AirLife Multi-Link™ Outperforms Cardinal Health Single-Patient-Use ECG Leadwire Set with GE Apex Pro Telemetry System

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INTRODUCTION

Electrocardiogram (ECG) is standard-of-care for monitoring the electrical activity of the heart for many patients in the hospital and can provide clinicians with valuable diagnostic information. The most visible component of the ECG is the QRS complex which is the combination of three waves (Q, R, and S) and corresponds to depolarization and contraction of the ventricles. Heart rate of a patient is measured by detecting the peak of the R waves while the QRS duration, amplitude, and shape can be useful in diagnosing cardiac problems such as arrhythmias, cardiac hypertrophy, and myocardial infarction.

While ECG system can provide valuable information to the clinician about the status of a patient by alarming, an excess number of alarms can result in alarm fatigue. As a result, clinicians become desensitized to alarms and often ignore, silence, or disable them.[1,2] A large percentage of alarms in the hospital are either false or non-actionable and many of these alarms originate from the ECG monitor system.[3] Several in-hospital deaths have been attributed to clinicians ignoring life-threatening alarms as a result of alarm fatigue,[4] and increased exposure to false alarms results in slower response times.[5]

The aim of this study was to compare the rate of false alarms of AirLife and Cardinal Health's ECG single-patient-use leadwire sets when used with the GE Apex Pro CH Telemetry device. Single-patient-use leadwires potentially reduce ECG alarms in the hospital compared to reusable leadwires though it likely varies by brand.[6,7] To test performance of the ECG leadwire sets to accurately measure heart rate, a Vital Signs Simulator was utilized to generate physiologically-relevant range of QRS complexes based on the 60601-industry standard. Ten AirLife and ten Cardinal Health samples were each tested with 45 QRS waveforms. All AirLife leadwire sets passed the tests under all QRS complex parameters. In contrast, more 90% of tests performed at the lowest QRS amplitude (0.5 mV) failed when using the Cardinal Health ECG leadwire sets. In these failures, an asystole alarm was triggered and therefore would contribute to alarm fatigue and take priorities away from the true needs of patients.

METHOD

Experimental Setup

The performance of AirLife and Cardinal Health ECG Leadwire sets when used with the GE Apex Pro CH Telemetry System were compared according to the protocol described in PRO-CA-HL-19-077 (Comparative Testing for X2V2). The tests described in AAMI ANSI IEC 60601-2-27, Section 201.12.1.101.15 were performed on ten samples of AirLife ECG leadwire set and ten samples of ECG leadwire sets available through Cardinal Health (Table 1).

	DESCRIPTION	CATALOG CODE	SAMPLE SIZE
AirLife	5-Lead Multi-Link Single-Patient-Use ECG Leadwire Set 5-Lead, Grabber, AHA, 75 cm/29''	2052133-007	10
Cardinal Health	GE ApexPro CH Telemetry Set 36''	33112	10

Table 1: Leadwire set models used for performance testing.

The leadwire sets were attached to the GE ApexPro CH Telemetry transmitter which sent the measurements to a monitor in the telemetry room. A calibrated Fluke ProSim 8 Vital Signs Simulator was used to generate QRS complexes of several combinations of QRS amplitude, QRS duration, and heart rate. An example experimental setup is pictured in Figure 1.

Figure 1: Photograph of example experimental setup. A five-lead snap/grabber combo leadwire set (Cardinal Health) connected to a Vital Signs Simulator (Fluke ProSim 8).

The shape of the simulated QRS complex and defining parameters is depicted in Figure 2, where a represents the QRS Amplitude and d the QRS Duration.

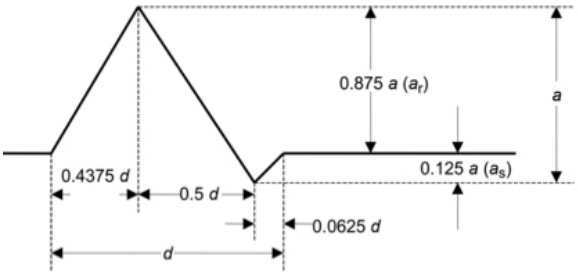

Figure 2: Simulated QRS complex used for heart rate accuracy and QRS detection testing. d: duration of QRS; a: QRS amplitude; a_r: Amplitude of QR segment; a_s: amplitude of RS undershoots. Reproduced from AAMI ANSI IEC 60601-2-27.

The Vital Signs Simulator was programed to imitate a wide range of QRS complex parameters. Specifically, fifteen combinations of QRS amplitude (0.5, 2.0 and 5.0 mV) and heart rate (30, 60, 120, 180, and 250 BPM) were tested for three different QRS durations of 70, 100 and 120 ms (Table 2). Therefore, a total of 45 different QRS waveforms were tested for each leadwire set sample. The pass criteria for each test was ±10% or ±5 BPM, whichever is greater.

QRS AMPLITUDE	INPUT RATE	EXPECTED RATE
0.5 mV	30 BPM	30 BPM
0.5 mV	60 BPM	60 BPM
0.5 mV	120 BPM	120 BPM
0.5 mV	180 BPM	180 BPM
0.5 mV	250 BPM	250 BPM
2.0 mV	30 BPM	30 BPM
2.0 mV	60 BPM	60 BPM
2.0 mV	120 BPM	120 BPM
2.0 mV	180 BPM	180 BPM
2.0 mV	250 BPM	250 BPM
5.0 mV	30 BPM	30 BPM
5.0 mV	60 BPM	60 BPM
5.0 mV	120 BPM	120 BPM
5.0 mV	180 BPM	180 BPM
5.0 mV	250 BPM	250 BPM

Table 2: Combinations of QRS amplitudes and Input Rates tested as well as the corresponding expected rate. The pass criteria for each test was ±10% or ±5 BPM, whichever is greater. These fifteen combinations of QRS amplitude and Input Rate were repeated for QRS durations of 70, 100, and 120 ms.

In additional tests, two QRS amplitude and QRS duration combinations were tested outside the specified range with the expected result that the system would not detect any QRS complexes and report a rate of 0 BPM (Table 3). For each test, the Vital Signs Simulator was configured for the specified QRS complex parameters and the value reported on the telemetry room monitor was recorded.

QRS AMPLITUDE	QRS DURATION	INPUT RATE	EXPECTED RATE
0.15 mV	120 ms	80 BPM	0 BPM
1 mV	10 ms	80 BPM	0 BPM

Table 3: QRS complex properties for tests outside of QRS amplitude and duration ranges. The measured rate must be exactly 0 BPM to pass these tests.

All tests were performed at the Staten Island University Hospital clinical environment in Staten Island, NY, United States on July 30, 2019 by personnel trained on the protocol.

Data and Statistical Analysis

For each sample and each test, the observed Heart Rate was compared to the Expected Rate. The sample passed the test if the Expected Rate was within the acceptance criteria and failed otherwise. The proportion of AirLife samples (p1) and Cardinal Health samples (p2) which passed the QRS accuracy tests were compared using a Fisher-Exact test. The null hypothesis that the same proportion of samples passed the QRS accuracy tests (H0:p1 = p2) was tested against the alternative hypothesis that the proportions were not equal (HA:p1 ≠ p2).

RESULTS

Table 4 compare the numbers of Cardinal Health and AirLife ECG leadwire set samples that passed for each combination of QRS Amplitude, QRS Duration and Input Rate. All ten AirLife leadwire sets passed the tests for all conditions. For a QRS Amplitude of 0.5 mV, the Cardinal Health ECG leadwire sets failed nearly all the tests regardless of Input Rate of QRS Duration. Specifically, of the 120 tests with a QRS amplitude of 0.5mV, 109 out of the 120 (90.8%) tests were failures. For all Cardinal Health failures, the system did not detect any QRS complexes and reported a rate of 0 BPM and presented an asystole false alarm. Expectedly, there was significantly higher rate of failures at 0.5 mV for Cardinal Health leadwire sets compared to AirLife leadwire sets ($p<0.0001$, Fisher-Exact test). The Cardinal Health leadwire set samples passed all tests with QRS amplitudes of 2.0 and 5.0 mV. Of the 450 tests (10 samples * 45 parameter combinations) with the AirLife leadwire sets, only five tests (1.1%) had an observed rate that was not identical to the expected rate. The maximum discrepancy between expected and observed rate was 2 BPM.

			CARDINAL HEALTH			AIRLIFE		
	QRS Duration:		70 ms	100 ms	120 ms	70 ms	100 ms	120 ms
	Sample Size:		10	10	10	10	10	10
QRS AMPLITUDE	INPUT RATE	EXPECTED RATE	NUMBER PASSED			NUMBER PASSED		
0.5 mV	30 BPM	30 BPM	1	0	2	10	10	10
0.5 mV	60 BPM	60 BPM	2	0	1	10	10	10
0.5 mV	120 BPM	120 BPM	1	0	2	10	10	10
0.5 mV	250 BPM	250 BPM	1	0	1	10	10	10
2.0 mV	30 BPM	30 BPM	10	10	10	10	10	10
2.0 mV	60 BPM	60 BPM	10	10	10	10	10	10
2.0 mV	120 BPM	120 BPM	10	10	10	10	10	10
2.0 mV	250 BPM	250 BPM	10	10	10	10	10	10
5.0 mV	30 BPM	30 BPM	10	10	10	10	10	10
5.0 mV	60 BPM	60 BPM	10	10	10	10	10	10
5.0 mV	120 BPM	120 BPM	10	10	10	10	10	10
5.0 mV	250 BPM	250 BPM	10	10	10	10	10	10

Table 4: Comparison of test results for Cardinal Health and AirLife ECG leadwire sets for different combinations of QRS Amplitude, Input Rate and QRS Duration. Ten samples were tested for each combination of parameters. Data in the table are the number of sample that passed based on the acceptance criteria of the observed rate within 10% of 5 BPM, whichever is greater, of the Expected Rate. Data for tests which had failed samples are highlighted in orange.

Table 5 summarizes the results of the tests performed with QRS amplitudes and durations outside of the specified QRS complex range. All ten Cardinal Health and AirLife samples passed these tests.

				CARDINAL HEALTH	AIRLIFE
			Sample Size:	10	10
QRS AMPLITUDE	QRS DURATION	INPUT RATE	EXPECTED RATE	NUMBER PASSED	
0.15 mV	120 ms	80 BPM	0 BPM	10	10
1.0 mV	10 ms	80 BPM	0 BPM	10	10

Table 5: Summary of results for tests with QRS complex properties for tests outside of QRS Amplitude and Duration ranges.

DISCUSSION

This study compared the performance of the AirLife and Cardinal Health leadwire sets when used in conjunction with the GE Apex Pro CH Telemetry System over the range of QRS Amplitudes, QRS Durations, and heart rates specified in AAMI ANSI IEC 60601-2-27 using a Vital Signs Simulator. All AirLife leadwire sets passed the tests under all QRS complex parameters. In contrast, the Cardinal Health ECG leadwire sets often failed to detect QRS complexes with QRS amplitudes of 0.5 mV. Specifically, more than 90% of the tests performed with a QRS amplitude of 0.5 mV failed over the entire range of QRS Duration or Rate. For these failures, the system missed all QRS complexes and presented an asystole false alarm (Figure 3). For the same QRS complex parameters, the tests with AirLife leadwire sets correctly presents a rate of 250 BPM (Figure 4).

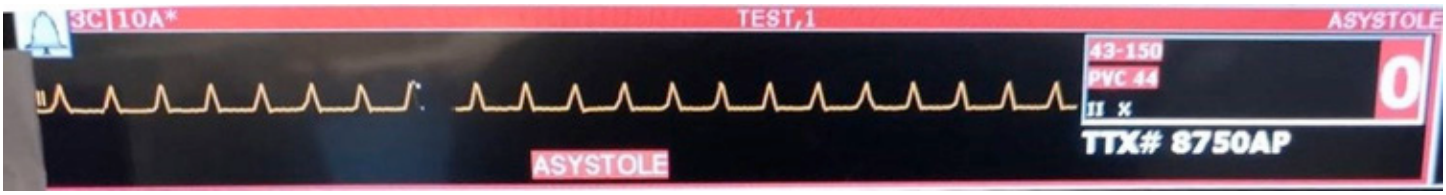

Figure 3: Representative tracing with a Cardinal Health leadwire with an Input Rate of 250 BPM. Note the asystole false alarm with a measured rate of 0 BPM.

Figure 4: Representative tracing with an AirLife leadwire set with an Input Rate of 250 BPM.

One key difference between the AirLife and Cardinal Health leadwire sets is their lengths. Specifically, AirLife leadwire sets are 29" and Cardinal Health's are 36". Since the GE ApexPro CH telemetry transmitter uses one lead as an antenna, it is possible this increased leadwire length results in signal attenuation and decreased signal quality.

"All AirLife leadwire sets passed the tests under all QRS complex parameters. In contrast, the Cardinal Health ECG leadwire sets often failed to detect QRS complexes..."

The AirLife 5-lead Multi-Link Single-Patient-Use ECG leadwire set, grabber, AHA 75 cm/29" was used for this protocol. While only this model was utilized, the results from this study are generalized to the other Multi-Link interface 29" leadwire sets. GE ApexPro CH telemetry system uses the leadwire set shielding as an antenna for the system. The single-patient-use and reusable leadwires sets have equivalent shielding in their design. Furthermore, the electrode connection type (i.e., snap or grabber), and the number of leads (i.e. 3, 5, or 6) does not have effect on the performance of the tests performed in this study because the electrical signal conductance properties are identical.
A QRS complex with an amplitude of 0.5 mV is not uncommon in the hospital and therefore this false asystole alarm can be expected to occur in clinical practice when these Cardinal Health ECG leadwire sets are used with the GE ApexPro CH telemetry system. Since asystole is a life-threating event, hospital personnel are trained to respond rapidly, thereby taking their time and attention from other patients. Furthermore, these false alarms will contribute to the growing alarm fatigue problem in hospitals, resulting in mistrust of and desensitization to alarms. While not directly examined in this study, distortion of the ECG signals by Cardinal Health leadwire sets could also result in incorrectly identifying or missing abnormal rhythms such as atrial or ventricular fibrillation.

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