

The upsurge in audible alarm use in medical equipment cannot be traced to any one cause. Certainly, liability is a big factor, but also the market trend of integrating more and more functions in each piece of medical equipment has generated the need for more types of warning sounds. Medical equipment suppliers have acknowledged that the multitude of sounds in medical facilities does cause concern with possible auditory overload, but without industry or agency guidance, each medical equipment manufacturer has continued to develop proprietary alarm solutions.

Efforts to harmonize alarm systems in medical equipment moved slowly over a period of several years (see MD&DI, Oct. 2001: *Answering the Call for Harmonization of Medical Device Alarms* by Michael E. Wiklund and Eric A. Smith). However, this changed in 2003 when international standard IEC 60601-1-8 was issued. Although this specification is voluntary, it is expected that many medical equipment manufacturers will eventually move toward meeting this specification because of the potential liability issues of not meeting it, or the fear of missing out on sales to larger institutions which can use their buying power to require compliance to IEC 60601-1-8.

### What is IEC 60601-1-8?

IEC 60601-1-8 is a comprehensive international standard that specifies basic safety and essential performance requirements and tests for alarm systems in medical equipment. Its 71 pages including four annexes covers both visual and audible alarms, but a vast majority of the specification is devoted to audible alarm issues for medical equipment and applications.

Comprehensive is a good word to describe this specification as it covers everything from what kind of medical condition should trigger an audible warning sound to the specific frequency and shape of the audible sound waveform. While it is impossible to cover everything listed in its 71 pages, many of its most important topics for audible alarms can be discussed in detail.

### Priority Condition

Before triggering an audible alarm, the priority of the condition that is being monitored by the medical equipment must be assigned. IEC 60601-1-8 gives guidance on whether a condition should be assigned a high, medium, or low priority. This guidance is based on the potential result of a failure to respond to the cause of the alarm condition and

how fast the potential harm could happen to the patient. For example, a high priority would be assigned if death or irreversible injury could happen quickly, but a low priority would be assigned if only minor injury or discomfort may happen after a period of time. It is up to the equipment designer to decide which specific conditions merit which priority. A heart rate of 170 on a treadmill test may warrant a low condition priority whereas this same heart rate at an intensive care monitoring station may be assigned a high priority.

### Audible Alarm Bursting

There are three burst requirements listed in IEC 60601-1-8. As this term is used here, a burst is essentially a pulse train of individual sounds (i.e. beep, beep, beep, pause, beep, beep beep). The three burst requirements correspond to the three priority conditions discussed in the last section. A high priority condition burst has 10 fast pulses that repeat, a medium priority condition burst has 3 slightly slower pulses that repeat, and a low priority condition burst has 1 or 2 even slower pulses that may optionally repeat. The number of pulses, the shape of the pulse train,

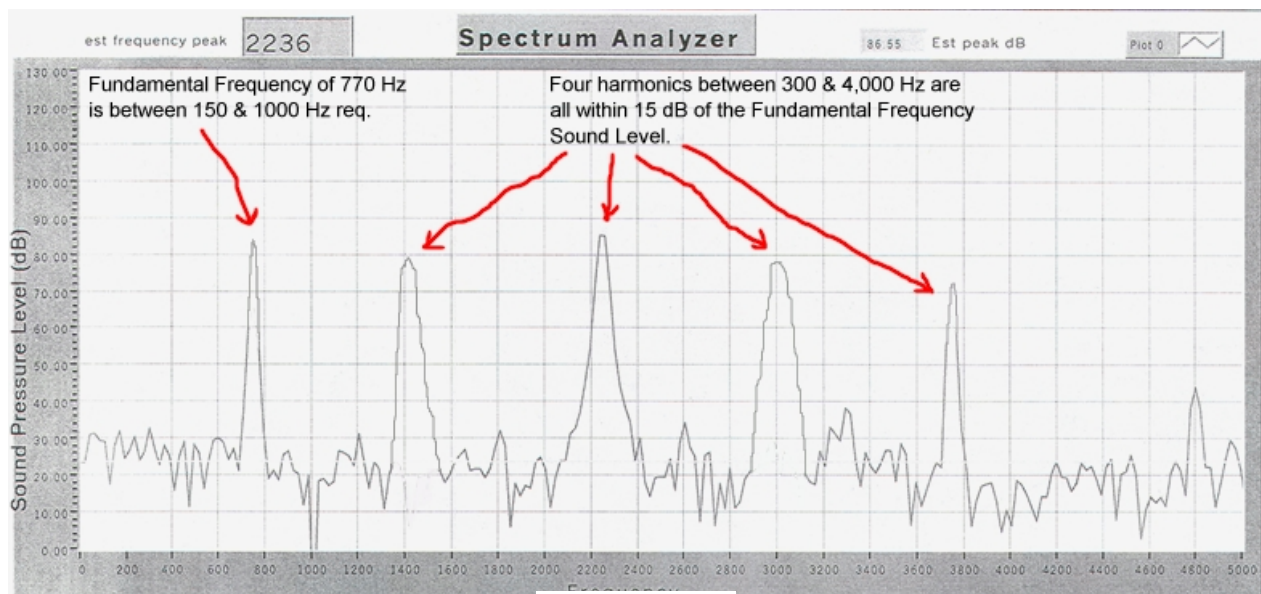


FIGURE I

and the spacing of the pulses for each of the priority conditions are spelled out in detail.

### **Characteristics of the Individual Pulses**

IEC 60601-1-8 requires that an individual sound pulse must have a fundamental frequency (musically known as pitch) somewhere between 150 to 1000 Hz, and there must be at least four harmonic sounds from 300 to 4000 Hz. Figure I shows a visible example of an audible sound that meets these requirements. The peak to the far left in Figure I is the fundamental frequency of the sound, and the four peaks to the right of the fundamental peaks represent the harmonic tones. To the ear, the resulting blended sound would be similar to hearing four different musical notes played at the same time. A final requirement for the sound pulse characteristic is that the sound level (measured in dB) of the four harmonic tones must be within  $\pm 15$  dB of the fundamental frequency tone.

### **Optional Melodies**

IEC 60601-1-8 requires that one set of audible warning sounds used in the medical equipment meet the requirements spelled out in the above sections. However, the specification does give the option of providing more than one set of audible warning sounds that vary the fundamental frequency of the audible warning sound. What this essentially means is that the equipment would play a musical melody instead of just beeping over and over with the same frequency sound. The sequence of musical notes for each melody is spelled out for several different kinds of medical applications. For example, a ventilation alarm is assigned one unique melody while a cardiac alarm has a different unique melody. By assigning a unique melody for each kind of medical equipment, the hope is that medical personnel can become familiar with each different kind of

melody and more quickly identify the source of an audible warning sound.

Why would a medical equipment designer provide the option of using the different musical melodies with their particular medical equipment? The reason would not be cost. The time and cost to design a system that could produce the melodies would be significant. However, an equipment designer may decide that they could gain a competitive advantage over their competition by providing this option. Also, large medical institutions may decide that the efficiencies gained by having all their medical equipment play these melodies out weighs any additional equipment cost.

### **Sound Level Requirements**

IEC 60601-1-8 contains only basic requirements for how loud the audible warning sounds need to be. The only requirement listed is that the high priority condition warning sound must be louder than the medium priority condition warning sound which must be louder than the low priority condition warning sound. A practical recommendation is that there should be 3 to 6 dB difference between each of the three priority condition warning sounds. It takes at least a 3 dB difference between two different sound levels before the human ear can tell that one sound is louder or softer than another sound, so anything less than 3 dB would not make sense. On the other hand, you don't want the high priority condition to be too much louder than the low priority condition, or either the low priority condition sound will be too soft to be heard, or the high priority condition sound will be too loud and distract those nearby.

How loud should the sound levels be? IEC 60601-1-8 does not answer this question. The specification authors are relying on the experience of the medical equipment designers, the audible alarm designers, and the equipment users to determine ultimately how loud the warning sounds should be. It is a fine line to make the warning sound loud

enough to be heard in all situations, but not so loud that the people near to the warning sound are not annoyed or distracted.

### **Technical Alarm Condition**

Besides the high, medium, and low priority conditions that require a warning sound to be issued, there may be other reasons for the medical equipment to trigger an audible sound. These conditions are called technical alarm conditions, and examples include issuing a sound due to a keyboard input error, a power failure, or equipment error. The requirement in IEC 60601-1-8 is that sounds issued for technical alarm conditions should not be easily mistaken for the sounds issued for the three priority conditions. While this seems to be common sense, it does not hurt to remind equipment designers that nurses don't like paging doctors only to find out that an equipment warning sound was caused by a blood pressure monitor power cord coming unplugged.

There are almost an unlimited number of ways to make technical alarm conditions sounds unique from the priority condition sounds. Examples include using very high frequency pitches, very short staccato or clicking sounds, or using sounds longer in length.

### **Reminder Signals**

It is not uncommon for equipment designers to allow the users of medical equipment to temporarily silence the audible alarms so that medical personnel can concentrate on resolving the condition of the patient that caused the alarm in the first place. IEC 60601-1-8 allows for the alarms to be temporarily silenced, but states that if the alarm condition is still present, it may be appropriate for the equipment to continue to issue a periodic "beep" or other indicating sound to remind the medical personnel that the alarm condition still persists even though the alarm sound itself has been muted.

### Verbal Alarm Option

IEC 60601-1-8 does allow for the medical equipment designer to use verbal messages instead of using the priority condition signaling detailed in the previous sections. The downside of using verbal messages is that the resulting system must be validated by clinical testing or by simulating clinical usability testing. This kind of validation testing can add significant cost to the development process and also delay the market introduction of the medical equipment. It is up to the equipment designer to decide if using verbal messages will give enough of a competitive advantage to overcome the higher development costs and longer development cycle times.

### How Can the Audible Alarm Requirements of IEC 60601-1-8 Be Met?

It will take some time for medical equipment designers to digest all the requirements in IEC 60601-1-8 and decide how to best meet these requirements for their particular piece of medical equipment. For some critical or large types of medical equipment, the increased time and cost of the development cycle and the increased cost of the equipment itself is not a large concern. However, other equipment providers may have a hard time passing on the increased component and development cost of their equipment to customers. For example, many pieces of medical equipment currently use low cost piezoelectric audible alarms for their audible alarm signaling. These are the same kind of alarms used in smoke detectors or at the check-out counters at grocery stores. These low cost alarms can no longer be used as they will not meet the complex frequency requirements of IEC 60601-1-8. While a higher priced audible alarm solution for a large X-ray system may be absorbed easily, a higher cost audible solution could require makers

of lower cost medical equipment to raise their equipment prices several percent to cover the increased development and component costs.

If low cost electronic alarms cannot meet the requirements of IEC 60601-1-8, what kind of alarm system can?

### High Cost Option

The high cost option to meeting IEC 60601-1-8 is to use a microcontroller or microprocessor to produce a complex frequency signal. This signal would contain the required fundamental frequency and the four harmonic sound frequencies illustrated in Figure I. To make this sound loud enough to be useful, a fairly large speaker would be required which would then require audio processors and high power electronic components to power the speaker. Such a solution would be very costly and would take significant expertise and time to implement.

### Lower Cost Option

Instead of producing the four harmonic sounds by electronic means, it is possible to produce these sounds acoustically. To accomplish this, a transducer or speaker can be mounted in a specially designed acoustic chamber. The user then only needs to apply a simple sine wave to the part, and the harmonic sounds are automatically generated inside the acoustic chamber. Many people have already heard one example of how multiple pitch sounds are generated acoustically. If you ever have heard someone blow into a wooden train whistle, you immediately hear several different sound frequencies at one time. This complex sound is in stark contrast to the single frequency sound produced by a referee's whistle.

Another advantage of mounting the transducer or speaker in this acoustic chamber is that the sound level can be increased significantly also by acoustic means. This means that high power components and audio processors are not needed.



FIGURE II

Figure II shows an octagonal plastic housing that contains an internally mounted miniature speaker. A specially designed acoustic chamber inside the octagonal housing shapes the sound waves so that the resulting sound that is emitted through the small front hole opening meets the frequency requirements of IEC 60601-1-8. Although the part only measures 22mm (dia) x 13 mm (hgt) and uses a 0.25 Watt speaker, it is capable of producing 95 dB at 10cm.

### Conclusion

Medical equipment designers are now in the process of determining if and how they would meet the requirements of IEC 60601-1-8. There is no doubt that meeting these requirements will add cost and lengthen the design cycles of medical equipment. Those medical equipment manufacturers that implement these requirements most efficiently will gain a competitive advantage over their competitors. One way to gain such an advantage is to work closely with knowledgeable suppliers who can help interpret the complex requirements in IEC 60601-1-8 and offer solutions that may not be obvious at first glance.

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