# An Analysis of Simultaneous Masking Between Reserved Alarm Sounds of the International Standard

by

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## DEDICATION

*This thesis work is dedicated to my mother and brother, Carrie and Obi, who have been constant sources of support and encouragement during the challenges of graduate school and life. I am beyond thankful for you both. This work is also dedicated to my late grandparents, Alex and Virgia, whose notable examples taught me to always work hard for the things that I inspire and to never give up.*

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## ABSTRACT

The international medical alarm standard (IEC 60601-1-8) was created to guide engineers with designing alarms that are easily perceivable by humans. The standard "specifies basic safety and essential performance requirements and tests for alarm systems in medical equipment" (O'Brien 2006). The IEC 60601-1-8 standard contains several reserved alarm sounds that use tonal melodies to represent common types of alarms. Regardless of the standard, practitioners can in any case neglect to hear and react to alarms. This problem has resulted in a significant amount of patient injuries and deaths. Unfortunately, the melodic tonal nature of the IEC 60601-1-8's alarms makes them susceptible to simultaneous masking, a condition where concurrent sounds interact in ways that make one or more of them imperceptible. It can be difficult to determine how simultaneous masking manifests in medical alarms. This is due to insufficient experimentation in detecting masking in all the potential alarm configurations used in medicine. In this work, we utilize a computational method that employs mathematical proof techniques to determine if masking is possible in a model of a configuration of medical alarms. We use this method to analyze the low and medium priority reserved alarm sounds, of the IEC 60601-1-8 standard at 70 dB and 80 dB. We describe the method, present the results of our analyses, discuss the results, and explore future research directions.

# INTRODUCTION

The IEC 60601-1-8 (2003-08-14) international medical alarm standard was created to guide engineers with designing and testing medical alarms that are easily perceivable by humans, without being unnecessarily distracting. To achieve this, the standard contains a set of reserved alarm sounds (for common alarm conditions) and instructions for generating additional alarms. Unfortunately, the melodic patterns of tones that are specified within the international medical alarm standard make them susceptible to simultaneous masking: a condition where multiple sounds interact in a way that prevents the human sensory system from hearing one of or more of them (Fastl & Zwicker, 2006).

Simultaneous auditory masking is a very real and serious problem that has been acknowledged by many experts and researchers (J. Edworthy & Hellier, 2005, 2006; Konkani, Oakley, & Bauld, 2012; Patterson & Mayfield, 1990) and experimentally detected in clinical settings (Momtahan, Hetu, & Tansley, 1993; Toor, Ryan, & Richard, 2008). Thus, it is one of the factors contributing to practitioners failing to respond to medical alarms (The Joint Commission, 2013b).

The Pennsylvania Patient Safety Authority (ECRI Institute & ISMP, 2009) reports 194 incidents (from June 2004 to December 2008) where practitioners failed to respond to telemetry monitoring alerts. Twelve of these incidents resulted in deaths. A Sentinel Event Alert (The Joint Commission, 2013a) reported 98 incidents where practitioners failed to respond to medical alarms (between January 2009 to June 2012): 8 resulted in patient death, 13 produced a "permanent loss of function," and 5 extended patient hospital stays. This is a dangerous issue and as the number of alarms in medicine increases, this problem will only worsen.

In this work, we employ the latest version of Dr. Matthew Bolton’s computational method, to evaluate the IEC 60601-1-8 low and medium priority alarm sounds, at 70 dB and 80 dB. In the following, we cover the background for understanding this method and an in-depth description of our research objectives. We then describe the method utilized in our analyses and the results. We ultimately discuss our results and explore future research possibilities.

## BACKGROUND

Below we discuss the information necessary for understanding our research. This includes background on the method and the reserved alarms sounds of IEC 60601-1-8.

### Method

Dr. Bolton’s latest computational method for detecting simultaneous masking (Bolton et al., ND, 2016; Hasanain et al., 2016, 2014, 2017) uses a unique combination of psychoacoustics and model checking to determine if masking is ever possible in a modeled configuration of medical alarms.

The psychoacoustics of simultaneous masking (Bosi & Goldberg, 2003) mathematically represent how the physical characteristics of a sound (its frequency/tone and volume) cause masking.  This is based on the reduction in the sensitivity of the sensory cells on the basilar membrane (the inner ear structure largely responsible for humans’ being able to distinguish between sounds) in the presence of other sounds. The shift in threshold is typically resented as a masking curve. The masking effect captured by masking curves is additive, therefore the potential for masking increases with the number of perceivable sounds in the environment (Lutfi, 1983). Specifics about the psychoacoustics used in Dr. Bolton’s method can be found in (Bolton et al., ND; Hasanain et al., 2017).

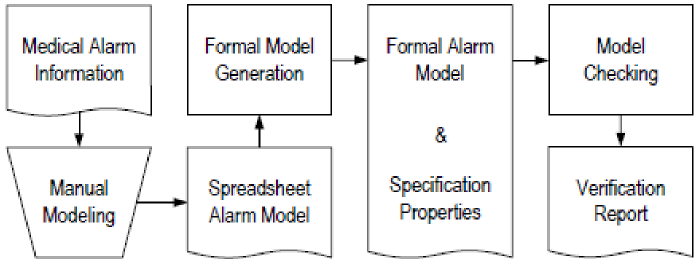



*Figure 1.* The method for using model checking to discover masking between concurrently sound medical alarms.

Model checking comes from the field of formal methods, where a formal model describes a system's behavior. This method is used to discover masking between concurrently sound medical alarms and is an automated approach for mathematically proving properties about system models. Model checking has traditionally been used in the analysis of computer hardware and software. However, a growing body of research has been exploring how it can be used in human factors (Bolton, 2017; Bolton, Bass, & Siminiceanu, 2013; Dix, 1991; Weyers, Bowen, Dix, & Palanque, 2017) and medical systems (Bolton & Bass, 2009, 2010; Bolton, Bass, & Siminiceanu, 2012) engineering.

When combined with psychoacoustics, in Dr. Bolton's method (Figure 1; Bolton et al. ND, 2016; Hasanain et al. 2017), alarms can be modeled in an excel spreadsheet which can then generate formal models of the represented alarms along with specifications for checking if masking can occur.

Dr. Bolton's method has been applied to several realistic medical alarms (Hasanain et al., 2016, 2014) including alarms that conform to IEC 60601-1-8 (Bolton et al., ND, 2016; Hasanain et al., 2017). However, it has never been used to analyze which of the reserved alarm sounds of IEC 60601-1-8 completely mask one another at 70 dB and 80 dB.

## The Reserved Alarms Sounds of IEC 60601-1-8

To improve alarm recognition and help alarm designers across the healthcare industry, IEC 60601-1-8 has a collection of reserved alarm sounds. These sounds represent common types of alarms that can be used across devices and cannot be used by other designed alarms. Each tone in these is described using a Helmholtz name (a letter representing a piano note). There is one general low priority alarm, eight medium priority alarms, and eight high priority alarms. The medium and low priority alarms are shown in Table 1. Each medium priority alarm melody has three sequential tones with short pauses in between. Each low priority alarm melody has two sequential tones with a short pause in between. High priority alarms (which are not further discussed in this research) constitute longer versions of the medium priority sounds.

Table 1. IEC 60601-1-8 Reserved Medium Priority Alarms

| Name | Alarm | | |
|---|---|---|---|
| General | c | c | c |
| Cardiac | c | e | g |
| Perfusion | c | f# | c |
| Ventilation | c | a | f |
| Oxygen | C | b | a |
| Delivery 1 | c | d | e |
| Delivery 2 | C | d | g |
| Failure | C | c | c |
| General Low Priority (Low) | e | c | |

Note. Letters are Helmholtz names and represent different musical pitches from piano notes. c is middle c (261.63 Hz). C (523.25 Hz) is an octave above c.

# OBJECTIVE

Previous analyses of the IEC 60601-1-8 compliant alarms and the similarity of the tones used in the reserved sounds (shown in Table 1), suggest there may be deeper masking problems within the standard. In this research, Dr. Bolton’s computational method was applied to evaluate the medium and low priority reserved alarm sounds, of the standard. We sought to characterize the masking potential of the standard by determining the minimum number of alarms required to completely mask each of these at 70 dB and 80 dB. Below we describe our methods and our results. We then discuss them and outline directions of future research.

## METHOD

Using Dr. Bolton's modified computational method, we modeled each of the medium and low priority reserved alarm sounds in Table 1. The computational method generated a script that would automatically change the volume of a given analyzed alarm to 70 dB while keeping the volume for the other alarms at base level (80 dB). To explore the 10 dB allowable range in alarm volumes (and further maximize the potential of masking), we also modeled all medium and low priority alarms at the base level of 80 dB. 80 dB represents an expected upper bound on the volume of a medical alarm.

## RESULTS

Results showing the minimum number of alarms required to totally mask each of the modeled IEC 60601-1-8 reserved alarm sounds at 70 dB and 80 dB are shown in the charts below:

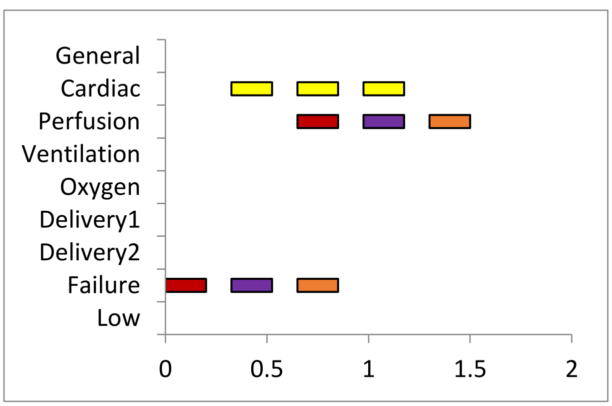



*Chart 1:* Cardiac alarm is at 70 dB, all others are at 80 dB

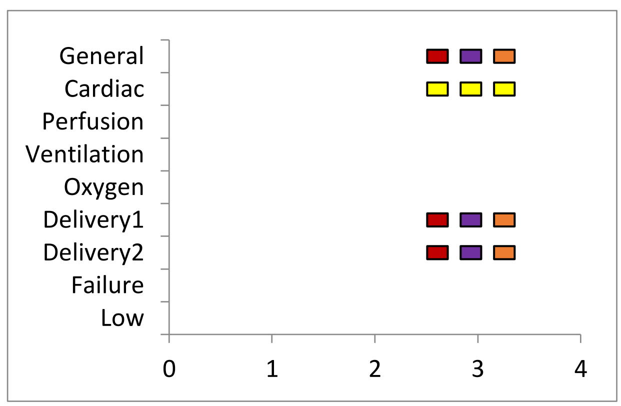



*Chart 2:* Cardiac and all other alarms are at 80 dB

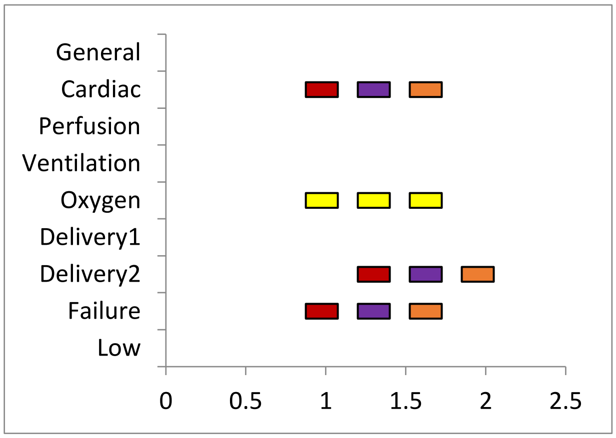



*Chart 3:* Oxygen alarm is at 70 dB, all others are at 80 dB

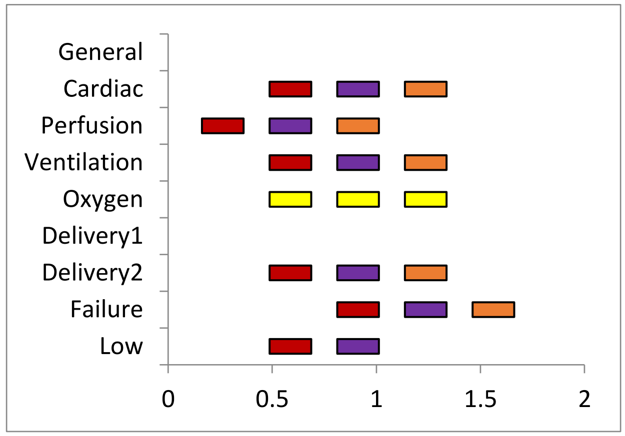



*Chart 4:* Oxygen and all other alarms are at 80 dB

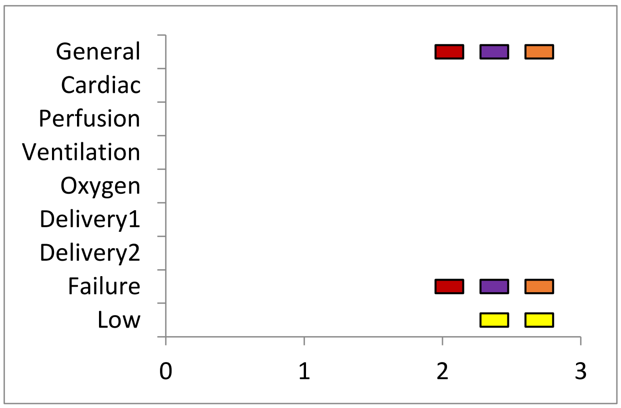



*Chart 5:* Low priority alarm is at 70 dB, all others are at 80 dB

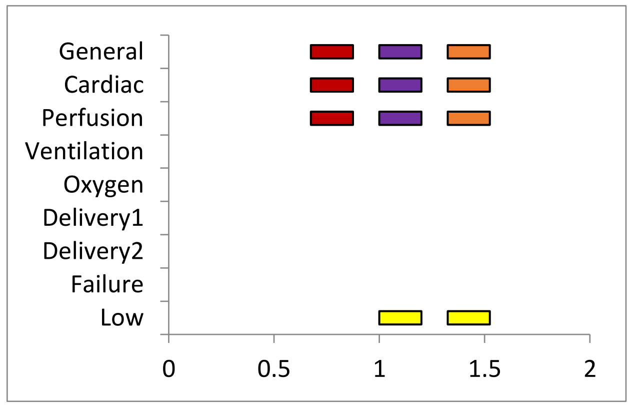



*Chart 6:* Low priority alarm and all other alarms are at 80 dB

Although not explicitly reported in this research, the analyses associated with each result in the charts above produced counterexamples. Each of these showed which other alarms masked the analyzed alarm and how that masking occurred.

There are several interesting results. First, when Cardiac alarms are at 70 dB while all other alarms are at base level, it only takes two other alarms to fully mask Cardiac (Perfusion and Failure at 80 dB). When all the alarms are at the same volume (80 dB), all but the Cardiac and Low alarms could only be totally masked by four or more other alarms. Second, within the allowable 10 dB range of variance in alarm volume, all but one of the alarms (Oxygen) can be totally masked by at least two other alarms. Third, at higher volumes, the Oxygen alarms are the least susceptible and the Cardiac and Low alarms are the most. At lower volumes, the Oxygen and Low alarms are the least susceptible while the Cardiac alarm is the worst. Surprisingly, the Low alarm could never be totally masked by less than 2 other alarms. The results of all analyzed alarm sounds can be found in the appendix.

## DISCUSSIONS AND CONCLUSIONS

In the work presented here, we used an updated version of Dr. Bolton's computational formal method to evaluate the medium and low priority alarms of the IEC 60601-1-8 international medical alarm standard. Our results show that masking is a concern for the analyzed alarm sounds. The fact that we found a problem with overlapping in each alarm type is an issue.

The literature does not indicate how many separate overlapping alarms people are able to differentiate, even if none of them are masked. Nonetheless, it is clearly better for alarms to have a higher minimum number of alarms that can totally mask it. It seems reasonable that a human would fail to hear one alarm when five or more other alarms are also sounding. If the alarms are kept at the same level (80 dB), the results are encouraging. This is because it takes a minimum of between 3 and 6 alarms to completely mask other alarms; with only two (Cardiac and Low) being masked by a minimum of 3 others at 80 dB. The low number observed for the Low alarm is not very concerning because it is less important than any of the other alarms that may be masking it. However, an examination of the Cardiac alarm results indicates that at 70 dB, it is at higher risk of being masked.

The results were less encouraging at the 70 dB level, than at 80 dB. When an alarm is 10 dB below base line (70 dB), all but the Oxygen alarm can be totally masked in the presence of 2 other alarms. This is concerning for several reasons. The international alarm standard allows for a 10 dB variation in alarm volumes within a given designed configuration. Therefore, even within the standard alarm sounds of a given device, there are still ways for nearly every alarm to be masked when three alarms sound simultaneously.

Our results also show variation in the ability of alarms to be masked. Oxygen is the alarm that is the most robust to simultaneous masking. Cardiac is clearly the most susceptible medium priority alarm. The Cardiac alarm was more susceptible to masking than Low, indicating that a discrepancy exists between alarm masking susceptibility and priority.

It is important to note that, while all our analyses used 80 dB (a realistic upper bound) as the baseline volume and the volume of a masker does impact masking curve shape (more masking is afforded by higher volumes), these variations are minor (Bosi & Goldberg, 2003). Therefore, we would not expect the results to significantly change with decreases in the base level volume. As such, our results collectively indicate that there is potential for masking being a serious issue for devices that are compliant with IEC 60601-1-8. Total masking can occur in the presence of three or fewer alarms with variations in volume that are consistent for alarms within and between devices.

If practitioners are unable to hear an alarm, they will not be able to respond to it. In a medical environment, where seconds can mean the difference between life and death, this could have profound implications for patient safety and health.

## Additional Analyses and Method Extensions

While the results discussed here are compelling, there are ways they could be expanded with future work. First, in this research we only covered the medium and low priority reserved alarm sounds from IEC 60601-1-8. The standard also has high priority alarms which are extended versions of the medium priority alarms from Table 1. High priority alarms should be evaluated for masking in future work. The high priority alarms could also be included in the analyses with medium and low priority alarms to see if the lower priority alarms could ever mask high priority alarms.

Secondly, Dr. Bolton's computational method contains features not currently used in the present analyses. This includes the ability to detect partial masking (where only part of an alarm is masked by one or more others) as well as the ability to account for additional frequencies that can be used in standard sound tones (IEC 60601-1-8, 2003-08-14). These features should be employed in future analyses.

Finally, we could research ways to that could possibly make the IEC 60601-1-8's alarms insusceptible to simultaneous masking. Designers may be able to manipulate or create variation in times between alarms, so at least a part of the alarm can be hearable.

### Discernibility of Concurrent Alarms

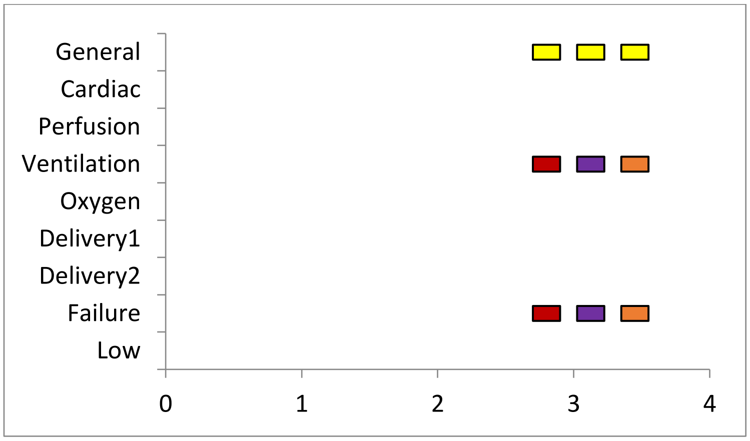
As previously stated, it is not clear how many individual alarms humans can cognitively differentiate even when masking does not occur. Work by Sanderson and Lacherez et al.

(Lacherez, Seah, & Sanderson, 2007; Sanderson, Wee, & Lacherez, 2006) discovered that the IEC 60601-1-8 alarms are difficult to learn and identify (from memory), especially when two or

more overlap (Lacherez et al., 2007). This suggests that this number may be low. Future work should investigate what this number is. This would help us better interpret our results.

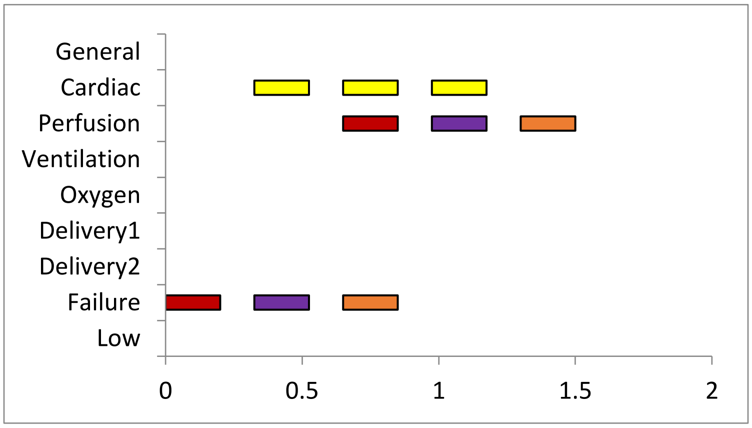
## APPENDIX

**Chart 1: General alarm at 70 dB**



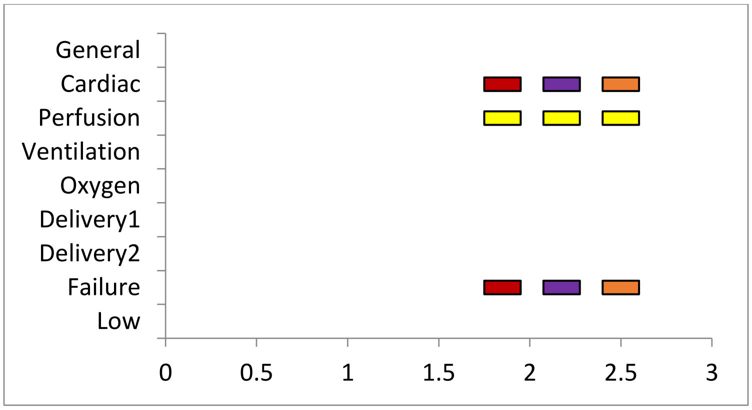

This chart represents General alarms at 70 dB, while all other alarms are at 80 dB. All three tones of the General alarm are fully masked by Ventilation and Failure alarms at 80 dB.

**Chart 2: Cardiac alarm at 70 dB**



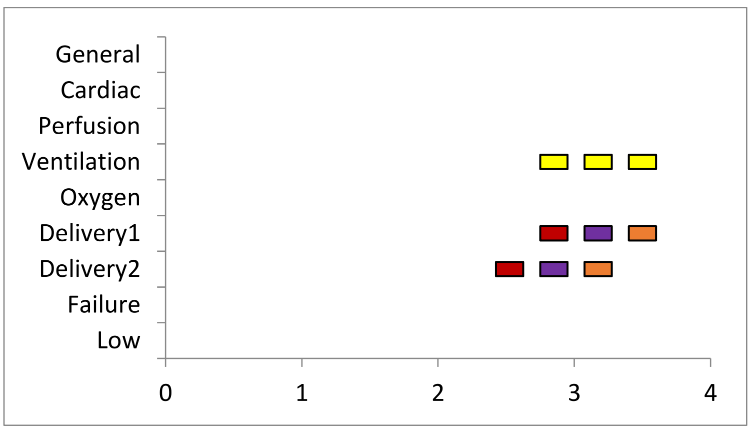

This chart represents Cardiac alarms at 70 dB, while all other alarms are at 80 dB. The last two tones of the Cardiac alarm are masked by Perfusion at 80 dB. The first two tones of the Cardiac alarm are masked by Failure at 80 dB.

**Chart 3: Perfusion alarm at 70 dB**



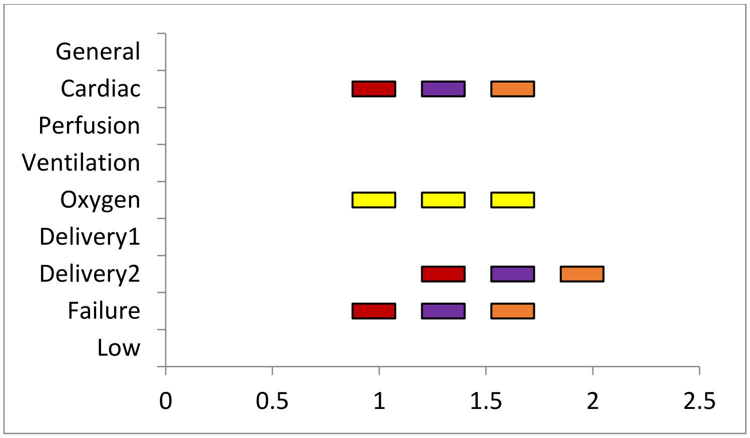

This chart represents Perfusion alarms at 70 dB, while all other alarms are at 80 dB. All three tones of the Perfusion alarm are fully masked by Cardiac and Failure alarms at 80 dB.

**Chart 4: Ventilation alarm at 70 dB**



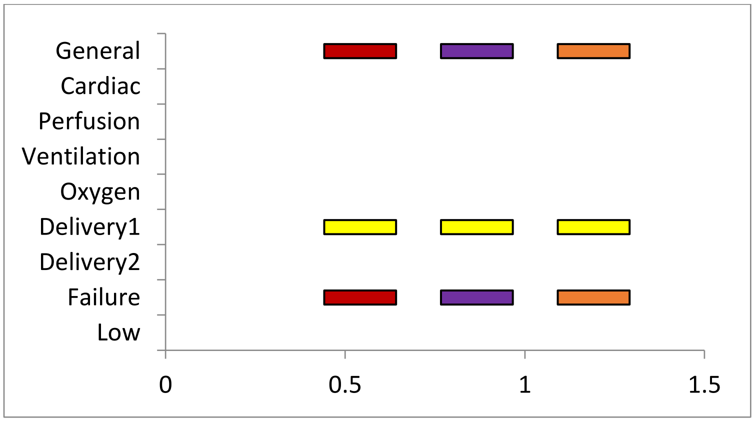

This chart represents Ventilation alarms at 70 dB, while all other alarms are at 80 dB. All three tones of the Ventilation alarm are fully masked by Delivery 1 at 80 dB. The first two tones of the Ventilation alarm are masked by Delivery 2 at 80 dB.

**Chart 5: Oxygen alarm at 70 dB**



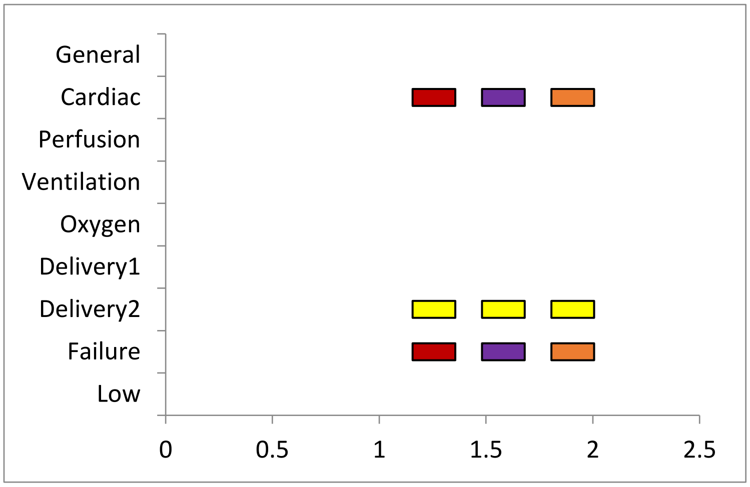

This chart represents Oxygen alarms at 70 dB, while all other alarms are at 80 dB. All three tones of the Oxygen alarm are fully masked by Cardiac and Failure alarms at 80 dB. The last two tones of the Oxygen alarm are masked by Delivery 2 at 80 dB.

**Chart 6: Delivery 1 alarm at 70 dB**



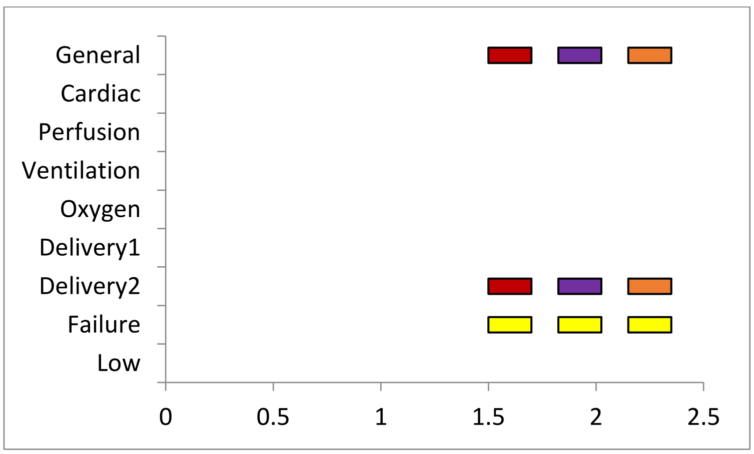

This chart represents Delivery 1 alarms at 70 dB, while all other alarms are at 80 dB. All three tones of the Delivery 1 alarm are fully masked by General and Failure alarms at 80 dB.

**Chart 7: Delivery 2 alarm at 70 dB**



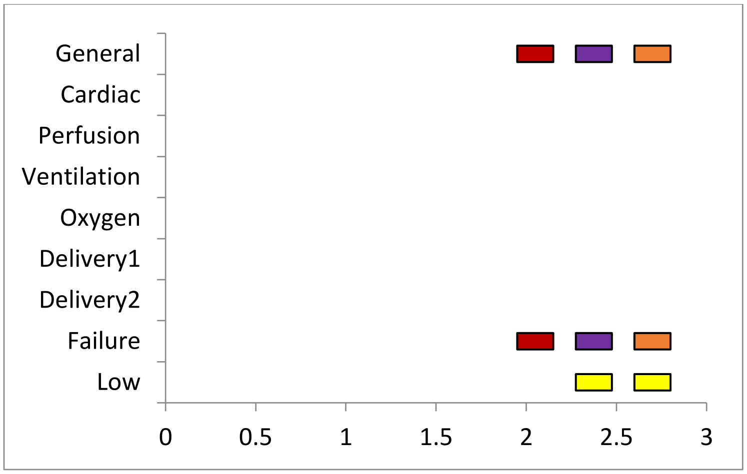

This chart represents Delivery 2 alarms at 70 dB, while all other alarms are at 80 dB. All three tones of the Delivery 2 alarm are fully masked by Cardiac and Failure alarms at 80 dB.

**Chart 8: Failure alarm at 70 dB**



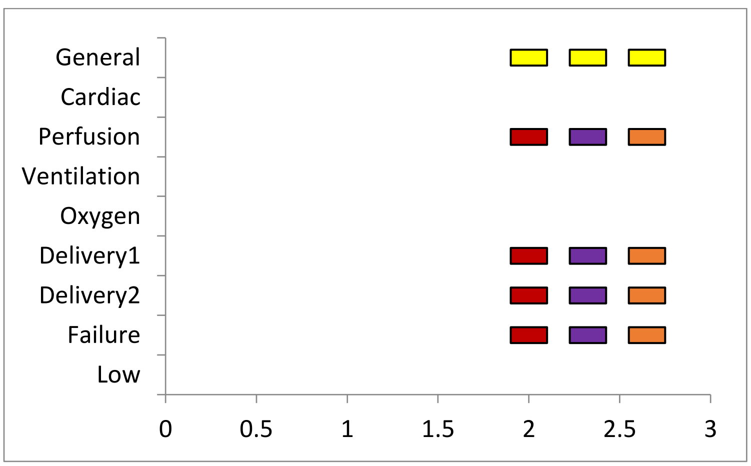

This chart represents Failure alarms at 70 dB, while all other alarms are at 80 dB. All three tones of the Failure alarm are fully masked by General and Delivery 2 alarms at 80 dB.

**Chart 9: Low priority alarm at 70 dB**



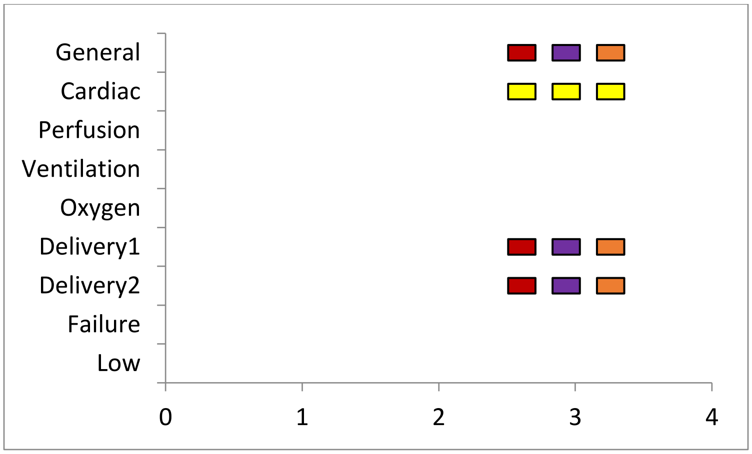

This chart represents Low priority alarms at 70 dB, while all other alarms are at 80 dB. All tones of the Low priority alarm are fully masked by General and Failure alarms at 80 dB.

**Chart 10: General alarm at 80 dB**



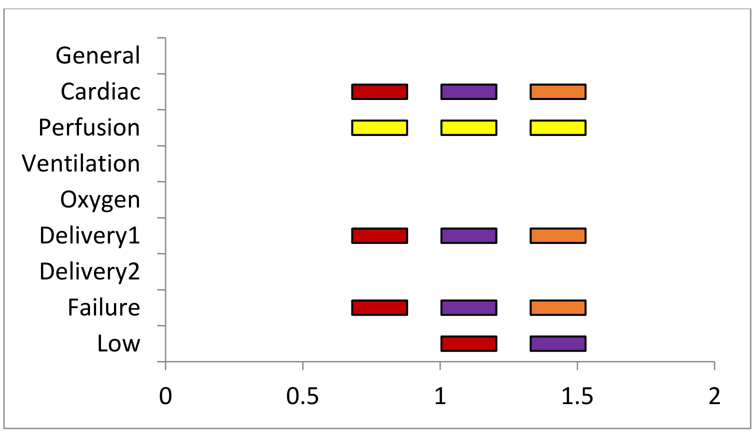

This chart represents General alarms at 80 dB. All tones of the General alarm are fully masked by Perfusion, Delivery 1, Delivery 2, and Failure alarms.

**Chart 11: Cardiac alarm at 80 dB**



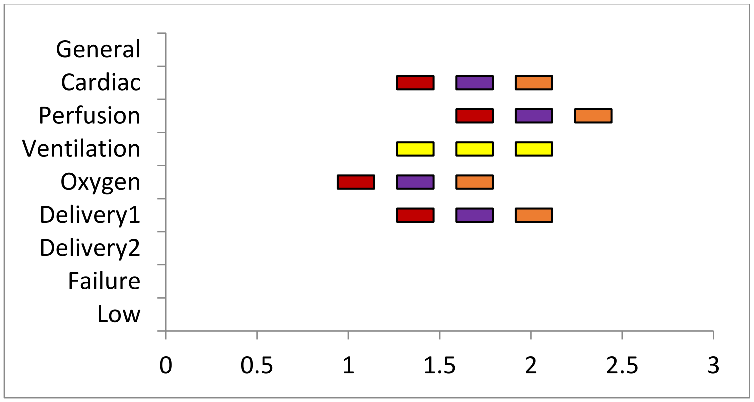

This chart represents Cardiac alarms at 80 dB. All tones of the Cardiac alarm are fully masked by General, Delivery 1, and Delivery 2 alarms.

**Chart 12: Perfusion alarm at 80 dB**



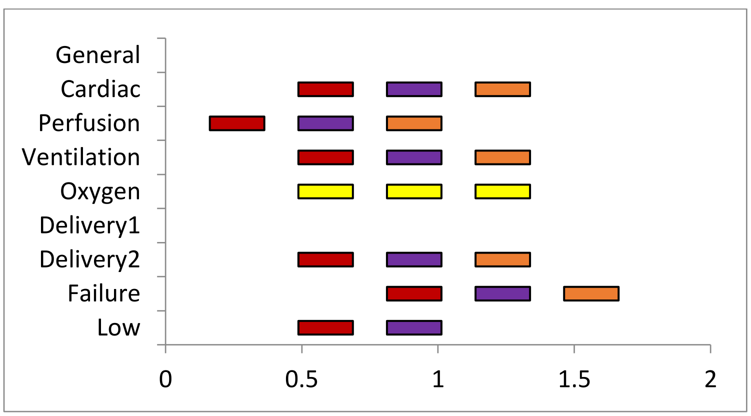

This chart represents Perfusion alarms at 80 dB. All tones of the Perfusion alarm are fully masked by Cardiac, Delivery 1, and Failure alarms. The Low priority alarm also masks the last two tones of the Perfusion alarm.

**Chart 13: Ventilation alarm at 80 dB**



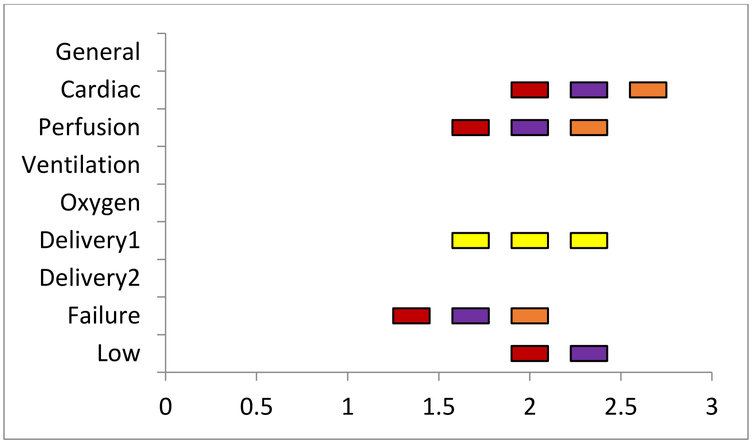

This chart represents Ventilation alarms at 80 dB. All tones of the Ventilation alarm are fully masked by Cardiac and Delivery 1 alarms. The first two tones of the Ventilation alarm are masked by Oxygen. The last two tones of the Ventilation alarm are masked by the Perfusion alarm.

**Chart 14: Oxygen alarm at 80 dB**



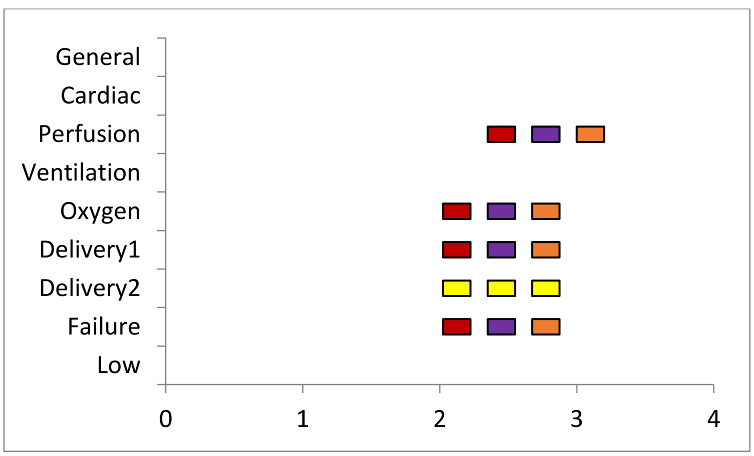

This chart represents Oxygen alarms at 80 dB. All tones of the Oxygen alarm are fully masked by Cardiac, Ventilation, and Delivery 2 alarms. The Low priority and Perfusion alarms mask the first two tones of the Oxygen alarm. The Failure alarm masks the last two tones of the Oxygen alarm.

**Chart 15: Delivery 1 alarm at 80 dB**



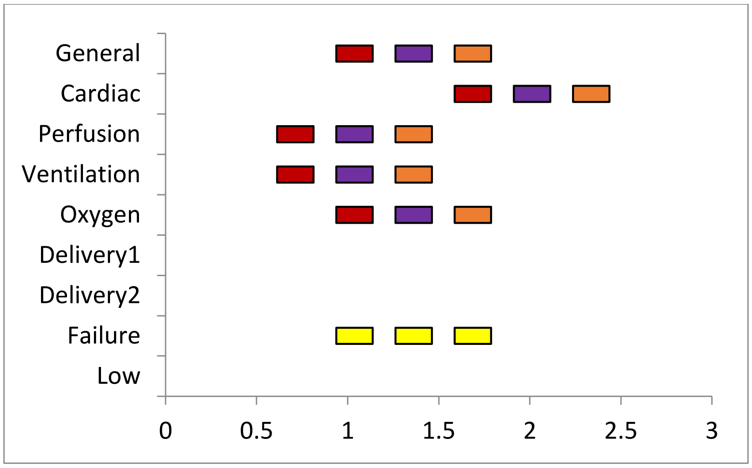

This chart represents Delivery 1 alarms at 80 dB. All tones of the Delivery 1 alarm are fully masked by the Perfusion alarm. The Failure alarm masks the first two tones of the Delivery 1 alarm. The Cardiac and Low priority alarms mask the last two tones of the Delivery 1 alarm.

**Chart 16: Delivery 2 alarm at 80 dB**



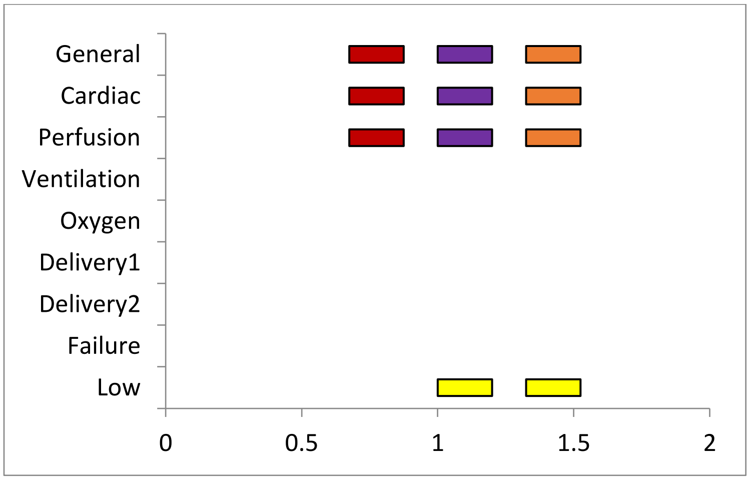

This chart represents Delivery 2 alarms at 80 dB. All tones of the Delivery 2 alarm are fully masked by Oxygen, Delivery 1, and Failure alarms. The Perfusion alarm also masks the last two tones of the Delivery 2 alarm.

**Chart 17: Failure alarm at 80 dB**




This chart represents all alarms at 80 dB. All tones of the Failure alarm are fully masked by General and Oxygen alarms. The Perfusion and Ventilation alarms mask the first two tones of the Failure alarm. The last tone of the Failure alarm is masked by the Cardiac alarm.

**Chart 18: Low priority alarm at 80 dB**




This chart represents all alarms at 80 dB. All tones of the Low priority alarm are fully masked by General, Cardiac, and Perfusion alarms.

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