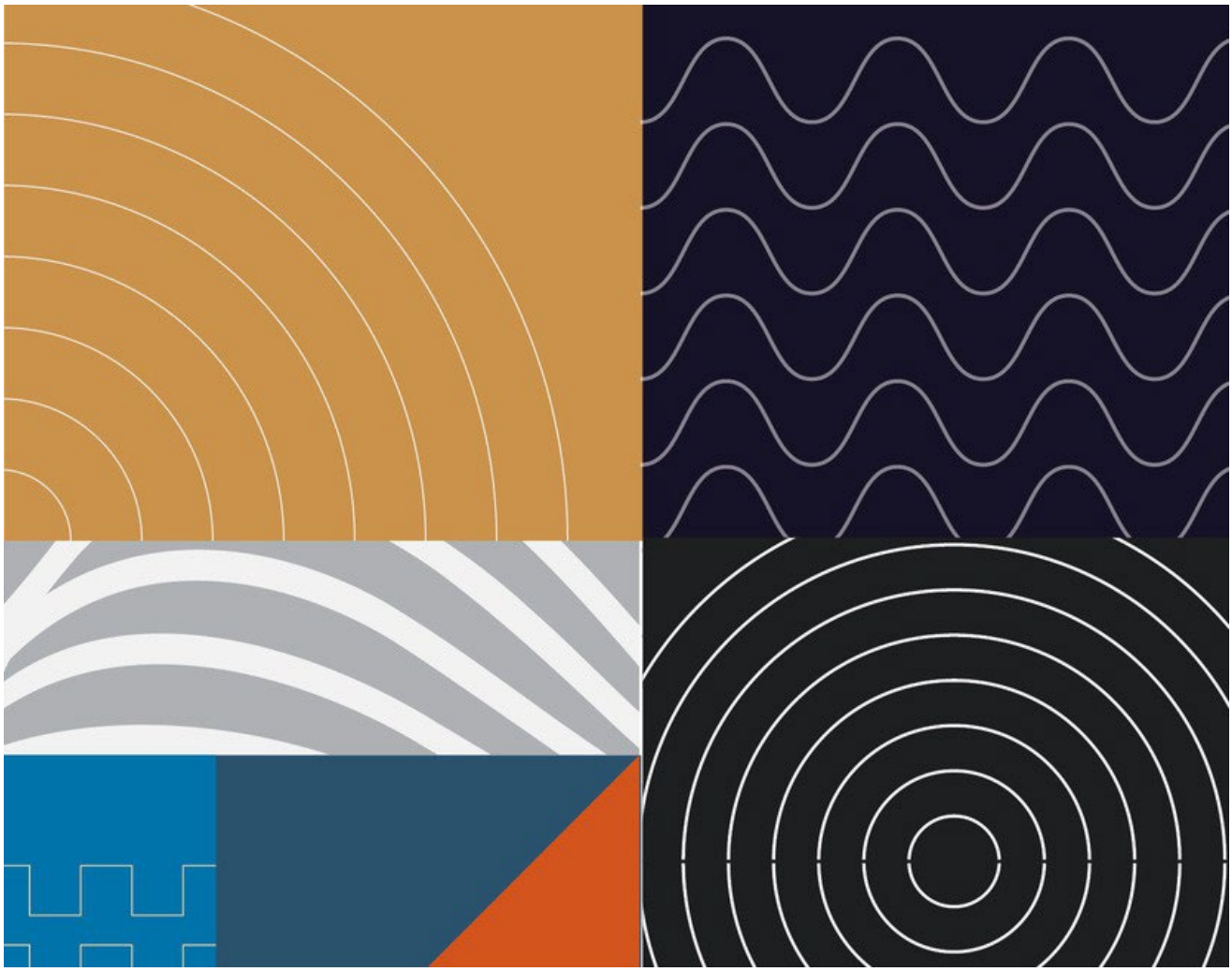
Medical Buzzers

IEC 60601-8 Application Guide



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IEC 60601-1-8 Compliant Audio

The recommendations given by PUI Audio in this document should be used for educational purposes only; following the guidance given in this paper does not guarantee compliance with IEC standards. The IEC 60601-1-8 standard should be referenced in all medical electronic equipment applications for compliance guidelines.

With the increased use of medical electronics in medicine today, the International Electrotechnical Commission (IEC) developed the IEC 60601-1-8 standard to regulate alarm signals. The intent of this is to prevent confusion when medical electronics equipment systems are sounding at the same time in the same room.

Previous iterations of the IEC 60601-1-8 standard (IEC 60601-1-8:2006+AMD1:2012) specified melodies for individual alarm conditions in terms of musical notes – e.g., a cardiac alarm system must emit the musical notes "c e g" to alert medical staff of a medium priority alarm condition. In the case of this escalating to a high priority alarm condition, the cardiac alarm system must then emit "c e g – g C" (*91).

Cause	Medium Priority	High Priority	Mnemonic Notes	Examples of alarm systems
Cardiac	c e g	c e g – g C	Trumpet call; Call to arms; Major chord	Anesthesia workstations that include cardiac monitors, multi-parameter monitors which include cardiac monitors, heart rate monitors, invasive or non-invasive blood pressure monitors, cardiac output monitors, peripheral perfusion monitors (plethysmographs), transesophageal echo, fetal heart rate monitors

Table 1

However, the IEC has found that the use of these more abstract "musical" alarm signals in noisy clinical environments can be less effective for communicating alarm conditions to medical staff than the use of distinguishable everyday sounds (*92).

The Latest Updates in IEC 60601-1-8

Following substantial research, the IEC released a revised version of the 60601-1-8 specification (IEC 60601-1-8 AMD2:2020) in 2020, redefining the standard for auditory alarms in medical systems. In contrast to previous versions, this revision does not recommend the use of the previous priority/note system for any type of alarm found in medical electronics (ME) equipment.

Instead, the terms *Auditory Icon* and *Auditory Pointer* were introduced. *Auditory Icons* are recommended to usually be everyday sounds- when associated with a ME equipment alarm, they cause a strong link between the sound and the alarm condition category in the user. For instance, the user would associate an *Auditory Icon* derived from the sound of a heartbeat with a cardiac system alarm.

They also are easier to localize due to the increased harmonic content (compared to discrete musical tones), posing less risk of being masked by other noise. The careful selection of a unique *Auditory Icon* means that other sounds that occur naturally in a clinical environment will not be confused with critical medical equipment alarms (*92).

Alarm Condition Source Category	**Auditory Icon Metaphor**	**Auditory Icon Description**
General*	-	-
Cardiovascular	“Lup-dup”; heartbeat sound	A stylized, square/triangle wave-based “heartbeat” sound, with no discernible frequency. Six pulses formed from three 2-pulse “lup-dup” sequence
Artificial Perfusion	Liquid disturbance, water churning, bubbles	Two approximately 1 s sequences of a strong water bubbling sound, separated by silence
Ventilation	A exhale single inhale followed by an exhale	A 1 s inhaling sound (like white noise), followed by a 0,5 s gap, followed by a slow exhale with a long tail
Oxygenation	Irregular, stylized dripping/saturation	Stylized irregular temporal pattern with some discernible pitch; a two-tone sequence superimposed on the six-tone pattern
Temperature / energy delivery	Whistling kettle	Complex sound including high frequency harmonics, rising slowly over approximately 2 s

Equipment or supply failure	Starting up a motor that shuts down suddenly	Spectrally complex sound of a motor revving up (increasing in frequency) over approximately 1,2 s then an abrupt stop tailing off for approximately 0,5 s
*General category has no *Auditory Icon*; only an *Auditory Pointer* is used.		

Table 2

Auditory Pointers are used to identify the specific device emitting an *Auditory Icon*, and to indicate the priority level of the alarm to the user. This is accomplished by mixing the two audio signals together, to create a combined *Auditory Icon + Pointer* tailored to specific medical equipment and alarm conditions. SPL requirements of the overall alarm signal have also been revised, so that the perceived volume of the alarm does not convey urgency (*109) (See Table 3).

Parameter	Less Urgent	More Urgent
Speed	Slow	Fast
Number of repeating bursts	1	4
Rhythm	Regular	Syncopated
Inter-pulse duration within a single burst	Regular / Slowing	Speeding up
Pitch Contour	Down / Up	Random
Pitch range	Small	Large
Musical Structure	Resolved	Atonal

Table 3

This combination allows operators of ME equipment to quickly determine the type of equipment generating the alarm, where it is, and to then respond appropriately to the individual device with the urgency it prescribes (*93).

While the IEC 60601-1-8 standard covers every aspect of the alarm signals and should be referred to as the ultimate reference with regards to the specific tones to use in ME equipment, there are three key points that should be kept in mind:

1) Alarm signals must be audible and recognizable. Almost everything else is a matter of taste and preference. The IEC's research committees have considerable data to show that both learnability and audibility are high with regard to the new alarm ME equipment alarm specifications (*92).

2) In terms of audibility and recognizability, the key factors that influence people's ability to detect and recognize ME equipment sounds are their age and their hearing ability, rather than their clinical role or some other local variable (*92).

3) Based on research evidence from the IEC showing the exceptional performance of these new alarm standards, if the operator of ME equipment has difficulty to hear and/or recognize any of these alarm signals, a solution other than auditory alarms (e.g., PUI Audio's Haptics) is more appropriate under that circumstance (*92).

*"Auditory ALARM SIGNALS cannot be imbued with magical properties allowing them to work in all possible environments, regardless of how extreme or unusual that environment might be" (*92).*

This statement by the IEC, directly quoted from the 60601-1-8 AMD2:2020 specification, illustrates a common misconception regarding ME equipment alarms. While based on studies in auditory cognition and perception, the recommendations by the IEC for alarm signals cannot cover every use case and condition that they may experience use in.

These specifications "follow best practice and are the best they can be, given what the committees know and can predict from the science" (*92). "There can be some cultural factors around suitability and recognizability, but this document permits development in these areas" (*92).

Key Requirements

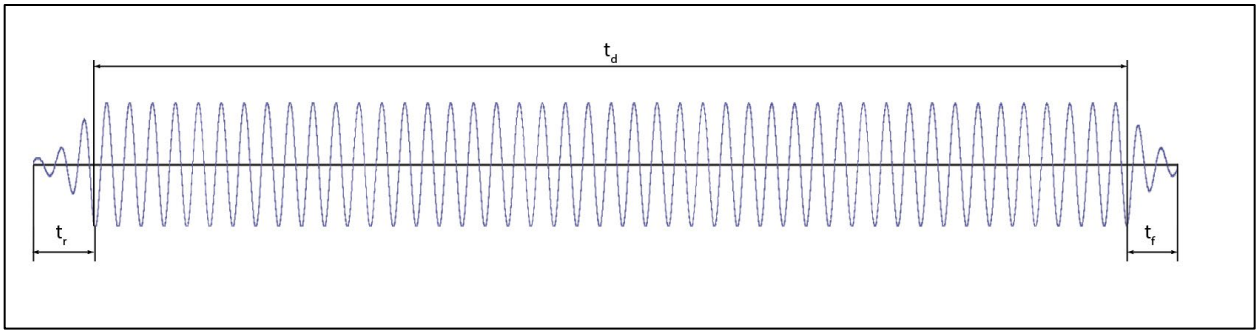
These are important requirements pertaining to the selection of a device from PUI Audio for use with the IEC's new recommendations for 60601-1-8 compliance.

For the *Auditory Icon (*109)*

1. The frequency range of the alarm signal should be between 200 Hz and 5000 Hz.
2. The frequency band of focus is between 500 Hz and 3000 Hz.
3. If the alarm is required to be heard across a long distance, the alarm frequency should be below 1000 Hz.
4. If the alarm is required to be heard around obstacles or through partitions, the frequency should be below 500 Hz.
5. The selected frequency band should differ from the most intense background frequencies in the ME equipment's expected environment of use.

For the *Auditory Pointer (*116)*:

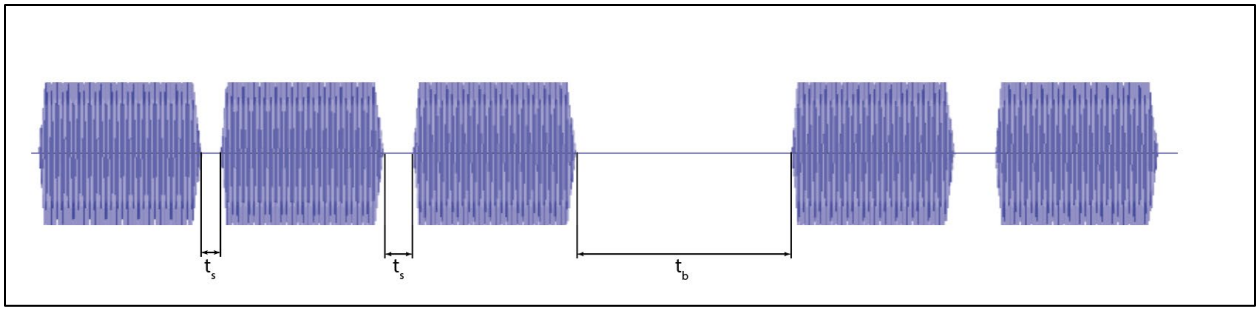
1. At least one frequency component that is among the five frequency components with the largest sound pressure level (harmonics) must be within the range of 150 Hz to 1000 Hz.
2. There must be at least five peaks (harmonics) in the frequency range between 150 Hz and 4000 Hz.
3. The effective pulse durations for each priority should be:
    i. High 25ms to 75ms
    ii. Medium 90ms to 200ms
    iii. Low 400ms to 600ms
4. Within the frequency range of 150 Hz to 4000 Hz, the relative sound pressure levels of the four frequency components with the largest sound pressure level (harmonics) should be within 15dB of each other.
5. Rise time of the *Audio Pointer* should not be so short as to create mechanical noise. Very fast rise times can create audible distortion due to mechanical limitations of the selected audio device.
6. Fall time of the *Audio Pointer* should be short enough to ensure pulses of *Audio Pointers* do not overlap.



t_r = pointer rise time

t_d = pointer pulse duration

t_f = pointer fall time



t_s = pointer pulse spacing (time from the end of one pulse to the start of the next pulse)
t_b = interburst interval (time from the end of one burst to the start of the next burst)

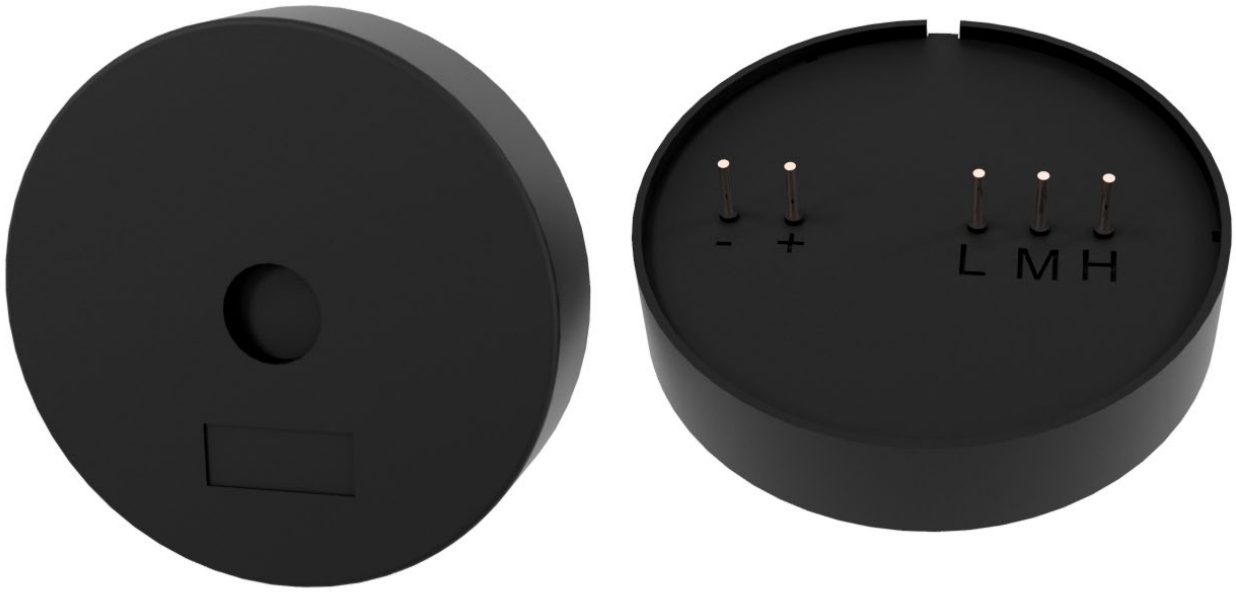
Additional *Auditory Pointer* burst characteristics—such as the number of *Auditory Pointer* pulses per burst, pulse spacing, inter-burst interval, and SPL consistency between pulses are also part of this standard. See the full IEC 60601-1-8 document for details on compliance.

Other methods of achieving 60601-1-8 compliance for auditory alarm signals are listed in detail in the IEC 60601-1-8 AMD2:2020 specification. This includes generating and validating alternative sources of alarm signals (e.g., synthesized verbal alarm signals), as well as adherence to previous waveform characteristics detailed in previous revisions of the specification.

PUI Audio has developed a resource for engineers to help determine what products will aid in meeting the guidelines and adding clarity to the patient experience. From our testing, we can deduce the characteristics of a speaker that makes it an ideal candidate to use within a Medical Device that needs to meet the criteria set forth by IEC 60601-1-8.

We've also included Steps to selecting the ideal speaker for your application and Speaker Integration Best Practices and Recommended Speakers. You can download the whitepaper for free and read it here.

Additionally, PUI Audio has introduced Medical Audio Indicators - These piezoelectric-based audio devices produce an IEC 60601-1-8 compliant alarm tone when a DC voltage is applied. Three priority levels are present in the device, in addition to the base tones, to ensure the appropriate urgency can be conveyed when the alarm is triggered.



Our engineering team is eager to work on developing new solutions and continuing to push the envelope. Curious to learn more? Ready to kick off a brainstorming session about your audio needs in the manufacturing industry? Reach out! Ask an engineer or chat with us. We are here to help.

*Note- *Pages noted above represent page number in the published IEC 60601-8, link noted below.

Resources:

IEC-60601-8 Published Paper

IEC Website- www.iec.ch

Product Pages: https://puiaudio.com/search?query=AMI