Technology Improvements in IEC 60601-1-8 Alarms

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Since the introduction of international specification number IEC 60601-1-8 in 2003, very few audible alarm drop-in options have been available to medical equipment designers. In an August 2006 MD&DI article, *Audible Alarms in Medical Equipment*, the first IEC 60601-1-8 compliant stand-alone medical audible device was introduced by Mallory Sonalert Products, Inc. with part number (P/N) MSS300R. This alarm consists of a specially designed speaker-housing assembly with no circuitry. What makes this device unique is that the user only needs to input a simple square wave signal with one frequency component, and the other needed harmonic sound frequencies are generated acoustically. This greatly simplifies implementation of an audible alarm sound in an IEC 60601-1-8 medical application since the medical equipment designer does not have to worry about generating a complex frequency signal or worry about making sure the various harmonic peaks are relatively equal in sound level as required by IEC 60601-1-8.

From 2006 to 2014, only two more models in the MSS speaker series were added- P/N's MSS5M1 & MSS5M0 which have DC circuitry to generate the audible sound, so only 5 Vdc needs to be applied.

IEC 60601-1-8 compliant P/N's MSS300R, MSS5M1, & MSS5M0 emit 90 dB @ 10 cm in a 23 mm x 14 mm compact package.

Needed Improvements

Some users have found that the three MSS speaker series alarm models are too soft in sound level for certain medical applications. Others have found that the units pull too much current due to the employment of a speaker to generate the needed sound frequencies. Medical applications that use super-capacitors as their back-up power source during a power failure situation are simply not able to accommodate any speaker driven audible alarms due to the high current draw. When Mallory began receiving this kind of feedback, R&D projects were started to improve the product offering.

More Power ≠ More Sound Level

One seemingly obvious idea to increase sound level is to use a higher power speaker. However, when this was tried, prototype after prototype failed to increase the over-all sound level to everyone's surprise. The break-through needed was to realize that the limitation in generating more sound level (and still meet IEC 60601-1-8) requires the use of a larger diameter speaker and sound chamber- not just the use of a higher power speaker. Further refinements led to a new series of IEC 60601-1-8 alarms which can emit a typical sound level at 100 dB @ 10 cm which makes them much more useful for louder environments such as operating rooms. This new SBS speaker series of IEC 60601-1-8 medical alarms features a louder sound level in a 45 mm diameter by 15 mm height package. Some options are available in a flange mount configuration and all options are available with pc pin terminations. The SBS series has parts available with and without circuitry, and the models that contain circuitry are rated 9 to 12 Vdc. Besides the SBS speaker series having a larger package size, the other trade-off needed to gain more sound level is more current draw. While the original smaller MSS series alarms average 150 mA for the high priority alarm, the louder SBS alarms average 200 mA.

Is an IEC 60601-1-8 Piezo Model Possible?

Piezoelectric transducers typically operate very well at one sound frequency. It has been generally known that edge mounting a piezoelectric transducer flattens the frequency response some, but because IEC 60601-1-8 requires such a wide range of frequencies, it seems impossible that any mounted type of piezoelectric transducer device can meet all the requirements of this IEC specification.

After Mallory developed the housing and tweaked in the sound chamber for the new SBS medical speaker series, against all common sense, one more attempt was made to see if it could be paired with a piezoelectric transducer to meet IEC 60601-1-8. As often said by Thomas Edison, persistence is the

IEC 60601-1-8 compliant SBS speaker series features sound levels of 100 dB @ 10 cm in a 45 mm x 15 mm package size. Some options available with the flange mount package and all options available with pc pin terminations.

IEC 60601-1-8 compliant SBT piezo series has the same housing size options but features less current making them suitable for battery or back-up power required applications.

key, and a piezoelectric-housing assembly was developed that can do the job. The result is the SBT medical piezo series which features a typical sound level of 90 dB @ 10 cm. Like the SBS series, some SBT model options are available in a flange mount housing configuration, but all options are available with pc pin terminations. Models are available both with and without circuitry, and the models that contain circuitry have two voltage range options- 3.3 to 5 Vdc and 9 to 12 Vdc. Most importantly, the average current level for the high priority sound in the SBT series is only 20 to 25 mA making them suitable for medical applications that run on batteries or use a super capacitor in power failure situations.

Priority Sounds vs Melodies

IEC 60601-1-8 has two different options for generating the alarm sounds. One is to stay with the same frequency profile and pulse this same sound at the required intervals to generate the three priority sounds. In this case, the human ear hears the same sound (which is composed of several different frequencies) pulsed on and off as needed. The 2nd option mentioned in IEC 60601-1-8 is to use the melody table listed in Annex F where different medical conditions are assigned specific individual melodies.

IEC 60601-1-8 Annex F Melody Listing

Cause	Medium Priority	High Priority
General	c c c	c c c - c c
Cardiac	c e g	c e g - g C
Artificial Perfusion	c f# c	c f# c - c f#
Ventilation	c a f	c a f - a f
Oxygen	C b a	C b a - g f
Temp/Energy Delivery	c d e	c d e - f g
Drug or Fluid Delivery	C d g	C d g - C d
Equipment or Supply Failure	C c c	C c c - C c
Cause	**Low Priority**	
Any	e c	

The letters in the table above represent musical notes where the note "c" represents the fundamental frequency of the audible alarm and must be less than 1,000 Hz.

These melodies are essentially little tunes that change in pitch per the tables in Annex F. The hope is that the medical personnel using medical equipment with alarms that use these melodies will become familiar with them which can help the medical personnel respond more quickly and more appropriately when a specific melody alarm sounds.

In the mid to late 2000's, affordable technology did not exist to implement these melody sounds in a small 23 mm x 14 mm package size. By 2015, the technology was available. So, in all three series (MSS speaker series, SBS speaker series, & SBT piezo series), Mallory has introduced the melody options called out in Annex F of IEC 60601-1-8. This gives medical equipment designers the option of either staying with the General Melody, which is essentially the same sound pulsed at different rates, or to use one of the specific melodies.

Conclusions

Through persistent R&D, Mallory has now expanded the IEC 60601-1-8 compliant medical alarm offering from 3 part numbers to 42 parts numbers. The SBS speaker series offers more sound level than the smaller MSS speaker series making it suitable for louder medical environments such as operating rooms. The SBT piezo series offers ultra-low current making it suitable for battery or back-up power applications that run on super-caps. In all three series, melody options are available letting medical equipment designers choose which sounds they need for their application.

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IEC 60601-1-8 Primer

- IEC 60601-1-8 is an international specification governing the use of audible and visual signals in medical equipment. It is a sub-section of IEC 60601.
- Equipment must use a high, medium, or low priority warning sound depending on the condition of the patient.
- The audible sound fundamental frequency < 1000 Hz.
- At least 4 harmonic frequencies are needed within ± 15 dB of the fundamental frequency.
- Has specific wave-form and timing requirements for the three priority sounds. This includes a sound rise time.
- Does not dictate the needed sound level. This is up to the individual medical application to decide.
- States that a lesser priority sound should not be louder than a higher priority sound, but the three priority sounds can all be equal in sound level.
- Optional melodies for specific medical applications/conditions are listed in Annex F.
- An amendment to the 2nd edition was issued in 2011-2012. You can purchase the amendment separately or as part of the 2nd edition.
- IEC 60601-1-8 is mandatory in Europe and voluntary in the U.S. However, various pressures in the industry are pushing U.S. medical companies to adopt this specification.