DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6th & Kipling St. (P.O. Box 25087) Denver, CO 80225-0087 (303)236-3000 Fax:(303)236-3100	12/8/2025-12/15/2025* FEI NUMBER 3020036682

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Jerome R. Edwards, CEO

FIRM NAME	STREET ADDRESS
Cardionxt	12011 Tejon St Ste 700
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Denver, CO 80234-2313	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, your firm's procedures, QOP-85-03, Corrective And Preventive Action (CAPA), Rev A, under section 4, states (b) (4) (b) (4) Your firm's procedures require you to conduct an investigation to determine the cause of an issue.

Your firm did not follow the procedures when evaluating complaint numbers 0016, 0017, and 0018, where a formal investigation was not conducted to determine the root cause of a software reset. Furthermore, your firm conducted a software stability study, QA-0008, iMap Software Stability Analysis, Rev A, noting issues of the software restarting (b) (4) percent of the time. The study found that the root cause was due to the iMap (b) (4) These (b) (4) in combination with copy, initialization, and deletion pointer operations lead to memory leaks and unexpected termination. This study stated the following, (b) (4) (b) (4) Software updates were implemented to solve the root cause mechanism in release candidate Essex 0.5.4b, iMap Controller version 1.0.3.0. Further testing was performed, resulting in no failures after the software ran for more than (b) (4) cycles. The implementation is sufficient for software release after

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	Hammam A Abdallah, Investigator X Hammam A Abdallah Inves igator Signed By: Hammam A. Abdallah -S Date Signed: 12-15-2025 12:13:29	12/15/2025

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verification testing as required." Your firm did not follow procedures when implementing a software change without opening a formal CAPA.

These issues continue to persist post-release of the product, including events involving patients in the field, having a direct impact on patients. For example; in complaint number 0016, due to the software crash, there was a 25 minute procedural delay, while the patient was under general anesthesia.

Since January 1st, 2023, your firm has manufactured (b) (4) Class II iMap Systems, K201094, which is intended for the display of compatible electrophysiology catheter position and cardiac electrical activity when used with the MultiLink CS Catheter during conventional electrophysiological procedures. Firm plans to begin commercial distribution in 2026.

OBSERVATION 2

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

Specifically, a review of 5 complaints revealed that your firm did not investigate for software crash incidents in 3 complaints, complaint numbers 0016, 0017, and 0018. Your firm's procedure QOP-85-02, rev D titled Complaints states in 4.4(b):

(b) (4)

According to your complaint descriptions, the following events occurred as a result from use of your iMap System, with no formal investigation as to the cause:

1) 0016: The complaint stated, "A crash occurred during the first case after the pre-mapping procedures

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were completed. Clinical Engineer was modifying the geometry by erasing points then paused operations and the iMap software crashed. Team restarted the computer and proceeded with the case... Formal investigation is waived in favor of continued testing, informal investigation by the software team, and continued actions to improve and test stability of the software".

2) 0017: The complaint stated, "Case was completed. Clinical Engineer was modifying the geometry by erasing points. Hill stopped described "heavily" shaving the geometry (erasing and modifying the geometry rendering). When she momentarily stopped erasing the geometry, the iMap software crashed. Team reset the system before the next case but did not continue working on the now-finished case... Formal investigation is waived in favor of continued testing, informal investigation by the software team, and continued actions to improve and test stability of the software per MM-20230310 and MM-20230809."

3) 0018: The complaint stated, "Team was setting up the iMap system before the case with the patient present. Clinical Engineer opened the iMap software, waited until the localizer screen indicated connection to/proper reading of EM signals via the green lights. Seconds after this occurred, the software crashed. This process was repeated (for a total of two incidents of the same events). Team power cycled the iMap. The iMap program returned to expected operation after this hardware restart. Procedure was able to continue as expected from there."

Since (b) (4) , your firm has manufactured (b) (4) Class II iMap Systems, K201094, which is intended for the display of compatible electrophysiology catheter position and cardiac electrical activity when used with the MultiLink CS Catheter during conventional electrophysiological procedures. Firm plans to begin commercial distribution in 2026.

OBSERVATION 3

Risk analysis is inadequate.

Specifically, Ranking of occurrence was inadequate in risk assessment. Risk Assessment Record for

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Risk Management Project iMap Software, Rev C, 03/02/2022 has definition of "(b) (4) " occurrence for Hazard no. 6, Software resetting during procedure. However, the incident has occurred three times in the field since the device was cleared for marketing by FDA.

Since (b) (4) , your firm has manufactured (b) (4) Class II iMap Systems, K201094, which is intended for the display of compatible electrophysiology catheter position and cardiac electrical activity when used with the MultiLink CS Catheter during conventional electrophysiological procedures. Firm plans to begin commercial distribution in 2026.

OBSERVATION 4

Procedures have not been adequately established to control product that does not conform to specified requirements.

Specifically, your procedures, QOP-83-01, Control of Non-conforming Product, Rev D require you to initiate a non-conformance for products when equipment failures could impact product safety, efficacy, or quality characteristics.
In complaint numbers 0016, 0017, and 0018, your firm failed to initiate a non-conformance for a unit that experienced a software crash.

In complaint number 0016 specifically, the software crash occurred while being used on a patient resulting in a significant procedural delay while the patent was under general anesthesia.

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OBSERVATION 5

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The information required by the Global Unique Device Identification Database for each medical device version or model required to bear a unique device identifier (UDI) was not provided.

Specifically, your firm has not registered with Global Unique Device Identification Database for your medical device.

Since (b) (4), your firm has manufactured (b) (4) Class II iMap Systems, K201094, which is intended for the display of compatible electrophysiology catheter position and cardiac electrical activity when used with the MultiLink CS Catheter during conventional electrophysiological procedures. Firm plans to begin commercial distribution in 2026.

OBSERVATION 6

The labels of the medical device(s) do not bear a unique device identifier (UDI) that meet the requirements of 801 Subpart B and 21 CFR 830.

Specifically, your firm does not obtain labels that bear a unique device identifier.

Since (b) (4), your firm has manufactured (b) (4) Class II iMap Systems, K201094, which is intended for the display of compatible electrophysiology catheter position and cardiac electrical activity when used with the MultiLink CS Catheter during conventional electrophysiological procedures. Firm plans to begin commercial distribution in 2026.

***DATES OF INSPECTION**

12/08/2025(Mon), 12/09/2025(Tue), 12/10/2025(Wed), 12/11/2025(Thu), 12/12/2025(Fri), 12/15/2025(Mon)

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Annotations to Observations

Observation 1:

Observation 2:

Observation 3:

Observation 4:

Observation 5:

Observation 6:

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."