



FAQ APPLICATION Guide

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

What is IEC 60601-1-8?

IEC 60601-1-8 is a detailed 121-page specification that covers the prerequisites for audible and visual alarm use in medical equipment. This spec. is a subsection of IEC 60601 which covers all medical equipment requirements. "IEC" specifications 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 is 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 their different versions of IEC 60601-1-8?

Of course. The committees in Europe cannot stand to leave a good specification 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 one 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), but it is in the best interest of the medical device company to move to AM2 (2020) when possible.

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).

How do I tell which IEC 60601-1-8 version Mallory's models are approved to?

On Mallory's medical alarm webpage, the product table details which version of IEC 60601-1-8 the alarm is qualified to. In general:

- Many of Mallory's MSS, SBS, & SBT models are qualified to both versions- AM1 & AM2 (2020). These models are qualified under Tables 3 & 4.
- The MSS, SBS, & SBT models which issue the melody tones are qualified to previous version IEC 60601-1-8 AM1 only. These models are qualified under Appendix F.
- The MSW models are approved to new version IEC 60601-1-8 AM2 (2020) only. These models are qualified under Appendix G, and use the sound files provided by IEC.

What sound level does IEC 60601-1-8 require?

The short answer is that IEC 60601-1-8 does not say what sound level should be used because that is up to the equipment designers to determine what sound level is needed for the application. Mallory recommends that the medical alarm be 6 to 10 dB louder than the ambient background noise. IEC 60601-1-8 does have some other sound level requirements:

- The Medium Priority sound needs to have the same or greater sound loudness as the Low Priority sound, and the High priority sound needs to have the same or greater sound loudness as the Medium Priority sound.
- Tables 3 & 4 has requirements for the relative sound level of the priority tone pulses (they must be within 10 dB of each other) and the relative sound level of the 4 largest sound frequency components (they must be within 15 dB of each other).

What is the sound level of Mallory's medical alarms?

- MSS, MSW, & SBT Series: 90 dB @ 10 cm
- SBS Series: 100 dB @ 10 cm