## **BD Alaris™ System with Guardrails™ Suite MX**

For BD Alaris<sup>™</sup> PC Unit Model 8015, Alaris<sup>™</sup> PC Unit Model 8015, and Alaris<sup>™</sup> PC Unit Model 8000 Software Versions 12.1.0, 10.5, 9.33, 9.19.1, 9.13, 9.12, 9.5, 9.2, 9.1, and Supported Modules

User Manual Addendum

2020-07

Part Number: P00000484-01



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#### BD Alaris™ System with Guardrails™ Suite MX User Manual Addendum

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If difficulties are encountered while using this software, refer to the user manual, service manual, or related service bulletin(s) before contacting BD. Provide a description of the difficulty experienced, any messages that were displayed at the time of the difficulty, and the software version. Before you return the software to BD, contact BD to get a return authorization number. Put the software in its original packaging (if available), write the return authorization number on the package, and return to the nearest facility.

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## Chapter 1 Introduction

Τh	is chapter contains the following topics:
	Purpose of Addendum
	Warnings, Cautions, and Notes

#### **Purpose of Addendum**

This addendum updates the BD  $Alaris^{TM}$  System with  $Guardrails^{TM}$  Suite MX User Manual for the following PCU software releases:

- PCU 8000: 9.5, 9.1
- PCU 8015: 12.1.0, 10.5, 9.33, 9.19.1, 9.13, 9.12, 9.5, 9.2, 9.1

The addendum provides supplemental information regarding:

- Attaching a module
- Set loading and infusion delivery
- Cleaning the device
- Inspecting the device

Sections and procedures from the existing BD  $Alaris^{TM}$  System with  $Guardrails^{TM}$  Suite MX User Manual for the PCU software releases above have been updated in this addendum to include new information, highlighted in **blue**. See your user manual for all other information for using your BD Alaris  $^{TM}$  System or Alaris  $^{TM}$  System.

#### Warnings, Cautions, and Notes

Product-specific warnings and cautions, covered in the applicable sections of this user manual, provide information needed to safely and effectively use the system.



#### WARNING

A statement that alerts the user to the possibility of injury, death, or other serious adverse reactions associated with the use or misuse of the device.



#### CAUTION

A statement that alerts the user to the possibility of a problem with the device associated with the use or misuse of the device.

#### NOTE:

Notes contain supplementary information or emphasize a point or procedure.

## Chapter 2 BD Alaris™ PCU Model 8015 and Alaris™ PCU Models 8015 and 8000

This chapter contains the following topics:

Warnings and Cautions	6
Location Matrix	8
Attaching a Module	C

#### **Warnings and Cautions**

#### General



#### WARNINGS

- Explosion risk if used in the presence of flammable anesthetic agents or gases.
- Assess patient's condition before silencing an alarm. Do not silence alarm if patient safety might be compromised.
- Before each use, verify that the alarm limits are appropriate for the patient.
- The system performs a self check during power up. The PCU should beep, no errors should occur, and if a module is connected, all LED segments should flash. If the system fails the self check, remove the failing PCU or module from use.
- When properly secured/snapped, the release latch provides a very secure connection between modules. If not properly latched, a module can be dislodged during operation.
- Securely attach modules as instructed to prevent damage to IUI connectors and/or interruption of therapy.
- Disconnect from main (AC) and battery power when performing maintenance.
- Use only CareFusion batteries. The use of third party batteries could affect the safety and efficacy of BD Alaris™ and Alaris™ products.
- The battery cannot be repaired and should not be opened.
- The battery is intended as a backup system. Leave the power cord connected to a hospital grade AC power source whenever available.
- Battery replacement should be performed by qualified service personnel while the instrument is not in use.
- Electrical shock hazard. Do not open case. Refer to qualified service personnel.
- Due to the intermittent nature of a wireless environment, some data can be lost if a connection cannot be established or is lost. The BD Alaris™ Systems Manager and wireless network card are designed to minimize these incidents but cannot eliminate them
- The system is not intended to replace supervision by medical personnel. The user must become thoroughly familiar with the system features, operation and accessories prior to use.
- Do not modify this equipment without authorization of the manufacturer. Authorization should be obtained through written communication from the manufacturer.



#### CAUTIONS

- Always use a grounded three-wire receptacle. Where the integrity of the protective earth grounding system is in doubt, operate on internal battery.
- Hyperbaric Chamber Operation:
  - The system is not certified for use in oxygen-enriched environments.
  - The system, with the exclusion of the EtCO<sub>2</sub> module, has been verified to operate with no malfunction alarms due to the hyperbaric chamber environment or unintentional key presses when used in a hyperbaric chamber.
  - The healthcare facility's hyperbaric safety director is responsible for all equipment used in the hyperbaric chamber environment.
- Should an instrument or accessory be dropped or severely jarred, it should be immediately
  taken out of use and inspected by qualified service personnel to ensure its proper function
  prior to reuse.
- If an instrument appears damaged, contact CareFusion for authorization to return it for repair.

#### **Location Matrix**

Use the table below to locate the pages in the *BD Alaris* TM System with Guardrails TM Suite MX User Manual for your PCU software release that are updated by the information in this addendum.

Read across a row to see the PCU software version, part number, and page in the applicable where the updates in this addendum provide additional information.

Page numbers are listed as if you were looking at a physical book with the number at the bottom of the page. For manuals where the page number is in x-y format, x is the chapter or section number, and y is the page within that chapter or section. For example, a page number of 1-3 indicates chapter or section 1, page 3.

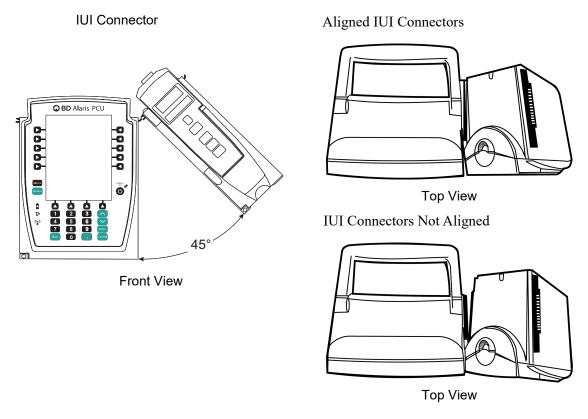
PCU Software Version	Part Number	Feature: Attaching a module
12.1	P00000225	p. 18
10.5	12281338	p. 1-3
9.33	P00000367	p. 1-3
9.19.1	P00000368	p. 1-3
9.13	P00000369	p. 1-3
9.12	P00000370	p. 1-3
9.5 PCU 8015	11777361	p. 1-3
9.1, 9.2 PCU 8015	11508981	p. 1-3
9.5 PCU 8000	11775730	p. 1-3
9.1 PCU 8000	11508980	p. 1-3

#### **Attaching a Module**

The system is designed to operate a maximum of four infusion or monitoring modules. Modules added in excess of four are not recognized by the system. The Alaris<sup>TM</sup> Auto-ID Module can be included as a fifth module. A module can be attached in any position; however, when mounted on an IV pole, it is recommended that a balanced configuration be maintained.

Application of adhesive tape or other materials to the sides of the PCU and modules can prevent proper latching.

1. Position free module at a 45° angle, aligning IUI connectors.





WARNING

When properly secured/snapped, the release latch provides a very secure connection between modules. If not properly latched, a module can be dislodged during operation.



WARNING

Securely attach modules as instructed to prevent damage to IUI connectors and/or interruption of therapy.

2. Rotate free module down against PCU or attached module until release latch snaps in place.

 -DD Alails	s™ PCU Mo	 una / tiant	 	una occo	

# Chapter 3 BD Alaris™ Pump Module Model 8100, Alaris™ Pump Module Model 8100, and Alaris™ Syringe Module Model 8110

#### This chapter contains the following topics:

Warnings and Cautions	
Location Matrix	
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Programming a Continuous Infusion	23
Restoring a Bolus Dose	30
Intermittent Infusion	
Rate/Volume Infusion	30
Volume/Duration Infusion	38
Secondary Infusion	41

#### **Warnings and Cautions**



#### WARNING

- Ensure syringe sizes and models are compatible with the Syringe Module. The use of any other syringe or administration set can cause improper pump operation, resulting in inaccurate fluid delivery, insufficient occlusion (blockage) sensing, or other potential hazards.
- Use the smallest compatible syringe size necessary to deliver the fluid or medication; this is especially important when infusing high risk or life-sustaining medications at low infusion rates (for example, < 5 mL/h, and especially flow rates < 0.5 mL/h). Using a larger syringe when infusing at low rates can lead to inadequate syringe pump performance including delivery inaccuracies, delay of therapy, and delayed generation of occlusion alarms. This is due to the increased friction and compliance of the syringe stopper with larger syringes.</li>
- Ideally, the Syringe Module should be level with the patient's heart. If the Syringe
  Module height is raised relative to the patient's heart level (for example, during patient
  transport), the increase in height of the Syringe Module can result in a temporary
  increase in fluid delivery or bolus until the flow rate stabilizes. Alternatively, if the
  Syringe Module is lowered relative to the patient's heart level, the decrease in the
  height of the Syringe Module may result in a decrease in delivery or under-infusion
  until the flow rate stabilizes.
- Electronically prime the syringe pump system before starting an infusion or after replacing a near-empty syringe with a replacement syringe.
- During programming and prior to starting an infusion, verify that the syringe size and model on the PCU display screen matches the syringe size and model loaded into the Syringe Module.
- The Pump and Syringe Modules are designed to stop fluid flow under alarm conditions. Periodic patient monitoring must be performed to ensure that the infusion is proceeding as expected. It is a positive displacement delivery system, capable of developing positive fluid pressures to overcome widely varying resistances to flow encountered in practice, including resistances to flow imposed by small gauge catheters, filters, and intra-arterial infusion. It is neither designed nor intended to detect infiltrations and does not alarm under infiltration conditions.
- The use of positive displacement infusion devices ported together with gravity flow infusion systems into a common IV site can impede the flow of common "gravity only" systems, affecting their performance. Hospital/ facility personnel must ensure that the performance of the common IV site is satisfactory under these circumstances.
- To prevent a potential free-flow condition, ensure that no extraneous object (for example, bedding, tubing, glove) is enclosed or caught in the Pump Module door. Free-flow condition can result in patient harm.
- To prevent a potential free-flow condition, do not use a Pump Module if it is damaged in any
  way or does not appear to be functioning as expected. Free-flow condition can result in
  patient harm.



#### CAUTION

- Use compatible components which have the smallest internal volume or "deadspace" to minimize residual volumes between the syringe and the patient when administering medications or fluids at low infusion rates (for example, < 5 mL/h, and especially flow rates < 0.5 mL/h). This reduces the amount of time it takes for fluid to reach the patient, maintains delivery accuracy, and reduces occlusion detection times.
- Minimize the height difference between the pump and the patient and avoid changes in the height of the Syringe Module (for example, during transport of critically ill patients) to prevent unintended fluctuations in the flow rate.
- If using multiple syringe pumps and it is not clinically feasible to have all pumps level with the patient's heart, place the high risk or life-sustaining medications as close to the heart level as possible. When infusing multiple high risk or life-sustaining medications, consider placing the ones infusing at the lowest rates as close to the level of the patient's heart as possible.
- Avoid use of manifolds with ports containing high pressure valves. High pressure valves
  require additional pressure (for example, 50 200 mmHg) to open and allow fluid flow. These
  high pressure valves may cause a significant delay in therapy followed by a sudden bolus
  once the valve is opened, particularly at low infusion rates (for example, < 5 mL/h, and
  especially flow rates < 0.5 mL/h).</li>

#### **Location Matrix**

Use the table below to locate the pages in the *BD Alaris* TM System with Guardrails TM Suite MX User Manual for your PCU software release that are updated by the information in this addendum.

Locate the PCU software version that you are using and the feature that you want to know more about. The table cell where PCU software version and feature intersect contains the page location in your user manual.

Page numbers are listed as if you were looking at a physical book with the number at the bottom of the page. For manuals where the page number is in x-y format, x is the chapter or section number, and y is the page within that chapter or section. For example, a page number of 1-3 indicates chapter or section 1, page 3.

PCU Software Version	Part Number	Preparing an Administration Set (Pump Module)	Programming a Continuous Infusion	Restoring a Bolus Dose	Intermittent Infusion	Rate/Volume Infusion	Volume/Duration Infusion	Secondary Infusion
12.1	P00000225	p. 64	p. 91	p. 103	p.104	p. 109	p. 111	p. 114
10.5	12281338	p. 2-3	p. 2-21	p. 2-32	p. 2-34	p. 2-42	p. 2-44	p. 2-55
9.33	P00000367	p. 2-3	p. 2-27	p. 2-38	p. 2-40	p. 2-45	p. 2-47	p. 2-51
9.19.1	P00000368	p. 2-3	p. 2-30	p. 2-41	p. 2-43	p. 2-48	p. 2-50	p. 2-54
9.13	P00000369	p. 2-3	p. 2-21	p. 2-32	p. 2-34	p. 2-38	p. 2-40	p. 2-44
9.12	P00000370	p. 2-3	p. 2-27	p. 2-38	p. 2-43	p. 2-44	p. 2-46	p. 2-50
9.5 PCU 8015	11777361	p. 2-3	p. 2-21	p. 2-32	p. 2-34	p. 2-38	p. 2-40	p. 2-45
9.1, 9.2 PCU 8015	11508981	p. 2-3	p. 2-21	p. 2-32	p. 2-34	p. 2-38	p. 2-40	p. 2-45
9.5 PCU 8000	11775730	p. 2-3	p. 2-21	p. 2-32	p. 2-34	p. 2-38	p. 2-40	p. 2-45
9.1 PCU 8000	11508980	p. 2-3	p. 2-21	p. 2-32	p. 2-34	p. 2-38	p. 2-40	p. 2-45

### Preparing an Administration Set (BD Alaris™ Pump Module)



#### WARNING

#### **Administration Sets:**

- Use only BD Alaris<sup>™</sup> Pump Infusion administration sets. The use of any other set can cause improper instrument operation, resulting in an inaccurate fluid delivery or other potential hazard. For a list of compatible administration sets, please refer to the Alaris<sup>™</sup> Pump Module Set Compatibility Card.
- Discard if packaging is not intact or protector caps are unattached.

#### **Priming**

- 1. Prepare primary solution container in accordance with manufacturer's user manual.
- 2. Open administration set package, remove set, and close roller clamp. (Refer to set's user manual.)
- 3. Insert administration set spike into prepared fluid container, following accepted hospital/facility procedure, and hang container 20 inches above pump module.
- 4. Allow solutions to warm to room temperature, if possible. (When infusing a chilled solution, air bubbles may form as cold solutions begin to warm).
- 5. Fill drip chamber to ½ full. Hang drip chamber vertically.
- 6. If container requires venting, open vent cap on administration set spike.
- 7. Priming tubing should be done slowly to help prevent turbulence. Slowly open roller clamp to prime tubing and clear air from injection sites and tubing fitments.
- 8. When priming is complete, close roller clamp.
- 9. Verify no fluid flow.

#### Loading

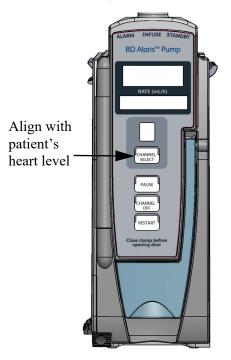
1. Pause the channel before replacing a new fluid container to avoid air from entering the IV tubing.



#### CAUTION

Ensure that the device is as close to level of patient's heart as possible. Patient's heart level should be in line with the CHANNEL SELECT key.

2. Ensure that the instrument is as close to the level of patient's heart as possible—the patient's heart should be in line with the **CHANNEL SELECT** key.





#### CAUTION

- Avoid use of manifolds with ports containing high pressure valves. High pressure valves require additional pressure (for example, 50 200 mmHg) to open and allow fluid flow. These high pressure valves may cause a significant delay in therapy followed by a sudden bolus once the valve is opened, particularly at low infusion rates (for example, < 5 mL/h, and especially flow rates < 0.5 mL/h).</li>
- 3. If a new set is being loaded, prime the set. See *Priming* in the *BD Alaris* TM *System with Guardrails* TM *Suite MX User Manual* for more information.
- 4. Open the Pump Module door.



#### WARNING

To prevent a potential free-flow condition, do not use a Pump Module if it is damaged in any way or does not appear to be functioning as expected. Free-flow condition can result in patient harm.

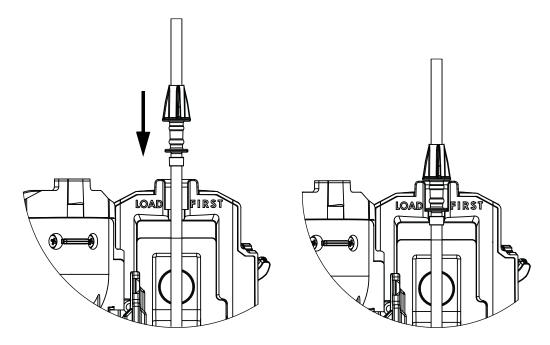
5. Look at all visible surfaces and moving parts for any sign of damage, including cracks and loose parts.



#### CAUTION

Insert upper fitment before installing safety clamp fitment.

- 6. Load the administration set, as follows:
  - a. Hold upper fitment above fitment recess and lower into recess. The upper fitment fits loosely in the recess.
  - b. Ensure that tubing is not twisted or stretched.

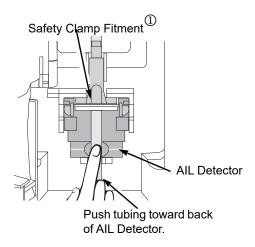


c. Press the safety clamp fitment into recess below mechanism.

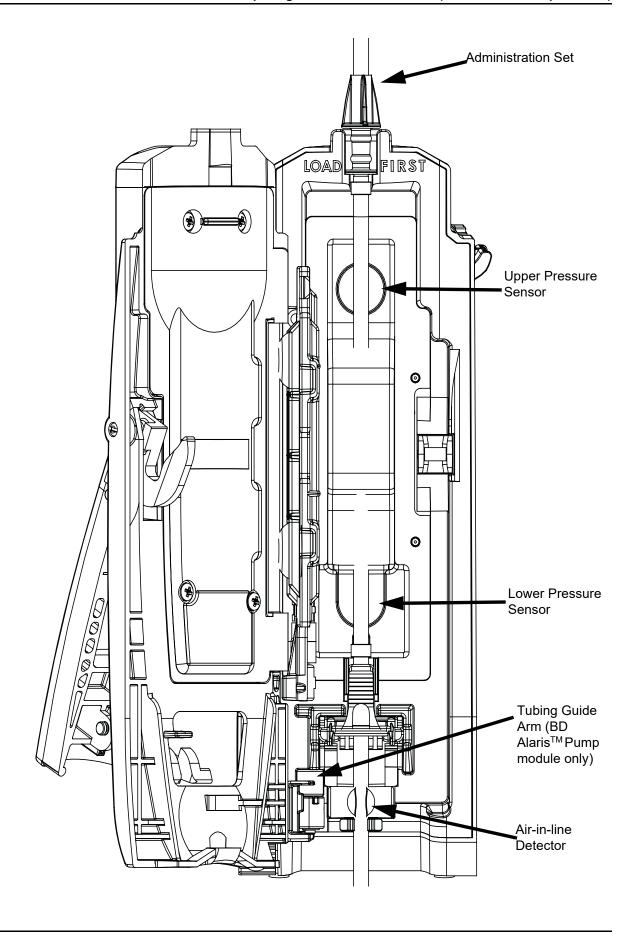


#### CAUTION

To reduce the potential for nuisance AIL alarms, ensure that tubing is fully inserted in the AIL detector.



d. Using a finger tip, firmly push tubing toward back of air-in-line (AIL) detector.





#### WARNING

- Do not touch the administration set while closing the door. Failure to follow this instruction can result in infusion rate inaccuracy.
- Ensure tubing placement is over pressure sensors.
- Ensure the upper fitment is not elevated above the receptacle on the pump.
   This could be caused by maintaining traction on the set (or stretching the set) while closing and latching the door. If the set is loaded in this manner, infusion inaccuracies may occur. To prevent a potential free-flow condition, ensure that no extraneous object (for example, bedding, tubing, glove) is enclosed or caught in the Pump Module door. Free-flow condition can result in patient harm.



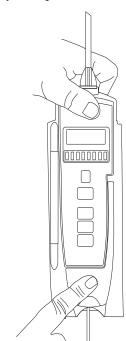
#### WARNING

For BD Alaris<sup>™</sup> Pump Module, ensure that the tubing guide arm is not missing and that it opens when the Pump Module door opens. A tubing guide arm failure can result in a nuisance air-in-line alarm. If there is a failure, send the Pump Module to CareFusion for repair.



#### CAUTION

- Failure to follow proper administration set loading instructions might lead to an instrument malfunction.
- Before operating the instrument, verify that the administration set is free from kinks and correctly installed.
- When reloading an administration set, leave the safety clamp fitment in the closed position. See Safety Clamp Fitment (Pump Module in the BD Alaris™ System with Guardrails™ Suite MX User Manual).
- 7. Close the door and latch, as follows:
  - a. Close the door and hold it in a closed position by grasping both the door and the instrument case with one hand.
  - b. Gently lower the latch.



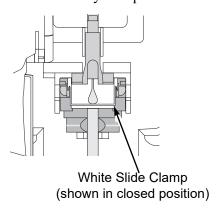
The safety clamp device is automatically disengaged. <sup>①</sup>

- 8. Open the roller clamp.
- 9. Verify that no fluid is flowing through the drip chamber.

#### Removing

- 1. Close the roller clamp.
- 2. Open the pump module door.

The set's safety clamp fitment automatically closes to prevent accidental free-flow.

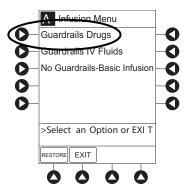


- 3. Remove set, as follows:
  - a. Gently pull tubing below air-in-line detector forward and out.
  - b. Lift upper fitment from upper fitment receptacle.
- 4. If set is being removed to begin a gravity flow:
  - a. Depress the blue ridged release tab on upper side of safety clamp device.
  - b. Slide the white slide clamp into blue fitment (open position).
  - c. Adjust the flow rate using set's roller clamp.

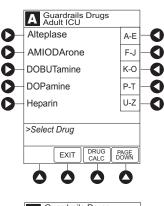
#### **Programming a Continuous Infusion**

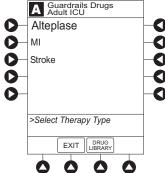
When using a drug listed in the drug library, the drug parameters are automatically calculated, based on:

- · Drug selected
- Weight entry (if required)
- Rate or dose entry
- VTBI entry (Syringe Module—if other than All)
- 1. Press the **GUARDRAILS DRUGS** soft key.



- 2. Press the soft key next to desired drug.
  - To view additional drugs/concentrations, press a soft key next to a letter group to navigate through alphabet, and/or PAGE UP and PAGE DOWN soft keys.



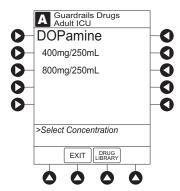


• If applicable, an optional hospital-defined therapy or clinical indication for delivery of this infusion could appear (as in illustrated example, which reflects use of Alteplase). Different limits can be defined for same drug with different therapeutic indications.

• Therapy indication appears on drug or IV fluid confirmation screen. Once drug or IV fluid has been confirmed, therapy indication appears in title bar.



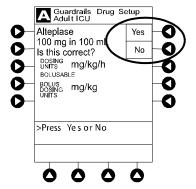
• If applicable, a weight-based or non weight-based option for delivery of this infusion could appear (as in illustrated example, which reflects use of Heparin).



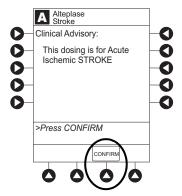
- If applicable, multiple concentration listings for delivery of this infusion could appear (as in illustrated example, which reflects use of Dopamine).
- 3. To continue programming, press the **Yes** soft key. <sup>①</sup> Bolus dose units appear if bolus dose is enabled.

or

To change selection, press the **No** soft key.



• If **Yes** was selected and facility has defined a clinical advisory for that drug, a message appears. To indicate information has been noted and continue programming, press the **CONFIRM** soft key.



• If **Yes** was selected to continue programming, drug amount and diluent volume (if defined in drug library) are automatically entered for selected drug.



- If the selected drug had "\_\_/\_ mL" concentration, the drug amount and diluent volume need to be entered.
- If the selected drug is not weight-based, **Not Used** is displayed in patient weight field.
- If hospital/facility practice guidelines identify selected drug as weight-based, a prompt for a patient weight in kilograms appears (as in illustrated example, which reflects use of Alteplase). ②③

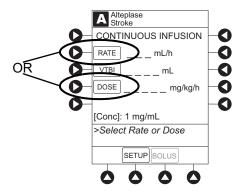


4. Verify correct parameters and press the **Next** soft key to confirm.

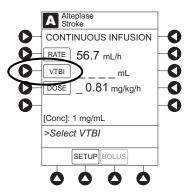
5. An optional hospital-defined and editable starting value for continuous infusion dose might already be entered.

or

To make a rate or dose entry, press the applicable soft key, **RATE** or **DOSE**, and use numeric data entry keys (other value is calculated and displayed).



- 6. To enter the volume to be infused, press the **VTBI** soft key and enter value.
  - Pump Module:
    - When VTBI is less than 10 mL, the entry can be to two decimal places (one-hundredth of a mL).
    - In drug calculation mode, System infuses at calculated rate rounded to nearest one-hundredth of a mL per hour (as displayed on the programming screen on the PCU). The rate shown in rate display on the Pump Module is rounded to nearest one-tenth of a mL per hour.
  - The **Bolus** soft key appears only if bolus dose is enabled within the selected profile, the drug is bolusable, and a VTBI is entered.

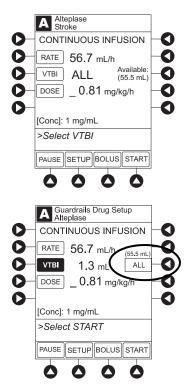


- Syringe Module:
  - If **ALL Mode** is enabled for syringe configuration in data set, **ALL** is displayed in **VTBI** field and estimated available volume in syringe is displayed.

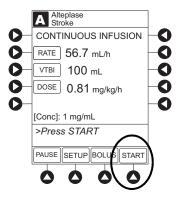
or

- If **ALL Mode** is disabled for syringe configuration in data set, estimated available volume in syringe is displayed when **VTBI** soft key is pressed.
- To enter or change a numeric VTBI value, press the **VTBI** soft key and enter value.

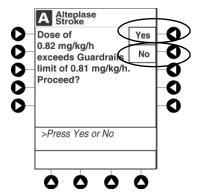
• To deliver entire contents of syringe: Keep an ALL VTBI value, or press the ALL soft key to change a numeric VTBI value to ALL.



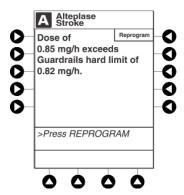
- 7. Verify the correct parameters and press the **START** soft key.
  - When beginning an infusion and periodically during an infusion, check the drip chamber, for both
    primary and secondary infusions, to ensure that the drip rate correlates to the intended infusion
    rate.
  - For a continuous infusion, the drug name and dose will scroll on the module message display.



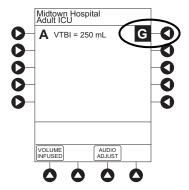
• If the programmed continuous dose infusion is outside the soft limit for that care area, an audio alert sounds and a visual prompt appears before programming can continue. If **Yes** soft key is pressed, programming continues; if **No** soft key is pressed, infusion needs to be reprogrammed.



• If the programmed continuous dose infusion is outside the hard limit for that care area, an audio alert sounds and a visual prompt appears before programming can continue. Infusion needs to be reprogrammed.



- If a dose outside of the soft limits has been entered and verified as correct, message display also shows either "LLL" for a low dose or "↑↑↑" for a high dose.
- If a soft limit is overridden, **G** icon is displayed. When **G** soft key is pressed, all applicable out-of-range limits are listed.



#### 8. Syringe Module:

- Unclamp tubing and attach administration set to patient.
- Unclamping tubing and starting infusion before attaching administration set to patient minimizes any potential bolus that can be released from pressure built up in set due to normal syringe loading and priming.

#### NOTE:

- ① The facility can choose to pre-populate standard drug concentrations, or leave a custom concentration (\_ / \_ mL) and allow the clinician to enter the desired concentration.
- ② Patient weight can be edited during a continuous infusion.
- ③ Once a patient weight is entered and an infusion is started for any module, the patient weight is automatically entered for any additional weight-based calculation. The patient weight remains an editable field, therefore patient weight can be adjusted for any module. Changing the patient weight on one module does not affect the patient weight on any other module.

#### NOTE:

Programming the secondary rate over 500 mL/h may result in concurrent flow with the primary container.

#### NOTE:

It is possible to program an infusion with a rate that is displayed with two decimal places (one-hundredth of a mL per hour) on the PCU for the pump module. However, due to space limitations on the pump module rate display, the rate is displayed to the nearest one-tenth of a mL per hour on the pump module. This value is only used for display purposes and the pump module is actually infusing at the more precise rate noted on the PCU.

#### **Restoring a Bolus Dose**

A bolus dose can be restored after it has completed, either prior to or after the module has been turned off, as indicated in the following procedures.

The display examples in this procedure represent restoring a bolus dose which was programmed using the drug library. Even where the displays are different when restoring a bolus dose which was programmed using a non-library drug, the procedure is the same.

- 1. Bolus Dose completed module not turned off:
  - a. Press the CHANNEL SELECT key.
  - b. Verify infusion parameters and press the **BOLUS** soft key.
  - c. Press the **RESTORE** soft key.
  - d. Verify dosing parameters and press the **START** soft key.
    - When beginning an infusion and periodically during an infusion, check the drip chamber, for both primary and secondary infusions, to ensure that the drip rate correlates to the intended infusion rate.
- 2. Bolus Dose completed module turned off:
  - a. Press the **CHANNEL SELECT** key.
  - b. Press the **RESTORE** soft key.
  - c. Verify parameters and press the **NEXT** soft key.
  - d. Verify infusion parameters and press the **BOLUS** soft key.
  - e. Press the **RESTORE** soft key.
  - f. Verify dosing parameters and press the **START** soft key.
    - When beginning an infusion and periodically during an infusion, check the drip chamber, for both primary and secondary infusions, to ensure that the drip rate correlates to the intended infusion rate.

#### NOTE:

- ① If the bolus dose feature is enabled, the **BOLUS** soft key appears in the Continuous Infusion screen and becomes active when a VTBI is entered.
- ② The bolus VTBI cannot exceed the programmed Continuous Infusion VTBI.
- ③ Programming and starting a bolus dose deletes any programmed delay.
- ④ If no continuous rate is entered or if the bolus dose VTBI equals the Continuous Infusion VTBI, the infusion ends when the bolus has been delivered. No KVO infusion follows.
- ⑤ To see details during the bolus infusion, press the **CHANNEL SELECT** key.
- (6) The pump module keypad is used in the illustration but the key is the same for the syringe module.

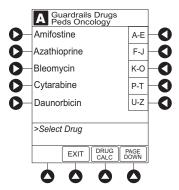
# Intermittent Infusion

When using a drug listed in the drug library, the drug parameters are automatically delivered, based on:

- Drug selected
- Weight or body surface area (BSA) entry (if required)
- Dose entry
- Rate or duration dose entry
- VTBI entry

Syringe Module: The KVO option is disabled when an intermittent infusion is programmed.

- 1. Press the Guardrails Drugs soft key.
- 2. Press soft key next to desired drug.
  - To view additional drugs, press the a soft key next to a letter group to navigate through alphabet, and/or PAGE UP and PAGE DOWN soft keys.
  - If applicable, an optional hospital-defined therapy or clinical indication for delivery of this infusion could appear. Different limits can be defined for same drug with different therapeutic indications.
  - If applicable, a weight-based, non weight-based, or BSA-based option for delivery of this infusion could appear.
  - If applicable, multiple concentration listings for delivery of this infusion could appear.



3. To continue programming, press the **Yes** soft key. ① or

To change selection, press the **No** soft key.



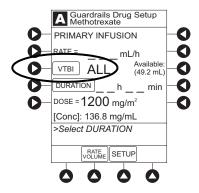
- If **Yes** was selected and facility has defined a clinical advisory for that drug, a message appears. To indicate information has been noted and continue programming, press the **CONFIRM** soft key.
- If **Yes** was selected to continue programming, drug amount and diluent volume (if defined in drug library) are automatically entered for selected drug.
- If selected drug had "\_\_/\_ mL" concentration, drug amount and diluent volume need to be entered.
- If selected drug is not weight-based, **NOT USED** is displayed in **PATIENT WEIGHT** field.
- If hospital/facility practice guidelines identify selected drug as weight-based or by BSA, a prompt for a patient weight in kilograms or BSA appears (as in illustrated example, which reflects the use of Methotrexate).



- 4. Verify correct parameters and press the **NEXT** soft key to confirm.
  - If the programmed total dose drug amount is outside the soft limit for that care area, an audio alert sounds and a visual prompt appears before programming can continue. If **Yes** soft key is pressed, programming continues; if **No** soft key is pressed, infusion needs to be reprogrammed.
  - If the programmed total dose drug amount is outside the hard limit for that care area, an audio alert sounds and a visual prompt appears before programming can continue. Infusion needs to be reprogrammed.
  - If a dose outside of soft limits has been entered and verified as correct, Message Display also shows either "LLL" for a low dose or "^^^" for a high dose.
  - If a soft limit is overridden, **G** icon is displayed. When **G** soft key is pressed, all applicable out-of-range limits are listed.

## 5. VTBI entry:

- Pump Module:
  - When VTBI is less than 10 mL, entry can be to two decimal places (one-hundredth of a mL).
  - VTBI is pre-populated with diluent volume of infusion. To change VTBI, press the **VTBI** soft key and enter new value.



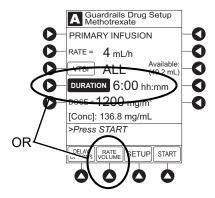
- Syringe Module:
  - If ALL Mode is enabled for syringe configuration in data set, **ALL** is displayed in VTBI field and estimated available volume in syringe is displayed.

or

- If ALL Mode is disabled for syringe configuration in data set, estimated available volume in syringe is displayed when **VTBI** soft key is pressed.
- To enter or change a numeric **VTBI** value, press the **VTBI** soft key and enter value.
- To deliver entire contents of syringe: Keep an ALL VTBI value, or press the ALL soft key to change a numeric VTBI value to ALL.



- 6. If an optional hospital-defined and editable starting value for intermittent duration is not already entered, enter duration or rate, as follows:
  - To enter duration, press the **DURATION** soft key and use numeric data entry keys (rate value is calculated and displayed).
  - To enter rate, press the **RATE VOLUME** soft key and enter infusion rate.



- 7. Verify correct parameters and press the **START** soft key.
  - When beginning an infusion and periodically during an infusion, check the drip chamber, for both
    primary and secondary infusions, to ensure that the drip rate correlates to the intended infusion
    rate.
  - If the programmed duration is outside the soft limit for that care area, an audio alert sounds and a visual prompt appears before programming can continue. If the **Yes** soft key is pressed, programming continues; if the **No** soft key is pressed, infusion needs to be reprogrammed.
  - If the programmed duration is outside the hard limit for that care area, an audio alert sounds and a visual prompt appears before programming can continue. Infusion needs to be reprogrammed.
  - If a soft limit is overridden, **G** icon is displayed. When **G** soft key is pressed, all applicable out-of-range limits are listed.
  - For an intermittent infusion, the drug name and dose will scroll on the module Message Display.

#### NOTE:

For an intermittent infusion, depending on how the drug library is programmed, the dose may display as a total dose, drug amount/kg or drug amount/BSA.

- 8. Syringe Module:
  - Unclamp tubing and attach administration set to patient.
  - Unclamping tubing and starting infusion before attaching administration set to patient minimizes
    any potential bolus that can be released from pressure built up in set due to normal syringe loading
    and priming.

#### NOTE:

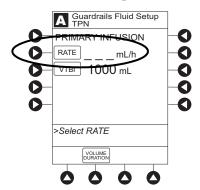
- ① The facility can choose to pre-populate standard drug concentrations, or leave a custom concentration (\_\_/\_\_mL) and allow the clinician to enter the desired concentration.
- ② Patient weight or BSA is not editable on that module during an Intermittent Infusion.
- ③ Once a patient weight or BSA is entered and the infusion started, the patient weight or BSA is automatically entered for any additional weight-based or BSA calculation. Prior to the start of an intermittent infusion, the patient weight or BSA remains an editable field so that patient weight or BSA can be adjusted for any module. Changing the patient weight or BSA on one module will not affect the patient weight or BSA on any other module.

#### NOTE:

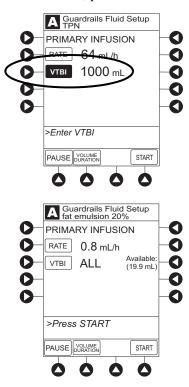
It is possible to program an infusion with a rate that is displayed with two decimal places (one-hundredth of a mL per hour) on the PCU for the Pump Module. However, due to space limitations on the Pump Module rate display, the rate is displayed to the nearest one-tenth of a mL per hour on the Pump Module. This value is only used for display purposes and the Pump Module is actually infusing at the more precise rate noted on the PCU.

# **Rate/Volume Infusion**

1. To enter flow rate, press the **RATE** soft key and use numeric data entry keys.



2. To enter **VTBI**, press the **VTBI** soft key and use numeric data entry keys.

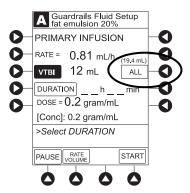


- Syringe Module:
  - If **ALL Mode** is enabled for syringe configuration in data set, **ALL** is displayed in **VTBI** field and estimated available volume in syringe is displayed.

or

- If ALL Mode is disabled for syringe configuration in data set, VTBI ALL option is not available and estimated available volume in syringe is displayed when VTBI soft key is pressed.
- To enter or change a numeric **VTBI** value, press the **VTBI** soft key and use numeric data entry keys.

• To deliver entire contents of syringe: Keep an ALL VTBI value, or press the ALL soft key to change a numeric VTBI value to ALL.



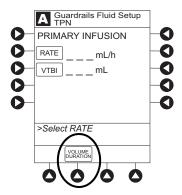
- 3. Verify correct infusion parameter entry and press the **START** soft key. <sup>①</sup>
  - When beginning an infusion and periodically during an infusion, check the drip chamber, for both
    primary and secondary infusions, to ensure that the drip rate correlates to the intended infusion
    rate.
  - If the programmed IV fluid is outside the soft limit for that care area, an audio alert sounds and a visual prompt appears before programming can continue. If the **Yes** soft key is pressed, programming continues; if the **No** soft key is pressed, infusion needs to be reprogrammed.
  - If the programmed IV fluid is outside the hard limit for that care area, an audio alert sounds and a visual prompt appears before programming can continue. Infusion needs to be reprogrammed.
  - If a soft limit is overridden, **G** icon is displayed. When **G** soft key is pressed, all applicable out-of-range limits are listed.

# 4. Syringe Module:

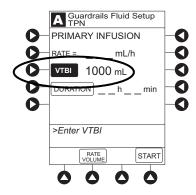
- Unclamp tubing and attach administration set to patient.
- Unclamping tubing and starting infusion before attaching administration set to patient minimizes
  any potential bolus that can be released from pressure built up in set due to normal syringe loading
  and priming.

# **Volume/Duration Infusion**

1. Press the **VOLUME DURATION** soft key.



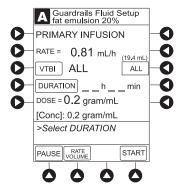
2. To enter VTBI, press the VTBI soft key and use numeric data entry keys.



- Syringe Module:
  - If **ALL Mode** is enabled for syringe configuration in data set, **ALL** is displayed in **VTBI** field and estimated available volume in syringe is displayed.

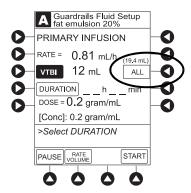
or

If **ALL Mode** is disabled for syringe configuration in data set, **VTBI ALL** option is not available and estimated available volume in syringe is displayed when **VTBI** soft key is pressed.

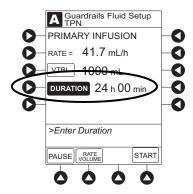


To enter or change a numeric **VTBI** value, press the **VTBI** soft key and use numeric data entry keys.

To deliver entire contents of syringe: Keep an ALL VTBI value, or press the ALL soft key to change a numeric VTBI value to ALL.

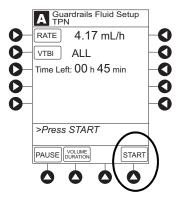


3. To enter volume duration, press the **DURATION** soft key and use numeric data entry keys. Rate is automatically calculated.



- 4. Verify correct infusion parameter entry and press the **START** soft key.<sup>②</sup>
  - When beginning an infusion and periodically during an infusion, check the drip chamber, for both
    primary and secondary infusions, to ensure that the drip rate correlates to the intended infusion
    rate.
  - If the programmed IV Fluid is outside the soft limit for that care area, an audio alert sounds and a visual prompt appears before programming can continue. If **Yes** soft key is pressed, programming continues; if **No** soft key is pressed, infusion needs to be reprogrammed.
  - If the programmed IV Fluid is outside the hard limit for that care area, an audio alert sounds and a visual prompt appears before programming can continue. Infusion needs to be reprogrammed.
  - If a soft limit is overridden, **G** icon is displayed. When **G** soft key is pressed, all applicable out-of-range limits are listed.
- 5. Syringe Module:
  - Unclamp tubing and attach administration set to patient.

• Unclamping tubing and starting infusion before attaching administration set to patient minimizes any potential bolus that can be released from pressure built up in set due to normal syringe loading and priming.



## NOTE:

- $\ensuremath{\textcircled{1}}$  The infusion can be paused by pressing the **PAUSE** soft key.
- ② To view infusion **Time Left** during a volume/duration infusion, press the **CHANNEL SELECT** key. To return to previous screen, press the **START** soft key.

#### NOTE:

It is possible to program an infusion with a rate that is displayed with two decimal places (one-hundredth of a mL per hour) on the PCU for the Pump Module. However, due to space limitations on the Pump Module rate display, the rate is displayed to the nearest one-tenth of a mL per hour on the Pump Module. This value is only used for display purposes and the Pump Module is actually infusing at the more precise rate noted on the PCU.

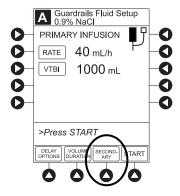
# **Secondary Infusion**

The following procedure should be used only when:

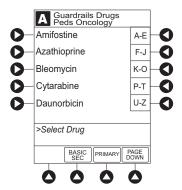
- Drug to be infused is listed in drug library,
- Primary infusion is running, and
- A check valve administration set is being used.

To program a primary infusion, see *Fluid Infusion* in the *BD Alaris*  $^{\text{TM}}$  *System with Guardrails*  $^{\text{TM}}$  *Suite MX User Manual.* To program a No Guardrails  $^{\text{TM}}$  - Basic Infusion, see *Manual Programming* — *No Guardrails Selections* in the *BD Alaris*  $^{\text{TM}}$  *System with Guardrails*  $^{\text{TM}}$  *Suite MX User Manual.* 

- 1. Press the **CHANNEL SELECT** key.
- 2. Press the **SECONDARY** soft key.



- 3. Press soft key next to desired drug.
  - To view additional drugs, press the a soft key next to a letter group to navigate through alphabet, and/or PAGE UP and PAGE DOWN soft keys.
  - If applicable, an optional hospital-defined therapy or clinical indication for delivery of this infusion could appear. Different limits can be defined for same drug with different therapeutic indications.
  - If applicable, a weight-based, non weight-based, or BSA-based option for delivery of this infusion could appear.
  - If applicable, multiple concentration listings for delivery of this infusion could appear.



4. To continue programming, press the **Yes** soft key. <sup>①</sup>

or

To change selection, press the **No** soft key.



- If **Yes** was selected and the facility has defined a clinical advisory for that drug, a message appears. To indicate information has been noted and continue programming, press the **CONFIRM** soft key.
- If **Yes** was selected to continue programming, drug amount and diluent volume (if defined in drug library) are automatically entered for selected drug.
- If selected drug had "\_\_/\_\_mL" concentration, drug amount and diluent volume need to be entered.
- If selected drug is not weight-based, **Not Used** is displayed in **PATIENT WEIGHT** field.
- If hospital/facility practice guidelines identify selected drug as weight-based, prompt for a patient weight in kilograms or BSA appear (as in illustrated example, which reflects use of Methotrexate). ②③



- 5. Verify correct parameters and press the **NEXT** soft key to confirm.
  - If the programmed total dose drug amount is outside the soft limit for that care area, an audio alert sounds and a visual prompt appears before programming can continue. If the **Yes** soft key is pressed, programming continues; if the **No** soft key is pressed, infusion needs to be reprogrammed.
  - If the programmed total dose drug amount is outside the hard limit for that care area, an audio alert sounds and a visual prompt appears before programming can continue. Infusion needs to be reprogrammed.
  - If a dose outside of soft limits has been entered and verified as correct, Message Display also shows either "LLL" for a low dose or "↑↑↑" for a high dose.

• If a soft limit is overridden, **G** icon is displayed. When **G** soft key is pressed, all applicable out-of-range limits are listed.

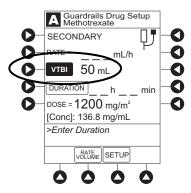


# WARNING

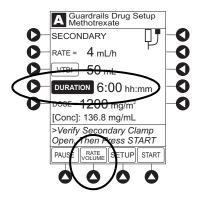
The secondary VTBI settings require consideration of such variables as factory overfill, medication additions. Underestimating the volume causes the remaining secondary solution to be infused at the primary rate; overestimating results in the primary solution being infused at the secondary rate. Multiple doses from a single container are not possible.

## 6. VTBI entry:

- When VTBI is less than 10 mL/h, entry can be to two decimal places (one-hundredth of a mL).
- VTBI is pre-populated with diluent volume of infusion. To change VTBI, press the **VTBI** soft key and use numeric data entry keys.



- 7. If an optional hospital-defined and editable starting value for intermittent duration is not already entered, enter duration or rate, as follows:
  - To enter duration, press the **DURATION** soft key and use numeric data entry keys (rate value is calculated and displayed).
  - To enter rate, press the **RATE VOLUME** soft key and use numeric data entry keys.





# WARNING

The clamp on the secondary administration set must be opened. If the clamp is not opened, the fluid is delivered from the primary container.

- 8. Open clamp on secondary administration set.
- 9. Verify correct parameters and press the **START** soft key.
  - When beginning an infusion and periodically during an infusion, check the drip chamber, for both
    primary and secondary infusions, to ensure that the drip rate correlates to the intended infusion
    rate.
  - If the programmed duration is outside the soft limit for that care area, an audio alert sounds and a visual prompt appears before programming can continue. If the **Yes** soft key is pressed, programming continues; if the **No** soft key is pressed, infusion needs to be reprogrammed.
  - If the programmed duration is outside hard limit for that care area, an audio alert sounds and a visual prompt appears before programming can continue. Infusion needs to be reprogrammed.
  - If a soft limit is overridden, **G** icon is displayed. When **G** soft key is pressed, all applicable out-of-range limits are listed.
- 10. Verify that drops are flowing from the secondary container drip chamber.

#### NOTE:

- ① The facility can choose to pre-populate standard drug concentrations, or leave a custom concentration (\_ \_ / \_ \_ mL) and allow the clinician to enter the desired concentration
- ② Patient weight or BSA is not editable during a Secondary Infusion.
- ③ Once a patient weight or BSA is entered and the infusion started, the patient weight or BSA is automatically entered for any additional weight-based or BSA calculation. Prior to the start of infusion, the patient weight or BSA key remains an editable field so that patient weight or BSA can be adjusted for any module. Changing the patient weight or BSA on one module will not affect the patient weight or BSA on any other module.

#### NOTE

Programming the secondary rate over 500 mL/h may result in concurrent flow with the primary container.

#### NOTE:

It is possible to program an infusion with a rate that is displayed with two decimal places (one-hundredth of a mL per hour) on the PCU for the Pump Module. However, due to space limitations on the Pump Module rate display, the rate is displayed to the nearest one-tenth of a mL per hour on the Pump Module. This value is only used for display purposes and the Pump Module is actually infusing at the more precise rate noted on the PCU.

# **Appendix A Troubleshooting and Maintenance**

# This chapter contains the following topics:

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Using IUI Connector Covers	53
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Drying and Inspection	

# **Warnings and Cautions**



# WARNING

- Perform device inspections to prevent a damaged device from being returned to patient use. Use of a damaged device can result in patient harm.
- Inspection of IUI connectors is required. Damaged IUI connectors can result in incorrect device operation. Use of a damaged device can result in patient harm.
- Failure to follow these instructions may result in potential hazards associated with damaged IUI connectors.
- Inserting a finger or other object into the IUI connector, when the module is attached to the PCU, could result in electrical shock.
- Do not return the device to patient use if there are cracks, surface contaminants, discoloration, or other damage to IUI connectors. Use of devices with damaged IUI connectors can result in patient harm. Send all damaged devices to Biomedical Engineering for repair.
- To prevent an electrical hazard:
  - Turn the instrument off and unplug the power cord from AC power before cleaning.
  - Do not spray fluids directly onto the instrument or into the IUI connectors.
  - Do not steam autoclave, EtO sterilize, immerse the instrument in fluids, or allow fluids to enter the instrument case.
  - Do not connect a module until the IUI connectors are thoroughly dry.
- Do not use compressed air to dry the instrument; this could force fluid into the instrument.
- Use IUI connector covers during cleaning to prevent damage to the IUI connectors. Use of a damaged device can result in patient harm.
- Do not wipe the air-in-line sensor with any cleaning product. Cleaning products can damage the sensor and lead to patient harm.
- Brush IUI connectors up and down. Do not brush them side-to-side.
   Brushing the IUI connectors side-to-side can damage the pins and result in patient harm.
- Missing screws and washers on the PCU can result in a loss of power and patient harm.
- Do not return a damaged device to patient use. Damaged devices can result in patient harm. Send the damaged device to Biomedical Engineering for repair.
- Do not store the device in a plastic bag. Storing a device in a plastic bag can lead to moisture buildup that can damage electronic parts and result in patient harm.



# CAUTION

- Preventive maintenance inspections should only be performed by qualified service personnel.
- Preventive maintenance inspections should be performed only by Biomedical Engineering.
- The use of chemicals that can damage the surface of the instrument and failure to follow the BD Alaris<sup>TM</sup> and Alaris<sup>TM</sup> product cleaning procedures and the cleaning solution manufacturer's recommended dilutions can result in an instrument malfunction or product damage, such as weakening and cracking of the case, and could void the warranty.
- Do not allow the cleaning solution to contact the IUI connector when cleaning the instrument.
- Do not use hard, abrasive or pointed objects to clean any part of the instrument.
- Do not allow cleaning solutions to collect on the instrument. Residue buildup might cause the moving parts to become sticky and hinder their operation over time.
- Certain chemicals can damage the surfaces of the instrument. Refer to the following website for a list of chemicals that should NOT be used: <a href="https://www.bd.com/alarissystemcleaning">www.bd.com/alarissystemcleaning</a>.
- Do not use chemicals that can damage the surface of the instrument. When possible use cleaning products that are recommended for use by CareFusion.

# **Location Matrix**

Use the table below to locate the pages in the *BD Alaris* TM System with Guardrails TM Suite MX User Manual for your PCU software release that are updated by the information in this addendum.

Locate the PCU software version that you are using and the feature that you want to know more about. The table cell where version and feature intersect contains the page location in your user manual.

Page numbers are listed as if you were looking at a physical book with the number at the bottom of the page. For manuals where the page number is in *x-y* format, *x* is the chapter or section number, and *y* is the page within that chapter or section. For example, a page number of 1-3 indicates chapter or section 1, page 3.

The section *Using IUI Connector Covers* is new content and is not included in this matrix.

PCU Software Version	Part Number	Inspection Requirements	Inspect IUI Connectors	Cleaning the Case	Cleaning the IUI	Drying and Inspection
12.1.0	P00000225	p. 344	pp. 345, 346	p. 348	p. 349	p. 349
10.5	12281338	p. 1-50 (PCU) p. 2-140 (Pump and Syringe Modules)	p. 1-50 (PCU) p. 2-141 (Pump and Syringe Modules) p. A-1	p. A-2	p. A-3	p. A-4
9.33	P00000367	p. A-26	pp. A-26, A-27	p. A-28	p. A-29	p. A-30
9.19.1	P00000368	p. 1-56 (PCU) p. 2-176 (Pump and Syringe Modules)	p. 1-56 (PCU) p. 2-176 (Pump and Syringe Modules) p. A-1	p. A-2	p. A-3	p. A-4
9.13	P00000369	p. 1-52 (PCU) p. 2-124 (Pump and Syringe Modules)	p. 1-52 (PCU) p. 2-124 (Pump and Syringe Modules) p. A-1	p. A-2	p. A-3	p. A-4
9.12	P00000370	p. 1-52 (PCU) p. 2-140 (Pump and Syringe Modules)	p. A-1	p. A-1	p. A-2	p. A-2
9.5 PCU 8015	11777361	p. 1-50, 2-124, 3-64, 4-33, 5-30, 6-18	p. 1-50, 2-124, 3-64, 4-33, 5-30, 6-18	p. A-1	p. A-2	p. A-2
9.1, 9.2 PCU 8015	11508981	p. 1-50, 2-124, 3-64, 4-33, 5-30, 6-18	p. 1-50, 2-124, 3-64, 4-33, 5-30, 6-18	p. A-1	p. A-2	p. A-2
9.5 PCU 8000	11775730	p. 1-48, 2-124, 3-64, 4-33, 5-30, 6-18	p. 1-50, 2-124, 3-64, 4-33, 5-30, 6-18	p. A-1	p. A-2	p. A-2
9.1 PCU 8000	11508980	p. 1-48, 2-124, 3-64, 4-33, 5-30, 6-18	p. 1-50, 2-124, 3-64, 4-33, 5-30, 6-18	p. A-1	p. A-2	p. A-2

# **Inspection Requirements**

To ensure that the BD Alaris<sup>TM</sup> System remains in good operating condition, visually inspect the system before each use. Check all visible surfaces and moving parts on the devices. If you observe damage in any way or find the device does not function as expected, return it to Biomedical Engineering for repair.



WARNING

Perform device inspections to prevent a damaged device from being returned to patient use. Use of a damaged device can result in patient harm.



# CAUTION

Preventive maintenance inspections should only be performed by qualified service personnel.

# **Inspect IUI Connectors**

If any surface contaminants or blue or green deposits are visible, the connector must be replaced.



# WARNING

Inspection of IUI connectors is required. Damaged IUI connectors can result in incorrect device operation. Use of a damaged device can result in patient harm.



# WARNING

Failure to follow these instructions may result in potential hazards associated with damaged IUI connectors.



# WARNING

Inserting a finger or other object into the IUI connector, when the module is attached to the PC unit, could result in electrical shock.



# CAUTION

Preventive maintenance inspections should be performed only by Biomedical Engineering.

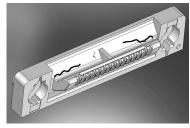


Figure 1: Male IUI Connector (right Side)

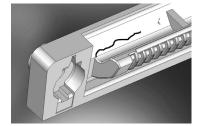


Figure 2: Male IUI Connector

- 1. Visually inspect the right side (male) IUI connector for cracks on the entire surface of the black colored plastic housing. See Figures 1 and 2 for the male IUI inspection area and typical cracks.
- 2. Visually inspect the left side (female) IUI connector for cracks on the edges of the black colored plastic housing.
- 3. If cracks are found, replace the IUI connector before use.



# WARNING

Do not return the device to patient use if there are cracks, surface contaminants, discoloration or other damage to IUI connectors. Use of devices with damaged IUI connectors can result in patient harm. Send all damaged devices to Biomedical Engineering for repair.

**NOTE:** While visually inspecting the IUI connectors, look for fractures on the connectors black-colored plastic. If you see any damage, do not use an instrument with fractured IUI connectors. The IUI connector must be replaced before the instrument can be used again.

# Cleaning

Inspect and clean the product as required per the following procedures. Read all warnings and cautions before continuing with this procedure.

# **Cleaning Products**

Refer to the following website for cleaning product information: www.bd.com/alarissystemcleaning.



# WARNING

- To prevent an electrical hazard:
  - Turn the instrument off and unplug the power cord from AC power before cleaning.
  - Do not spray fluids directly onto the instrument or into the IUI connectors.
  - Do not steam autoclave, EtO sterilize, immerse the instrument in fluids, or allow fluids to enter the instrument case.
  - Do not connect a module until the IUI connectors are thoroughly dry.
- Do not use compressed air to dry the instrument; this could force fluid into the instrument.



## CAUTION

- The use of chemicals that can damage the surface of the instrument and failure
  to follow the BD Alaris<sup>TM</sup> and Alaris<sup>TM</sup> product cleaning procedures and the
  cleaning solution manufacturer's recommended dilutions can result in an
  instrument malfunction or product damage, such as weakening and cracking of
  the case, and could void the warranty.
- Do not allow the cleaning solution to contact the IUI connector when cleaning the instrument.
- Do not use hard, abrasive or pointed objects to clean any part of the instrument.
- Do not allow cleaning solutions to collect on the instrument. Residue buildup might cause the moving parts to become sticky and hinder their operation over time.
- Certain chemicals can damage the surfaces of the instrument. Refer to the following website for a list of chemicals that should NOT be used: www.bd.com/alarissystemcleaning.
- Do not use chemicals that can damage the surface of the instrument. When
  possible use cleaning products that are recommended for use by CareFusion.

# **Using IUI Connector Covers**



# WARNING

Use IUI connector covers during cleaning to prevent damage to the IUI connectors. Use of a damaged device can result in patient harm.

## Order information:

Color	Part Number/Quantity	Location
Green	49000418/10	All IUI connectors except the PCA right-side IUI connector
Pink	49000419/5	Only the PCA right-side IUI connector







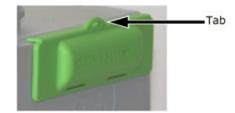
Non-PCA Modules

Left side of PCA Module

Right side of PCA Module

- 1. Inspect IUI connector covers for any damage. Do not use the cover if there is visible cracking, indentations, severe bending, or it is not fitting over the IUI connector.
- 2. Align the sockets of the covers with the mounting screws of the IUI connectors.





3. Ensure the tab points upward and press the cover firmly onto the IUI connector.

## **NOTE:**

- IUI connector covers should be cleaned when soiled using 70% isopropyl alcohol.
- It is recommended that the IUI connector covers are replaced after six months of use.
- Discard IUI connector covers when there is visible cracking, indentations, severe bending, or if they fail to remain engaged with the IUI connector.

# **Cleaning the Case**

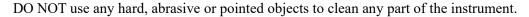
#### NOTE

Use the recommended healthcare-grade solutions and DO NOT use chemicals that can damage the surfaces of the instrument.

- 1. Make sure the instrument is upright, turned off, and the power cord is unplugged.
- 2. Attach an IUI connector cover to each IUI connector. There are two IUI connectors per device.
- Wipe all the exposed device surfaces.
   DO NOT use a cloth that drips. Be sure to wring out the cloth to squeeze out excess liquid.



4. Use a dedicated soft-bristled brush to clean the case to remove any visible residue. The brush may also be used to clean narrow or hard-to-reach areas.







# WARNING

Do not wipe the air-in-line sensor with any cleaning product. Cleaning products can damage the sensor and lead to patient harm.

- 5. Follow the cleaner manufacturer's instructions on the time to leave it on the device surface. Then, wipe off the cleaner using a soft cloth dampened with water.
  - DO NOT allow the cleaner to collect on the instrument.

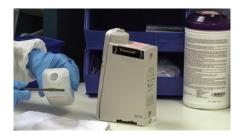


# **Cleaning the IUI Connector**

- 1. Remove the IUI connector covers.
- 2. Apply 70% isopropyl alcohol (IPA) directly to the dedicated IUI connector cleaning brush. To prevent cross-contamination, do not dip the brush into the IPA.

DO NOT use the same brush used on the case to clean the IUI connectors. Doing so could inadvertently transfer the cleaner or contaminants to the electrical contacts.

Take care not to allow fluids to come in contact with electrical components and openings, with the exception of the IUI connector, as outlined below. Ensure that the rubber boot is secured before and during cleaning to help prevent fluid from entering the electrical RJ45 plug.





# WARNING

Brush IUI connectors up and down. Do not brush them side-to-side.

Brushing the IUI connectors side-to-side can damage the pins and result in patient harm.

3. Clean both IUI connectors with the dedicated IUI connector cleaning brush. Brush the IUI connectors up and down. Do not brush them side-to-side.

To avoid accidentally depositing fluid on the connectors, DO NOT use any spray cleaners anywhere near the IUI connectors.

NEVER ALLOW ANY CLEANER OTHER THAN 70% IPA TO CONTACT THE IUI CONNECTORS.



# **Drying and Inspection**



# WARNING

Inserting a finger or other object into the IUI connector, when the module is attached to the PC unit, could result in electrical shock.

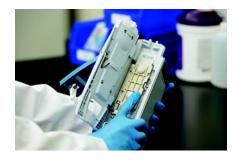
1. Confirm that the instruments and IUI connectors are completely dry for approximately 15 minutes before connecting them to another device.

DO NOT attach devices that have not fully dried to one another. "Wet mating" can hinder proper instrument operation.



2. Inspect surfaces and moving parts for signs of damage, such as cracks and broken parts. Open the Pump Module and PCA Module doors and inspect the parts inside.

DO NOT use a device with any damage. Send it to Biomedical Engineering for repair.



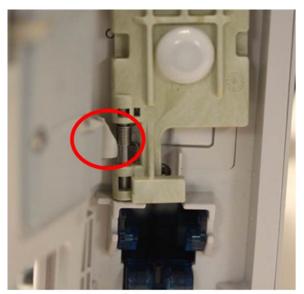
# Examples of damage inside the Pump Module door:



Cracked hinge on membrane frame



Broken platen post



Broken platen lower hinge bracket



Membrane frame breakage



# WARNING

Missing screws and washers on the PCU can result in a loss of power and patient harm.

3. Inspect the bottom of the PCU to check if any of the four battery screws or washers are missing. If any of the screws or washers are missing, send the device to Biomedical Engineering for repair.





# WARNING

Do not return a damaged device to patient use. Damaged devices can result in patient harm. Send the damaged device to Biomedical Engineering for repair.

4. Inspect the IUI connectors on each PCU and module prior to use.



**Deposits on IUI connector** 



Bent pin on a male IUI connector



# WARNING

Do not return the device to patient use if there are cracks, surface contaminants, discoloration or other damage to IUI connectors. Use of devices with damaged IUI connectors can result in patient harm. Send all damaged devices to Biomedical Engineering for repair.



# WARNING

Do not store the device in a plastic bag. Storing a device in a plastic bag can lead to moisture buildup that can damage electronic parts and result in patient harm.