## Original Article

# Diagnostic Efficacy of a Single-Lead Ambulatory 14-Day ECG Monitor in Symptomatic Children

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## ABSTRACT

**Background:** The CardioSTAT is a single-lead ambulatory electrocardiography monitor that has been validated for use in adult patients. Recording is made through 2 electrodes positioned in a lead-I configuration, and the device allows monitoring for 2, 7, or 14 days. We sought to investigate the efficacy of this device in children with paroxysmal palpitations.

**Methods:** In phase I, the quality of tracings from simultaneous CardioSTAT recordings and D1-lead recordings of a standard 12-lead electrocardiography machine in 23 children were compared. Phase II

## RÉSUMÉ

**Contexte :** Le CardioSTAT est un moniteur d'électrocardiographie ambulatoire à dérivation unique dont l'utilisation a été validée chez les patients adultes. L'enregistrement se fait au moyen de 2 électrodes positionnées dans une configuration de type « dérivation I », et l'appareil permet un suivi pendant 2, 7 ou 14 jours. Nous avons cherché à étudier l'efficacité de cet appareil chez les enfants atteints de palpitations paroxystiques.

**Méthodologie :** Dans la phase I, la qualité des tracés provenant d'enregistrements simultanés de CardioSTAT et d'enregistrements de

Children and teenagers are frequently evaluated for paroxysmal symptoms suggestive of arrhythmia, such as palpitations, dizziness, and chest discomfort. These symptoms generate a lot of anxiety in patients and their families and may sometimes unmask a significant problem that necessitates a specific intervention (medication, catheter ablation, pacemaker, etc.).[1-5] Holter monitoring for 24 or 48 hours may not allow the determination of the rhythm during symptomatic episodes if the episodes are infrequent. Handheld event recorders, such as the Cardiomemo, have been available for long-term ambulatory electrocardiogram (ECG) monitoring in pediatrics for many years. Although handheld event recorders are useful in patients with uncommon and symptomatic events, they may miss short or unfelt potentially

harmful episodes.[6] Subcutaneously implantable event monitors enable the detection of all arrhythmias (infrequent, of short duration, and unfelt), but they do so at the cost of a more invasive and costly intervention in a child.[7-9]

A novel device, the CardioSTAT (Icentia Inc., Quebec, QC), has been validated for use in adults to detect arrhythmias.[10] It is an ambulatory ECG monitor with continuous recording of a single-lead tracing. The device is less cumbersome than a regular 3-lead Holter monitor; it is waterproof and has a longer recording capacity (2, 7, or 14 days). Like the Holter monitor, it has an event button that can be activated to signal symptoms. Electrodes can be replaced by the patient during prolonged monitoring periods.

The purpose of this study was to validate the diagnostic accuracy of the CardioSTAT monitor in children. The study was conducted in 2 phases. The aim of phase I was to assess the possibility of accurately interpreting the cardiac rhythm using CardioSTAT ECG tracings, compared with using standard 12-lead ECG tracings, in children with a variety of cardiac rhythms. Phase II was aimed at demonstrating the superiority of the CardioSTAT monitor in determining the underlying rhythm (abnormal rhythm or sinus rhythm variant) during symptomatic suspected cardiovascular events in children, compared with the currently used 24-hour Holter monitor or handheld event recorder. Secondary purposes of the second phase were to demonstrate the capacity of the CardioSTAT monitor to

was a prospective observational cohort study comparing arrhythmia detection using the CardioSTAT vs currently used devices (24-hour Holter monitor and the Cardiomemo loop recorder) in 52 children complaining of palpitations.

**Results:** In Phase I, all but 3 rhythm strips were correctly identified. The pacing spikes on 3 strips were not adequately identified by the observers for the CardioSTAT recording. In Phase II, symptomatic episodes were reported in 42%, 73%, and 100% of subjects during monitoring with the Holter, Cardiomemo, and CardioSTATdevices, respectively. An abnormal rhythm was detected in 13%, 23%, and 35% of subjects by the Holter, Cardiomemo, and CardioSTAT monitors, respectively. The underlying rhythm during symptomatic events was determined in 90% of cases with the CardioSTAT monitor, whereas it was determined in only 19% and 29% of cases using the Holter and Cardiomemo monitors, respectively.

**Conclusions:** The CardioSTAT monitor provided good-quality tracings and was superior to the 24-hour Holter monitor and the Cardiomemo loop recorder in determining the presence or absence of pathologic arrhythmia in the study cohort.

la dérivation I d'un appareil d'électrocardiographie standard à 12 dérivations a été comparée chez 23 enfants. La phase II était une étude de cohorte observationnelle prospective comparant la détection de l'arythmie à l'aide du moniteur CardioSTAT par rapport aux appareils utilisés actuellement (moniteur Holter à surveillance sur 24 heures et enregistreur d'événements portatif Cardiomémo) chez 52 enfants se plaignant de palpitations.

**Résultats :** Dans la phase I, toutes les bandes d'enregistrement sauf trois ont été correctement identifiées. Les spicules de stimulation n'ont pas été correctement détectés par les observateurs sur trois bandes d'enregistrement du moniteur CardioSTAT. Dans la phase II, des épisodes symptomatiques ont été signalés chez 42 %, 73 % et 100 % des sujets pendant la surveillance avec les appareils Holter, Cardiomémo et CardioSTAT, respectivement. Un rythme anormal a été détecté chez 13 %, 23 % et 35 % des sujets par les moniteurs Holter, Cardiomémo et CardioSTAT, respectivement. Le rythme sous-jacent pendant les événements symptomatiques a été déterminé dans 90 % des cas avec le moniteur CardioSTAT, alors qu'il n'a été déterminé que dans 19 % et 29 % des cas, respectivement, avec les moniteurs Holter et Cardiomémo.

**Conclusions :** Le moniteur CardioSTAT a fourni des tracés de bonne qualité et s'est révélé supérieur à l'appareil Holter à surveillance sur 24 heures et à l'enregistreur d'événements portatif Cardiomémo pour déterminer la présence ou l'absence d'arythmie pathologique dans la cohorte étudiée.

identify abnormal paroxysmal arrhythmias in children, to evaluate the quality of tracings obtained in children when they wear the single-use recording monitor for 14 days, and to evaluate the risk of cutaneous side effects or any other undesirable side effects of the device in children.

## Methods

### Design

Phase I was a single-centre cross-sectional study conducted in a tertiary pediatric cardiology centre. Phase II was a multicentre cohort study conducted in 3 Canadian tertiary pediatric cardiology centres. The study was reviewed and approved by each participating site's institutional research ethics review board. The subject's parent or guardian provided written informed consent, and minor subjects provided verbal or written assent, when appropriate. We obtained authorization from Health Canada for both phases of the study.

### Phase I

Children aged 5 to 15 years, in whom various rhythm disturbances were identified using a 12-lead ECG (MAC 5000 or Marquette, GE, Chicago, IL) were recruited. We excluded children who had chronic skin disease, skin allergies, or acute scars or burns at the site of CardioSTAT installation. Tracings recorded with a standard ECG were the reference with which the CardioSTAT recordings were compared. The patient's rhythm was simultaneously recorded for 1 minute with the CardioSTAT monitor (horizontal position at the second intercostal space above the sternum; Fig. 1) and an ECG rhythm strip in lead D1 (right and left arms, which mirrors the CardioSTAT recording). The tracings were printed separately and analyzed blindly by an experienced

pediatric cardiologist (P.C.) and a pediatric electrophysiologist (J.M.C.). The following variables were compared: overall quality of the tracings, adequacy of P and QRS detection, and rhythm interpretation. The quality of tracings was rated as good (good quality with only occasional artifacts), average (recognizable P and QRS but presence of multiple artifacts), or mediocre (P and QRS difficult to identify and presence of artifacts throughout the tracing).

### Phase II

Children between the ages of 5 and 17 years seen in ambulatory pediatric cardiology with symptomatic paroxysmal cardiovascular symptoms, including palpitations, presyncope, syncope, and nonspecific malaise, and for whom investigations with a Holter monitor and/or an event recorder were deemed necessary, were eligible. Exclusion criteria were having chronic skin disease, skin allergies, or acute scars or burns at the anterior portion of the thorax. On day 1, a 14-day single-use recording monitor (a CardioSTAT) was installed. A 24-hour Holter monitor was also installed on day 1 on the thorax in the usual fashion, to be removed after 24 hours. Finally, a Cardiomemo loop recorder was given to the subject for 4 weeks, with the recommendation to apply the device to the thorax and record the rhythm during symptomatic events. A diary was provided to record events and symptoms for the full 4-week duration of the study. Any cutaneous or more general side effects were also recorded. Research staff communicated by telephone on day 15 to inquire about any side effects experienced that were related to wearing the CardioSTAT. The CardioSTAT monitor was mailed by the parent or subject directly to Icentia Inc. (Quebec, Canada), where it was decoded by a trained technician and transmitted to the study team.

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## Rhythm assessment

All tracings were analyzed blindly and independently by an experienced pediatric cardiologist (P.C.) and a pediatric electrophysiologist (J.M.C.). The quality of tracings was analyzed as described above. CardioSTAT, Holter, and Cardiomemo monitor tracings were blindly reviewed for number of symptomatic episodes and determination of the rhythm during symptomatic episodes. The detection of asymptomatic rhythm anomalies was also assessed blindly in the Holter and CardioSTAT tracings. Specifically, the CardioSTAT report that was transmitted to the study team contained all rhythm strips with presumed arrhythmia, the percentage of tracings with noise that precluded interpretation, the mean, minimal, and maximal heart rate, and the longest RR interval. Noise was defined as an uninterpretable signal, because of either artifact, interference, or lead disconnection. Noise was calculated as a percentage of the total recording time.

## Primary outcomes

The primary outcomes of the study were (i) the probability of determining the rhythm (sinus rhythm variant or abnormal) during symptomatic events in children, and (ii) the probability of identifying abnormal arrhythmia (whether symptomatic or not). In this study, the identification of a single abnormal rhythm tracing during a symptomatic event was sufficient to classify this abnormal rhythm as being responsible for the patient's symptoms. On the other hand, we arbitrarily determined that ≥5 episodes of symptomatic sinus rhythm were required in the absence of any other pathologic arrhythmia to affirm that sinus rhythm or sinus tachycardia was the cause of the symptoms.

## Statistical analyses

Continuous variables are described as mean ± standard deviation when normally distributed, and as median and interquartile range when not normally distributed. Categorical variables are expressed as frequencies and percentages. McNemar's test (McNemar–Bowker's symmetry test in case of more than 2 categories) was used to compare the quality of tracing, the presence of events, and the presence of anomalies, as measured by the Holter vs the CardioSTAT monitor, and by the Cardiomemo vs the CardioSTAT monitor. Statistical analyses were performed using SAS statistical software v.9.4 (SAS Institute, Cary, NC) with a 2-sided significance level set at $P < 0.05$. Bonferroni-corrected significance level was set at 0.025, considering 2 tests used for each research hypothesis verification.

## Results

### Phase I

A total of 23 children (16 boys), aged $9.3 \pm 2.3$ years, were recruited. Their mean weight and height were $27.9 \pm 10.6$ kg, and $123.3 \pm 31.3$ cm, respectively. Tracings recorded with a standard ECG in lead D1 were compared with those obtained using the CardioSTAT. The following rhythms were evaluated: 9 sinus rhythms (including tracings with abnormal QRS morphologies such as bundle branch



**Figure 1.** Horizontal positioning of the CardioSTAT device at the second intercostal space above the sternum in a 9-year-old child.

block or preexcitation), 2 junctional escape rhythms, 4 ventricular arrhythmias, 3 heart blocks, 1 atrial arrhythmia, 3 paced rhythms, and 1 sinus rhythm with bundle branch block.

Results are shown in Table 1, and typical examples are shown in Figure 2. The observers accurately identified the rhythm on the CardioSTAT tracings, for all unpaced rhythms. They were not able to specifically identify the paced rhythms because the CardioSTAT filters did not clearly render the pacing spikes on rhythm strips (Fig. 2C).

### Phase II

A total of 52 subjects completed phase 2. The age of the subjects ranged from 5 to 17 years (mean of $13 \pm 4$ years), and 29 were female (56%). The subjects' mean weight and height were $51 \pm 18$ kg and $153 \pm 19$ cm, respectively.

Phase II results are summarized in Table 2. The quality of tracing was categorized as good in 86%, 42%, and 96% for the CardioSTAT, Cardiomemo, and Holter devices, respectively. No Cardiomemo tracings were available in 14 cases (27%), as the subjects either did not transmit any rhythms during symptomatic events or did not experience any symptomatic events during the 4-week period. Although 79% of transmitted Cardiomemo tracings were of good or average

**Table 1.** Qualitative assessment of the CardioSTAT monitor

| Qualitative measure | n (%) |
| --- | --- |
| Tracings of good quality | 23/23 (100) |
| P wave correctly identified | 20/22 (91) |
| QRS correctly identified | 23/23 (100) |
| Adequate interpretation of non-paced rhythms | 20/20 (100) |
| Adequate identification of paced rhythms | 0/3 (0) |

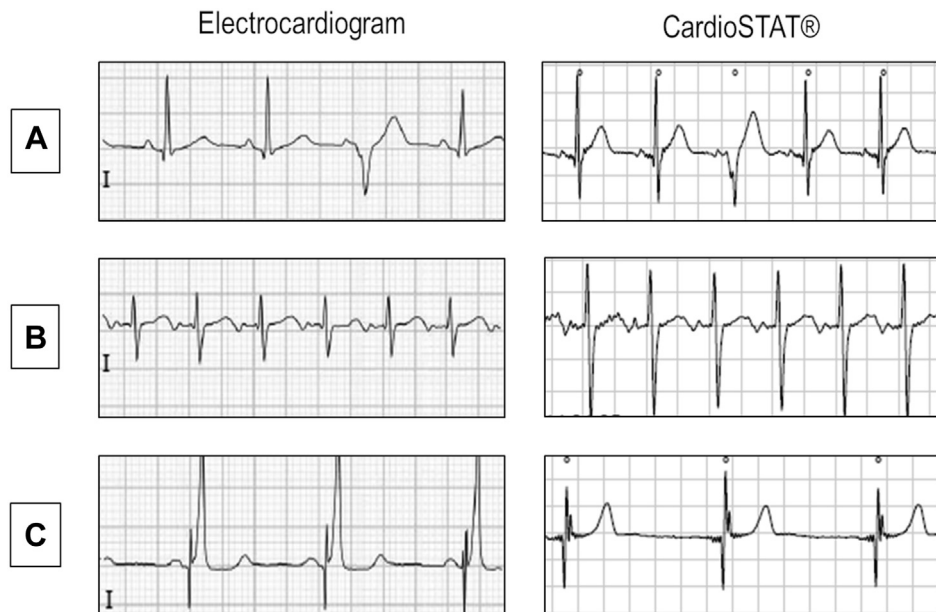P wave = atrial depolarization; QRS = ventricular depolarization.

**Figure 2.** Rhythm strips comparing electrocardiogram (left) and the CardioSTAT (right): (**A**) ventricular premature beat; (**B**) ectopic atrial rhythm; and (**C**) sinus rhythm with ventricular pacing. Of note, (**C**) electrocardiogram (left) shows a P wave followed by clear pacing spikes before the QRS interval, whereas the CardioSTAT (right) shows an unclear P wave and a pacing spike before the QRS interval.

quality, 21% were categorized as mediocre. Noise was reported for 25% ± 15% of the recorded time in the CardioSTAT recordings, reducing the time for arrhythmia detection accordingly.

All subjects reported at least one symptomatic event on at least one device. All 52 subjects recorded at least 2 events on the CardioSTAT (mean of 24 symptomatic events per subject). In contrast, 38 of 52 subjects (73%) recorded at least one event on the Cardiomemo (mean of 1.6 events per subject), and 22 of 52 (42%) did so while using the Holter monitor (mean of 1.2 events per subject). An abnormal rhythm during symptoms was found by the CardioSTAT monitor in 16 of 52 subjects (31%). Examples are shown in Figure 3. In addition, the CardioSTAT fortuitously revealed a case of Wolff-Parkinson-White (WPW) syndrome with intermittent pre-excitation in 2 subjects. The pre-excitation was observed with the Holter monitor as well, but it was not detected by the Cardiomemo, and it was not present on the 12-lead ECG. For these 2 subjects, 18 of 52 abnormal traces (35%) were detected with the CardioSTAT. Abnormal traces were identified less frequently by the Cardiomemo (12 of 52 subjects; 23%) and the Holter monitor (7 of 52 subjects; 13%). A normal sinus rhythm was found during symptomatic episodes in 34 of 52 subjects (65%) using the CardioSTAT. This proportion was lower for the Cardiomemo (26 of 52; 50%) and the Holter (12 of 52; 23%) devices. Considering our threshold of ≥5 symptomatic episodes per subject to be confident that symptoms occur during normal sinus rhythm, the CardioSTAT identified 29 of 52 (56%) symptomatic subjects with sinus rhythm, whereas this proportion was 3 of 52 (6%) for both the Cardiomemo and Holter monitors.

Overall, the rhythm during symptomatic episodes, either normal or abnormal, was clearly determined to be sinus or abnormal in 47 of 52 subjects (90%). This proportion dropped to 29% for the Cardiomemo recorder, and to 19% for the Holter monitor ($P < 0.001$).

Cutaneous side effects were reported in 27 (52%) of the study subjects during the CardioSTAT period of the study. These were characterized as local dermatitis or isolated pruritus in 35% and 17% of subjects, respectively. Only 4 required local application of an ointment to relieve pruritus. There were no long-term or serious side effects.

**Table 2.** Comparison of the Holter, Cardiomemo, and CardioSTAT monitors

| Characteristic | Holter | Cardiomemo | CardioSTAT |
|---|---|---|---|
| Quality of tracings* | | | |
| Good | 50 (96) | 16 (42) | 45 (86) |
| Average | 2 (4) | 14 (37) | 7 (14) |
| Mediocre | 0 | 8 (21) | 0 |
| Subjects with symptomatic events | 22 (42) | 38 (73) | 52 (100) |
| Reported symptomatic events | 1.2 ± 2.6 | 1.6 ± 1.6 | 24 ± 27.5 |
| Abnormal rhythm findings | 7 (13) | 12 (23) | 18 (35) |
| Premature atrial contraction | 2 (4) | 2 (4) | 5 (10) |
| Premature ventricular contraction | 2 (4) | 1 (2) | 1 (2) |
| Supraventricular tachycardia | 1 (2) | 7 (13) | 7 (13) |
| Ventricular tachycardia | 0 | 0 | 1 (2) |
| Other wide complex tachycardia | 0 | 2 (4) | 2 (4) |
| Wolff-Parkinson-White syndrome | 2 (4) | 0 | 2 (4) |
| Clear rhythm identification during symptomatic events | 10 (19) | 15 (29) | 47 (90) |

Values are n (%) or mean ± standard deviation.

* 14 cases were missing in the Cardiomemo group (no tracings transmitted for evaluation).

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**Figure 3.** Examples of rhythm strips recorded with the CardioSTAT monitor on different participants: (**A**) nonsustained ventricular tachycardia in a hypertrophic cardiomyopathy patient; (**B**) a patient with Wolff-Parkinson-White syndrome in sinus rhythm; (**C**) a patient with wide complex tachycardia that proved to be caused by a Mahaim fiber upon electrophysiologic study; and (**D**) supraventricular tachycardia in a symptomatic 10-year-old boy. bpm, beats per minute; min, minimum.

## Discussion

The CardioSTAT monitor has been validated for use in adults, to detect arrhythmias.[10] The purpose of this study was to evaluate the diagnostic accuracy of the CardioSTAT in children, and to assess its superiority in determining the rhythm (sinus rhythm variant or abnormal) during paroxysmal events in children (palpitations and syncope), compared with routinely used devices. In Phase I, we found the accuracy of the CardioSTAT single-lead recording to be excellent for non-paced rhythm, compared with the gold-standard ECG lead-D1 recording. However, pacing spikes were masked by the filtering of the CardioSTAT, and the interpretation of paced rhythms was impaired. In Phase II, we found that abnormal rhythms during symptomatic episodes, as well as a clear determination of the rhythm causing symptoms, were more likely to be identified by the CardioSTAT monitor, compared with the Cardiomemo and Holter monitors. It was expected that a shorter—24-hour—monitoring period would identify fewer episodes. Nevertheless, it is interesting that a 14-day period of continuous monitoring could clearly identify more abnormal rhythms and more causes of paroxysmal symptoms, compared with the longer but intermittent monitoring with the Cardiomemo.

Children are frequently investigated for paroxysmal symptomatic events. The clinician must define the underlying rhythm as either a pathologic arrhythmia or simply a benign sinus rhythm variant. It is expected in clinical practice that normal sinus rhythm and sinus tachycardia will be found in a significant number of symptomatic patients, and in such cases, only conservative measures and reassurance need to be offered. In this study, although sinus rhythm was frequently the only

rhythm detected with the Holter and Cardiomemo monitors, the small number of symptomatic events reported in most patients with these devices did not provide the clinician with reasonable certainty that this benign rhythm was the only rhythm occurring during symptomatic events. When sinus rhythm was the only rhythm detected during symptomatic events, we arbitrarily determined that a minimum of 5 episodes was required to clearly indicate that the sinus rhythm was responsible for the symptomatic episode. Under these conditions, it was possible to identify the underlying rhythm (sinus or abnormal) during the symptomatic events in 90%, 29%, and 19% of subjects with the CardioSTAT, Cardiomemo, and Holter monitors, respectively. Furthermore, with the CardioSTAT monitor, sinus rhythm was the only rhythm repeatedly detected in $20 \pm 13$ symptomatic events in 34 of the 52 subjects. This high number of events enables the clinician to confidently affirm that the symptomatic rhythm is a sinus rhythm variant, and reassurance may be reasonably given to the patient.

The CardioSTAT technology has other advantages over conventional longer-term Holter ambulatory ECG monitoring.[11] The CardioSTAT is a small device that is very light and easy to wear. At the end of the monitoring period, the device is mailed to Icentia Inc. (Quebec) for analysis. Parents do not need to bring the device back to the clinic, as is required for the Holter and Cardiomemo monitors. Electrodes can be replaced if they fall off during the recording period. The device is also water resistant, allowing patients to shower with it, an important quality to help enhance compliance for long-term monitoring. The CardioSTAT allows for different monitoring durations (2, 7, and 14 days).

On the other hand, it is a single-use device, with a cost that varies between 250 and 350 Canadian dollars, including technical analysis at Icentia Inc.

This study also revealed some pitfalls of the CardioSTAT monitor. Although the device was kept in place for a mean of 12.9 days, the mean duration of interpretable rhythm was only 9.4 ± 2.8 days. The main reason for this limitation was that the reported level of noise precluding interpretation of the rhythm was high, with noise reported in 25% ± 15% of the recorded time, with elimination of the tracings for arrhythmia detection. This noise level compares unfavorably to the 8.5% noise level recorded by Nault et al.[10] and can be explained partly by the fact that the CardioSTAT monitor was worn for only 24 hours in that study, compared with a mean of 12.9 days in our study. A degradation of the skin—electrode contact during long-term wear of the device is a possibility, and this may justify providing extra pairs of electrodes in case the initial ones deteriorate.

Skin dermatitis and pruritus were reported in 52% of subjects wearing the CardioSTAT monitor, requiring local topical therapy in 15%, and resulting in discontinuation of the observation period in 8 of 52 subjects. Consequences were minor, with no long-term repercussions. The Cardiomemo does not cause skin irritation or pruritus, as it is only very briefly and occasionally applied to the thorax. This difference must be weighed against the benefit of continuous monitoring, compared to the intermittent monitoring of the Cardiomemo and other devices.

The protocol proposed to evaluate whether the CardioSTAT is superior to the 2 standard ambulatory ECG monitoring devices was demanding for this active pediatric cohort. The study subjects had to tolerate a 24-hour Holter monitor on day 1, a 14-day CardioSTAT monitor on days 1-14, and the recording of symptomatic events with the Cardiomemo device on days 1-28, as well as completing the diary. Wearing the Holter and CardioSTAT monitors simultaneously for 24 hours required motivation by the patient, and reporting symptomatic events on both devices may have been confusing for patients. The long-term period of wear of the CardioSTAT may have had a negative influence on the number of transmitted loop-recorder events during the first 14 days of the study. However, that influence was not present during the second 14-day period of the study, as the loop recorder was the only device available to report symptomatic events.

The studied devices did not record the same ECG lead during phase 2 of the study. However, there was an excellent correlation in the interpretation of the study rhythms by the 2 blinded observers. The difference in ECG lead did not influence the rhythm determination during symptomatic events. Finally, other long-term continuous monitoring options are available, and we cannot say whether our results apply to those.

## Conclusion

The CardioSTAT offers the option of noninvasive long-term ambulatory monitoring in children. It delivers good-quality tracings that improve the ability to determine the cardiac rhythm during symptomatic paroxysmal events in children and teenagers. The device is an addition to the currently used Holter and loop recorders available to the clinician caring for young patients with suspected paroxysmal rhythm disturbances.

## Disclosures

The authors have no conflicts of interest to disclose.

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