BD Alaris™ EMR Interoperability

BD Alaris™ PCU Model 8015 and Alaris™ PCU Model 8015
BD Alaris™ Systems Manager
Calculation Services
BD Care Coordination Engine (CCE) with Infusion Adapter

User Reference Guide

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BD Alaris™ EMR Interoperability User Reference Guide

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About This Guide

This guide provides information about BD Alaris™ EMR Interoperability. This guide is intended for use by hospital IT personnel who may interact with BD Alaris™ interoperability. This guide assumes the user is familiar with the use of the BD Alaris™ System with Guardrails™ Suite MX. For questions pertaining to the use or behavior of the BD Alaris™ System or BD Alaris™ Systems Manager, consult the respective user manual.

This guide does not describe any aspect of the interoperable third-party systems or applications that subscribe to the data published by BD Care Coordination Engine (CCE) and the infusion adapter. Users are advised to consult their interoperable third-party system vendors for information on implementation, support, and troubleshooting of the systems and applications that consume the data transmitted by CCE and infusion adapter.

Note the following terminology in this guide:

- The terms *BD Alaris™ PCU* or *PCU* refer to both the BD Alaris™ PCU and the Alaris™ PCU.
- The terms *BD Alaris™ Pump Module* or *Pump Module* refer to both the BD Alaris™ Pump Module and the Alaris™ Pump Module.
- The terms *BD Alaris™ Syringe Module* or *Syringe Module* refer to both the BD Alaris™ Syringe Module and the Alaris™ Syringe Module.

Indications for Use

The BD Alaris™ System with Guardrails™ Suite MX is a modular infusion pump and monitoring system for the continuous or intermittent administration of fluids to adult, pediatric, and neonatal patients through clinically accepted routes of administration: intravenous (IV), intra-arterial (IA), subcutaneous, epidural, or irrigation of fluid spaces. See Pediatric, Neonate, and Adult Patient Population Tables for the module-specific variations. Administered fluids include pharmaceutical drugs, red blood cells, and other blood components (platelets and fresh frozen plasma) as required for patient therapy. The BD Alaris™ System is an interoperable system capable of communicating and exchanging data with compatible information technology systems.

The BD Alaris™ System includes the PC Unit (PCU) and one or more of the following: Pump Module, Syringe Module, end-tidal CO_2 ($EtCO_2$) Module, Auto-ID Module, patient-controlled analgesia (PCA) Module, and associated software applications. $EtCO_2$ Module is a capnograph that continuously monitors end-tidal carbon dioxide ($EtCO_2$), fractional inspired carbon dioxide ($FiCO_2$), and respiratory rate (RR).

BD Alaris™ Pump Module and Syringe Module and Alaris™ PCA Module are indicated for varying patient populations, routes of administration, and infusates.

Pediatric* and Neonate** Patient Populations

Module	Route of Administration	Infusates
BD Alaris™ Pump Module	Intravenous	Fluids, pharmaceutical drugs including high-alert medications, chemotherapy, and parenteral nutrition; red blood cells, platelets, and fresh frozen plasma.
	Subcutaneous	Fluids and pharmaceutical drugs approved for subcutaneous use.
	Epidural	Pharmaceutical drugs approved for epidural use.
	Intra-arterial	Pharmaceutical drugs approved for intra-arterial use.
BD Alaris™ Syringe Module	Intravenous	Fluids, pharmaceutical drugs including high-alert medications, chemotherapy, and parenteral nutrition; red blood cells, platelets, and fresh frozen plasma.
	Subcutaneous	Pharmaceutical drugs approved for subcutaneous use.
	Epidural	Pharmaceutical drugs approved for epidural use.
	Intra-arterial	Pharmaceutical drugs approved for intra-arterial use.
Alaris™ PCA Module	Intravenous	Pain management drugs approved for intravenous use.
	Epidural	Pain management drugs approved for epidural use.

*Pediatric Patient Population: one month to 21 years

**Neonate Patient Population: Newborns up to one month, includes preterm or term

Adult Patient Population

Module	Route of Administration	Infusates
BD Alaris™ Pump Module	Intravenous	Fluids, pharmaceutical drugs including high-alert medications, chemotherapy, and parenteral nutrition; red blood cells, platelets, and fresh frozen plasma.
	Subcutaneous	Fluids and pharmaceutical drugs approved for subcutaneous use.
	Epidural	Pharmaceutical drugs approved for epidural use.
	Intra-arterial	Pharmaceutical drugs approved for intra-arterial use.
	Irrigation of fluid spaces	Fluids approved for irrigation.
BD Alaris™ Syringe Module	Intravenous	Pharmaceutical drugs used for intravenous use.
	Subcutaneous	Pharmaceutical drugs approved for subcutaneous use.
	Epidural	Pharmaceutical drugs approved for epidural use.
	Intra-arterial	Pharmaceutical drugs approved for intra-arterial use.
Alaris™ PCA Module	Intravenous	Pain management drugs approved for intravenous use.
	Subcutaneous	Pain management drugs approved for subcutaneous use.
	Epidural	Pain management drugs approved for epidural use.

Intended Use Environment

The following BD Alaris™ System devices are intended to be used in a professional healthcare facility. These devices may be disconnected from the AC source and transported within the healthcare setting.

- BD Alaris™ PCU
- BD Alaris™ Pump Module
- BD Alaris™ Syringe Module
- Alaris™ PCA Module
- BD Alaris™ $EtCO_2$ Module
- Alaris™ Auto-ID Module

The following software are intended to support the BD Alaris™ PCU and its connected modules within the healthcare setting:

- BD Alaris™ Guardrails™ Editor
- BD Alaris™ Systems Manager
- BD Alaris™ Systems Maintenance
- BD Care Coordination Engine
- Infusion Adapter
- Calculation Services

The BD Alaris™ Guardrails™ Editor software is intended to be used by a healthcare professional in their desired workspace. The BD Alaris™ System Maintenance software is intended to be used by service personnel in their desired workspace.

Contraindications

Situations in which the device should not be used because the risk of use clearly outweighs the benefits.

BD Alaris™ System Contraindications

- The BD Alaris™ System is contraindicated for enteral route of administration.

Warnings, Cautions, and Notes

Product-specific warnings and cautions, covered in the applicable sections of this guide, provide information needed to safely and effectively use BD Alaris™ EMR Interoperability.

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 of a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient or damage to the equipment or other property.

NOTE:
Notes contain supplementary information or emphasize a point or procedure.

Summary of Warnings and Cautions

WARNINGS

- **When affixing labels to the BD Alaris™ System or to modules (for example, barcode labels for easy barcode scanning), a label applied in error can lead to the improper display of data in the interoperable third-party system. BD recommends that hospitals establish quality controls to ensure accuracy of the labeling (See *About the Software on page 5* and *Labels and Barcodes on page 12*).**
- **Encryption of data in transit must be configured at the BD system level for all involved components (See *In-Flight Data Encryption on page 10*).**

CAUTIONS

- Improperly configured Health Level Seven International (HL7) interfaces can lead to the improper display of data in the interoperable third-party system. Notify BD technical support when changes are made to the interfaced systems (for example, when a vendor upgrades their software) to ensure that the HL7 interface remains properly configured (See *About the Software on page 5* and *HL7 Message Configuration on page 9*).
- CCE and infusion adapter require all system clocks to be synchronized at the time of installation with a common time server in order for APRs to be exchanged between the systems. Unsynchronized system clocks can result in messages being processed out of order or data failing to be displayed in the third-party system as expected (See *About the Software on page 5* and *Installing CCE and Infusion Adapter on page 8*).
- Changing or confirming the time on the BD Alaris™ System can cause the BD Alaris™ System clock to become out of synchronization with the Systems Manager and CCE and infusion adapter clocks. Clocks that are out of synchronization can lead to data being documented at the incorrect time in the interoperable third-party system (See *About the Software on page 5* and *Installing CCE and Infusion Adapter on page 8*).
- When the BD Alaris™ System receives an APR message, it confirms the following before pre-populating the requested infusion pump parameters on the PCU:
  - The PCU is in a programmable state.
  - The APR matches an entry in the active profile.
  - The intended Pump Module or Syringe Module is in a programmable state (See *Product Interactions on page 14*).
- If the APR is for a subsequent bag on the Pump Module, the following infusion pump parameters must match between the subsequent infusion and the running infusion:
  - Drug or Fluid name (alias or NDC)
  - Drug Amount (not applicable for fluids)
  - Drug Amount units (not applicable for fluids)
  - Diluent Volume (not applicable for fluids)
  - Dosing units (not applicable for fluids)
  - Patient weight/BSA (See *Product Interactions on page 14*)

Product Compatibility

The following table lists the compatibility between the BD Alaris™ PCU, BD Alaris™ Systems Manager, and the components of BD Alaris™ EMR Interoperability.

PCU	Systems Manager	Calc Services	Infusion Adapter	Guardrails™ Editor
12.3.1	12.5	1.1.1	1.6 or 1.7.x	12.1.3

NOTE:
The preceding table shows only the most current compatibility.

Conventions

This document uses the following conventions:

- The names of document titles, cross-references, and text that require emphasis are formatted in *italics*.
- The names of buttons, menu commands, options, icons, file names, and folders are formatted in **bold**.
- User input is formatted in **`Courier bold`**.

Definitions and Symbols

Term/Symbol	Definition
APR	Automated programming requests - the infusion order parameters transmitted from the interoperable third-party system to the BD Alaris™ System for autoprogramming of infusion parameters.
Autoprogramming	Pre-populating infusion parameters on a device by means of an interoperable third-party system such as an EMR.
Bandwidth	The amount of data that can be transmitted in a given time period.
BD Alaris™ EMR Interoperability	Solution involving the BD Alaris™ System with Guardrails™ Suite MX (BD Alaris™ System, BD Alaris™ Systems Manager, BD Alaris™ Guardrails™ Editor, and BD Alaris™ System Maintenance) as well as the components/products that make up the Interoperability solution (Calculation Services, Infusion Adapter, and CCE) Provides bidirectional interoperability between the BD Alaris™ System and the hospital's electronic medical record (EMR) system to support automation of manual workflows for pump programming and infusion administration documentation.
BD Alaris™ EMR Interoperability for Autodocumenation	Includes the BD Alaris™ System with Guardrails™ Suite MX (BD Alaris™ System, BD Alaris™ Systems Manager, BD Alaris™ Guardrails™ Editor, and BD Alaris™ System Maintenance) as well as the components/products that make up the interoperability solution (Calculation Services, Infusion Adapter, and CCE) Describes the data exchange between the BD Alaris™ System and the EMR where the pump automatically communicates infusion status data and near real-time infusion events to the EMR, automating the infusion administration documentation process.
BD Alaris™ EMR Interoperability for Autoprogramming	Includes the BD Alaris™ System with Guardrails™ Suite MX (BD Alaris™ System, BD Alaris™ Systems Manager, BD Alaris™ Guardrails™ Editor, and BD Alaris™ System Maintenance) as well as the components/products that make up the interoperability solution (Calculation Services, Infusion Adapter, and CCE) Describes the data exchange between the BD Alaris™ System and the EMR where infusion order parameters are wirelessly sent from the EMR to the BD Alaris™ System pre-populating the pump, automating the infusion pump programing process.
BD Alaris™ Interoperability	Solution involving the components/products that make up the Interoperability solution (Calculation Services, Infusion Adapter, and BD Care Coordination Engine)
BD Alaris™ PCU (PCU)	The core of the BD Alaris™ system that provides a common user interface for programming infusions and monitoring. **NOTE:** Throughout this guide, PCU refers to both the BD Alaris™ PCU and the Alaris™ PCU.
BD Alaris™ Pump Module (Pump Module)	An infusion module that interacts with the PCU to deliver fluids, medications and blood products. The pump module supports multiple infusion types, including fluids, primary continuous medications, and primary or secondary intermittent medications. **NOTE:** Throughout this guide, Pump Module refers to both the BD Alaris™ Pump Module and the Alaris™ Pump Module.

Term/Symbol	Definition
BD Alaris™ Syringe Module (Syringe Module)	An infusion module that interacts with the PCU, designed for facilities that administer medications from syringes. The syringe module supports multiple infusion types including fluids, and continuous or intermittent medications. **NOTE:** Throughout this guide, Syringe Module refers to both the BD Alaris™ Syringe Module and the Alaris™ Syringe Module.
BD Alaris™ System with Guardrails™ Suite MX	Includes the BD Alaris™ System, BD Alaris™ System Maintenance, BD Alaris™ Guardrails™ Editor, and BD Alaris™ Systems Manager.
BD Alaris™ System	The BD Alaris™ System consists of the PCU (PC Unit) and one or more infusion or monitoring modules - such as Pump Module, Syringe Module, PCA Module, $EtCO_2$ Module, or Auto-ID Module.
BD Alaris™ Systems Manager (Systems Manager)	A web-based infusion device management application that captures infusion data analytics, updates drug libraries, and establishes connectivity for interoperability.
BD Care Coordination Engine (CCE)	A passthrough messaging engine that provides a framework for routing messages to plug-in adapters. Adapters process device-specific inbound or outbound messages received or sent from/to external systems such as Health Information System (HIS). CCE does not interface or communicate directly with the PCU or Systems Manager. All communication with Systems Manager or Calculation Services is conducted by the Infusion Adapter software sub-system. CCE is a non-device medical device data system (MDDS).
Calculation Services	A software application component with a set of predefined rules that are performed only when certain parameters are not sent from the EMR when programming with interoperability.
EMR	Electronic medical record
HIS	Hospital information system
HL7	Health Level 7 - A set of standards covering international healthcare informatics interoperability.
Idle module	An infusion module that is attached to a powered on BD Alaris™ PCU, but the module is not in use. The module is not infusing, not programmed, not in the process of being programmed, not paused, not delayed, and not alarming.
IHE	Integrating the Healthcare Enterprise. IHE HL7 PCD-10 and PCD-01 are HL7 event and periodic messages per IHE. In this guide, these messages are referred to as PCD-10 and PCD-01. IHE HL7 PCD-03 is the autoprogramming request per IHE. In this guide, these messages are referred to as PCD-03.
Infusion Adapter	A software application installed as a component on CCE. It is responsible for device-specific message format transformation to HL7. Infusion adapter communicates with external information systems and BD Alaris™ Systems Manager.
Interfaced system	General term used to describe the interoperability of the BD Alaris™ System, Systems Manager, BD Alaris™ EMR Interoperability, and the interoperable third-party system used to make information about the BD Alaris™ System remotely available to clinical and other users.

Term/Symbol	Definition
Interoperable third-party system	General term used to describe an external system and its applications that transmit data to the BD Alaris™ System with Guardrails™ Suite MX.
Interoperablity	The ability to enable requests for pre-population of infusion parameters from a third-party system to the BD Alaris™ System and also to send infusion status information from the BD Alaris™ System to the third-party system.
IT	Information technology
Latency	The amount of time required for data to travel from point A to point B.
Module	For the purposes of this user guide, Module refers to the BD Alaris™ Pump Module, Alaris™ Pump Module, and/or the BD Alaris™ Syringe Module, and Alaris™ Syringe Module
NDC	National drug code
Pump Module subsequent infusion	A term used to describe programming an active Pump Module. *Subsequent infusion* refers to new bags (or syringes or containers used with the Pump Module); it does not include titrations/rate changes. An APR for a matching subsequent infusion can be transmitted to a Pump Module for the following infusion types: fluid, continuous or a primary intermittent infusion. An APR for a matching subsequent infusion can be transmitted to a Pump Module that is infusing, paused, delayed, or alarming (including Infusion Complete - KVO).
Pump Module subsequent infusion matching criteria	Autoprogramming an active Pump Module is allowed if all of the following infusion parameters match between the subsequent infusion APR and the running infusion: • Drug or Fluid name (alias or NDC) • Drug Amount (not applicable for fluids) • Drug Amount units (not applicable for fluids) • Diluent Volume (not applicable for fluids) • Dosing units (not applicable for fluids) • Patient Weight/BSA **NOTE:** If the infusion that is running on the Pump Module is a custom concentration, the drug amount and diluent volume still must match between the incoming subsequent infusion APR and the running infusion. **NOTE:** The above matching criteria do not apply to the Syringe Module.
Remote infusion data display	An interoperable third-party system, the purpose of which is to make infusion pump data available for remote viewing on a near real-time basis for various uses. Note that the BD Alaris™ EMR Interoperability interfacing to remote infusion pump data displays supports remote viewing of infusion pump status only for infusions administered via the Pump Module and Syringe Module.
RTLS	Real-time locating system; also referred to as an asset-tracking system.
Therapy	A feature that allows different limits to be defined in the drug library for the same medication with different therapeutic indications. An optional hospital-defined therapy or clinical indication for delivery of an infusion.

Term/Symbol	Definition
UDI	The unique device identifier (UDI) is a number assigned by the U.S. Food and Drug Administration (FDA) to identify a specific medical device.
User	Entity (such as a hospital or integrated delivery network) that purchases, deploys, and uses the interfaced system.
VTBI	Volume to be infused

Chapter 1
Introduction

BD Alaris™ EMR Interoperability provides bidirectional interoperability between the BD Alaris™ System and the hospital's EMR system to support automation of manual workflows for pump programming and infusion administration documentation.

This chapter provides an overview of BD Alaris™ EMR Interoperability.

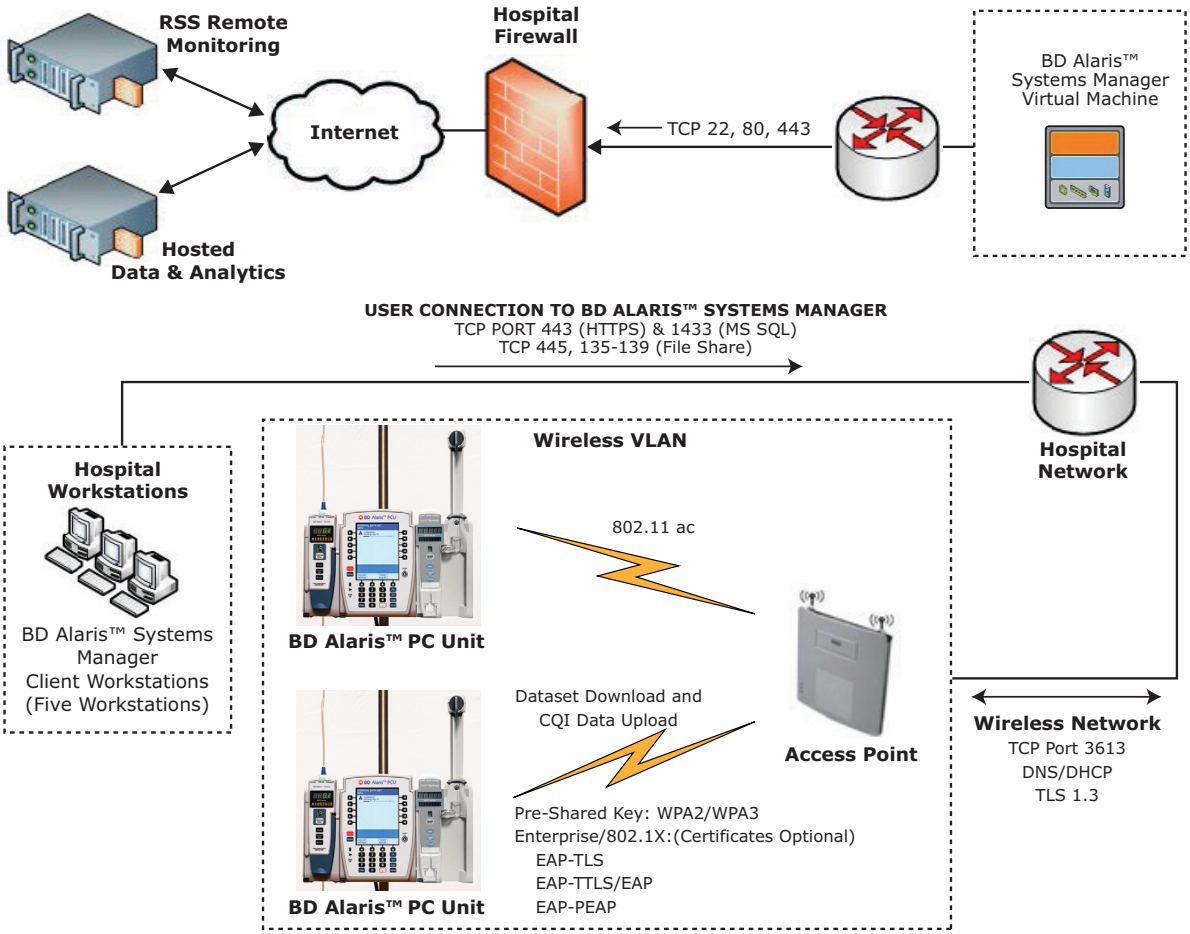
Overview

BD Alaris™ EMR Interoperability includes the following components:

- BD Alaris™ System with Guardrails™ Suite MX, which includes:
  - BD Alaris™ System, which is comprised of the PCU and one or more of the following infusion or monitoring modules:
    - Pump Module
    - Syringe Module
    - PCA Module (interoperability not currently supported)
    - $EtCO_2$ Module (interoperability not currently supported)
    - Auto-ID Module (interoperability not currently supported)
  - BD Alaris™ Systems Manager
  - BD Alaris™ Guardrails™ Editor
  - BD Alaris™ System Maintenance

  For information on the components of the BD Alaris™ System with Guardrails™ Suite MX, consult the respective user manual.
- BD Care Coordination Engine (CCE): The BD Alaris™ System interface platform that provides the means to exchange data between external systems (for example, EMR/HIS). CCE is a non-device medical device data system (MDDS).
- Calculation Services: A set of predefined rules that are performed only when certain parameters are not sent from the EMR when programming with interoperability. See *Calculation Services on page 25* for more information.
- Infusion adapter: The CCE component that interacts with external EMR/HIS vendor systems utilizing a bidirectional HL7 interface. Infusion adapter communicates with external information systems (for example, EMR/HIS) and Systems Manager.

The diagram below shows the network overview



Functional Design

BD Alaris™ EMR Interoperability for Autoprogramming functionality is designed to enable an interoperable third-party system (for example, the electronic medical record (EMR)) to transmit infusion pump parameters to the BD Alaris™ System for pre-population.

BD Alaris™ Interoperability for Autodocumentation functionality is designed for interfacing to interoperable third-party systems, remote infusion data display, and real-time locating system (RTLS) vendors for the purposes of populating data for infusions administered in the patient record, providing near real-time remote display of running infusions for various uses, or enhancing RTLS applications with device utilization information.

BD Alaris™ System is an FDA-regulated device. Appropriate validation is necessary to ensure exchange of data between our system and other information technology systems, software applications, and networks is accurate, effective, secure and consistent. BD does not allow the use of unqualified third-party integration engines with the BD Alaris™ System and CCE.

About the Software

BD Alaris™ Interoperability allows the ongoing flow of data between the BD Alaris™ System and third-party systems. The infusion adapter is deployed on top of a CCE installation.

NOTE:
The infusion adapter is only installable on CCE.

NOTE:
With BD Alaris™ EMR Interoperability, the BD Alaris™ System and external applications can receive, transmit, and display infusion information for infusions administered via the Pump and Syringe Modules. BD Alaris™ EMR Interoperability receives and transmits information about the following:

- The PCU and modules administering the infusion
- The patient (patient ID and any patient-specific information coming from the BD Alaris™ System)
- The infusion being administered

This includes information such as module ID, patient ID, rate, dose, and volume information for all infusions and infusion types that are programmed using the Pump Module and Syringe Module.

NOTE:
The infusion adapter transmits messages (PCD-10 Event or PCD-01 Periodic) in sequential order as generated by the BD Alaris™ System. Timestamps are identical for all messages transmitted within the same second.

If PCD-10 or PCD-01 messages are consumed/utilized in any order other than that which they are transmitted to the interoperable third-party system, this use is considered out of compliance with the HL7 Infusion Status Message Specification for infusion adapter. BD is not responsible for improper use or display of infusion event or status information transmitted to the interoperable third-party system.

WARNING

When affixing labels to the BD Alaris™ System or to modules (for example, barcode labels for easy barcode scanning), a label applied in error can lead to the improper display of data in the interoperable third-party system. BD recommends that hospitals establish quality controls to ensure accuracy of the labeling.

CAUTIONS

- Improperly configured Health Level Seven International (HL7) interfaces can lead to the improper display of data in the interoperable third-party system. Notify BD technical support when changes are made to the interfaced systems (for example, when a vendor upgrades their software) to ensure that the HL7 interface remains properly configured.
- CCE and infusion adapter require all system clocks to be synchronized at the time of installation with a common time server in order for APRs to be exchanged between the systems. Unsynchronized system clocks can result in message being processed out of order or data failing to be displayed in the third-party system as expected.
- Changing or confirming the time on the BD Alaris™ System can cause the BD Alaris™ System clock to become out of synchronization with the Systems Manager and CCE and infusion adapter clocks. Clocks that are out of synchronization can lead to data being documented at the incorrect time in the interoperable third-party system.

NOTE:
Hospitals are responsible for providing adequate security measures within their network environments to comply with current HIPAA (Health Insurance Portability and Accountability Act) requirements. HIPPA data is encrypted at rest in the Alaris™ System databases and while in transit from the devices to Systems Manager.

NOTE:
The BD Alaris™ System will provide an option to override the existing patient ID if the APR request contains a patient ID that is different from the one stored on the BD Alaris™ System.

NOTE:
The BD Alaris™ System cannot autoprogram infusion parameters for an APR that does not match to an alias for a unique entry in the Guardrails™ drug or fluid library. BD recommends that users establish quality controls to ensure the accuracy of aliases for autoprogramming of infusion parameters.

Chapter 2
Installation and Setup

This chapter describes the prerequisites for installing BD Alaris™ EMR Interoperability. The following topics are included:

Installing CCE and Infusion Adapter

Installation

CCE and the infusion adapter are installed by BD integration engineers only. Hospital IT must first grant the BD integration engineer remote access to the previously installed instance of CCE to complete installation of the infusion adapter software.

CAUTION

CCE and infusion adapter require all system clocks to be synchronized at the time of installation with a common time server in order for APRs to be exchanged between the systems. Unsynchronized system clocks can result in message being processed out of order or data failing to be displayed in the third-party system as expected.

CAUTION

Changing or confirming the time on the BD Alaris™ System can cause the BD Alaris™ System clock to become out of synchronization with the Systems Manager and CCE and infusion adapter clocks. Clocks that are out of synchronization can lead to data being documented at the incorrect time in the interoperable third-party system.

HL7 Message Configuration

After the infusion adapter has been installed, the HL7 interface to the interoperable third-party system must be configured. This work is completed by a BD integration engineer in conjunction with hospital IT and an appropriate representative from the vendor of the interoperable third-party system.

CAUTION

Improperly configured Health Level Seven International (HL7) interfaces can lead to the improper display of data in the interoperable third-party system. Notify BD technical support when changes are made to the interfaced systems (for example, when an interoperable third-party system vendor upgrades their software) to ensure that the HL7 interface remains properly configured.

In-Flight Data Encryption

The architecture of BD Alaris™ EMR Interoperability provides the ability to encrypt in-flight data between the individual BD components as an additional security measure to protect protected health information (PHI). During implementation, this feature is enabled by design and it requires no intervention or configuration by the end user or customer IT department.

WARNING

Encryption of data in transit must be configured at the BD system level for all involved components.

SQL Database Deployment

The architecture of BD Alaris™ EMR Interoperability provides two options for SQL database deployment on implementation. Depending on the desired level of availability/redundancy, hospital IT can choose to have the individual system databases reside within the confines of their individual virtual machines, or they can be deployed to a customer's SQL farm.

Contact your BD implementation project manager to discuss these options if interested in utilizing the deployed SQL database option.

NOTE:
If the deployed SQL database option is utilized, all BD SQL databases must be deployed to the customer's infrastructure. BD does not provide support for mixed-mode operation.

Labels and Barcodes

After the infusion adapter has been installed and configured, the hospital must affix labels to the PCU or modules to assist with engagement of the interoperable third-party system mechanism to route infusion pump data to the correct patient record; for example, patient-to-device association/disassociation.

WARNING

When affixing labels to the BD Alaris™ System or to modules (for example, barcode labels for easy barcode scanning), a label applied in error can lead to the improper display of data in the interoperable third-party system or transmission of an infusion order to the wrong module. BD recommends that hospitals establish quality controls to ensure accuracy of the labeling.

Chapter 3
General Information

The following topics are included in this chapter:

NOTE:
It is important to:

- Review the references of your interoperable third-party system regarding the mechanism to route infusion data to the correct patient record.
- Validate the interoperable third-party system vendor's functionality independent of the BD Alaris™ System.

NOTE:
When supported by your interoperable third-party system, the following outcomes may occur if the mechanism to route infusion pump data to the correct patient record is not properly followed:

- Infusion pump data may be transmitted to the wrong patient's record.
- Clinical decisions may be based on incorrect infusion data.

It is important for clinicians to verify all patient infusion information prior to signing/committing the data into the patient record. BD is not responsible for functionality of the interoperable third-party system.

Product Interactions

CCE and the infusion adapter work with the BD Alaris™ System and Systems Manager to:

- Receive IV infusion parameters from the interoperable third-party system for autoprogramming on the BD Alaris™ System.
- Transmit infusion status messages for consumption by external systems, including other BD software solutions.

NOTE:
Hospitals are responsible for providing adequate security measures within their network environments to comply with current HIPAA (Health Insurance Portability and Accountability Act) requirements. HIPPA data is encrypted at rest in the Alaris™ System databases and while in transit from the devices to Systems Manager.

NOTE:
It is expected that the clinician using autoprogramming functionality reviews and verifies that all infusion pump parameters pre-populated on the PCU are correct prior to starting the infusion. If the infusion pump parameters fail to pre-populate on the PCU, it is expected that the clinician consults the interoperable third-party system for messaging prior to starting the infusion.

When CCE and infusion adapter receive a message from an interoperable third-party system requesting that an infusion pump be pre-populated on the BD Alaris™ System (APR), it confirms the HL7 message format, checks for the presence of required data fields, and ensures that the module and PCU to which the APR is to be transmitted are supported models and running supported software versions (see *Message Confirmation on page 19* for more information on supported hardware and software versions). If the message format is incorrect or any required data fields are missing, the APR is rejected by the infusion adapter. A message is transmitted back to the interoperable third-party system notifying it of the cause of the rejection. Once the required data fields are confirmed, the APR message is then transmitted from CCE to Systems Manager to be forwarded to the BD Alaris™ System for autoprogramming of the infusion pump parameters.

When the BD Alaris™ System receives an APR from Systems Manager, it confirms that the infusion pump parameter data contained within the APR are the appropriate data type for each individual required field.

CAUTION

When the BD Alaris™ System receives an APR message, it confirms the following before pre-populating the requested infusion pump parameters on the PCU:

- The PCU is in a programmable state.
- The APR matches an entry in the active profile.
- The intended Pump Module or Syringe Module is in a programmable state.

CAUTION

If the APR is for a subsequent bag on the Pump Module, the following infusion pump parameters must match between the subsequent infusion and the running infusion:

- Drug or Fluid name (alias or NDC)
- Drug Amount (not applicable for fluids)
- Drug Amount units (not applicable for fluids)
- Diluent Volume (not applicable for fluids)
- Dosing units (not applicable for fluids)
- Patient weight/BSA

NOTE:
Regardless of an infusion being manually programmed or autoprogrammed through an APR, the Guardrails™ limit check continues to be performed when the clinician presses the start button and not at the time of entry/pre-population.

If the subsequent bag APR is rejected, the infusion pump parameters do not populate on the PCU and the message regarding rejection appears in the interoperable third-party system.

The following information cannot be confirmed by the BD Alaris™ System prior to pre-population of the infusion pump parameters on the PCU and must be addressed by the clinician when encountered:

- Infusion pump order parameters derived by the BD Alaris™ System.
- Infusion pump order parameters provided in the APR message exceed disposable limits (examples: rate exceeds maximum allowable rate for a syringe; VTBI exceeds volume available in a syringe).
    - Clinician must manually modify the violated parameter to continue with infusion programming.
- Infusion pump order parameters violate limits for the drug entry.
    - Limits do not differ between infusions that are manually programmed or those that are autoprogrammed through an APR.
    - Clinicians are notified that the infusion exceeds a limit only once they attempt to start the infusion.

The Systems Manager transmits event messages that it receives from the BD Alaris™ System to the infusion adapter. For a full list of supported infusion events, refer to the *Infusion Adapter v1.7 HL7 Infusion Status PCD-10/ PCD-01 Message Specification User Guide*. (This guide is available upon request.) CCE and the infusion adapter translate the message they receive from the Systems Manager into IHE HL7 and transmit that message to interoperable third-party systems.

The BD Alaris™ System is also capable of transmitting periodic infusion status updates for currently running infusions. The frequency with which the BD Alaris™ System transmits periodic infusion status updates is configurable; however, that frequency depends upon the number of Pump Modules and Syringe Modules deployed and communicating to the Systems Manager.

When CCE and the infusion adapter receive a message from an interoperable third-party system, they confirm the HL7 message format and check for the presence of required data fields (see *Message Confirmation on page 19* for more information). If the message format is incorrect or any required fields are missing, the message is rejected by the infusion adapter and a message is transmitted back to the interoperable third-party system, notifying it of the cause of the rejection. Once the required data fields are confirmed, the infusion message is transmitted. For a full list of supported infusion messages, see the *Infusion Adapter v1.7 HL7 Infusion Order Message PCD-03 Specification User Guide*. This guide is available upon request.

NOTE:
The intermittent nature of a wireless environment may result in BD Alaris™ System dropping from the wireless network but still being powered on. While disconnected, it is not able to accept APR requests from, or transmit status and event messages to, Systems Manager. However, BD Alaris™ System can still be programmed manually and synchronizes its status and event messages when connectivity is restored.

For questions pertaining to the use or behavior of the BD Alaris™ System or Systems Manager, consult the respective user manuals.

The Importance of Routing Infusion Data to the Correct Patient Record

Prior to using the interoperable third-party system to transmit infusion data generated by the PCU for documentation into the patient's record, it is important to understand the link between the interoperable third-party system and the PCU and specific infusion module. This link allows infusion parameters from the pharmacy-verified order to be transmitted from the interoperable third-party system to a specific infusion module. The same link allows infusion data to be transmitted from that infusion module to the patient record in the interoperable third-party system.

It is important to:

- Understand the linkage of the order to a specific infusion module. This linkage (for example, patient-to-device association and disassociation) can only be achieved by the interoperable third-party system vendor. Contact your interoperable third-party system vendor for detailed instructions. Note that BD has no involvement in or responsibility for the linkage between the interoperable third-party system and the infusion module.
- Understand the importance of discontinuing the linkage of infusion data transmitted to the patient record which is only achieved through the interoperable third-party system vendor. Contact your interoperable third-party system vendor for detailed instructions.
- Review the workflow used by your interoperable third-party vendor (for example, EMR vendors) to transmit infusion data from the infusion module to the patient record. Use the interoperable third-party system vendor references and user manuals regarding the proper procedures for use.
- Validate the interoperable third-party system vendor's functionality independent of the BD Alaris™ System.
- Validate the BD Alaris™ System with your interoperable third-party system vendor to ensure infusion pump data is properly routed to the correct patient record.

The following outcomes may occur if the BD Alaris™ System infusion module(s) and the infusion pump data is not properly routed (for example, linked) to the correct patient record according to the interoperable third-party vendor's recommended workflow:

- Infusion information may be sent to the incorrect patient's electronic medical record.
- There is potential for clinical decisions to be made based on the incorrect infusion information.

It is important for clinicians to verify all patient infusion information prior to signing/committing the information into the patient record. BD is not responsible for functionality of interoperable third-party vendor solutions.

Consult the interoperable third-party system vendor to ensure the link between the interoperable third-party system vendor and the PCU has been correctly established. Failure to confirm this link may result in infusion pump data transmitted by the PCU improperly routed to the incorrect patient record.

When establishing correct routing or linkage between the infusion module and your interoperable third-party system vendor:

- Contact your interoperable third-party system vendor for detailed instructions.
- The Alaris™ Auto-ID Module has no effect on establishing routing of linkage between the infusion module and your interoperable third-party system vendor. The Auto-ID Module can assign a patient ID to the PCU but does not ensure correct routing of infusion data to the correct patient record.
- The PCU and infusion modules are not aware of correct routing of infusion data to the correct patient record. This linkage/routing is managed through the interoperable third-party system vendor.
- Pressing **Yes** or **New Patient?** on the BD Alaris™ System does not ensure correct routing of infusion data to the correct patient record. Contact your interoperable third-party system vendor for detailed instructions. This procedure can only be done through the interoperable third-party system vendor.

Product Features

BD Alaris™ EMR Interoperability for Autoprogramming (PCD-03)

BD Alaris™ EMR Interoperability for Autoprogramming supports pre-population of infusion parameters of fluids, continuous, intermittent (primary and secondary) infusions for initial bags hung; and fluids, continuous, primary intermittent for subsequent bags.

The pre-population of infusion parameters workflow for subsequent bags is unchanged from the initial bag. The infusion parameters for the subsequent bag must meet the required matching criteria. If the matching criteria are met, the infusion parameters populate on the PCU without interruption of the currently running infusion.

NOTE:
It is expected that the clinician using autoprogramming functionality reviews and verifies that all parameters pre-populated on the PCU are correct prior to starting the infusion. If the infusion parameters fail to populate on the PCU, it is expected that the clinician consults the interoperable third-party system for messaging prior to hanging the bag.

If the subsequent bag APR contains an infusion parameter that affects/changes the current infusion rate, the user encounters a pop-up message notifying them of a recalculation of the rate. The pop-up message presents following selecting **START**. This pop-up requires selecting **Yes** or **No**. Selecting **Yes** accepts the rate change and starts the infusion. Selecting **No** returns the infusion to its current infusion rate and updates the VTBI to the volume contained in the APR.

Infusion parameters that could affect rate:

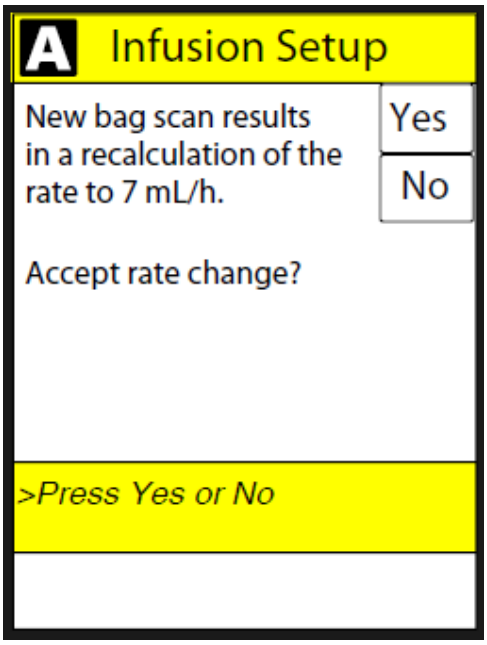
- Rate: for fluid or continuous infusions
- Dose: for continuous infusions
- Duration: for intermittent infusions

NOTE:
BD Alaris™ EMR Interoperability for Autoprogramming does not support autoprogramming of infusion parameters for an APR that would result in a basic infusion being programmed. All APRs must match to a Guardrails™ drug or fluid library entry for the infusion parameter autoprograming to occur.

It may be possible to start an infusion or basic infusion on the BD Alaris™ System (for example, in the case of a verbal order where an infusion was started before the order was entered into the interoperable third-party system).

To ensure the correct infusion order is linked to the correct infusion module (for example, association and routing of infusion pump data to correct patient record), contact your interoperable third-party system vendor for detailed instructions on how to do this.

Example of Infusion Setup message



Message Confirmation

When CCE and infusion adapter software receive an infusion APR message, it confirms the following message components before transmitting the APR to the BD Alaris™ System:

- Message format—CCE and infusion adapter accept and transmit infusion APR messages provided in an HL7 format that conforms to the IHE messaging standards to the BD Alaris™ System. For more information on the messaging specifications for BD Alaris™ EMR Interoperability for Autoprogramming, refer to the *Infusion Adapter v1.7 HL7 Infusion Order Message PCD-03 Specification User Guide*.
- Message content—CCE and infusion adapter accept and transmit infusion APR messages that contain at least the data fields required by it to the BD Alaris™ System. For more information on the required APR data fields for BD Alaris™ EMR Interoperability for Autoprogramming functionality, refer to the *Infusion Adapter v1.7 HL7 Infusion Order Message PCD-03 Specification User Guide*.
- Supported hardware and software versions—CCE and infusion adapter accept and transmit to the BD Alaris™ System infusion APR messages intended for:
  - BD Alaris™ PCU Model 8015
  - PCU software version v12.3.1
  - BD Alaris™ Pump Module Model 8100
  - BD Alaris™ Syringe Module Model 8110

For all infusion APR messages provided in the correct format, containing all required data fields, and intended for a BD Alaris™ System with supported hardware and software, CCE and the infusion adapter will forward the message to the BD Alaris™ System and transmit an acknowledgment message to the system from which the APR originated.

For all infusion APR messages provided in an incorrect format, not containing all required data fields, or intended for an unsupported module model, PCU model or software version, CCE, the infusion adapter, or the PCU discards the APR and transmits a rejection message to the interoperable third-party system from which the APR originated, notifying it of the cause.

For more information on the messaging specifications for the BD Alaris EMR™ Interoperability for Autoprogramming functionality, refer to the *Infusion Adapter v1.7 HL7 Infusion Order Message PCD-03 Specification User Guide*.

Message Confirmation at the BD Alaris™ System

When the BD Alaris™ System receives an infusion APR message, it confirms the following before pre-populating the requested infusion parameters on the PCU:

- The PCU is in a programmable state when:
  - It is in normal operation mode.
  - It has at least one supported module attached.
  - It contains at least one drug or fluid entry in the active profile.
  - The panel is unlocked.
  - It is not alarming or malfunctioning.
  - The Main Status page is displayed.
- The intended module is in a programmable state when:
  - The active profile contains at least one drug or fluid entry for the module.
  - The module is not malfunctioning.
  - The Pump Module on which a primary infusion is to be run is idle (not infusing, not programmed, not in the process of being programmed), unless a subsequent bag is being administered.
  - The Pump Module on which a secondary infusion is to be programmed is programmed with a primary infusion that supports the requested secondary infusion.

  NOTE
  If the APR message does not specify whether the APR is to be autoprogrammed as a primary or secondary infusion, the BD Alaris™ System determines whether to autoprogram the infusion as primary or secondary based on the state of the intended module. The APR is autoprogrammed as a primary infusion on an idle module, assuming that the configuration of the entry in the active profile supports it. The APR is autoprogrammed as a secondary infusion on a running or programmed module, assuming that the configuration of both the primary and secondary entries in the active profile supports it.
- System and profile limits—The infusion parameters provided in the APR must be within the BD Alaris™ System and active profile limits.
- APR matches an entry in the active profile—APRs are matched to an entry in the active profile when:
  - The identifier provided in the APR matches a drug alias or NDC in the active profile.
  - The specified module supports the requested infusion type (for example, the Pump Module supports secondary infusion types, but the Syringe Module does not).
  - Requested drug amount and units matches the drug amount and units in the active profile for the specified module.
  - Requested diluent volume and units matches diluent volume and units in the active profile for the specified module.

- Requested dosing units matches dosing units in the active profile for the specified module.
- Requested dose modifier matches dose modifier in the active profile for the specified module.
- Requested time units matches time units in the active profile for the specified module.

When the BD Alaris™ System receives an APR from the Systems Manager, it confirms the infusion parameter data contained within the APR are the appropriate data type for each individual required field.

When the BD Alaris™ System receives an APR message, it confirms the following before pre-populating the requested infusion parameters on the PCU if:

- The PCU is in a programmable state.
- APR matches an entry in the active profile.
- The intended Pump Module or Syringe Module is in a programmable state.

If the APR is for a subsequent bag on the Pump Module, the following infusion parameters must match between the subsequent APR and the running infusion:

- Drug or Fluid name (alias or NDC)
- Drug Amount (not applicable for fluids)
- Drug Amount units (not applicable for fluids)
- Diluent Volume (not applicable for fluids)
- Dosing units (not applicable for fluids)
- Patient Weight/BSA

If the subsequent bag APR is rejected, the infusion parameters do not populate on the PCU and the message regarding rejection appears in the EMR/HIS.

NOTE:
The BD Alaris™ System cannot autoprogram infusion parameters for an APR that does not match to an alias for a unique entry in the Guardrails™ drug or fluid library. BD recommends that users establish quality controls to ensure the accuracy of aliases for autoprogramming of infusion parameters.

NOTE:
BD Alaris™ EMR Interoperability does not support autoprogramming of infusion parameters for infusions identified as bolus orders, multi-dose orders (not available in PCU v12.1 and later), or titrations.

NOTE:
For all APR messages transmitted to the BD Alaris™ System, the dose to be administered to the patient—never the dose dispensed—must always be transmitted. Instances can exist when the dose to be administered and the dose dispensed may be the same, resulting in equivalent values, but the dose to be administered must always be transmitted regardless.

BD views infusion parameters transmitted to the BD Alaris™ System from pharmacy-verified orders as the source of truth. Transmission of any values other than the dose to be administered to the patient is a programming error and places the interoperable third-party system vendor out of compliance with this message specification.

For example:

a. The following order is placed for patient John Doe in the interoperable third-party system.
    - FENTANYL 10 MCG/ML IV PEDIATRIC, 2 mcg/kg for 2.9 kg patient = 5.8 mcg Admin Dose

b. Clinician removes a 1 mL vial of Fentanyl with a concentration of 10 mcg/1 mL from the medication dispensing cabinet.

c. Clinician draws 0.58 mL (5.8 mcg) from the vial into a syringe for administration to the patient and loads the syringe into the BD Alaris™ System.

d. Clinician scans the patient, scans the dispensed vial, scans the Syringe Module, and then uses the interoperable third-party system to transmit the infusion parameters to the BD Alaris™ System.

e. The values transmitted to the BD Alaris™ System are: drug amount of 10 mcg, diluent volume of 1 mL, patient weight of 2.9 kg, and VTBI of 0.58 mL.

f. The BD Alaris™ System then calculates the dose as 3.448 mcg/kg. This occurs because the dispensed dose values (10 mcg/1 mL) were incorrectly transmitted to the BD Alaris™ System. Had the correct administered dose values (5.8 mcg/0.58 mL) been transmitted, the dose would have been calculated correctly as 2 mcg/kg.

NOTE:
Only the therapies that match the dosing units in the APR display on the PCU for selection by the clinician. If only one therapy matches the dosing units in the APR, then that therapy is automatically selected.

For subsequent infusions, therapies are not displayed again. The therapy that was selected for the initial infusion is used for all subsequent infusions.

Once a therapy is selected, the therapy name displays at the top of the drug/fluid confirmation page in the title, below the drug or fluid name on the infusion setup and programming pages on the PCU.

CCE and Infusion Adapter - Infusion Status (PCD-01 and PCD-10)

NOTE:
It is important to:

- Review the references and user manuals of your interoperable third-party system regarding the mechanism to route infusion data to the correct patient record.
- Validate the interoperable third-party system functionality independent of the BD Alaris™ System.
- Validate your interoperable third-party system regarding the mechanism to route infusion data to the correct patient record (for example: patient-to-device association and disassociation).

Message Format

CCE and infusion adapter transmit infusion status messages in an HL7 format that conforms to the IHE messaging standards. For more information on the messaging specifications for CCE and infusion adapter software, refer to the *Infusion Adapter v1.7 HL7 Infusion Status PCD-10/PCD-01 Message Specification User Guide*.

Message Content

CCE and infusion adapter provide infusion status messages for all infusions administered by the Pump Module and Syringe Module. Infusion status messages contain the following two types of data:

- Data necessary for the interoperable third-party system to identify the specific infusion order for the specific patient that the infusion status message is describing. Examples include BD Alaris™ System ID and module ID.
- Data describing the state of that infusion. Examples include rate, dose, and volume infused. For more information about the specific infusion status message data fields transmitted by the BD Alaris™ System, refer to the *Infusion Adapter v1.7 HL7 Infusion Status PCD-10/PCD-01 Message Specification User Guide*.

Message Triggers

CCE and infusion adapter provide infusion status messages describing the current status of an infusion on an event basis and on a periodic basis.

Event-based reporting—An infusion status message is generated when an event, such as an infusion start, a transition from secondary to primary infusion, or an infusion complete occurs. When such an event occurs, an infusion status message representing a snapshot of that infusion at that moment in time is transmitted by CCE and infusion adapter. This message represents exactly what was occurring with that infusion at the moment the event occurred—the rate of infusion, the dose being administered, the cumulative volume infused up to that point in time, and so on. For a full list of supported infusion events, refer to the *Infusion Adapter v1.7 HL7 Infusion Status PCD-10/PCD-01 Message Specification User Guide*.

Periodic reporting—An infusion status message is generated periodically at a configurable frequency. Infusion status is reported for each Pump Module or Syringe Module attached to a powered-on PCU. The frequency of the periodic updates is configurable, but depends on the number of BD Alaris™ Systems and modules deployed and communicating to the Systems Manager. Like the event-based infusion status messages described above, if the module is infusing, the periodic infusion status message represents a snapshot of the running infusion—the rate and dose at which the infusion is being administered and the cumulative volume infused up to the point at which the periodic infusion status message is generated. If the module is idle, the periodic infusion status message simply reports that the module is idle.

Event-based and periodic infusion status messages are generated and transmitted independently of each other. Neither means of transmitting infusion status messages is dependent upon the other. CCE and the infusion adapter can be configured to report infusion status messages on one or both bases according to the user's preference.

Cumulative volume infused describes the total amount of fluid that has been infused into a patient over a given period of time. Unlike the rate, which describes the flow of the infusion at that particular moment in time, cumulative volume infused describes the period of time from the start of the infusion to the time of the message. Therefore, to report cumulative volume infused, the BD Alaris™ System contains internal logic to define the start of a new infusion.

The BD Alaris™ System defines the start of a new infusion as any of the following:

- Initial programming of infusion parameters
- Change to any programmed infusion parameters (such as VTBI, drug name, or concentration) EXCEPT rate or dose
- Promotion of basic infusion to a Guardrails™ drug or fluid infusion
- Restoration of infusion after infusion completes

NOTE:
In each of these start-of-new-infusion scenarios, the cumulative volume infused transmitted by CCE and the infusion adapter in the infusion status message upon infusion start is 0 mL.

Bolus Workflows

NOTE:
BD Alaris™ EMR Interoperability does not support autoprogramming of infusion parameters for bolus orders, multi-dose orders (not available for PCU v12.1 and later), or titrations.

Intravenous (IV) bolus dose administration and documentation workflows are complex and may vary from hospital to hospital. The BD Alaris™ System offers a bolus option for continuous medications. However, some caregivers may choose to deliver a bolus by programming a rate change for a short time period. Each of these bolus delivery methods results in different infusion status information being transmitted by the BD Alaris™ System.

In the case of a bolus being programmed and delivered as a rate change, the BD Alaris™ System transmits the same set of messages that it transmits for all rate change scenarios: a stop of the infusion at the previously programmed or running rate followed by a start of the infusion at the new programmed rate. In this scenario, the BD Alaris™ System is not aware that the rate change constitutes the delivery of a bolus. In the case of a bolus being delivered using the bolus option on the BD Alaris™ System, the BD Alaris™ System transmits the same set of messages as in the rate change scenario EXCEPT that it provides an indication in the MODE field that the rate change is for the delivery of a bolus.

This distinction is important when documenting volumes infused. This distinction is important because a hospital may document bolus volumes delivered in a number of ways. Therefore, the hospital needs to work with their interoperable third-party system vendor to ensure that the bolus documentation workflow selected can be supported by the interoperable third-party system.

The BD Alaris™ System reports the bolus volume infused as part of the total volume infused for the continuous infusion from which the bolus is delivered, not as a separate infusion. As an example, the BD Alaris™ System is programmed to deliver a continuous infusion of insulin at 3 units/hr and then the bolus feature is used to deliver a bolus of 10 units. The 10 units that were delivered as a bolus are accumulated in the total volume infused, which are reported as 13 units at the completion of the bolus. The BD Alaris™ System reports volumes infused in this manner regardless of whether the bolus feature is used or a simple rate change is programmed. However, if the bolus feature is used, the 10 units that are delivered as a bolus are flagged as such in the Active Sources field of the HL7 infusion status message.

In this example, a hospital may want the total volume infused for both the continuous infusion and the bolus reported together as one value, or they may want the bolus volume infused documented separately. It is important to discuss bolus documentation workflows with your interoperable third-party system vendor to understand what bolus documentation workflows your interoperable third-party system vendor can support and the bolus administration workflows that may be required to support the bolus documentation workflow selected.

Calculation Services

Calculation services is a set of predefined rules that are performed only when the following parameters are not sent from the EMR when programming with interoperability:

- Infusion duration (VTBI divided by rate)
- Body surface area (BSA) (total dose divided by modified dose)
- Weight-based dose (total dose divided by patient weight)
- Flow rate (weight-based rate multiplied by patient weight)
- Reduced concentration values (drug amount divided by diluent amount)

No additional calculations are performed beyond what is described above. The rules are defined by calculation services through BD's internal design controls. However, the specific EMR interface determines which predefined rules are used.

Calculation services receives the following data parameters to perform calculations according to the rules listed above:

- Duration
- Rate
- GiveAmount
- DoseTimeUnit
- PatientBSA
- Patient Weight
- GiveDoseRateAmount
- DoseAmount
- GiveStrength
- GiveStrengthUnit
- DoseDryUnit
- DoseModifierUnit
- GiveStrengthVolume
- WeightBasedRate
- ReducedConcentration

Calculation services validates the above data parameters. If the parameters are incomplete or invalid or the requested values cannot be calculated, calculation services sends a rejection message to the infusion adapter.

The Unique Device Identification (UDI) for Calculation Services version 1.1:

UDI (01)10885403510489(10)110

The Unique Device Identification (UDI) for Infusion Adapter version 1.7:

(01)10885403510472(10)170

Chapter 4
Troubleshooting and Maintenance

This chapter describes the troubleshooting and maintenance techniques for CCE and infusion adapter.

The following topics are included:

General Troubleshooting

This section describes the steps to follow when troubleshooting the performance of BD Alaris™ EMR Interoperability. For additional information, see *Troubleshooting on page 43*.

Hospital IT User

Upon being notified by a clinician that the system is not working as expected, hospital IT should do the following:

Troubleshooting for pre-population of infusion order parameters

- If infusion parameters are not pre-populated on the BD Alaris™ System following an APR being transmitted and the interoperable third-party system displays no error message, **STOP**—follow interoperable third-party system troubleshooting procedures or contact your interoperable third-party system vendor to continue troubleshooting.
- If infusion parameters are not pre-populated on the BD Alaris™ System following an APR being transmitted and the interoperable third-party system displays an error message with the cause of the failure:

  Follow any instructions in the error message displayed in the interoperable third-party system to attempt to resolve the issue.

  - For the following user errors, educate the clinician as to the proper functioning of the system (note that the list below is intended to provide troubleshooting guidance around the types of error messages a clinician might encounter; this list is neither an exact nor exhaustive list of the error messages that may be displayed by the interoperable third-party system. Consult your interoperable third-party system vendor for a complete list of error messages that may be displayed and their meanings):
    - Error states that the module is busy or currently infusing.
      - Cause of the error: Clinician has attempted to transmit an APR for an infusion to a module that is infusing, programmed, or in the process of being programmed.
      - Response: Re-educate the clinician on the proper functioning of the infusion parameter autoprogramming functionality:
        - For primary infusions, the module must be idle (for example, Main Status screen is displayed) for an APR to be accepted.
        - For secondary infusions (piggybacks), the module must be running a primary infusion that is configured within the Guardrails™ drug library to support secondary infusions.
    - Error states that infusion cannot be programmed as a piggyback or secondary.
      - Cause of the error: Clinician has attempted to transmit an APR for a secondary infusion to a module that does not have a primary infusion programmed.
      - Response: Program a primary infusion, then attempt the APR again.
      - Cause of the error: Clinician has attempted to transmit an APR for a secondary infusion to a module that is infusing a primary infusion that is not configured in the Guardrails™ Editor to support secondary infusions.
      - Response: Attempt the APR again, transmitting the APR to a module that is infusing a primary infusion that supports secondary infusions.

- Error states that the requested BD Alaris™ System, PCU, or module is offline or cannot connect.
  - Cause of the error: BD Alaris™ System is offline or is not communicating to the Systems Manager.
    - BD Alaris™ System may be located in an area of poor wireless connectivity.
    - BD Alaris™ System may be in the process of establishing a connection to Systems Manager.
    - Hospital wireless network is not functioning.
    - Systems Manager or CCE and the infusion adapter are not functioning.
  - Response: Try transmitting the APR again; the BD Alaris™ System may have fallen off the network briefly and be in the process of re-establishing connection to the Systems Manager.

- For error messages that pertain to invalid infusion parameters, invalid units, or an inability to match the drug or drug parameters to a Guardrails™ Editor entry, **STOP**—escalate to the pharmacy to resolve the discrepancy between the ordered infusion parameters and the Guardrails™ Editor entry for the ordered infusion.
- For error messages that pertain to wireless connectivity issues or BD Alaris™ System or modules that cannot be found, **STOP**—ensure hospital wireless is functioning correctly and the BD Alaris™ System is able to communicate with the Systems Manager.

- If infusion parameters are pre-populated on a BD Alaris™ System, or for a module, other than that intended when the APR was transmitted, check the barcode or other hospital-applied unique identifier for the BD Alaris™ System or module in question for accuracy.
  - If the label applied to the BD Alaris™ System or module does not match the model and serial numbers for the PCU or module, **STOP**—remove the incorrect label and apply the correct label.
  - If the label applied to the BD Alaris™ System or module appears to have been applied correctly, check the mapping of the identifier on the label to the model and serial number of the PCU or module within the interoperable third-party system.
    - If the mapping is incorrect, **STOP**—correct the mapping.
    - If the mapping appears to be correct, yet the issue is not resolved, **STOP**—call your interoperable third-party system vendor to continue troubleshooting.

Troubleshooting for remote asset tracking applications

For remote asset tracking applications, collect module and PCU serial numbers and any other unique identifiers assigned to the module and BD Alaris™ System for the purpose of the interface from the clinician and skip to step *3* on *Troubleshooting on page 43*.

Troubleshooting for automatic documentation in the interoperable third-party system and remote infusion data displays

NOTE:
It is important to:

- Review the references and user manuals of your interoperable third-party system regarding the mechanism to route infusion data to the correct patient record.
- Validate the interoperable third-party system vendor's functionality independent of the BD Alaris™ System.
- Validate your interoperable third-party system regarding the mechanism to route infusion data to the correct patient record (for example: patient-to-device association and disassociation).

It is important for clinicians to verify all patient infusion information prior to signing/committing the information into the patient record. BD is not responsible for functionality of interoperable third-party system solutions.

For automatic documentation in interoperable third-party system and remote infusion data displays, follow these troubleshooting steps to identify the interoperable third-party system that is the source of the problem:

1. Determine whether a specific error message has been presented in the interoperable third-party system.
   - If there is an error message, **STOP**—troubleshoot according to directions provided by interoperable third-party system vendor.
   - If there is no specific error message, then go to the next step.
2. Understand why the clinician believes the system is not functioning properly and whether an event, as described in *Message Triggers on page 23*, occurred on the BD Alaris™ System that should have resulted in infusion status data being displayed in the interoperable third-party system.
   - If incorrect data is being displayed in the interoperable third-party system, **STOP**—follow interoperable third-party system troubleshooting procedures or contact your interoperable third-party system vendor to continue troubleshooting.
   - If infusion status data fails to display in the interoperable third-party system, ascertain from the clinician whether the missing data is event-based or periodic-based:
     - Event-based data: Ascertain whether an infusion pump event, as described in *Message Triggers on page 23*, occurred on the BD Alaris™ System that should have resulted in infusion status data being populated or displayed in the interoperable third-party system.
       - If no infusion event occurred, **STOP**—troubleshooting is complete.
         - If the clinician doesn't engage the interoperable third-party system mechanism to route infusion data to the patient record, infusion data will not appear in the interoperable third-party system. This also applies to infusion data for infusions started prior to engaging the interoperable third-party mechanism to route infusion data to the correct patient record. Check with your interoperable third-party system about this mechanism capability.

- The interfaced system provides an event-based infusion status message only if the following are true:
  - An infusion event occurs on the BD Alaris™ System, as described in *Message Triggers on page 23*.
  - The interoperable third-party mechanism to route infusion data to the patient record is engaged (for example: patient/device association).

NOTE:
Review the references and user manuals of your third-party system regarding the mechanism to route infusion data to the correct patient record. Only your third-party system vendor is responsible for ensuring the mechanism to route infusion data to the correct patient record is achieved.

The BD Alaris™ System is not responsible for ensuring infusion data is routed to the correct patient record.

- If an infusion event did occur, yet no message was displayed in the interoperable third-party system as expected, then ensure that the interoperable third-party mechanism to route infusion data to the patient record is engaged according to the interoperable third-party functionality.
  - If the user has not properly established the interoperable third-party mechanism to route the infusion data to the patient record, **STOP**—help the clinician to contact the interoperable third-party system vendor for detailed instructions to establish the mechanism before continuing with troubleshooting steps.
  - If the user has properly established the mechanism between infusion pump and patient record, yet no message was displayed in the interoperable third-party system as expected, then collect the following information from the clinician (this information is used to identify the message in question in future troubleshooting steps):
    - Patient ID
    - Module/PCU serial number AND unique identifier (need both serial number of the module/PCU AND any other unique identifier assigned by the hospital for the purposes of the interface); it is possible that the module or PCU has been labeled with the wrong unique identifier.)
    - Time of the event (the more accurate the event time is known, the better)
    - Drug/fluid name
    - Rate of infusion
    - Dose (if applicable)
- Periodic reporting: If periodic infusion status reports, as described in *Message Triggers on page 23*, fail to be displayed in the interoperable third-party system, then collect the following information from the clinician (this information is used to identify the message in question in future troubleshooting steps):
  - How much time has passed since the last periodic infusion status report was displayed in the interoperable third-party system.
  - Patient ID
  - Module/PCU serial number AND unique identifier (need both serial number of the module/PCU AND any other unique identifier assigned by the hospital for the purposes of the interface; it is possible that the module or BD Alaris™ System has been labeled with the wrong unique identifier.

- Drug/fluid name
- Rate of infusion
- Dose (if applicable)

3. Ask the clinician whether they have experienced this problem with this infusion only, or with other infusions as well.
   - Problems are typically either localized to a single BD Alaris™ System or hospital-wide.
   - A single instance may indicate a different problem than a hospital-wide occurrence.
   - This information helps BD or your interoperable third-party system vendor to better assist you in future troubleshooting steps.

   Once this information is collected from the clinician, troubleshooting can be managed by hospital IT and the system vendors from this point forward.
4. Use the monitoring tools provided by the integration engine and/or interoperable third-party system and the infusion information provided by the clinician to verify that the message in question was received by the integration engine and/or interoperable third-party system.
   - If the BD Alaris™ System device or infusion data was received by the intermediary system and/or interoperable third-party system, but did not display in the user application, **STOP**—follow the troubleshooting procedures established by the integration engine and/or interoperable third-party system to solve this problem.
   - If the BD Alaris™ System device or infusion data was not received by the integration engine and/or interoperable third-party system, use the tools provided by the integration engine and/or interoperable third-party system to ascertain whether the error is within that integration engine and/or interoperable third-party system—whether the integration engine and/ or interoperable third-party system is rejecting incoming messages, for example:
     - If the integration engine and/or interoperable third-party system has received the BD Alaris™ System device or infusion data, **STOP**—follow troubleshooting procedures established by the integration engine and/or interoperable third-party system to solve this problem.
     - If the integration engine and/or interoperable third-party system has not received the BD Alaris™ System device or infusion data, or if it cannot be determined whether the integration engine and/or interoperable third-party system received the data, then go to the next step.
5. Ensure that the hospital wireless network is functioning properly and that the BD Alaris™ System is online and connected to the Systems Manager.
   - If hospital wireless network is not functioning properly, **STOP**—repair hospital wireless network before resuming troubleshooting steps. Note the following:
     - If the cause of the problem is the wireless network, correcting the wireless network does not result in the BD Alaris™ System device or infusion data in question immediately being displayed in the interoperable third-party system.
     - If the user has properly established the mechanism between infusion pump and patient record, the data is displayed in the interoperable third-party system after the BD Alaris™ System, Systems Manager, and CCE and infusion adapter have synced, which may be a few seconds or longer depending on how long the BD Alaris™ System was disconnected from the Systems Manager.
   - Using the PCU serial number, check the PCU Inventory report in Systems Manager to ensure that the PCU or module in question is online and connected to the Systems Manager.

- If the PCU is offline, then ensure that wireless coverage in the location of the PCU is robust enough to support the interoperable third-party system.
  - If wireless coverage in the location of the PCU is not robust enough to support the interoperable third-party system, **STOP**—repair the hospital wireless network before resuming troubleshooting steps. Note the following:
    - If the cause of the problem is the wireless network, correcting the wireless network does not result in the BD Alaris™ System device or infusion data in question immediately being displayed in the interoperable third-party system.
  - If wireless coverage in the location of the BD Alaris™ System is robust enough to support the interface, yet the BD Alaris™ System is not communicating with the Systems Manager, then check the following:
    - Ensure that the BD Alaris™ System is time-synchronized with the Systems Manager; for instructions on how to check the time on the BD Alaris™ System, refer to the *BD Alaris™ System with Guardrails™ Suite MX User Manual.*
      - If the BD Alaris™ System is not time-synchronized with the Systems Manager, the BD Alaris™ System must be power-cycled (powered off and powered back on) in order bring it in sync with the Systems Manager.
        - Only power-cycle the BD Alaris™ System when it is safe to do so.
        - Inform the clinician that manual documentation practices need to be continued for all infusions running on modules attached to the BD Alaris™ System in question until the BD Alaris™ System is power-cycled and synchronizes time with the BD Alaris Systems Manager.
      - If the BD Alaris™ System is time-synchronized with the Systems Manager, **STOP**—call BD technical support to continue troubleshooting this problem.

6. If, after completing these troubleshooting steps, the cause of the problem cannot be determined:
   - Contact your interoperable third-party system vendor. They are able to help you work backward to determine where the problem has occurred.
   - Contact BD technical support if previous troubleshooting has eliminated the integration engine and/or interoperable third-party system as the source of the problem.

Time of Day

The time of day on the BD Alaris™ System is used to time stamp all events that occur on the BD Alaris™ System (PCU and attached modules). This time stamp is contained in all outbound infusion event and status messages transmitted to interoperable third-party system vendors.

Time of day is set either through manual confirmation by a qualified user of the BD Alaris™ System or automatically upon wireless connection to the Systems Manager.

Time of Day Synchronization

NOTE:
The Systems Manager server must always synchronize time of day using the same time source as the interoperable third-party system vendor, typically a customer-provided network time protocol (NTP) server. The Systems Manager is the time source for all wirelessly connected PCUs.

Upon connection to the Systems Manager, a request to update the time of day is transmitted to the PCU. If the time of day differs from the Systems Manager time of day by more than 5 seconds and is not in a Time

of Day Locked state (see *Time of Day Locked on page 34* for more information), the time of day on the PCU is updated.

NOTE:
The Systems Manager does not force time synchronization. The Systems Manager requests that the PCU update its time. If the PCU responds that it is unable to change the time of day due to a Time of Day Locked state, the Systems Manager makes no additional attempts unless one of the following two conditions are met:

- Daylight Savings Time change
- Re-connection to the Systems Manager

In Systems Manager v12.x, time synchronization is updated for connected PCUs on a periodic basis configured for every 8, 12, 16, or 24 hours.

Time of Day Locked

NOTE:
Daylight Savings Time changes can impact the time of day reported by the BD Alaris™ System in any messages transmitted to interoperable third-party systems; concurrently this change can also impact the time of day reported by interoperable third-party system in any message transmitted to the BD Alaris™ System. BD recommends that the interoperable third-party system vendor be contacted prior to any Daylight Savings Time change to determine what impact this may have on documentation or transmission of APRs to the BD Alaris™ System. Additionally, BD recommends that if possible, as determined using best clinical judgment, any BD Alaris™ System that may have been placed in a Time of Day Locked state be power-cycled to ensure the time of day is synchronized after a Daylight Saving Time change event occurs.

The time of day on the PCU is in a locked state and remains locked until the PCU is power-cycled under the following circumstances:

- Time of Day is locked for manual update if:
  - A clinician has programmed an infusion using DELAY UNTIL mode and the infusion has not yet started; or
  - A clinician has programmed an infusion using MULTIDOSE mode (not available in PCU v12.1 and later).

NOTE:
Using the DELAY FOR mode does not place the time of day in a locked state.

Time of Day Drift

Due to the physical nature of disparate systems, the possibility exists that the time of day on each system may, over a period of time, fall out of synchronization. When troubleshooting either autoprogramming of infusion parameters or automatic documentation in the interoperable third-party system, it is important to remember that time of day synchronization can be a factor.

If it is determined that the time of day on an PCU is not synchronized, the following steps may be taken to re-synchronize the time of day with the Systems Manager:

Disable and then Enable the Wireless Connection

1. Press the **OPTIONS** key.
2. Press the **PAGE DOWN** soft key two times.
3. Press the **WIRELESS CONNECTION** soft key.
4. Press the **DISABLE** soft key.
5. Repeat steps 1 through 4, pressing the **ENABLE** soft key in step 4.

Power Cycle the BD Alaris™ System

NOTE:
This option should only be performed by qualified clinical staff and only if deemed acceptable.

1. On the PCU, press the **OPTIONS** key.
2. Press the **POWER DOWN ALL CHANNELS** soft key.
3. After the BD Alaris™ System has fully powered down, on the PCU, press the **SYSTEM ON** key.
4. When the **NEW PATIENT?** prompt appears, press the **YES** or **NO** soft key (as appropriate), then select or confirm the Profile.

The **RESTORE** feature can be used to recall previous programming if for the same patient.

Supporting the Product

Monitoring

Currently, the Care Coordination Engine (CCE) provides monitoring tools for use only by BD integration engineers. These tools are employed by BD customer support to provide active monitoring of customer systems and to support customers who notify BD of a problem with the system. See *General Troubleshooting on page 28* for more information on troubleshooting the system and notifying BD customer support of a problem.

Redundancy/Failover

CCE supports backup and restore procedures.

The user is responsible for backing up CCE virtual machines according to user-established protocols.

- If the user has elected to use the BD backup solution for CCE, restoration of the system is done by BD integration engineers and typically occurs after troubleshooting has determined that restoration is necessary.
- If the user has elected to use their own backup solution for backing up CCE, restoration is the responsibility of the user and may occur after troubleshooting has determined that restoration is necessary.

Virtual machines provided by BD do not provide appropriate licensing for any sort of high availability. The two prominent failover strategies to emerge from architecture investigations are VMware™ vSphere™ and Microsoft™ Failover Clusters in Windows Server™ 2016.

VMware vMotion™ and high availability would only apply for software-only environments where the customer provides the VM with any additional licensing costs.

CCE software is not supported in a Microsoft failover cluster because of the high degree of complexities in the configuration of a cluster.

The nature of technology demands that any solution should be tested during implementation.

Patching

BD integration engineers apply applicable BD and Microsoft patches to CCE and the infusion adapter on an as-needed, periodic basis, usually not more frequently than every month. Patching CCE and the infusion adapter requires downtime of the software. CCE and infusion adapter patching is coordinated with the Systems Manager patching to minimize planned system downtime. Prior to implementation of CCE and the infusion adapter, the hospital provides BD a point of contact for reporting planned outages. BD notifies the designated contact of planned outage in advance. Notify clinical staff in advance to plan for the outage accordingly.

Appendix A
Performance

This section describes the performance characteristics of CCE and the infusion adapter in terms of the latency of an infusion status message from the time it is received by CCE and the infusion adapter to the time it is transmitted by CCE and the infusion adapter for given conditions, wireless network characteristics, and BD Alaris™ System deployment sizes.

This appendix contains the following topics:

Assumptions

These performance expectations are based on the assumption that the BD Alaris™ System is connected to the hospital's wireless network. If a BD Alaris™ System is not connected to the hospital's wireless network, messages generated at the BD Alaris™ System cannot be transmitted to the BD Alaris™ Systems Manager or transmitted to external systems by CCE and the infusion adapter. Therefore, the quality or robustness of the wireless network is critical to the functioning and performance of CCE and the infusion adapter.

The performance of the BD Alaris™ System-BD Alaris ™ Systems Manager-CCE and infusion adapter system varies from environment to environment based on a number of intervening variables, such as wireless protocol employed, quality of the wireless network and the presence of gaps in the wireless network, wireless network traffic, and so on. Performance of the BD Alaris™ System-BD Alaris™ Systems Manager-CCE and infusion adapter system cannot be guaranteed because gaps in the wireless network (for example, far corners or elevators) result in BD Alaris™ Systems being unable to connect to the BD Alaris™ Systems Manager. In addition, the dynamic and increasingly technical hospital environment is likely to result in greater wireless network noise and traffic over time, thereby degrading the quality of the wireless network.

CCE and Infusion Adapter Initialization Operating Conditions

CCE and infusion adapter initialization operating conditions are defined as the combination of the start of CCE and the infusion adapter and the first message received by CCE and the infusion adapter from a given BD Alaris™ System. For a given BD Alaris™ System, this initialization condition could last a few minutes to a few hours. This is because the first message CCE and the infusion adapter receive from a given BD Alaris™ System triggers a historical log sync between CCE and infusion adapter and Systems Manager for all messages logged by the Systems Manager for at least the previous twelve hours.

A BD Alaris™ System is considered to be operating under these conditions the first time it transmits a message to the Systems Manager after the start of CCE and infusion adapter regardless of the duration of time since the start of those services (one day, one month, one year). For this reason, BD recommends that an equipment check-in be completed following the start of CCE and the infusion adapter. This check-in can help ensure that:

- All BD Alaris™ Systems have been powered on and connected to the Systems Manager.
- Logs have been synchronized between the Systems Manager and CCE and infusion adapter.
- No BD Alaris™ System remains in CCE and infusion adapter initialization condition post go-live with a third-party vendor.

Attempting to utilize CCE and the infusion adapter while the system is in its initialization condition is not recommended.

Data Set Upload/CQI Download Operating Conditions

Data set upload/CQI download operating conditions are defined as any point in time during which a data set is in the process of being deployed to BD Alaris™ Systems or CQI while data is in the process of being downloaded from BD Alaris™ Systems. The impact of a data set upload or CQI download on the performance of BD Alaris™ EMR Interoperability varies from environment to environment based on a number of intervening variables, such as wireless protocol employed, quality of the wireless network and the presence of gaps in the wireless network, wireless network traffic, and so on. The performance of CCE and the infusion adapter are negatively impacted under these conditions.

Normal Operating Conditions

Normal operating conditions are defined as all operating conditions (except CCE and infusion adapter initialization operating conditions, Guardrails™ data set upload/CQI download operating conditions, and Data Agent stored procedure execution at the scheduled time of day) where all of the following are true:

- The BD Alaris™ System, Systems Manager, CCE and the infusion adapter are powered on and functioning as designed.
- The BD Alaris™ System is connected to the wireless network and to the Systems Manager.
- The BD Alaris™ System is capable of transmitting messages to the Systems Manager.

The performance of the BD Alaris™ System-Systems Manager-CCE and infusion adapter system varies from environment to environment based on a number of intervening variables, such as wireless protocol employed, quality of the wireless network and the presence of gaps in the wireless network, wireless network traffic, and so on. However, CCE and the infusion adapter are designed to sustain 5600 messages per minute for infusion status reporting under nominal operating conditions and assuming the periodic infusion status reporting has been configured properly for the number of BD Alaris™ Systems and modules deployed (consult Global Customer Support for recommended periodic interval settings). For autoprogramming of infusion parameters, the BD Alaris™ System is designed to support response times of less than 10 seconds (from the time CCE and the infusion adapter receive the infusion program request message to the time CCE and the infusion adapter transmit the message to BD Alaris™ Systems Manager) under nominal operating conditions.

Appendix B
Troubleshooting

Use this checklist in conjunction with the *Troubleshooting and Maintenance* chapter.

This appendix contains the following topics:

Hospital IT Checklist

Step	Troubleshooting Activity	Yes/No	Next Step
1	Interface is for:	Interoperable third-party system documentation or patient display	*2*
		Remote asset tracking location	*6*
		Pre-population of infusion parameters	*11*
2	Error message has displayed in interoperable third-party system or remote infusion data display.	Yes	*25*
		No	*3*
3	Incorrect data is populating in the interoperable third-party system or remote infusion data display.	Yes	*25*
		No	*4*
4	Infusion event failed to automatically populate in the interoperable third-party system.	Yes	*5*
		No	*25*
5	Is the mechanism to route infusion status data to the patient record in the interoperable third-party system engaged?	Yes	*6*
		No	*26*
6	BD Alaris™ System device or infusion data in question was received by the intermediary or interoperable third-party system.	Yes	*25*
		No	*7*
7	Hospital wireless is functioning properly.	Yes	*8*
		No	*27*
8	BD Alaris™ System is online.	Yes	*10*
		No	*9*
9	Wireless coverage in BD Alaris™ System location is sufficient.	Yes	*10*
		No	*27*
10	BD Alaris™ System is connected to Systems Manager.	Yes	*28*
		No	*28*
11	Infusion parameters fail to pre-populate; no error message displayed by transmitting system.	Yes	*25*
		No	*12*
12	Infusion parameters fail to pre-populate; error message is displayed by transmitting system.	Yes	*14*
		No	*13*
13	Infusion parameters populate on a PCU or a module, other than that intended.	Yes	*20*
		No	*25*

Step	Troubleshooting Activity	Yes/No	Next Step
14	Error states that the module is busy or currently infusing.	Yes	*26*
		No	*15*
15	Error states that infusion cannot be programmed as a piggyback or secondary.	Yes	*26*
		No	*16*
16	Error states that the required PCU or module is offline or cannot connect.	Yes	*27*
		No	*17*
17	Error states that a parameter value (such as dose or rate) is outside the allowable range or exceeds a limit.	Yes	*22*
		No	*18*
18	Error states that the units specified for a given parameter are invalid or do not match the Guardrails™ drug library.	Yes	*22*
		No	*19*
19	Error states that the ordered infusion cannot be matched to an entry in the Guardrails™ drug library or that the drug or fluid cannot be found.	Yes	*22*
		No	*25*
20	The barcode label applied to the PCU or module matches the model and serial numbers for the PCU or module.	Yes	*21*
		No	*23*
21	The mapping of the identifier on the barcode label to the model and serial number of the PCU or module within the interoperable third-party system appears to be correct.	Yes	*25*
		No	*24*
22	Escalate to pharmacy or ordering physician to resolve the discrepancy between the ordered parameters and the Guardrails™ programmable parameters.	-	-
23	Remove the incorrect label and apply the correct label.	-	-
24	Correct the mapping of the identifier on the barcode label to the model and serial number of the PCU or module.	-	-
25	Troubleshoot according to directions provided by interoperable third-party system vendor or contact transmitting or interoperable third-party system vendor for further support.	-	-
26	Educate clinician on proper functioning of system.	-	-
27	Address wireless connectivity issues and/or repair hospital wireless.	-	-
28	Call BD technical support to continue troubleshooting.	-	-

BD Alaris™ System Error Code Translation Table

When trying to determine why an APR is unable to be pre-populated on the BD Alaris™ System, the table below can be a helpful reference. All error messages displayed below assume that the infusion APR itself was properly formatted and that infusion APR rejections are occurring at the PCU level and not at the interface level.

NOTE:
Each interoperable third-party system vendor may translate these error messages into different terminology so the information provided below may not be displayed in the interoperable third-party system in the exact listed verbiage.

NOTE:
When an infusion APR is rejected, no information is displayed on the PCU. All error code information is transmitted back to the interoperable third-party system for presentation.

PCU Error Code ID	PCU Error Code	HL7 Application Error Code	HL7 Application Error Message	Example
94	PRO_UNABLE_TO_MATCH_MEDICATION_TO_PROFILE	9010	Unable to match medication to drug library	This error can occur when the BD Alaris™ System, upon receipt of a properly formatted infusion APR, is unable to match the ordered infusion to a fluid or medication in the currently selected Guardrails™ drug library profile.
95	PRO_SEC_REQUIRES_SUPPORTING_PRI	9013	Unable to program medication as piggyback	Cannot program a secondary when the primary is not running or the primary does not support a secondary.
96	PRO_MODULE_ALREADY_INFUSING	9002	Infuser/channel is currently infusing	This error can occur when attempting to transmit an APR to a module that cannot accept a program or cannot accept a program for a subsequent bag/container.
97	PRO_INFUSION_UNITS_NOT_VALID	9008	Invalid units for parameter (ParameterName)	This error can occur when the dose and/or drug amount units are not supported by the BD Alaris™ System as indicated by the “parameter name.” **NOTE:** Parameter name refers to the specific field in the APR that contains the unsupported dose and/or units.

PCU Error Code ID	PCU Error Code	HL7 Application Error Code	HL7 Application Error Message	Example
98	PRO_PCU_NOT_PROGRAMMABLE	9017	Infuser cannot accept program	This error can occur when the PCU is NOT in the Remote Order Ready state. Remote Order Ready state is defined as: The PCU is displaying the main status or the unmodified page that is displayed immediately after CHANNEL SELECT is pressed on a module.
99	PRO_MODULE_NOT_PROGRAMMABLE	9017	Infuser cannot accept program	This error can occur when the PCU is NOT in the Remote Order Ready state. Remote Order Ready state is defined as: The PCU is displaying the main status page or the unmodified page that is displayed immediately after CHANNEL SELECT is pressed on a module.
101	PRO_INVALID_PM_MODEL_NUMBER	9001	Unknown infuser or channel	This error can occur when the MODEL NUMBER contained in the APR transmitted to the PCU is not valid. The only model numbers supported are 8100 for the Pump Module and 8110 for the Syringe Module.
102	PRO_INVALID_PM_SERIAL_NUMBER	9001	Unknown infuser or channel	This error can occur when the PCU SERIAL NUMBER contained in the APR does not match the serial number of the receiving PCU.
119	PRO_MODULE_NOT_ATTACHED	9001	Unknown infuser or channel	This error can occur when the BD Alaris™ System Pump or Syringe Module that the clinician is attempting to program is not attached to the BD Alaris™ System that is being used.
142	PRO_MODULE_NOT_SUPPORTED	9001	Unknown infuser or channel	This error can occur when the clinician is attempting to program a module other than a Pump or Syringe Module, for example the Alaris™ PCA Module, which does not support pre-population of the infusion parameters.

PCU Error Code ID	PCU Error Code	HL7 Application Error Code	HL7 Application Error Message	Example
152	PRO_OVER_LIMIT	9005	Parameter (ParameterName) outside of allowable range	This error can occur when a specific parameter value contained in the APR is outside of (over) the allowable range. For example, the APR contains a rate of 9999 mL/hr, when maximum allowable rate for the Pump Module is 999 mL/hr.
153	PRO_UNDER_LIMIT	9005	Parameter (ParameterName) outside of allowable range	This error can occur when a specific parameter value contained in the APR is outside of (under) the allowable range. For example, the APR contains a rate of 0.01 mL/hr, when lowest allowable rate is 0.1 mL/hr for the Pump Module.
154	PRO_MISSING_DATA	9003	Missing required program parameter(s) (ParameterName1, ParameterName2,...)	This error can occur when the APR transmitted to the PCU is missing a component required to successfully pre-populate the infusion parameters. Examples include a missing value in the VTBI field, or missing weight for a weight-based infusion.
156	PRO_OUT_OF_RANGE	9005	Parameter (ParameterName) outside of allowable range	This error can occur when a specific parameter value contained in the APR is outside of the allowable range. Examples include: Alias value exceeding 12 characters, or Patient ID exceeding 16 characters.
157	PRO_INVALID_DATA	9004	Invalid program parameter(s) (ParameterName1, ParameterName2,...)	This error can occur when a parameter contained in the APR transmitted to the PCU contains an invalid value. Examples include: the rate field containing the text value FIFTY instead of the numeric value 50, both the NDC and Alias have values present when only one field can be populated, or the NDC contains a non-numeric value.
161	PRO_SUBSEQUENT_ORDER_MISMATCH	9017	Infuser cannot accept program for subsequent bag	This error can occur when attempting to transmit an APR to a module that is executing a subsequent supported infusion program and the subsequent bag matching criteria are not met.