Medtronic

AccuRhythm™ AI ZA400, ZA420

post-processing library and pause 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 pause algorithm, Model ZA420. These components work together to reduce the number of false-positive pause 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 pause episodes that contain ECG data from compatible Medtronic insertable cardiac monitors (ICMs). The AccuRhythm AI post-processing library classifies the results of the algorithm's adjudications as either "AI false episodes" or "AI true or indeterminate episodes."

The AccuRhythm AI ECG classification system operates as follows:

- When the remote-monitoring system receives pause episodes with ECG data, it initiates the AccuRhythm AI pause algorithm, Model ZA420, which adjudicates the episodes.
- 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."
- 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 pause algorithm, Model ZA420, does not have its own indications for use.

There are no known contraindications for the AccuRhythm AI post-processing library, Model ZA400, and the AccuRhythm AI pause algorithm, Model ZA420.

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 pause algorithm, ZA420, for Reveal LINQ

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

The following performance data comes from a set of 1562 Reveal LINQ ICM patients from 714 clinics. From these patients, a dataset was collected containing 3193 pause episodes from 288 patients across 2243 episode days (days with at least one ICM-detected pause episode). Syncope was the Reason for Monitoring provided for 41.3% of these patients (119 out of 288). A total of 1271 pause episodes from 148 patients were adjudicated as true pause, while the remaining 1922 were adjudicated as false pause.

Table 1. True alerts preserved and false alerts reduced by the AccuRhythm AI pause algorithm, ZA420

	Pause classification algorithm
Daily relative sensitivity (true alerts preserved)[a]	99.9%
Daily relative specificity (false alerts reduced)[a]	80.2%

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

Table 2. Episode-detection performance metrics for the AccuRhythm AI pause algorithm, ZA420

	Gross	**Patient Average**	**GEE (95% confidence bound)[a]**
Relative sensitivity[b]	99.9%	99.9%	99.9% (99.4% - 100.0%)
Positive predictive value	81.5%	59.3%	60.2% (54.0% - 66.0%)

[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 Reveal LINQ pause detection algorithm.

2.5.2 AccuRhythm AI pause algorithm, Model ZA420, for LINQ II

Table 3 shows data on the reduction of false alerts and preservation of true alerts by the AccuRhythm AI pause algorithm. *Table 4* shows the algorithm's episode-detection performance.[2]

[1] Medtronic data on file.
[2] Medtronic data on file.

The following performance data comes from a set of 3416 LINQ II ICM patients from 287 clinics. From these patients, a dataset was collected containing 2766 pause episodes from 382 patients across 1713 episode days (days with at least one ICM-detected pause episode). Syncope was the Reason for Monitoring provided for 43.2% of these patients (165 out of 382). A total of 674 pause episodes from 122 patients were adjudicated as true pause, while the remaining 2,092 were adjudicated as false pause.

Table 3. True alerts preserved and false alerts reduced by the AccuRhythm AI pause algorithm, ZA420

	Pause classification algorithm
Daily relative sensitivity (true alerts preserved)[a]	100.0%
Daily relative specificity (false alerts reduced)[a]	97.4%

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

Table 4. Episode-detection performance metrics for the AccuRhythm AI pause algorithm, ZA420

	Gross	**Patient Average**	**GEE (95% confidence bound)[a]**
Relative sensitivity[b]	99.7%	99.3%	99.7% (98.7% - 99.9%)
Positive predictive value	95.0%	80.1%	85.0% (79.1% - 89.4%)

[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 pause detection algorithm.

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