

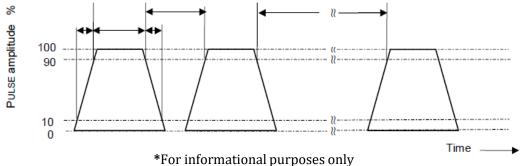
With the increased use of medical electronics in medicine today, the International Electrotechnical Commission (IEC) developed the **IEC 60601-1-8** standard to regulate alarm signals to prevent confusion, when several instruments are sounding at the same time in the same room.

While the IEC 60601-1-8 standard covers every aspect on the alarm signals, and should be referred to as the ultimate reference with regards to the specific tones to use in your device, there are three main requirements that pertain to speaker selection:

- 1. A pulsed frequency between 150 Hz and 1 kHz
- At minimum of four harmonics of the pulsed frequency between 300 Hz and 4 kHz
- **3.** The sound pressure level (SPL) of the harmonics must be within ±15 dB of the pulsed frequency

Additional pulse requirements—such as pulse duration, rise time, and fall time—are also part of this standard, but pertain more to the input signal sent to the speaker.

Below is an example of the type of waveform characteristics* that may be used to meet the IEC 60601-1-8 criteria. The flat portion of the waveform is used to create the harmonics from the fundamental pulsed frequency.

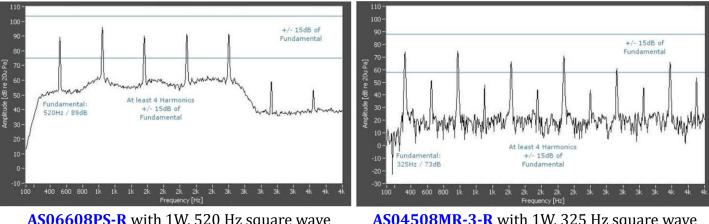


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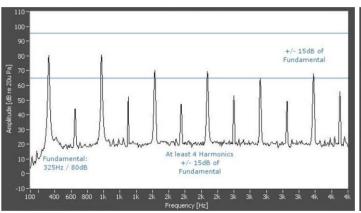


PUI Audio has taken the performance criteria called out by IEC 60601-1-8 and performed studies on speakers to gauge which specifications stand out as most important when selecting speakers to meet the criteria.

Each test below was performed with the speaker mounted to a test baffle, and a B&K measurement microphone connected to a Listen, Inc. SoundCheck test system set to spectral analyzer mode.

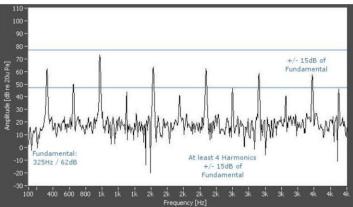


<u>AS06608PS-R</u> with 1W, 520 Hz square wave Microphone spaced at 10cm from test baffle



AS04004PO-R with 1W, 325 Hz square wave Microphone spaced at 10cm from test baffle

AS04508MR-3-R with 1W, 325 Hz square wave Microphone spaced at 10cm from test baffle



AS02808MR-R with 1W, 325 Hz square wave Microphone spaced at 10cm from test baffle

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.

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Steps to selecting the ideal speaker for your application:

1. Reference IEC 60601-1-8 to ensure correct tone selection for your product. Below is an example of tonal requirements* for different product applications.

Cause	MEDIUM PRIORITY	HIGH PRIORITY	Mnemonic notes	Examples of type of ALARM SYSTEM	
General	ссс	ссс–сс	Fixed pitch	Other ALARM SYSTEMS that do not readily fall into one of the following categories, including but not limited to electrical or non-oxygen gas supply systems, EEG monitors, intracranial pressure monitors, laparoscopic gas insufflation systems, calf compressor systems, etc. Optionally this sound is permitted for the ALARM SYSTEM of any kind of equipment.	
Cardiac	сеg	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.	
Ventilation	caf	caf – af	Inverted major chord; Rise and fall of the lungs	Anesthesia workstations which include ventilators (but which do not include cardiac monitors); lung ventilators, spirometers, CO ₂ monitors, ventilator disconnect (airway pressure) monitors, etc.	
Oxygen	Cba	Cba–gf	Slowly falling pitches; Top of a major scale; Falling pitch of an oximeter	Pulse oximeters, transcutaneous / tissue oxygen monitors, oxygen analyzers, oxygen concentrators, oxygen gas supply lines.	
Drug or fluid delivery	Cdg	C d g – C d	Jazz chord (inverted 9th); Drops of an infusion falling and "splashing" back up	Volumetric infusion pumps, syringe drivers, anesthetic agent delivery systems or analyzers.	
Equipment or supply failure	Ссс	C c c – C c	Falling or dropping down	Any device when it experiences loss of power or other major failure of the device.	

- 2. Convert the tones into their respective frequency. Use this musical note to <u>frequency conversion chart</u> to assist you.
- Based upon the lowest musical note's frequency (where C⁴, or middle C, would be ~261 Hz), you would start filtering for speakers with a resonant frequency of 261 Hz or lower.
- 4. If you need to meet a target SPL—70 dB at 1 meter is a good rule-ofthumb—you would then additionally filter for speakers that can achieve that SPL while observing the speaker's power rating.



Speaker Integration Best Practices

• If possible, mount the speaker to the inside face of the outer housing. This maximizes the speaker's measured output. Leave a keep-out area of at least 3mm between the speaker's diaphragm and the surface in front of it.

• Ensure that the speaker is mounted in such a way to create a seal along the outer edges of the speaker's frame. This reduces cancelation that occurs if the front of the speaker's diaphragm/cone can interact with the back of the diaphragm/cone. Cancelation can cause a reduction in output below 1 kHz.

• As the signal to the speaker is a trapezoidal waveform, or a square wave, power handling needs to be calculated using the formula below. Do not exceed the rated power (not the maximum instantaneous power, which is meant for use with voice or music) of the speaker.

 $Power = \frac{Volts \ peak^2}{Impedance}$

Exceeding the speaker's rated power will cause damage over time. Typically the type of damage will be broken voice coil tinsel leads or a burned voice coil that causes open load resistance, or a deformed voice coil former which locks the voice coil in the magnetic motor.

• Mounting the speaker within an enclosure will improve performance at and below the resonant frequency of a speaker. Please <u>contact PUI Audio</u> for more information regarding the correct enclosure volume for your application.

• If your application will be chemically cleaned in a hospital environment, choose a speaker that has been treated (our WR series speakers) or a speaker with a Mylar or aluminum diaphragm.



Recommended Speakers

PUI Audio is the go-to speaker source for medical applications. Decades of experience in assisting the world's leading Medical Device manufacturers allows us to recommend the following speakers for IEC 60601-1-8 devices:

& Response	Part Number	Dimensions (in mm)	Resonant Frequency	SPL @ 10cm at Rated Power	SPL @ 1m at Rated Power
esp	AS02704MS-N50-LW100-R	27L x 27W x 6.6H	350 Hz	96 dB	76 dB
	<u>AS03204MS-3-R (4 ohm)</u> <u>AS03208MS-3-R (8 ohm)</u>	32.7L x 31.7W x 16.5H	200 Hz	101 dB	81 dB
ide uei	AS03604MR-N50-R	36D x 18H	200 Hz	103 dB	83 dB
ligh Fre	<u>AS06004PS-R (4 ohm)</u> AS06008PS-R (8 ohm)	66.8L x 66.8W x 26.5H	160 Hz	109 dB	89 dB
ior Hi	AS09208AR-R	92D x 44.6H	90 Hz	112 dB	92 dB
H Superior	AS03608AS-R	36L x 36W x 16.8H	250 Hz	98 dB	78 dB
	<u>AS05308AS-R</u>	53L x 53W x 34H	230 Hz	108 dB	88 dB
	<u>AS06504PS-X-R</u>	65.0L x 65.0W x 36.7H	130 Hz	111 dB	91 dB

/or f I Ico	Part Number	Dimensions (in mm)	Resonant Frequency	SPL @ 10cm at Rated Power	SPL @ 1m at Rated Power
5		20D x 3H	500 Hz	93 dB	73 dB
an	AS02808MR-LW152-R	28D x 5.2H	500 Hz	95 dB	75 dB
Lead-Wired	AS03608MR-LW100-R	36D x 4.6H	500 Hz	101 dB	81 dB
	AS04004PO-2-LW152-WR-R	40L x 28.5W x 11.7H	420 Hz	100 dB	80 dB
	ASE04508MR-LW150-WP-R	45L x 36W x 20H*	420 Hz	98 dB	78 dB
	AS06608MR-LW152-R	66L x 66W x 12.5H	380 Hz	101 dB	81 dB
	AS07104PO-LW152-R (4 ohm) AS07108PO-LW152-R (8 ohm)	71L x 41W x 25H	250 Hz	104 dB	84 dB
	ASE06008MR-LW150-R	60L x 30W x 10.3H*	300 Hz	101 dB	81 dB
	*Denotes speaker with enclosure				

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e for	Part Number	Dimensions (in mm)	Resonant Frequency	SPL @ 10cm at Rated Power	SPL @ 1m at Rated Power
rable stance	AS04004MR-N50-WP-R	40D x 21.5H	160 Hz	105 dB	85 dB
	<u>AS04504PS-X-R</u>	45.4L x 43.3W x 29.2H	170 Hz	110 dB	90 dB
l Dul Resi	<u>AS05804PS-X-R</u>	58.3L x 55.3W x 33.8H	140 Hz	109 dB	89 dB
and	AS04004PO-2-WR-R	40L x 28.5W x 11.7H	420 Hz	106 dB	86 dB
	AS04004PR-WR-R	40L x 40W x 17.5H	180 Hz	104 dB	84 dB
Rugged Eleme	<u>AS04008PS-4W-WR-R</u>	40L x 28.3W x 11.5H	380 Hz	101 dB	81 dB
۳ ۳	AS06608PS-WR-R	66.3L x 66.3W x 29H	230 Hz	115 dB	95 dB
	AS07104PO-LW152-WR-R (4 ohm) AS07108PO-LW152-WR-R (8 ohm)	71L x 41W x 25H	250 Hz	104 dB	84 dB

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