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What is This?

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"This is your heart speaking. Call 911."

Implantable vibrotactile alarms show great potential as early warning devices to prevent damage and death from heart attacks.

By Mary Carol Day & Christopher Young

FEATURE AT A GLANCE:
Early warning for heart attacks could save many lives. We conducted three studies to design and evaluate multimodal alarms and patient training for an implanted heart attack detector. An implanted device provided vibrotactile alarms subcutaneously, and a pager-like device provided auditory and visual alarms. Temporal alarm patterns connoted an urgent emergency alarm ("Call 911") and a less urgent alarm ("See your doctor"). In the third, clinical, study, most patients (94%) correctly responded to the alarms at 1, 3, and 6 months after device implantation. Subcutaneous vibrotactile alarms show great potential for use in critical medical applications.

KEYWORDS:
medical devices, cardiac monitoring, vibration, perceived urgency, medical alarms, temporal alarm patterns

Acute myocardial infarction is a leading cause of mortality in the United States. Annually, more than a million people experience a heart attack, and more than a third of those die before arriving at a hospital. The average symptom-to-hospital time of almost 3 hours has remained the same for more than a decade, despite multiple educational campaigns (e.g., Diercks et al., 2010; Gibson, 2001). Early warnings and elimination of uncertainty so that people seek immediate medical attention could save many lives and prevent heart damage.

Medical progress has been unprecedented in the first decade of the current century. However, communication between medical technology (which tracks real-time physiological functions) and people (caregivers and patients) remains inadequate. Alarms and warnings have long been an important area of investigation for human factors/ergonomics specialists (Stanton, 1994). Research has increased greatly on the use of medical alarms, including vibrotactile alarms, for medical personnel in operating rooms and intensive care units (Edworthy & Hellier, 2006). Vibrotactile alarms, either alone or in combination with visual or auditory alarms, are not missed or ignored by medical staff as frequently as are visual or auditory alarms (e.g., Ng, Man, Fels, Dumant, & Ansermino, 2005).

Far less research has focused on the use of alarms to warn *patients* of significant medical events. Advancing technology now enables 24-hour monitoring outside the hospital, so patients themselves (as well as doctors) can be warned of significant events. Because the alarm might occur at any time, an alert provided by an implanted medical device, unlike a portable device, could be especially beneficial.

Auditory alarms are currently provided with some implantable cardioverter-defibrillators, but research has indicated that many patients do not hear the alarms, perhaps because of age-related hearing loss or ambient noise (Simons, Feigenblum, Nemirovsky, & Simons, 2009). Subcutaneous vibrotactile alarms could be a viable alternative when used alone or in combination with auditory alarms.

Alarm design is critical because successful alerting, accurate patient identification of alarm type, and appropriate patient response can mean the difference between life and death. In this article, we describe human factors/ergonomics work on alarms for a medical device that is designed to alert high-risk cardiac patients about an impending or immediate heart attack (Fischell et al., 2010). The alarms are multimodal and provide redundant subcutaneous vibrotactile, auditory, and visual information. Here we briefly summarize three studies on the design and validation of subcutaneous vibrotactile patient alarms: (a) a study of alarm temporal patterns and vibrotactile magnitudes, (b) a study of learning and memory for the alarms, and (c) the initial clinical study with patients at high risk of a heart attack.

DESIGN GOALS FOR THE ANGELMED GUARDIAN®

The medical device described in this article (AngelMed Guardian®) offers two levels of alarm urgency. A high-priority alarm ("Emergency") indicates that the patient may be having a heart attack and should call 911. A low-priority alarm ("See Doctor") indicates that a condition has been

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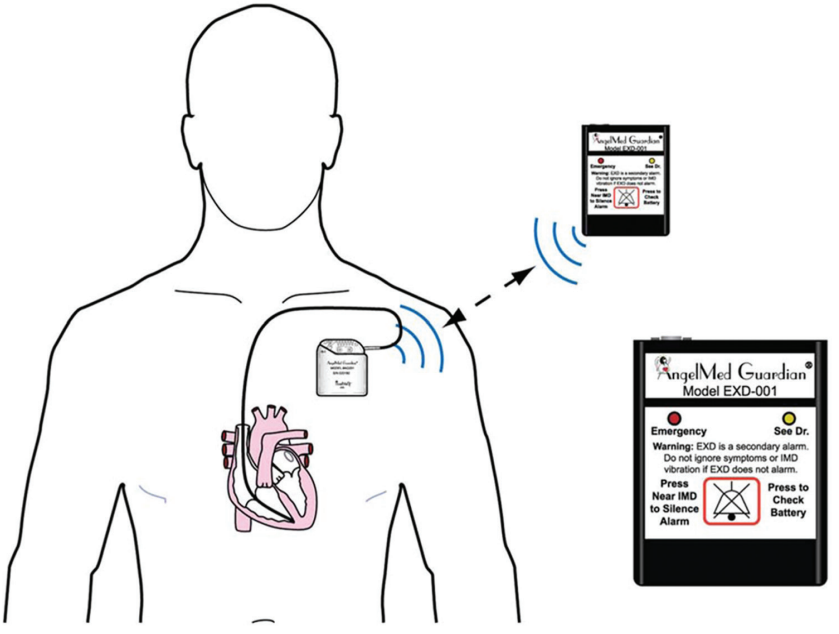

Figure 1. The AngelMed Guardian® implanted medical device (IMD) and external device (EXD). The IMD provides vibrotactile alarms, and the EXD provides auditory and visual alarms. The alarms can be silenced after 30 seconds when the patient places the EXD over the left chest and presses the EXD's alarm silence button.

detected that requires a doctor visit within 48 hours (e.g., a device setting needs adjustment). Clearly, the Emergency alarm is more urgent than the See Doctor alarm.

The alarms are provided by both an implanted medical device (IMD) similar in size to a pacemaker, which is placed in the upper left chest, and an external device (EXD), similar in size to a pager (Figure 1). The IMD continuously monitors the heart's electrical activity. When it detects an alarm event, it vibrates in one of two temporal patterns, each corresponding to one of the alarms, and wirelessly communicates with the EXD. The EXD then emits an auditory alarm and flashes a red or yellow light-emitting diode (LED), labeled *Emergency* or *See Doctor*.

Our primary goals were to design the Emergency and See Doctor alarms so that they

(a) are perceptible (i.e., are felt and heard),
(b) have distinct and identifiable temporal patterns,
(c) have perceptual properties that connote their meaning (i.e., their level of urgency), and
(d) are easily learned and remembered.

The highest priority was to design the two subcutaneous vibrotactile alarms delivered by the implanted IMD. The IMD's vibrotactile alarms are critical because the IMD cannot be left behind, as the EXD can. Also, implanted vibrotactile alarms (of appropriate magnitude) should always be perceptible, unlike the EXD's auditory alarm, which might not be heard if it is masked by noise or heavy clothing or if the patient is hearing impaired. Neither previous research nor standards have provided guidance on the design of temporal, vibrotactile alarms.

PREVIOUS RESEARCH AND GUIDELINES RELEVANT TO ALARM DESIGN

In 2004, during the early planning of these studies, we could find no information – either published or through conversations with experts – on the use of subcutaneous, temporal vibrotactile patterns for alarms. Furthermore, although cutaneous vibration was being used as an alarm in cell phones, there was little research exploring the use of two or more temporal vibrotactile patterns to signal *different* alarms. We found it encouraging that van Veen and van Erp (2003) noted that people can perceive and describe temporal patterns of vibration, although training may be necessary.

The basic literature documents that vibration perception varies with age, individual differences, and body location (Goble, Collins, & Cholewiak, 1996; Stuart, Turman, Shaw, Walsh, & Nguyen, 2003). Studies also report that vibration sensitivity may decrease in people with diabetes, who are at increased risk of heart disease (Bergenheim, Borssen, & Lathner, 1992). These data indicate that different vibration magnitudes should be used to accommodate sensitivity differences related to age, disease, and other individual differences. Alarms should be strong enough to be noticed but not painful. Also, because different parts of the body differ in vibration sensitivity, vibrotactile perception should be tested on the skin above the area where the medical device would be implanted.

Both frequency and displacement (that is, the maximum amplitude/distance, peak to peak, that the vibrating object moves during one vibration cycle) influence detection thresholds and perceived magnitude of cutaneous vibration (see Jones & Sarter, 2008, for a review). The greatest sensitivity is attained at frequencies between 150 Hz and 300 Hz, and perceived magnitude increases with greater displacement. However, frequency and displacement interact to determine perceived magnitude; for example, higher and lower frequencies may require greater displacement to match the perceived magnitude of vibration at an optimal frequency.

Time parameters are also important. A vibrotactile stimulus must occur for at least 200 milliseconds to attain its highest perceived magnitude, and interstimulus intervals should be at least 100 to 200 milliseconds to provide distinct pulses.

In contrast to the limited literature on vibrotactile warnings, there is a large body of literature on auditory warnings, with specific information on characteristics that affect

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perceived urgency. Perceived urgency increases with speed (shorter inter-pulse intervals), with density (that is, the percentage of the alarm during which sound is present), and with the number of repeating pulses (Edworthy, 1994; Marshall, Lee, & Austria, 2001). An international standard for medical alarms (IEC 60601-1-8; International Electrotechnical Commission [IEC], 2006) provides specific guidelines, consistent with the urgency literature, for creating high-, medium-, and low-priority *auditory* alarms. According to the IEC standard, our Emergency and See Doctor alarms are high-priority and low-priority alarms, respectively. For a high-priority alarm, the standard specifies a repeating pattern of 10 pulses of equal duration with interpulse intervals providing a rhythm of 3-2-3-2, followed by a longer interburst interval (Figure 2, top). A low-priority alarm comprises a repeating pattern of 1 or 2 pulses with an interburst interval longer than that for the high-priority alarm (Figure 2, bottom).

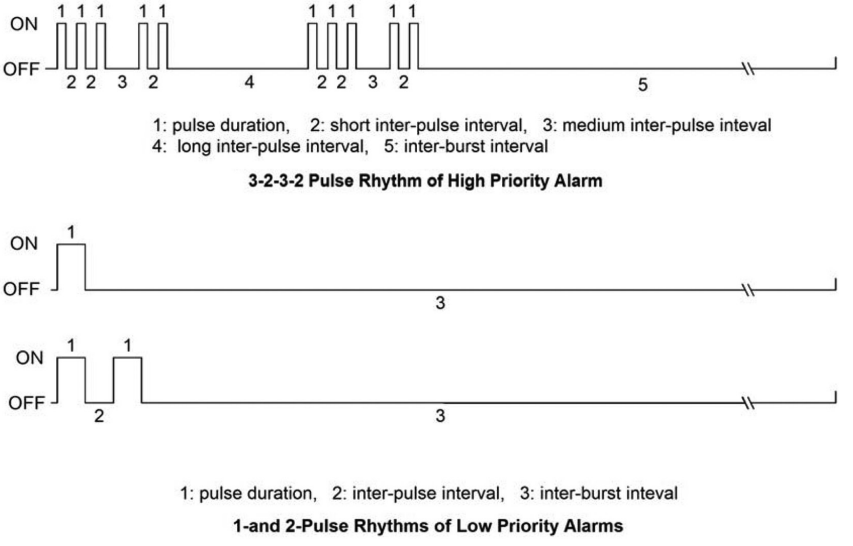

Figure 2. High- and low-priority temporal patterns specified in IEC 60601-1-8. The top panel shows the 3-2-3-2 pattern of the high-priority alarm, and the bottom panel shows the one- and two-pulse patterns of the low-priority alarm.

IEC 60601-1-8 also provides guidelines for colors and flash rates for visual alarms. High priority (Emergency) is red, low priority (See Doctor) is yellow, and the high priority flash rate (in Hz) is faster than the medium- and low-priority flash rates. Colors and flash rates for the EXD's visual alarms conformed to the IEC standards, except that the low-priority flash rate was based on the guidelines for a medium-priority alarm. The guidelines specify that a low-priority alarm should be on continuously, but we opted to use a flashing LED for the low-priority alarm because it would be more noticeable.

STUDY 1: TEMPORAL ALARM PATTERNS AND VIBROTACTILE MAGNITUDE

In our first study, we compared three high-priority and three low-priority temporal patterns for the Emergency and See Doctor alarms, respectively, and evaluated three magnitudes for the vibrotactile alarms.

We used the rhythm in the IEC auditory guidelines to vary perceived urgency for high- and low-priority alarms. The high-priority patterns comprised 10 pulses in a 3-2-3-2 rhythm, and the low-priority patterns comprised 2 longer pulses. However, we needed to lengthen the pulse durations and interpulse intervals specified in the IEC standard to make the pulses clear and distinct in the vibrotactile modality. We selected three candidate high-priority and three candidate low-priority patterns on the basis of pilot study results.

Tables 1 and 2 present the temporal parameters of the high- and low-priority patterns, respectively. The patterns differed in pulse durations and interpulse intervals. We used the same rhythm and time parameters for the vibrotactile and auditory alarms to provide not only multimodal but also cross-modal alarms (i.e., the same parameters were conveyed via different modalities).

To vary vibration magnitude, we used pulse width modulation, or duty cycle (i.e., the percentage of time that current is supplied to the DC vibration motor during each 5-millisecond period of a pulse). Because frequency and displacement could not be varied independently and because displacement decreases as frequency increases, we needed to find duty cycles for which the interaction of frequency and displacement provided differences in perceived vibration magnitude. Three duty cycles were tested: low (40%), medium (55%), and high (95%).

For the auditory alarms, we used a 500-Hz frequency. Research has indicated that age-related hearing losses are greater above 500 Hz than at or below that frequency (Crocker, 1997).

Procedure and results. For this study, 20 people (6 males, 14 females) between the ages of 55 and 74 years participated. The vibrotactile patterns were presented against the skin of the participant's chest over the area where an IMD would be implanted. An IMD "holster" made of Velcro® and Ace™ bandages held the IMD in place. We controlled vibrotactile temporal patterns and duty cycles using wireless radio communication between a computer and the IMD. During vibrotactile testing, participants listened to music through headphones to mask auditory cues produced by the vibration motor. An EXD, also controlled by computer, delivered the

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Table 1. Temporal Parameters for High-Priority Patterns

	Duration (in milliseconds)		
Temporal Parameter	Fastest	Middle	Slowest
Pulse duration	300	300	400
Short interpulse interval	300	400	500
Medium interpulse interval	900	1,100	1,400
Long interpulse interval	1,800	2,000	2,500
Interburst interval	5,000	5,000	6,000

Table 2. Temporal Parameters for Low-Priority Patterns

	Duration (in milliseconds)		
Temporal Parameter	Fastest	Middle	Slowest
Pulse duration	500	600	700
Interpulse interval	600	800	800
Interburst interval	6,000	6,000	6,000

auditory patterns. In this study, the EXD did not provide visual alarms.

Ratings and selection of vibration magnitude. First, we asked participants to rate the strength (1 = *extremely weak*, 7 = *extremely strong*) of a 6-pulse alarm delivered at the three different duty cycles; 6 pulses is midway between the 2 and 10 pulses of the low- and high-priority alarms. Then we presented each duty cycle again, and participants rated the *appropriateness* of the strength for indicating a heart problem. Finally, using a paired comparison task, we asked participants to select their preferred strength for an alarm. This selection was then used in the remaining vibrotactile tasks of the study.

Different duty cycles created different perceived vibration magnitudes. Participants rated the medium and high duty cycles as stronger than the low. Participants also rated the high duty cycle as more appropriate for the alarm than the low duty cycle, but there was no significant difference between the medium duty cycle and the other two. It is important to note that 65% of the participants preferred the high duty cycle, 25% the medium, and 10% the low, which confirms the importance of offering different duty cycles to accommodate individual differences.

Vibrotactile alarms: Urgency and alarm categorization. We used two measures to investigate whether the three high- and three low-priority alarms differed in perceived urgency. First, each of the six alarms was presented for about 30 seconds, and participants rated each on a 7-point scale (1 = *not at all urgent*, 7 = *extremely urgent*). After the urgency ratings, participants were told for the first time that one alarm pattern would be used for an Emergency alarm, which means "Call 911 immediately," and one for a See Doctor alarm, which means "See the doctor within a day or two." After each of the six alarms was played, participants indicated whether they thought it should be Emergency or See Doctor.

The results clearly indicated that the high-priority temporal patterns conveyed a greater sense of urgency than the low-priority patterns. Urgency ratings were significantly higher for the high-priority ($M = 4.9$) than the low-priority ($M = 3.0$) patterns, with no significant differences between the three high-priority and between the three low-priority patterns (Figure 3). Furthermore, each pattern tended to connote its meaning. The percentage of correct categorizations for each pattern – with no prior instruction – ranged from 75% to 100%, which is significantly greater than chance.

Auditory alarms: Urgency and alarm categorization. Following the same procedures used for the vibrotactile alarms, participants provided urgency ratings and Emergency

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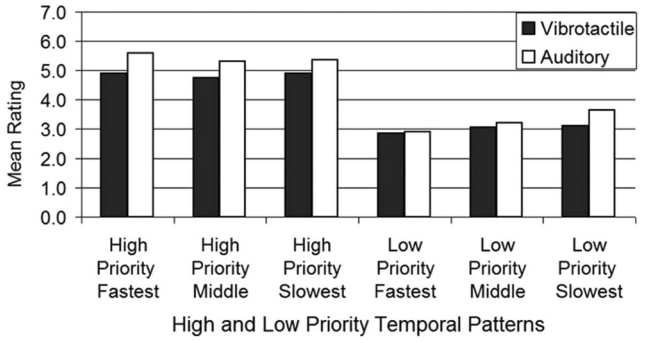

Figure 3. Urgency ratings for vibrotactile and auditory high- and low-priority patterns. Ratings were made on a 7-point scale (1 = *not at all urgent*, 7 = *extremely urgent*). The ratings for the vibrotactile and auditory patterns were not statistically compared but are shown together to indicate the similar ratings for high- and low-priority patterns in each modality.

or See Doctor categorizations for the three high- and three low-priority patterns presented in the auditory modality.

The results paralleled those for the vibrotactile alarms. The urgency ratings for the high-priority patterns ($M = 5.4$) were significantly higher than for the low-priority patterns ($M = 3.3$), with no significant differences between the three high-priority and between the three low-priority patterns (Figure 3). The percentage of correct categorizations for each pattern – with no instruction – ranged from 85% to 100%.

Preferred vibrotactile temporal patterns. Participants were then asked which of the three high-priority patterns and which of the three low-priority patterns they preferred. Their choices and the reasons given helped us specify the final patterns.

A 5-minute vibrotactile alarm. Finally, we wanted to ensure that the participant's preferred high-priority temporal pattern and preferred duty cycle did not cause pain or extreme discomfort across a 5-minute period, which is the longest time an alarm would be on continuously. We did not want the characteristics of the alarm per se to add to a patient's stress.

Each participant's preferred high-priority vibrotactile pattern was played at his or her preferred duty cycle, simultaneously with the auditory alarm of the same temporal pattern. The auditory alarm was played simultaneously because during the pilot study, participants had said that the vibrotactile alarm felt stronger when they heard the auditory alarm and/or the vibration motor. Ratings on a 7-point scale indicated little or no discomfort, stress, or pain.

Discussion and conclusions. Perceived strength of the vibrotactile alarm was successfully varied by duty cycle. Within the range of frequency and displacement provided by the vibration motor, perceived strength increased as duty cycle increased.

The high- and low-priority patterns differed significantly in both urgency and connotation. In both vibrotactile and auditory modalities, (a) the high-priority patterns conveyed more urgency than the low-priority patterns, and (b) prior to training, the high- and low-priority patterns were correctly categorized by most participants as Emergency or See Doctor, respectively. These results suggested that patients would easily learn and remember the alarm patterns.

Our basic approach was successful for designing both duty cycles that differed in perceived vibrotactile strength and temporal patterns that differed in perceived urgency. The results also suggested possible improvements. Many participants mentioned that the lower duty cycles felt very weak, so we increased the low duty cycle from 40% to 45% and the medium duty cycle from 55% to 70%. Also, because we wanted the differences between the low- and high-priority patterns to be a large as possible, we (a) shortened some of the interpulse intervals to *increase* the perceived urgency of the high-priority pattern and (b) reduced the number of pulses from two to one and lengthened the interval between pulses to *decrease* the perceived urgency of the low-priority pattern. The final temporal patterns are shown in Table 3.

Table 3. Final Temporal Parameters for High-Priority (Emergency) and Low-Priority (See Doctor) Patterns

	Duration (in milliseconds)	
Temporal Parameter	High Priority (Emergency)	Low Priority (See Doctor)
Pulse duration	300	600
Short interpulse interval	400	
Medium interpulse interval	1,100	
Long interpulse interval	1,500	
Interburst interval	2,900	7,400

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Ideally, we would have conducted another study to evaluate our modifications to the alarm patterns and magnitudes. Instead, given our development schedule, we incorporated the changes in our next study, assuming that any problems would show up then.

STUDY 2: TRAINING, LEARNING, AND MEMORY FOR ALARM PATTERNS

If patients always kept the EXD with them and looked at the LEDs when they felt or heard an alarm, they could determine the type of alarm from the LED labels (see Figure 1, page x). However, patients may not always have the EXD with them. For the alarms to be effective, patients must be able to learn the meanings of the high- and low-priority temporal patterns, remember them over time, and know how to respond to them – even in the absence of the EXD. In this next study, we assessed learning and memory for vibrotactile alarms delivered by the IMD and for multimodal alarms delivered by the IMD and EXD together. Simultaneously, we evaluated the effectiveness of the training program designed for patients.

Pilot study. During a pilot study, we discovered that participants identified the alarms by the required response (i.e., call 911 or make a doctor's appointment) rather than by labels (Emergency or See Doctor). Consequently, we revised the training and evaluation procedures to highlight the action required rather than the label. For example, after an alarm, the participant was asked, "What would you do if this alarm occurred?" rather than "What is this alarm?"

We also learned that participants perceived and described the high-priority 10-pulse alarm (3-2-3-2) as a 5-pulse alarm (3-2). Therefore, we adjusted our training and described the high-priority pattern as a repeating 5-pulse pattern to be consistent with the participants' perception.

Patient training. Patient training was designed to do the following:

(a) Help patients accurately impose structure on the two vibrotactile patterns. Participants had difficulty recognizing and describing the differences between the two patterns when they were described only abstractly; for example, a 3-2 rhythm. Therefore, we verbalized each pattern before playing it (e.g., "The Emergency alarm is five short vibrations in a 3-2 pattern, like 'brrr-brrr-brrr brrr-brrr'").
(b) Have patients describe the alarms orally. We found that people initially had difficulty describing the pattern after feeling it, even though they were sure they "had it." Performance improved when participants provided an oral description.
(c) Provide repetition of the vibrotactile alarms to ensure learning. Throughout the training protocol, participants were exposed to each vibrotactile alarm pattern seven times. After they had learned to recognize the two vibrotactile patterns, they rapidly learned the corresponding auditory patterns.
(d) Have patients select their preferred vibration strength to respond to individual differences in vibration perception.
(e) Teach patients to respond appropriately to the EXD's auditory and visual alarms and to turn off the alarms using the EXD button.
(f) Ensure that patients will call 911 if they cannot identify the alarm pattern.

Methodology. For this study, 44 participants (22 male and 22 female; half between 55 and 64 years of age and half between age 65 and 82) were given the instructions described previously, which a patient would receive after IMD implantation. An IMD holster held the IMD against the participant's skin on the upper left chest. During vibrotactile-only training and testing, participants wore headphones with music to mask the sound of the vibration motor. Headphones were removed during training for multimodal alarms (IMD+EXD).

For the alarms to be effective, patients must be able to learn the meanings of the temporal patterns and know how to respond to them.

Ten minutes after the end of training, participants were given a learning test in which an alarm was presented. We asked them what they would do if that alarm occurred. Emergency and See Doctor alarms were presented in both IMD-only (vibrotactile) and IMD+EXD (vibrotactile-auditory-visual) modalities. Following the learning test, participants rated the ease of telling the difference between the two alarms in both modalities. Then, 6 weeks later, the participants returned for the memory test, which followed the same procedure as the learning test.

Results. On the learning test, 100% of the participants correctly responded to both alarm types (Emergency and See Doctor) presented on the IMD-only and on the IMD+EXD. The mean rating for ease of discrimination on a 1-to-7 scale (1 = *extremely easy*, 7 = *extremely difficult*) was 1.1 for the IMD-only alarms and 1.3 for the IMD+EXD alarms.

On the 6-week memory test, 95% of the participants correctly stated how they would respond to the multimodal IMD+EXD alarms; the percentage correct was not significantly different from our target of 95% accuracy. However, only 74% correctly responded to the IMD-only alarms, which was significantly lower than our target of 90% accuracy.

As in the first study, more participants selected the higher than the lowest duty cycles: 61%, 33%, and 6% for high, medium, and low, respectively.

Discussion and conclusions. The 74% accuracy rate for response to the IMD-only alarms was of some concern. However, our participants differed significantly in motivation from "real" patients: They did not have a life-threatening

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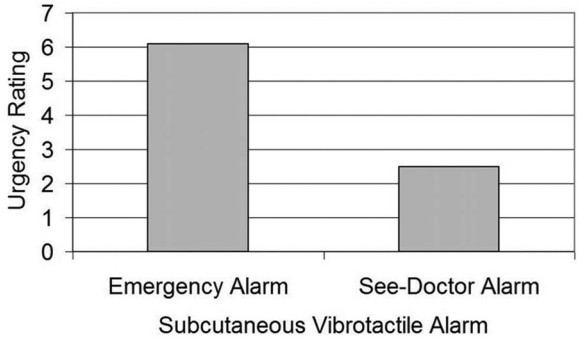

Figure 4. Urgency ratings for the subcutaneous vibrotactile Emergency and See Doctor alarms after IMD implantation. Ratings were made on a 7-point scale (1 = *not at all urgent*, 7 = *extremely urgent*).

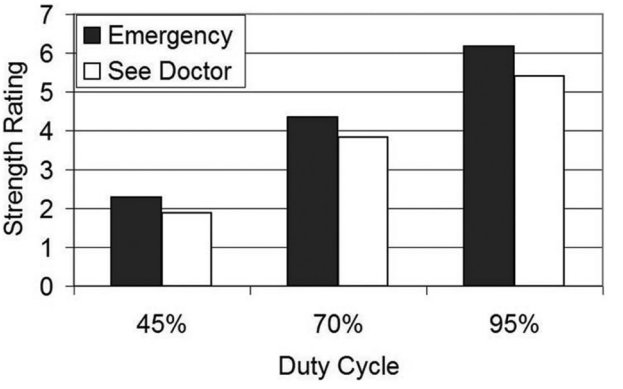

Figure 5. Strength ratings for subcutaneous vibrotactile alarms after IMD implantation. Ratings were made on a 7-point scale (1 = *extremely weak*, 7 = *extremely strong*).

heart condition, they had not been given a patient manual to review, and most said they had not thought about the alarms since training.

It was not clear whether or how the temporal patterns could be made more distinct or to better convey their meaning, so we entered our first clinical trial using the temporal patterns, magnitudes, and patient training that were evaluated in this second study.

STUDY 3: CLINICAL TRIAL

Our first clinical trial was conducted with 17 (12 male, 5 female) patients at high risk for heart attack, who ranged in age from 41 to 70 years. We collected data before and immediately after patient alarm training and at 1-, 3-, and 6-month follow-up visits.

Subcutaneous vibrotactile perception before training. After IMD implantation but before patient training, we had our first opportunity to collect data on *subcutaneous vibrotactile perception.* This was the first time the patients had felt the subcutaneous alarms. First, each of the Emergency and See Doctor vibrotactile alarms was presented for about 30 seconds at the medium (70%) duty cycle. After each alarm, patients rated urgency on 7-point scale (1 = *not at all urgent*, 7 = *extremely urgent*). Urgency ratings were significantly higher for the Emergency alarm ($M = 6.1$) than for the See Doctor alarm ($M = 2.5$). See Figure 4.

Second, the two alarms were played again at the medium duty cycle, and patients rated "how easy it is to tell the difference between the two alarms" on a 7-point scale (1 = *extremely easy*, 7 = *extremely difficult*). Patients thought the alarms were very distinct ($M = 1.3$). Third, the two alarms were played at the low, medium, and high duty cycles (45%, 70%, and 95%, respectively), and patients rated the alarm strength for each on a 7-point scale (1 = *extremely weak*, 7 = *extremely strong*). Strength ratings increased with duty cycle, and each duty cycle was significantly different from the others for both alarm types (Figure 5).

Finally, we explained the meanings (but not the temporal patterns) of the two alarms to the patients. Each alarm was then presented, and the patient was asked whether it was an Emergency or a See Doctor alarm. All patients correctly categorized the two vibrotactile temporal patterns as Emergency or See Doctor.

These results confirmed that the subcutaneous vibrotactile alarms were distinct, varied in perceived urgency, and connoted their meanings. Also, duty cycle successfully varied perceived vibration strength for subcutaneous alarms.

Patient training and follow-up visits. After the initial testing, clinical staff trained patients using the patient training procedure evaluated in Study 2. All patients learned how to respond to the alarms when alerts were presented on the IMD-only (vibrotactile) and on the IMD+EXD (vibrotactile, auditory, and visual). After training, all were certain they could easily identify the alarms in the future. Patients took home a patient manual with instructions about the alarms and other aspects of the medical device, as well as a patient ID card with diagrams of the alarm patterns.

Following training, patients returned for follow-up visits at 1, 3, and 6 months. At each visit, medical staff assessed whether patients could accurately identify the two alarms and whether there were any changes in strength ratings or preference for duty cycle, perhaps as a result of postsurgical healing.

At the beginning of each patient visit, the two alarms were presented on the IMD only and the IMD+EXD, and patients were asked how they would respond. On all of the follow-up visits, all but 1 of the 17 patients correctly identified the alarms on both the IMD only and on the IMD+EXD. (It was always the same patient who was incorrect; during follow-up visits, his behavior suggested possible undiagnosed cognitive difficulties.) Thus, across patients, accuracy never fell below 94%.

For strength ratings, each alarm was presented at each of the three duty cycles, and patients rated them on a 7-point

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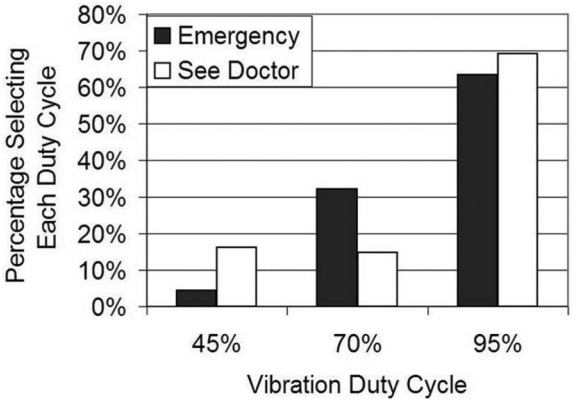

Figure 6. Percentage of patients selecting each vibration duty cycle for each alarm, averaged across 6 months.

scale (1 = *extremely weak*, 7 = *extremely strong*). Overall, vibration strength ratings were consistent over time. Also, patients' preferences for a particular vibration strength did not change significantly across the 6-month period for either the Emergency or the See Doctor alarm. Figure 6 shows the duty cycles selected for each alarm, averaged across the four patient visits.

WHAT WE LEARNED

Most significantly, we found that two *subcutaneous* and *temporal* vibrotactile patterns can successfully provide alarms for a critical medical application. To our knowledge, this is the first time that two different subcutaneous, temporal vibrotactile patterns have been used to convey information.

A growing body of research has indicated the value of vibrotactile communication in many contexts, including medical care, combat, mobile devices, and even radiation detection (Herring & Hallbeck, 2009). In noisy or high-workload environments, vibrotactile cues may be more effective than auditory or visual cues in attracting and directing attention as well as in conveying basic information (Jones & Sarter, 2008; Ng et al., 2005). In addition, such cues offer use of an alternative communication channel when auditory or visual channels are overloaded. Much of this research has involved wearable vibrotactile devices. The work reported here extends the findings on cutaneous vibrotactile communication by demonstrating that *subcutaneous* vibrotactile temporal patterns can be effectively used for alerting and communication via implanted devices.

Because of the critical nature of these medical alarms, it was important to optimize both alerting and communication functions. Therefore, the patient alarms were designed to be multimodal: vibrotactile, auditory, and visual. Furthermore, the vibrotactile and auditory alarms were simultaneous and congruent (i.e., they conveyed the same information at the same time). Research with other applications has shown faster response times and improved performance with congruent multimodal stimuli than with single-modality stimuli (Merlo, Gilson, & Hancock, 2008).

In addition to being congruent, the vibrotactile and auditory alarms were cross-modal – in other words, they used the same *amodal* parameters (i.e., parameters available in both modalities) to convey information (Lewkowicz, 2000). The rhythm, speed, and density of the Emergency and See Doctor alarms were the same in the vibrotactile and the auditory modality. In both modalities, urgency ratings were significantly higher for Emergency than for See Doctor alarms, indicating that these amodal parameters had the same effect in both auditory and vibrotactile modalities.

Perceptual enhancement is another potential advantage for simultaneous, congruent multimodal alarms that use the same amodal parameters. Our participants and patients sometimes mentioned that the vibrotactile alarm felt stronger when they simultaneously heard the auditory alarm or the sound of the vibration motor. In fact, others have reported that multisensory integration can result in super-additive outcomes – that is, outcomes larger than the sum of their component parts (Spence & Ho, 2008). Furthermore, Laurienti, Burdette, Maldjian, and Wallace (2006) found that because sensory sensitivity declines with age, older adults benefit more than younger adults from congruent information provided in multiple sensory modalities. Thus, the use of simultaneous, congruent amodal vibrotactile and auditory alarms may be especially important for older adults.

Our results provide support for adjusting vibration magnitude on a patient-by-patient basis to accommodate individual, disease-related, and age differences in vibration sensitivity. Each of the three duty cycles was selected by some of the patients. Within the range of frequencies and displacement offered by our DC vibration motor, perceived magnitude increased as duty cycle increased. However, because both frequency and displacement affect perceived magnitude, subjective testing is required for motors in which frequency and displacement vary simultaneously.

We found that in a clinical setting, the vibrotactile alarms can be easily learned and remembered after 6 months. In Studies 1 and 2, we identified several procedures that may have contributed to successful patient training:

- Provide instructions to help the patient structure the vibrotactile alarm; for example, "The alarm is a 3-2 pattern like brrr-brrr-brrr brrr-brrr."
- Provide sufficient repetitions of the vibrotactile alarm so that the patient can learn to feel the structure of the pattern.
- Describe the alarm as it is perceived by the user; for example, users experienced two 5-pulse patterns rather than a 10-pulse pattern for the Emergency alarm.
- Train patients for the response to alarms (e.g., call 911) rather than for the alarm label (e.g., Emergency).

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We used existing standards and guidelines to the extent reasonable. The IEC 60601-1-8 standard for medical alarms provided specifications for visual alarms and a starting point for vibrotactile and auditory alarms, and FDA guidances highlighted important processes for usability engineering in a medical environment. The human factors/ergonomics experts at the FDA provided feedback at significant junctures in the planning and conduct of our HF/E research. Their feedback improved our alarm research and design and undoubtedly contributed to the approval of our first clinical trial.

The studies reported here demonstrate the value of HF/E expertise applied at key phases in the design of medical devices. Initial basic research and subsequent evaluation in simulated use studies resulted in medical alarms that were later shown to work for patients at risk of heart attacks. It is significant that this approach has been successful in the design of a product that will save lives.

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