Non-Invasive Detection of Medication Adherence using a Digital Smart Necklace

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***Abstract*—Studies have revealed that non-adherence to prescribed medication can lead to hospital readmissions, clinical complications, and a host of other negative patient outcomes. Though many techniques have been proposed to improve patient adherence rates, they suffer from clear drawbacks such as high complexity, user burden, and low accuracy. In this paper, we propose a two step system for detecting user adherence to medication. First, force-sensitive resistors are used to determine when the pill bottle has been opened. Subsequently, medication ingestion is detected using a smart necklace equipped with a piezoelectric sensor. Evaluations confirm high accuracy of the proposed technique.**

I. Motivation and Background

Prior research has shown that non-adherence to prescribed medications can result in poor patient outcomes and inaccurate assessment of treatment effectiveness [1][2]. For example, non compliant schizophrenia patients are at significantly higher risk for depression, arrest, and substance abuse [3]. In fact, poor adherence to medication can result in medical complications, hospital readmissions, and even death [4]. Many methods have been proposed to improve patient adherence rates including pill counts, self-reporting, interviews, and electronic tracking systems, but these methods suffer from several shortcomings ranging from high user burden, significant complexity, and overestimation of adherence [5]. It has been claimed that even the most effective techniques have not led to significant improvements in adherence, which necessitates further research in this area [2].

In this paper, we propose a novel two-step system for monitoring patient adherence. The first step is detection that the medicine bottle has been opened, using a force-sensitive resistor. This information is coupled with the next step: detection of a pill swallow using a smart necklace, which includes a piezoelectric sensor resting in the lower trachea. The skin motion during the swallow of a medication has a unique pattern that can be used to confirm that the medication has been ingested after the bottle is opened. Data from the necklace is acquired by sampling the piezoelectric sensor strip, which generates a voltage in response to the mechanical stress of deglutition (swallowing). Data acquired from the necklace is transmitted to an Android application for processing using the low-power Bluetooth LE protocol, where classification algorithms are capable of distinguishing between swallowed medication and other types of swallows such as saliva and water. Though neither step in adherence detection is free of errors, the smart necklace provides an additional layer of information which can improve detection of noncompliance and provide real-time feedback via smart-phone. For example, a potential pill swallow is much more likely to be prescribed medicine if the swallow occurs moments after the bottle has been opened. Thus, the complete system is able to reduce the false positive rate of the necklace for many use cases.

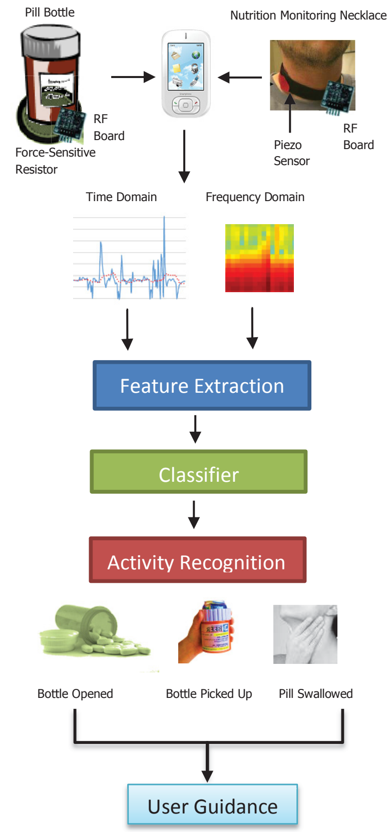

Fig. 1. This figure shows the proposed system architecture. Pill swallows are identified using a wireless-enabled smart necklace coupled with a Bluetooth-enabled smart pill bottle.

We evaluate adherence based on two different kinds of medicines and supplements: chewables, which are typically targeted towards children in the form of vitamins, asthma medication, Tylenol, and ADHD treatment, and capsules, which are more appropriate for adults. Various use cases

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are outlined in Figure 3. Our proposed system extends prior work at ensuring medication adherence; the figures in green represent those steps which cannot be detected by most smart pill boxes.

The paper is organized as follows. In Section II, we provide a brief overview of related works, with a particular focus on electronic assessment techniques. In Section III, the hardware architecture of the proposed system is described. Section IV describes the algorithms used for detecting pill swallows and the bottle opening, while Section V describes the experimental procedures. Section VI and VII provide experimental results and concluding remarks.

II. Related Work

Prior studies have shown that medication adherence, which can range from 0% to over 100%, is typically approximately 50%. Though many methods of improving adherence have been proposed, a recent survey by McDonald et al. has suggested that even the most effective interventions have failed to provide significant improvements in adherence, though many have managed to make marginal improvements. The various methods fall under two primary categories: indirect and direct methods. Indirect methods include self-reporting, interviews, pill counting, and computerized compliance monitors. Within this category, pill counts and self-reports have shown significant overestimation in user compliance. Direct methods include biological markers, assessment of body fluids, and tracer compounds [6]. Since direct methods feature very high user burden, we primarily focus our discussion on indirect methods.

Several smartphone apps such as MyMedSchedule, MyMeds, and RxmindMe, provide advanced functionality for medication reminders. These applications issue reminders, allow users to manually enter their dosage information, and record when they have taken their medication. However, these applications are generally untested, and can not verify compliance without user involvement [7]. In [8], Sterns et al. mounted a pill bottle onto a personal digital assistant running the RxmindMe software, and successfully trained elderly subjects with an average age of 72 to operate the software used to monitor adherence. This work suggests that users from a variety of age groups and backgrounds have the ability and motivation to use electronic monitoring devices if given adequate training. Other works propose cell phone reminders and in-home technology to transmit reminder messages, but results are mixed [4].

The "smart blister" has been proposed as a semi-automated, indirect method of assessing adherence. When empty blister cards are returned to the pharmacy, information is scanned and downloaded. This work is a step in the right direction, but the substantial error and lack of real-time features necessitate additional refinements [9]. The work described in [5] describes a portable, wireless-enabled pillbox suitable for elderly and those suffering from dementia. Similar approaches for electronic detection and smart pill boxes have also been proposed [10][11][12]. These devices generally suffer from the

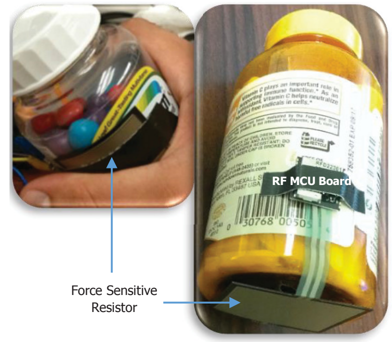

Fig. 2. This figure shows how an ordinary pill bottle is modified with sensors, which allow the system to detect when medication is removed.

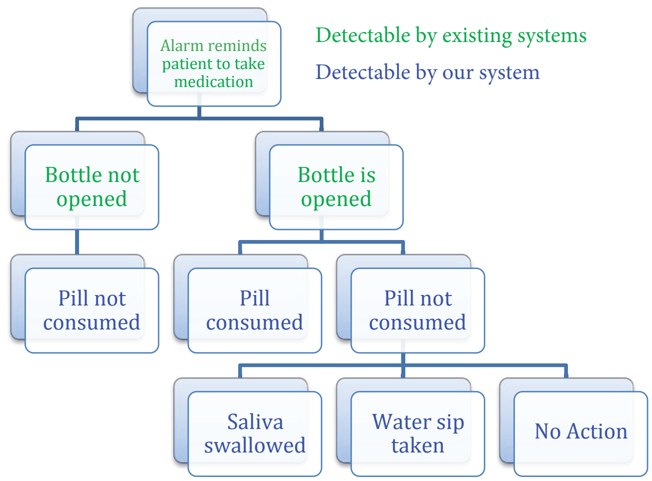

Fig. 3. Different use cases that the system should identify when it is time for a patient to take his or her medication. The capabilities of existing systems are shown in green, while blue includes features unique to our system.

same shortcoming: they cannot determine if the medication is ingested or simply removed and discarded [13][14][15].

One notable exception is the recently unveiled plastic sleeve from AMIKO [16], which fits on several standard types of medicine containers and reports if medication has been removed from the bottle using MEMS sensors such accelerometers and gyroscopes. They are also capable of tracking if an inhaler is used, aggregating results on a mobile application. In another work, Valin et al. successfully identified medication adherence using a series of images and associated image processing algorithms [17]. To the best of our knowledge, no other ingestion-monitoring device has been proposed for medical adherence purposes, but several other digital systems have been developed for evaluation of swallow disorders and monitoring eating habits [18][19][20][21]. Another smart bottle that has entered the market is the Vitality Glowcap[22]. This smart device can detect when pills are removed, reports information to caregivers, and can request prescription refills with the push of a button.

III. Hardware Architecture

The system architecture is shown in Figure 3. Movement from the smart pill bottle is combined with swallow detection to detect ingestion of medication, which is then reported to a SmartPhone app with cloud integration. In this section, we describe the hardware components of our system.

A. Necklace

The smart necklace, shown at the top of Figure 4, is used to detect when pills are swallowed. It is based on a small piezoelectric sensor, also known as a vibration sensor, which generates a voltage in response to the mechanical stress caused by skin motion during a swallow event. The piezoelectric strip is fastened such that it is contact with the skin of the lower-neck, but not too tight as to restrict motion. The voltage from the piezoelectric sensor is sampled at a rate of 20Hz by the small Bluetooth LE enabled microcontroller board, and transmitted to a mobile phone for processing. The mobile application uses several algorithms to classify the incoming data into broad categories: saliva swallow, medication swallow, chewable-vitamin swallows, and neither.

The piezoelectric sensor used is the LDT0-028K, which consists of a 28 μm PDVDF polymer film laminated to a 0.125 mm substrate, which produces voltages within standard CMOS input voltage ranges when deflected directly. The necklace can operate under conditions ranging from 0 to 85 degrees, Celsius. The LDT0 is available with added masses at the tip, which reduce the resonant frequency but can greatly increase the sensitivity of the device. In the configuration without an added mass at the tip, the baseline sensitivity is approximately 50 mV/g, with sensitivity at resonance of 1.4 V/g [23].

The simple modification described in this section can be used to convert any standard pill bottle into a smart bottle at low-cost. The bottle, shown in Figure 2, is mounted on top of a flat force-sensitive resistor. Force-sensitive resistors, commonly used in pressure sensing applications, vary their resistance in response to external forces. This principle enables our system to detect the act of opening the bottle. Typically, the bottle will be opened either by placing the bottom against a hard surface and applying downward pressure while twisting the cap, or by picking the bottle up, opening it, and placing it back down on the surface. Figure 2 shows two different locations at which the force sensitive resistor could be placed, in order to detect when the bottle has been opened. In our implementation, the resistor was placed at the bottom of the bottle, but it is also possible to place it on the side of the bottle to detect grip. Note in Figure 2 that the terminals of the resistor are connected to the inputs of a small, RF enabled microcontroller unit which transmits data via Bluetooth to a smartphone application.

Because the necklace's swallow detection is not always precise due to signal noise caused by upper-body motion, the addition of force-sensitive resistors to the bottle add an extra layer of information to improve the assessment of medication adherence. Furthermore, the majority of existing technologies which detect when the bottle is opened often cannot detect if medication is removed. This technology is intended to supplement, rather than replace, such systems.

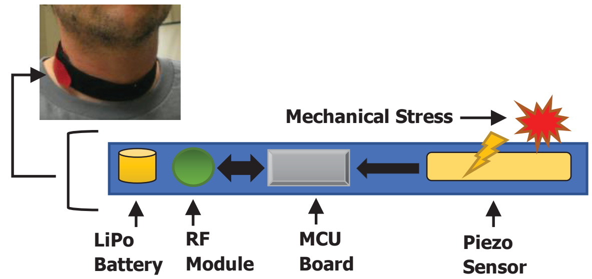

Fig. 4. This figure shows the necklace used to detect pill swallows. A piezoelectric sensor is sampled by an RF-enabled microcontroller unit, which is powered by a lithium-polymer battery.

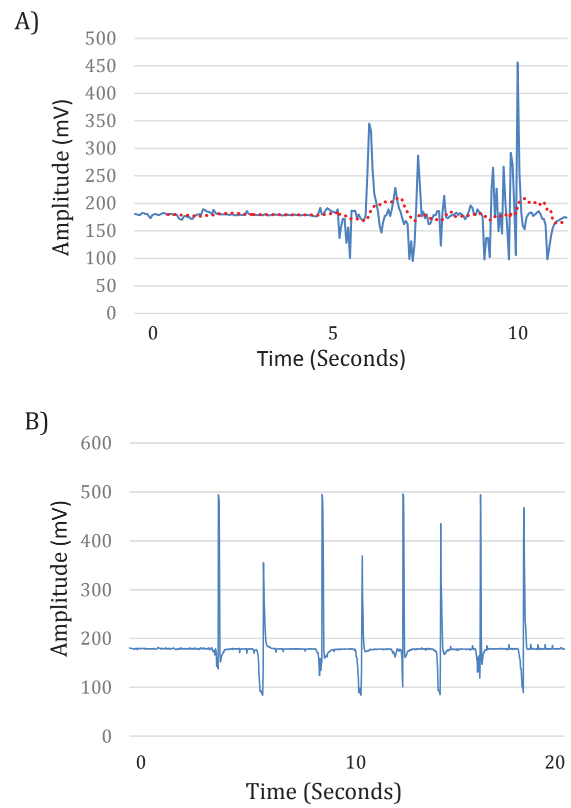

Fig. 5. Figure A shows how the bottle cap being opened and closed without being lifted off the ground is detected, based on downward pressure. The red waveform is a processed version, using a moving average filter. Figure B shows a waveform corresponding with the bottle being picked up and placed back down four times, without pauses in between.

IV. Algorithm Design

A. Bottle Movement

Figure 1 shows the algorithm used to detect when the bottle has been picked up and put down, which can suggest, but not guarantee, that medication has been taken. In this algorithm, the variable "count" represents the total number of times the bottle has been interacted with, which in effect is a peak

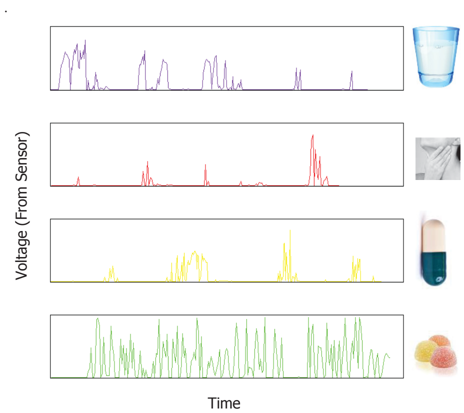

Fig. 6. The time domain waveforms for vibration sensor data corresponding with several actions is shown above: water sips, saliva swallows, capsule swallows, and chewable vitamin chews and swallows. Each action has clearly distinguishable features which are used for classification.

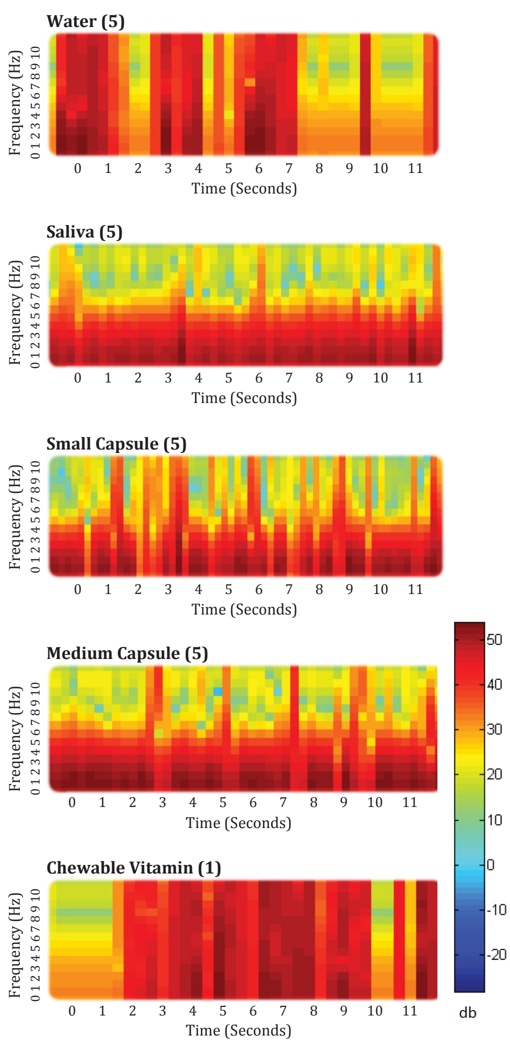

Fig. 7. The spectrograms for various events reveal characteristics which can be used to distinguish them. For example, the chewing involved in the ingestion of a chewable vitamin produces a broad range of frequencies, as shown in figure E. The distinguishing features between capsule swallows and saliva swallows appear to be the magnitude of the high frequency components.

detection count. The term 'jump' refers to a system-specific debouncing mechanism that corresponded with ten seconds in our evaluation. The characteristic waveform corresponding with this activity is shown in Figure 5. Note that pressure applied to the bottom of the bottle causes a spike in voltage. The same algorithm can be used to detect when the bottle is gripped by the hand, and released. The data is first smoothed, and the average value is calculated for each window. Subsequently, the peaks caused by the voltage fluctuations can be detected using a thresholding technique. The WindowSize used was 21 samples, corresponding to slightly over one second of data, though the various parameters of this relatively simple algorithm must be modified based on the exact materials used and bottle dimensions.

Algorithm 1: Bottle Detection Algorithm

```
LowPassFilter(Data) for i = 1:WindowSize:Size(Data) do
    avg = AverageValue(Data[i]:Data[i+Window]);
    for j = i:i+WindowSize do
        diff = abs(avg - Data[i])
        if diff < threshold then
            Count++
            j = j + jump
```

B. Swallow Identification

The time-domain waveforms acquired by the piezoelectric sensor, which are transmitted to the mobile application for processing, are shown in Figure 6. Clearly, different actions such as water sips and chewable vitamin intake can be distinguished visually. The time domain waveforms show not only the swallows, represented clearly by a peak or a dip in the waveform, but also show chewing in the form of low-frequency noise. Useful features that can be extracted from the time domain waveforms include standard deviation, maximum value, and detection of multiple swallows within a time frame. Additional features can be extracted by producing a spectrogram, which is essentially a heat map showing time on one axis and frequency on the other. Each coordinate from the two-dimensional plane has a value corresponding with the magnitude of the frequency component at that time. Spectrograms can clearly show changes in the frequency spectrum over time for different food types, which are useful features for classification and detection. The spectrograms for several actions can be seen in Figure 7. Visually, the differences are quite pronounced; chewable vitamin ingestion patterns have a relatively uniform frequency distribution over

TABLE I
LIST OF MAJOR FEATURES EXTRACTED

Mean	Standard Deviation	Skewness
Geom. Mean	Mean of Std Z-Scores	IQT Range
Harm. Mean	Kurtosis	Correlation
Range	Median Abs. Deviation	Partial Corr.

an extended period of time, followed by a pause right before the swallow at the end of the time sample. Otherwise, capsule swallow spectrograms show a brief period of high frequency components (between 6 and 10 Hz) lasting approximately .2 seconds centered around the swallow, followed by primarily lower frequencies between 0 and 5Hz between swallows.

For each one-second swallow window, the time axis was divided into 7 bins, and the frequency axis was divided into 17 bins. A Hamming window was used of length w = 32, and an FFT length of nfft = 32 was used with 50% overlap. The features extracted in both time and frequency domain are shown in Table I. These features were selected based on the Correlation-based feature subset selection algorithm described in [24]. This algorithm considers both the predictive ability of features as well as redundancy between them to produce the best results.

C. Sensor Fusion

When the necklace software detects a swallow and classifies it as a pill, the probability that this classification is correct is generally a function of the precision of the classifier. However, the precision reported by the classifier does not take into consideration the relative likelihoods of the different events taking place.

The probability that a pill has been ingested, **p** when the classifier reports a pill swallow, $\hat{\mathbf{p}}$ can be determined using Bayes theorem.

$$\Pr\left(\mathbf{p} \mid \hat{\mathbf{p}}\right) = \Pr\left(\hat{\mathbf{p}} \mid \mathbf{p}\right) \cdot \frac{Pr(\mathbf{p})}{Pr(\hat{\mathbf{p}})} = Recall(\mathbf{p}) \cdot \frac{Pr(\mathbf{p})}{Pr(\hat{\mathbf{p}})} \quad (1)$$

Alternatively, the probability **p** given **b** and $\hat{\mathbf{p}}$, in which **b** is the event in which the bottle is opened, is shown below. Note that Pr(**b** and $\hat{\mathbf{p}}$) is defined as the probability of detecting a pill swallow some time ΔT after the bottle is opened.

$$\Pr\left(\mathbf{p} \mid \mathbf{b} \wedge \hat{\mathbf{p}}\right) = \Pr\left(\mathbf{b} \wedge \hat{\mathbf{p}} \mid \mathbf{p}\right) \frac{Pr(\mathbf{p})}{Pr(\mathbf{b} \wedge \hat{\mathbf{p}})} \quad (2)$$

This can be approximated as the following:

$$\Pr\left(\mathbf{p} \mid \mathbf{b} \wedge \hat{\mathbf{p}}\right) = Recall(\mathbf{p}) \cdot \frac{Pr(\mathbf{p})}{Pr(\mathbf{b} \wedge \hat{\mathbf{p}})} \quad (3)$$

$$= \frac{Pr(\mathbf{p}) \cdot Recall(\mathbf{p})}{Pr(\mathbf{b}) \cdot prc(\mathbf{p}) + Pr(other) \cdot (1 - prc)}$$

Lastly, we make some simplifying assumptions. First, we define $f_{\mathbf{p}}$ and $f_{\mathbf{b}}$ as the frequency of pill swallows and bottle openings. Then, we assume that the majority of false positives for medication adherence come from saliva swallows, as prior research [25] has confirmed. This is due to their high frequency, as well as their resemblance to the characteristics of pill swallows. Therefore, the final equation is:

$$\Pr\left(\mathbf{p} \mid \mathbf{b} \wedge \hat{\mathbf{p}}\right) = \frac{f_p \cdot Recall(\mathbf{p})}{f_b \cdot prc(\mathbf{p}) + f_{slv} \cdot (1 - prc)} \quad (4)$$

TABLE II
CONFUSION MATRIX FOR CLASSIFICATION RESULTS.

	Predicted					
Actual	Chew	Saliva	Cap	Speak	Water	*Recall*
Chewable	24	0	4	0	2	80%
Saliva	0	29	0	0	1	96.6%
Capsule	1	2	27	0	0	90%
Speaking	0	0	0	28	2	93.3%
Water Sip	2	1	0	0	27	90.0%
Precision	88.8%	90.62%	87.09%	100%	84.35%	

V. Experimental Procedure

Each subject was instructed to swallow ten empty gel capsules and chewable vitamins over the course of several days. An internal dataset of 25 subjects was used for data corresponding with saliva swallows and water sips to establish a baseline, while additional data collection from five subjects were obtained for the chewable vitamins and gel capsules. Swallows were annotated using a button on the associated Android mobile application, which modified the log files accordingly. The subjects were instructed to take a small sip of water with the gel capsules, and to pause for a few seconds before proceeding to the next capsule. The chewable vitamins were taken one at a time without water.

The pill bottles with the force-sensitive resistors were picked up and placed back down on a surface approximately 80 times by three subjects. The bottles were also opened and closed by these subjects for a total of 60 times with pauses of random intervals between.

VI. Experimental Results

A. Bottle Movement Detection

Using the algorithm described prior, the signal processing peak-detection algorithm was able to identify when the bottle was picked up and placed back down with an accuracy of 98%, with no false positives and one false negative. The technique in which the bottle cap was opened while the bottle rested on a solid surface provided lower accuracy, with a detection rate of 90%, no false positives, and 10% false negatives.

B. Swallow Detection

Five activities were classified using data acquired from the smart necklace. These categories as well as the classification results are shown in Table II. These results were achieved with the BayesNets classifier, which provided the strongest results. A total of 150 instances were classified. These results indicate that gel capsule swallows can be reliably and consistently distinguished from saliva swallows and water sips. Given the thirty capsule swallows, 27 were classified correctly. Of the remaining three, two were misclassified as saliva swallows, and one as a chewable vitamin.

C. Sensor Fusion Results

Based on Equation 1, we evaluate the probability **p** given $\hat{\mathbf{p}}$. The recall experimentally has been determined to be approximately 90.0%. We assume that the average subject takes two medications per day (a frequency f_p of 2.3e $^{-5}$ swallows

/ second). Prior research in [25] has shown that the average adult will swallow approximately 590 times during the course of a full day. Based on [25], swallows saliva at a rate of $1.0e^{-2}$ times per second which we define as f_{slv}. Therefore, equation 1 show that the probability $\mathbf{p}$ given $\hat{\mathbf{p}}$ is **2.3**%. Though this equation makes several simplifying assumptions, the results nevertheless suggest that a reported medication swallow is largely meaningless when taken independently, because so few pills are consumed during the course of a day compared to saliva swallows.

To evaluate the efficacy of the pill bottle, we must make some assumptions about when and how individuals take pills, since no data collected in real-world environments is available. For demonstration, we assume that medication is taken within 30 seconds of opening the bottle. Using Equation 4, we have

$$\Pr(\mathbf{p} \mid \mathbf{b} \wedge \hat{\mathbf{p}}) = .90 \cdot \frac{2}{2 \cdot prc + 1 \cdot (1 - prc)} = \mathbf{96}\%$$

This confirms that bottle timing is a critical supplement to the smart necklace in estimating adherence.

VII. Conclusion

Patient adherence is critical to the successful treatment of many diseases. In this paper, we propose and evaluate a two-step system for detecting when a pill bottle is opened, and when a pill is consumed. These two mechanisms coupled with the mobile application can passively monitor adherence and inform caregivers of patient status. Results confirm that medications can be identified using the smart necklace, and are clearly distinguishable from saliva swallows and water sips.

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