



Article Silent Neonatal Incubators, Prototype Nica+

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Abstract: Objectives: The purpose of this study was to evaluate and compare the noise levels in current incubator models and a prototype designed to improve acoustic comfort in neonatal incubators. Methods: Tests were carried out on three different models of incubators and a prototype called Neonatal Incubator Acoustic Comfort Class (NICA). The tests measured both internal and external sound pressure levels under laboratory conditions. The noise index has been taken as the A-weighted equivalent continuous sound pressure level (LAeq,T) for a time interval of 1 min. Results: The results obtained show variations between the different models of incubators, although, overall, they are high values (around 56/60 dBA). The results prove that premature newborns under normal conditions of using these incubators are exposed to noise levels above international recommendations. The new incubator design minimizes noise generation and generates noise levels lower than international recommendations. The results obtained from the prototype (NICA+) show the effectiveness of the proposed design in improving acoustic comfort in neonatal incubators. The data show that the noise levels generated by the prototype under normal operating conditions are significantly lower than international recommendations.

Keywords: neonates; sound pressure; incubator; noise source; NICU; infants

1. Introduction

1.1. From the Incubator

In 1929, Julius H. Hess [1] introduced one of the first proposals for incubators, documented under the reference US1900342A, and the patent was officially granted in 1933. This innovation pertained to infant incubators and sought to create an incubator consisting of a modified cradle and a detachable canopy. This design allows the crib to transform into an incubator suitable for premature or delicate infants.

By August 1967, JR, Grosholz et al. [2], presented a widely adopted operational blueprint used by many manufacturers in the incubator design realm. This blueprint is grounded on a system including a ventilation circuit for convection-based heat transfer and humidity enhancement aided by the airflow through a container with.0in the same ventilation circuit, as detailed in patent US3335713A.

1.2. Regulation

Broadly speaking, thermal regulation stands out as a crucial determinant in the survival and well-being of newborns [3]. Most incubators maintain infants' temperature through the circulation of warm air, with heat transfer predominantly occurring via convection. Positioned beneath the incubator compartment, the heating and humidification



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Copyright: © 2024 by the authors. Licensee MDPI, Basel, Switzerland. This article is an open access article distributed under the terms and conditions of the Creative Commons Attribution (CC BY) license (https:// creativecommons.org/licenses/by/ 4.0/). systems play a pivotal role. Air circulation is helped by either a fan or a turbine, drawing air from the external environment. Subsequently, the air passes through a heating element and a temperature measurement device before traversing a water tank, used for humidification when necessary. Finally, the conditioned air is propelled into the chamber where the patient is situated. From the start of the first infant incubator in 1929 to the current day, all implemented enhancements have been directed at refining this system.

1.3. Of the Advances

Advancements in mitigating the noise levels produced by the incubator itself have appeared more recently. In 2013, Northern Illinois University was granted the patent US20130204617A1, outlining an "apparatus, system, and method for noise cancellation and communication tailored for incubators and associated devices" [4]. Since then, within this domain, patents have been granted focusing on both active and passive control of the noise originating within incubators. Some aim to drop the noise, while others strive to set up a proactive sound environment conducive to the well-being of premature neonates. The aim is to recreate an environment akin to the mother's womb.

In 2014, patent WO2015029044A2 [5] introduced a noise-damping system reliant on an acoustic attenuation module. This module, guided by one or more sensors, shows the characteristics of the sound, and generates destructive interference to counteract that specific sound.

Examinations of noise levels within incubators reveal that the primary sources of noise originate from air circulation, motors, pumps, and fans sustaining diverse life support functions. Additionally, alarms from various monitors, maintenance devices, the cries of newborns, the operation of opening and closing doors, and conversations among professionals near the incubator contribute significantly to the overall noise environment [6]. It is noteworthy that several noises, including those generated by CPAP (continuous positive airway pressure), may undergo amplification within the confined space of an incubator.

1.4. Interior Comfort

A critical consideration for the well-being of a newborn in the incubator is the internal noise level. The sound environment within a modern incubator, particularly at low frequencies, can potentially reach levels that may pose harm to the developing infant. A huge part of the noise is concentrated at lower frequencies, making it challenging to mitigate through conventional methods [7].

The choice of materials for the incubator cover also plays a crucial role in shaping the internal sound environment. Typically constructed from acrylic materials, such as methacrylate, these covers are approximately 6 mm thick, effectively isolating the microenvironment inside the incubator from the external surroundings [8]. While they serve the purpose of shielding the baby from drafts and low temperatures, their impact on the internal sound environment stems from the acoustic properties of these materials. Although they create a barrier between the external and microenvironment, these materials are highly reflective, fostering a reverberant environment that amplifies the higher noise levels generated by the incubator devices. This situation is particularly concerning for premature infants and could potentially lead to sensorineural hearing loss [9].

In this context, premature babies show a diminished response to auditory stimulation compared to those born at term [10].

While multi-walled enclosures are recognized, most enclosures stay transparent to surrounding sounds, leading to an elevation in sound levels near the child's ears [11]. Notably, the noise levels produced by these enclosures have not been adequately considered in the technological advancements of such devices.

The detrimental effects of noise are contingent on various objective factors, including frequency, intensity, exposure duration, and acoustic rest intervals, along with subjective factors such as patient susceptibility [12]. Consequently, premature neonates are more vulnerable to the impacts of ambient noise compared to full-term births. The degree

of compromise increases with lower gestational age, as incomplete brain development heightens the risk of abnormal brain maturation [13]. Hearing impairment is diagnosed in 2% to 10% of premature babies, a significantly higher rate than the 0.1% seen in the general pediatric population [14].

1.5. About the Environment

In the Neonatal Intensive Care Unit (NICU) setting, it has been seen that sound pressure levels within incubators vary between 44.2 dBA (Lmin) and 84.2 dBA (Lmax), with an LAeq (24 h) of 50.4 dBA. Activities with peak levels (LCpeak) near 108.3 dBC have also been found, and the highest levels are concentrated at low frequencies, staying below 45 dBA starting from 250 Hz [15].

The NICU sound environment is characterized by high noise levels, with short duration and irregularly spaced nuisance noises often exceeding the maximum acceptable level of 45 decibels (dB), according to international guidelines [16]. Notably, most of the noise within the incubator originates from external sources. While the average noise level in modern NICUs hovers around 62 dBA, various tests conducted in these units reveal that external noise can reach maximum levels of 88.8 dBA, in contrast to 84.1 dBA internally. However, on average, most studies report noise levels between 55 dBA and 67 dBA, with impulse noises surpassing 140 dB (resulting from actions like tapping the incubator to stimulate apneic preterm infants). Additionally, noises generated during the handling of incubators span from 72.5 dB (placing a formula bottle on top of the incubator) to 98.4 dB (closing side openings). Providing an adequate environment in the NICU is essential since neonates admitted to these rooms are born prematurely, with low weight, and/or with serious health problems. According to the AAP, exposure to noise levels above 45 dBA can cause cochlear damage or even disrupt the normal growth and development of the neonate [17]. That is why the AAP recommends that neonatal care areas should include sound absorption units or incorporate other means to ensure that the combination of continuous background noise and transient sounds in any area of patient care does not exceed a cumulative noise level (LAeq per hour) of 45 dBA, a level (L10) of 50 dBA, and a maximum level (Lmax) that must not exceed 65 dBA [18].

1.6. Of the Recommendations

Presently, the permissible noise levels within incubators are delineated by UNE-EN 60601-2-19 [19]. This standard stipulates that under standard operational conditions (control temperature of 36 °C and maximum humidity), the sound level within the infant compartment should not exceed a sound pressure level of 60 dBA. Furthermore, when any incubator alarm is activated, the sound level in the neonatal compartment should not surpass 80 dBA [20].

Although the same standard aligns with the recommendations of the AAP, it notes that it is not advisable to expose premature neonates to ambient sound environments exceeding 50 dBA. As a guideline, the standard underscores the importance for manufacturers to ensure that sound levels in the incubator room align with the 45 dBA recommendation by the AAP and the 30 dBA recommendation made by the WHO more than three decades ago [21].

Regarding legislation about the potential noise exposure for neonatal patients, consideration should be given to the calculation described in NTP 270 [22], while considering the AAP's recommendation that it is not prudent to subject premature neonates to ambient sound environments higher than 45 dBA.

1.7. Of the Prototype

The technical challenge at hand is to devise a functional incubator that meets the requisite temperature and humidity conditions for medical use, ensuring necessary pressure and airflow, while simultaneously mitigating noise and vibrations within. The goal is to achieve a substantial reduction in both indoor and outdoor noise, adhering to recommendations from international organizations like the AAP and the WHO [23]. A collaborative effort involving the Acoustic Engineering Laboratory, alongside the departments of Automatic Engineering, Electronics, Architecture, Computer Networks, and the Department of Mechanical Engineering and Industrial Design at the Higher School of Engineering (ESI) of the University of Cádiz, has led to the development of a prototype. This prototype, presented in patent form as OEPM P202330766 [24], includes an incubator equipped with a system designed to enhance the acoustic comfort of the newborn.

This work aims to present preliminary results obtained in free-field conditions within hemi-anechoic rooms using the developed prototype. These results will be compared with those obtained under identical working conditions in three incubator models provided by the neonatal service of the intensive care unit at the "Puerta del Mar" University Hospital in Cádiz, as detailed in earlier works [25,26].

2. Material and Methods

2.1. Instrumentation Used

For the measurements, sound level meters including models 2270 and 2250, along with the Brüel and Kjaer model 4231 calibrator, were employed. Prior to conducting measurements, thorough verification and calibration of all equipment were undertaken. Environmental conditions such as temperature, pressure, and humidity in both chambers were recorded before each measurement session.

The microphones used were the model $4966 \frac{1}{2}$ free-field condenser microphone for Brüel and Kjaer 225 and 2270 portable analyzers.

The recorded data underwent processing using the Evaluator Type 7820 software from Brüel and Kjaer using the BZ7225 Version 4.7.4 application, and further analysis was carried out using Microsoft Excel. These meticulous steps ensure the accuracy and reliability of the bought instruments for comprehensive evaluation and interpretation.

2.2. Measurement Procedure

This study presents the outcomes of tests conducted on the prototype within the hemianechoic rooms of the Acoustic Engineering Laboratory at the Higher School of Engineering (UCA). The tests were executed following the standard: UNE-EN ISO 3745:2012/A1:2018 [26].

Outside, the microphones were placed on a tripod 1.5 m from the incubators, in all cases, the positions were the same. Inside, the microphones were placed in the position where the newborn's head would be located.

Three different operating modes were defined for the evaluation: stop situation, normal operation, and temperature alarm for each of the incubators.

The measuring equipment has been calibrated in accredited metrology laboratories and is under metrological control. Nevertheless, on-site verification tests were carried out (before and after each measurement).

The analysis focused on sound pressure levels, both internal and external, in various incubator models and the comfortable acoustic class (NICA+) prototype of neonatal incubators (Figures 1–3). These tests aimed to supply comprehensive insights into the acoustic performance of the prototype in comparison to existing incubator models under different operational conditions. The blue circle indicates the position of the microphone inside the incubator.

The analysis of sound pressure levels involved recording various parameters both inside and outside, encompassing the following values: LAeq,Ti, LCeq,Ti, LAIeq,Ti, LAFmax, LAFmin, L10, L50, and L90. These values were captured in 1/3 of an octave frequency band, between 12.5 Hz and 20 KHz.

All measurements were carried out in hemi-anechoic rooms under controlled conditions, so the acoustic environment is dominated by direct free-field sound.

In the data analysis, the highest level of LAeq, Ti value obtained was considered. For the evaluation of background noise, the LAeq, Ti value with the lowest level reached in the external microphones was used. This approach ensures a comprehensive and representative evaluation of sound pressure levels both within and outside the prototype incubator across different frequency bands.

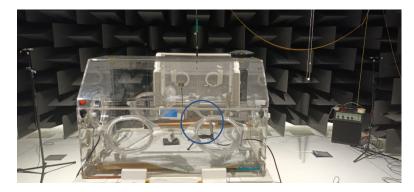


Figure 1. OHMEDA OHIO incubator, Care Plus.



Figure 2. DRÄGER Caleo incubator.

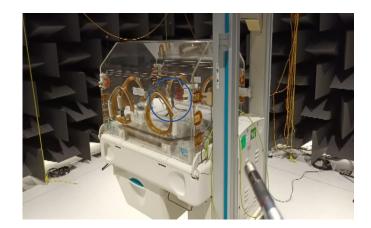


Figure 3. OHMEDA GIRAFFE incubator.

In this work, the declared value of uncertainty is 2.5 dB, for a coverage factor of k = 2 (95% probability), where the position of the microphone and the uncertainty of the equipment calibration chart have been taken into account (class 1 measurement).

3. Results

The results obtained reveal variations among the three incubator models, with overall high values averaging around 56/60 dBA under normal conditions. The impact of alarms can worsen these figures. The results show that premature babies, when these incubators are used regularly, are subjected to noise levels that exceed recommended international

guidelines. It is important to note that the values related to the three incubator models are consistent with those presented and published in our recent works [25,26]. This underscores the significance of addressing and mitigating the noise exposure levels within the incubator environment for the well-being of premature infants.

3.1. Background Noise (Incubators Stopped)

To assess the ambient noise both outside and inside the incubator, measurements were conducted on the three incubator models and the prototype within a "stop" situation, all positioned inside the hemi-anechoic rooms. The results are detailed in the following table [Table 1].

				Outdoor (2	2250) [dBA]			
Incubator Model	L _{Aeq,Ti}	L _{Ceq,Ti}	L _{AIeq,Ti}	L _{AFmax}	L _{AFmin}	L ₁₀	L ₅₀	L ₉₀
01 Care Plus Rever	17.8	35	17.8	18.2	17.5	17.9	17.5	17.1
02 Dräger Medical	17.8	35.7	17.8	18.8	17.5	18.0	17.8	17.6
03 Giraffe	17.8	34.0	17.8	18.4	17.5	18.0	17.8	17.6
Prototype (NICA+)	17.75	32	17.77	18.42	17.46	17.94	17.74	17.62
	Indoor (2270) [dBA]							
Incubator Model	L _{Aeq,Ti}	L _{Ceq,Ti}	L _{AIeq,Ti}	L _{AFmax}	L _{AFmin}	L ₁₀	L ₅₀	L ₉₀
01 Care Plus Rever	17.7	42.7	18.9	27.6	16.5	17.8	17	16.2
02 Dräger Medical	16.9	36.6	17.1	19.9	16.5	17.1	16.8	16.6
03 Giraffe	17.0	34.3	17.1	19.1	15.8	17.2	17.0	16.8
Prototype (NICA+)	16.87	35.87	17.08	19.16	16.38	17.19	16.79	16.61

Table 1. Incubators stopped (background noise) in hemi-anechoic rooms.

Observing the data, it becomes evident that the differences in background noise are minimal. On average, an LAeq,Ti value of 18 dBA outdoors and 17 dBA indoors was recorded. This suggests a relatively consistent background noise level both inside and outside the incubator environment during the "stop" situation.

The background noise conditions saw during various tests exhibit similarities from a frequency of 200 Hz and above. Nevertheless, lower frequencies may show slight variations influenced by the physical attributes of the hemi-anechoic rooms. These discrepancies could be ascribed to the stated cut-off frequency of the chamber itself, affecting the observed outcomes.

In these measurement conditions, it becomes clear that the sound pressure levels in 1/3 of an octave band (interior/exterior) closely resemble those sen in the hemi-anechoic rooms. This similarity suggests that the levels are attenuated by the walls forming the incubator compartment. The enclosure of the incubator compartment plays a crucial role in shaping and attenuating the background noise, especially at lower frequencies.

3.2. Incubator Working

To obtain sound pressure values within and outside the incubator, measurements were carried out for each of the three incubator models in an operational setting, alongside the prototype placed in the hemi-anechoic rooms. The data collected under these circumstances are outlined in the next table [Table 2].

To a last a Madal	Outdoor (2250) [dBA]							
Incubator Model	L _{Aeq,Ti}	L _{Ceq,Ti}	L _{AIeq,Ti}	L _{AFmax}	L _{AFmin}	L ₁₀	L ₅₀	L ₉₀
01 Care Plus Rever	31.9	44.3	32.9	33.3	30.4	32.8	32.0	31.2
02 Dräger Medical	23.7	38.6	24.3	24.8	22.8	24.1	23.7	23.3
03 Giraffe	32.6	40.1	33.3	33.6	32.1	33.0	32.6	32.1
Prototype (NICA+)	18.4	43.32	18.66	20.88	17.66	19.11	18.21	17.89
	Indoor (2270) [dBA]							
Incubator Model	L _{Aeq,Ti}	L _{Ceq,Ti}	L _{AIeq,Ti}	L _{AFmax}	L _{AFmin}	L ₁₀	L ₅₀	L90
01 Care Plus Rever	55.2	69.7	56.2	56.9	53.7	55.9	55.5	55.1
02 Dräger Medical	48.8	54.8	49.8	50.3	47.5	49.3	48.8	48.3
03 Giraffe	56.3	63.2	56.9	57.2	55.2	56.7	56.3	55.9
Prototype (NICA+)	22.82	51.25	26.3	35.22	16.8	25.78	20.68	17.37

Table 2. Incubators running semi-anechoic chamber.

Upon analyzing the results, the Giraffe model displayed the highest sound pressure values (weighted equivalent continuous level A LAeq,Ti), recording 56.3 dBA when measured inside the newborn enclosure. This incubator also showed the highest external noise level, measuring at 32.6 dBA. In contrast, under identical conditions, the Dräger model showed the lowest levels, measuring below 50 dBA within the incubator and emitting an external level of 23.7 dBA.

It is noteworthy that while certain authors recorded sound pressure levels lower than 60 dBA, which falls within the tolerance limit specified in the IEC 60601-2-19 standard [21], these measurements were conducted during the shutdown condition. Conversely, during incubator operation at a controlled temperature of 36 °C with maximum humidity settings, other authors recorded levels exceeding 60 dBA.

In comparison, the results obtained from the prototype show significantly lower values, both internally and externally, as illustrated in Figures 4 and 5. This underscores the prototype's efficacy in achieving reduced sound pressure levels when compared to the three studied incubator models.

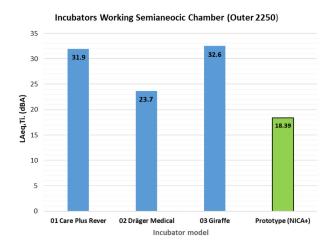


Figure 4. Incubators working (outer).

Indeed, several authors have highlighted that sound levels, particularly at low frequencies, within a modern incubator can reach levels that might be detrimental to the developing newborn. It is proven that common electrical devices and ventilation systems produce low-frequency noise, typically below 100 Hz. Earlier research suggests that exposure to such low frequencies can cause balance disturbances in both humans and mice during

adulthood [27]. Furthermore, non-auditory physiological and psychological effects may arise from low-frequency noise levels, even when they are below the individual hearing threshold [28].

Incubators Working Semianeocic Chamber (Inside 2270) 65 60 55 50 55.2 AAP 45 40 48.8 (dBA) WHO 35 **Tit** 10 25 20 22.82 15 10 5 0 01 Care Plus Re 02 Dräger Me 03 Giraff totype (NICA+) Incubator model



Figure 6 illustrates the evolution of the sound spectrum in 1/3 of an octave within the incubators. Upon analyzing the graph under the specified measurement conditions, variations in sound pressure levels across third-octave bands are clear, highlighting distinct behaviors depending on the incubator model. Notably, the Dräger Medical incubator shows superior performance compared to the other two models. In contrast, the Care Plus incubator displays less favorable acoustic behavior in the frequency range between 25 Hz and 160 Hz and between 2.5 kHz and 6.3 kHz. However, the Giraffe incubator contributes more significantly to sound in the frequency range between 315 Hz and 1.6 kHz. This detailed analysis offers valuable insights into the nuanced acoustic characteristics of different incubator models across various frequency bands.

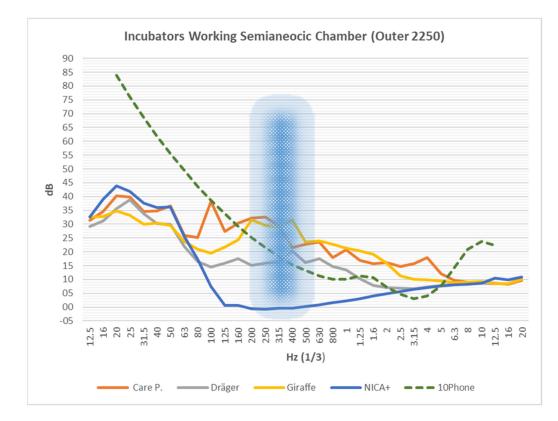


Figure 6. Incubators working (inside).

The representation of the 40 dB equal loudness contour normalized to 10 dB at 1 kHz is depicted as a dotted line in Figure 6. The spectrum area between 200 Hz and 500 Hz is particularly crucial as it is the range of sound frequencies to which a neonate is sensitive. According to Gerhardt et al. [29], a 27-week fetus can only hear low-frequency sounds (below 500 Hz), taking an added two weeks to detect frequencies above 500 Hz. However, there is a considerable disparity in results among researchers about fetal hearing sensitivity.

The study by Hepper and Shahidullah [30] aligns with Gerhardt et al.'s work, showing the hearing cut-off frequency for fetuses from 19 to 27 weeks at 500 Hz. Additionally, Lahav A et al. [31] agrees in placing hearing sensitivity above 1000 Hz from 33 weeks of gestation.

On the contrary, Avery et al. [32] assert that the hearing sensitivity range of a fetus in the third term of pregnancy is 500 to 1000 Hz, and that of a full-term newborn is 400 to 4000 Hz. The values obtained in the prototype, even below the curve of equal loudness for 10 phones, suggest potential benefits, especially for premature infants at 27 weeks of gestation.

Notably, the potential risks of exposure to low-frequency noise levels [33] for neonates and their potential adverse effects on newborn health have not been extensively studied. This underscores the importance of continuous monitoring and treatment of the noise levels to which they are exposed. Harrison [34] emphasizes concerns about exposure to doses of high-frequency noise (>800 Hz) during the stage when the auditory system of premature infants is not fully developed.

Despite these considerations, the study's data show that the highest values are indeed concentrated in the low frequencies. This underscores the importance of added research and heightened attention to the acoustic environment in the Neonatal Intensive Care Unit.

3.3. Incubator Running under the Influence of the Temperature Alarm

To evaluate the impact of alarms inside and outside the incubator, measurements were performed on each of the three incubator models within the hemi-anechoic rooms. The data collected under these circumstances are outlined in the following table [Table 3].

Incubator Model OUTER	LAeq,Ti dBA	Incubator Model INSIDE	LAeq,Ti dBA
01 Care Plus +T	56.60	01 Care Plus +T	59.10
01 Care Plus	31.90	01 Care Plus	55.20
NICA+01 Care	25.61	NICA+ 01 Care	22.88
02 Dräger + T	72.55	02 Dräger + T	58.44
02 Dräger	23.68	02 Dräger	48.83
NICA+ 01 Dräger	48.87	NICA+ 01 Dräger	58.44
03 Giraffe + T	58.01	03 Giraffe + T	56.61
03 Giraffe	32.55	03 Giraffe	56.30
NICA+ 01 Giraffe	26.24	NICA+ 01 Giraffe	58.89
NICA+	18.39	NICA+	22.82

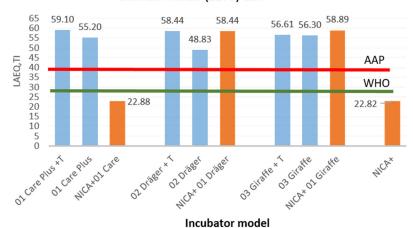
Table 3. Incubators running under the influence of the temperature alarm.

4. Discussion

Upon examination of the results, it becomes clear that the Care Plus model showed the highest sound pressure values (weighted equivalent continuous level A LAeq,Ti), measuring at 59.1 dBA inside the newborn enclosure. Conversely, the Dräger model produced the highest level of noise outside, registering at 72.6 dBA. This discrepancy is attributed to the arrangement of the alarm system in the Dräger incubator. The data supply valuable insights into the acoustic impact of alarm systems within different incubator models, both internally and externally.

In this scenario, the Giraffe incubator model stands out for providing a lower level of sound pressure inside the newborn's enclosure (Figure 7). This variation could be ascribed to the unique arrangement of the alarm system and its distinct acoustic characteristics across incubator models. Nevertheless, it is crucial to emphasize that even in the instance of

the Giraffe incubator, the recorded values are still notably elevated, surpassing international recommendations.



Incubators Working + Temperature alarm Semianeocic Chamber Inside (2270) dBA

Figure 7. Incubators running with the influence of the temperature alarm (inside).

For the prototype, the values are approximations. The values for the operational prototype include the corresponding contribution of the temperature alarm from each incubator model (for each third of an octave band). In this estimated situation, the prototype's values are below those of other incubators, illustrating that even under these conditions, it is possible to keep sound levels below international recommendations.

In the context of incubator operation with the temperature alarm activated, the Dräger Medical incubator shows a higher sound amplitude externally compared to the other two incubator models, particularly in medium and high frequencies. In contrast, the Care Plus incubator generates lower noise output in this specific scenario. This detailed analysis offers valuable insights into the comparative acoustic performance of different incubator models during alarm conditions.

In Figure 8, you can see the evolution of the sound spectrum in 1/3 of an octave, inside the incubators.

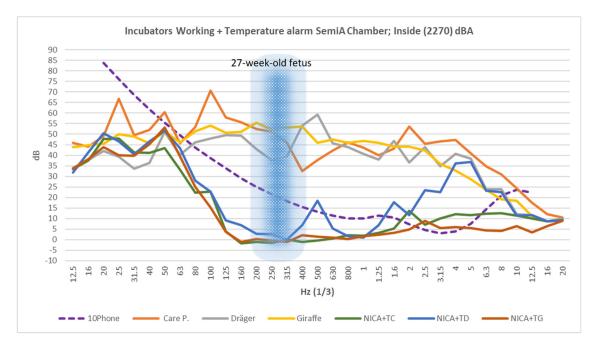


Figure 8. Incubators running with the influence of the temperature alarm (inside).

The observations from the three estimated situations for the prototype revealed that the values in 1/3 of an octave are lower than those measured in various incubator models, particularly in the frequency range of greatest sensitivity for the neonate. This shows that, even under these conditions, the prototype is proven to have a more favorable acoustic profile compared to the analyzed incubator models, particularly in the frequency bands crucial for neonatal sensitivity.

5. Conclusions

The results derived from the NICA+ prototype is highly promising, confirming the effectiveness of the design proposal and the significant enhancement in the acoustic comfort of neonatal incubators.

The obtained values show that, under regular operating conditions of the prototype (NICA+), premature newborns may experience noise levels below international recommendations.

Considering the findings from this study and earlier research, it is recommended that tones used in alarms be designed with consideration for the gestational week of the newborn.

Implementation of acoustic conditioning solutions in the design of neonatal intensive care units is crucial, as once the incubators are controlled, the focus shifts to the surrounding sound environment.

6. Patents

Patent: 202330766; Spanish Patent and Trademark Office, Ministry of Industry. The article we are presenting focuses on the results obtained in a project that we have been developing for five years. As a result of this research, we have developed a prototype, consisting of an incubator with a system for improving the acoustic comfort of the neonate. NICA+. This prototype, presented in the form of a patent as OEPM P202330766, includes a neonatal incubator equipped with a system designed to improve the acoustic comfort of the newborn.

Author Contributions: All authors contributed to the study's conception and design. Conceptualization, R.H.-M. and R.B.-B.; Methodology, R.H.-M., V.P.-R., J.L.B.-J. and F.F.-Z.; Software, A.M.-E.; Validation, A.M.-E.; Formal analysis, R.H.-M. and V.P.-R.; Investigation, R.H.-M., V.P.-R., J.L.B.-J., A.M.-E.; R.B.-B. and F.F.-Z.; Resources, R.H.-M.; Data curation, J.L.B.-J. and F.F.-Z.; Writing—original draft, V.P.-R.; Writing—review & editing, R.H.-M. and F.F.-Z.; Visualization, R.B.-B.; Project administration, R.H.-M.; Funding acquisition, R.H.-M. All authors have read and agreed to the published version of the manuscript.

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Data Availability Statement: The data obtained to carry out this work are based on original sound recordings, processed using specific software, specifically the 7820 Evaluator, developed by the company Brüel & Kjær. The 7820 type requires a license and associated HASP dongle to function. For this reason, it is necessary to apply certain restrictions to these data. The data sets generated and/or analysed during the current study are not publicly available. Still, they are available through the authors upon reasonable request and with the permission of the director of the Acoustic Engineering Laboratory of the University of Cádiz (Ricardo Hernandez-Molina).

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Conflicts of Interest: The authors declare no competing interests.

References

- Hess, J.H. Infant Incubator Filed 5 August 1929, Patented 7 March 1933, Patent Office Julius H. Hess, of Chicago, Illinois infant Incubator Application Filed 3 August 1929. Serial No. 383,403. Available online: https://neonatology.net/pdf/JuliusHessIncubatorPatent-1.pdf (accessed on 23 August 2022).
- Grosholz, J.R.; Wallacel, J.D. 3,335,713. Infant Incubator mlm 3 November 1963, 8 Sheets-Sheet 1 11111. Available online: https://patents.google.com/patent/US3335713A/en (accessed on 23 August 2022).
- 3. Xavier Pardel, Apuntes de Electromedicina: "Incubadora Neonatal. CENETEC; 21 September 2023. Available online: https://www.pardell.es/incubadora-neonatal.html (accessed on 1 January 2021).
- Kuo, S.M.; Liu, L. Apparatus, System, and Method for Noise Cancellation and Communication for Incubators and Related Devices; Northern Illinois Research Foundation. 2013. US13/837,242. US20130204617A1. Available online: https://patents. google.com/patent/US9542924B2/en (accessed on 23 August 2022).
- Uri Rapoport; Incubator with a Noise Muffling Mechanism and Method Thereof. Application PCT/IL2014/050785 Events. 2014. Available online: https://patents.google.com/patent/WO2015029044A3/en (accessed on 23 August 2022).
- Ricardo, H.-M.; Zacarías, F.; Puyana, V.; Rodríguez, V.M.; Beira, J.L.; Luis, A.J.; Simón, L.L. "Análisis del ambiente sonoro en una Unidad de Cuidados Intensivos de Neonatología", XI Congr. Iberoam. Acústica; X Congr. Ibérico Acústica; 49° Congr. Españ 23augustol Acústica-TECNIACUSTICA'18-. 2018. Available online: https://produccioncientifica.uca.es/documentos/625e80415 52a9e6dec053328 (accessed on 2 February 2022).
- Almadhoob, A.; Ohlsson, A. Sound reduction management in the neonatal intensive care unit for preterm or very low birth weight infants. *Cochrane Database Syst. Rev.* 2015, 1, CD010333. [CrossRef] [PubMed]
- Rodríguez-Montaño, V.M.; Beira-Jiménez, J.L.; Puyana-Romero, V.; Cueto-Ancela, J.L.; Hernández-Molina, R.; Fernández-Zacarías, F. Acoustic Conditioning of the Neonatal Incubator Compartment: Improvement Proposal. *Front. Pediatr.* 2022, 10, 955553. [CrossRef] [PubMed]
- 9. Stennert, E.; Schulte, F.; Vollrath, M. Incubator Noise and Hearing-Loss. Early Human Development. *Early Hum. Dev.* **1977**, *1*, 113–115. [CrossRef] [PubMed]
- 10. Barreto, E.D.; Morris, B.H.; Philbin, M.K.; Gray, L.C.; Lasky, R.E. Do former preterm infants remember and respond to neonatal intensive care unit noise? *Early Hum. Dev.* **2006**, *82*, 703–707. [CrossRef] [PubMed]
- 11. De Oliveira Rodarte, M.D.; Fujinaga, C.I.; Leite, A.M.; Salla, C.M.; da Silva, C.G.; Scochi, C.G.S. Exposure and Reactivity of the Preterm Infant to Noise in the Incubator. *CoDAS* **2019**, *31*, e20170233. [CrossRef]
- 12. Morata, T.; Santos, U. Efeitos do ruído na audição. Rev. Ciência Elem. 2018, V6, 083. [CrossRef]
- da Silva Reis Santana, L.; Silva, L.; Silva, R.; Carvalho, J.; Santana, W.; Rossi-Barbosa, L.A.; Ruas, E. Measurement of Acoustic Noise Levels in a Neonatal Intensive Care Unit. *REME Rev. Min. Enferm.* 2015, 19, 27–310. Available online: https://www. researchgate.net/publication/282460547_Measurement_of_acoustic_noise_levels_in_a_neonatal_intensive_care_unit (accessed on 14 April 2019).
- 14. Wroblewska-Seniuk, K.; Greczka, G.; Dabrowski, P.; Szyfter-Harris, J.; Mazela, J. Hearing Impairment in Premature Newborns— Analysis Based on the National Hearing Screening Database in Poland. *PLoS ONE* **2017**, *12*, e0184359. [CrossRef] [PubMed]
- Fortes-Garrido, J.C.; Velez-Pereira, A.M.; Gázquez, M.; Hidalgo-Hidalgo, M.; Bolívar, J.P. The Characterization of Noise Levels in a Neonatal Intensive Care Unit and the Implications for Noise Management. J. Environ. Health Sci. Eng. 2014, 12, 104. [CrossRef]
- 16. Darcy, A.E.; Hancock, L.E.; Ware, E.J. A descriptive study of noise in the neonatal intensive care unit. Ambient levels and perceptions of contributing factors. *Adv. Neonatal Care* **2008**, *8*, S16–S26. [CrossRef]
- Knutson, A.J. Acceptable Noise Levels for Neonates in the Neonatal Intensive Care Unit. *Indep. Stud. Capstones*, p. Program in Audiology and Communication Sciences, W. 2012. Available online: https://digitalcommons.wustl.edu/cgi/viewcontent.cgi? article=1643&context=pacs_capstones (accessed on 5 May 2021).
- American Academy of Pediatrics. Committee on Environmental Health. Noise: A Hazard for the Fetus and Newborn. *Pediatrics* 1997, 100, 724–727. [CrossRef]
- Jackson, A.D.M. Guidelines for Perinatal Care. Am. Acad. Pediatr. 1986. (Electromedical equipment. Part 2-19:2021: Requirements for Basic Safety and Essential Operation of Baby Incubators). Available online: https://www.acog.org/clinical-information/ physician-faqs/-/media/3a22e153b67446a6b31fb051e469187c.ashx (accessed on 5 May 2021).
- EN IEC 60601-2-2:2018; Medical Electrical Equipment—Part 2-2: Particular Requirements for the Basic Safety and Essential Performance of High Frequency Surgical Equipment and High Frequency Surgical Accessories. IEC: London, UK, 2018. Available online: https://standards.iteh.ai/catalog/standards/clc/bd56ff83-1df5-41e8-89aa-f89f5abdf25d/en-iec-60601-2-2-2018 (accessed on 20 September 2022).
- ANSI/AAMI/IEC 60601-2-19:2009; Medical Electrical Equipment—Part 2-19: Particular Requirements for the Basic Safety and Essential Performance of Infant Incubators. ANSI: Washington, DC, USA. Available online: https://webstore.iec.ch/publication/ 64023 (accessed on 17 January 2022).
- NTP 270: Evaluación de la Exposición al Ruido. Determinación de Niveles Representativos; Instituto Nacional de Seguridad e Higiene en el Trabajo. 1991. Available online: https://www.insst.es/documents/94886/327166/ntp_270.pdf/9c674732-ce77-48 1f-8c38-ffc03579bb75 (accessed on 17 January 2022).
- Waye, K.P. A caring sound environment in hospitals? *Care Sound* 2013, 11–26. Available online: https://www.researchgate.net/publication/342834682_A_caring_sound_environment_in_hospitals (accessed on 15 December 2021).

- 24. Hernandez, R.; et al. Patent Technological Report: Incubator with a System to Improve the Acoustic Comfort of the Newborn. Spanish Patent and Trademark Office OEPM P202330766, Madrid. 12 September 2023. As it is protected by the Patent Law, it is only available through the Acoustic Engineering Laboratory of the University of Cádiz, with prior permission.
- Hernández-Molina, R.; Rodríguez-Montaño, V.M.; Jiménez, J.L.B.; Puyana-Romero, V.; Cueto-Ancela, J.L.; Zacarías, F.F. Diagnosis del Ruido en el Interior de Incubadoras Neonatales en Condiciones de Campo Libre. 53° Congreso Español de Acústica -Tecniacústica 2022; ID-13 SEA. Available online: https://documentacion.sea-acustica.es/publicaciones/Elche22/ID-13.pdf (accessed on 12 April 2021).
- 26. Fernández-Zacarías, F.; Beira-Jiménez, J.L.; Puyana-Romero, V.; Hernández-Molina, R. Diagnosis of Noise Inside Neonatal Incubators under Free-Field Conditions. *Acoustics* **2023**, *5*, 354–366. [CrossRef]
- Ohgami, N.; Oshino, R.; Ninomiya, H.; Li, X.; Kato, M.; Yajima, I. Risk Assessment of Neonatal Exposure to Low Frequency Noise Based on Balance in Mice. *Front. Behav. Neurosci.* 2017, 11, 30. [CrossRef] [PubMed]
- Leventhall, G.; Pelmear, P.; Benton, S. A Review of Published Research on Low Frequency Noise and its Effects. UK Department for Environment, Food and Rural Affairs. 2003. Available online: https://www.researchgate.net/publication/237245317_A_ Review_of_Published_Research_on_Low_Frequency_Noise_and_its_Effects (accessed on 15 March 2022).
- 29. Gerhardt, K.J.; Abrams, R.M. Fetal Exposures to Sound and Vibroacoustic Stimulation. J. Perinatol. 2000, 20, S21–S30. [CrossRef]
- 30. Hepper, P.G.; Shahidullah, B.S. Development of fetal hearing. Arch. Dis. Child.-Fetal Neonatal Ed. 1994, 71, F81–F87. [CrossRef]
- 31. Lahav, A. Questionable sound exposure outside of the womb: Frequency analysis of environmental noise in the neonatal intensive care unit. *Acta Paediatr.* 2014, 104, e14–e19. [CrossRef] [PubMed]
- 32. Avery, G.B.; Fletcher, M.A.; MacDonald, M.G. Neonatología: Fisiopatología y Manejo del Recién Nacido; Médica Panamericana: Madrid, Spain, 2001.
- Schust, M. Effects of low frequency noise up to 100 Hz. Noise Health 2004, 6, 73–85. Available online: https://pubmed.ncbi.nlm. nih.gov/15273025/ (accessed on 10 November 2021).
- 34. Harrison, L.L.; Roane, C.; Weaver, M. The Relationship Between Physiological and Behavioral Measures of Stress in Preterm Infants. *J. Obstet. Gynecol. Neonatal Nurs.* 2004, 33, 236–245. [CrossRef]

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