the pump via the AvosetPad, a device provided by Eitan Medical that uses Bluetooth and near-field communication to connect the pump and the PC.

The Programming Tool supports:

- Creating a customized drug list
- Creating predefined treatment programs
- Defining default pump settings for all pumps in the fleet or all pumps at a specific location
- Performing software upgrades on the pump as they are made available by Eitan Medical
- Providing access to pump event logs

The Programming Tool is the programming module within the Insights platform. The Insights platform includes other modules for managing the entire fleet of pumps (not covered in this manual).

## **About This Manual**

#### 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 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.

#### **Intended Audience**

Clinicians and medical technicians who perform pump programming.

#### **Document Conventions**

#### **Information Identification Symbols**

The following messages in this manual indicate special information:



This is a note to alert to unusual or special information.



#### Caution

Indicate instructions which, if not followed, may result in damage to the equipment or to the quality of treatment.

#### **Terms and Abbreviations**

Term	Definition
AFFV	Anti-Free-Flow Valve
BLE	Bluetooth Low Energy
DC	Direct Current
DFU	Directions for Use
EMC	Electromagnetic Compatibility
EMI	Electromagnetic Interference
KVO	Keep Vein Open
ME	Medical Equipment
mg	milligram
mL	milliliters
MRI	Magnetic Resonance Imaging
NFC	Near Field Communication
PCA	Patient Controlled Analgesia
Rate	The amount of fluid infused in an hour
RF	Radio Frequency
VI	Volume Infused (the amount of volume already infused during the current treatment)
VTBI	Volume to Be Infused (the amount of fluid programmed or remaining to be infused)

## **Compliance and Classification**

The software complies with the requirements of the following international standards:

- IEC 62304; 2006+AMD1:2015—Medical device software—Software life cycle processes
- IEC 60601-1-6; 2010—Medical electrical equipment—Part 1-6: General requirements for basic safety and essential performance—Collateral standard: Usability
- IEC 62336-1; 2015—Medical devices—Part 1: Application of usability engineering to medical devices
- IEC 60601-1; 2005/AMD1:2012—Medical electrical equipment—Part 1: General requirements for basic safety and essential performance

## **General Warning and Safety Information**

- This software is intended for use only with the Avoset Infusion Pump.
- To ensure safety and proper operation, read this user manual before operating this application, and read the Avoset Infusion Pump User Manual before handling the Avoset pump.
- Only trained personnel should use the Avoset Programing Tool.

# **Chapter 2: Installation and Getting Started**



## **System Requirements**

#### Minimum Recommended

In order to use the Avoset Programming Tool, a driver (the Avoset Agent), must be installed on any PC that will be used to program a pump. These are the system requirements needed for that PC to support the Avoset Agent:

Hardware	• CPU – Intel Core I3 1.6GHz or higher
	• at least 4G RAM
	<ul> <li>monitor supporting 1920 x 1080 screen resolution</li> </ul>
	available USB 2 or 3 port
Operating System	Either of the following (or newer):
	Microsoft Windows 10 Client Version 1607+ 32 Bit
	Microsoft Windows 10 Client Version 1607+ 64 Bit
Firewall Settings	Any installed firewall must allow access to eitanmedical.com domain and port:443.
Supported Protocols	HTTPS
Other	an Internet connection
	Google Chrome 92 or newer
	.Net Framework 4.7.2

#### System Hardening

System hardening is the process of reducing security risks to your computer system. We recommend:

- Restrict access to any PC running the Insights platform.
- Use password protection on the PC.

Note

- Set automatic logoff (Sleep) to the minimum time allowed.
- Disable automatic password filling (do not use "remember me").
- Change passwords frequently.



Eitan Medical uses OKTA services to support computer security.

## Installing the Avoset Agent Driver

The Avoset Agent driver must be installed on each PC that will be used to program pumps.

- **1.** Before beginning, make sure that you have an account set up by Eitan Medical, including:
  - your username
  - a temporary password
  - the installation program for the Avoset Agent driver (Agent\_App.exe)
  - the login URL (a link to the website for the login process)



#### Note

Contact Eitan Medical at <u>support@eitanmedical.com</u> if you are missing anything.

- 2. Add the login URL (the above-mentioned link) to your antivirus or firewall whitelist.
- 3. Run Agent\_App.exe.

A popup screen appears as the Avoset Agent is installed and then closes automatically.

Click the icon <sup>22</sup> in the PC's taskbar and click Connect.

This only has to be done once; the icon 🗱 in the taskbar shows that the Avoset Agent is connected.

## Initial Sign-in

Each user receives an email from Eitan Medical containing their username, a temporary password, and a link to activate the account. Initial sign-in must be done on a PC in which the Avoset Agent is installed.



#### Caution

Do not disclose your username, password, or any other user credential information to others.

- **1.** From the email, click **Activate Account**.
- 2. Enter your username and password and click Sign In.
- **3.** The first time you attempt to sign in, you are prompted to change your password and set up email authentication.
- 4. After resetting your password, sign in again.If you have forgotten your password, click Forgot Password? and follow the prompts.
- 5. If you are a user with higher privileges (Master Manager), you are required to go through a multifactor authentication process. After the Sign In screen, there is an Authentication screen. Follow

the prompts to receive a code, enter it, and click **Verify**. (For details about user types, see *User Types and What They Can Do* on p. 13.)

- 6. In the Welcome screen, you can sign as either:
  - Account: this allows you to see data from all different branched of your organization. In this sign-in option, pump programming is disabled.
  - Location: this allows you to see data from a specific branch (location). In this sign-in option, pump programming is enabled.

Your user account was set up to give you access to one or more locations associated with your Avoset account.

7. Select the language (English is the default) and click Go.



### **Orientation and Navigation**

After signing in, the Insights platform opens. The Programming Tool is part of this platform:

	Dashboard				*] Welcome Alon AvosetTestingAccount - Jerusolem E	nglish Help
Contocors	Amount of Pumps Count of Pump SPC on ALL Results	Amount of Patients 782 Count Of Patient ID On All Results	Pumps by Type	Pumps Alarms - Locations AvvestTestingAccount - Jerusalem	Pumps by Software Version 7 11.0.57900 4 0.154944 1 11.2.5900 1 11.2.5956 1 11.0.58756 1	Î
Ardiente     Ardiente     Ardiente     Aragister Pump     Avaset Programming     Ordiguration ~     2	Pumps with Alarms - 24 Hours 4 A400i-3268 4 A400i-3267 2	Repetitive Specific Alarms Last week A4001-3140 5 A4001-2785 3 A4001-2785 2	Specific Alorms lost week 24 Remove And Reintert Set Alorm accourted 13 Upsteam Occlusion Alorm accourted 10 Desamteum Occlusion Alorm accourted 10	Total 1 Top te 1 Total Treatments 206 Court of ID On ALL Beautr	Total 31 Total Completed Treatments 67 Count of 0 On Completed Treatments Results	
	Tatal 2 Tata 2 of 2	2 A4001-3100 1 A4001-3285 1 Total 5 Total 5 Total 5	Cassette Misplaced Alarm occurred 9 Unprimed Set Alarm occurred Total II 10 Top 5 of II > 33			

Кеу	Function				
1	Main screen. When you sign in, the default view is the Insights Dashboard, which contains information about the fleet. When you access the Programming Tool, this area becomes the main work area for programming.				
2	The navigation pane. This is where you access the Programming Tool.				
3	User information area showing who is currently signed in, the account and location, and the language.				

#### **Navigation Pane Overview**

To access the Programming Tool:



The Configuration default settings for pumps, the drug list,

#### **Accessing Event Logs**

Pump event logs are accessed through the Fleet View on the Insights platform.



For details, see Accessing the Event Log on p. 22.

# **Chapter 3: Pump Programming**

### Introduction

Pumps can be programmed as described in this section, or by using a library program as a shortcut to complete some parameters (see *Using a Program Library* on p. 12).

Programming is similar for all program types (Continuous, Intermittent, Taper, or PCA).

- The parameters that must be defined vary depending on the program type.
- You cannot complete a program if you have left mandatory fields blank, or if you have entered incorrect values in a field (for example, something outside the defined range). Error information appears in red under the field.
- Some values are calculated automatically based on other fields. For example, entering Rate and VTBI will automatically provide Duration. Calculations appear in a blue box next to the fields.
- You always have an opportunity to review everything before the program is downloaded to the pump.

This represents the workflow you follow when programming a pump without using the Program Library. Each stage is explained in detail in this chapter in *Workflow Detail* on p. 9.



The Programming screen displays your progress in this green workflow bar at the top of the screen.

	(	🔗 Pair pump ——— 😡	Continuous ———	Enter Parameters ———	Confirm & Send		
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### **Workflow Detail**

#### Signing In

- 1. From the Google Chrome browser, open the login website.
- 2. In the Sign In screen, enter your username and password and click Sign In.

If you have forgotten your password, click Forgot Password?



#### Note

Users with higher privileges (Master Manager) require multi-factor authentication for security. They get an Authentication screen and must follow the prompts. (For details about user types, see *User Types and What They Can Do* on p. 13.)

3. In the Welcome screen, select your location from the list, select the language, and click **Go**.



#### Note

To program a pump, you must sign in to a location in which you are physically located.

4. Continue with *Pairing the Pump*, below.

#### **Pairing the Pump**

To connect a pump to the Programming Tool, it must be paired using the AvosetPad.



#### Note

A pump can only be paired to one PC at a time.

- 1. Make sure the pump battery is sufficient (not showing low battery icon).
- Plug the AvosetPad into an available USB port on the PC.
   A blinking red light on the AvosetPad indicates that its wireless is working and it is ready to pair with a pump.
- From the navigation pane, select Avoset Programming. The Pair Pump screen appears.

	1) Poir pump	- (3) Select Program		— 🕘 Confirm & fiend ——	(i) tending	- (i) Complete	
eitan medical							Pump Connected: No
				Pair Pump 🛛			
() Dashboard							
Floot View				Call and a state of the state o			
Potients							
Register Pump							
O Avoset Programming			Turn the pur	no on and place it on Avos	etPad		
<ul> <li>Configuration ~</li> </ul>							
insightsOO V 120.0 Programming Tool V 1.0.0.0							100

**4.** Turn on the Avoset pump.

The pump screen displays a self-check.

Pairing can only occur within the first 2 minutes after the pump is turned on.

5. Place the pump on the AvosetPad, screen facing up, with the ((\*)) symbol on the back of the pump aligned with the wireless LED on the pad.

The Programming Tool displays **Connecting to Pump**.



- 6. Once the pairing is successful:
  - On the AvosetPad, the red and green lights should be on and steady.
  - The pump beeps and its screen displays CONNECTED TO PC.
  - This appears on the Programming Tool main screen:

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60		
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	OGRAMMING	
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START PRO		

If pairing is not successful after few minutes, turn the pump off and on and try again. If problems persist, see *Chapter 6: Troubleshooting* on p. 23.

- **7.** Click **Start Programming** to start programming that pump with a new field-by-field treatment program.
- 8. Continue with *Creating a New Program*, below.

#### **Creating a New Program**

- 1. Under **Create New Program**, select the infusion type for the new program:
  - Continuous
  - Intermittent
  - Taper
  - PCA
- 2. Select the drug from the list. You can scroll or start typing the name.
- 3. Select the programming unit (mL, mg, or mcg).
- **4.** Enter the infusion parameters according to the prescription. The Programming screen presents the required fields based on the selected program type. For details about parameters for each program type, see *Appendix A: Program Parameters* on p. 28.
- **5.** To use the default settings configured specifically for this location, select the **Use default settings** checkbox.

Otherwise, click **Review/Edit Pump Settings** to open the Pump Settings screen and review all settings to make sure that they are appropriate for the selected program.

- If you want to make any changes, make them and click **Save**. When you return to the Programming screen, the **Use custom settings** checkbox is checked.
- You can restore the default settings by clicking **Review/Edit Pump Settings** and clicking **Restore to Default Settings**.



#### Note

For a list of all pump settings, see Appendix B: Default Settings on p. 33.

- 6. To set a delayed start for the treatment, enter an **Infusion Start Date** and an **Infusion Start Time**. If nothing is entered in these fields, no delay is applied.
- 7. Click Continue.
- 8. Before completing the programming, review the parameters and pump settings if desired, then click **Confirm & Send**.

The program is downloaded to the pump and the pump screen displays NEW PROGRAM RECEIVED to indicate the that selected program has been successfully received by the pump.

- 9. Click Done.
- **10.** Remove the pump from the AvosetPad and confirm on the pump that the correct program has been downloaded.

## Using a Program Library

A program from a library is a shortcut alternative to field-by-field programming. Library programs are predefined programs that have been set up in your system. Your location may have several programs to choose from.



Libraries programs can be partially defined, leaving some program parameters to be completed by the user.

To program a pump with a pre-defined program from a library:

Note

- 1. Sign in (see *Signing In* on p. 9).
- 2. Pair the pump (see *Pairing the Pump* on p. 9).
- **3.** From the **Select Program from Library** area of the Programming screen, select a category. All programs within that category are displayed. These are programs that were defined by your facility for your location.
- 4. Choose the program and click **Select**.
- 5. Depending on how the library program was defined, you may need to enter some parameters.
- Review the parameters and pump settings. Then click Confirm & Send.
   The program is downloaded to the pump and the pump screen displays NEW PROGRAM RECEIVED to indicate the that selected program has been successfully received by the pump.
- 7. Click Done.
- 8. Remove the pump from the AvosetPad and confirm on the pump that the correct program has been downloaded.

# **Chapter 4: Configuration**

#### Note

Training is required for special users performing configuration, which includes default settings, the drug list, and libraries, as these changes may affect the whole system.

Users with authorization to change default settings must go through multifactor authentication when signing in.

#### **Basic Concepts**

Since only users with higher privileges can make changes that affect more than one pump, it is important to understand the different user types as well as the impact of signing in to a location.

#### User Types and What They Can Do

The Avoset Programming Tool supports different levels of access and functionality based on different authorization levels.

- User: Users are typically managers of a location (branch) and nurses. Users can:
  - program pumps
  - view default settings
  - edit a pump's settings
  - update pump software
  - view a pump's event log
  - view the drug list
- **Master Manager:** This person can perform any action, including settings that affect the entire account. In addition to all of the above actions, the Master Manager can:
  - edit the drug list
  - edit default pump settings
  - create and edit library programs



#### Caution

If you sign in at the account level, the changes you make in the Programming Tool can affect *all locations* and *all pumps* programmed from *this point on*.

The Programming Tool provides a confirmation screen as a reminder:

Changes will be applied to all locations.

Changes that are done in the Account workspace will be applied to all locations.

The Master Manager can click **Apply** to proceed or **Cancel** to cancel the changes.

#### Locations

How the Master Manager is logged in affects the changes made:

Logged in at	Changes to	Affects
Account Level	drug list	All locations
	<ul> <li>program libraries</li> </ul>	
	<ul> <li>pump defaults</li> </ul>	
A specific location	drug list	Pumps used for that location
	<ul> <li>program libraries</li> </ul>	only
	<ul> <li>pump defaults</li> </ul>	

Users are able to sign in at specific locations, according to how their user account was set up.

## **Defining Default Pump Settings for Locations**

The Programming Tool comes with factory default pump settings. By customizing default pump settings for a location or the Account (entire fleet), you can save time and effort while better controlling your fleet of Avoset pumps.



#### Caution

The Programing Tool comes with factory default pump settings. These settings can be modified according to your facility medical protocols.

References in this document to specific drugs and drug doses are for illustration purposes only. Refer to specific drug product labeling for information concerning appropriate administration techniques and dosages.

- 1. Sign in as described in *Signing In* on p. 9. As a Master Manager, you are required to complete multi-factor authentication. Follow the prompts from the Authentication screen to receive the 6-digit code, enter it, and click **Verify**.
- 2. In the Welcome screen, sign in at the Account level to make changes that affect all locations, or at a specific location to make changes only for that location.
- **3.** From the navigation pane, select **Configuration**. Select **Default Settings**. Settings affect:
  - All pump programming, regardless of program type. This includes Alarms, Audio, and Prime. These become the default settings that apply to all pumps programmed from that point on.
  - Program-specific settings. This includes Continuous, Intermittent, PCA, and Taper. These become default settings that apply only for programming of that infusion type. Again, the defaults apply to pumps programmed from that point on.
  - Password protection, which includes password settings specific to each program type.

- 4. Click a tab to open it. Within the selected tab, set changes as desired. Click **Save** to save the changes.
  - You may click **Save** after making changes in each tab, or after making all changes.
  - Clicking **Discard** removes any changes made after the previous Save.

# A

For a complete list of all settings and their factory defaults, see Appendix B: Default Settings on p. 33.

## **Working with Program Libraries**

Note

Libraries are where pre-defined treatment programs are stored. These programs act as programming shortcuts, providing some (or all) of the parameters for the user, thus simplifying the programming.



#### Note

A library program does not have to have all parameters predefined. You may create programs that require completion by the user for a specific patient. For example: you could have a PCA program of Morphine with mg as the program unit, but without the rest of the information (for example, Rate, VTBI, etc.). The user programming the pump with this library program would be required to complete these parameters before the program could be downloaded to the pump.

#### **Managing Categories**

Programs can be grouped together in categories of similar treatment types. You can create as many categories as you wish. For example:

- by delivery type
- by location
- by treatment classification (such as *oncology*)
- by patient condition or disease
- by drug type

To create a category:

1. Click the three dots next to the category bubble (here showing **General**) and click **Manage Categories**:

Manage Categorie		
Create New Program		Manage Categories
Greatentingian	Create Ne	w Program

- 2. In the Manage Categories screen, enter a new category name and click Add.
- 3. Click Close to close the Manage Categories screen.

To edit a category name:

- 1. Access the Manage Categories screen (see above).
- 2. Under Edit Existing Categories, click the pencil icon 🖊 next to the category to change.
- 3. Change the name as desired and press Enter.
- 4. Click **Close** to close the Manage Categories screen and save the changes.

#### Adding a New Program

To create a new program:

1. From the navigation pane, open **Configuration** and select **Program Libraries**.

¢	Welcome Alon Avoset festi	sgAccount - Jerusalem English Help
	Program Library	
eitan medical care à beyond	Filter by (BU) (Generar) ;	Pump Connected: No
Dashboard	Create New Program	
Floot View		
Patients		
Register Pump		
Avoset Programming		
Configuration A		
Pump Default Settings		
Program Settings		
Program Ubrary		
insightsoo v 120.0 Programming Tool v 1.0.0		80 111

#### 2. Click Create New Program.

The Create New Program screen appears.

ć			+3 We	doome Alon AvosetTestingAccount - Jerusalem English Help
	Program Library			
eitan medical		Create New Program	×	Pump Connected: No
Cone & beyond.	Filter by Fovorities (50) (General) [	Q. Select Program Tune		
	24 Hr Morphine			
(E) Dashboard	Create New Program Duroson D1 Prs	Enter Program Name		
(B) Flood View	/ = +	Q. Assign to Category .		
A Patients		· · · · · · · · · · · · · · · · · · ·		
Register Pump		Add to Favorites		
Avoset Programming				
Configuration ~				
Pump Detouit Settings				
Program Settings				
Drug List.				
Program labrary.				
Insights 60 V 1200			CONTINUE	when.
				•
				0

- 3. Select the program type (Continuous, Intermittent, Taper, or PCA).
- 4. Enter a name. Use a name that will make sense to your users.
- 5. Assign the program to a category from the list.



#### Note

Categories must be created before they appear on this list. See *Managing Categories* on p. 16.

6. If you click **Add to Favorites**, this program is marked with the heart icon and appears in the Favorites category.

7. Proceed to complete the programming (see *Creating a New Program* on p. 11).

#### Modifying a Program

To modify an existing program:

- 1. From the Program Library screen, select the desired program.
- 2. Click its pencil icon.
- **3.** Click **Edit Treatment**.
- 4. Make any desired changes and click **Save**.
- **5.** If any of the changed parameters caused recalculation, click **OK** in the Parameter Recalculated screen.
- 6. Click **Save** again to save your changes and close the program screen.

#### **Deleting a Program**

To remove a program from the library:

- 1. From the Program Library screen, select the desired program.
- 2. Click its trash can icon.
- **3.** In the Delete Program screen, click **Delete** to confirm deletion, or click **Cancel** to exit without deleting.

## **Editing the Drug List**

The Programming Tool comes with a drug list of all approved medications and fluids that can be used with the Avoset pump according to your country. You cannot add drugs to the list. However, you can customize the list. For example, you may have a short name to use for convenience. For example, the generic drug name Fluorouracil (as appears in the drug list) may be abbreviated to appear as  $5_{\rm FU}$  on the pump screen.

## Note If you

If you require a drug that is not on the list, contact Eitan Medical at <a href="support@eitanmedical.com">support@eitanmedical.com</a>.

#### Viewing the Drug List

To view the drug list:

- 1. From the main screen, select **Configuration > Drug List**.
- 2. All drugs are listed alphabetically. Scroll or use the search field to find a specific drug.
- 3. You can filter the list by selected or unselected drugs (the checkbox to the left of each drug).

#### **Editing the List**



#### Note

Only Master Managers may edit the drug list.

To edit the drug list for all locations, sign in at the Account level. To edit for a location, sign in to that location.

To edit the drug list:

- 1. To edit a drug's name, click the pencil icon to the right of the drug. Type the preferred name.
- 2. To remove a drug from appearing in the drug list, deselect the checkbox to the left of the drug name.
- 3. When you are done with the edits, click **Save**.

#### **Restoring to Manufacturer Drug List**

To restore the drug list so that the drug name as originally provided is what appears on the pump screens (and remove any name modifications you have made):

- 1. Click **Restore to Factory Defaults** at the bottom of the drug list.
- 2. Click Yes to confirm (or No to cancel).

# **Chapter 5: Other Actions**

## **Clearing the Pump**

Clearing a pump removes the current treatment program saved on the pump, preparing it for manual continuous programing. This is useful for several reasons:

- You will have ready-to-go pumps available in case of Internet or computer problems.
- You won't accidentally send out a pump that contains the wrong program.



Note

A pump *does not* need to be cleared before programming it with a different treatment program.

To clear a pump:

- 1. Sign in (see *Signing In* on p. 9).
- 2. Pair the pump (see *Pairing the Pump* on p. 9).
- 3. After pairing, click Start Programming.
- 4. Click Clear Program.
- **5.** To use the default settings configured specifically for this location, select the **Use default settings** checkbox.

Otherwise, click **Review/Edit Pump Settings** to open the Pump Settings screen and review all settings to make sure that they are appropriate for the selected program.

- If you want to make any changes, make them and click **Save**. When you return to the Programming screen, the **Use custom settings** checkbox is checked.
- You can restore the default settings by clicking **Review/Edit Pump Settings** and clicking **Restore to Default Settings**.



#### Note

For a list of all pump settings, see Appendix B: Default Settings on p. 33.

- 6. Click Continue.
- **7.** Before completing the programming, review the parameters and pump settings if desired, then click **Confirm & Send**.

The status bar shows the download progress. When completed, the pump screen displays **PROGRAM CLEARED**.

- 8. Click Done.
- 9. Remove the pump from the AvosetPad.

#### **Updating Pump Software**

When a new version of the pump software is released, you will be informed by Eitan Medical.

To update the pump software:

1. After pairing the pump, select **Software Update**.



2. In the **Pump Software Update** screen, select the language for the pump software, the software version, and click **Upload**.

The screen shows the update progress. If the upload fails, see *Pump Software Update Issues* on p. 26.



Caution

Do not remove the pump from the AvosetPad during the software update.

#### Accessing the Event Log

Each pump has a log that records its events. The log is automatically uploaded to the Insights platform whenever the pump is connected (via the AvosetPad).

To access a pump's event log:

- 1. Sign in (see *Signing In* on p. 9).
- 2. From the navigation pane, select **Fleet View**.

The Fleet View screen shows all pumps in the fleet.

	<b>`</b>				weicome alon     AvosetTestingA	ccount - Jerusalem English
	Fleet Viewer					
o eitan medical care & beyond"	Fleet view Fle	eet View History				
	Q Start typing to search	h for Pumps				
	Fleet (43)					
	Pump SN	Software Version	Software Update Date	Registered Location Name	Registration Date	Pump Status
	A4001-2757	1.1.0.67000	2001-01-01	AvosetTestingAccount - Jerusalem	2021-10-06	Free
nboard	A4001-2800	0.1.163548	2001-01-01	AvosetTestingAccount - Jerusalem	2021-10-03	Free
Wimm	A4001-2759	1.1.0.66341	2001-01-01	AvosetTestingAccount - Jerusalem	2021-09-30	Froe
	A4001-2753	1.1.2.64731	2001-01-01	AvosetTestingAccount - Jerusalem	2021-09-30	Free
ents	A4001-3285	1.1.0.67000	2001-01-01	AvosetTestingAccount - Jerusalem	2021-09-30	Free
	A4001-3266	1.1.0.67000	2001-01-01	AvosetTestingAccount - Jerusalem	2021-09-29	Froo
ster Pump	A4001-3053	1.1.2.67000	2001-01-01	AvosetTestingAccount - Jerusalem	2021-09-29	Free
t Programming	A4001-3267	1.1.0.67000	2001-01-01	AvosetTestingAccount - Jerusalem	2021-09-29	Free
	A4001-2785	1.1.0.67000	2001-01-01	AvosetTestingAccount - Jerusalem	2021-09-23	Free
guration 🗸	A4001-2842	1.1.2.66395	2001-01-01	AvosetTestingAccount - Jerusalem	2021-09-14	Free
	A4001-3226	1.1.0.67000	2001-01-01	AvosetTestingAccount - Jerusalem	2021-09-13	Free
	A4001-2796	1.1.0.65876	2001-01-01	AvosetTestingAccount - Jerusalem	2021-09-05	Free
	A4001-3705	1.1.0.67000	2001-01-01	AvosetTestingAccount - Jerusalem	2021-09-05	Free
	A4001-2778	1.1.2.66383	2001-01-01	AvosetTestingAccount - Jerusalem	2021-09-05	Free
	RESULTS PER PAGE: 20	50 100			66	× 1 2 3 × ×

**3.** Click on a pump in the list.

The pump information appears with three tabs across the top: **Treatments**, **Event Log**, and **Registration History**.

#### **4.** Click the **Event Log** tab.

The pump's event log displays each event with a date and timestamp.

# **Chapter 6: Troubleshooting**



Note

Contact your service provider or Eitan Medical if you have an issue that is not resolved with the troubleshooting information in this chapter.

#### **Sign-in Issues**

Symptom	Cause	Solution
Unable to sign in.	There is a problem with your user setup (for example, you are not assigned to any location).	Contact your Administrator and provide the specific codes that appear on the screen.

#### **Display Issues**

Symptom	Cause	Solution
Screen text appears distorted; some functions not shown.	Google Chrome browser is zoomed at >100%.	Reset the browser zoom to 100%.
	The display setting (scale and layout) of >100% does not support the application.	Reset the display setting (scale and layout) to the recommended value.

### **Pump Pairing Issues**

Error Message	Cause	Solution
PUMP DISCONNECTED	Pump prematurely disconnected from PC.	<ol> <li>Remove pump from AvosetPad.</li> </ol>
		2. Turn off the pump.
		3. Turn the pump back on.
		<ol> <li>Verify the AvosetPad red light is blinking.</li> </ol>
		<ol> <li>Place the pump on the AvosetPad with its wireless mark on top of the wireless mark on the pad. This must be done within the first 2 minutes after turning the pump on.</li> <li>Verify the green and red lights on the AvosetPad are blinking.</li> </ol>
No beep occurs when the pump is placed on the AvosetPad.	AvosetPad <mark>red</mark> light is not blinking.	Reconnect the AvosetPad to the PC.
or PUMP DISCONNECTED	AvosetPad green light is off when pump is placed on it.	Verify the Bluetooth icon is displayed on the pump, otherwise turn the pump off and back on and repeat the pairing process.
	AvosetPad green light is off when pump is placed on it.	Verify that the wireless symbol on the pump's back is aligned with the wireless LED on the AvosetPad.
	Bluetooth icon is not displayed on the pump.	Turn the pump off and back on. The Bluetooth icon is displayed for 2 minutes only.

## Pump Programming Issues

Error Message	Cause	Solution
ERROR IN PROGRAMThe connected purpleRECEIVEDreceive the program	The connected pump did not receive the program correctly.	Click <b>Resend</b> to resend the program. This clears the pump of any programming.
		To quit programming without sending the program to the pump, click <b>Quit Programing</b> .

Error Message	Cause	Solution
SENDING PROGRAM FAILED The connected pump did not receive the program, due to disconnection.	The connected pump did not receive the program, due to	Click <b>Resend</b> to resend the program.
	To quit programming without sending the program to the pump, click <b>Quit Programing</b> .	
CLEAR PROGRAM FAILED	The connected pump did not have its program cleared after selecting <b>Clear Program.</b>	Click <b>Clear</b> to try again.
		Click <b>Cancel</b> to keep the current program on the pump, without clearing it.
ACCESS TO AVOSET	Pump programming is grayed out (inactive).	Sign out and sign in to the
PROGRAMMING IS NOT		relevant location, then start
PERMITTED WHEN WORKING		programming.
IN THE ACCOUNT LEVEL		

## **Configuration Saving Issues**

Error Message	Cause	Solution
FAILED TO SAVE	Edited default pump settings, drug list or program settings were not saved due to network issues.	Verify you are connected to the network and try to save again.

## Library Issues

Symptom or Error Message	Cause	Solution
CATEGORY WAS NOT FOUND	The category selected was deleted by another user.	Create the category or have a Master Manager create it.
PROGRAM WAS NOT FOUND	The program selected was deleted by another user.	Create the program or have a Master Manager create it.
DELETE CATEGORY FAILED	Unable to delete a category due to network issues.	Verify you are connected to the network and try to save again.
DELETE PROGRAM FAILED	Unable to delete a program due to network issues.	Verify you are connected to the network and try to save again.
Trash icon and pencil icon are missing next to a program name (unable to edit or delete a program).	The program you are trying to edit or delete is a program created for the entire account. It can be deleted or edited only at the account level.	If you are a Master Manager for the account, sign out of the location you are logged into, and then sign in to the account.
Trash icon and pencil icon are missing next to a category name (unable to edit or delete a category).	The category you are trying to edit or delete is a category created for the entire account. It can be deleted or edited only at the account level.	If you are a Master Manager for the account, sign out of the location you are logged into, and then sign in to the account.

Symptom or Error Message	Cause	Solution
UNABLE TO ASSIGN PROGRAMS TO AN EXISTING CATEGORY	The category you are trying to assign programs to is a category created for the entire account. It can be edited only at the account level.	If you are a Master Manager for the account, sign out of the location you are logged into, and then sign in to the account.

### Pump Software Update Issues

Error Message	Cause	Solution
UPDATED FAILED	The connected pump was not updated with the selected software due to connection	Verify the pump is paired, and restart the software update process.
	issues.	Without restarting the software update process, the pump retains the software it had before attempting to update.

## **Authorization and Operational Issues**

Error Message	Cause	Solution		
UNAUTHORIZED	Application security.	Sign out and sign back in.		
YOU ARE NOT AUTHORIZED	YOU ARE NOT AUTHORIZED You may have been logged in			
TO VIEW THIS PAGE for an unexpected leng time.		נוו טו		
FAILED TO LOAD DATA	The application (PC) is unable to reach the database.	Check the network connection.		
он NO!	The application (PC) was	Contact IT to bring up the database with Avoset support.		
IT SEEMS YOUR COMPUTER	disconnected from the Avoset database.			
GOT DISCONNECTED FROM				
THE AVOSET SERVER.				
PLEASE CONTACT YOUR IT				
FOR SUPPORT.				

## **Programming Error Messages**

Error Message	Cause	Solution
MANDATORY FIELD	Trying to continue without all required parameter values filled in. The program cannot be saved.	Fill in all required parameters.
RANGES [XX], CHECK ALL ENTERED PARAMETERS OR THE PUMP SETTINGS	The entered parameter value is outside the permitted range. The program cannot be saved.	Consult the prescribing authority to edit either the infusion program or the program settings.
DELAYED START CANNOT BE SET TO THE PAST	The entered delayed start cannot be saved as the date or time has already passed. Invalid issues includes: • Number of months >12 • Number of days >31 • Total delay period > 1 year • Setting past time	Edit the date or time of day to valid values.

# **Appendix A: Program Parameters**

Here are the parameters for each type of program.

#### Continuous

Using a continuous infusion program, the pump infuses the solution volume at a constant rate. To create a continuous program, enter two of the following parameters:

- Volume to be infused (VTBI)
- Rate
- Duration (calculated and displayed on the screen)

Here are the parameters to complete for programming a new Continuous treatment:

Program Section	Setting	Definition
Continuous	Dosing Unit	The prescribed dosing:
Settings		<ul> <li>mL when the treatment is rate-based (mL/h, or volume over duration)</li> </ul>
		<ul> <li>mcg or mg when the treatment is dose-based (mcg/h, or amount over duration)</li> </ul>
	Concentration	(Optional) Amount of drug in one mL of fluid. This parameter only appears if you chose a dosing unit of mcg or mg.
	Rate or Dose Rate	Volume or amount of drug infused per hour.
	VTBI	Volume to be infused.
	Duration	Period of time over which the fluid is infused.
Optional Infusion Settings	Delayed Start	The date and time after which the treatment can start, scheduled treatment.
		Your browser's settings determines the format that the time appears (AM/PM or 24-hour).

#### Intermittent

In an intermittent program, the pump infuses the programmed dose volume over the dose duration, and at the programmed dose interval (frequency). KVO can be programmed to run between intermittent doses. For an intermittent program, a dose reminder can be set. When Dose Reminder is selected, the pump notifies the user before the next intermittent dose is due.



Here are the parameters to complete for programming a new Intermittent treatment:

Program Section	Setting	Definition	
Intermittent	Dosing Unit	The prescribed dosing:	
Settings		<ul> <li>mL when the treatment is rate-based (mL/h, or volume over duration)</li> </ul>	
		<ul> <li>mcg or mg when the treatment is dose-based (mcg/h, or amount over duration)</li> </ul>	
	Concentration	(Optional) Amount of drug in one mL of fluid. This parameter only appears if you chose a dosing unit of mcg or mg.	
	Dose Volume	Volume of each intermittent dose.	
	Dose Amount	Drug amount of each intermittent dose	
	Dose Duration	Period of time over which a single dose is infused.	
	Dose Interval	The frequency of doses delivered.	
	KVO	Keep Vein Open—low rate applied between doses.	
	Total Duration	Period of time over which the entire volume is infused (the time to deliver all doses).	
	VTBI	Volume to be infused (includes all doses and KVO).	
Optional Infusion Settings	Dose Reminder	Alert for the patient that a dose is about to start. The alert is only active when the pump is paused between doses.	

Program Section	Setting	Definition	
	Delayed Start	The date and time after which the treatment can start, scheduled treatment.	
		Your browser's settings determines the format that the time appears (AM/PM or 24-hour).	

#### Taper

In a taper program, the pump infuses the solution volume (VTBI) at a constant rate, with optional tapering (ramping).

- When taper up duration is entered, the pump starts infusing by gradually increasing the rate until the plateau rate is reached.
- When taper down duration is entered, the pump finishes infusing by gradually decreasing the rate until a complete stop.

At the end of the treatment KVO rate may be applied (according to the pump configuration settings).



Here are the parameters to complete for programming an Intermittent treatment:

Program Section	Setting	Definition
Taper Settings	VTBI	Volume to be infused.
	Total Duration	Period of time over which the solution is infused.
	Plateau Rate	Volume of solution infused per hour, following taper up when applied.
		The Programming Tool calculates this parameter automatically.
Optional Infusion Taper Up Duration P Settings w		Period of time at the beginning of the infusion over which the rate gradually increases until the plateau rate is reached.
	Taper Down Duration	Period of time towards the end of infusion over which the rate gradually decreases until the treatment ends.

Program Section	Setting	Definition
Delayed Start (Optional) The date and can start, scheduled tre		(Optional) The date and time after which the treatment can start, scheduled treatment.
		Your PC's system settings determines the format that the time appears (AM/PM or 24-hour).

#### PCA

The Patient Controlled Analgesia (PCA) mode allows the pump to deliver medication at a continuous rate (optional) with limited boluses activated by the patient.



Here are the parameters to complete for programming a new PCA treatment:

Program Section	Setting	Definition
PCA Settings	Dosing Unit	The prescribed dosing:
		<ul> <li>mL when the treatment is rate-based (mL/h, or volume over duration)</li> </ul>
		<ul> <li>mcg or mg when the treatment is dose-based (mcg/h, or amount over duration)</li> </ul>
	Concentration	(Optional) Amount of drug in one mL of fluid. This parameter only appears if you chose a dosing unit of mcg or mg.
	VTBI	Volume to be infused.
	Basal Rate	Amount of drug delivered continuously per hour.
	Bolus Amount	Amount of drug delivered (in mg or mcg) as a bolus.
	Bolus Volume	Volume of drug delivered (in mL) as a bolus.
	Lockout Duration	Minimum time that must elapse after a bolus before the next bolus is available.

Program Section	Setting	Definition	
	Additional Limit	Added restriction over the availability of boluses to the patient. Options include:	
		No Limit	
		Max Boluses per Hour	
		Total Dose Limit	
	No Limit	No additional limit on top of the lockout time. The patient can receive a bolus as soon as the lockout time elapses.	
	Maximum Boluses per Hour	In addition to the lockout time, within an hour the patient boluses are limited to the maximum boluses defined per hour.	
	Total Dose Limit	In addition to the lockout time, the patient boluses temporarily become unavailable if the amount of medication delivered has reached the total dose defined within the defined duration.	
Optional Infusion Settings	Loading Dose Amount	(Optional) Amount delivered as an initial dose (in mg or mcg) at the beginning of infusion.	
	Loading Dose Volume	(Optional) Volume delivered as an initial dose (in mL) at the beginning of infusion.	
	Delayed Start	The date and time after which the treatment can start, scheduled treatment.	
		Your browser's settings determines the format that the time appears (AM/PM or 24-hour).	

# **Appendix B: Default Settings**



Note

This chapter is intended for Master Managers.

The following tables lists all fields (settings) in the Avoset pump and software.

- **Category Name:** The tab in the Pump Default Settings screen where the field is found.
- **Setting Name:** The name of the setting as it appears in the Programming Tool. In some cases, a second name is listed if the field is viewed under specific pump settings, where only fields applicable to that treatment program are displayed.
- **Delivery Mode:** The delivery mode (program type) for which the field is applicable.
- **Factory Default Value:** The factory default defined by Eitan Medical.
- **Possible Values** or **Ranges**: If a field has a set list of values to choose from, they are shown here. Settings with Off/On values have a slider control. Minimum and maximum values for the field, if applicable.

## **General Settings**

Category Name	Setting Name	Factory Default Value	Possible Values or Ranges (Min. / Max.)	
Alarms	Air in Line	2 mL	Off, 0.1, 0.2, 0.5, 2 mL	
Alarms	Accumulated Air Detection	Off	Off (0 mL), <b>On</b> (1 mL)	
Alarms	Occlusion Sensitivity	Medium	Low (1.6), Medium (1.2), High (0.5)	
Alarms	Pump Unattended	10 minutes	2, 5, 10 minutes	
Alarms	Time Offset (for using the pump in a different time zone)	0	-6, -5, -4, -3, -2, -1, 0, +1, +2, +3, +4, +5, +6	
Alarms	(Intermittent only) Time To Change Bag Reminder	10 minutes	10, 20, 30 minutes	
Prime	Prime Reminder	Off	Off, <mark>On</mark>	
Prime	Prime Volume	Off	Off, <mark>On</mark>	
Audio	Alarm Volume	High	Low, High	
Audio	Keys Volume	Low	Off, Low, High	

These settings are applicable to all program types (delivery modes).

## **Password Protection Settings**

These settings are applicable to all password protection parameters as they apply to different program types (delivery modes).

Category Name	Delivery Mode	Setting Name	Factory Default Value	Possible Values or Ranges (Min. / Max.)
Passwords	All	Passwords	298	Min: 100 Max: 999
Passwords	Continuous	Automatic Prime	LOCKED	UNLOCKED, LOCKED
Passwords	Continuous	Edit Infusion	LOCKED	UNLOCKED, LOCKED
Passwords	Intermittent	Automatic Prime	LOCKED	UNLOCKED, LOCKED
Passwords	Intermittent	Edit Next Dose Start Time	LOCKED	LOCKED
Passwords	РСА	Automatic Prime	LOCKED	LOCKED
Passwords	РСА	Clear PCA Bolus History	UNLOCKED	UNLOCKED, LOCKED
Passwords	РСА	Edit Infusion	LOCKED	LOCKED
Passwords	РСА	Clinical Bolus	LOCKED	LOCKED
Passwords	Taper	Automatic Prime	LOCKED	UNLOCKED, LOCKED
Passwords	Taper	Edit Infusion	UNLOCKED	UNLOCKED, LOCKED
Passwords	Taper	Immediate Taper Down	UNLOCKED	UNLOCKED, LOCKED

## **Program-specific Settings**

These settings are applicable to specific program types (delivery modes).

#### Continuous

Category Name	Setting Name	Factory Default Value	Possible Values or Ranges (Min. / Max.)
Continuous	KVO Rate	0 mL/h	Min: 0.1 mL/h Max: 10 mL/h
Continuous	Minimum Rate	0.1 mL/h	Min: 0.1 mL/h Max: Max Rate Value
Continuous	Maximum Rate	300 mL/h	Min: Min Rate Value Max: 300 mL/h
Continuous	Minimum VTBI	0.1 mL	Min: 0.1 mL/h Max: Max VTBI Value
Continuous	Maximum VTBI	9999 mL	Min: Min VTBI Value Max: 9999 mL
Continuous	Minimum VTBI	0.1 mL	Min: 0.1 mL/h Max: Max VTBI Value
Continuous	Dosing Unit	On	Off, <mark>On</mark>

Category Name	Setting Name	Factory Default Value	Possible Values or Ranges (Min. / Max.)
Intermittent	Default KVO Rate	empty	Min: Min KVO Max: Max KVO
Intermittent	Default Total Duration	empty	Min: 00h:11m Max: 999h:59m
Intermittent	Default Call-back Before Dose	empty	Min: 00h:05m Max: 1h:00m
Intermittent	Minimum Dose Rate	0.1 mL/h	Min: 0.1 mL/h Max: Max Dose Rate
Intermittent	Maximum Dose Rate	300 mL/h	Min: Min Dose Rate Max: 300 mL/h
Intermittent	Minimum Dose Volume	0.1 mL	Min: 0.1 mL Max: Max Dose Volume
Intermittent	Maximum Dose Volume	999 mL	Min: Min Dose Volume Max: 999 mL
Intermittent	Minimum Dose Duration	00h:01m	Min: 00h:01m Max: Max Dose Duration
Intermittent	Maximum Dose Duration	24h:00m	Min: Min Dose Duration Max: 24h:00m
Intermittent	Minimum Dose Interval	00h:11m	Min: 00h:11m Max: Max Dose Interval
Intermittent	Maximum Dose Interval	96h:00m	Min: Min Dose Interval Max: 96h:00m
Intermittent	Minimum KVO	0.1 mL/h	Min: 0.1 mL/h Max: Max KVO
Intermittent	Maximum KVO	10 mL/h	Min: Min KVO Max: 10 mL/h
Intermittent	Minimum VTBI	0.1 mL	Min: 0.1 mL Max: Max VTBI
Intermittent	Maximum VTBI	9000 mL	Min: Min VTBI Max: 9000 mL
Intermittent	Dosing Unit	On	Off, On

#### Intermittent

#### PCA

Category Name	Setting Name	Factory Default Value	Possible Values or Ranges (Min. / Max.)
РСА	KVO Rate	0 mL/h	Min: 0.1 mL/h Max: 10 mL/h
PCA	(*6) Bolus Rate	125 mL/h	Min: Min Bolus Rate Max: Max Bolus Rate
РСА	Minimum VTBI	0.1 mL	Min: 0.1 mL Max: Max VTBI
РСА	Maximum VTBI	9999 mL	Min: Min VTBI Max: 9999 mL
PCA	Minimum Continuous Rate	0.1 mL/h	Min: 01. mL/h Max: Max Continuous Rate
PCA	Maximum Continuous Rate	100 mL/h	Min: Min Continuous Rate Max: 100 mL/h
PCA	Minimum Bolus Volume	0.1 mL	Min: 0.1 mL Max: Max Bolus Volume
PCA	Maximum Bolus Volume	50 mL	Min: Min Bolus Volume Max: 50 mL

Category Name	Setting Name	Factory Default Value	Possible Values or Ranges (Min. / Max.)
РСА	Minimum Lockout	00h:01m	Min: 00h:01m Max: Max Lockout Duration
РСА	Maximum Lockout	24h:00m	Min: Min Lockout Duration Max: 24h:00m
РСА	Minimum Boluses	1 per hour	Min: 1 per hour Max: Max Number of Boluses
РСА	Maximum Boluses	60 per hour	Min: Min Number of Boluses Max: 60 per hour
РСА	Minimum Total Dose Limit	1 mL	Min: 1 mL Max: Max Total Dose Limit
РСА	Maximum Total Dose Limit	9999 mL	Min: Min Total Dose Limit Max: 9999 mL
PCA	Minimum Loading Dose Volume	0.1 mL	Min: 0.1 mL Max: Max Loading Dose Volume
РСА	Maximum Loading Dose Volume	50 mL	Min: Min Loading Dose Volume Max: 50 mL
РСА	Minimum Bolus Rate	0.1 mL/h	Min: 0.1 mL/h Max: Max Bolus Rate
РСА	Maximum Bolus Rate	300 mL/h	Min: Min Bolus Rate Max: 300 mL/h
РСА	Loading Dose	On	Off, <mark>On</mark>
PCA	Dosing Unit	On	Off, On

### Taper

Category Name	Setting Name	Factory Default Value	Possible Values or Ranges (Min. / Max.)
Taper	Immediate Taper Down	Off	Off, On
Taper	KVO Rate	0 mL/h	Min: 0.1 mL/h Max: 10 mL/h
Taper	Minimum VTBI	10 mL	Min: 10 mL Max: Max VTBI
Taper	Maximum VTBI	9999 mL	Min: Min VTBI Max: 9999 mL
Taper	Minimum Taper Up	00h:10m	Min: 00h:10m Max: Max Taper Up Duration
Taper	Maximum Taper Up	03h:50m	Min: Min Taper Up Duration Max: 03h:50m
Taper	Minimum Taper Down	00h:10m	Min: 00h:10m Max: Max Taper Down Duration
Taper	Maximum Taper Down	03h:50m	Min: Min Taper Down Duration Max: 03h:50m
Taper	Minimum Total Duration	00h:10m	Min: 00h:10m Max: Max Total Duration
Taper	Maximum Total Duration	96h:00m	Min: Min Total Duration Max: 96h:00m
Taper	Minimum Plateau Rate	0.4 mL/h	Min: 0.4 mL/h Max: Max Plateau Rate
Taper	Maximum Plateau Rate	300 mL/h	Min: Min Plateau Rate Max: 300 mL/h