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1 Introduction In recent times, the rate of premature births has grown steadily owing to several factors including an increase in the mother’s age, assisted reproduction, multifetal pregnancies, premature membrane breakage, bacterial infections, and other medical recommendations, such as preeclampsia (Ananth CV et al., 2006). Premature births have been estimated to account for 75– 80% of all perinatal deaths (Ovalle A et al., 2012), of which 40% o occur within the first 32 weeks of pregnancy (Goldenberg RL et al., 2008). Although advanced care increases the chances of survival in neonatal intensive care units (NICUs), there is growing concern about the overstimulation that newborns are subjected to in these wards. Overstimulation of a newborn’s immature system produces stress that results in disproportionate energy expenditure and may affect curing, recovery, and growth-related processes (Ananth C V, et al., 2006). Stress in this scenario originates mainly from ambient light and noise, tactile and stimulative handling, and care of the neonates (Peng NH et al., 2014). Noise exposure is a necessary, continuous form of sensory stimulation for premature neonates and one that is thus ordinarily included in interventions for this type of patient (Krueger C et al., 2012). A loud sustained noise and especially a loud intermittent noise is not welcome by anyone, but it can be especially harmful to newborns. —so harmful as to result in stress-derived functional disorder high noise levels can not only lead to hearing losses in neonates (Stennert E et al., 1977) but also lower mean blood pressure (Slevin M et al., 2000), increase heart and breathing rate, decrease oxygen saturation (Bremmer P et al., 2003) and impair the self-regulatory capacity of newborns (Shimizu A et al., 2015). Also, the mid and long-term effects of cyclical stimulation with high sound pressure levels can have psychological impacts with behavioral consequences (Trapanotto M et al., 2004). Although a quiet hospital is impossible,

reducing current noise levels to acceptable levels is essential to ensure that patients do well (Cardoso SMS., 2015), especially neonates, who are still immature and more vulnerable to the adverse effects of noise as a result. Clinical practice has shown that reducing some stimuli such as noise, light, odors, handling, pain, and inappropriate positions can alleviate neurological damage and ease the development of a more robust central nervous system in neonates (Gascón Gracia S ., 2011). Fetuses in their mothers' wombs have the advantage over neonates in incubators where the former are surrounded by amniotic fluid and abdomen tissues — two efficient attenuators of external noise. It should be noted that womb inner structures substantially reduce sound levels at frequencies above 500 Hz. For example, animal experiments conducted by Gerhardt and Abrams showed that a 72 dB signal at 500 Hz was reduced by 24 dB, while others at higher frequencies were reduced more markedly (by 38 dB at 1000 Hz and 48 dB in 2000–4000 Hz). These layers can filter out a great part of the high-frequency energy, in fact, they work as a bandpass filter that allows fetuses to hear low-frequency sounds (200–800 Hz)only (Abdollahi FZ et al., 2017). Due to the filtering effect of maternal tissues, a 27-week-old fetus can only hear low-frequency sounds (below 500 Hz) and takes an additional two weeks to detect frequencies above 500 Hz (Gerhardt K et al., 2000). 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 (Avery GB et al., 2001). Consequently, premature infants may be exposed to high levels of high-frequency noise (>800 Hz) for long periods, early in the development of their auditory system (Harrison LL., 2004). According to the American Academy of Pediatrics (AAP), noise levels above 45 dBA can cause cochlear damage or even arrest normal development in neonates (AAP. 1997). Several authors have concluded that exposure to high noise levels can affect neural development by favoring unwanted neural pathways and placing neonates under the task of hearing disorders and learning disabilities in the future (Neille J et al., 2014). Although these disorders are also seen in infants with normal hearing thresholds, they are more frequently found in preterm children (Kurtzberg et al., 1988). Noise damage essentially depends on objective factors such as frequency, sound pressure level, exposure time, and acoustic rest time (Morata T et al., 1996). However, the susceptibility to ear damage can be influenced by disease or hereditary factors. Thus, premature neonates are more vulnerable to the impacts of ambient noise than are terminal. The shorter a pregnancy is, the more markedly compromised can the newborn's health be by the effect of incomplete brain development and an increased risk of abnormal brain maturation (Da Silva Reis Santana L et al., 2015). In relation to recommended noise in hospital rooms and particularly in NICUs, as early as 1974 the US-EPA recommended that all hospital spaces should be free of noise at levels greater than LpA ≤45 dB (Knutson AJ. 2012),. Since the goal was to protect patients' public health and well-being, a safety margin of 5 dBA was added to this level and LAF10 = 50 dB was set (Agency USEP., 1974). Although these limits were initially considered inadequate (especially for NICUs), the US EPA later issued added recommendations that the World Health Organization (WHO) adopted, as noise levels should never be exceeded in areas of neonatal care. For this reason, the AAP recommends that the LAeq,1h, resulting from the combination of continuous and transient noise in neonatal care areas not exceed that level. In addition, the general noise level must not exceed LAF10,1h =50 dB, and the maximum level must never exceed LAFmax= 65 dB (AIA.,2001; White RD 2006). Reducing noise levels in a NICU is rather difficult owing to the considerable number and variety of sources contributing to its acoustic environment. The main factor to be considered in developing effective solutions here is the NICU structure (physical design). The Spanish Pediatric Association has issued some recommendations about room space and placement of NICUs in hospital buildings to ease the right development of premature neonates (Agra Varela Y et al., 2014). Other noise problems can originate from a variety of factors such as room size and conditioning, and the presence of specific noise sources (Naresh SM. 2003). The catalog of noise sources at NICUs comprises monitor alarms, support equipment, HVAC systems (heating, ventilation, and air conditioning), phones, and health staff activities (Hernandez Molina R et al., 2018). Other sources of noise to consider include the implementation of recent technologies such as those of motorized toilet paper, towel dispensers, or hand dryers can raise noise levels rather than lower those (Brandon DH et al., 2008). Based on reported data and the specific recommendations of Philbin and Evans (Philbin MK et al., 2016), NICU design should follow the noise levels in the RC 35 curve. The logarithmic sum of the octave band levels set by the RC 35 curve is approximately 42 dB. As cautioned by these authors, however, if an LAeq,1h value of 42 dB is used as the starting point in designing and constructing a NICU. All of this serves as justification for this work that aims to characterize the levels and spectral composition of the total noise present in a NICU room and inside two different incubators and using scientific evidence, determine if these levels are compatible with the proper auditory development of preterm infants. 2. - Materials and Methods To carry out the work, a test was designed in the NICU of the "Puerta del Mar" University Hospital (Cádiz, Spain). This test consisted of two series of noise measurements carried out simultaneously over 24 hours, recording the main magnitudes at one-second intervals. For health reasons, and to exclude neonate-generated noise, the two target incubators were empty but working in normal conditions. To do so, two sound level meters were used. The first one is a Brüel & Kjaer type 2270 and the other is a B&K 2250 [http://bitly.ws/ykxX]. To verify the proper functioning of the equipment a Sound Calibrator B&K 4231 was used. The data was downloaded and later analyzed using the software from the same manufacturer, the B&K 7820 (Evaluator) [http://bitly.ws/yb53]. (Table 1) The microphone of the B&K 2250 was placed inside the two empty analyzed incubators to assess the influence of noise on the neonates. Despite the potential noise absorption or reflection by the incubator panels, and their influence on the measurements, the aim was to show the noise a neonate held in the incubator could hear. For this purpose, the microphone was mounted on a small tripod that was placed on the mattress, approximately 10 cm above the area where the neonate's head would rest. (Figure 1). Two sets of measurements were carried out. The incubator studied in the first set of measurements was an Ohmeda Medical Giraffe Omni Bed (Giraffe) [http://bitly.ws/yhku]. This incubator is situated at one end of the room away from the staff worktable (Figure 2). The incubator studied in the second measurement series was an Ohmeda Medical Ohio Care Plus 3000 model (OCP 3000) [http://bitly.ws/yhm4]. In this case, the incubator was located in the main area of the room near the staff's workbench. The number of occupied incubators increased from 7 in the first measurement series to 9 in the second. During the two sets, and simultaneously, the noise from the room is measured using the B&K 2270. The location of the microphone is chosen between the analyzed incubator and other adjacent and occupied incubators. The microphone was approximately 1.5 m from the nearest wall and the ceiling. The main parameter recorded were the wide band weighted and unweighted continuous equivalent sound levels (LAeq), and the 1/3 octave noise spectra from 12.5 to 20 000 Hz (LAeq), The rest of the parameters are the maximum and minimum response-weighted levels (LAFmax and LAFmin, respectively), the impulse-weighted levels (LAIeq) and the C-weighted peak levels (LCpeak). 3. - Results 3.1. - Noise inside the NICU The NICU ambient noise levels measured in the two series ranged from LpA 46.6 to 90.3 dB. The LAeq,24 h value was 60.0 dB in the first round of measurement and 63.8 dB in the second, and LCpeak was 109.0 and 109.1 dB, respectively, and this can be seen in figure 3. The noise source producing the highest sound pressure level was conversations in the NICU room (Jonckheer P., 2004). 3.2. - The noise inside the incubators: Sound pressure levels in the first round of measurements ranged from LpA = 44.2 dB (minimum value) to LpAmax =84.2 dB, with LAeq, 24 h = 50.4 dB, and LCpeak close to 108.3 dB. As can be seen in figure 4, the highest sound pressure levels were in the medium and high- frequency ranges, where they never exceeded LpA≤45 dB. Sound pressure levels in the second series of noise measurements ranged from LpA=54.5 dB (minimum value) to LpAmax =86.8 dB, LAeq,24 h was 58.5 dB, and LCpeak close to 104.4 dB. As in the first series, the highest sound pressure levels occurred in the medium and high-frequency ranges (figure 5). 4. - Discussion Although the sound level meters were placed in the same dispositions in the NICU for both series, measurements in the second exceeded those in the first. This was largely the result of the greater number of neonates present in the NICU —and hence of the also greater number of items of electrical and medical equipment running in the NICU, and of the higher volume needed by the staff to communicate— in the second. As can be seen from figure 3, noise levels invariably exceeded the recommended limit (LpA≤ 45 dB) in the high and mid-frequency ranges but fell below the limit above 5000 Hz. It is interesting to note that a 100 Hz tone appears in the frequency spectrum as a consequence of the electrical supply (second harmonic of the alternating current frequency in Spain). 4.1. - Are neonates held in incubators exposed to so high noise levels? This is the main question addressed in this work. Although the walls of an incubator can attenuate noise by LpA=10–12 dB, this reduction is downgraded, especially in the mid-and high- frequency range (Fernández Zacarías F, et al., 2018), by inner noise from the fan motor used to adjust the temperature and relative humidity in the incubator. A comparison of the frequency spectrum for the NICU room and the incubator inner space (Figure 6) reveals that noise levels in the two environments were similar but also that those in the 20–250 Hz range were higher in the incubators and those in the 315–2500 Hz range in the room. Noise levels inside incubators can be as high as LpA= 57 dB even if levels on the outside do not exceed LpA=40 dB (Plangsangmas V et al., 2012). Some authors have reported mean and maximum levels of 57.0 and 88.8 dB, respectively (Fortes-Garrido JC et al., 2014). As noted earlier, the noise inside an incubator comes mainly from its fan, the water recycling circuit, door opening and closure, and equipment alarms (Vendramini P et al., 2011). Thus, although noise within an incubator should not exceed LpA= 60 dB according to, the standard ANSI/AAMI/IEC 60601-2-19:2009, alternative recommendations have set the limit (as said previously) at LpA≤ 45 dBA (B. Beccrglund, T et all 1999). The first measurement series supplied noise levels inside the Giraffe model [http://bitly.ws/ykwm]. Based on them, inner noise exceeded LpA≤45 dB; however, as can be seen from the acoustic spectrum (Figure 4), such levels were lower than the recommended limits. By contrast, the second measurement series, performed on the OCP 300 model [http://bitly.ws/yhm4], exceeded the recommended limit over the frequency range of 200–4000 Hz (Figure 5). This result suggests that an OCP 3000 incubator is "noisier" than a Giraffe incubator; also, it is consistent with reported data for earlier comparative studies (Rodríguez Montaño VM et al., 2018) where, however, the differences were not so marked. A comparison of the sound spectrum recorded in the NICU and inside the incubator is shown in Figure 7. If the noise levels existing inside the incubator are correlated with those present in the NICU (for 24 hours), it is verified that the variations inside the incubator are very small between the day and night periods, remaining very stable and with values higher than those recommended at all times. This fact indicates that the noise inside the incubator room is barely influenced by the noise generated in the NICU since its background noise is very high (Figure 8) Answering the question asked above requires considering the location and position of the incubator in each measurement series. Thus, the Giraffe incubator was at one end of the room far from the staff's workbench, while the OCP 3000 incubator was in the main area, close to the workbench. This was the main reason inner noise levels were much higher in the OCP 3000 model —noise near the workbench is typically much higher than in other NICU locations. Hepper and Shahidullah (Hepper PG SB et al., 1994) explored the response of human fetuses to external auditory stimuli, they found 19 to 27-week-old fetuses to respond to low- frequency noise below 500 Hz but none to be sensitive to sound in the 1000–3000 Hz range. Furthermore, fetuses only responded to frequencies above 1000 Hz after 33 weeks of pregnancy (Lahav A et al., 2015). The fetal hearing system shows an increased spectral sensitivity at both low and high frequencies, in addition to a lower hearing threshold (Aslin RN et al., 1983). 5. - Conclusions According to the results obtained and the bibliography consulted, the location of the incubator in the NICU room can directly affect the sound environment perceived by the newborn inside the incubator. This favors exposure to noise levels above international recommendations. Given the influence that certain frequency bands can have on the newborn's hearing development, it is necessary to improve the sound environment inside the incubator. For this, a previous study of acoustic conditioning in the neonatal intensive care unit is necessary. Once the room has been characterized, areas within it must be reserved to locate certain neonates according to their gestational age. Considering that the audible range of neonates (between 400 Hz and 4 kHz) depends on the week of gestation, these studies should incorporate frequency analysis (1/3 octave) to determine the acoustic quality and hearing protection of infants. newly born. 5.1. – Future areas of research From our point of view, it is necessary to implement solutions aimed at improving the design and acoustic conditioning of the NICU room. As indicated by (Krueger C., 2012), it would also be very important to implement actions such as staff training, continuous noise monitoring, relocation of alarms, and improvement in their design. Introducing improvements in the design of the incubators themselves aimed at reducing the noise levels that they themselves generate, this is where the authors are developing their work and where a patent is expected soon 6. - Acknowledgments The authors are grateful to the NICU staff of the "Puerta del Mar" University Hospital (Cadiz, Spain), for their help in the development of this work. 7. - Disclosure of Funding "This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors." 8. - Disclosure of any Conflict of interest None.

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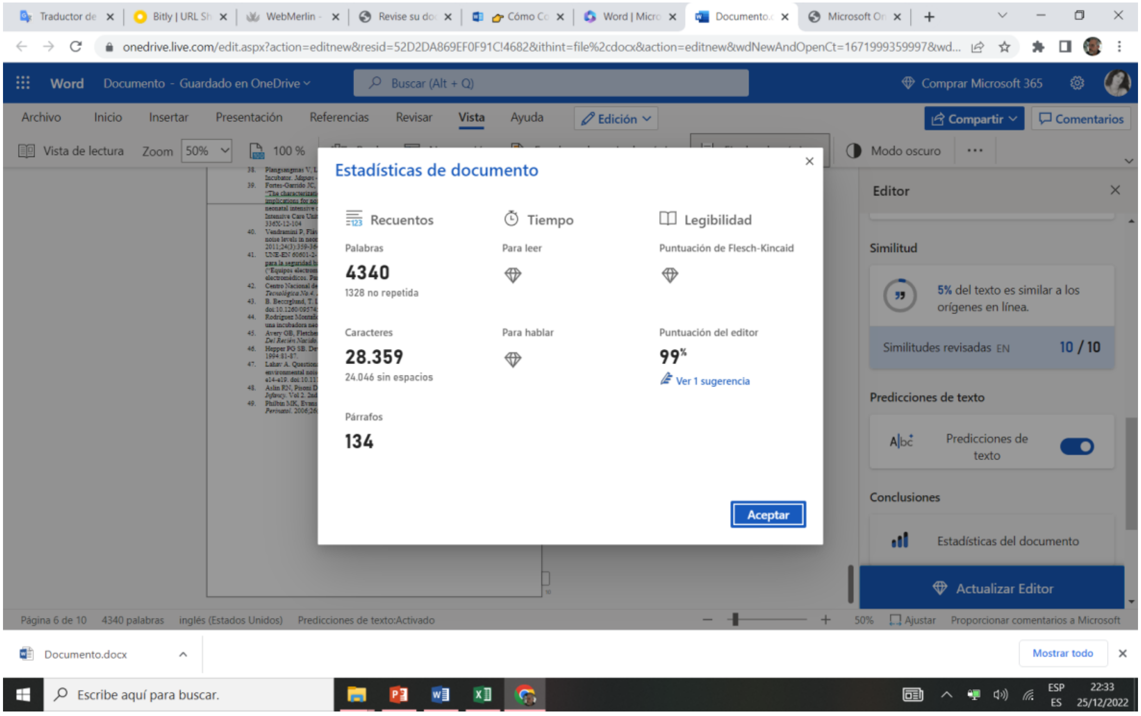

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