



FAQ's for Mallory's IEC 60601-1-8 Medical Alarms

What is IEC 60601-1-8?

IEC 60601-1-8 is a specification that covers the prerequisites for audible & visual alarm use in medical equipment. This specification is a subsection of IEC 60601 which covers all requirements for medical equipment. "IEC" spec.'s are controlled by committees in Europe.

Is IEC 60601-1-8 compliance required in the U.S?

Yes- for new medical equipment in the U.S, and it's also required for Europe and Canada.

What does IEC 60601-1-8 specifically cover for audible alarms?

There are many detailed and complicated requirements for audible alarms in IEC 60601-1-8:

- Up to 3 medical priority tones (low, medium, & high) may be used.
- For each medical priority tone, all required aspects of the sound profile are listed.
- For each medical tone, there are different melodies available depending on the medical application, and there is a "general" melody which can be used for any medical application.
- Requirements are listed for any non-medical sound that the equipment uses such as a beep when a button on the medical equipment is pressed.

Do I need to be worried about all the detailed requirements in IEC 60601-1-8?

Only if you are on the medical equipment design team, or if you are a Mallory engineer tasked with making audible alarms which meet all requirements of IEC 60601-1-8.

Are there different versions of IEC 60601-1-8?

Of course. The committees in Europe can't stand to leave a good spec. alone. The most current revision is IEC 60601-1-8 AM2 (2020) which was issued in 2020 as the name indicates. The previous revision was IEC 60601-1-8 AM1. A new version is scheduled to be released in 2024.

Are medical companies aware of new version IEC 60601-1-8 AM2 (2020)?

There will be people at the medical companies aware of this new version. That being said, if the current medical equipment design team is tasked with meeting previous version IEC 60601-1-8 AM1, they may not be aware of the new AM2 (2020) version, and they may not currently care that there's a new version.

Is there a transition period for IEC 60601-1-8 AM2 (2020)?

Yes. Countries usually give at least 3 to 4 years before a new revision is required. So, there's medical equipment currently being designed and tested to AM1 and AM2 (2020). It's in the best interest of the medical device company to move to AM2 (2020) as quickly as they are able to.

What changes were made in IEC 60601-1-8 AM2 (2020)?

IEC 60601-1-8 offers options for different melodies depending on the medical application. For the previous version IEC 60601-1-8 AM1, the melodies were specified in detail similar to writing the individual notes on a musical score. In new version AM2 (2020), these detailed melodies are deleted, and IEC provides .WAV sound files to be used for the different melodies.

What are the melody options in IEC 60601-1-8?

Cardiac, Drug or Fluid Delivery, Equipment or Supply Failure, Artificial Perfusion, Temperature or Energy, Oxygen, and Ventilation. Also, General melody for use in any medical application.

How do we know that Mallory's medical alarms meet IEC 60601-1-8?

All of Mallory's medical alarms were tested by UL and approved to IEC 60601-1-8. This means medical device designers can have confidence the Mallory alarms will work as intended in the medical equipment.

Which version of IEC 60601-1-8 does Mallory's medical alarms meet?

For IEC 60601-1-8 AM1, Mallory has hundreds of models in the MSS, SBS, & SBT series qualified. When IEC 60601-1-8 AM2 (2020) was released, UL approved all MSS, SBS, & SBT models that do not use the melody tones to AM2 (2020).

In addition, Mallory submitted to UL our new MSW Series models which uses the IEC supplied melody sound files, so the MSW Series models are approved to IEC 60601-1-8 AM2 (2020).

Which IEC 60601-1-8 version is Mallory's medical models approved to?

You can see which version of IEC 60601-1-8 the alarm is qualified to on the medical alarm product tables. For example, here is the [MSS & MSW product table](#) webpage. In general:

- Most of Mallory's MSS, SBS, & SBT models are qualified to both versions.
- The MSS, SBS, & SBT models which issue the melody tones are qualified to previous version IEC 60601-1-8 AM1 only.
- The new MSW models are approved to new version IEC 60601-1-8 AM2 (2020) only.



Mallory's IEC 60601-1-8 Medical Alarms are **manufactured** in Indianapolis, Indiana with **lead-times** of stock to 4 weeks, they are [UL](#) and [CUL](#) Approved, and 100% Tested by Mallory to IEC 60601-1-8.

New 60mm Stacklight Product Video



Mallory has published our **60mm Stacklight Product Video** highlighting their revolutionary light and sound features.

For a device like a Stacklight, it's difficult to get a feel for how it works from static pictures, so the video really shows off the advantages of Mallory's [60mm Stacklights](#) including:

- 1 to 5 Stacks Available (Red, Yellow, Green, Blue, & White)
- State-of-the-Art Brilliant LED's
- 24 Vac/dc or 120 Vac
- Pole or Direct Mount
- Preferred 2000 Hz Sound Frequency
- UL & CUL Approved, NEMA 12, IP-52
- Each Unit Includes 4 Sound Options:
 - Continuous
 - Medium Pulse (5 pps)
 - Slow Double Pulse
 - Continuous Tone for 5 Seconds Followed by a Short Pulse Tone Every 1 Second

Mallory is the only manufacturer to offer 4 sounds in every Stacklight, and two of the sounds are unique to the industry:

- The **Slow Double Pulse** sound is a double beep which is issued every 2 seconds. This tone is not a common warning sound that is heard in facilities, so the slow double pulse sound will catch the operator's attention more quickly than a continuous or single beeping tone.
- The **Continuous** sound followed by a **Short Pulse** sound is used in situations where it may take a while for the machine condition to be fixed. This means that the operator or technician can continue to work on the equipment without the distraction of a loud continuous tone.

Applications finding Mallory's 60mm Stacklights useful:

Machine Tooling

Water Treatment

Printing Machines

Food Machinery

Conveyors

Industrial Label Machines

Brewing & Distilling

Large Medical Equip.

Semiconductor Fabrication

Flow Control Equip.

Pharmaceutical Equip.

General Industrial Control

Metal Detection

Packaging Equip.

Inspection Equip.



Mallory's [30mm and 60mm Stacklights](#) are **manufactured** in Indianapolis, Indiana with **lead-times** of stock to 4 weeks. Approvals include [UL](#), [CUL](#), NEMA 12, & IP-52.