WIRELESS MEDICAL DEVICE AUDIO ALARM

Marko Pavlin
In.Medica d.o.o.
Levičnikova 34, 8310 Šentjernej, Slovenia
Tel: +386 7 3934959
e-mail: marko.pavlin@inmedica.si

ABSTRACT

Audio alarming system for medical devices requires attention at some very specific segments. The clinical environment is full of disturbances and every alarm sound is not an exception. This paper presents some aspects of (audio) alarming within clinical environment and associated problems. Low power operation and limited resources for implementation are just on top of the problems related to the user experience. The presented solution is following the specific standards and is flexible enough to provide audio signals, which can be generated with small microcontroller. The described alarm generator was evaluated in laboratory and during clinical evaluation in real clinical environment with patients. The results are presented at the end of the paper.

1 INTRODUCTION

The fundamental requirement for every medical device is to operate safely. The patient monitoring equipment indicates device failure or urgent condition of the physiological parameters through the alarm system, which is part of the device's user interface.

The state of every patient treated in the operation theatre (OR), high dependency unit (HDU) or intensive care unit (ICU) is monitored on a regular basis. Before making decision about patient treatment, the caregivers must consider many data sources with very heterogeneous information. In addition to patient's medical history, radiology images, biochemical analyses they rely on data generated by vital signs monitors. This live stream of data is beyond cognitive capabilities of a nurse, therefore parameter limits are set to detect adverse situations. When one or more vital signs are out of predefined limits, the physiological alarm is triggered. Second type of alarms is technical alarm, which is related to the medical device operation. Every medical device may have its own set of alarms and can vary for every patient and every procedure.

The patient's safety can be compromised with issues related to the alarm efficiency. The alarm problems may cause severe injury or death of a patient [1]. The United States Food and Drug Administration (FDA) keeps records of all device-associated adverse events, which resulted in suspected deaths, serious injuries and malfunctions [3]. The FDA Manufacturer and User Facility Device Experience (MAUDE) database was queried within the time period from 1997 to 2011. The advanced search was set to »Audible alarm« product problem and »Death« as the event type. The results for each year are shown in Fig. 1. The alarms can be repeated, exciting, confusing and annoying. Sometimes the hospital staff removes permanently these alarms [2].

The diagram in Fig.1 correlates with the IEC60601-1-8 standard, which was prepared in 2001 providing guidance for alarms application, their performance and safety requirements and testing procedures.

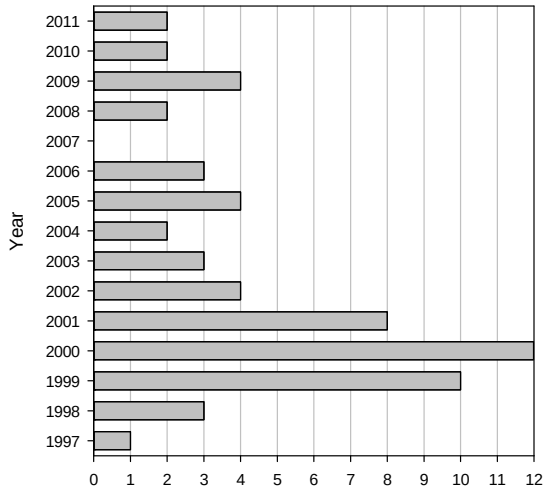

Figure 1: *Number of deaths caused by medical device audio alarm failures (per year from 1997 to 2011).*

The alarm related issues associated to medical devices have been reviewed in literature. It has been pointed out that alarms are less than optimal due to poor design and implementation. One of the main reasons was that the cognitive capacity and processing mechanisms of the user were not taken into account [2]. The authors summarized suggestions of characteristics of an ideal alarm sound to be: easy to localize, resistant to masking, ensuring other communication and easy to remember.

2 AUDIO ALARMS IN CLINICAL DEVICES

Audio alarming signals are present not only in the clinical devices but also in other parts of industrial and transport segments. The efficiency of alarms is diminished by increasing number of false alarms, excessive loudness and nuisance, which also limits the localization [6,7].

2.1. Localization

Human ear uses two principal mechanisms to predict sound location. The interaural time differences are dominant at low frequencies and interaural level differences dominate at mid to high frequencies [8]. Ideal alarm sound have to be harmonically reach within wide frequency spectrum to provide good localization.

2.2. Number of alarm sounds

The increasing number of alarms is a result of increasing quantities of data generated by patient monitoring equipment. The number of alarms may quickly exceed the cognitive capabilities of the medical staff. The resulting ignorance of some alarms can generate problems and critical mistakes in the health decision-making process [9]. The number of alarms should take into account the human ability to remember about seven pieces of unrelated information, where alarm sounds are only one of the items the hospital caregivers have to process in parallel. The number of alarm sounds should therefore be limited. This can be realized by using intelligent alarming systems, where the main limiting factor for implementation represents the variety of different patient monitoring equipment without practical options to cooperate via common data processing channel. One of the promising options could be electronic medical record (EMR) system, which may introduce some level of intelligence in alarming systems. However, EMR is not available in all hospitals. Additionally, automated alarm processing provides only better prioritization and could not diminish the number of alarms. The clinicians have to process all alarms and alerts anyway [10]. Another way to reduce the number of alarms is to standardize the alarms and assign specific alarms for specific functions, which trigger the alarm sounds. This is partially handled with IEC60601-1-8 standard by introducing some sort of auditory icons. These auditory icons are sounds, which are related to its function.

2.3. Speech

Some research evidence indicates that synthetic sounds are harder to learn than other types of sounds. A study [11] compared synthesized alarm sounds with speech. The later clearly showed the advantage to instantly symbolize the problem without any erudition required. The speech processor however is beyond limitations of low power embedded device for wireless patient monitoring.

3 AUDIO ALARM IMPLEMENTATION

The most straightforward implementation could be the playback of a recorded version of the alarm sound. There are two main issues with implementation within wireless medical devices. The embedded electronic system has limited resources and power consumption should be kept low to avoid bulky batteries. Sound playback from one of the standard formats, like MP3 is available as single-chip solution [4]. Unfortunately, the device like that is not qualified for medical use. The validation process of such a device could be long, expensive or even not possible. The solution is an own implementation of the alarm system, which is optimized to the available processing hardware and power capabilities. It is more efficient to generate alarms within the existing software code of the embedded device.

Function	Description
Clock generator	Provides all required clock signals to digitally construct the alarm tones, their envelopes and sequence.
Amplitude controller	Controls single tone amplitude modulation: rise time, fall time and sustain amplitude.
Tone sequencer	Sequencer provides correct alarm tone sequence and set the required tempo.
Tone generator	Polyharmonic generator combines funda-mental and higher harmonic sine waves to single tone.

Additionally, there are many advantages: the software validation is required in any case, the smart alarm system can be more flexible, the validated code can be standardized and reused in many devices and possible corrections during validation process are much easier in order to meet the IEC60601-1-8 specifications.

3.1 Programmable audio synthesizer

Four building blocks of the audio signal generator are listed in Table I.

3.2. Amplitude controller

The amplitude controller dynamically sets the tone amplitude. A variable volume also provides proper tone start and end. The tone should start from zero amplitude and end to zero amplitude to avoid unwanted noises. The tone amplitude rise decay is controlled with this module. Rise and fall times define the pervasiveness of the tone, which is related to the level of the alarm urgency.

3.3. Tone sequencer

The tone sequences are defined by standard 60601-1-8. The characteristics of the sequence depend on type and priority of the alarm. The sequencer sets the characteristics of a single tone and provides delays between the tones. Higher priority alarms have more tones and the sequence is

repeated. The tempo of the higher priority alarms is faster than that of the lower priority alarms. Both, the different number of tones and different tone tempo help to distinguish the priority of the alarm.

3.4. Tone generator

Two tap IIR filter shown in Fig. 2 can be used as a very effective sine wave generator. Response calculation at current discrete time step $g[n]$ requires only two results from the past calculations $g[n\text{-}1]$ and $g[n\text{-}2]$. The mathematical operations are limited to multiplication and subtraction (Eq. 1).

$$g[n] = 2\cos\beta g[n-1] - g[n-2] \qquad (1)$$

During initialization two values have to be set for each frequency:

$$g[-1] = 0 \quad (2) \qquad g[-2] = 2\pi \frac{f_x}{f_s} \qquad (3)$$

The algorithm, also known as Goertzel Algorithm can be implemented in a typical embedded microcontroller with limited processing power and memory space.

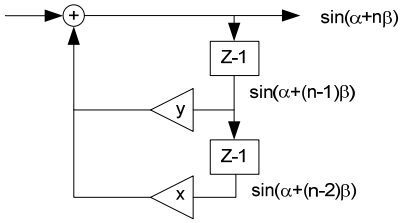

Figure 2: *Two tap IIR filter as signal generator (Goertzl algorithm).*

The initialisation coefficients can be calculated in advance to avoid inclusion of a floating point library into code. During development and code testing, the library routine for trigonometric functiuons occupied 2560 bytes of code and additional 288 bytes of constants. After optimisation with the pre-calculated tables for Goertzel initialization, the initialisation routine occupied only 131 bytes of code and 35 bytes of constants.

3.5. Implementation

Presented audio alarm system was implemented in wireless patient monitoring interface. The interface replaces the cables between a patient and a vital signs monitor. The device has no patient monitoring functions and no physiological signal processing.

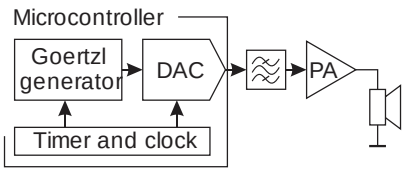

Figure 3: *Alarm generator block diagram*

The implementation of physiological alarms would require much higher validation effort. However, the technical alarms are implemented with all recommendations. Block diagram of the alarm sound generator is shown in Fig. 3. Microcontroller internal timer provides time base for Goertzl algorithm for generating polyharmonic tones. The same timer synchronises the amplitude modulator and the sequencer. The calculated sequential data feed the Digital-to-Analog Converter (DAC) at the sampling frequency rate. The sample rate was set to f_S= 25kHz (Eq. 3), which is above the normal audio hearing range. The DAC output is filtered with five-pole RC band-pass filter. Despite its simplicity, the filter proved to be effective and inexpensive solution, which has passed the tests in the process of evaluation.

4 EVALUATION OF ALARM GENERATOR

Two sets of tests were done during the evaluation process. First, the technical performance was evaluated. The second part of evaluation was performed during clinical evaluation of the device.

4.1. Technical evaluation

Technical evaluation process was conducted by measuring the following features: spectral analysis, signal to noise ratio, amplitude test and sequence test. Spectrum analysis tests were performed to verify the spectral content of the signal and to estimate signal to noise ratios. The diagram in Fig. 4 shows the measured spectrum of a single tone with the fundamental frequency and four higher harmonics. The code for the Goertzl algorithm provides adjustable amplitude for each harmonic. With fine adjustments, the harmonic contents of each frequency component can be altered to generate the proper tone.

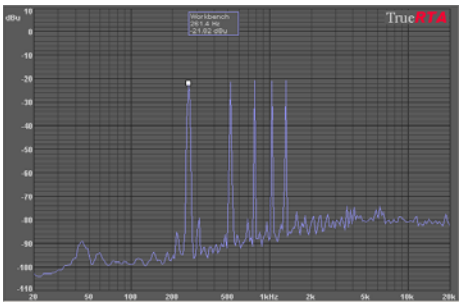

Figure 4: *Single tone spectrum with fundamental frequency and four higher harmonics. Note C4(262Hz) is shown.*

The test was repeated for all tones associated to notes from C4 to C5. The generated frequency spectrums were measured and the error between required and actual frequency of every harmonic was calculated. The results for all tones and all harmonics are shown in Fig. 5. The error was kept below 0,2% for the first four frequencies (fundamental and three harmonics). At the fourth harmonic frequency, the error was higher, but kept below 1% (Fig. 5). The frequencies at the fourth harmonic are higher and sampling frequency should be higher to minimize this error.

From practical point of view, the 1% error in the fourth harmonic frequency cannot be heard by an average listener.

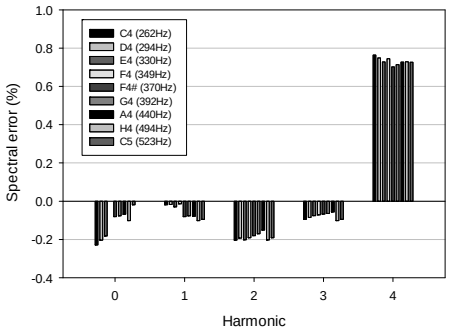

Figure 5: *Spectral errors of generated tones for fundamental frequency and four harmonics.*

The signal to noise ratio was measured with True RTA spectrum analysis software running on PC with sound capture card. The measured SNR was between 68dB and 70dB, which is considered as excellent result.

The last technical test was the measurement of amplitude and note sequence. The test was performed with digital oscilloscope. The generated signal envelope and timing of the signal pulses were measured. The results were compared to the requirements from IEC 60601-1-8.

4.2. Clinical evaluation

The device was evaluated within clinical environment (Fig. 6). The clinical investigation of the wireless device looked at the performance of the system in an intensive care unit, compared the fidelity of the data and tested the usability. The usability test evaluated how the system performed during user actions and tested primary operating functions of the user interfaces. Within the usability test, the sound alarming system was tested. During the test no complains about audio alarming system were delivered.

5 CONCLUSION

Development of an audio alarm generator was presented. The alarming within clinical environment requires special attention. The implementation of audio alarm generator within low power embedded device ia s challenging issue. Every microampere counts when developing small low power embedded interface for patient monitoring. At the same time, the result should provide same level of quality and flexibility when compared to “larger brothers”. The most attractive part of the presented solution is flexibility, because it provides porting the solution to any embedded microcontroller device with at least one timer and one DAC (internal or external). The quality and performance was tested and proven during technical evaluation within the laboratory as well as during clinical evaluation in the real clinical environment with real patients.

Figure 6: *Intensive care unit during clinical evaluation.*

References

[1] Alexander G, Staggers N. A Systematic Review on the Designs of Clinical Technology: Findings and Recommendations for Future Research. *ANS Adv Nurs Sci.* 2009 ; **32**(**3**): 252–279 (2011)

[2] J. Edworthy and E. Hellier. Alarms and human behaviour: implications for medical alarms. *British Journal of Anaesthesia* **97** (**1**): 12–17 (2006)

[3] FDA, Manufacturer and User Facility Device Experience. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm. Accessed: September 2013.

[4] VLSI Solution Oy Entrance G, 2nd floor Hermiankatu 8 FI-33720 Tampere, Finland. VS1005g Datasheet, Version: 0.52, 2012-11-07.

[5] Y. Song et al. The software generation and the comparison of decoding approach of DTMF signal. *Control and Decision Conference (CCDC):* 1054-1057 (2010)

[6] Williams S, Beatty PCW. Measuring the performance of audible alarms for anaesthesia. *Physiol Meas* **26**: 571–581 (2005)

[7] Loeb RG et al. Recognition accuracy of current operating room alarms. *Anesth Analg* **75**: 499–505 (1992)

[8] Carlile, S. Delaney, S. Corderoy, A. The localisation of spectrally restricted sounds by human listeners. *Hearing Research* **128**, (**1–2**): 175-189 (1999)

[9] X Hu et al. Predictive combinations of monitor alarms preceding in-hospital code blue events. *Journal of Biomedical Informatics* **45**: 913–921 (2012)

[10] Chen HT, Ma WC, Liou DM. Design and implementation of a real-time clinical alerting system for intensive care unit. *Proc AMIA Symp* **11**: 131–135 (2002)

[11] Stephan, Karen L., et al. Learning and retention of associations between auditory icons and denotative referents: Implications for the design of auditory warnings. *Human Factors: The Journal of the Human Factors and Ergonomics Society* **48.2**: 288-299 (2006)