DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Harbor Bay Parkway Alameda, CA 94502-7070 (510)337-6700 Fax:(510)337-6702	7/15/2024-7/31/2024* FEI NUMBER 3007208829

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Amit (NMI) Relia , Vice President of Quality

FIRM NAME	STREET ADDRESS
iRhythm Technologies Inc	699 8th St Ste 600
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
San Francisco, CA 94103-4901	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 WE OBSERVED:

OBSERVATION 1

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

Specifically, you have not adequately established your corrective and preventive action procedure, *SOP0020 Corrective and Preventive Action Rev 12*, dated 21 Nov 2023.

a) You also have not adequately established your quality data analysis procedure, *DOP0333 Complaint Trending Process Guidelines Revision 01*, dated 18 Jun 2024, in that you have not analyzed all relevant quality records, complaints, and other sources of quality data to identify existing and potential causes of nonconforming products, or other quality problems. For example, your firm received approximately 4,014 complaints related to your Certified Cardiographic Technician (CCT) personnel operations from 05/02/2022 to 07/19/2024, including issues/events related to CCT personnel misreading arrythmia data and providing such misclassified data to end users for diagnosis purposes.

However, your firm is not adequately analyzing these complaints, issues, or events to identify the rate of occurrence or detect recurring quality problems. You also have not initiated any corrective and preventive actions to investigate the cause or identify the action(s) needed to correct and prevent recurrence of this quality problem. Furthermore, you have not conducted a

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Health Hazard Evaluation for this quality concern, nor are you adequately evaluating these quality complaints/events to determine reporting requirements under 21 CFR § 803.

b) On 06/05/2024, you communicated a new plan/policy of analyzing algorithm functionality data to ensure your devices were performing to specified intended uses, and to determine malfunction reporting requirements under 21 CFR § 803, and you implemented this new plan/policy on or around 07/02/2024. The newly established sensitivity control limit for algorithm sensitivity was breached for the second quarter of CY 2024 in that the algorithm sensitivity rate for detecting Atrial Fibrillation cardiac arrythmia events was determined to be 88.710%, (b) (4) the [(b) (4)]% control limit threshold. However, no corrective and preventive action or health hazard evaluation has been initiated, nor has a related risk analysis been performed. Additionally, you have not included all relevant data inputs for your (b) (4), therefore your resulting calculations are not an all-inclusive quality metric (see Observation 2).

Furthermore, you implemented this plan on or around 07/02/2024 to support your decision and process to not report algorithm misread/misinterpretation events as malfunctions under 21 CFR § 803. Alternatively, you seemingly have no established plan for making related reporting decisions for retroactive or future events/complaints.

c) Your firm initiated and/or conducted a Product Evaluation Report, *PER-2022-0014*, *Field Risk Assessment Number 230213*, with approval signatures dated 02/21 & 22/2023, and *Skin Irritation Complaints Trend HHE-*(b) (4), with effective date 30 Nov 2022, in response to an observation of an increase in complaint trending data related to skin irritation complaints and events. The results of these evaluations document that no further corrective actions were taken, and the *Skin Irritation Complaints Trend HHE-*(b) (4), states in part, "No Action is recommended", "No further action required. Complaint process will continue to track and trend frequency of occurrences and escalate as required. MDR and Vigilance reporting will be performed per already established processes".

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However, skin irritation related complaints and MDR trending data from January 2021 to June 2024 indicate a continued upward trend in skin irritation related complaints, issues, and events. No further corrective and preventive action, health hazard evaluation, or risk analyses have been performed and documented for skin irritation complaints and concerns since the *Field Risk Assessment Number 230213* was approved on 02/21 & 22/2023.

OBSERVATION 2

Risk analysis is inadequate.

Specifically, you have not adequately implemented your procedure, *DOP0284 Risk Management Guidelines Revision 03*, dated 19 July 2024, and your risk analyses are inadequate for your Zio AT, Zio XT, Zio Monitor, and Zeus System Software medical devices.

a) You have not evaluated the risk associated with your Certified Cardiographic Technician (CCT) personnel operations to ensure that your Zio AT, Zio XT, Zio Monitor, and Zeus System Software medical devices conform to defined user needs and intended uses.

Your CCT personnel review and interpret the cardio-graphic and arrythmia event data after patient wear, provide and/or confirm arrythmia indication data, and provide such arrythmia event data to clinical end users for diagnosis purposes. However, your Zio AT, Zio XT, and Zio Monitor Master Hazard Analysis documents do not adequately evaluate the potential risk associated with your CCT personnel operations, as a function of your medical devices.

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Additionally, your firm received approximately 4,014 complaints related to your Certified Cardiographic Technician (CCT) personnel operations from 05/02/2022 to 07/19/2024, including issues/events related to CCT personnel misreading arrythmia data and providing such misclassified data to end users for diagnosis purposes.

b) You have not included all relevant data inputs for your (b) (4) ; therefore, it is not an accurate or all-inclusive quality metric. False positive arrythmia events, as well as duplicated algorithm miss events are not included as data input sources for your (b) (4) , which you use for algorithm functionality monitoring.

For example,

a. Complaint COMP-2024-8814 created 05/04/2024, Z ticket number (b) (4) , and the Visual Timeline document referencing device serial number (b) (4) , document that the Zeus System Software medical device misinterpreted/misread the cardiographic data as a Superventricular Tachycardia arrythmia event during patient wear, although it was later confirmed by a CCT to be an Atrial Fibrillation arrythmia event. This algorithm misread event was not included as a data input for your (b) (4) quality metric, dated 01/01/2024-06/30/2024.

b. Complaint COMP-2024-13230 created 06/24/2024, and Z ticket number (b) (4) , referencing device serial number (b) (4) , document that the Zeus System Software medical device did not detect a Ventricular Tachycardia cardiac arrythmia event during patient wear. This algorithm misread event was not included as a data input for your (b) (4) quality metric, dated 01/01/2024-06/30/2024, due to other Ventricular Tachycardia cardiac arrythmia events being accurately reported during patient wear.

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OBSERVATION 3

An MDR report was not submitted within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device has malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Specifically, you routinely do not report required information after becoming aware of events that allege your Zio AT, Zio XT, Zio Monitor, and Zeus System Software medical devices have malfunctioned and would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur. You also have not adequately implemented your procedure, *SOP0023 Adverse Event Reporting Revision 14*, dated 31 Oct 2023.

a) You routinely do not report complaints and events alleging that your Certified Cardiographic Technician (CCT) personnel have misread or misinterpreted cardio-graphic arrythmia event data after patient wear of your devices and provided such misinformation to clinical end users for diagnosis purposes. The following complaints represent examples of such complaints that were not submitted as Medical Device Reports as malfunction events:

    1. Complaint COMP-2024-13285, created 25 Jun 2024, documents a Delayed MDN as a result of a CCT misread/misinterpretation of cardiographic arrythmia event data. Specifically, the CCT misread/misinterpreted the arrythmia data, dated 06/03/2024, as *SVT*, although it was later determined to be *Sinus*, *VT*, and *SVT* arrythmia events. Complaint COMP-2024-13285 states in part, "Notified (b) (6), (b) (7)(C) (RN) on 25 Jun 2024 at 12:14 PM CDT", "notified on the delayed MDN, account indicated there was a delay in referral to EP but that did not result in any pt harm nor did they indicate a delay in treatment specifically". Complaint COMP-2024-13285 further documents that no Medical Device Report was submitted for this event.

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2. Complaint COMP-2024-11115, created 30 May 2024, documents a Change in Interpretation as a result of a CCT misread/misinterpretation of cardiographic arrythmia event data. Specifically, the CCT misread/misinterpreted arrythmia data, dated 05/05/2024, as *High Grade AVB Block (including VA due to HGAVB)* although it was later determined to be *Atrial Flutter*, *Atrial tachycardia with block*. The CCT misread/misinterpreted additional arrythmia data, dated 05/06/2024, as *High Grade AVB Block (including VA due to HGAVB)* although it was later determined to *Atrial Flutter*, *Atrial Tachycardia with block*. Complaint COMP-2024-11115 further documents that no Medical Device Report was submitted for this event.

3. Complaint COMP-2024-13335, created 26 Jun 2024, documents a Change in Interpretation as a result of a CCT misread/misinterpretation of cardiographic arrythmia event data. Specifically, the CCT misread/misinterpreted arrythmia data, dated 05/27/2024, as *Slow Atrial Fibrillation* although it was later determined to be *Sinus (No AF in scan, FDAF was Post Report Only)*. Complaint COMP-2024-13335 states in part, "Notified (b) (6), (b) (7)(C) on 18 June 2024 at 3:18 PM CDT", "The patient had their diltiazem DCd as a result of the notification of the slow HR, but no changes or new medications were prescribed for the AF specifically, so no pt harm". Complaint COMP-2024-13335 further documents that no Medical Device Report was submitted for this event.

4. Complaint COMP-2023-8904, created 23 Aug 2023, documents a delayed MDN as a result of a CCT misread/misinterpretation of cardiographic arrythmia event data. Specifically, the CCT misread/misinterpreted arrythmia data, dated 08/12/2023, as *Sinus, Ventricular Trigeminy* although it was later determined to be *Complete Heart Block*. Complaint COMP-2023-8904 states in part, "Per (b) (6), (b) (7)(C) the Patient has a hx of CHB and before the monitor was put on, the MD was planning to put in a pacemaker. Plans for the pacemaker have not changed with the notification of CHB yesterday however (b) (6), (b) (7)(C) states that they would have brought the patient in sooner for pacemaker placement had they been notified sooner". Complaint COMP-2023-8904 further documents that no

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Medical Device Report was submitted for this event.

b) You routinely do not report complaints and events alleging algorithm misinterpretations/misreads of cardio-graphic arrythmia event data, as malfunctions of your medical devices' intended uses. The following complaints represent examples of such complaints that were not submitted as Medical Device Reports as malfunction events:

1. Complaint COMP-2024-13230, created 24 Jun 2024, documents a delayed MDN as a result of an algorithm miss of arrythmia data, dated 06/03/2024. Specifically, the arrythmia event data indicated a *Ventricular tachycardia* event, although this cardiac event was not transmitted during wear, as intended. Complaint COMP-2024-13230 states in part, "Notified (b) (6), (b) (7)(C) (RN) on 25 Jun 2024 at 12:14 PM CDT", "notified on the delayed MDN, account indicated there was a delay in referral to EP but that did not result in any pt harm nor did they indicate a delay in treatment specifically". Complaint COMP-2024-13230 further documents that no Medical Device Report was submitted for this event.

2. Complaint COMP-2024-12573, created 19 Jun 2024, documents a Change in Interpretation as a result of an algorithm misinterpretation/misread of arrythmia data, dated 05/26/2024. Specifically, the algorithm misinterpreted/misread the arrythmia event data as *Slow Atrial Fibrillation*, although it was later determined to be *Sinus (No AF in scan, FDAF was Post Report Only)*. Complaint COMP-2024-12573 states in part, "Notified (b) (7)(C), (b) (6) on 18 Jun 2024 at 3:18 PM CDT", "The patient had their diltiazem DCd as a result of the notification of the slow HR, but no changes or new medications were prescribed for the AF specifically, so no pt harm". Complaint COMP-2024-12573 further documents that no Medical Device Report was submitted for this event.

3. Complaint COMP-2023-9112, created 29 Aug 2023, documents a New MDN as a result of two algorithm misses of arrythmia data, dated 08/05/2023 & 08/06/2023. Specifically,

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the arrythmia event data indicated two, separate *Complete Heart Block* events, although these cardiac events were not transmitted during wear, as intended. Complaint COMP-2023-9112 states in part, "Per (b) (6), (b) (7)(C) the Patient has a hx of CHB and before the monitor was put on, the MD was planning to put in a pacemaker. Plans for the pacemaker have not changed with the notification of CHB yesterday however (b) (6), (b) (7)(C) states that they would have brought the patient in sooner for pacemaker placement had they been notified sooner". Complaint COMP-2023-9112 further documents that no Medical Device Report was submitted for this event.

***DATES OF INSPECTION**

7/15/2024(Mon), 7/16/2024(Tue), 7/17/2024(Wed), 7/18/2024(Thu), 7/19/2024(Fri), 7/22/2024(Mon), 7/23/2024(Tue), 7/24/2024(Wed), 7/25/2024(Thu), 7/31/2024(Wed)

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Annotations to Observations

Observation 1:

Observation 2:

Observation 3:

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