Heart-to-Heart (H2H): Authentication for Implanted Medical Devices

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ABSTRACT

We present Heart-to-Heart (H2H), a system to authenticate external medical device controllers and programmers to Implantable Medical Devices (IMDs). IMDs, which include pacemakers and cardiac defibrillators, are therapeutic medical devices partially or wholly embedded in the human body. They often have built-in radio communication to facilitate non-invasive reprogramming and data readout. Many IMDs, though, lack well designed authentication protocols, exposing patients to over-the-air attack and physical harm.

H2H makes use of ECG (heartbeat data) as an authentication mechanism, ensuring access only by a medical instrument in physical contact with an IMD-bearing patient. Based on statistical analysis of real-world data, we propose and analyze new techniques for extracting time-varying randomness from ECG signals for use in H2H. We introduce a novel cryptographic device pairing protocol that uses this randomness to protect against attacks by active adversaries, while meeting the practical challenges of lightweight implementation and noise tolerance in ECG readings. Finally, we describe an end-to-end implementation in an ARM-Cortex M-3 microcontroller that demonstrates the practicality of H2H in current IMD hardware.

Previous schemes have had goals much like those of H2H, but with serious limitations making them unfit for deployment—such as naïvely designed cryptographic pairing protocols (some of them recently broken). In addition to its novel analysis and use of ECG entropy, H2H is the first physiologically-based IMD device pairing protocol with a rigorous adversarial model and protocol analysis.

Categories and Subject Descriptors

J.3 [**Computer Applications**]: Life and Medical Sciences - Medical information systems; C.3 [**Computer Systems Organization**]: Special-Purpose and Application-Based System, Real-time and embedded systems

General Terms

Security, Design

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Keywords

Implantable Medical Devices; IMD Security; Security Protocols

1. INTRODUCTION

Implantable Medical Devices (IMDs) apply continuous monitoring and automatic therapies to the treatment of chronic medical disorders. Implanted either partially or fully in patients' bodies, IMDs are often sophisticated devices containing batteries, embedded CPUs, radios, sensors, and actuators. As clinical trials validate IMDs' efficacy [22] and as IMDs treat a broadening range of disorders, their use is growing. For instance, in the United States, over 100,000 patients a year receive implantable cardioverter defibrillators (ICDs) [19], which detect dangerous heart rhythms and administer electric shocks to restore normal activity. Other IMDs include pacemakers, neurostimulators, and implantable drug pumps.

Powered IMDs generally contain radios for communication with external devices called *commercial device programmers* that can reprogram IMDs and extract patient data from them. Such wireless communication permits safe, non-invasive access to IMDs. But it also brings the security risks of embedded control into the human body. Seminal work by Halperin et al. [20], for example, exposes design flaws in a common ICD that enable attackers to seize unauthorized control wirelessly, and potentially harm victims.

Our work here addresses the tension between two critical requirements for IMDs. On the one hand, IMDs must offer reasonably permissive access-control policies when life-threatening medical events occur. Emergency responders may need to reprogram IMDs or extract patient data from them, and shouldn't incur fatal treatment delays by contacting care providers for device-specific keys or passwords. On the other hand, overly loose access-control policies expose IMDs to unauthorized wireless access, such as those illustrated by the Halperin et al. attack, that can physically harm patients or expose their medical data [20].

1.1 Heart-to-Heart (H2H)

Our solution is a system called *Heart-to-Heart* (H2H). H2H implements a simple access-control policy for IMDs that we call "touch-to-access": A medical instrument (e.g., commercial device programmer), which we call generically a *Programmer*, obtains access to a patient's IMD if and only if it has significant physical contact with the patient's body. An important facet of touch-to-access is *forward security*. Authentication to the IMD lapses once the instrument loses physical contact with the patient.

Touch-to-access offers a practical and effective balance between the competing access requirements of permissiveness in emergencies and resistance to attacks. The policy is also common sense: Physical access to a patient means the ability to harm or cure.

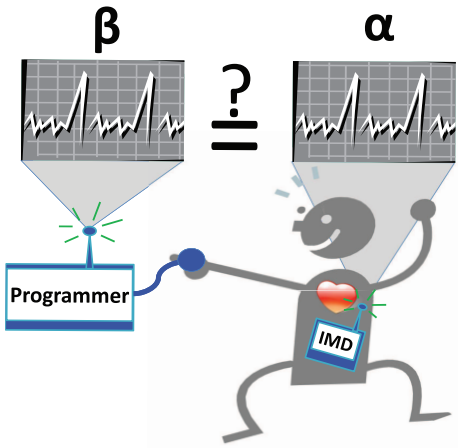

Figure 1: Basic H2H operation. The Programmer and IMD take individual ECG readings, respectively β and α. If $\beta \approx \alpha$, then the IMD grants access to the Programmer.

H2H enforces a touch-to-access policy using a time-varying biometric, often called a *physiological value* (PV). When a Programmer seeks access to an IMD, it initiates an authentication session. The IMD takes a reading α of the PV; at the same time, the Programmer takes its own reading β. If β is "nearly equal" to α, then the Programmer obtains access to the IMD. ("Near equality," as we explain later, is needed because PV readings are noisy.)

The H2H architecture can in principle rely on any PV, but we focus here specifically on use of the waveform produced by the heart, known as an ECG (electrocardiogram). Thus H2H is well suited for authentication to cardiac IMDs such as ICDs and pacemakers, today the largest class of powered IMDs. In principle, though, H2H can work with *any* IMD equipped to measure ECG anywhere in the body, not just cardiac devices. As we show, suitably processed ECG samples effectively constitute a low-bandwidth stream of random bits well suited to forward-secure authentication.

Briefly, then, in H2H a Programmer and IMD take independent, time-synchronous ECG readings. The IMD compares the two results to enforce a touch-to-access policy on wireless access by the Programmer. Figure 1 depicts the basic operation of H2H.

1.2 Challenges and contributions

Several previous schemes have sought to perform ECG-based pairing with IMDs like H2H, but have had serious shortcomings. Most notably, previous schemes have relied on cryptographic pairing protocols without rigorous adversarial modeling or security analysis. As a result, two of the most recent of them [23, 48] were shown in a 2013 paper [39] to have serious cryptographic flaws.

Thus designing a practical system such as H2H with rigorous security assurances has effectively remained an open problem, one that raises several technical challenges.

The first challenge is demonstrating that ECG is a suitable PV for authentication. H2H derives a *key source* from the patient's ECG signal, a sequence of key bits that authenticate a Programmer to an IMD. Secure touch-to-access authentication requires that the key source be *truly random*, ideally that constituent bits have high entropy and are statistically independent from one another and over time. The key source is then hard for an attacker to guess without physical access to the patient and also ensures forward-security, i.e., that old key source bits don't reveal future ones.

Previous work has explored the statistical properties of ECG waveforms for key generation, but not the important impact of read error rates on authentication false positive and false negative rates. We present experiments on real patient ECG data showing that it's possible (with errors) to extract roughly four truly random and statistically uncorrelated bits from the ECG wave corresponding to a single heartbeat. Collection over a 15-second interval suffices for strong Programmer authentication (a false acceptance rate of about 2.7×10^{-9} and false rejection rate of 10^{-4}).

We also introduce an optimal scheme in H2H for testing PV validity, i.e., testing $\alpha \approx \beta$. Our scheme relies on the Neyman-Pearson Lemma, rather than naïvely on Hamming distance, as in previous work.

Good statistical properties, however, don't ensure that ECG can enforce the touch-to-access policy in H2H. Recently developed systems can read cardiac rhythms *remotely* via videocamera, and even accurately measure a patient's pulse. (Skin color changes subtly with cardiac rhythms.) In Section 3.3, we very briefly report our implementation and test results for the best known of these systems [35] and show that it doesn't reveal statistically significant information about the ECG key source used by H2H.

Given a good key source, a *cryptographic pairing protocol* is needed between the Programmer and IMD. Two features of H2H make cryptographic pairing a challenge. First, when the Programmer and IMD synchronously sample the key source, their respective readings β and α are *noisy*: Often $\beta \approx \alpha$, but exact equality $\beta = \alpha$ isn't obtained. Cryptographic tools such as password-authenticated key agreement (e.g., [5]) require exact equality, while error-tolerant ones, e.g., [14, 24], sacrifice entropy needlessly in our setting here.

Second, the IMD has tight *computational and power constraints*. Microcontrollers in common use for IMDs today can perform only lightweight cryptography. As IMDs are long-lived devices (with an average lifetime today of five to seven years [15]), and battery replacement requires surgical intervention, power conservation is essential. H2H can protect new IMDs as well as legacy in-vivo IMDs with upgradable firmware, as long as the H2H implementation meets the IMD's limited memory and computational resources.

We present a new pairing protocol that exploits the fact that key source bits are statistically uncorrelated, and thus that we can treat α and β as one-time authentication values. We demonstrate its security in a strong adversarial model that includes man-in-the-middle attacks, such as the jam-and-replay attacks feasible in a wireless environment.

Our H2H pairing protocol requires only a low-exponent RSA encryption (tens of modular multiplications) and a few AES invocations and hash computations by the IMD. We demonstrate a full implementation of H2H on an ARM Cortex-M3 processor.

In summary then, our contributions are:

- *Statistical characterization of ECG for authentication:* Using real-world ECG measurements [30], we experimentally quantify the extractable entropy in ECG signals. (We demonstrate use of the Neyman-Pearson Lemma to achieve optimal use of this randomness.)
- *Cryptographic pairing protocol:* We present a novel, lightweight, noise-tolerant cryptographic scheme for Programmer-to-IMD pairing in H2H. We formalize an adversarial model and outline proofs of security.
- *Implementation:* We describe a full implementation of H2H in an ARM Cortex-M3 processor, reporting resource requirements such as code size and power consumption, and demonstrating the feasibility of H2H for use in contemporary IMDs.

Organization

We introduce our statistical model for ECG waveforms and operational, trust, and adversarial models for H2H in Section 2. A detailed statistical analysis of real-world ECG waveforms and our proposed entropy extraction techniques follows in Section 3. We specify the cryptographic device-pairing protocol for H2H in Section 4. We describe an implementation of H2H in Section 5. We review related work in Section 6, and conclude in Section 7 with a discussion of future work. Appendix A outlines a security analysis of the H2H device-pairing protocol; detailed modeling and analysis is deferred for the full version of this paper.

2. MODELING

Before diving into details on H2H, some basics on ECG and our associated statistical model are in order, as well as discussion of our operational, trust, and adversarial models.

2.1 ECG model

Figure 2 is a schematic depiction of the ECG waveform of a healthy patient. The so-called R-peak is the most prominent feature of the ECG waveform; it corresponds to the "beat" in a heartbeat. The time between two consecutive R-peaks, or the heartbeat duration, is commonly referred as the inter-pulse interval (IPI). As the figure shows, a typical ECG cycle includes other physiologically significant, named features: The P-wave, which occurs before the R-peak, the QRS complex, which includes sharp valleys before and after the R-peak, denoted by Q and S respectively, and the T-wave, following the S valley.

The heart rhythm is governed by the parasympathetic nervous system, in which many non-linearly interacting processes give the IPI its well-studied chaotic nature [7, 31]. The ECG waveform, and parasympathetic network more generally, are influenced by both long-term trends such as circadian rhythm and short-term temperature and respiratory changes. Thus ECG waves simultaneously exhibit both long term patterns and short-term chaotic behavior.

The ECG signal is well modeled as a stochastic process. The existence of long-term patterns renders the process non-stationary, meaning that the parameters of its underlying distribution, e.g., mean and variance, fluctuate over time. We introduce transforms for H2H, however, that eliminate long-term variations, creating a residual signal that is well-approximated by a wide-sense stationary stochastic process, i.e., one whose first and second moments don't change over time. Previous work observed a strongly random element in IPI time series values [7], motivating later use of IPIs as a natural source of randomness [9].

Like H2H, previous systems also exploited the natural *synchronization* property of IPIs. Slight shifts in the time interval over which IPIs are derived don't impact IPI values, which are computed relative to R-peaks, not absolute time.

Entropy and security: We show that it is possible to extract four *high-grade* random bits per IPI from our processed ECG source, i.e., bits that have maximal entropy and are fully uncorrelated. We use this entropy measure to characterize the security of H2H formally using our main theorem, Theorem 1. An important new aspect of our work is quantification and use of the different error rates incurred by individual high-grade random bits via the Neyman-Pearson Lemma. This simple approach marks a notable advance over earlier work, which assigned the same significance to all random bits. Our improvement enables authentication with the optimal, i.e., minimum possible, false positive rate for a given false negative constraint.

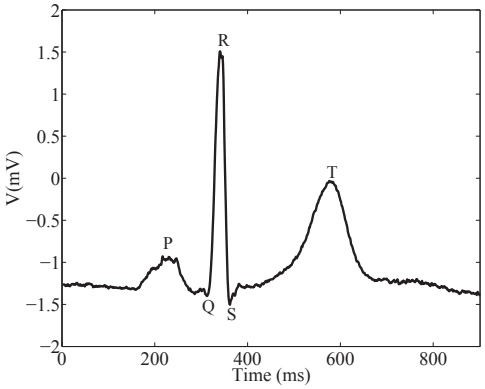

Figure 2: A typical ECG waveform from lead V2 which is recorded from chest. R-peak is the most prominent feature.

2.2 Operational and trust models

We envision use of H2H primarily for *emergency* authentication, when medical personnel, e.g., emergency medical technicians (EMTs), need access to a patient's IMD, but have no pre-established keys or trust relationship. Rapid and reliable access to the IMD is important. Thus H2H harvests PV randomness efficiently to achieve quick authentication.

We assume no public-key infrastructure (PKI) for certification of trustworthy programmers. The challenges of key revocation, tamperproofing of programmers to prevent key compromise, etc., are substantial. Similarly, we assume it's impractical for medical personnel to contact an authority on the fly for access credentials, as this approach would require an infrastructure of broad (indeed, worldwide) and robust trust relationships. Thus H2H relies exclusively on the touch-to-access policy for authentication.

The ECG waveform goes flat when an acute heart attack occurs. Similarly, in some late-stage terminal diseases, the parasympathetic network collapses and as a result, the ECG waveform loses most of its entropy. The hugely distorted ECG waveform resulting from such conditions is readily identifiable. In such cases, H2H is designed to enter a promiscuous mode in which any Programmer may access the IMD: For these acute events, the risks of medical failure greatly outweigh those of malicious attack. Additionally, these extreme medical conditions occur rarely.

In non-emergency situations, for instance, when a patient is receiving routine medical care, it may be practical for medical personnel to retrieve device-specific keys. But in unusual situations, e.g., patients traveling abroad, lost keys, and so forth, H2H is additionally useful as a secondary or backup authentication mechanism.

2.3 Adversarial model

We design H2H for a strong adversarial model that assumes the presence of an attacker during a Programmer-to-IMD authentication session. This adversary is active. It has complete network control, i.e., can drop (jam), modify, replay, and forge messages at will. (The adversary can't compromise the Programmer or IMD, which would render protection of the IMD impossible.) While the presence of an adversary during a medical emergency is admittedly a strong assumption, we believe it is prudent to design robust security for critical systems such as IMDs by default.

Protecting against strong, active adversaries in a pairing protocol isn't straightforward. As mentioned above, recent breaks of two recent such protocols illustrate the challenge [39].

3. AUTHENTICATION PROCESS

Several papers, e.g., [36, 45, 48], have proposed IMD authentication based on IPIs. Their common motif is extracting the purely uncorrelated random bits from IPIs and utilizing them as a key. As previously stated, IPIs are not independent across time. So most previous approaches were confined to utilizing only a portion of the quantized IPIs for key derivation. These protocols generate a key by quantizing IPIs and then concatenating the three or four least significant bits of the quantized IPIs. The Programmer is then authenticated if and only if the Hamming distance between the keys generated by the two communicating parties is less than a predefined threshold value.

The four least significant bits of IPIs (IPI_4) are known to be independently and identically distributed (i.i.d.). We confirmed this characteristic by studying a 2Mbit dataset consisting of 48 half-hour ECG records of 47 subjects from the MIT-BIH Arrhythmia Database [30], 549 two-minute records of 290 subjects from the PTB Database [6], and 250 records of 250 patients from MGH/MF Waveform Database [47], each roughly 30 minutes in length. All of these databases are available at [1]. We note that while these widely referenced databases contain records from patients with abnormal cardiac rhythms, these and similar databases remain standards for the study of ECG-based biometric authentication. (See, e.g., [45, 48].) Such use is substantiated by an extensive body of literature (e.g., [17, 42, 49]) documenting *stronger* chaotic effects in healthy hearts than in diseased ones.

We applied the NIST suite of statistical tests [41] to our dataset. The outputs of the NIST statistical tests are p-values listed in Table 1. These p-values represent the probability that the dataset was generated by a random process. If this value is less than a threshold (usually 1%), the randomness hypothesis is rejected. Table 1 shows that the p-values are all greater than 1%.

Table 1: p-value of several NIST statistical tests for IPI_4. These bits pass all of the random tests.

NIST test	p-value
Runs	0.311310
Rank	0.879647
Longest runs	0.185359
Frequency	0.011830
Universal test	0.013223
Approximate entropy test	0.464725
FFT test	0.131301
Linear complexity	0.612269

The lack of correlation between bits allowed previous work to use a simple Hamming distance metric to compare received and measured bits. Prior work, however, did not characterize and optimize for the *error rates* on sampled bits resulting from noisy IPI readings. More precisely, we define the error rate as the probability, for a given IPI-derived bit, that two devices, e.g., a Programmer and IMD, read the same IPI at different points on the body but output differing bit values.

Lacking the ability to obtain IPI measurements from IMDs in our lab, we estimate the error rates for IPI-derived bits in the H2H setting by means of two external ECG leads, on the left arm and right arm of subjects. The electric potential of the ECG lead III between the left arm of subjects and their left foot is taken as a surrogate for the ECG from the IMD. Similarly, the electric potential of the ECG lead II between the right arm and left foot is taken as a surrogate for the ECG recorded by the Programmer and IMD. It should be noted that we are using the interval between consecutive prominent R-peaks, instead of analyzing the whole waveform as in [44]. Therefore, H2H is not sensitive to the location of leads on the body. Any other lead configuration could have been used in our analysis. We performed this analysis with other lead configurations and didn't find any significant variations in the error rate of least significant bits.

In the next step of analysis, the IPI values of these two readings from leads II and III are calculated and quantized. They are then converted to a Gray-code representation to minimize the difference between the quantized bits caused by error in measurement.

The Hamming distance between these two sets of bits is then taken as a surrogate for the error rate between IPI measurements by the IMD and Programmer. The results of our experiment are reflected in the "Error rate" column of Table 2 for IPI values quantized to 8-bit representation. The last column shows the 95% confidence interval of the error rates. We again used an aggregate of MIT-BIH [30], PTB Database [6], and MGH/MF Database [47] to estimate these error rates.

The table shows that the error rate varies considerably across quantized bits; the lower the significance of the bit, the higher its error rate and entropy. In the next subsection, we describe our statistical approach—a departure from the naïve Hamming approach of previous work—to compare PV readings during authentication with suitable weighting for individual bit errors.

Bit	Entropy	Error rate	95% CI	Denoted by
8 (MSB)	0.27	0.001	–	–
7	0.80	0.003	–	–
6	0.90	0.004	–	–
5	0.98	0.006	–	–
4	1	0.009 (e_4)	0.008 – 0.012	x_4
3	1	0.018 (e_3)	0.015 – 0.021	x_3
2	1	0.039 (e_2)	0.035 – 0.043	x_2
1 (LSB)	1	0.080 (e_1)	0.075 – 0.086	x_1

Table 2: Average entropy and the estimated error rate of quantized bits, along with their 95% Confidence Interval (CI).

3.1 Quantifying the probability of skin contact

It's convenient to treat the IMD PV α as *correct*. Error rates then characterize honest or attacker deviation from α.

A PV in H2H includes only the four least significant bits of an IPI, which we denote collectively by IPI_4. The bits in IPI_4 are i.i.d. random variables. Thus, an adversary that hasn't made skin contact with a victim, and has no information about IPIs, can at best guess an IPI_4 value by assigning random values to each of its constituent bits. Suppose that n is the number of distinct IPI_4 instances read in an H2H authentication session. Then the total number of incorrect guesses by Adv for any given one of the four IPI_4 bit positions can be modeled as a binomial distribution with Bernoulli trial probability of 0.5, denoted by $B(n, 0.5)$.

The total number of incorrect bit outputs for a given bit position i by a valid Programmer with skin contact can be modeled by another binomial distribution $B(n, e_\mathrm{i})$. Here, e_i is the error rate of bit $i \in \{1, 2, 3, 4\}$ as given in the third column of Table 2.

Figure 3 compares the distributions of incorrect guesses by an adversary (with no skin contact) against those of a valid Programmer, for $n = 20$. The solid line is the distribution for the adversary on any of the four bit positions. For the Programmer, $x_i = B(n, e_\mathrm{i})$ denotes the random variable corresponding to total incorrect values

in bit position i. The adversary is seen to produce significantly more errors than the Programmer in all bit positions.

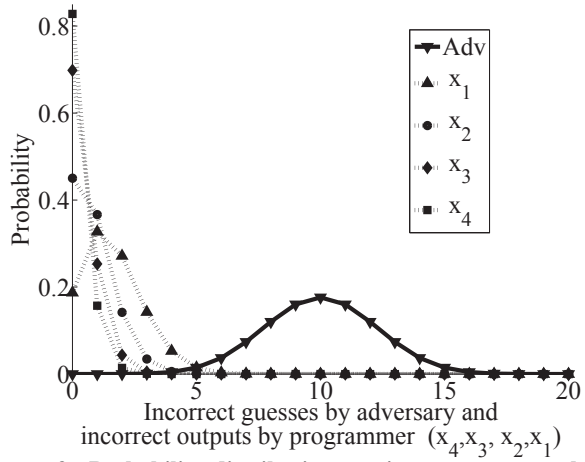

Figure 3: Probability distributions on incorrect guesses by a valid Programmer (dotted lines) and an adversary (solid line), for $n = 20$ (reading of 20 IPI_4 values). Here, x_1, x_2, x_3, and x_4 denote random variables on Programmer errors for bits positions 1, 2, 3, and 4 respectively. The distribution for the adversary is identical across bit positions. Clear separation is seen between valid and adversarial distributions, even for bit positions with relatively high error rates (e.g., for x_1).

3.2 Neyman-Pearson hypothesis testing

Recall that the goal in the H2H authentication process is to determine whether $\alpha \approx \beta$, where the IMD reads PV α and the Programmer submits PV β. Determining whether Programmer PV β is authentic, i.e., resulting from skin contact, may be viewed as a *hypothesis test*. The underlying hypothesis is that the Programmer's claimed PV β is drawn from the probability distribution of an honest Programmer, instead of an adversary's guessing distribution.

This observation motivates use of the well known Neyman-Pearson Lemma [32] to distinguish between honest and adversarial authentication attempts. Let *error value* u denote the set of errors in β, i.e., bit positions that differ from α. In our context, then, Neyman-Pearson Lemma states that for a given maximum acceptable false negative rate, the false positive rate is minimized as follows. For a fixed threshold value Th (whose computation we discuss below), a submitted Programmer value β is accepted as valid only when the following criterion holds:

$$\log\left(\frac{P(u)}{Q(u)}\right) > Th, \tag{1}$$

where $P(\cdot)$ denotes the probability of an adversary with no skin contact yielding error value u and $Q(\cdot)$ denotes the probability of a valid Programmer yielding u. We model distributions $P(\cdot)$ and $Q(\cdot)$ according to the binomial distributions discussed above and depicted in Figure 3.

We observe that as the bits in a given bit position i are i.i.d., the correctness of a PV is invariant to *which* IPI_4 values contain erroneous bits. The authenticity of a PV β is thus determined based on only the *total* number of correct or incorrect values in each bit position. So we can treat u as an *equivalence class* of PVs. In particular, it's convenient to regard u as a vector $\vec{u} = \langle u_1, u_2, u_3, u_4\rangle$, where u_i denotes the total number of IPIs in β that are incorrect in bit position i—again, that differ from those in α.

Now, $P(\vec{u}) = \prod_{i=1}^{4} P_i(u_i)$ and $Q(\vec{u}) = \prod_{i=1}^{4} Q_i(u_i)$, where $P_i(u_i)$ and $Q_i(u_i)$ denote the probability of a total of u_i incorrect IPI values for bit position i in adversarial and honest scenarios, respectively. It follows that:

$$\log\left(\frac{P(\vec{u})}{Q(\vec{u})}\right) = \sum_{i=1}^{4} \log\left(P_i(u_i)\right) - \sum_{i=1}^{4} \log\left(Q_i(u_i)\right). \tag{2}$$

Based on Equation 2, we can construct complete, compact representations of $P(\vec{u})$ and $Q(\vec{u})$. For a given value of n, it suffices to build a table containing $\log P_i(u_i)$ and $\log Q_i(u_i)$ for $i \in \{1, 2, 3, 4\}$ and $u_i \in \mathbb{Z}_n$. Because the error rate of the adversary is 1/2 for *all* bit positions, $Q_i(u_i) = Q_j(u_j)$ for any $i, j \in \{1, 2, 3, 4\}$. Thus, it suffices to store $\log Q_i(u_i)$ values for $i = 1$ only. Consequently, the full table contains just $(4 + 1) \times (n + 1) = 5n + 5$ values.

Given such a table, performing the Neyman-Pearson test in Equation 1 requires just $(4+1) = 5$ table lookups, eight additions, and one subtraction. This computation is *online*, i.e., performed during authentication. The storage and computational efficiency of our table-driven approach to Neyman-Pearson testing proves valuable in our implementation of H2H, described later.

One issue remains. The Neyman-Pearson Lemma states the existence of threshold Th, but doesn't specify how to compute Th. We now describe an algorithm to compute Th in our setting. Note that computation of Th takes place *offline*: Th need only be computed once and can then be programmed into an H2H-enabled IMD.

Computing Neyman-Pearson threshold value Th: It turns out that the space $(\mathbb{Z}_n)^4$ of possible values of $\vec{u}$ is relatively small. As we show below, $n \leq 50$ is sufficient to achieve our desired strength of authentication for H2H, meaning that the total number of possible values of $\vec{u}$ is at most $50^4 = 6,250,000$. Consequently, we can compute Th essentially by means of a brute force algorithm.

We specify this algorithm in pseudocode below as Algorithm 1. Algorithm 1 computes Th for a target false-negative rate FN_{Req}. It first constructs a matrix $M[n^4][3]$ with n^4 rows, one for each $\vec{u} \in (\mathbb{Z}_n)^4$, and three columns. For each row $\vec{u}$, Column 1 contains $P(\vec{u})$, Column 2 contains $Q(\vec{u})$ and Column 3 contains $\log \frac{P(\vec{u})}{Q(\vec{u})}$.

The rows of M are sorted in ascending order with respect to Column 3 values. Then, from top (smallest) to bottom (largest), Column 1 values are accumulated in a variable p until the lowest row τ is reached for which the cumulative value $p \leq FN_{\text{Req}}$. The Column 3 value of row τ, namely $M[\tau][3]$, is the optimum threshold value Th. By summing Column 2 values over the first τ rows, we also obtain the corresponding false-positive rate (FP). (A computation failure outputs special symbol $\perp$.)

The dominant cost of Algorithm 1 is sorting. Thus its asymptotic complexity is $O(n^4 \log n)$. In practice, as n is small, the algorithm executes quickly. For example, we implemented Algorithm 1 in MATLAB on a machine with a 3.4GHz Intel i7-2600 CPU running Windows 7. It took 0.2 second to calculate Th for $n = 15$ and around 8 seconds for all values of n from 1 to 25.

Again, we emphasize that Algorithm 1 is run as a precomputation offline, not in the IMD.

Setting parameters in H2H: In our H2H implementation, we set the false negative rate (FN_{Req}) to 10^{-4}. In practical terms, this means that a valid Programmer with skin access would fail on average in one in every 10,000 attempts; it would fail twice consecutively at most once in every 100,000,000 attempts. We believe this choice achieves adequate failure resilience for real-world scenarios.

Algorithm 1 Neyman-Pearson threshold Th computation

```
Inputs: n, {e_i}_{i=1}^4, FN_Req
Outputs: Th, FP

P[1 : n + 1] ← binomial(n, 0.5);
for i = 1 to 4 do
    Q[1 : n + 1][i] ← binomial(n, e_i)
end for
j = 1;
for u⃗ = ⟨u_1, u_2, u_3, u_4⟩ ∈ (Z_n)^4 do
    M[j][1] = ∏_{i=1}^{4} P[u_i];
    M[j][2] = ∏_{i=1}^{4} Q[u_i][i];
    M[j][3] = log(M[j][1] / M[j][2]);
    j ← j + 1;
end for
sort M on M[·][3] (Column 3);
p ← 0; j ← 0
while p ≤ FN_Req do
    j ← j + 1;
    p ← p + M[j][2];
end while
τ ← j − 1;
if τ < 1 then output ⊥; halt
end if
FP ← Σ_{k=1}^{τ} M[k][1];
Th ← M[τ][3];
```

Figure 4 illustrates the tradeoffs between false negative rates (FN_{Req}) and false positive rates (FP), for varying numbers n of IPI_4 values used in authentication. Table 3 gives detailed FP values for our implementation choice $FN_{\text{Req}} = 10^{-4}$ and, for comparison, for $FN_{\text{Req}} = 10^{-3}$. Naturally, the lower FN_{Req}, the higher FP.

In addition to FN_{Req}, the other key parameter choice in H2H is the number n of IPI_4 values measured for authentication. The larger n is, the better FN_{Req} and FP are. As n grows, though, so does the ECG measurement time in an H2H authentication.

In our implementation, we have chosen to set $n = 15$. Given our choice of $FN_{\text{Req}} = 10^{-4}$, the corresponding false positive rate is $FP = 2.7 \times 10^{-9}$. We chose this FP to demonstrate the feasibility of a *strong* level of authentication. As a point of comparison, this FP is lower than the false acceptance rate of a typical, eight-digit RSA SecurID token [40]. (While the false acceptance rate for such a token is nominally 1×10^{-8}, allowances for synchronization errors and multiple tries make it somewhat weaker.) Lower FPs, and thus lower values of n, are likely to be acceptable in practice.

Table 3: FP values achieved for our implementation choice $FN_{\text{Req}} = 10^{-4}$ and, for comparison, for $FN_{\text{Req}} = 10^{-3}$. Average PV read time is given in the last column.

n	$FN_{\text{Req}} = 10^{-3}$	$FN_{\text{Req}} = 10^{-4}$	Avg. read time (secs.)
5	3×10^{-3}	1.1×10^{-3}	3– 5
10	1.15×10^{-6}	7.9×10^{-6}	7–10
15	0.2×10^{-9}	2.7×10^{-9}	11–15
20	0.27×10^{-12}	5.38×10^{-13}	15–20
25	0.32×10^{-17}	8.4×10^{-17}	18–25

The average resting heart rate is 60-80 beats per minute [2]. Thus, for $n = 15$, the recording time would on average take between 7 to 10 seconds. The last column of Table 3 lists the average range of PV read times (in seconds) for different choices of n.

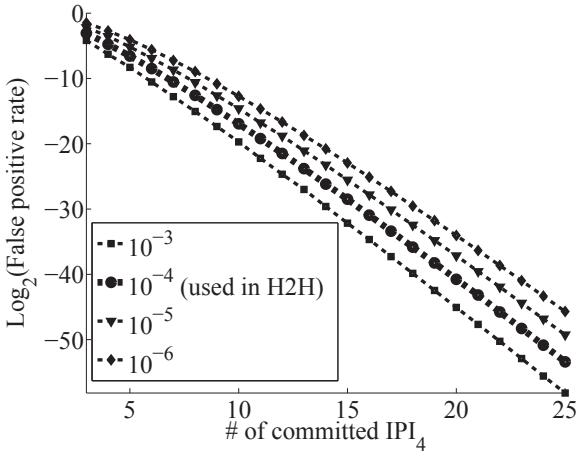

Figure 4: False positive rates achieved by Neyman-Pearson hypothesis testing for various false negative rates.

Summary: In H2H, we apply Neyman-Pearson hypothesis testing to determine whether to accept a Programmer-submitted PV β as authentic or reject it. We first compute the error value $\vec{u}$ of β. Error value $\vec{u}$ captures the total number of errors u_i in each IPI_4 bit position i in β (by comparison with the IMD PV α). We then perform Neyman-Pearson testing of $\vec{u}$ via Equation 1. This test involves computation using Equation 2, and is made efficient by precomputing a small table of u_i value probabilities and Neyman-Pearson threshold Th, both of which are stored in the IMD.

An attacker can, of course, make multiple attempts against the IMD and the Programmer as well. In Section 4, we formally characterize the success probability of such attacks relative to FP. Exponential backoff in the IMD is one helpful countermeasure.

3.3 Remote attack

We also briefly investigated an attack on H2H based on remote cardiac activity monitoring. The best reported remote heart rate monitoring result is achieved by photoplethysmography (PPG) [35]. PPG traces changes in skin color caused by temporal variations in the concentration of blood on the skin surface.

Poh et al. [35] have reported moderately accurate IPI estimation using a commercial webcam at an approximate distance of 50cm from human subjects. We reproduced and evaluated their scheme at the same distance with a 30 frame per second (FPS) camera recording video of the subjects' faces for PPG evaluation over a two minute period. Our camera had twice the FPS rate of the camera in [35].

We have not been able, however, to achieve error rates as low as those reported in [35] for any of our test subjects. (We have contacted the authors and requested clarification of details and their original dataset for validation, but have received no response.) The average error rate for the four least significant bits (IPI4) of all four subjects in our PPG experiment were close to 50%, i.e., to random guessing— substantially higher than those achievable by a Programmer with skin access and yielding little advantage to a remote attacker targeting H2H. We conclude that without significant advances, PPG is unlikely to pose a significant threat to H2H.

4. PROGRAMMER-TO-IMD PAIRING PROTOCOL

We now describe the design of the H2H PV-based cryptographic pairing protocol. First we explain our design principles, both why we don't use existing cryptographic protocols and how we exploit special features of the H2H setting to achieve simple, efficient protocol design. We then present the protocol and a security analysis.

A naïve approach to authentication might work as follows. The Programmer establishes a secure connection with the IMD (via TLS, for instance). The two devices then take respective PV readings α (IMD) and β (Programmer). The Programmer transmits β to the IMD. If $\beta \approx \alpha$, i.e., β is close to α, the IMD accepts the Programmer as valid.

The problem with this approach is that it's vulnerable to a man-in-the-middle attack. An adversary Adv can simultaneously pose as the IMD in a session with the Programmer and as the Programmer with the IMD. On receiving β from the Programmer, Adv forwards it to the IMD, resulting in a successful authentication.

Password-authenticated key-exchange (PAKE) schemes [5], are designed precisely to address such attacks, and might seem an appropriate tool for H2H. The PVs α and β measured respectively by the IMD and Programmer may be treated as passwords: The Programmer gains access to the IMD by demonstrating its approximate knowledge of "password" α, i.e., that it knows β such that $\alpha \approx \beta$.

There are two problems with PAKEs. First, due to read errors in our setting, the IMD must check for *approximate* equality, i.e., $\alpha \approx \beta$. But a PAKE requires *exact* equality. More involved approaches, e.g., bit-by-bit password testing, or use of fuzzy extraction, e.g., [14] can convert PAKE into a "fuzzy" tool for approximate equality testing.

But PAKE presents a second problem: Computational cost. While the several modular exponentiations required by a single PAKE execution are feasible on many devices, they constitute more computation—and more energy expenditure, in particular—than desired on IMDs, which are highly constrained in terms of power and computational resources. A "fuzzy" PAKE would require even more computation.

Thankfully, as it turns out, PAKE is overengineered for H2H. It's possible to support approximate matching of α and β *and* gain better computational efficiency than PAKE.

4.1 Protocol overview

Our key observation is that the readings α and β in H2H are *one-time values*. In contrast to passwords, which are generally multi-use, α and β are transient. Fresh readings may be used to authenticate every session and, as we have demonstrated experimentally above, readings are statistically independent across time.

Consequently, it is possible to reveal α and β safely at the end of our authentication protocol—something not possible, of course, with static passwords. The protocol can thus rely primarily on (very fast) symmetric-key commitment and decommitment rounds and explicit IMD testing of the condition $\alpha \approx \beta$, rather than minimal-knowledge cryptographic comparison.

Our protocol has two phases: (1) A *secure-channel setup* phase, which uses (lightweight) public-key cryptography to create a secure but unauthenticated channel between the IMD and Programmer and (2) An *authentication* phase, in which the two devices use a commitment / decommitment scheme to check whether $\alpha \approx \beta$.

Secure-channel setup. In the first phase of our protocol, the IMD and Programmer establish a *secure channel* via TLS. The IMD assumes the role of the TLS client; the Programmer, that of a TLS server. That is, only the Programmer presents a certificate. When instantiated with RSA, TLS requires little client computation, just one low-exponent ($e = 2^{16} + 1$) modular exponentiation.

Our protocol makes use of an output from TLS session what we call a *label* s. Given that at least one of the two entities is honest, s is random and thus unique (with overwhelming probability). It isn't secret, however. In practice, s might be, e.g., the hash of the TLS session key. For convenience, we abstract away the details of TLS and just model it as a protocol SecChannel that establishes a secure channel between two entities and outputs random label s.

SecChannel (in practice, TLS) creates a secure channel in the sense that it provides confidentiality, integrity, and freshness. But it doesn't provide authentication: The IMD doesn't present a certificate, and doesn't validate the Programmer's. (As explained above, H2H avoids the burden of a PKI.) Put another way, when an IMD first sets up a secure channel, it has no assurance that it has paired with a *valid* Programmer, i.e., one actually in contact with the patient. Similarly, a Programmer doesn't know if it's communicating with a valid IMD. Thus the next protocol phase.

Authentication. In the authentication phase, the two devices commit to their respective PV readings α and β. Each device binds its commitments to the label s of the secure channel on which it is communicating (preventing its re-use, prior to decommitment, on a different channel).

The IMD can then safely decommit α for the Programmer, as it has already received a commitment for β.

If the Programmer determines that $\alpha \approx \beta$, then it decommits β. Otherwise, it rejects the session. This selective decommitment helps ensure that the Programmer only reveals β to a valid IMD (one that knows $\alpha \approx \beta$), preventing re-use of β by an adversary. If the Programmer had been the party who decommits first, an adversary would have easily mounted a man-in-the-middle attack.

The IMD itself then verifies that $\alpha \approx \beta$, and makes an accept / reject authentication decision.

After an invalid authentication attempt, IMD waits a full PV read cycle before accepting a new authentication request. This delay prevents interleaving attacks, in which a Programmer's session overlaps with two IMD sessions. (This is in fact necessary to achieve Theorem 1 below.)

4.2 Protocol specification

The H2H authentication protocol is specified in Figure 5. Some technical preliminaries are needed.

Define $\mathcal{V}$ as the space of valid PVs. Let $\mathsf{dist} : \mathcal{V} \times \mathcal{V} \to \mathbb{R}_0^+$ denote a pairwise distance metric on $\mathcal{V}$. Let τ denote the time required for a device to read a PV.

We make use of a commitment scheme Commit with message space $\mathcal{V}$ and key space $\{0,1\}^k \times \{0,1\}^k$. We denote a commitment of message pair $(m, s) \in \mathcal{V} \times \{0,1\}^k$ under key $w \in \{0,1\}^k$ by $C = \mathsf{Commit}((m, s); w)$. We adopt the convention of decommitment as verification of correct commitment, i.e., decommitting m under key w involves the check $C \stackrel{?}{=} \mathsf{Commit}((m, s); w)$.

For simplicity of analysis, we treat Commit as an ideal functionality [8], i.e., as unconditionally hiding and binding. When either device outputs the message `reject`, rejecting the session, it terminates communication on the session channel. Additionally, devices support only serial sessions, not concurrent ones.

4.3 Security analysis

We consider an adversary Adv that fully controls the channel between the IMD and Programmer, i.e., Adv can deliver, drop, modify, and forge messages as desired. Adv can't corrupt the IMD or

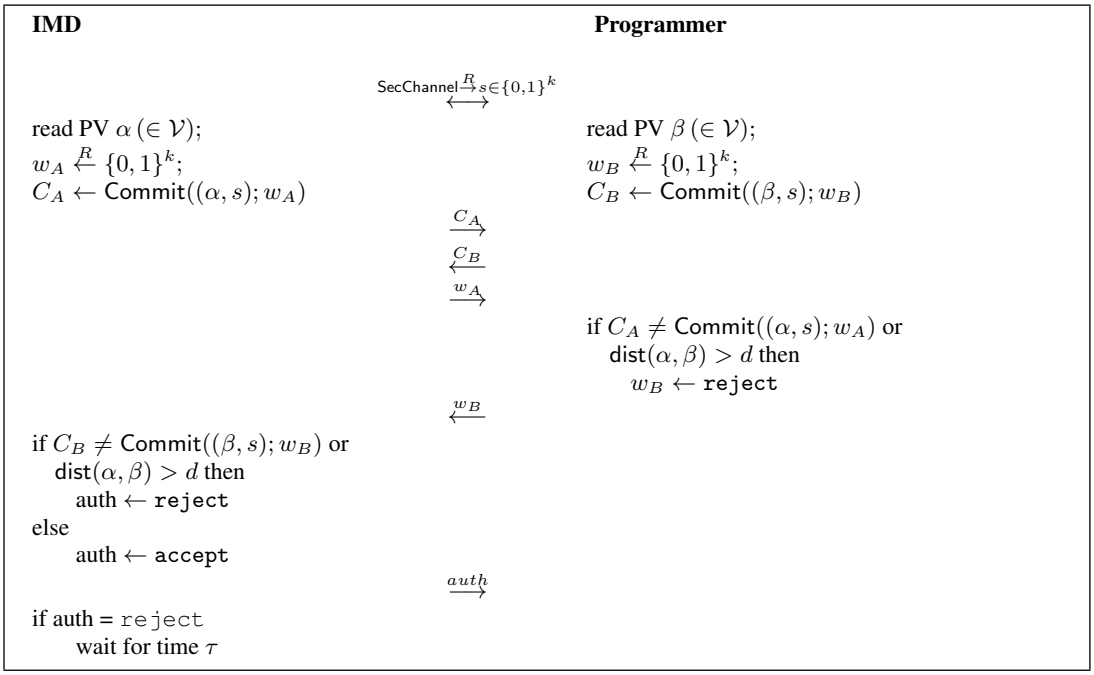

Figure 5: H2H pairing protocol.

Programmer, however. (If it could, protection of the IMD wouldn't be possible.) Here we briefly present our formal security model and main theorem. Appendix A contains more details.

We assume that readings α and β by the IMD and Programmer come from probability distributions defined by a model $\mathcal{M}$. Given $\mathcal{M}$, p_1 denotes the maximum probability that Adv can guess a valid PV reading in one try, i.e., given legitimate PV reading α, that Adv can guess a v such that $\mathsf{dist}(v, \alpha) \leq d$. In other words, p_1 is the authentication probability characterized in Section 3.

Similarly, p_2 denotes the maximum probability that Adv does so in exactly two tries. More precisely, given simultaneous PV readings α and β, p_2 is the maximum probability, given a known, failed guess for α, that Adv guesses a valid PV reading for β.

We define the security of H2H in terms of an experiment in which Adv succeeds if it can authenticate to the IMD, i.e., cause it to output `accept` for a session with Adv on SecChannel. To convey intuition for the resistance of H2H to man-in-the-middle attacks, we give the following lemma with a proof sketch. Here $\mathsf{succ}^{H2H}_{\mathsf{Adv}}(1,1)$ denotes the probability that Adv succeeds when it initiates a single session each with the Programmer and IMD.

LEMMA 1. *For PV model $\mathcal{M}$, $\mathsf{succ}^{H2H}_{\mathsf{Adv}}(1,1) \leq p_1 + p_2 - p_1 p_2$.*

Proof: [sketch] Adv's goal is to initiate a session on SecChannel with the IMD such that it outputs `accept`. To do so, Adv must send the IMD (simulated Programmer commitment) C'_B, with corresponding value β' such that $\mathsf{dist}(\alpha, \beta') \leq d$. Recall that we model Commit as an ideal functionality, both unconditionally hiding and binding. As the commitment C_A of the IMD is thus hiding, Adv can obtain an advantage over random guessing for β' only by interacting additionally with the Programmer.

Suppose therefore that Adv has initiated a session with the Programmer prior to completion of its session with the IMD. Adv sends the Programmer (simulated IMD) commitment C''_A on PV α''. Each instance of SecChannel emits a uniformly random label. Thus the Adv-IMD session has label s' and the Adv-Programmer session label s'' such that $s' \neq s''$. (For simplicity, we disregard the negligible-probability event $s'' = s'$.)

Two cases arise, depending on whether Adv sends (simulated Programmer) commitment C'_B to the IMD before or after sending a decommitment w''_A to the Programmer.

Case 1: Commitment C'_B precedes decommitment w''_A. C_B is bound to label s''. To cause the IMD to accept, however, C'_B must be bound to label s'. (Intuitively, binding commitments to SecChannel labels prevents Adv from "stitching together" two distinct channels in a man-in-the-middle attack.) Given these bindings and the hiding property of Commit for C_B and C_A, then, Adv must commit to PV β' in C'_B that is independent of PVs α and β. Thus Adv must guess β' at random, and the IMD outputs `accept` with probability p_1.

Case 2: Commitment C'_B follows decommitment w''_A. As Adv sends C''_A prior to any decommitments, and commitments are hiding, Adv commits in C''_A to a PV α'' that is independent of previous transcript values, and thus correct with probability at most p_1. On sending decommitment w''_A, Adv learns whether α'' was correct. With this knowledge Adv may then submit a PV guess β' in C'_B to the IMD with success probability at most p_2.

Adv's maximum success probability, achieved for Case 2, is $p_1 + (1 - p_1)p_2$. $\square$

Defining $\mathsf{succ}^{H2H}_{\mathsf{Adv}}(q_i, q_r)$ as the probability that Adv succeeds in at least one session with at most q_i queries (session initiations) with IMD and q_r with the Programmer yields our main theorem:

THEOREM 1. *Given PV model $\mathcal{M}$ and $q = q_i + q_r$ with even-valued q, $\mathsf{succ}^{H2H}_{\mathsf{Adv}}(q_i, q_r) \leq 1 - (1 - (p_1 + p_2 - p_1 p_2))^{q/2}$.*

Theorem 1 reflects the fact that Adv's best strategy against H2H is to initiate sessions simultaneously with the IMD and Program-

mer, which respectively read PVs α and β. Adv tries to authenticate to Programmer by guessing β. If this fails, Adv tries to authenticate to IMD by guessing α; it gains a small advantage from knowing that its guess for β was incorrect. (The need for even q in our theorem is technical: The proof assumes the adversary can mount $q/2$ distinct attempts against the two devices.) A proof is sketched in Appendix A.

H2H-specific analysis: For the special case of H2H, Theorem 1 can be simplified. Let $\mathcal{M}_{H2H}$ and dist_{H2H} denote the PV distribution model and (Neyman-Pearson-induced) distance metric respectively for H2H. We can then show:

COROLLARY 1. *Given PV model $\mathcal{M}_{H2H}$ and distance metric dist_{H2H}, and $q = q_i + q_r$ with even-valued q, $\mathsf{succ}^{H2H}_{\mathsf{Adv}}(q_i, q_r) \leq 1 - (1 - 2p_1)^{q/2}$.*

In other words, *the probability of a successful attack in a given session by* Adv *is at most twice its authentication probability*, as characterized in Section 3.

4.4 Privacy

H2H protects patient privacy in two senses. First, the IMD doesn't release a public key (as a Programmer does), or any other static identifier. As α is random, and protocol values are random (or pseudorandom), H2H thus provides logical-layer *tracking privacy*: An adversary can't correlate distinct RF sightings of a given IMD, i.e., can't track a patient wirelessly from a distance. (For cautions about physical-layer wireless tracking, however, see [12].) Second, the randomness of α *prevents leakage of medically significant data*, e.g., cardiac abnormalities evident in a full ECG waveform.

5. PROTOTYPE IMPLEMENTATION

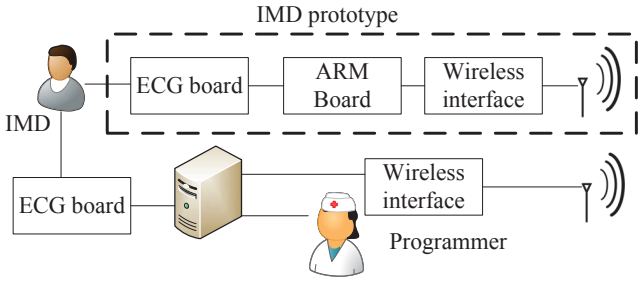

Figure 6: High-level view of the H2H prototype. The IMD parts are in the dotted box on top. The Programmer runs on a PC.

In this section, we present a prototype implementation of H2H. A high-level architecture is shown in Figure 6. The IMD prototype consists of three boards:

1. A Leopard Gecko EFM-32 microcontroller (EFM32LG-DK3650);
2. an ECG analog A/D front end (TI ADS1298); and
3. a wireless sensor modem (TI CC430F5137).

Leopard Gecko is a 32-bit ARM Cortex-M3 processor with an attractive power-consumption profile and convenient power debugging tools. In our implementation, the microcontroller communicates with the ECG analog front end and the wireless board. The EFM-32 also extracts ECG features and communicates with the Programmer using TLS. Figure 7 shows our implementation components. The following three subsections give details.

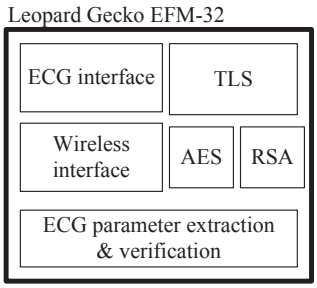

Figure 7: Main components of the implementation.

5.1 Secure channel implementation

Recall that the IMD and Programmer establish a channel between them using TLS. The IMD performs the operations of an ordinary TLS client and the Programmer those of an ordinary server.

TLS is designed to provide an encrypted and authenticated channel between two communicating parties [26]. *Standard TLS authentication assumes a PKI, however, which H2H doesn't, as noted above.* Thus the one deviation from normal TLS usage in H2H is that the IMD doesn't verify the Programmer certificate against a PKI. Instead, H2H authentication, i.e., ECG PV comparison, is performed after the TLS handshake to authenticate the channel.

Our H2H prototype uses RSA for the master secret key exchange in TLS, AES-128 for encryption, and SHA256 as the hash function. SHA256 also serves as the commitment function $\mathsf{Commit}(.)$ in the H2H pairing protocol.

We chose RSA for key exchange because RSA encryption with a small public exponent is the fastest key-exchange option for TLS [33]. In our implementation, the RSA public exponent is set to $2^{16} + 1$. The RSA modulus and message length are set to 2048 bits to conform with current NIST key length recommendations [4].

Our RSA implementation is designed to comply with the MISRA-C standard. MISRA-C [28] is a set of software development recommendations to achieve high levels of reliability for critical embedded devices. For example, MISRA-C prohibits use of dynamic memory allocations. The code size, the number of clock cycles, and approximate power consumption of various blocks of the TLS handshake are listed in Table 4.

Table 4: Approximate resource overhead of each of the component blocks of our H2H implementation. Here, "# of cycles" and "power" denote resource costs for a single call to the block.

Block name	Size (Kb)	# of cycles	Power (μ Watt)
AES encryption	2	6600	8
AES decryption	2	8400	10
RSA encryption	5	5000000	20000
MD5	1	5000	4
SHA256	3	10000	5
R-peak detection	4	5000	2

5.2 Random number generation

H2H requires a cryptographically secure pseudo-random number generator (PRNG) for RSA ciphertext padding, key generation and nonce selection in TLS, and commitment (as shown in Figure 5). We use a NIST-recommended PRNG based on cipher-block chaining (CBC) [27], with AES as the underlying block cipher. The PRNG requires an initial random seed. We generate this seed offline and store it in the IMD's non-volatile memory. (In a commercial IMD, it can be, e.g., set at the time of manufacture.)

5.3 ECG parameter extraction

Our H2H prototype annotates ECG R-peaks by applying a simple length transformation to the ECG waveform using an open-source algorithm called "WQRS." In this algorithm, the arc length of the waveform over a moving window is compared against a threshold to detect heartbeats [34]. Its resource overhead is is specified in Table 4. (An implementation of WQRS is available on the PhysioNet website [1].)

6. RELATED WORK

Several early research and development efforts in medical electronics have addressed safety and reliability of IMD devices, particularly the problem of unexpected failures [29]. Increased networking of embedded devices and emergence of pervasive healthcare technologies motivated security and privacy investigations for general sensor networks and body sensor networks [25, 43, 46].

Halperin et al. [21] first discussed the security and privacy challenges caused by resource constraints and inflexibility in existing IMD designs, and highlighted fundamental tensions among privacy, security, safety, and utility. Fu [16] argued that improving IMD security requires a balance between technology and regulation.

Halperin et al. [20] gave the first systematic and pragmatic security analysis of a real commercial IMD, an implantable cardiovascular defibrillator (ICD). They showed that these devices are susceptible to attacks by malicious programmers that breach patient privacy and, even more seriously, can effect changes to data and functioning, potentially harming patients. Their work highlighted the pressing need for authentication of programmers to IMDs.

Programmer-to-IMD authentication, as noted above, is straightforward if the Programmer and IMD share a preexisting key. (Authentication tokens have the same simplicity, but similar risks of IMD inaccessibility with credential loss.) Authentication without a pre-established relationship, as treated by H2H, is more challenging. Three broad technical approaches bear comparison with H2H.

Distance bounding. Halperin et al. [20] introduce authentication techniques involving an implanted piezo device that generates a random key and emits it acoustically such that the Programmer can only receive it at close range. This approach is complementary to H2H. It results in faster key agreement, needing a mere 400ms to emit a 128-bit key. A serious drawback, however, is that it requires special implantation of the piezo device. This implantation must be at a depth of 1 cm or so from the skin, ruling out incorporation into deep-body IMDs, such as ICDs. Additionally, eavesdropping on acoustic emanations isn't a well studied security problem.

A promising related approach, by Rasmussen et al. [38], uses ultrasound-based distance bounding (with an RF channel as well) to authenticate Programmer access to an IMD, achieving an access policy similar to, but slightly looser than touch-to-access. Their system requires RF shielding, however, amplifying IMD engineering complexity. In contrast, H2H is agnostic to transmission medium and does not incur the added cost or energy for ultrasound. For some IMDs, e.g., brain implants, RF antennas are of prohibitive length, and alternatives, e.g., infrared, are preferred. Finally, distance-bounding protocols' security models have historically proven fragile (see, e.g., [11, 37]).

Shielding. The idea of blocking inappropriate access to an IMD was first proposed in [13] via a device called a Communication Cloaker. The idea was further explored by Gollakota et al. [18]. Their proposed device, called a *shield*, is worn near the body and used to authenticate / mediate Programmer (or other) communications with the IMD. A shield doesn't require modification of existing IMDs. It protects communications with the IMD using a full duplex radio device acting as a jammer-cum-receiver.

IMDGuard [48] is a similar method for IMD protection involving a third party, high-powered device worn externally, called a Guardian. The Guardian authenticates programmers on behalf of the IMD. Like H2H, it requires special-purpose IMD functionality.

While these devices provide more general functionality, H2H has several advantages over them: (1) H2H doesn't require an external device, which is a burden on patients and increases the risks of system failures and unreliability; (2) H2H doesn't require jamming, which, as employed to counter attacks in [18,48], can interfere with other RF devices and potentially lead to legal complications.

While the shield has the benefit of legacy compatibility, we note that a growing number of legacy IMDs are built using programmable microcontrollers with in-vivo upgradable firmware, allowing an upgrade to the H2H protocol as long as its (lightweight) resource requirements are satisfied.

PV/ECG-based authentication. The use of PVs to secure inter-sensor communications in body area networks (BANs) was first introduced in [9]. Numerous works subsequently used the randomness in ECG IPIs for IMD authentication, e.g., [3, 10, 36, 45]. None, however, provided a rigorous entropy or protocol-security analysis. (In fact, the motivation for PV-derived keys in BANs is unclear. To pair *user-controlled devices* in *non-emergency settings*, even device passwords would seem practical.)

Most similar to H2H are two schemes: A protocol in IMDGuard for pairing the Guardian with an IMD and a generic body-area network pairing protocol called OPFKA (Ordered-Physiological-Feature-based Key Agreement) [23]. Like H2H, these protocols make use of ECG measurements to authenticate a Programmer to an IMD. As noted above, however, both protocols lack rigorous security analysis and have been shown in recent work to have serious cryptographic weaknesses [39]. (We also note that the reported hardware implementation overhead for the IMDGuard protocol greatly exceeds that of H2H.)

Compared with previous PV-based authentication schemes in general, H2H is the first work that: (1) Includes a statistical analysis of the full stochastic ECG waveform to demonstrate bit independence over time; (2) Quantifies and uses the individual error rates of the high-grade random bits to distinguish between honest and adversarial Programmers in an optimal way (via the Neyman-Pearson Lemma); and (3) Offers a formally analyzed PV-based cryptographic device pairing protocol.

7. CONCLUSIONS AND FUTURE DIRECTIONS

This paper addressed the problem of authenticating external medical controllers and programmers to Implantable Medical Devices (IMD). Presently available IMD devices can be wirelessly accessed and even upgraded / controlled by external devices under loose access-control policies, rendering them vulnerable to attack. This threat, and the vital role of most IMDs, argue an urgent need for trustworthy Programmer-to-IMD authentication schemes. The main challenges are a lack of pre-existing keys in emergency and other situations and the fact that IMD resource constraints forbid the use of heavy cryptographic or signal-processing modules with high energy consumption.

We presented the design and implementation of Heart-to-Heart (H2H), a lightweight "touch-to-access" scheme for Programmer-to-IMD authentication. The touch-to-access policy is enforced in H2H by a time-varying biometric, ECG heartbeat data. We performed new statistical analyses of the ECG data, including quan-

tification of the error rates of high entropy bits. H2H draws on these analyses to achieve the first ECG-based authentication scheme that distinguishes honest from adversarial ECG signals in a rigorous statistical model and with a minimal false positive rate for a given false negative bound. We devised a novel cryptographic device pairing protocol for H2H that exploits ECG randomness to secure against active attacks, while satisfying the lightweight implementation requirements and noise margins for reliable authentication. Our end-to-end realization in an ARM Cortex-M3 microcontroller confirmed the practicality and low overhead of H2H for current-generation IMDs.

8. ACKNOWLEDGMENTS

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APPENDIX

A. SECURITY ANALYSIS

In this appendix, we briefly sketch a security analysis of the H2H authentication protocol, outlining a formal model and giving our main theorem with proof sketches. We defer a complete model, analysis, and proofs for the full version of this paper.

A.1 Model overview

Statistical modeling. We model the process of PV sampling in terms of a set $\mathcal{V}$ of PV values and function pair $(\mathsf{sample}, \mathsf{noise})$. We call $\mathcal{M} = (\mathcal{V}; (\mathsf{sample}, \mathsf{noise}))$ the *PV model* for H2H.

At the time of PV reading a *true* PV γ is sampled from $\mathcal{V}$ under a distribution defined by probabilistic function $\mathsf{sample}(t, \tau) \to \gamma \in \mathcal{V}$, where t denotes the sampling time and τ the sampling interval length. We assume that $\mathsf{sample}(t, \tau)$ and $\mathsf{sample}(t + \tau', \tau)$ are independent and identically distributed for any $\tau' \geq \tau$. We also assume that $\mathsf{sample}(t, \tau)$ is identically distributed for any t, i.e., that it's a stationary process. Thus we let $\mathsf{sample}(\cdot, \tau)$ denote a PV sample of duration τ taken at an arbitrary time.

We model noise in PV reading by the IMD and Programmer respectively by $\alpha \leftarrow \mathsf{noise}(\gamma)$ and $\beta \leftarrow \mathsf{noise}(\gamma)$, for probabilistic function $\mathsf{noise} : \mathcal{V} \to \mathcal{V}$. (A model extension can capture different noise in the IMD and Programmer.)

Cryptographic modeling. We treat SecChannel as an ideal functionality. A player P can invoke SecChannel with any other player P' of its choice. The functionality then outputs a unique label $s \in \{0,1\}^k$ to P and P', or else outputs a failure symbol $\perp$. All messages labeled with s are privately delivered between P and P'; an adversary can block messages, but otherwise can't see, modify, or reorder them. Honest players support only one instance of SecChannel at a given time. Recall that we also treat Commit as an ideal functionality, i.e., perfectly hiding and binding.

Adv can at any time cause the Programmer to initate an H2H session or itself initiate an H2H session with the IMD.

Adversarial model. We assume a Programmer and IMD executing serial sessions and uncorrupted by Adv. We define security with respect to an experiment involving an adversary Adv that knows $\mathcal{M}$ and fully controls the channel between the IMD and Programmer. There is a query interface send that communicates messages to the IMD and Programmer. Adv may send arbitrary queries m of the form $\mathsf{send}(entity, m)$ for $entity \in$ (IMD, Programmer). A special query $\mathsf{send}(entity, \texttt{start})$ causes a device to initiate

the H2H protocol, i.e., execute SecChannel. To cause the IMD and Programmer to pair, Adv calls $\mathsf{send}(Programmer, \texttt{start})$, then sends $\mathsf{send}(IMD, \texttt{start})$) from the Programmer to IMD.

Suppose Adv sends at most q_i `start` queries to the IMD and q_r `start` queries to the Programmer over the course of the security experiment. We define $\mathsf{succ}^{H2H}_{\mathsf{Adv}}(q_i, q_r)$ as the probability that Adv causes the IMD to output `accept` for a session where it communicates with Adv on SecChannel.

A.2 Main theorem

We now summarize our main result. First, define:

$$p_1 = max_{a' \in \mathcal{V}}(\mathsf{pr}[\mathsf{dist}(a', a) \leq d \mid a \leftarrow \mathsf{noise}(\gamma), \gamma \leftarrow \mathsf{sample}(\cdot, \tau)]).$$

Here, p_1 is the probability that making an *unconditioned* query, i.e., knowing $\mathcal{M}$ only, Adv can successfully guess a valid PV. (We can think of p_1 as a type of minentropy.)

Similarly, define:

$$p_2 = max_{a', b' \in \mathcal{V}}(\mathsf{pr}[\mathsf{dist}(a', a) \leq d \mid \mathsf{dist}(b', b) > d, a \leftarrow \mathsf{noise}(\gamma), b \leftarrow \mathsf{noise}(\gamma), \gamma \leftarrow \mathsf{sample}(\cdot, \tau)]).$$

Here, p_2 is the maximum probability, given a failed PV guess b' for β, that Adv can guess a valid PV a' for a.

We have earlier presented Lemma 1, which is as follows.

LEMMA 1. *For PV model $\mathcal{M}$, $\mathsf{succ}^{H2H}_{\mathsf{Adv}}(1,1) \leq p_1 + p_2 - p_1 p_2$.*

We now build on Lemma 1, to show that Adv maximizes its probability of success by making $q/2$ pairs of queries to the IMD and Programmer, and that its success probability for each pair of queries is at most $succ^{H2H}_{\mathsf{Adv}}(1,1)$. Theorem 1 results:

THEOREM 1. *Given PV model $\mathcal{M}$ and $q = q_i + q_r$ with even-valued q, $\mathsf{succ}^{H2H}_{\mathsf{Adv}}(q_i, q_r) \leq 1 - (1 - (p_1 + p_2 - p_1 p_2))^{q/2}$.*

Proof: [sketch] Given Lemma 1, it suffices to show that Adv maximizes its probability of success by making $q/2$ pairs of queries to the IMD and Programmer, and that its success probability for each pair of queries is at most $succ^{H2H}_{\mathsf{Adv}}(1,1)$.

Given output `reject`, the IMD waits a full cycle (time τ) before initiating another session (taking input `start`). Suppose, then, that the IMD initiates local session i at time t, and thus reads $\alpha_i \leftarrow \mathsf{noise}(\mathsf{sample}(t, \tau))$. Then the IMD will only initiate a fresh session $i+1$ at time $\geq t + \tau$.

Thus if the Programmer initiates a session with PV β, then β will be independent of α_i provided that β is read at time $t + \tau$ or later. Thus, as the Programmer only initiates a session at time $t + \tau$, any Programmer PV reading β is independent of at least one of α_i or α_{i+1}. In general, then, any PV reading by the Programmer correlates with at most one α_i.

Consequently, can make at most one conditioned query, i.e., query with information about γ, per unconditioned query. It can do so only by initiating overlapping sessions with the IMD and Programmer. Given q queries in total, Adv can create at most $q/2$ such sessions. Thus, $\mathsf{succ}^{H2H}_{\mathsf{Adv}_{q_i,q_r}} \leq 1 - (1 - \mathsf{succ}^{H2H}_{\mathsf{Adv}_{1,1}})^{q/2}$.

A.3 Application to H2H

H2H carries two distinctive properties of uniformity that permit a simplification of Theorem 1. In particular:

- *Uniformly random PVs:* In PV probability model $\mathcal{M}_{H2H}$ for H2H, PVs are distributed uniformly at random (but correlated). That is, $\alpha, \beta \in_U \mathcal{V}$.
- *Uniform regions of validity:* For our Neyman-Pearson-derived distance metric dist_{H2H} in H2H, the number of valid PV guesses β is identical for any α in $\mathcal{V}$. (The distance between two PVs depends on their bit differences, not the PVs' specific bit values.)

Thus we can show (proof omitted):

COROLLARY 1. *Given PV model $\mathcal{M}_{H2H}$ and distance metric dist_{H2H}, and $q = q_i + q_r$ with even-valued q, $\mathsf{succ}^{H2H}_{\mathsf{Adv}}(q_i, q_r) \leq 1 - (1 - 2p_1)^{q/2}$.*