



FAQ's- IEC60601-1-8 Medical Alarms

Index:

General Alarm Technology	Pages 2 - 3
Electrical Application Issues	Page 4
Mechanical Application Issues	Page 5
Soldering & Washing Issues	Pages 6
Sound Issues	Pages 7 - 8
Environmental Issues	Pages 9 - 10
Warranty	Page 11

General Alarm Technology

Q: What is an electronic audible alarm?

A: An electronic audible alarm produces an audible warning sound using electronic means. This is in contrast to electro-mechanical alarms that produce sound by mechanical means. Examples of electro-mechanical alarms include the old clapper type alarm clocks, school bells, and car horns. Examples of applications that use electronic audible alarms include smoke detectors and microwave ovens.

Q: What else are audible alarms called?

A: Buzzers, beepers, audible signals, piezo's, sounders, alerts, audio alarms, indicators, transducers, and various combinations of these terms (audio alerts, piezo indicators, etc.).

Q: How do electronic audible alarms work?

A: Audible alarms work by using electronic components to convert the user's input voltage into an appropriate oscillating signal that drives a metal sounder diaphragm or a speaker diaphragm. This diaphragm then physically flexes up and down producing air pressure waves that the human ear interprets as sound. For a more detailed description, please read the Article titled, "[Audible Alarm Basics](#)" and see Technical Application Guide, "[Piezoelectric Alarm Operation](#)".

Q: How does a piezoelectric transducer work? How do speakers work?

A: Piezoelectric type alarms utilize a piezoelectric transducer which consists of a metal disc that has a ceramic material bonded to it. When voltage is applied to the ceramic material, it causes the metal disc to physically flex. If the piezoelectric transducer is physically flexed at an appropriate frequency, the air pressure waves are produced that are heard as an audible sound.

Speakers utilize an electromagnet which causes the diaphragm to flex when an alternating signal is applied.

Q: Why are both piezoelectric and speaker technologies used for audible alarms?

A: Alarms that use piezoelectric technology draw less current, are capable of louder sound levels, and do not generate magnetic fields (possible EMI/EMC concerns). Alarms that use speakers excel at low frequency and multi-frequency sounds. Because the IEC60601-1-8 spec. calls for multiple frequencies and a low frequency fundamental frequency, Mallory did not originally think that this technology could be used, but after some significant R&D work, Mallory developed such a device.

Q: How are electronic audible alarms constructed?

A: Electronic audible alarms are considered components by equipment designers, but in actuality, they are a complex electromechanical assembly. See Technical Application Guide, "[Piezoelectric Alarm Construction](#)".

Q: What is the difference between an indicator and a transducer?

A: An indicator is an electronic alarm that has internal circuitry. The user only needs to apply an input voltage, and the alarm will automatically sound.

A transducer does not contain any internal circuitry. The user has to supply the complex AC signal that will make the sounder diaphragm flex at the appropriate rate and amplitude.

Q: When should I use an indicator and when should I use a transducer?

A: Indicators are always appropriate to use. Mallory's design engineering (which holds over a dozen active patents) has already designed the most efficient circuit needed to produce the required sound and has tested that circuit against a wide variety of environmental conditions.

Transducers may be justified to use when there is sufficient volume to the application to justify the time and expense required to design, de-bug, test, re-design, and validate the circuit design needed to drive the transducer under the environmental extremes that will be seen in the application. While the operation of the transducer may seem simple from the outside, there are many potential application problems that can arise unexpectedly.

Electrical Application Issues

Q: What does the input impedance of a piezoelectric transducer type device (no circuitry) look like?

A: The input impedance of a piezoelectric transducer looks like pure capacitance. The current and voltage waveforms across the transducer can be predicted from the source voltage impedance and the transducer capacitance.

Q: For a piezoelectric transducer type device, what effect does the source impedance have on the resulting sound level?

A: For Mallory Sonalert piezoelectric transducer type alarms, the sound level curves are generated with a square-wave with a 50-Ohm source impedance. You can increase the source impedance to a few hundred Ohms with negligible effect on the resulting sound output.

Q: Do your mounted speakers without circuitry have polarity?

A: No. You can connect the speaker drive signal across the speaker terminals either way even though polarity is indicated on the label or implied by red and black wires.

Q: How do I drive your mounted speaker models (no circuitry)?

A: For Models MSS300R, SBS300PC, & SBS300FL, you need to apply a 325 Hz square wave to the device. Since the speaker is 8 ohms, you'll most likely use an audio amplifier chip capable of driving an 8 ohm speaker. Mallory recommends using a maximum of 2.8 Volts peak-to-peak. Since you are in control of the signal, you'll also have to make sure you meet the rise time called out in IEC60601-1-8 as well as the beeping rates for the high, medium, & low priority sounds.

Q: How do I implement the rise time requirement for your mounted speaker models?

A: For Models MSS300R, SBS300PC, & SBS300FL, there is no circuitry included. Sound level from the speaker is proportional to the peak-to-peak voltage applied, so to implement the rise time requirement, you must ramp up the voltage to the speaker. If you don't have the capability to do this, you can consider using models MSS5M0, SBS12M0PC, or SBS12M0FL. These models include circuitry, but emit a constant tone which includes the rise time. It is still up to you to turn these models off and on at the appropriate rate to meet the timing requirements for the high, medium, and low priority sounds. You can also consider models SBS12M1PC which includes circuitry and is capable of meeting all requirements of IEC60601-1-8.

Q: How do I power the models with circuitry?

A: See the application guide for these models which has the wiring diagram and possible circuit implementations.

Mechanical Application Issues

Q: I want to seal the buzzer to the back of my panel. How do I do that?

A: There are two options. One is to use silicone adhesive. The other option is to use a neoprene gasket with adhesive on one side. Mallory has such as gasket for the MSS, MSR, MSO, and MSE Series. The accessory gasket part number is ACC12.

Q: Can I bury the alarm inside my equipment?

A: Yes, but the alarm will be attenuated 15-20 decibels. This means that the sound level will be about $\frac{1}{2}$ to $\frac{1}{4}$ as loud as it would be if it was mounted externally or if there were openings made in the enclosure so that the sound could radiate out. For a full discussion on mounting alarms inside of equipment, read the article titled, "[Audible Alarm Use and Equipment Integrity Issues.](#)"

Q: Can Mallory provide custom terminations?

A: Yes! Visit our contact page on the website or email info@mallory-sonalert.com or call 317-612-1000

Soldering & Washing Issues

Q: What is the recommended hand soldering temperature for Mallory audible alarms?

A: 330°C for 1.5 seconds or 270°C for 4 seconds.

Q: What is the recommended wave solder temperature for Mallory audible alarms?

A: 270°C for 3 seconds.

Q: What could happen if I deviate from the recommended solder temperatures and times?

A: Unlike resistors, capacitors, IC's, or other components, electronic alarms are actually a complex electro-mechanical assembly. Unless you are using a transducer or buzzer unit that utilizes spring clip connections, there are usually a multitude of solder joints internal to the audible alarm. If you put too much heat for too long of a time on the audible alarm terminals, you can cause a variety of problems including:

1. The solder joint connecting the audible alarm terminal to the PC board may re-flow causing a cold solder joint.
2. Components on the circuit board near to the terminal may heat up and fail due to either thermal shock of the component or cold solder joints.
3. The solder plating on the terminals may fail.

Q: Can I send my board mount audible alarm through a wash after soldering?

A: It is only recommended to wash those audible alarms that are sealed in the back and have a wash label over the sound opening. Not all board mount audible alarms are available in this configuration, so it is recommended to view the part data sheet or visit our contact page on the website or email info@mallory-sonalert.com or call 317-612-1000

Q: What will happen if I wash the audible alarm and either it is not sealed in the back or doesn't have a wash label?

A: If the part does not have a wash label, the cleaning solution will get into the front of the part through the front hole acoustic opening. This will not likely damage the part, but an audible alarm will likely not sound (or barely sound) if there is liquid solution in this front chamber. The cleaning solution may dry out over time on its own, or it can be removed more quickly by using an air circulating oven. However, the time it takes for the part to dry out depends on many different factors.

If the part is not sealed in back, several things may happen. The cleaning solution may get trapped inside the part and may seep out over time or at an inappropriate time. If the part has a circuit board, the cleaning solution may get up on the circuit board and cause electrical shorting and possibly permanent damage to the part or the circuit board the part is mounted on. Finally, the cleaning solution may cause corrosion internally to the audible alarm which could result in the part failing catastrophically or slowly over time.

Sound Issues

Q: How is sound level measured?

A: Sound level is measured in decibels (abbreviated dB). The dB scale is an arbitrary scale that reflects the loudness of the sound that is being measured. It ranges from 0 dB (threshold of hearing) to 130 dB (threshold of pain). For a better understanding of the decibel sound level scale, see Technical Application Guide, "[Decibel Sound Level Scale](#)".

Q: How loud does my audible alarm need to be?

A: The audible alarm should be at least 10 dB louder than the ambient background noise so that it can be easily heard. You can estimate the ambient background noise by using the chart found in the Technical Application Guide, "[Decibel Sound Level Scale](#)" or you can use a sound level meter to measure the actual ambient noise level.

Q: When is a sound level twice as loud as another?

A: Every time the sound level increases by 10 dB, it will sound twice as loud to the human ear. For example, an alarm specified as 90 dB at 2 feet will sound half as loud as one specified as 100 dB at 2 feet.

Q: What does distance have to do with sound level?

A: Sound level falls off over distance. We intuitively know this because we have to talk louder (or even shout) when people are farther away. The rule of thumb is that every time the distance doubles, the sound level drops off by 6 dB. For example, if an audible alarm measures 60 dB at 2 feet, by the time it reaches 4 feet, it will only be 54 dB. By the time it reaches 8 feet, it will only be 48 dB, and so on.

Q: How come some audible alarms are specified at 2 feet and some are specified at 10cm? How do I compare alarms at various distances?

A: Unfortunately, there is no one standard distance for specifying the sound level for audible alarms. However, there are some common distances such as 2 feet (60 cm), 1 foot (30 cm), and 10 cm (4 in). An excel spreadsheet has been developed to convert among the most common distances used. The link for the spreadsheet is in our TECHNICAL RESOURCES webpage.

For example, if you want to compare an alarm that is specified as 100 dB at 10 cm and one specified as 88 dB at 2 feet, you must choose one distance that you want to use to compare the parts. Using the distance conversion spreadsheet, you would find that 88 dB at 2 feet equates to 103 dB at 10 cm, so the alarm specified as 88 dB at 2 feet is actually louder than the other one when they are compared apples to apples.

Q: How sensitive is the human ear to sound level changes?

A: Most people can only distinguish a sound level change only when it increases or decreases by 3 decibels. For example if a person was listening to an audible alarm that changed from 90 to 92 dB,

that person would most likely say that the alarm did not get louder. If the sound level changed from 90 dB to 93 dB, the person would say that the sound level is slightly louder. If the sound level changed from 90 to 96 dB, the person would say that the sound level is significantly louder. If the sound level changed from 90 to 100 dB, the person would say that the sound level is twice as loud as before.

Q: What does dBa (A-Weighting) mean?

A: dB is the abbreviation for decibels which is how the sound level of audible alarms is measured. The “a” in dBa means that the sound level was measured on an A-Weighting scale. The A-Weighting scale was developed to compensate for the fact that the human ear is not a perfect microphone. By applying the A-Weighting scale to sound level measurements, you put the different frequencies (pitches) that the audible alarms produce on an even basis (i.e. comparing apples to apples). Mallory always uses A-Weighting for their sound level measurements, but not all audible alarm manufacturers are this diligent.

Q: What is the acoustic sound chamber and how does it work?

A: The acoustic sound chamber of audible alarms includes the area inside the housing that is in front of the sounder element and includes the front hole opening.

The sound chamber does not work like organ pipes. In organ pipes, there are standing waves of different size depending on the frequency generated. This is why the organ pipes are different lengths. If the standing wave principle was used for electronic audible alarms, the alarms would have to be many inches or feet in length.

Perhaps the best way to explain how the acoustic sound chamber works is to think of it using a more visceral medium. If you think of the air sound waves being replaced by water, the sound chamber would work by providing an efficient shape for the water to move out of the housing without being obstructed by eddies, reverse currents, and dead spots. Essentially, the acoustic sound chamber provides a low impedance path for the air pressure wave to escape the housing with maximum intensity.

Q: Can Mallory provide a custom sound?

A: Yes! Visit our CONTACT US webpage or email info@mallory-sonalert.com or call 317-612-1000

Environmental Issues

Q: Which specification are these IEC 60601-1-8 alarms approved to?

A: These alarms are UL and CUL approve to the specific IEC spec- IEC60601-1-8. At final test, Mallory uses the same software that UL used to approve these alarms to verify that each alarm meets the requirements of IEC 60601-1-8.

Q: I want to seal the buzzer to the back of my panel. How do I do that?

A: There are two options. One is to use silicone adhesive. The other option is to use a neoprene gasket with adhesive on one side. Mallory has such as gasket for the MSS, MSR, MSO, and MSE Series. The accessory gasket part number is ACC12.

Q: Are your alarms CE Marked?

A: The alarms, buzzers, transducers, speakers, and other products & accessories sold by Mallory Sonalert Products, Inc. are individual components that must be incorporated into final equipment in order to be useful. Since their safety and use depends to a very large extent on how they are incorporated, they are not covered by the various European Directives, and need not be CE marked. In fact, per the Low Voltage Directive, components must **not** be CE Marked.

Q: What is the shelf life of an audible alarm?

A: Mallory is not aware of anyone who has ever had a shelf life issue with our alarms. That being said, some alarm models contain aluminum electrolytic capacitors. The recommended shelf life for these capacitors is 5 to 10 years depending on how they are used. Our application of these capacitors is not especially sensitive to the shelf life issues of these components, so we would expect that they would last 8-10 years or longer in our alarms just sitting on the shelf (no voltage applied during that time).

Q: What is the Mean Time Between Failure (MTBF) for Mallory Alarms?

A: MTBF data has only been generated for the SC, SNP, and SBM Series. Historical life test data at maximum temperature and voltage has resulted in the following failure rates for a majority of the models in these series that we sell when calculated per Mil-Handbook-217:

F.R. = 0.08% per 1000 hrs @ 60% confidence level

MTBF = 1,250,000 hrs @ 60% confidence level.

Q: What is the ECCN Number for Mallory Alarms, Buzzers, & Speakers?

A: Mallory Sonalert Products alarms, buzzers, and speakers do not require an ECCN Number. However, if you absolutely need to assign an ECCN Number, use EAR99 (which means that our product is not regulated).

Q: What are the typical failure modes for piezoelectric audible alarms?

A: Customer returns of Mallory audible alarms for failure to operate are very rare. Of the few parts returned each year, the vast majority of the root cause of failure is an over-voltage or voltage spike condition caused by the customer's application. For more details, see Technical Application Guide, "[Typical Failure Modes](#)".

Q: What environmental tests do your alarms meet?

A: Design Engineering uses a variety of tests during the verification and validation design phases. These tests can include: surge voltage, reverse voltage, hot & cold life tests, room temperature life test, humidity, vibration, shock, salt spray, and terminal strength. The Environmental Tests for each alarm are listed in that alarm's Environmental Durability PDF available on the website.

Q: What is the Moisture Sensitivity Level (MSL) of Mallory alarms?

A: MSL 1 (Unlimited)

Q: I have a special environmental requirement, can Mallory help me?

A: Yes! Use our CONTACT US webpage, email info@mallory-sonalert.com or call 317-612-1000

Warranty

The seller warrants the goods to be supplied hereunder will conform to the pertinent specifications, drawings and approved samples, if furnished, and that such goods will be of good materials and workmanship and free of defects if properly installed and used as sold by Seller. If within one-year period from the date of shipment to Purchaser such goods, not having been subject to misuse, alteration, modification, neglect. Improper installation or unauthorized repairs not exposed to an abnormal environment, are shown not to be in conformity or are shown to be defective in workmanship or materials, Seller's sole and exclusive obligation under this warranty is to repair or replace such goods, provided return is made prepaid to Seller or its designated representative with the following tagged information: (i) date of shipment of such goods to Purchaser; (ii) date such goods are determined to be non-conforming or defective; and (iii) specifying the apparent non-conformity or defect. No claim will be allowed under this warranty unless Purchaser notifies Seller of such claim within 30 days after Purchaser learns of facts giving rise to such claim. Purchaser's failure to test, inspect and make claim within such one-year period shall be conclusive evidence that the goods shipped were satisfactory in all respects. The liability of Seller under the forgoing warranty shall not exceed the price charged by Seller for the goods which give rise to the Purchaser's claim. THE AFORESAID WARRANTY IS EXCLUSIVE AND IN LIEU OF ALL OTHER WARRANTIES WHETHER EXPRESS OR IMPLIED (INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR PURPOSE), EXCEPT OF TITLE. SELLER ASSUMES NO LIABILITY FOR ANY SPECIAL, INDIRECT, CONSEQUENTIAL, INCIDENTAL OR OTHER DAMAGES OF ANY TYPE (INCLUDING, BUT NOT LIMITED TO, DAMAGES RELATED TO LOST SALES AND PROFITS, EXCESSIVE OR INCREASED COSTS AND EXPENSES, FIELD RECALL AND RETROFIT, COSTS AND EXPENSES , DOWNTIME COSTS AND CLAIMS OF CUSTOMERS OR PURCHASER FOR SUCH DAMAGES) RESULTING FROM NON-CONFORMING OR DEFECTIVE CONDITION OF ANY GOODS SOLD BY SELLER TO PURCHASER HEREUNDER, AND PURCHASER ASSUMES ALL LIABILITY FOR ALL CONSEQUENCES ARISING OUT OF ITS USE OR SALES OF SUCH GOODS. THE AFORESAID REMEDY OF PURCHASER IS EXCLUSIVE AND THIS LIMITATION OF LIABILITY PROVISION SHALL APPLY TO ANY AND ALL CLAIMS OR SUITS BASED UPON NEGLIGENCE, BREACH OF CONTRACT, BREACH OF WARRANTY, STRICT LIABILITY, OR ANY OTHER LEGAL THEORY UPON WHICH LIABILITY MAY BE ASSERTED AGAINST SELLER BY PURCHASER OF OTHERS.