Medtronic

AccuRhythm™ AI ZA400, ZA410

post-processing library and AF algorithm

Clinician Manual Supplement

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

Contents

1 Introduction

1.1 About this manual

This manual describes the intended use and operation of the AccuRhythm AI ECG classification system. This system includes the AccuRhythm AI post-processing library, Model ZA400, and the AccuRhythm AI atrial fibrillation (AF) algorithm, Model ZA410. These components work together to reduce the number of false-positive AF episodes from compatible Medtronic insertable cardiac monitors (ICMs).

2 AccuRhythm AI ECG classification system feature description

2.1 AccuRhythm AI ECG classification system overview

The AccuRhythm AI ECG classification system adjudicates AF episodes that contain ECG data from compatible Medtronic insertable cardiac monitors (ICMs) and classifies the results of the algorithm's adjudications as either "AI false episodes" or "AI true or indeterminate episodes."

2.1.1 AccuRhythm AI ECG classification system for Reveal LINQ

The AccuRhythm AI ECG classification system operates as follows when used with Reveal LINQ ICMs:

1. When the remote-monitoring system receives AF episodes with ECG data, it initiates the AccuRhythm AI AF algorithm, Model ZA410.
2. The AF algorithm, Model ZA410, adjudicates the episodes and classifies the results of the adjudications as either "AI false episodes" or "AI true or indeterminate episodes."
3. The AccuRhythm AI ECG classification system then returns the adjudication status for the episodes to the remote-monitoring system.

2.1.2 AccuRhythm AI ECG classification system for LINQ II

The AccuRhythm AI ECG classification system operates as follows when used with LINQ II ICMs:

1. When the remote-monitoring system receives AF episodes with ECG data, it initiates the AccuRhythm AI AF algorithm, Model ZA410, which adjudicates the episodes.
2. The AccuRhythm AI post-processing library, Model ZA400, classifies the results of the algorithm's adjudications as either "AI false episodes" or "AI true or indeterminate episodes."
3. The AccuRhythm AI ECG classification system then returns the adjudication status for the episodes to the remote-monitoring system.

2.2 Intended use

The intended use of the AccuRhythm AI ECG classification system is to reduce false positive cardiac arrhythmia episodes.

2.3 Indications and contraindications

2.3.1 Indications and contraindications - Reveal LINQ ICM

Refer to the Reveal LINQ ICM Clinician Manual for indications and contraindications for the Reveal LINQ ICM.

2.3.2 Indications and contraindications - LINQ II ICM

Refer to the LINQ II ICM Clinician Manual for indications and contraindications for the LINQ II ICM.

2.3.3 Indications and contraindications - AccuRhythm AI ECG classification system

The AccuRhythm AI post-processing library, Model ZA400, does not have its own indications for use.

The AccuRhythm AI AF algorithm, Model ZA410, does not have its own indications for use.

There are no known contraindications for AccuRhythm AI post-processing library, Model ZA400, and AccuRhythm AI AF algorithm, Model ZA410.

2.4 Precautions

The AccuRhythm AI ECG classification system may incorrectly adjudicate a true positive episode as an AI false episode, causing that episode to be suppressed in the remote-monitoring system. See *Section 2.5* for more information on the algorithm's accuracy.

2.5 Algorithm performance data

2.5.1 AccuRhythm AI AF algorithm, Model ZA410, performance data for Reveal LINQ

Table 1 shows data on the reduction of false alerts and preservation of true alerts by the AccuRhythm AI AF algorithm. *Table 2* shows the algorithm's episode-detection performance, and *Table 3* shows its duration-detection performance.[1]

The following performance data comes from a set of 4285 Reveal LINQ ICM patients from 1195 clinics. From these patients, a dataset of 5236 AF episodes from 491 patients across 2033 episode days (days with at least one ICM-detected AF episode) was collected. AF ablation or AF management was the Reason for Monitoring provided for 39.3% of the patients (193 out of 491). A total of 2898 AF episodes from 295 patients were adjudicated as true AF, while the remaining 2338 episodes from an overlapping set of 263 patients were adjudicated as false AF.

Table 1. True alerts preserved and false alerts reduced by the AccuRhythm AI AF algorithm, ZA410

	AF classification algorithm
Daily relative sensitivity (true alerts preserved)[a]	98.2%
Daily relative specificity (false alerts reduced)[a]	89.5%

[a] Compared to the Reveal LINQ AF detection algorithm.

Table 2. Episode-detection performance metrics for the AccuRhythm AI AF algorithm, ZA410

	Gross	Patient Average
Relative sensitivity[a]	97.9%	95.2%
Positive predictive value	93.0%	86.0%

[a] Compared to the Reveal LINQ AF detection algorithm.

Table 3. Duration-detection performance metrics for the AccuRhythm AI AF algorithm, ZA410

	Gross	Patient Average
Relative sensitivity[a]	100.0%	95.6%
Relative specificity[a]	26.9%	86.6%
Positive predictive value	96.9%	86.7%
Negative predictive value	97.1%	93.2%

[a] Compared to the Reveal LINQ AF detection algorithm.

[1] Medtronic data on file.

2.5.2 AccuRhythm AI AF algorithm, ZA410, performance data for LINQ II

Table 4 shows data on the reduction of false alerts and preservation of true alerts by the AccuRhythm AI AF algorithm. *Table 5* shows the algorithm's episode-detection performance, and *Table 6* shows its duration-detection performance.[2]

The following performance data comes from a set of 3031 LINQ II ICM patients from 411 clinics. From these patients, a dataset of 1856 AF episodes from 955 patients across 955 episode days (days with at least one ICM-detected AF episode) was collected. AF ablation or AF management was the Reason for Monitoring provided for 42.9% of the patients (409 out of 955). A total of 972 AF episodes from 499 patients were adjudicated as true AF, while the remaining 884 episodes from an overlapping set of 528 patients were adjudicated as false AF.

Table 4. True alerts preserved and false alerts reduced by the AccuRhythm AI AF algorithm, ZA410

	AF classification algorithm
Daily relative sensitivity (true alerts preserved)[a]	99.0%
Daily relative specificity (false alerts reduced)[a]	88.2%

[a] Compared to the LINQ II AF detection algorithm.

Table 5. Episode-detection performance metrics for the AccuRhythm AI AF algorithm, ZA410

	Gross	Patient Average	GEE (95% confidence bound)[a]
Relative sensitivity[b]	99.2%	98.8%	99.1% (98.0% - 99.6%)
Positive predictive value	85.8%	85.1%	85.3% (82.5% - 87.7%)

[a] Generalized Estimating Equation (GEE) estimates and the 95% confidence bound are shown to adjust for multiple episodes per subject. An exchangeable correlation structure was utilized in the GEE model to account for multiple observations per subject.
[b] Compared to the LINQ II AF detection algorithm.

Table 6. Duration-detection performance metrics for the AccuRhythm AI AF algorithm, ZA410

	Gross	Patient Average
Relative sensitivity[a]	100.0%	98.7%
Relative specificity[a]	28.9%	80.6%
Positive predictive value	99.2%	85.6%
Negative predictive value	98.4%	98.9%

[a] Compared to the LINQ II AF detection algorithm.

[2] Medtronic data on file.

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