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Assessment of environmental noise and its effect on neonates in a Neonatal Intensive Care Unit

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ABSTRACT

A method for analyzing the influence of noise on newborns is proposed. The method consists of defining three different types of time interval (quiet, noisy and nursing) and, for each period, environmental noise levels, heart rate, mean arterial pressure and oxygen saturation is continuously measured. The statistical analysis of the influence of the equivalent noise level, rather than instantaneous noise level, on the behavior of the physiological variables is carried out. Great influence of noise is found by using this method, which is also easily translatable to other intensive care units as actual noise conditions are used in the investigation. Moreover, episodes of Bradycardia, Hypoxia and Hypertension are easily related to simultaneous direct nursing activity or a short but high enough noise event, suggesting that both sustained noisy environment and isolated peak noises lead to the alteration of the physiological variables.

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1. Introduction

Noise, understood as being an undesirable sound for the recipient, turns out to be a regular feature of a Neonatal Intensive Care 40 Unit (NICU) [1]. There are universally accepted recommendations for tolerable noise limits in neonatal units [2–4]. Nevertheless, noise levels detected in a number of NICUs often exceed these recommendations [5,6], bringing with them potential risks for the short and long-term development of newborns [7].

Among the numerous secondary effects of excessive noise expe-46 rienced by premature newborns whilst in hospital [8], there are 47 48 descriptions of changes in the cardio-respiratory system and of cerebral perfusion [7,9]. Stabilizing the immature infant's cerebral 49 50 blood flow during the first few days of life has been put forward as one of the strategies to prevent the appearance of intraventricular 51 52 hemorrhage (10). Moreover, the use of earmuffs in newborns 53 improves sleep efficiency, increase the time of quiet sleep [11,12], reduces the fluctuation in oxygen saturation, stabilizes 54 the behavioral state [13] and may facilitate weight gain [14]. 55

There is little literature studying the response of extremely pre-56 57 mature newborns to the habitual noise in a NICU during their first 58 days of life and not using artificial, additional sources of noise. In most cases the patients are exposed to a high level of synthetic noise over short intervals of time (see [7] for a summary of previous research), that has little to do with the real conditions of ambient noise in a NICU. Williams et al. [15] established the variation of heart rate (HR) and mean arterial blood pressure (MABP) according to the level of environmental noise through the analysis of the temporal correlation of these variables measured second by second during a period of 15 min for a collection of eight neonates, obtaining a statistically significant, albeit rather low correlation between noise, HR and MABP. Slevin et al. [16] used another approach that consists of comparing averaged values of physiological variables, including HR, MABP and oxygen saturation (SpO₂), measured under conditions of quietness and the normal NICU environment. Results showed a significant decrease of MABP and a possible increase of HR during the normal period. However, the normal period includes discontinuous noise and infant nursing as well, so that it is not possible to distinguish the real effect of noise on the preterm infants.

In this manuscript, a procedure to evaluate the effect of noise on preterm infants is proposed, defining the periods of quietness, nursing and noisiness that take place during the normal activity of the NICU, and comparing the average, maximum and minimum values of HR, MABP and SpO₂ obtained in several of those periods.

2. Methodology

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The proposed methodology consists of the statistical compar-82 ison of the average of several physiological variables measured 83

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Fig. 1. View of the incubator and the location of the outside microphone (top left of the picture).

under three different intervals of quietness, nursing and noisiness. The study protocol was approved by the Hospital Ethics Committee and Informed Consent was obtained from parents before measurements began.

The NICU patients' room contains up to seven incubators with its own equipment. The NICU is an "open doors" unit, with no restriction to parents' access, encouraging them to spend as much time in there as possible. The main noise sources of the NICU room are alarms, the opening and closing of the incubator's drawer and door, loud conversations, equipment ventilators, the sound of mobile phones, using furniture and normal conversations.

The patient studied was a preterm newborn, with a gestational age of 25 weeks and two days, and weighing 600 grams at birth. He is a second twin in a dichorionic-diamniotic pregnancy. The study was performed between the fifth and seventh day after birth. From birth, the patient had presented respiratory distress syndrome (for which he required mechanical ventilation and received two doses of intratracheal surfactant) and a patent ductus arteriosus, which was being treated with ibuprofen. He was treated with antibiotics for clinical suspicion of infection. Because he presented hemodynamic instability, an umbilical arterial access was inserted. The patient was also treated with a continuous infusion of morphine

Table 1

Noisy intervals	without	nursing.
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(1.5 mcg/kg/h) and was placed in a Giraffe Incubator[®] (Ohmeda company), which remained covered with a thick blanket during periods of rest.

Noise was continuously monitored for 56 h in two different locations [17]. The main position is inside the incubator, as close as possible to the infant ear position avoiding any chance of contact between the newborn and the microphone. It is intended in this position to measure the real noise exposure of the patient and thus reflections from the incubator are included as in practice. The secondary location is outside the incubator (Fig. 1), far away from any noise source, in order to avoid the direct field of any source and measure the quantity of environmental noise in the unit. The A-weighted equivalent sound level was measured every second ($L_{eq,A,1s}$) and recorded in a storage unit for post-process. The two sound level meters used in this study are Cesva C310 using Cesva PA13-697 microphones (Type I), and they were calibrated before and after the measurements using in field Cesva CB-5 calibrator.

In order to identify the source of the resulting noise levels, continuous direct observation was carried out by the research staff, writing down the source of the sounds and the approximate time interval of its occurrence. Nursing manipulation of the patient were also collected, since they can cause physiological changes in the neonate and produce a rather high sound level inside the incubator, circumstances that would lead to confusion in the data.

The patient's physiological constants were collected continuously by a Tram 451 M Module[®] and Solar 8000 M/i Monitor[®] (GE Medical Systems Information Technologies). The vital signs monitored by the Tram 451 M module which were used for the study were 12-lead ECG analysis, continuous invasive blood pressure and hemoglobin oxygenation (Masimo SpO₂). All information was transferred in real time to the MetaVision[®] Clinical Information System (*i*MDsoft), from which the data was extracted for the study using Matlab.

2.1. Data analysis

The instantaneous relation between noise levels and physiological time histories, given the great variability of the data, showed in the past a rather weak correlation [15]. In this study, the whole measurement time (56 h) was divided into different classes of intervals according to the following classifications: quiet, noisy and nursing. This procedure yielded several different time intervals *T* for each class.

Noise events	Time	Leq inside	Leq outside	Av HR	Max HR	Min HR	Av MABP	Max MABP	Min MABP	Av SpO_2	$Max SpO_2$	$Min \; SpO_2$
(a), (b), (c)	13:40-14:10	59.5	62.1	150.0	159.3	128	48.7	55.0	42	92.0	96.0	81
(d), (e)	16:50-17:10	60.1	65.7	144.0	149.0	124	49.8	54.3	44	97.5	98.6	94
(d)	1:55-2:05	64.0	65.8	143.7	147.0	139	51.2	62.6	44	96.5	97.0	95
(d), (e)	4:15-4:30	63.4	65.5	133.1	141.6	82	49.5	62.6	38	95.3	96.6	88
(d)	5:50-6:05	63.0	65.2	134.8	141.6	118	49.8	63.3	41	95.6	96.6	92
(d), (f)	8:15-8:30	63.3	65.8	128.1	139.3	77	50.6	61.6	38	91.7	94.0	88
(d), (f), (c)	10:45-11:00	63.6	65.9	147.9	155.6	139	46.5	55.3	33	92.7	94.0	89
(d), (f), (g)	11:05-11:20	63.5	65.9	143.2	150.3	110	49.1	63.3	41	90.3	94.0	84
(d), (e)	11:40-12:10	63.3	65.7	141.2	155.0	94	55.0	67.6	44	93.1	95.3	87
(d), (b), (f), (c)	13:15-13:25	63.1	65.6	148.6	153.6	137	53.0	56.0	43	93.3	94.6	92
(d), (g)	14:25-14:35	63.1	65.6	136.6	143.0	127	48.5	53.6	44	89.6	89.6	88
(d), (f), (e)	16:30-16:50	63.0	65.4	144.4	147.6	125	43.5	48.0	38	91.0	92.6	86
(f), (c)	19:30-19:40	62.9	65.4	158.4	162.6	151	-	-	-	91.3	94.0	87
(d), (e), (c)	9:20-9:35	62.7	65.6	164.9	169.6	156	-	-	-	84.9	97.6	66
(a), (g)	14:50-15:00	62.4	65.3	164.9	167.6	159	-	-	-	86.2	94.3	74
(a), (d), (e)	17:40-18:00	62.4	65.2	149.9	151.6	145	-	-	-	91.4	94.3	81
Average value	(260 min)	62.5	65.2	145.4	152.2	122	49.7	58.7	42	92.2	95.2	85

(a) Normal conversation. (b) Furniture. (c) Opening and closing the drawer of the incubator. (d) Alarms. (e) Opening and closing the portholes of the incubator. (f) Loud conversation. (g) Mobile phone.

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Table 2

Quiet intervals.

Events	Time	Leq inside	Leq outside	Average HR	Max HR	Min HR	Average MABP	Max MABP	Min MABP	Average SpO ₂	Max SpO ₂	Min SpO ₂
Silence/Murmurs	14:31-14:43	54.6	56.2	146.7	155	120	50.5	54.7	44	95.3	96.7	92
Silence/Murmurs	22:32-23:01	53.9	60.9	148.3	151	144	47.7	53.0	42	97.7	98.7	97
Silence/Murmurs	04:43-05:05	52.9	60.4	145.2	147	132	42.0	49.7	37	95.7	97.3	95
Silence/Murmurs	10:25-10:38	53.8	61.3	136.1	148	151	42.7	43.3	38	94.7	96.0	95
Silence/Murmurs	17:26-17:40	53.6	61.4	145.7	139	139	43.2	45.7	42	97.7	95.7	92
Silence/Murmurs	18:16-18:29	53.4	61.3	141.4	147	150	42.7	43.3	38	94.6	98.0	97
Silence/Murmurs	05:45-05:55	53.2	61	150.8	145	142	-	-	-	95.7	97.3	87
Silence/Murmurs	14:20-14:40	52.6	60.4	142.1	161	162	-	-	-	96.8	97.3	83
Silence/Murmurs	16:05-16:15	53.1	61	156.0	157	151	-	-	-	93.1	96.3	95
Average value	143 min	53.4	60.4	145.0	151.9	140	45.3	49.0	40	96.8	98	92

Table 3

Nursing intervals.

Manipulation events	Time	Leq inside	Leq outside	Average HR	Max HR	Min HR	Average MABP	Max MABP	Min MABP	Average SpO ₂	Max SpO ₂	Min SpO ₂
(a), (b), (c), (d)	12:15-12:40	58.2	62.6	146.4	152.0	134	45.7	57.3	38	90.9	95.0	81
(e), (b)	13-13:20	61.2	61.8	146.1	153.0	105	46.6	56.6	37	89.1	96.3	83
(f), (g) (d), (c)	15:55-16:20	60.6	65.8	133.8	157.6	66	62.9	76.3	46	89.4	99.3	74
(a), (g)	18:10-18:35	62.4	65.7	135.6	156.3	106	62.0	84.0	48	88.9	97.0	78
(e)	18:50-19:05	62.1	65.7	142.5	147.6	111	52.3	56.0	45	96.3	97.0	95
(f), (g), (d), (c)	23:35-00:10	63.5	65.7	137.5	158.3	97	50.8	78.0	37	94.8	96.6	76
(g), (a)	2:25-2:40	63.7	65.7	135.3	142.6	122	44.8	58.0	36	95.6	96.6	91
(f), (d)	5:20-5:35	63.2	65.4	140.3	143.6	130	44.5	52.3	38	94.8	96.0	93
(f), (g), (d), (c)	6:50-7:05	63.4	65.4	131.9	150.3	96	64.8	74.3	43	95.0	99.0	85
(f), (g), (d), (c)	8:55-9:15	63.5	66.0	127.4	148.0	72	68.8	88.6	42	86.6	97.6	51
(e)	10:00-10:15	63.4	65.7	146.2	156.3	140	45.3	55.3	33	92.7	94.0	89
(a), (c), (b)	10:55-11:05	63.5	65.9	143.2	150.3	110	49.1	63.3	41	90.3	94.0	84
(f), (g), (d), (c)	12:10-12:20	63.3	65.7	141.2	155.0	94	55.0	67.6	44	93.1	95.3	87
(b), (c), (d)	12:30-12:45	63.2	65.6	149.5	159.0	138	54.8	65.0	47	93.3	96.3	86
(f), (g), (d), (c)	13:40-13:50	63.1	65.6	139.1	165.3	109	62.5	81.3	44	88.7	92.0	78
(e)	14:00-14:15	63.1	65.6	136.6	143.0	127	48.5	53.6	39	89.6	89.6	88
(a), (b), (d)	14:55-15:05	63.0	65.5	145.7	149.3	126	48.4	53.6	40	89.3	91.3	78
(f), (g), (d), (c).	15:55-16:05	63.1	65.5	134.1	150.3	96	60.3	67.3	51	84.6	94.6	60
(b), (c), (d)	17:05-17:25	63.0	65.4	144.4	147.6	125	43.5	48.0	38	91.0	92.6	86
(f), (g), (d), (c)	18:55-19:10	63.0	65.4	146.0	164.3	87	41.4	50.3	40	86.5	98.6	66
(b), (c), (d)	19:50-20:00	62.9	65.4	158.4	162.6	151	-	-	-	91.3	94.0	87
(e)	8:20-8:30	62.9	65.5	141.6	145.3	134	-	-	-	92.6	98.0	82
(a), (c), (d)	8:50-9:00	62.8	65.6	147.0	147.0	144	-	-	-	95.3	97.3	94
(b), (c)	9:40-9:55	62.7	65.6	164.9	169.6	156	-	-	-	84.9	97.6	66
(f), (g), (d), (c)	10:00-10:10	62.7	65.6	136.4	152.6	91	-	-	-	94.0	99.3	83
(f), (g), (d), (c)	11:30-12:00	62.6	65.5	168.2	169.0	109	-	-	-	84.2	97.6	73
(b), (c)	11:45-12:00	62.6	65.4	160.2	163.0	155	-	-	-	93.1	96.6	82
(c)	12:55-13:05	62.5	65.4	158.0	162.0	151	-	-	-	91.4	95.0	85
(b), (c)	13:55-14:05	62.5	65.4	158.3	161.6	154	-	-	-	91.0	93.3	82
(a)	14:35-14:50	62.4	65.3	164.9	167.6	159	-	-	-	86.2	94.3	74
(f), (g), (d), (c)	15:15-15:25	62.4	65.3	152.7	168.0	90	-	-	-	89.3	98.6	72
(f), (d)	16:45-16:55	62.5	65.3	147.2	158.6	105	-	-	-	83.6	86.0	59
(b), (c)	17:10-17:20	62.4	65.2	149.9	151.6	145	-	-	-	91.4	94.3	81
Average value	505 min	62.5	65.5	145.3	149.8	116	52.75	65.72	39	90.7	95.8	79

(a) Diaper change. (b) Repositioning the mattress. (c) Placing the mask. (d) Change of position. (e) Feeding. (f) Aspiration. (g) Cure of injuries.

148 For each interval, values were obtained for an A weighted 149 equivalent sound level $L_{eq,A,T}$ inside and outside the incubator. 150 Quiet intervals were defined as those with an absence of noise 151 and activity of any kind so that only background noise is measured. 152 Noisy intervals were defined initially as those in which the average 153 noise level inside the incubator was 4 dB (following Slevin et al. 154 [16] above the average value of the interior noise of the quiet inter-155 vals, without coinciding with nursing activity on the newborn. However, a differential of +6 dB gives more clear influence of noise 156 on physiological variables and all the analysis is carried out consid-157 ering the latter differential. Finally, nursing intervals are defined by 158 159 the existence of nursing care on the patient without considering

the noise level reached inside the incubator. Note that the baby is not taken out of the cut during the nursing so the interior noise will arise.

For the same intervals, the maximum, minimum and averaged values of the following physiological variables were also obtained: HR measured in beats per minute (bpm); MABP, measured in millimeters of mercury (mmHg) and SpO₂ measured in percentage of oxygen in blood. The maximum and minimum physiological variables were calculated from an average size 3 filter on the data vector. This filter averaged each three consecutive data points, following steps of one data point so that another vector of the same size as the vector or raw data is obtained. The higher number was

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Table 4

Activities in the NICU's room, occurrence in noisy intervals and its approximate environmental noise level inside the cot.

Activity	Leq (dBA)	Number of noisy events
Opening and closing the portholes of the incubator	65-70	6/16 (37.5%)
Murmurs	30	
Normal conversation	45-50	3/16 (18.75%)
Loud conversation	60–70	5/16 (31.25%)
Opening and closing the drawer of the incubator	75-80	5/16 (31.25%)
Fixation of the syringe	70-75	
Moving the furniture	55	2/16 (12.5%)
Ventilator of the equipment	60	
Sound of the mobile phone	75-80	2/16 (12.5%)
Alarms	65-80	12/16 (75%)
Background noise (no NICU working)	42-45	
Background noise (NICU working)	50-55	

selected for the maximum and the lower number for the 172 minimum. 173

Once all the data was arranged by time intervals, it was possible 174 175 to conduct a statistical analysis in order to find out if the behavior 176

of physiological variables depends on the quantities of noise.

Table 5

Concretely, two types of hypothesis tests, also called significance 177 tests, were carried out: Wilcoxon and Student t-test for related 178 samples. The statistical hypothesis for this study is an affirmation 179 about whether noise affects the physiological variables of the 180 neonates. Therefore, the hypothesis could be: 181

- Null (H₀): assuming that the physiological variables are random and there are no differences between noisy and quiet moments.
- Alternate (H_a): assuming that physiological variables are different with and without noise and that noise is statistically significant.

Before performing any test, a determinate order must be followed to obtain a more significant and valid result. The first step is to check whether the population distribution is normal, which means finding out if the physiological variables follow a normal distribution, by using the Kolmogorov-Smirnov test. For this statistical analysis only intervals longer than 10 min are used so that the majority of the measurement time was not used since the conditions did not suit the definition of the intervals (short noises, short manipulations of the baby or environmental noise under the trigger value of 6 dB above quiet periods) and thus ensuring the clear predominance of noise, nursing or quietness in each of the selected intervals.

A second analysis was also carried out and focused in linking the occurrence of clinical episodes such as bradycardia

Noisy versus quiet intervals.								
Physiological variable	Value	Normality?	Test	P value	Is the noise statistically significant?			
HR	Average	Yes	T-Student	0.0405	Yes			
			Wilcoxon	0.037				
	Maximal	Yes	T-Student	0.372	No			
			Wilcoxon	0.4595				
	Minimal	Yes	T-Student	0.006	Yes			
			Wilcoxon	0.0075				
MABP	Average	Yes	T-Student	0.005	Yes			
			Wilcoxon	0.014				
	Maximal	Yes	T-Student	0.015	Yes			
			Wilcoxon	0.014				
	Minimal	Yes	T-Student	0.0215	Yes			
			Wilcoxon	0.0315				
SpO ₂	Average	Yes	T-Student	0.047	Yes			
			Wilcoxon	0.057				
	Maximal	Yes	T-Student	0.109	No			
			Wilcoxon	0.131				
	Minimal	Yes	T-Student	0.025	Yes			
			Wilcoxon	0.037				

Table 6

Nursing versus quiet intervals.

Physiological variable	Value	Normality?	Test	P value	Is the manipulation statistically significant?
HR	Average	Yes	T-Student	0.076	No
			Wilcoxon	0.1665	
	Maximal	Yes	T-Student	0.243	No
			Wilcoxon	0.254	
	Minimal	Yes	T-Student	0.0095	Yes
			Wilcoxon	0.0065	
ЛАВР	Average	Yes	T-Student	0.030	Yes
			Wilcoxon	0.0215	
	Maximal	No	Wilcoxon	0.009	Yes
	Minimal	Yes	T-Student	0.0925	No
			Wilcoxon	0.075	
SpO ₂	Average	Yes	T-Student	0.0585	No
			Wilcoxon	0.0845	
	Maximal	No	Wilcoxon	0.287	No
	Minimal	Yes	T-Student	0.018	Yes
			Wilcoxon	0.0185	

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Table 7

Nursing versus noisy intervals.

Physiological variable	Value	Normality?	Test	P value	Is noise statistically significant?
HR	Average	No	Wilcoxon	0.163	No
	Maximal	No	Wilcoxon	0.007	Yes
	Minimal	No	Wilcoxon	0.0175	Yes
MABP	Average	Yes	T-Student	0.274	No
	-		Wilcoxon	0.407	
	Maximal	No	Wilcoxon	0.0205	Yes
	Minimal	Yes	T-Student	0.3795	No
			Wilcoxon	0.3915	
SpO ₂	Average	No	Wilcoxon	0.2345	No
	Maximal	Yes	T-Student	0.1195	No
			Wilcoxon	0.1025	
	Minimal	Yes	T-Student	0.172	No
			Wilcoxon	0.2545	

Table 8

Noisy (>58 dB) versus quiet intervals.

Physiological variable	Value	Normality?	Test	P value	Is noise statistically significant
HR	Average	Yes	T-Student	0.15	No
			Wilcoxon	0.245	
	Maximal	Yes	T-Student	0.075	No
			Wilcoxon	0.0661	
	Minimal	Yes	T-Student	0.02	Yes
			Wilcoxon	0.0055	
MABP	Average	Yes	T-Student	0.0855	No
			Wilcoxon	0.06	
	Maximal	Yes	T-Student	0.0315	Yes
			Wilcoxon	0.025	
	Minimal	Yes	T-Student	0.405	No
SpO ₂			Wilcoxon	0.355	
	Average	Yes	T-Student	0.049	Yes
			Wilcoxon	0.056	
	Maximal	Yes	T-Student	0.009	Yes
			Wilcoxon	0.0085	
	Minimal	Yes	T-Student	0.003	Yes
			Wilcoxon	0.0025	

(HR < 120 bpm [18]), hypoxemia (SpO₂ < 88% [19]) and hyperten-202 203 sion (MABP > 49 mmHg [10]) to noise events. In this analysis, all 204 the events suffered by the baby during the complete monitoring 205 time were identified and after that, the cause of such a response was pursued and linked to one of the defined intervals. 206

3. Results and discussion 207

208 Only one patient was available for the investigation, but was 209 representative of his gestational age. This limitation was overcome by taking a long time measurement which gives a reasonable 210 amount of data to establish significant statistical results to support 211 the proposed method of analysis. The actual data set for the statis-212 213 tical analysis is composed by 16 noisy intervals, 9 quiet intervals and 33 nursing intervals. All of the intervals last between 10 and 214 215 35 min and the total interval time of each class are 260, 143 and 216 505 min respectively. The result of each interval and also the aver-217 aged results of the measured variables for each class interval are 218 shown in Tables 1–3. The averaged L_{Aeq} values for the grouped quiet intervals inside the incubator is almost 10 dBA below the 219 same parameter for noise or nursing intervals, thus demonstrating 220 a clear difference between quiet and other intervals. However, and 221 222 surely by chance, the averaged *L_{Aeq}* for grouped noisy and nursing 223 intervals present the same value of 62.5 dBA. In general terms, the 224 noise levels found in the present study are quite similar to other results published in the literature regarding noise levels in NICUs [1,5,6], therefore the methodology and results could be extrapo-226 227 lated to other NICU rooms or even general proposed Intensive Care Unit [20] in order to seek for the effect of noise on physiological variables. Table 4 seems to indicate that the main source of noise is from the alarms, since they appear in the 75% of the noisy intervals considered with a noise level of up to 80 dB(A) but also the own noise sources of the NICU gives also quite high noise levels [17]. It must be noted that some common actions such as opening and closing the incubator or its drawer also produce instantaneous loud noise levels.

The results of Tables 1–3 show differences in the mean values for most of the indicator variables studied under different conditions, finding a noticeable short term decrease of HR and SpO₂ and also short term increases of MABP, results that are generally consistent with previous published research [7,21–25]. It is worth to note that, under noisy environment, Min. HR shows a 20 units decrease and thus being very close to the limit of bradycardia, that Min. SpO₂ reduces its value below the limit of hypoxemia and that the Max. MABP reaches values clearly above the hypertension and hence a great significance of the variations should be expected.

Statistical analysis should confirm whether or not physiological variables are affected by noise, looking for a different statistical distribution of these variables under low and high noise conditions, provided that there is no other change in environmental variables that could influence the results. The results are summarized in 225

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Table 9

Clinical events detected under nursing. Initial value means the value at the beginning of the clinical event. Event value means the most critical value reached. Time interval reflects the time at where the initial and event values are picked up.

Event	Day	Time interval	Initial value	Event value	% Variation
Hypertension	15	12:34-12:38	41	59	43.90
(mmHg)	15	13:11-13:15	39	63	61.53
	15	15:57-16:20	46	80	73.91
	15	18:10-18:35	47	87	85.10
	15	18:51-19:05	45	59	31.11
	15	23:35-00:10	46	85	84.78
	16	05:29-05:33	38	54	42.10
	16	06:51-07:05	43	76	76.74
	16	08:59-09:15	42	93	121.4
	16	10:50-11:00	44	58	31.81
	16	12:10-12:15	45	62	37.77
	16	12:30-12:45	44	67	52.27
	16	13:40-13:50	44	83	88.63
	16	14:58-15:02	40	59	47.50
	16	15:56-16:05	45	74	64.44
	15	15:58-16:20	50	80	60.00
	15	23:41-23:55	47	85	80.85
	16	06:50-07:10	43	76	76.75
	16	08:59-09:16	49	93	89.80
	16	13:45-13:51	48	83	72.92
	16	16:04-16:07	56	68	21.43
	15	16:10-16:17	148	66	55.40
	15	18:23-18:28	131	106	19.08
	15	19:03-19:05	143	111	65.38
Bradycardia (bmp)	15	23:41-23:46	158	97	38.61
	16	06:51-06:57	136	96	29.41
	16	09:00-09:04	143	72	49.65
	16	09:09-09:11	141	81	42.55
	16	13:44-13:47	171	109	36.26
	16	16:03-16:06	141	96	31.91
	17	15:24-15:26	172	90	47.67
	15	16:07-16:17	86	74	13.95
	16	09:01-09:04	90	51	43.33
Hypoxemia (%)	16	13:43-13:46	90	78	13.33
	16	16:03-16:10	88	60	31.82
	17	15:22-15:28	90	66	26.67
	17	16:43–16:57	89	67	24.72

Table 10

Clinical events detected under noisy conditions. Initial value means the value at the beginning of the clinical event. Event value means the most critical value reached. Time interval reflects the time at where the initial and event values are picked up.

Success	Day	Time interval	Initial value	Event value	% Variation
Hypertension (mmHg)	15	13:47-13:58	45	57	26.66
	15	16:53-17:00	44	59	34.09
	16	02:01-02:05	47	75	59.57
	16	04:18-04:26	38	66	73.68
	16	05:57-06:04	44	69	56.81
	16	08:16-08:20	39	59	51.28
	16	08:25-08:30	39	67	71.79
	16	10:55-11:00	44	58	31.81
	16	11:15-11:18	45	67	48.88
	16	11:44-11:48	44	70	59.09
	16	11:51-12:10	45	77	71.11
	16	13:15-13:25	43	61	41.86
	16	02:02-02:04	47	75	59.57
	16	05:57-06:01	44	69	56.82
	16	11:14-11:18	45	67	48.89
	16	11:43-11:47	44	70	59.09
	16	04:17-04:21	134	82	38.81
Bradycardia (bmp)	16	08:24-08:29	138	77	44.20
	16	11:14-11:16	148	110	25.68
	16	11:43-11:45	145	94	35.17
Hypoxemia (%)	17	09:29-09:38	96	66	31.25

Tables 5–7. In general terms, all the variables are found to follow 251 Normal distribution, thus both the T-Student and Wilcoxon tests 252 253 are carried out, obtaining very similar results for both tests in most 254 cases.

Table 5 shows that statistically significant differences are found (significance level *p* is set for lower values than 0.05) between all the quantities measured due to the presence of noise when compared to those of quiet moments, except for the max. HR and the 258

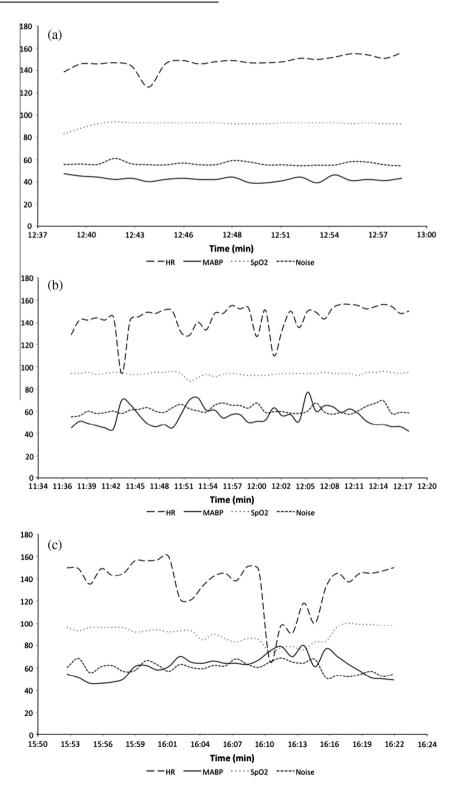
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Table 11

Clinical events under quiet moments. Time interval reflects the time at where the initial and event values are picked up.

Success	Day	Time interval	Initial value	Event value	% Variation
Hypertension (mmHg)	15	14:31-14:35	46	60	30.43
	15	22:35-22:38	43	57	32.55
	16	04:47-04:50	48	51	6.250
	16	10:26-10:27	38	52	36.84

max. SpO2, confirming the general behavior observed when com-259 paring the mean results of Table 1. The same procedure of compar-260 ison is applied to the population of physiological values obtained 261 under manipulation and the values corresponding to quiet inter-262 vals (Table 6). In general, different statistical behavior is found, 263 although not in all of the variables: max. and averaged HR, min. 264 MABP, averaged SpO2 and max. SpO2 seem not to be affected by 265 nursing, which suggests different effect of noise and nursing on 266





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267 the neonate. The comparison of the statistical distribution of the 268 variables under noise events and under nursing should clarify if 269 noise and nursing have the same effect on the patient. Table 7 sum-270 marizes the results of such a comparison and several differences 271 arise, demonstrating that noise and manipulation have a different 272 effect on the patient. Concretely, the variables most affected by 273 noise, which are min. HR and max. MABP, do not distribute 274 statistically in the same way as under manipulation. It can thus 275 be concluded that, in general terms, the effect of noise on a neonate 276 is not equivalent to the effect of manipulation, although it shows a rather similar response. Finally, Table 8 is equivalent to Table 5 but 277 278 considering noise intervals as those with an $L_{Aeq,T} > 58$ dB, i.e. with a differential of +4 dB respect to quiet intervals as did Slevin et al. 279 [16]. Results show different behavior of the physiological variables 280 281 for noise intervals (+4 dB) and quiet intervals, but differences are 282 lesser that using the differential of +6 dB, suggesting some correla-283 tion between the intensity of the noise and the intensity of the 284 effect on the newborn. 285

Fig. 2 shows some time history examples of $L_{Aeq,1min}$, HR, MABP and SpO₂ for quiet, noisy and nursing intervals. It is clear that the physiological variables are altered by exposure to noise since they do not remain stable as they otherwise do in quiet moments. Concretely, the HR follows an irregular behavior that resembles the biphasic heart rate response found in previous research [15] showing, in the present case, an initial quite dramatic decrease in HR followed by a small HR acceleration. The alteration is even greater when the patient is nursed, as can be seen in Fig. 2(c), confirming the greater numerical variation found in the averaged values of minimal HR and maximal MABP under nursing.

296 An account of all the events of Bradycardia, Hypoxemia and 297 Hypertension was carried out for the complete monitoring time 298 (not only the intervals considered in the statistical analysis). In all cases was found some direct nursing activity or a noise event simul-299 300 taneous to the clinical event. To carry out the analysis the classifica-301 tion of quiet, nursing and noisy intervals is still maintained with the 302 difference that there is no limiting time for defining the period, as 303 what it is pursued is the MAX value and not the averaged response. 304 Thus, the noisy interval is now a period of (any) time that fulfills the 305 condition of $L_{Aea,T} > 60$ dB. Tables 9–11 collected all the clinical 306 events according the interval in which they happened.

It is worth noting that there are no events of Hypoxemia and 307 308 Bradycardia during the quiet intervals. However, 6 and 1 episodes of Hypoxemia, and 10 and 4 of Bradycardia are registered respec-309 310 tively under nursing and in a noisy environment. These figures cannot be directly compared since the total time for each kind of 311 312 interval is different. If time is taken into account, Bradycardia takes 313 place at rates of 0.02 and 0.015 events/min for nursing and a noisy 314 environment, and Hypoxemia at rates of 0.012 and 0.004 events/ 315 minute respectively. Those results suggest a greater occurrence 316 of events during nursing intervals. If these rates are applied to 317 the total time under quiet conditions (143 min), the results would show 3 clinical events of Bradycardia and 1 case of Hypoxemia, 318 thus it seems clear that the absence of events in a quiet environ-319 320 ment is significant, especially in this particular case of a sick and 321 extremely premature newborn.

The average MABP for the patient is 45.3 mmHg and the stan-322 323 dard deviation is 3 mmHg, so that the limit proposed [10] suits this study well. Under this condition, 21 Hypertension events were 324 325 counted under nursing (0.064 events/min), 16 under noisy condi-326 tions (0.078 events/min) and only four for quiet moments 327 (0.038 events/minute). Note also that from the four events regis-328 tered during quiet moments, two of them give a maximum value 329 which is very close to the individual limit of 45.3 + 6 bmp, so the 330 ratio of Hypertension occurrence is clearly higher for nursing and 331 noisy intervals than for quiet intervals. Moreover, the ratio of variation of the MABP for the clinical events under noisy environment is in most cases close or above the 50% of increase. 333

4. Conclusions

A procedure to detect the effect of environmental noise on new-335 borns was proposed and tested on one patient with a gestational 336 age of 25 weeks and two days, and weighing 600 g at birth. The 337 procedure consisted of statistically comparing the averaged values 338 of noise inside and outside the incubator, HR, MABP and SpO₂ 339 taken for a time intervals lasting 10 min at least. Three different 340 intervals of clear predominance of quietness, nursing and noisiness 341 were defined after direct observation of the patient. A noisy inter-342 val is defined when the averaged noise level is 6 dB above the back-343 ground noise. Results show that noise altered most of the 344 physiological variables considered (only the maximal HR and the 345 maximal SpO₂ are not statistically affected by noise) and had an 346 effect on the newborn rather similar to that of nursing, something 347 not strange as nursing activity in itself gives a noisy environment. 348

As a complementary strategy, the identification of clinical epi-349 sodes such as Bradycardia, Hypoxia and Hypertension is carried 350 out for all the monitored time. In all cases some direct nursing 351 activity or a noise peak is found to take place simultaneously. From 352 these results, it seems that noise infers in different ways on the 353 newborn. On one side, sustained (averaged) noisy environment 354 lead to consistent alteration of the (averaged) physiological vari-355 ables. On the other side, isolated short noises can punctually alter 356 the physiological variables, although its effect is not as consistent 357 as using averaged data. Hence regulation of noise in NICU should 358 consider both types of noise inside the cot and limit the averaged 359 sound level as well as the, for example, maximum noise level. 360

The followed procedure is based on the actual noise conditions that can be found in any NICU and relies on averaging the results rather than finding instantaneous event-correlation, although the latter effect must be also be taken into account.

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