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Estimation of patient compliance in application of adherent mobile cardiac telemetry device

Jonathan M. Engel, *Member, IEEE*, Niranjan Chakravarthy, Rodolphe P. Katra, Scott Mazar, *Member, IEEE,* Imad Libbus, Abhi Chavan, *Senior Member, IEEE*

***Abstract*—In an in home usage outpatient setting, patient compliance is a key factor in determining the adoption and efficacy of treatment for any illness and is paramount for patient dependent medical technologies such as mobile patient monitoring systems. As a leader in the development of these technologies, Corventis has deployed its NUVANT™ Mobile Cardiac Telemetry System to thousands of patients around the world. The NUVANT system includes an externally worn adherent sensing device, the PiiX, whose proper application is critical to the on-patient longevity and thus performance of the NUVANT system. Patient compliance in this context is a universal challenge for such patient-applied adherent devices. Understanding and tracking a problem is key to solving it and the integrated suite of vital sign sensors in the Corventis PiiX offers a unique opportunity for extracting patient application compliance information from the incoming health data. Analysis of data from 5000 randomly selected patients has shown that improper application of the PiiX is a factor in 2.3% of patients. However, no reduction in adherent device longevity or performance was observed. Such information is a valuable feedback metric for product design, instructions for use, packaging of medical technologies, level of customer support and replacement costs.**

I. Introduction

LOW-cost, high-impact point-of-care health care technologies such as mobile patient monitoring systems are being rapidly introduced to the market as the convergence of low cost, high performance electronics, sensing, miniaturization, processing power, and algorithm development technologies enable small and affordable wearable devices. Companies such as Toumaz, Proteus, CardioNet, iRhythm, Intelesens, and Corventis have developed or are developing wearable point of care non-invasive devices to address a number of health conditions. Many are focusing on mobile cardiac outpatient telemetry (MCOT) monitoring with systems that allow long-term at-home use and include adherent devices that must be applied to the patient's skin to collect electrocardiogram (ECG) signals [1]-[3]. While the prescribing physician or medical professional may assist in the initial application of the adherent device, it is often up to the patient or patient's caregiver to properly apply subsequent adherent devices while in the out-patient setting [4]. This is both a strength and a weakness of these sophisticated external adherent patient monitoring systems. While potentially reducing clinical visits and healthcare costs, the performance and ultimately the adoption of these technologies hinge on the ability and willingness of the patient to properly self apply the adherent device. Improper application such as poor site preparation, incorrect placement and orientation, adhesive fouling, as well as patient induced damage to the device can impact signal performance, device longevity, and patient comfort. Pre-market, in-house R&D testing as well as safety and efficacy clinical studies can only assess application compliance to a limited degree. A complete characterization of the scope of patient adherence to the Instructions For Use (IFU), ease of layman application, and patient acceptance issues requires a phase 4 study or an after-market release retrospective analysis to capture the real world experience with such technologies.

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All authors with Corventis, Inc, Saint Paul, MN 55108 USA. Corresponding author: Jonathan Engel. Phone: 651-925-3808; fax: 651-389-3251; e-mail: jonathan.engel@corventis.com).

II. The NUVANT System

As a pioneer in the field of mobile patient monitoring, Corventis has developed the NUVANT mobile cardiac telemetry system, which includes a patient wearable device that provides near real time feedback on cardiac arrhythmias and other vital signs [2], [5]. These signals are relayed via wireless link to a networked gateway, the zLink, which transmits the patient data to the Corventis monitoring center

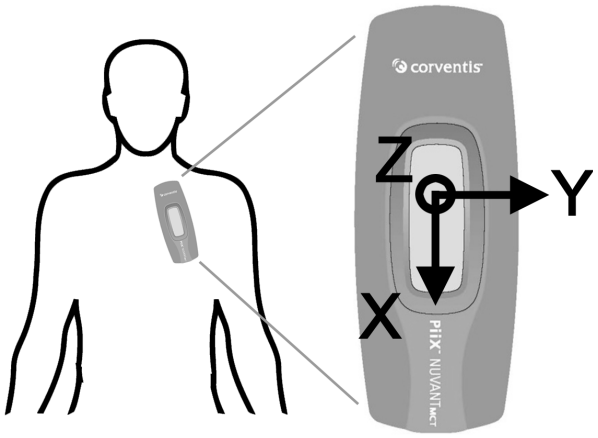

Fig. 1. Application site for Corventis NUVANT PiiX is on upper region of left torso. Detail shows the coordinate frame for the accelerometer relative to the PiiX. Z-axis positive direction is out of plane of page.

where the data is reviewed and made available to the attending physician. Patient compliance from an application and wear perspective is critical to the on-patient longevity of the NUVANT wearable adherent monitoring device, the PiiX. Following the FDA approved instructions for use (IFU), the patient, caregiver, physician or medical professional prepares the skin site, prepares the PiiX for application, and applies the adherent PiiX to the patient's skin (Fig. 1). Several aspects of the application process are critical for the device to function as designed at a high level of performance. The cleanliness of the underlying skin, the removal of excess body hair from the wear site, prevention of wrinkling and self-adhesion of the PiiX, as well as proper positioning and orientation of the PiiX on the patient's torso are all important. While designed to be robust to variations in all of these factors, system performance in terms of signal quality, device longevity, and patient comfort can be adversely impacted in the event of severe deviation from the IFU. As such it is important to minimize these deviations through IFU as well as PiiX design.

Towards this end Corventis uses sensor data from the PiiX as a feedback mechanism to measure patient compliance and track the performance of design improvements. A key sensor is the accelerometer which is used to assess the application orientation of the PiiX on the patient. When worn in an orientation contrary to that indicated in the IFU the mechanical performance, cardiac signal morphology, and patient comfort can suffer. Bio-impedance is another measure useful for assessing patient compliance, where higher initial baseline impedance is indicative of failure to follow the IFU indications for skin site preparation A possible outcome of these problems with patient compliance is early end-of-life for the PiiX even though ECG signal detection may not be impacted. Presented here is a retrospective study of patient PiiX application compliance in regard to adherent device orientation and skin preparation using de-identified patient data collected using the Corventis NUVANT system.

III. Methods

The PiiX adherent device includes a 3-axis accelerometer for the purpose of measuring a variety of relevant health data such as patient posture, sleep orientation, activity duration and intensity, and fall detection. Another sensing modality is the detection of the impedance of the patient tissue underlying the PiiX, the so-called bio-impedance. After application, the PiiX collects a series of baseline readings across the integrated sensor suite. The baseline data stream yields accelerometer and bio-impedance readings that are used to calculate a mean acceleration vector and mean bio-impedance value for each patient. Analysis of this data was carried out retrospectively on archived patient data and as such was not and could not be used to modify patient care or device usage during the prescription period.

Based on the known orientation of the accelerometer within the PiiX and a few assumptions, the accelerometer can also be used to estimate the orientation of the PiiX on the body. These assumptions are that at the time of application the patient is awake, is either standing or sitting upright or in some range of recline, the PiiX is applied to the upper left pectoral region as indicated in the IFU (Fig. 1), and that the maximum detected acceleration vector is due to gravitation. Several of these assumptions can be verified by analysis of the signals from the PiiX at application baseline as well as subsequent data sets and have been found to be reasonable.

In compliance with HIPAA regulations, baseline de-identified data collected at application from 5000 randomly selected patients was run through our orientation algorithm to calculate a gravity vector relative to the PiiX and classify the data into three categories; worn incorrectly, patient reclined, and worn correctly. Similarly, mean bio-impedance values were generated from the patient baseline data collected within 15 minutes of application. Fig. 1 shows the PiiX and the orientation of the positive accelerometer coordinate frame. PiiX worn incorrectly are defined as those that return a negative gravity vector with max acceleration in the x-axis. Patient reclined PiiX are defined as those that return a gravity vector with max acceleration in the z-axis and greater than 45 degrees from vertical inclination. This reclined group has returned an acceleration vector that is difficult to classify in regard to correct or incorrect application orientation and represents the largest source of uncertainty in our analysis. PiiX worn correctly make up the remainder of patients.

IV. Results and Discussion

The results of accelerometer data analysis from the 5000 patient set are detailed in Fig. 2 and Fig. 3. Fig. 2 shows the computed gravity vector normalized to g's in a Cartesian coordinate system. Fig. 3 shows the computed gravity vector spherical inclination and azimuth coordinates with the radius ignored and assumed to be ~1 g. Zero azimuth and inclination indicates a gravity vector that is parallel to the long axis of the PiiX corresponding to the PiiX being perfectly vertical as shown in the right side of Fig. 1. The resulting populations are summarized in Table 1. Using the given category definitions, 2.3% of all PiiX are estimated to be applied incorrectly, with 22% of patients reclining during baseline data collection, and the remainder applied correctly. The heat map in Fig. 4 clearly shows the high concentration of PiiX applied in the intended orientation. Visual spot checking of

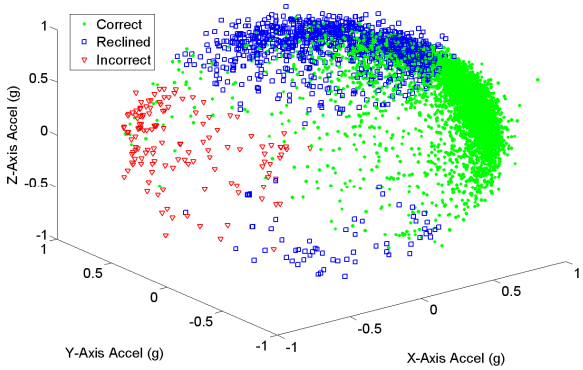

Fig. 2. Baseline gravity vector data for study population in Cartesian coordinates normalized by gravity. Data forms a sphere with concentrations of data around the x=1g direction indicating proper PiiX application.

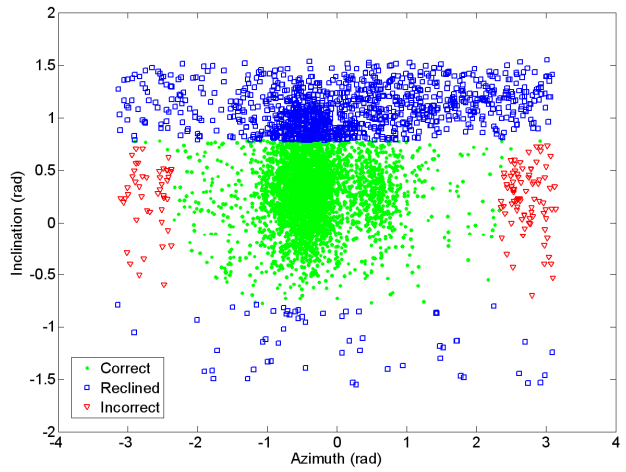

Fig. 3. Baseline gravity vector data in spherical coordinate inclination and azimuth. The regions of correct, reclined, and incorrect application of the PiiX can be seen based on original set of assumptions.

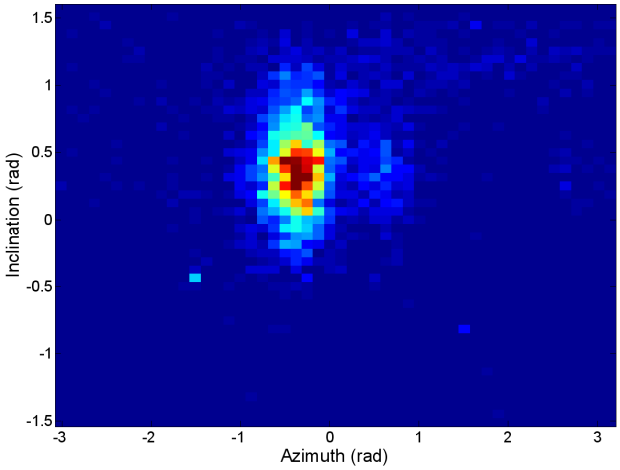

Fig. 4. Heatmap of baseline gravity vector data in spherical coordinate inclination and azimuth. The region of greatest intensity representing proper application of the PiiX can be more clearly seen based on original set of assumptions. Majority of patient data is clustered in this region.

TABLE I
ORIENTATION CLASSIFICATION RESULTS

Group	Original Assumptions	Expanded Assumptions
Correct	3772	3772
Reclined	1110	942
Incorrect	118	286

ECG waveforms of patients indicated as having an incorrectly applied PiiX confirms the classification results, with inverted QRS complexes observed. For comparison, if the "incorrectly worn" constraints are expanded to include PiiX worn at a negative angle up to horizontal and that of patients reclining at a negative angle, the percentage of incorrectly worn PiiX increases to 5.7% as summarized in Table I. Further discussion focuses on the populations defined by the original rather than expanded set of assumptions.

Data collected in the lab under controlled conditions shows that application of the PiiX device to the patient without skin preparation in accordance with the IFU yields increased baseline bio-impedance measurements, with increases in the range of 10-20 Ohms being typical. The details of this result are outside the scope of this paper but it is presented to frame the hypothesis that similar failures to follow the IFU in the field could yield increased patient baseline bio-impedance. It is further hypothesized that patients who incorrectly apply the PiiX will be less likely to follow the IFU regarding site preparation, leading to an increase in baseline bio-impedance. To test this hypothesis, we analyze the bio-impedance data for the populations of patients identified using accelerometer data. Comparison of these groups shows a mean bio-impedance of 66.8 Ohms for PiiX incorrectly applied and 61.2 Ohms for PiiX correctly applied. A test of statistical significance using an unpaired single tail t-test with unequal variance shows that the difference in mean between the two groups has a 7% probability of being due to chance (P=0.07). As shown in the histograms of Fig. 5 the distributions of bio-impedance data from the various patient populations are somewhat normal and the use of a t-test reasonable. Data for patients determined to be reclining had a mean of 67.8 and P=1.8E-8 which is as expected as the influence of posture on bio-impedance can be dramatic. The uncertainty in the true orientation of the applied PiiX and the patient posture at baseline data collection require these data to be taken in context.

Additional analysis comparing the wear times of PiiX from the incorrectly and correctly worn groups shows no significant reduction in wear longevity for the incorrectly worn group. Longevity is defined as the number of hours for which patient cardiac data is successfully received. An unpaired t-test could not reject the null hypothesis that the mean longevities were identical (P=0.83). This would appear to invalidate our concerns regarding the impact of patient compliance on device longevity. It is notable that due to the retrospective nature of this study, the ratio of PiiX applied by the physician to those applied by the patient or caregiver can only be estimated as approximately 15% based on examination of a smaller sample.

In order to put this type of opportunistic data collection to use tracking the impact of changes in the product on compliance, we are tracking metrics such as the proportion of

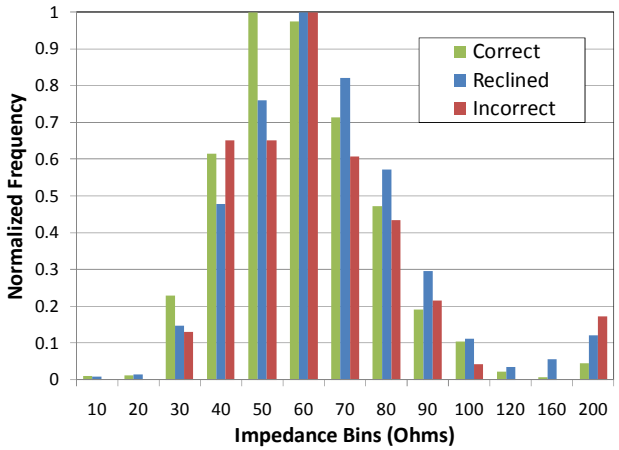

Fig. 5. Baseline bio-impedance histogram with normalized frequencies.

incorrectly applied PiiX over time. While these analyses are ongoing and the details proprietary, the trends suggest that measures targeted towards compliance can impact the rate of incorrectly applied PiiX.

V. CONCLUSIONS

Based on the analysis of patient data, the application orientation compliance of the PiiX component of Corventis' NUVANT system is fairly robust, with only 2.3-5.7% of PiiX being applied incorrectly depending on analysis criteria. The population of patients applying the PiiX in the incorrect orientation also exhibits significantly different mean bio-impedance that may indicate deviation from skin site preparation IFU directives. The impact of incorrect orientation appears to be minimal from a device longevity perspective. While the data cannot be confirmed directly since this is a retrospective analysis with no direct patient contact, this type of analysis is fundamentally useful for any technology that relies on telemetry without patient access. A prospective study could be performed to confirm these findings but such a study would alter the findings since patients may self select and tend to not represent the patient cohort used in this analysis as well as the "white coat" effect of increased scrutiny of PiiX application. Therefore this analysis, even though not controlled or prospective provides a reasonable vignette into patient adherence to IFU with adherent MCOT technologies.

Comparison of these results with similar adherent MCOT systems is not possible due to a dearth of available data. However, studies of patient compliance with other self administered medical tasks suggest the result is better than average [6]-[8]. Additionally, the presented estimate of the rate of incorrectly applied PiiX is limited by the set of given assumptions. However, we believe that the strength of this approach lies in the automated extraction of information from a large data sample size and represents a powerful method of measuring patient response to IFU, sales force and physician training, as well as packaging and device design factors. Monitoring these types of statistics is a useful tool in identifying changes in population response as well as improving the customer experience and ultimately adoption of technologies such as the Corventis NUVANT system.

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