The Noise of Biomedical Devices for Domiciliary Use on the Example of a Nebulizer

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Abstract

Widely available and inexpensive biomedical devices for domiciliary use may emit noise. Nebulizers are one of them. They allow taking drugs in the form of vapours thanks to vaporization under reduced pressure using an ejector (vacuum generator). The sources of noise in a nebulizer are an air compressor and a vaporizing tip. The presence of two sources with a different noise character and unfixed spatial orientation allows to classify a nebulizer as a device with extensive sound sources (DESS). The article presents the results of acoustic measurements of the nebulizer and its components. Differences in the nature of components' noise were found and their estimates were compared. Noise hazards for the device's user were determined and the premises for the noise parameterization of devices of this type were specified.

Keywords: nebulizer, devices with extensive sound sources (DESS), sound power level, biomedical devices

1. Introduction

Currently a wide range of biomedical devices for domiciliary use is available on the market. Some of them generate noise e.g.: electronic blood pressure monitors, oxygen concentrators, dialysis stations or insulin pumps. Sound sources of these devices are usually quite a distance from the user's ears. However, there is a type of devices for which, during normal use, the user's hearing organ is close to the sound source.

This are nebulizers - devices for administering drugs stored in a liquid form by the inhalation route, through their earlier evaporation as a result of a rapid reduction of pressure [1] using the ejector [2]. This method of administering drugs is in many cases determined by their increased efficacy, lack of reaction from the digestive system, ease of administration and other [3]. Nebulizers are also used to administer medicines to children and the elderly, for whom taking orally medication is difficult or impossible [4]. Studies show that patients indicate the nebulizer noise as a device defect [5].

These devices are a source of both the low and the high frequency noise [6]. However, they do not generate noise level exceeding 85 dB, which would oblige manufacturers to declare noise level according to standards in force [7]. There is also no standard test code for determining the noise of this type of devices, such as there is for washing machines or vacuum cleaners [8].

However, in order to meet the market requirements and customers' expectations, manufacturers place information on the level of noise emitted by nebulizers, which is 55 dB on average. Among the nebulisers available on the Polish market about 50% of devices lack manufacturer’s information on the level of emitted noise. In all cases, there is no information about the operating conditions of the device when determining the noise level. The situation on this segment of market in previous years was similar [9].

Nebulizers meet the criteria that allow them to be classified as devices with extensive sound sources (DESS) [10]. They consist of a central unit - a multi-piston air compressor, an elastic hose and a vaporizing tip (ejector). Figure 1 shows the tested device. Two operating modes are considered. The first is compact arrangement (the tip is fixed to the compressor) for air humidification in the room. The second is inhalation with the tip by the user’s face, when components are located at a distance. The distance between the compressor and the tip is limited by the length of the hose. This spatial arrangement means that the ratio between distance from the user's ear to the compressor and the distance from the user's ear to the tip can be large. Therefore, for this type of devices it is necessary to verify the noise of both components.

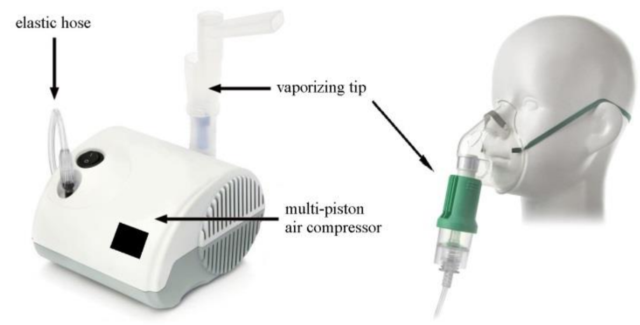

Figure 1. The tested device – nebulizer, in compact arrangement on the left, vaporizing tip with mask on the right [11]

2. Research methodology

The purpose of this work was to parameterize the selected device, a nebulizer during operation at nominal conditions (loaded compressor, vaporisation), according to the DESS definition.

The tested object is a device for which 55 dB noise level was declared. It is assumed that under the term noise level manufacturer means the A-weighted sound pressure level averaged over the measurement surface that is in the distance of 1m from the reference box. Devices of this type are not intended for continuous operation. Vaporisation of 5 ml of liquid (the maximum volume of commercially available substances intended for vaporisation) takes about 10 minutes. Measurements of sound pressure were made in accordance with ISO 3746: 2011 [12]. Then the sound power levels of the device treated as a whole and separately for the compressor and the tip were determined. Figure 2 shows the components of the device and specifics of the noise emitted by them. When measuring the compressor the load was only the attached hose (the tip was detached). While, for the measurements of the tip, a saline solution was used as the load. The vapour was sucked out of the measuring space. The device was identically treated for measurements in compact arrangement.

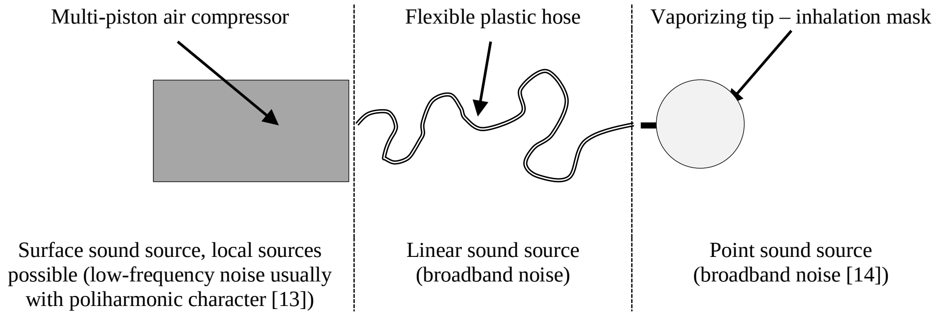

Figure 2. Components of a nebulizer according to the DESS definition and specifics of noise emitted by them [10]

The measurements were carried out in a room meeting requirements from ISO 3746:2011 standard [13]. The room's volume equals 260 m^3, the acoustic absorption of the room was tested experimentally by measuring the reverberation time. The K_2 correction was approx. 0.5 dB each time. The largest dimension of the device did not exceed 200 mm. Therefore it was decided to use the measuring distance d = 300 mm.

For the measurements of acoustic pressure the following equipment was used: polarized free-field microphone G.R.A.S. 40 BF compatible with pre-amplifier G.R.A.S. 26 AK, pre-amplifier Brüel & Kjær NEXUS Type 2691, data acquisition module Vib DAQ 4+ and PC with DASY Lab software in which digital signal processing application was elaborated. During the acquisition of the acoustic signal, the following settings were used: sampling frequency f_s = 97.66 kHz, measurement block size 8192 samples, frequency band from 20 Hz to 48.83 kHz. Calibration of the measurement system was carried out before and after measurements using the acoustic calibrator type KA-10 No. 363, L_p = 94 dB for 1000 Hz. Measurements were done in five points on the measurement surface in accordance with the standard guidelines. Each acquisition lasted 30 seconds.

3. Research results

The results of the acoustic pressure measurements are provided in this chapter. Figure 3 shows the octave spectra of the average sound pressure level L_{p_AVG} on the measuring surface at a distance of 300 mm from the device (average of results in five measurement points). It is easy to notice that the noise generated by the compressor is rather low-frequency and dominates in the first 6 octaves of the human hearing range and the noise generated by the tip is high-frequency and dominates above 1 kHz. The linear L_{p_AVG} of the tip is about 6 dB higher than the linear L_{p_AVG} of the compressor. The difference increases after corrections and for the A sound is near to 9 dB. Moreover the pressure levels measured over the tip in each case are higher by at least 5 dB than the pressure levels measured in other points, which proves the high directionality of this component.

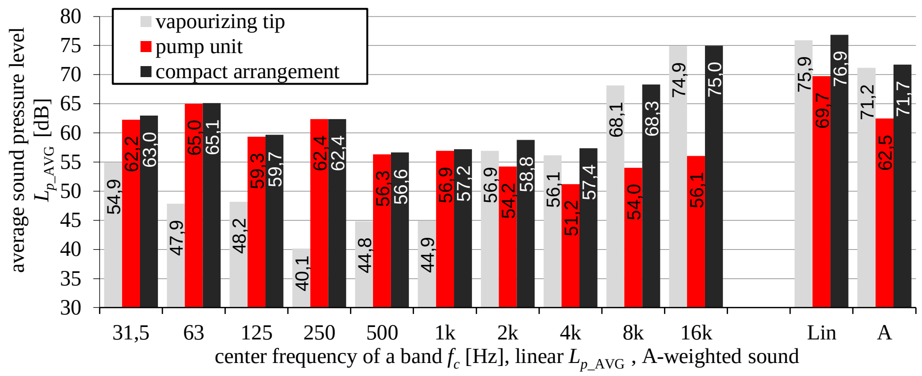

Figure 3. Noise emitted by tested device treated as compact arrangement and as DESS

Due to the measuring distance, the sound power level L_{WA} is not much different from the average A sound. The smallest recorded difference between L_{p_AVG} and the background was 24.5 dB. The L_{WA} of the compressor is equal 64 dB, the L_{WA} of the tip during vaporization is equal 71.9 dB, total L_{WA} in compact arrangement equals 72.6 dB. The difference between the results of measurements in compact arrangement and the recalculated sum of the sound power levels of the compressor and the tip measured separately is less than 1 dB. This fills within the precision of the survey method of determining L_{WA} of devices.

Figure 4 shows the narrowband spectrum of the L_{p_AVG} generated by the working compressor in the band from 20 Hz to 4000 Hz. The figure confirms that the noise generated by this component is of a polyharmonic character. The basic frequency of about 47 Hz is related to the number of revolutions and the number of cylinders [13].

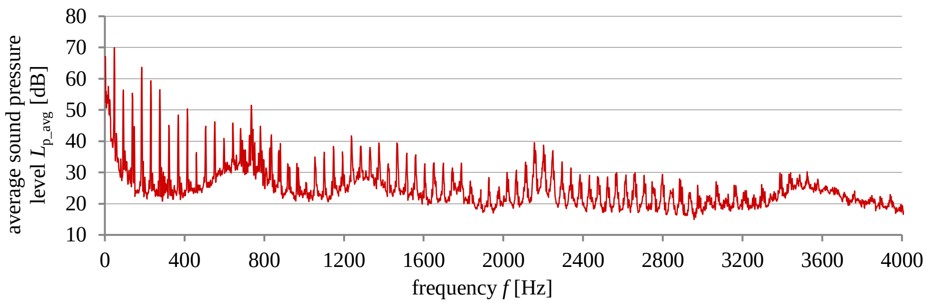

Figure 4. Narrowband spectrum of average acoustic pressure level measured 300mm from the multi-piston air compressor

Furthermore, in Figure 5, the spectra of the L_{p_AVG} measured at 300 mm from the compressor and from the tip in the whole measuring frequency range from 20 Hz to 48.83 kHz are shown.

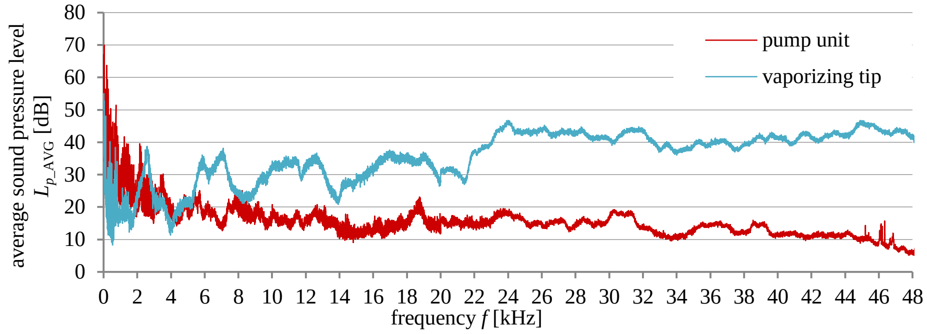

Figure 5. Full narrowband spectrum of average acoustic pressure level measured 300mm from the multi-piston air compressor and from vaporizing tip

The noise generated by the tip is a broadband noise covering almost the entire measurement band. Ultrasounds have significant share. The linear L_{p_AVG} in the band from 20 kHz to 48.8 kHz for the tip was 82.3 dB while the linear L_{p_AVG} for the compressor was 54.8 dB with an ultrasound background equal to 43 dB. There is a high probability that during vaporization there occurs simultaneous cavitation of the vaporized substance which would be responsible for part of the ultrasonic noise [15, 16]. In the frequency range from 5 kHz to 48 kHz, the L_{p_AVG} generated by the tip is higher than L_{p_AVG} of compressor. Considering the fact that the tip is in the near acoustic field from the user's ears, its acoustic parameters are more important. It should be noted that there were no exceedances of acceptable sound pressure levels both in the audible band and in the ultrasonic band [7]. Nevertheless, exposure to noise generated by the nebulizer may be harmful and unpleasant for the user [17].

4. Conclusions

Nebulizers can be successfully considered as DESS. The tested object consists of two important sound sources - a compressor generating low-frequency polyharmonic noise with L_{WA} of 64 dB and a vaporizing tip generating high frequency and ultrasonic broadband noise with L_{WA} of 71.9 dB. The noise generated by the flow of compressed air through the hose is irrelevant and its value is indistinguishable from the background.

In the case of the tested device, and probably for other devices of this type, it is not necessary to describe them using more than one parameter. However, this should be the L_{WA} of the vaporizing tip or L_{p_AVG} in the near acoustic field. The procedure specified in the standard for acoustic measurements of vacuum cleaners [8] seems to be the most suitable to determine the noise of nebulizers due to the differences in L_{WA} and L_{p_AVG}, determined for the tip and for the compressor.

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