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November 1, 2016

Dear Valued Alaris™ System Customer
ATTN: Director of Biomedical Engineering

In line with our commitment to continuously improve patient care, BD offers our customers innovative solutions for collecting and analyzing infusion information from the Alaris System. Protecting and securing that data is a top priority for BD and we are committed to transparency and corrective action when issues arise.

In the spirit of this transparency, we wanted to make you aware that a customer reported that they found residual infusion log data from another hospital on their Knowledge Portal for infusion technologies application ("IKP"). When this issue was brought to our attention, we immediately began an investigation and determined that when Alaris PC units ("PCU") are moved between facilities, the standard data clearing procedure did not adequately clear all infusion data ("Data") from the PCU. BD recommends clearing all Data from a PCU when it is moved between facilities (i.e. rental units, managed asset customers). See **Attachment A** for the Data attributes not erased from the PC units using the standard clearing procedures.

As part of our investigation, BD analyzed infusion records from all of our customers who use the IKP application starting from November 2005 to the present and led to the following important findings:

- The relative number of misdirected infusion records is very small. Approximately 1% of records reviewed were associated with an incorrect facility
- Misdirected infusion records were accessible only to other facilities that are "covered entities" under HIPAA
- All misdirected infusion records are de-identified and therefore do not constitute Protected Health Information ("PHI")

Following our protocol for product security, we engaged a leading expert in patient-data privacy, who determined that all misdirected data in the IKP application was de-identified, and therefore did not constitute PHI, as defined by the Health Information Portability and Accountability Act ("HIPAA"). Our analysis concludes that all the data is de-identified based on both the statistical expert opinion and the HIPAA 4-factor risk analysis. Therefore, we believe it is not a reportable breach under HIPAA.

Customers who use the Alaris Server but not the IKP application or those who do not use the Alaris Server are less likely to be affected by this issue. Customers who do not use devices from rental providers or other hospitals are also less likely to be affected by this issue.

Follow-up Actions by Customers:

- For PCUs that are not moved between facilities, no action is required.
- For PCUs that are moved between facilities, please refer to Service Bulletin 597 for the updated data clearing procedures.

Follow-up Actions by Authorized Distributors:

- For PCUs that are moved between facilities, please refer to Service Bulletin 597 for the updated data clearing procedures.

Follow-up Actions by BD:

- New software will be released on November 7, 2016 to block all infusion data that is not associated with your facility(ies) from transferring into your IKP.
- Service Bulletin 597 will be released on November 2, 2016 to inform customers and authorized distributors of the new procedures to clear all infusion data logs in situations where a PCU is leaving a customer facility (e.g. rental return)
- All data currently in IKP that is not associated with your facility(ies) will be sequestered and no longer available for viewing by December 31, 2016

We recognize that you may have additional questions on this issue and invite you to join us for a live webinar where BD will have our business leaders and technical and privacy experts in attendance.

Webinar Dates & Times	**Registration**
Friday, 11/4/2016 • 12:00PM PT / 3:00PM ET	www.webcasts.com/carefusiondata
Monday, 11/7/2016 • 9:00AM PT / 12:00PM ET • 1:00PM PT / 4:00PM ET	
Tuesday, 11/8/2016 • 9:00AM PT / 12:00PM ET • 1:00PM PT / 4:00PM ET	

If you are unable to attend a webinar or have additional questions regarding this issue, please contact:

BD Contact	Contact Information	Areas of Support
BD Support Center	Phone: 888-562-6018 Phone hours: 7:00am to 4:00pm PT, Monday - Friday Email: SupportCenter@carefusion.com	Questions Related to this Specific Issue
BD Product Security	Email: Product.Security@bd.com	General Product Security Questions
Technical Support	Phone: 888-812-3229 Phone hours: 6:00am to 5:00pm PT, Monday – Friday Email: DL-US-INF-Tech-Support@carefusion.com	Technical Questions for Alaris System

BD sincerely regrets the inconvenience this may cause you. Thank you for your continued support while we address the situation and put in place safeguards to prevent recurrence. BD is committed to serving your infusion product needs, and our primary objectives are patient safety, exceptional product reliability, product security and the highest level of customer support.

Sincerely,

Jennifer Sipple
Vice President, Global Alaris System Platform
Infusion Solutions

Enclosures:

- **Attachment A: Data Attributes**
- **Attachment B: FAQs**

ATTACHMENT A: Data Attributes Available from the Alaris System CQI and Infusion Historical Logs

Above_Below	Indicates whether the upper or lower limit threshold was violated
ActualDurationSeconds	Number of seconds between an infusion event and the previous infusion event during an infusion session.
Alarm	Describes the status of the module's alarm.
AlertLimit	Indicates the limit value for the field that was violated. This value is provided by the drug library
AlertType	Indicates the type of the limit that has caused the alert. Can be "H" (Hard) or "S" (Soft).
AllMode	Indicates whether the infusion was using the 'AllMode' feature to automatically set VTBI to the syringe volume available
AnesthesiaMode	Indicate whether anesthesia mode was is use at the time of this event
BSA	The body surface area of a patient (units: m2)
ClinicianID	Indicates the ID number for the clinician
Concentration	Indicates the concentration of the drug administered (i.e. drug amount per diluent volume)
ConcentrationUnit	Indicates the units used for the concentration.
DatasetID	Unique code identifies a Guardrails Dataset.
DatasetName	Name given by the hospital to associate with the DatasetID
DiluentVolume	Indicates the amount of fluid used to dilute a drug.
DoseUnit	Indicates the units of measure for the dose value
DrugAmountInfused	Indicates the drug amount for this infusion
DrugAmountUnits	Indicates the drug amount units of measure.
DrugDoseCalcBasis	Indicates the modifier value for a drug's dose (i.e. whether a weight based or non-weight based or BSA based modifier is applied)
DrugName	Drug name given by the hospital to associate with the DatasetID
FacilityID	Indicates the facility ID associated with this infusion
FieldLimit	Indicates the name of the field that caused this alert
HardSoft	Indicates the type of the limit that has caused the alert. Can be "H" (Hard) or "S" (Soft).
InfusionCategory	Infusion categories: Basic - uses the infusion settings manually without going through Guardrails® option Guardrails - uses Guardrails® for automatically setting the infusion parameters Unknown - infusion device is unable to determine infusion category.
InfusionDeviceVersion	Indicates the software version number for a specific unit (attached, PCU)
InfusionDoseCalcBasis	Indicates the modifier value for a drug's dose (i.e. whether a weight based or non-weight based or BSA based modifier is applied)
InfusionModifier	Indicates the quantifier for this infusion. (Initial, Resultant, Primary, Secondary)

InfusionProgramming	Indicates the origin of infusion, i.e. Manual Programming, Auto_ID Programming, Pre-Population Programming, etc
InfusionSetup	This element defines the infusion segment for the current infusion program.
InitialPatientWeight	Indicates the initial Patient weight
LimitCheckMode	Indicates whether the limit checking mode is 'smart' or 'always'. If set to 'smart', the system applies an algorithm to limit the number of alerts.
LogTime	Provides the device local Date and Time of the recorded event
LogVersion	Indicates the log version for the Guardrail log header.
Model	Indicates the PCU Model used
ModuleSerialNumber	Indicates the model number of the specific device that was attached to the PCU
NonInfusionCause	Indicates the reason this event was logged (ex. Cancel, Detach, Module Malfunction, New Patient, Profile Changed, Channel Deselection, etc)
OrderID	Indicates the ID number for this order.
PatientBSA	the body surface area for the patient.
PatientIdentifier	ID of the patient receiving the infusion
PatientWeight	The patient's weight in kilograms for the active infusion program
PCALockoutInterval	Indicates the minimum required time between successive PCA doses.
PCAMaxLimit	Indicates the maximum accumulated dose within the MAX_LIMIT_PERIOD window allowed for this infusion. Set to 0.0 to indicate accumulated dose checking is disabled
PCAMaxLimitPeriod	Indicates the size of the window used to determine max dose
PCAPauseLinkage	1 or 0 if a PCA Module is used otherwise is NULL
PCUSerialNumber	Unique serial number assigned to each PCU device
PlusMinusLimit	Indicates the difference in Programmed Value from the limit value
ProfileName	Identifies the profile in use at the time of the event
ProgrammedDose	Programmed GR Dose amount of infusion based on Guardrails® settings. Is Null for basic infusions.
ProgrammedDurationSeconds	Guardrails® setting for total duration, in seconds. Is Null for basic infusions.
ProgramType	Indicates the type of program that was being programmed or modified
PropPatientWeight	Indicates the resulting patient's weight after changes were applied
PumpState	Indicates the state that the pump is in
Rate	Indicates the infusion rate.
RateCalcBasis	Indicates the modifier value for BDAR (i.e. whether a weight based or non-weight based or BSA based modifier is applied)
RateUnit	Indicates the units of measure for the rate of infusion
SequenceID	Indicates the sequence ID number this snapshot is associated with
SnapshotID	Indicates the ID number of the snapshot
StartReasonCode	It provides information as to what caused a report to be generated.

StartTime	Local date and time when a transactional event within an infusion session occurred such as an alarm, infusion start, infusion transition, etc.
State	Describes the state of infusion device at the time of an infusion
TherapyName	Indicates the name of the therapy selected for this infusion.
VolumeInfusion	Numerical value of amount infused at the time of the alert.
VolumeToBeInfuse	Numerical value of VTBI.
WeightUnit	Indicates the units of measure for patient's weight