BD Alaris™ System

BD Alaris™ System v12.1.2 Customer Highlights

The following modules and ancillary software will be updated as a part of the BD Alaris™ System v12.1.2 software release:

BD Alaris™ System modules	**BD Alaris™ Ancillary Software**
BD Alaris™ PC Unit model 8015 (PCU)	Alaris Systems Manager (server) 12.3
Alaris™ PC unit model 8015 (PCU)	BD Alaris™ System Maintenance (ASM) 12.3
BD Alaris™ pump module model 8100	BD Alaris™ Guardrails™ Editor (GRE) 12.1.x
Alaris™ Syringe module model 8110	
Alaris™ PCA module model 8120	
Alaris™ EtCO2 module model 8120	

Note: The SpO2 module will no longer work with v12.1.2 and will be not be updated. No updates will be required for continued compatibility with the Auto-ID module.

Release features

Resolved software and cybersecurity issues

1. **Software errors related to System Error Code 255-XX-XXX**

   The software errors that triggered System Error Code 255-XX-XXX have been resolved.

2. **Delay Options programming**

   When a user programs the infusion using the Delay Options feature, the infusion will get an end of infusion alarm (vs firmware versions prior to 9.33).

   Pump Module infusions will always end in KVO (except secondary infusions and bolus).

   Syringe Module infusions will always end in KVO (except intermittent infusions and when the KVO feature is disabled).

3. **Low Battery Alarm Failure**

   Two software errors that could result in low battery alarm and very Low Battery alarm have been resolved. To enable the fix, upgrade the PCU devices with v12.1.2 firmware and re-baseline the battery through one of the following:

   1) Replace the battery with a new fully charged battery
   2) Recondition the existing battery according to the Technical Service manual

4. **Keep Vein Open (KVO) / End of Infusion alarms priority**

   All end of infusion alarms, "Infusion Complete-KVO" and "Infusion Complete", have been changed from medium to high priority alarms.

5. **Use Errors related to Custom Concentration programming**

   First, the BD Alaris Guardrails™ User Interface (UI) has been updated to alert the clinician of the potential risk of programing errors during custom concentration programming. The first screen alerts the clinician of a "Possible over-dose" or "Possible under-dose" and provides the clinician with additional information on why they are receiving the alert. The second screen allows the

clinician to decide on the path forward – to continue with the programming (soft limit) or reprogram (hard limit).

Additional protection to Custom Concentration programming by requiring pharmacy to set hard minimum and maximum concentration values, in the Guardrails™ Editor software version 12.1.2.
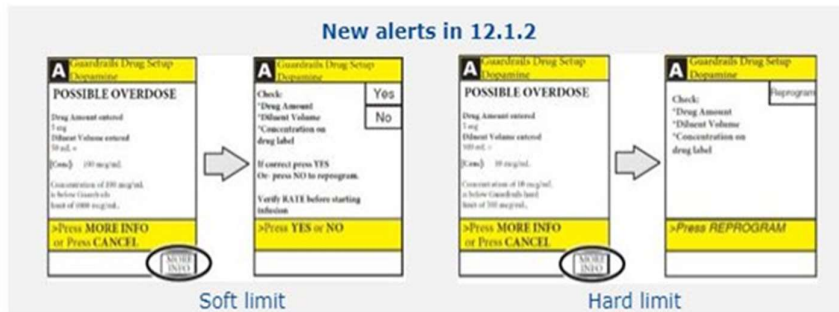
6. **Interpeak (IPnet) TCP/IP stack vulnerability**

Addresses reported vulnerabilities in the BD Alaris™ PCU software that could potentially impact connected devices leveraging the Interpeak IPnet standalone TCP/IP networking stack. Customers should implement compensating controls to minimize risk and impact in addition to exploring other potential solutions as directed in the posted product security bulletin.

7. **BD Alaris 8015 PCU and BD Alaris Systems Manager Network Session vulnerability**

Addresses reported network session vulnerability within the authentication process between specified versions of the BD Alaris™ PCU and the BD Alaris™ Systems Manager that could potentially impact connected devices. Customers should upgrade their Systems Manager and BD Alaris™ System Maintenance to version 12.3.0 and PCU firmware to version v12.1.2 in addition to following mitigations and compensating controls listed in the corresponding product security bulletin to minimize risk and impact.

Clinical Highlights

1. **Notification of No Guardrails™ protection in Basic infusion programing**

The BD Alaris™ PCU now has a clear indicator to inform users that programming in "Basic Infusion" lacks BD Alaris™ Guardrails™ protection.

- Updated infusion menu page: changed to "No Guardrails – Basic Infusion."

- "No Guardrails" text displays across all subsequent screens when programming in basic infusion, basic secondary infusion and drug calculation.

- An optional Clinical Advisory may be configured to reiterate the selection of No-Guardrails infusion. A customizable message can be enabled or disabled by profile.
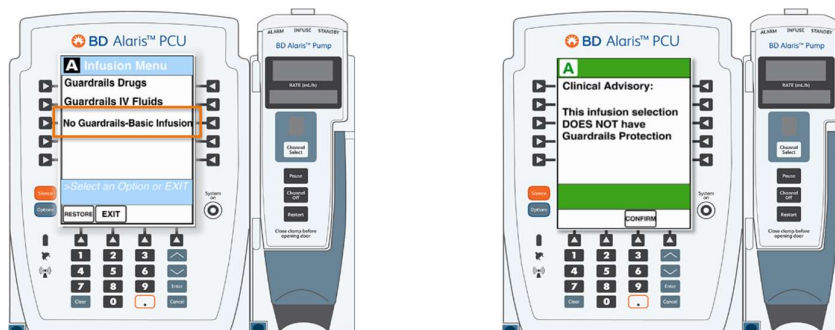
2. **BD Alaris™ Guardrails™ limit notification includes the value programmed.**

The Hard and Soft Limit notification screens now display the programmed value and the BD Alaris™ Guardrails™ limit. This provides users with a quick comparison of the programmed value and the corresponding limit to help address the alert.
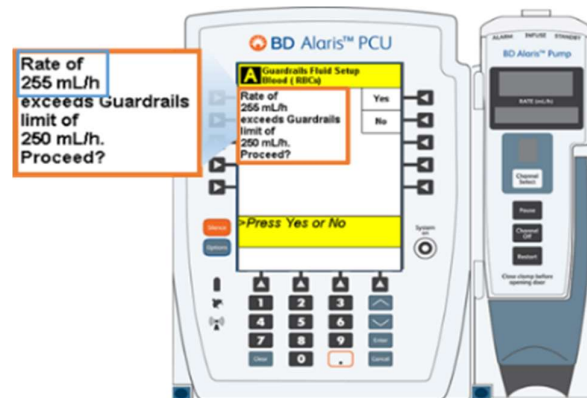

3. **Open Secondary Clamp Notification**

A notification prompt on the PCU reminds the clinician to open the Secondary clamp prior to starting the secondary infusion. This prompt aims to address one of the most common user errors in the administration of secondary infusions: forgetting to open the roller clamp.
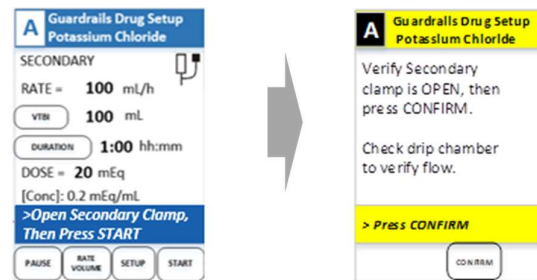
4. **Delay Until time selection removed from Delay Options**

The "delay until" feature has been removed. The "delay for" feature allows the clinician to program an infusion to start at a future time between 1 minute and 11 hours and 59 minutes. Additionally, the delayed infusion will revert to KVO at completion.
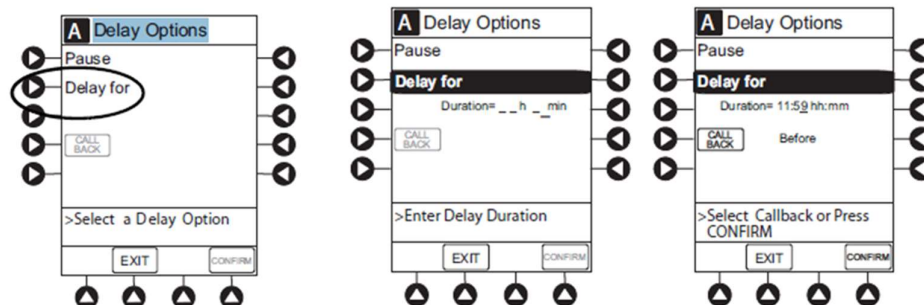
5. **Two Additional Air-in-line thresholds**

Two additional air-in-line threshold options, 125 microliters (mcL) and 175mcL, added to support the clinical needs of variable patient populations. The air-in-line threshold is configurable by profile within BD Alaris™ Guardrails™ Editor.

6. **Wireless Access Point (BSSID) reporting**

   The PCU reports the last-known Access Point connection to the Systems Manager (server) within last 7 days. A text description of the Access Point's physical location within the facility can be configured. A status report of last-known device location at the profile level, as well as device software version, modules and serial number can be generated on Systems Manager.

7. **Wireless card update**

   The a/b/g/n wireless card driver has been updated to support connection of 400+ devices to the wireless network.

8. **New "Clear all logs" feature to support HIPAA compliance**

   Addition of this feature facilitates data removal includeing ePHI logs to support HIPAA Compliance.

9. **End of support for SpO2 module**

   The SpO2 module will no longer work with v12.1.2 software. If the user attaches the SpO2 module to the PCU, a "Channel Error" pop-up message will be displayed.

10. **BD Alaris™ Guardrails™ Editor (GRE) changes**

    - Compatible with Windows 10 operating system.
    - Update to the Syringe master list to change "Terumo 50/60 ml" to "Terumo 60 ml."

11. **Cybersecurity and network security updates**

    - Certified by Underwriter's Laboratory-Cybersecurity Assurance and Compliance (UL-CAP).
    - Improved database encryption with strengthened password rules for ASM.
    - Updated to support more robust and stringent security requirements including encryption of data in transit using LDAP-S (between BD Alaris™ System Manager (SM) and hospital active directory).
    - Data in transit between the PCU and the BD Alaris™ Systems Manager is encrypted using Advanced Encryption Standard (AES) 128-bit encryption using Cipher Block Chaining (CBC).

Version 12.1.2 Matrix

Alaris™ System software comparison

Alaris System features		v9.12 (2012)	v9.19 (2015)	v9.33 (2017)	v12.1.2 (2021)
Clinical	2,500 drug/fluid setups	●	●		
	Increased dosing precision and range		●	●	●
	10,000 drug fluid setups			●	●
	Enhanced NEOI			●	●
	Prioritized alarms			●	●
	Display "No Guardrails" for basic infusions				●
	Display programed value for GR alerts				●
	Enhanced GR alert for custom concentrations				●
	Open Secondary Clamp Notification				●
	More AIL threshold config options				●
Interoperability	a/b/g wireless card	●	●	●	●
	a/b/g/n wireless card		●	●	●
	Increased wireless card capacity: 400+ devices				●
	Bidirectional interop w Cerner	●	●	●	●
	Bidirectional interop w Epic		●	●	●
	Bidirectional interop w Allscripts			●	●
	Bidirectional interop w iatric Systems (for MEDITECH)			●	●
	Enhanced subsequent IV bag		●	●	●
Cybersecurity	WPA2	●	●	●	●
	WIN Server OS	2003	2003	2008	2012/2016
	SQL database server	2005	2005	2008	2012/2016
	FIPS 140-2 certified	●	●	●	Pending
	ASM authentication	●	●	●	●
	ASM password encryption				●
	SM authentication	●	●	●	●
	SM password encryption				●
	Enhanced comm error checking (CBC or ECB)	ECB	ECB	ECB	CBC
	Updated OpenSSL libraries		●	●	●
	DDOS hardening			●	●
	AES 128-bit	●	●	●	●
ANALYTICS	Infusion Knowledge Portal (IKP)	●	●	●	●
	Wireless access point connection reports in SM				●