The Importance of Noise Attenuation Levels in Neonatal Incubators

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Abstract

Background: It is known that high noise levels can be harmful to the preterm infant, causing physiological and psychological disorders. It is also known that premature babies spend a lot of time in an incubator. In this sense, many studies show that incubator noise levels can range from 45 dB to 70 dB. However, these differences in noise levels depend, fundamentally, on the methodology used, which is very varied. The aim of this study is to know the levels of noise from fan in the incubator itself and how much it is able to isolate the noises coming from the outside.

Methods: It were characterized the acoustic behavior of several models of incubators. For this purpose it was measured the incubators noise level within an anechoic chamber. It was also used a 4224 pink noise generating source to determine the isolation levels of the incubators and one microphones inside the incubator and another one outside connect to a SVAN958 noise analyzer.

Results: The incubators produced continuous equivalent noise levels of between 53.5 dB and 58 dB. The analysis of isolation showed that the level varied from one incubator to another, between 5.2 dB and 10.4 dB. In addition, the isolation level in one-third octave bands varied from one incubator model to another.

Conclusions: Preterm infants in an incubator are exposed to noise levels very far from the international recommendations, even if the incubators are meeting the noise criteria set out in the IEC60601-2-19: 2009 standard of 60 dBA under normal use conditions.

Introduction

Although high levels of noise are undesirable for anyone, the situation can be alarming in preterm infants, especially taking into account that they are born before their hearing system has had the opportunity to fully mature, and could cause them sensorineural hearing loss [1]. In this sense, preterm infants have a reduced response to auditory stimulation compared with full-term infants. [2].

Several investigations reveal that the stressful environment in Neonatal Intensive Care Units (NICUs) causes in premature infants functional disorders. High noise levels not only contribute to neonatal hearing loss [1][3][5] but also affect physiological factors: reduction in mean blood pressure [6], increased heart rate (HR) and respiratory rhythm, and the decrease of oxygen saturation (O-sat) [7], as well as neonates' ability to self-regulate [8]. The mid-to long-term effects of repeated stimulation by high intensity sounds have also been shown to have an influence on psychological factors, and therefore, they could have important repercussions on the newborn behavior [1][9-11].

1.1 Other effects

Mean total sleep time in 24 hours of a newborn is approximately 15 hours, half of which is done during the night and the other half during the day [13]. Some studies indicate that during sleep time the Sound Pressure (SP) Level is within the limits recommended by the international laws, while the rest of the time
is very far from the recommendations [13]. It has also been proven that moderate acoustic changes, between 5 and 10 dBA can disrupt the sleep of very early preterm infants [15].

Other studies described the energy expenditure (EE) estimation method, based on a relationship between cardiorespiratory function (HR and O-sat) and measured EE. In this sense environmental stressors, such as noise, affect the development of preterm infants, so it is necessary to reduce the stressful stimulations to conserve energy for growth [15].

1.2 Noise at NICUs

Much of the noise inside the incubator comes from sources outside the incubator. So, although the average noise level in the most modern NICUs are around 62 dBA [16], The tests performed in NICUs show that the outside noise to the incubator reach levels of 80.4 dBA vs 79.1 dBA inside [17-18], in spite of the educational programs carried out for noise reduction.

At times, the incorporation of new technologies is not adequately controlled, so the noise level is increased rather than reduced (motorized paper, towel dispensers, hand dryers, etc.) [19]. On the other hand, the alarms of the various monitors and maintenance apparatuses, the crying of the newborn and the activity of the staff are usually the principle sources of noise [20].

Sound pressure levels in NICUs exceed the American Academy of Pediatrics (AAP) recommendations, regardless of whether there are variations in noise levels from one hospital to another. This can be due to several reasons, like the conditioning, the size of the room or noisy sources. Therefore, some researchers measured mean and maximum values of 57.0 dBA and 88.8 dBA, respectively [21], while others measured values of 66.8 dBA and 84.1 dBA, respectively, within the incubator [3]. However, in general, most of the studies revealed mean noises between 55 dBA and 67 dBA [3][21-22] and impulse noise above 140 dB (banging incubator to stimulate apneic premature infant) [7]. On the other hand, the noise generated during the handling of the incubators are between 72.5 dB (placing bottle of formula on top of the incubator) and 98.4 dB (closing an isolette cabinet) [23].

While some authors recorded SP levels lower than 60 dBA, which are within the tolerance limit specified in IEC 60601-2-19. These measures were carried out during power-off condition and during the operation of incubator at a controlled temperature of 36 ºC with a maximum humidity setting [24] other authors recorded SP Levels were greater than 60 dBA [25]. In this sense, some authors indicate that sound levels, especially at low frequencies, within a modern incubator may reach levels that are likely to be harmful to the developing newborn [25] however, others think that high frequency sound levels could be the truly damage by analogy with sound spectra of the gravid uterus[26]. Other studies indicate that the Incubator cover seem to have some short-term effects on sleep quality in premature infants by reducing disturbing light and noise [27].

1.3 Action program
Due to high noise in NICUs, many researchers propose measures to tackle this problem, such as the proper design of the NICU to minimize background noise [28], or implement an educational noise reduction program [17][29-30] or earmuffs as a measure to improve sleep efficiency, thus increasing the quiet sleep time [31].

Studies of noise measurements inside the incubator show that the major sources of noise come from the water recirculation circuit of the fan, opening and closing of doors, alarms of the teams and the conversations of professionals close to the incubator, causing the noise levels inside the incubator to be far from the recommendations of international organizations [32]. Absorption panels have been placed in the incubator to solve this problem, obtaining significant noise reductions [33].

Sound frequencies within incubators are markedly different from sound frequencies within the gravid uterus [26]. Attenuation of sound intensity $\geq$ 1,000 Hz is desirable because it is similar with sound spectra of the gravid uterus [26][34]. In this sense, the tests performed and the results of spectral sound analysis indicated that acoustic foam panels significantly reduced sound frequencies $\geq$ 500 Hz. [26].

Thus, although the AAMI / IEC standard for incubators sets the limit of the noise level within the incubators at 60dB [35-36], this level is very far from the 45 dBA recommended by the AAP and 30 dBA recommended by WHO [37][39].

1.4 Objective.

It must be stressed that there are few studies assessing the spectrum of noise recorded within the incubator. In this sense, it can be a key factor for the specialist doctor to know the acoustic features of the various incubator models.

A previous study showed that the attenuation of the Ohmeda Medial Giraffe incubator was 12 dBA [40], and the noise recorded in its interior below 45 dBA. However, other incubator models recorded values between 57 and 60 dBA. So this situation is not clear, the difference is too great [41-42], in the latter case, far from 45 dBA. It was suggested that the noise should be limited to 45 dBA during the design of the incubator, more than 30 years ago [43].

The scientific databases showed evidence of great variability in relation to the methods employed to measure noise levels in the NICU environment and in the incubators [44-45], highlighting inconsistencies in sample size and representativeness, configurations of measurement devices, places where noise was captured and evaluation of circumstances that contribute to the present levels [45].

Therefore, the main objective of this study has its roots on the need to know the fidelity of data collected from scientific databases, as well as the behavior of several incubator models (Ohmeda Giraffe incubator, Ohmeda Care Plus 3000 and Ohmeda Care Plus 4000), from the acoustic point of view.

Materials And Methods
The acoustic behavior of three types of incubators was compared: Ohmeda Giraffe Omnibed (OGO), Ohmeda OHIO Care Plus Access 3000 (OCP3000) and Ohmeda OHIO Care Plus Access 4000 (OCP4000). The three incubators were chosen between the best preserved incubators.

Several test were defined to carry out the objectives. For the tests, the external generator type and the on/off status of the incubators under controlled conditions were taken into account. Thus, for each of the incubators the following variations were analyzed:

- Incubator off, without any external noise sources except background noise.
- Incubator on, without any external noise sources, except the noise of the incubator itself and the background, at a controlled temperature of 36 °C with a maximum humidity setting.
- Incubator off and an external noise generator two meters away from the incubator.
- Incubator on and an external noise generator two meters away from the incubator, at a controlled temperature of 36 °C with a maximum humidity setting.

For this study it was used a Svan 958, class 1 four-channel sound & vibration analyser of the brand Svantek. This one is the capability to perform advanced analysis simultaneously to the level meter mode, which allows to obtain four-channel analysis like FFT or octave band analysis. With SV958 was used the preamplified microphone SV 12L of the brand Svantek, a Class 1 Acoustic Calibrator type 4231 and a sound source type 4224 of the brand Brüel and Kjaer.

All the tests were made in an anechoic chamber to avoid the effect of reflections and acoustic interference. The cutoff frequency of the anechoic chamber was estimated at 100 Hz. The microphones were located at approximately the same position during the experiment. One of them inside the incubator, at the height where the infant supports the head and mounted on a tripod about 10 cm high, and the other on the outside of the incubator to 1.5 meter away from the fan and 2 meters from the external noise source. Calibrations were made for all tests, before the first measurement and after the last measurement. The noise data were recorded in: PCM digital audio, wav, 48 kHz sampling frequency and 24-bit quantization. Although the full band spectrum was recorded, but was analyze the audio band spectrum (20Hz to 20 KHz). A frequency analysis of one-third octave bands with (dBA) and without (dB) A-weighted filter was performed.

The post-processing was done using Matlab software. Each test lasted one minute at 48 samples/s. The incubator doors were kept closed for all tests. The external noise source power was initially set, after pretest to evaluate the greatest possible attenuation in the incubators, and no modifications were made during all the tests, only turning the source on/off. In spite of this, the registered values of the noise source oscillated between 82 and 85 dBA. However, this situation affects both microphones (inside/outside) in the same way, therefore, does not mean any problem.
Results And Discussion

The results are presented in two different ways: on the one hand, by graphical representation (1/3 octave) of the differences between the noise measured by the microphone outside the incubator and the microphone inside the incubator; And on the other hand, by tables, where overall noise levels can be evaluated in linear and A-weighted.

2.2 Incubators off and door closed, no external noise source.

Figure 1 shows that at 63 Hz and 80 Hz, common to the three incubators, the differences are negative, that is, the values inside the incubators are higher than outside. A priori, the reason for this phenomenon is unknown since the external microphone record did not show tonalities, so it is necessary to perform more tests. On the other hand, the OCP3000 incubator is the one that shows the worst behavior in low frequency, below the 160 Hz, despite this, the overall noise recorded outside and inside of incubator was similar. This is due to the representation in thirds of octaves, the low frequency bands have less energy than the high frequency bands.

Table 1 shows the overall values, which were measured with the incubators switched off and the doors closed. It can be seen that the background noise level was about 40 dBA, both inside and outside the incubator. The differences between the noise levels outside and inside the incubator were not higher than 0.2 dBA.

<table>
<thead>
<tr>
<th>Model</th>
<th>Leq_Inside (mean/sd)</th>
<th>Leq_Outside (mean/sd)</th>
<th>Difference (Out-In)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>dB</td>
<td>dBA</td>
<td>dB</td>
</tr>
<tr>
<td>GIRAFFE</td>
<td>40.2</td>
<td>40.0</td>
<td>0.59</td>
</tr>
<tr>
<td>OCP3000</td>
<td>40.1</td>
<td>39.9</td>
<td>0.58</td>
</tr>
<tr>
<td>OCP4000</td>
<td>40.2</td>
<td>40.0</td>
<td>0.58</td>
</tr>
</tbody>
</table>

2.3 Incubators on and door close, no external noise source.

When the incubator is on and the major noise source is the incubator fan, therefore, the noise recorded by the microphone inside the incubator will be precisely the fan noise. Noise level outside the incubator will depend on its insulation.
Table 2. Overall noise level inside and outside the incubator. Incubator on.

<table>
<thead>
<tr>
<th>Model</th>
<th>Leq_Inside (mean/sd)</th>
<th>Leq_Outside (mean/sd)</th>
<th>Difference (Out-In)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>dB</td>
<td>dB</td>
<td>dBA</td>
</tr>
<tr>
<td>GIRAFFE</td>
<td>56.7</td>
<td>0.17</td>
<td>56.5</td>
</tr>
<tr>
<td>OCP3000</td>
<td>56.1</td>
<td>0.31</td>
<td>56.6</td>
</tr>
<tr>
<td>OCP4000</td>
<td>52.1</td>
<td>0.17</td>
<td>51.9</td>
</tr>
</tbody>
</table>

Table 2 shows that if background noise is very low, the fan noise transmitted to the outside is reduced up to 16 dB by the insulation of the incubator itself, however, to ensure this situation a reverberation study is necessary. Therefore, during a period of lower background noise (night time), premature infants might be exposed to high levels of noise and not be perceived from the outside. On the other hand, it could think that this situation is an additional problem in NICUs with a large number of incubators, since the noise in the room would increase. However, the fact that in most of the rooms there is at least 1 meter of separation between incubators, distance sufficient to avoid noise pollution between adjoining incubators, assuming that all of them are of similar characteristics.

Figure 2 shows that the whole spectrum of noise differences is negative, exceeding more than 25 dB in any frequency band. Therefore, the noise inside the incubator far exceeds ambient noise. However, although background noise must be separated from incubator noise to know how much noise is from the fan, the fact that in broadband most of the noise levels are 3 dB higher than the background noise indicates the low contribution of background noise inside the incubator.

The OCP4000 incubator is the one that generates the lowest total noise in dBA, by little difference. However, it is also the one that the smallest difference represents between the noises inside and outside, therefore, it has a lower insulation, which will be verified when tested with an external noise source.

2.4 Incubators off, door closed and external noise source on.

When the external noise generator is activated, a pattern noise is emitted (pink noise from 100 Hz to 4 kHz, which contains equal energy per measurement band and thus has one-third octave band level which is constant with frequency). In this case the incubator was turned off, therefore, the only source added was the external source of bruel 4224.
Table 3. Overall noise level inside and outside to the incubator. Incubators off. External sound source.

<table>
<thead>
<tr>
<th>Model</th>
<th>Leq_Inside (mean/sd)</th>
<th>Leq_Outside (mean/sd)</th>
<th>Difference (Out-In)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>dB</td>
<td>dB</td>
<td>dBA</td>
</tr>
<tr>
<td>GIRAFFE</td>
<td>74.6</td>
<td>0.22</td>
<td>74.4</td>
</tr>
<tr>
<td>OCP3000</td>
<td>74.8</td>
<td>0.20</td>
<td>74.6</td>
</tr>
<tr>
<td>OCP4000</td>
<td>77.6</td>
<td>0.14</td>
<td>77.4</td>
</tr>
</tbody>
</table>

Table 3 shows the situation that occurs when the background noise is much greater than the incubator noise itself. Therefore, analyzing the noise levels recorded inside and outside the incubator, it can be deduced that the incubator insulate the noise from the outside, reducing up to 10.8 dBA. Consequently, even with the incubator on, the dominant noise would have been the external source.

Figure 3, shows that the insulation characteristics vary from one incubator to another. In this sense, the OCP4000 incubator has worse insulation, because it is the incubator with the lowest insulate values at high frequency (high energy band). The OCP4000 incubator loses efficacy at high frequency, precisely in the frequency band where the uterine structure protects the fetus. [33, 34].

2.5 Incubators on, door closed and external noise source on.

Two sources of noise have now been added since the external source and incubator are turned on. The results of measurements in these conditions are shown in Table 4.

Table 4. Overall noise level inside and outside to the incubator. Incubators on. External sound source.

<table>
<thead>
<tr>
<th>Model</th>
<th>Leq_Inside (mean/sd)</th>
<th>Leq_Outside (mean/sd)</th>
<th>Difference (Out-In)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>dB</td>
<td>dB</td>
<td>dBA</td>
</tr>
<tr>
<td>GIRAFFE</td>
<td>75.1</td>
<td>0.33</td>
<td>74.9</td>
</tr>
<tr>
<td>OCP3000</td>
<td>75.8</td>
<td>0.25</td>
<td>75.6</td>
</tr>
<tr>
<td>OCP4000</td>
<td>76.6</td>
<td>0.21</td>
<td>76.4</td>
</tr>
</tbody>
</table>

It can be seen from Table 4 that the attenuation values are similar to the results of the previous test (Incubators off and external sound source on), with values up to 9.7 dBA. Furthermore, it is important to note that, due to the insulation of 10 dB, the background noise must have average levels of approx. 68 dB for the noise inside the incubator was affected by outside noise. Considering that a noise source is dominant if it has 3 dB more than background noise, it would have to add 3 dB and attenuation of the incubator to know the lower level that the new noise source should have ($55 + 3 + 9.7 = 67.7$ dB).
Regarding the behavior of the incubators, although the overall attenuation of the Girafe and OCP3000 are very similar, however, there are differences at high frequency between the two, and the Giraffe incubator is a bit better in high frequency. However, in the low frequency band (below 400 Hz), the OCP3000 incubator has better attenuation characteristics. In general, taking into account the general behavior of broadband noise (20 Hz - 20 KHz), the OCP3000 incubator is the best choice.

Little difference was detected between the measured noise with open and closed doors, the most favorable difference was +2 dB (giraffe incubator), and the most unfavorable difference was -1.6 dB (higher inside than outside of the OCP4000 incubator).

Figure 5 shows the attenuation curves in one-third octave of each of the tested incubator models. In this figure we can verify that Giraffe and OCP3000 incubators have similar attenuation profiles. However, there is a noticeable difference with the OCP4000 incubator, fundamentally between 1000 Hz and 20000 Hz.

All tests performed to compare values between incubators (kruskall Wallis and Mann-Whitney) showed p-values <0.05. This indicates, as it expected, that there are no significant differences between incubator models.

Conclusion

A. Incubator off.

If the background noise outside the incubator is less than or equal to 45 dBA (level recommended by the AAP), the noise inside the incubator will be approximately equal to background noise.

B. Incubator on.

If the background noise outside of the incubator is less than the higher noise emitted by the incubator fan (general situation at night), the patient in the OCP3000 incubator (the one with better isolation) will be exposed to a dose of noise, using a reference period of 8 hours (the dose at which a worker would be exposed under the same conditions), according to the following expression:

$$Dose \geq 56dBA + 10 \times \log \frac{T}{8}$$

Where T It is the time the newborn is in the incubator. Thus, a patient in an incubator is exposed to a minimum dose of noise in 24 hours equivalent to 4.8 dBA more than the noise generated by the incubator fan (dBA).

Under the most optimistic conditions of this study (Giraffe/OCP3000 incubators) the noise level will always be greater than 56 dBA, value much higher than those recommended by international
organizations. Therefore, this situation can become worrying at night, where the background noise is, or should be, relatively low.

In order for a new source of noise outside the incubator to be dominant in the incubator, the noise level emitted by the new source must be greater than 3 dBA plus the insulation value. In this study, for the OCP3000 is: 56+10.8 +3= 69.8 dBA. Under this assumption the patient would be exposed to a noise level greater than 59 dBA.

C. Which incubator to recommend?

The OCP 4000 is the one with the lowest fan noise for the night time, but the OCP3000 is the one with the best insulation, for the noisy periods. Therefore, there is no suitable incubator to isolate the noise.

D. It is necessary to regulate the noise insulation level in incubators, in third of octave band.

The three incubator models analyzed showed different behavior against noise, doubling levels from one model to another. The models of incubators with better and worse behaviors against noise were Giraffe and OCP4000 respectively, within the three models analyzed. Although the attenuation of the Giraffe model is similar to the OCP3000 model, the spectrum in thirds of octaves of the Giraffe shows a better redistribution of levels of insulation. This is mainly due to the design of the box and the thickness of the materials.

E. It is necessary that international standards such as IEC to follow international recommendations (AAP and WHO) to reduce noise from incubators under normal conditions of use up to 45 dBA.

The noise levels measured inside the incubators comply with the IEC60601-2-19 standard, which sets its limit at 60 dBA, under normal conditions of use. However, this requirement does not guarantee 45 dBA inside of incubator under conditions of very low background noise.

**Declarations**

**Acknowledgements**

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Figure 1

Background noise (Incubators off). Spectral difference between outside and inside the incubator (dB).
Figure 2

Incubators on. Spectral difference between outside and inside the incubator (dB).
Figure 3

Incubators off and External source on. Spectral difference between outside and inside the incubator (dB).

Figure 4

Incubators on and external source. Spectral difference between outside and inside the incubator (dB).
Figure 5

Frequency-dependent attenuation level for the worst situation (Mean – StdDev).