DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417 oradevices3firmresponse@fda.hhs.gov	3/2/2020-4/6/2020* FEI NUMBER: 2016493

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Michael E. Garrison, Worldwide President, Medication Management Solutions

FIRM NAME	STREET ADDRESS
CareFusion 303, Inc.	10020 Pacific Mesa Blvd
CITY, STATE, ZIP CODE, COUNTRY San Diego, CA 92121-4386	TYPE ESTABLISHMENT INSPECTED Medical Device Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Procedures for corrective and preventive action have not been adequately established.

Specifically,

A) Corrective Action # CA-2018-0161 was initiated on 08/11/18 [currently in the implementation phase] to address an elevated number of complaints related to failure of the Inter-unit Interface (IUI) connectors due to corrosion or contamination. The IUI is used to attach the Alaris Point of Care Unit (PCU) to the fluid delivery modules, including the Large Volume Pump module (LVP module), Syringe Module, and Patient Controlled Analgesia (PCA) modules. A failed IUI may result in interruption of communication or power between the PCU and the modules (or channels), which could result in interrupted infusion to the patient.

The CAPA investigation states that the Risk Assessment (Document #10000136488, dated 02/13/17) concluded that the probability of patient harm was extremely low and the risk was deemed Acceptable; the Risk Assessment states that contamination or corrosion of the IUIs can lead to loss of communication or power between the PCU and the modules, and concludes that (b) (4)

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(b) (4)". However, this conclusion fails to consider that one of the complaints evaluated in the Risk Assessment (Notification #301057349 [Complaint #46601], dated (b) (6), (b) (7)(C)) reports a communication failure that contributed to, or resulted in, death of a patient (MDR #2016493-2015-00154). It was also noted that your LVP Hazard Analysis File (Document #10000179249) shows the Severity of harm from the hazard (b) (4) L."

Furthermore, the CAPA investigation did not take into consideration additional complaints received since the Risk Assessment was conducted in 2017. Review of your complaint data shows that, since June 2018, your firm has received 104 complaints related to communication errors or channel disconnects caused by corroded, contaminated, or damaged IUIs, including two complaints reporting death of the patients (Complaints # 303875 and 311797, dated (b) (6), (b) (7)(C) and (b) (6), (b) (7)(C) respectively).

Lastly, the Risk Assessment states that the products are not violative because the issues reported (b) (4)"; however, the CAPA investigation shows additional root causes, including component design, damage caused during the manufacturing process, and cleaning instructions not adequate because they do not address current cleaning practices.

The CAPA investigation fails to demonstrate that the safety risk was appropriately assessed to ensure that containment and corrective actions implemented are commensurate with the risk posed to patients.

B) Since June 2018, your firm has received six complaints related to Alaris Infusion system shutdown due to intermittent contact with the battery (in the Point of Care Unit (PCU)). One of the six complaints (Complaint # 348495, dated (b) (6), (b) (7)(C) reports the death of a patient and states:

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"The patient was receiving an Epinephrine infusion at (b)(mcg/kg/min when the device powered off; the patient was without support for approximately 14 minutes and the device did not alarm for a low battery prior to shutting off." Three other complaints (Complaints # 299007, 308407, and 329026, dated 04/05/19, 06/07/19, and 10/21/19, respectively) were reported to the FDA as Medical Device Reports for malfunctions that could result in death or serious injuries if the event was to recur.

Complaint #348495 states that the root cause of the reported incident is attributed to battery screws missing, which resulted in intermittent battery contact when the system was being handled or moved during the patient ambulation. Further review of open issue trackers revealed that your firm initiated Tracker #15249 in February 2015 to investigate Complaint #23505 (dated 09/16/14) which reported a device that "exhibited a communication error during an infusion and possibly stopped". The Tracker Investigation Notes entry dated 01/26/18 shows that your firm was able to duplicate the error; (b) (4) caused the system power to "reset when on main battery and is re-powering ON by itself in a watch dog alarm…This was accomplished by (b) (4)". However, Tracker #15249 remains open (since 2015) and your firm has yet to implement corrective actions to address this potential unintended shutdown of the system, when operating in battery power, that could result in death of patients due to interruption of an infusion.

C) The Issue Tracking procedure (Document #0309-004-000-SWI) establishes the requirements for tracking and resolving issues and action items identified during development, verification and validation, as well as life-cycle testing of software systems (using the issue tracking application (b) (4)). The scope of the procedure "(b) (4)" resulting from review meetings. However, your firm is using the Issue Tracking system to document investigation and corrective actions of non-software related issues, and no procedures have been established to ensure that investigation of these non-software Trackers are completed in a timely manner and that effective corrective actions are implemented. Review of the list of current "Open Issues other than Software" shows 10 open Trackers that have yet to be addressed,

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five of which have been open for more than 5 years (the oldest one opened in 2007). For example, the following issues reported by customers have yet to be addressed:

- Tracker Issue ID 09621 (dated 02/07/07) - A PCU was in a hospital and started to smoke and melt the plastic of the rear housing and IUI connector during an infusion.
- Tracker Issue ID 11867 (dated 03/19/09) – A hospital reported serious risk from infection due to the accumulation of fluids and foreign materials in the handle system.
- Tracker Issue ID 15249 (dated 02/03/15) - The PCU was running an infusion, 2 minutes later it was powered on (without powering off first). CareFusion has identified a software issue with the Alaris PCU where the PCU experiences loss of power and when powered up may experience system error (b) (4) .

OBSERVATION 2

Procedures for receiving, reviewing, and evaluating complaints by a formally designated unit have not been adequately established.

Specifically,

A) The Complaint Handling procedure versions in effect since June 2018 (Document #1501-000-000-SOP, Versions 6 and 7 (formerly entitled Product Monitoring Process)) require customer complaints to be evaluated for reportability as Medical Device Reports (MDRs). However, review of the Alaris Infusion system complaint data extracted from your (b) (4) database shows that 47,951 complaints closed between June 2018 and March 2020 fail to include documentation of determination of whether the events need to be reported to the FDA as MDRs.

For example, the list includes 39 complaints reporting over/under infusion of medication where product evaluation confirmed the malfunctions (e.g., Complaint #s 278117, 284503, and 339487, dated 12/06/18, 01/17/19, and 12/19/19, respectively). Review of the complaint data shows that your firm has reported over (b) (4) events of over or under infusion events, some of which were reported because the device caused or contributed to patient death (e.g., Complaint # 327976

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(over infusion), dated(b) (6), (b) (7)(C)) or resulted in serious injuries (e.g., Complaint #314010 (under infusion), dated(b) (6), (b) (7)(C).

B) The Complaint Handling procedure requires customer complaints for any written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device after it is released for distribution; however:

a) Review of service records for Alaris Infusion devices that were returned for "Recall Repairs" revealed that your firm identified additional unrelated failures. Review of the "Failure Mode Codes" shows 66 devices where your firm identified failures related to the quality, labeling, durability, reliability, or performance of the devices that were not categorized as complaints. For example:

Repair Date	Notification #	Product	Failure Mode Code Desc
02/21/2020	301555099	(b) (4)	
02/18/2020	301532159		
02/18/2020	301513637		
02/10/2020	301538513		
02/7/2020	301550391		
02/6/2020	301088356		
12/17/2019	301518806		
11/7/2019	301522225		
10/31/2019	301526567		
10/24/2019	301524421		
10/24/2019	301518048		
09/23/2019	301509943		
09/13/2019	301511343		
05/14/2019	301480310		
10/5/2018	300902486		
09/7/2018	301064075		

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b) Review of service records for Alaris Infusion devices that were returned for "Preventive Maintenance / Calibration revealed that your firm identified 76 failures related to the quality, labeling, durability, reliability, or performance of the devices that were not categorized as complaints. For example:

Repair Date	Notification #	Product	Failure Mode Code Desc
03/2/2020	301482491	(b) (4)	
03/2/2020	301556514		
02/28/2020	301485599		
02/25/2020	301554168		
02/21/2020	301553802		
02/20/2020	301553803		
02/20/2020	301553579		
02/18/2020	301533356		
02/13/2020	301551163		
11/20/2019	301531452		
10/21/2019	301522539		
10/3/2019	301522435		
08/20/2019	301492790		
07/31/2019	301485662		
12/10/2018	301445023		
06/18/2018	301385284		

OBSERVATION 3

Complaints involving the possible failure of a device to meet any of its specifications were not evaluated and investigated where necessary.

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Specifically, the Complaint Escalation procedure (Document #1501-006-000-SWI-SD-INF, dated 01/05/18) is used to determine the level of investigation needed and defines the criteria for escalation of complaints for further Level [b)(4)] investigation. The procedure requires that customer reports of devices (b) (4) to be escalated for further investigation. However, the procedure requires escalation of (b) (4) issues if they are related to (b) (4) issues; the procedure does not require escalation of over/under infusion failures due to other issues that could result in over/under infusions (e.g., broken bezel, defective sensor, and broken door latch).

For example, I observed 39 complaints for the Alaris Large Volume Pump (LVP) where the customers' reports of over/under infusion (Reported Problem Codes (b) (4) and (b) (4)) were confirmed (e.g., Complaint #s 278117, 284503, and 339487, dated 12/06/18, 01/17/19, and 12/19/19, respectively) but the complaints were not escalated for Level [b)(4)] investigation to ensure that corrective actions were implemented as needed, considering that the Severity of Harm of over/under infusions is categorized, in your LVP Hazard Analysis, as Catastrophic because over or under infusions can result in life threatening conditions or lead to death. These 39 complaints do not include documentation of risk evaluation (Risk fields are blank), or documentation of why corrective action was not needed.

This is a repeat observation from the previous inspection dated 07/17/18 – 09/06/18.

OBSERVATION 4

A violation of the FD&C Act involving a device which might present a risk to health was not reported to FDA.

Specifically, in September 2011 your firm implemented a Plastics Replacement Program in response to a continued increase in customer complaints reporting parts breaking on the Alaris System Point of Care Unit (PCU), Large Volume Pump (LVP) Module, Syringe Module, and Patient Controlled Analgesia (PCA) Module (e.g., Complaints #300703408, 300707119, 300707356, 300708390, 300714250, 300733995). Overall your firm has received [b)(4)] complaints since September 2010 for parts breaking on the Alaris system. The parts affected include front and rear cases, front doors, handles, and

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bezels. For example, Complaint #300869721 (dated 03/07/13) reports "12 Pump Modules with large cracks of the bezel…the cracks are so bad that when a primed set is loaded, it free flows". An investigation conducted by your firm in 2011 (CAPA CA-2011-0256) concluded that the cause of the breakages was (b) (4).

Your firm utilized the Plastics Replacement Program to execute a field correction of affected Alaris devices. In October 2011, your firm mailed 1,743 letters to (b) (4) customers notifying them of the Plastics Replacement Program and that parts were available, at no charge to the customer, for repair of the devices. Customers were also enrolled in the Program and entered into contractual agreements which included a "Schedule" with the terms of the agreements (e.g., covered parts, coverage period of 60 months for new customers, instructions for requesting replacements); as of 03/26/20, your firm has (b) (4) active contracts. Since implementation of the program, your firm has shipped (b) (4) replacement parts to customers to correct the defective devices.

The Hazard Analysis Files for the Alaris PCU, LVP Module, Syringe Module, and PCA Modules identify the risk to patients from the reported breakages; for example:

- PCU and LVP Module - (b) (4) (Severity of Harm = (b) (4)).
- (b) (4) (Severity of Harm = (b) (4)).

Your firm utilized the Plastics Replacement Program to execute a field correction of affected Alaris devices, circumventing your formal Corrections and Removals Management process (defined in the Document #0208-000-000) and your firm did not report this field correction to the FDA.

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OBSERVATION 5

Procedures for design verification have not been adequately established.

Specifically, your Design Verification procedure (Document #0306-000-000, dated 03/06/12) requires that the quality representative (b) (4) . However, the following design verification records (pertaining to the (b) (4) of the (b) (4)) do not include scientific justification for a sample size of (b) (4) devices:

- System verification testing of the EtCO2 Module (b) (4) : EtCO2 8300, (b) (4) Test Report, Document # 10000345097, dated 02/05/19 (per Test Protocol # (b) (4) , dated 06/26/18)
- Testing to demonstrate the accuracy of controls and instruments (including (b) (4)): Alaris EtCO2, 8300, (b) (4) EtCO2 Essential Performance Measurement Accuracy of Controls and Instruments Test Report, Document # 10000350737, dated 02/20/19 (Test Protocol (b) (4) , dated 02/18/19)

The Test Protocols for these design verification tests state that a minimum sample size of (b) (4) is based on the Sample Size Selection procedure (Document #1701-008-000-SWI); however, this procedure does not include a scientific, or statistically valid, justification for the sample size of (b) (4) for design verification.

This is a repeat observation from the previous inspection dated 07/17/18 – 09/06/18.

OBSERVATION 6

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Written MDR procedures have not been implemented.

Specifically, the Medical Device Reporting (MDR) procedures (Product Monitoring procedure and Regulatory Reporting procedures, versions dated March 2018 – February 2020) require submission of MDRs for deaths, serious injuries and malfunctions within (b) (4) after becoming aware of the event. However, review of MDRs submitted by your firm since June 2018 for the Alaris Infusion systems and disposables revealed that your firm has submitted 100 late MDRs identified as follows:

- 11 reports of serious injuries (including 5 submitted > 30 days late (e.g., Complaint #310529) and one submitted 111 days late (Complaint #261954)
- 89 reports of malfunctions (including 14 submitted > 100 days late (e.g., Complaints #306408, 270933, 270774) and 2 submitted >270 days late (Complaints #345491, and 345492)

OBSERVATION 7

Procedures or instructions for performing servicing activities have not been adequately established.

Specifically, the Servicing procedure (Document # 1601-000-000-SOP, dated 10/08/12) requires reports that represent an MDR (Medical Device Report) reportable events to be processed as complaints; however, 142 out of 142 service records reviewed for the Alaris Infusion system do not include evidence to demonstrate that the records were reviewed for MDR determination. The records include the following reported device failures:

Repair Date	Notification #	Product	Failure Mode Code Desc
03/2/2020	301482491	(b) (4)	
03/2/2020	301447802		
03/2/2020	301556514		
02/21/2020	301553802		
02/20/2020	301553803		

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02/13/2020	301551163
12/12/2019	301528292
11/7/2019	301512091
10/21/2019	301457015
12/10/2018	301445023
06/28/2018	301408144
06/18/2018	301385284

(b) (4)

OBSERVATION 8

Validation of device software is incomplete.

Specifically, your software development procedure (Software Development Alignment to (b) (4) Practices, Document #0304-003-071-S-INF, dated 01/25/19) does not include a requirement to ensure that software development testing is conducted in accordance with reviewed and approved test cases to ensure appropriate test coverage. For example, no records were provided to demonstrate that the following software development testing was executed in accordance with reviewed and approved test cases:

- Alaris System (b) (4), Software Development Test Record, dated 12/10/19
- Alaris System (b) (4), Software Development Test Record, dated 02/04/20
- Alaris System (b) (4), Software Development Test Record [not released yet but testing already partially executed]

***DATES OF INSPECTION**

3/02/2020(Mon), 3/03/2020(Tue), 3/04/2020(Wed), 3/05/2020(Thu), 3/06/2020(Fri), 3/09/2020(Mon), 3/10/2020(Tue), 3/11/2020(Wed), 3/12/2020(Thu), 3/13/2020(Fri), 3/16/2020(Mon), 3/17/2020(Tue), 3/18/2020(Wed), 3/19/2020(Thu), 3/20/2020(Fri), 3/23/2020(Mon), 3/24/2020(Tue), 3/25/2020(Wed), 3/26/2020(Thu), 3/27/2020(Fri), 3/30/2020(Mon), 3/31/2020(Tue), 4/01/2020(Wed), 4/02/2020(Thu), 4/03/2020(Fri), 4/06/2020(Mon)

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Annotations to Observations

Observation 1:

Observation 2:

Observation 3:

Observation 4:

Observation 5:

Observation 6:

Observation 7:

Observation 8:

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