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A computationally efficient formal method for discovering simultaneous masking in medical alarms

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Keywords: Medical alarms Masking Psychoacoustics Formal methods Model checking	Numerous patient injuries and deaths have been caused by medical practitioners failing to respond to medical alarms. Simultaneous masking, where concurrently sounding medical alarms result in one or more being unhearable, is partially responsible for this problem. In previous work, we introduced a computational formal method capable of proving (formally verifying) if masking could occur in a modeled configuration of medical alarms. However, the scalability of the method limited the applicability and completeness of its analyses. In the work presented here, we show how we re-implemented the method with a series of realistic and scralability of the new version of the method with a series of realistic and scralability of the new version of the method with a series of realistic and scralability of the new version of the method with a series of realistic and scralability of the new version of the method with a series of realistic and scralability of the new version of the method with a series of realistic and scralability of the new version of the method with a series of realistic and scralability of the new version of the method with a series of realistic and scralability of the new version of the method with a series of realistic and scralability of the new version of the method with a series of realistic and scralability of the new version of the method with a series of realistic and scralability of the new version of the method with a series of realistic and scralability of the new version of the method with a series of realistic and scralability of the new version
	case studies. Our results show that the new version of the method replicates and improves detection capabilities compared to the legacy method and does so with significant reductions in verification times. We discuss the

patient safety implications of our results and explore directions for future research.

1. Introduction

There are a number of problems with auditory medical alarms that can make them difficult to hear and respond to [25,13]. According to the Pennsylvania Patient Safety Authority [24], there have been 194 documented problems with operators failing to properly respond to telemetry monitoring alerts between June 2004 and December 2008, including 12 deaths. According to a 2013 Sentinel Event Alert, 98 alarm-related non-response incidents were reported from January 2009 to June 2012. Eighty of these produced patient death, 13 resulted in a "permanent loss of function," and 5 caused patient hospital stays to be extended [57].

These problems are directly related to the fact that medical alarms sound at rates and in numbers that are incompatible with human sensory, perceptual, and cognitive capabilities [25,17,62,57,43]. For example, the Joint Commission [57] found that, in one day, hundreds of alarms can be produced by a single patient. This aggregates into tens of thousands of alarms sound daily across a given hospital. Because of these issues and the difficulties hospitals have had in solving them, the ECRI Institute has identified medical alarms as one of the most significant technological hazards to patient safety for more than a decade [23,53].

Problems with the design of medical alarm auditory parameters are

largely acknowledged as a contributor to these problems [23,61,58,57]. In particular, the Joint Commission's 2014 National Patient Safety Goal (NPSG) to "improve the safety of clinical alarm systems" claimed that "individual alarm signals are difficult to detect" [58].

One problem that can make it difficult for humans to respond to medical alarms is simultaneous masking. In simultaneous masking, sounds playing in parallel can interact in ways that prevents humans from hearing one of or more of them due to limitations of the human sensory system [30]. A number of researchers have acknowledged that simultaneous masking is a problem with medical alarms and at least partially responsible for non-responses [28,46,41,27,26,49,48]. Furthermore, experimental results do indeed show that simultaneous masking exists in modern medical environments. Momtahan et al. [47], who analyzed 26 alarms from an operating room and 23 from an intensive care unit, found 25 pairs of alarms where one could be completely masked by the other. Toor et al. [59], discovered low priority sounds present in an operating room could easily mask higher priority alarms. It is important to note that these analyses only partially elucidate the problem because neither accounted for the additive effect of masking: where a sound can be masked by the interaction of multiple simultaneously playing sounds. Medical alarms (including those in the international standard [40]) are usually represented as melodies (patterns) of tonal sounds. These are particularly susceptible to

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simultaneous masking [30,12]. Given that the probability of masking increases with the number of concurrently sounding alarms [39,12,65], the sheer number of alarms in modern medical environments [56] practically assures that masking is occurring.

Even with these results, the preponderance of medical alarm safety research has focused on other problems [25]. This is likely a symptom of the complexity of the masking problem. Specifically, it can be extremely difficult to detect auditory masking experimentally because it may only occur for particular interactions of multiple, concurrentlysounding medical alarms. Given the number of possible medical alarms, overlaps between them, and the masking potential associated with additive masking, it is practically impossible to evaluate every alarm configuration to find potential masking experimentally.

To address this problem, we developed a computational method [35,34,36,11] that can detect masking in configurations of tonal medical alarms. The method uses a novel combination of psychoacoustics and model checking. The psychoacoustics describe simultaneous masking mathematically by relating sounds' frequency/tone and volume to the biologically-grounded masking effect the sounds have [12,5,52,2,15,14]. Model checking is an automated approach for performing mathematical proofs (a process called formal verification) on models of concurrent systems [16]. When these technologies are used together in our method, an analyst can model the sounding behavior of multiple alarms and use model checking to prove whether the represented alarms can mask each other. This method has been used to analyze real medical alarm configurations [36,11]. However, these analyses could take days to analyze even one alarm. Furthermore, the nature of the verification process limited the number of alarm interactions that could be considered in a proof. Thus, the analyses could conceivably miss interaction problems.

In the research presented here, we describe an improved version of our method. This improves its masking detection capabilities while simultaneously improving its scalability. Below we provide the necessary background to understand the different versions of our methods. We then present an updated version of the method and report results that demonstrate its improved scalability and analysis capabilities with both synthetic and realistic applications. We ultimately discuss the implications of our results and explore avenues of future research.

2. Background

Below, we review the relevant research on model checking, the psychoacoustics of simultaneous masking, and our method.

2.1. Model checking

Model checking comes from the computer science field of "formal methods". In this context, formal methods are rigorous mathematical languages and techniques for specifying, modeling, and verifying systems [64]. Specifications describe desirable system properties, systems are modeled using mathematical languages, and verification mathematically proves whether or not the model satisfies the specification.

Model checking performs formal verification automatically [16]. A model describes a system's behavior, usually as a finite state machine: model variables with particular values represent state and changes in variable values (state) represent transitions. Specification properties are typically represented in a temporal logic [29], which use Boolean algebra, temporal operators, and system model variables to assert desirable system conditions. Verification processes prove whether the model satisfies the specification by exhaustively searching through the system model's statespace looking for violations. If the specification property proves to be true, the model checker returns a confirmation. If the property does not hold, the model checker returns an execution trace through the model called a counterexample. This shows exactly how the specification was violated. Model checking is especially good at discovering problems in systems with concurrency, where system elements can interact in ways unanticipated by designers and analysts [33]. Model checking is typically in the evaluation of discrete systems (where state is easily represented by discrete, categorical or ordinal variables). However, hybrid modeling and analysis techniques can account for continuous state variables [21,38,50]. They do this by mapping discrete model states (like the sounding state of an alarm) to continuous, real-valued quantities. For example, when using timed automata [1,21], every model discrete state is assigned a time represented by a real number.

Model checking's major limitation is scalability. As concurrent elements are added to a formal model, the size of the model's statespace increases exponentially [16]. This "state explosion problem" can lead to situations where the model takes too long or is too big to verify. Because of this, analysts will often use abstraction techniques to model the systems they want to analyze [45].

Even with this limitation, model checking has demonstrated its utility for a variety of applications, especially for computer hardware and software [64]. Researchers have used model checking to successfully find and correct human factors issues in automated systems [10,20,63,6,51] and medical systems [4,3,7–9,54,60]. However, outside of our previous efforts on alarm masking modeling and detection [35,34,36,11], no work has used model checking to find safety problems associated with human sensation and perception. Below we describe how our previous efforts worked. However, before we can do this, we need to explain the psychoacoustics of masking.

2.2. The psychoacoustics of simultaneous masking

The psychoacoustics of simultaneous masking mathematically describe how the physical characteristics of a sound (its volume and tone/ frequency) produce masking. These are based on the excitation patterns of the basilar membrane: the physical structure in the human ear that is predominately responsible for the human ability to distinguish between sounds [12,5,52,2,15,14]. These models predict how a masking sound (the *masker*) will stimulate receptors on the inner ear's basilar membrane based on its volume and its relative frequency to a potentially masked sound (the *maskee*). This stimulation results in a higher volume threshold (in dB) that the volume of the *maskee* must exceed to be perceivable [12].

The psychoacoustics of masking represent frequency on the Bark scale [22]. The Bark scale maps a frequency in Hz to a position on the basilar membrane (the spiral tube in the inner ear's cochlea) where that frequency most strongly stimulates the receptors (see Fig. 1). A sound's frequency in Hz (f_{sound}) is converted to Barks by [22]

 $z_{sound} = 13 \cdot \arctan(0.00076 \cdot f_{sound}) + 3.5 \cdot \arctan((f_{sound}/7500)^2).$ (1)

The "masking curve" then represents the masking threshold as:



Fig. 1. Depiction of how peak stimulation of sounds in Hz occurs at different Bark locations along the basilar membrane.

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