Technical Article

Demystifying Medical Alarm Designs, Part 1: IEC60601-1-8 Standard Requirements

Uttam Sahu

Sanjay Pithadia co-authored this technical article.

If you have ever heard the not-so-melodic alarm of a patient monitor in an intensive care unit (ICU) or even on a TV show or movie set in a hospital, you might remember that these alarms have particular patterns. These specific patterns help a caregiver distinguish between critical and non-critical alarms from a distance.

A patient's life often depends on the proper functionality of medical devices used in an ICU. These medical devices must comply with basic safety and performance requirements defined by various standard bodies like those established by the International Electrotechnical Commission (IEC). In most cases, the "essential" performance of a medical device includes raising both visual and auditory alarms in order to alert caregivers to take corrective action. Thus, a medical alarm acts as an essential function in such medical devices.

Multiparameter patient monitors, neonatal warmers and incubators, anesthesia delivery systems, dialysis machines, infusion pumps, ventilators, and surgical equipment are all examples of medical equipment that need an alarm.

A medical alarm system needs to be functional for all intended uses, as well as foreseeable misuses and single-fault conditions identified for the specific device. It needs to implement redundancy and must be audible inside the ICU without having audio harmonic cancellation. Some medical device standards such as neonatal incubators also demand a minimum sound pressure level at a specific distance from the medical equipment.

The IEC 60601-1-8:2006 lists the requirements for an alarm system in medical equipment. In medical equipment like neonatal incubators, the visual and auditory alarms can act as complementary alerts. However, in devices like ventilators and suction pumps, the alarm system needs to implement explicit redundancy.

The IEC60601-1-8 standard classifies alarms according to a low, medium or high priority of an abnormality or failure event. Accordingly, the visual alarms have defined colors such as green, amber, and red that correspond to priority levels, and the auditory alarms have defined waveform patterns, acoustic levels and harmonic responses.

The IEC standard is very specific for auditory alarms, defining the pulse frequency range, shape of the pulses and pattern of the signal burst. The standard also defines a maximum amplitude difference between the pulses. However, the most challenging requirement is the maximum amplitude difference between the first four harmonics, which is measured in the acoustic domain in an anechoic chamber with a reflective floor. The harmonics requirement makes sure that there are no spots in the ICU where the direct and reflected harmonics of the auditory alarm cancel each other, which would make the alarm practically inaudible. Plus, hardware-based real-time tuning of parameters during compliance testing is challenging and expensive.

All of these constraints create long learning cycles for medical device designers, who are mainly electrical, mechanical or software engineers.

Figure 1 provides a glimpse into typical terminology of alarm designs and requirements. It shows three important aspects of the alarm tone: the burst, the pulse envelope and the pulse.

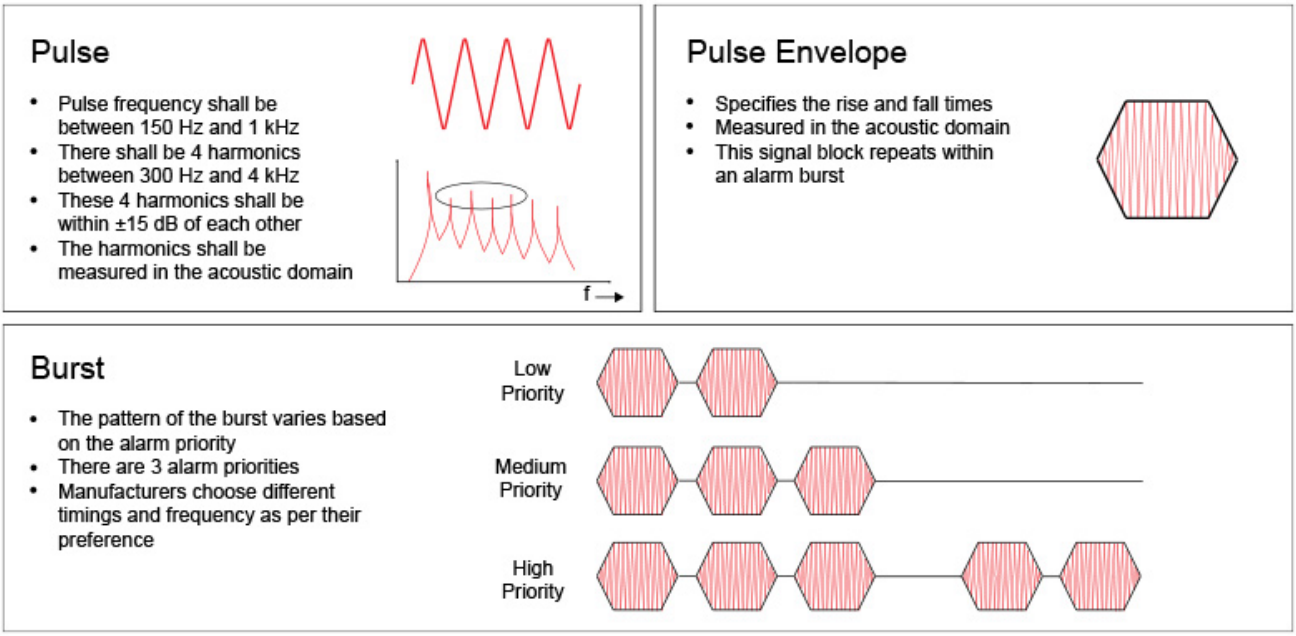

Figure 1. Medical Alarm Terminology

For the alarm pulse, the fundamental frequency needs to be between 150 Hz and 1 kHz so that the first four harmonics are between 300 Hz and 4 kHz. In terms of amplitude, these four harmonics should be within ±15 dB of each other. The pulse envelope has specific rise and fall time requirements in the range of 7.5 ms to 100 ms that are measured in acoustic domains. The burst frequency varies depending on alarm priority (low, medium or high). Medical equipment manufacturers can choose different burst timings and frequency.

The IEC standard specifies all of these different parameters. In the next installment of this series, we will talk about the design considerations and existing implementation techniques for medical alarms.

Additional resources:

- Learn more about TI's technologies for medical applications.
- Explore our alarm tone generator reference design.
- Read more about guidelines for medical alarm system software design.

IMPORTANT NOTICE AND DISCLAIMER

TI PROVIDES TECHNICAL AND RELIABILITY DATA (INCLUDING DATA SHEETS), DESIGN RESOURCES (INCLUDING REFERENCE DESIGNS), APPLICATION OR OTHER DESIGN ADVICE, WEB TOOLS, SAFETY INFORMATION, AND OTHER RESOURCES “AS IS” AND WITH ALL FAULTS, AND DISCLAIMS ALL WARRANTIES, EXPRESS AND IMPLIED, INCLUDING WITHOUT LIMITATION ANY IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR NON-INFRINGEMENT OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS.

These resources are intended for skilled developers designing with TI products. You are solely responsible for (1) selecting the appropriate TI products for your application, (2) designing, validating and testing your application, and (3) ensuring your application meets applicable standards, and any other safety, security, regulatory or other requirements.

These resources are subject to change without notice. TI grants you permission to use these resources only for development of an application that uses the TI products described in the resource. Other reproduction and display of these resources is prohibited. No license is granted to any other TI intellectual property right or to any third party intellectual property right. TI disclaims responsibility for, and you will fully indemnify TI and its representatives against, any claims, damages, costs, losses, and liabilities arising out of your use of these resources.

TI’s products are provided subject to TI’s Terms of Sale or other applicable terms available either on ti.com or provided in conjunction with such TI products. TI’s provision of these resources does not expand or otherwise alter TI’s applicable warranties or warranty disclaimers for TI products.

TI objects to and rejects any additional or different terms you may have proposed.

Mailing Address: Texas Instruments, Post Office Box 655303, Dallas, Texas 75265