"Development of a non-invasive baby sleep monitoring and intelligent control system for the prevention of unexpected death in previously healthy babies and early detection of risky situations."

D.1.3
Definition of Patterns and Thresholds

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1 Introduction

1.1 Objective

This deliverable is addressed to present the results from the following tasks:

Task 1.5. Signal and Threshold Risks definition
The aim of this task is to validate the information about risk situations from the review in D1.2 measuring the defined parameters with current technology in order to establish the requirements for the biosensing textiles that will be developed during WP3.

IBV and PIN will perform experiments with 6 babies in their laboratories and clinics with medical biomonitoring devices for direct physiologic measures (respiratory rate, skin temperature, movements) and extra biosensors for indirect measure (abdominal and thoracic pressure, pH, surface temperature), to measure the variability of those signals in near-to-reality conditions, and confirm that the defined ranges coincide with the experimental. All the sensors used in these trials will use current technology (no integrated in textiles, no wireless and most cases invasive).

These trials will complete the information about the performance needed by the biosensing textiles, such as sensitivity (lower threshold of the measurement scale), precision, signal sampling rate, and accuracy (size of the error).

1.2 Scope

This document covers the following points:

- In **section 2** is shown the description of the protocol carried out during the experiments according to task 1.5. In order to optimize the development of Task 2.6 (test with 36 babies) by knowing before stimulus to be used in the design of experiments, it was agreed (kick-off meeting) that tests of Task 1.5 with 6 babies should also include pilot tests with several stimulus.
- In **section 3** is shown the description of the thresholds and patterns of the physiological signals. These limits were already described in D 1.1 and D1.2. In this section, they are completed with real data coming from test with babies.
- Description of the performance needed by the biosensing textiles is described in **section 4**.

1.3 Integration within the project objectives

This deliverable belongs to the "**WP1**. Users characterization and system requirements" which is part of the research section in the "Research, Technological development and innovation activities". This deliverable is the input to the "**Task 2.2. Model to interpretate the biosignals with risk situation**" belonging to "**WP2**. Development of SIDS Preventive Actuations", corresponding to the technological development of the above mentioned activities, as shown in the Figure 1. And together with D1.2, it is also an input for "**WP3** Development of Biosensing textiles".

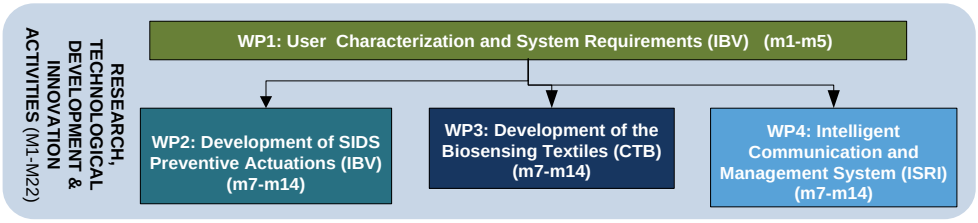

Figure 1. Block diagram.

2. Protocol

In order to optimize the development of Task 2.6 (test with 36 babies) by knowing before stimulus to be used in the design of experiments, it was agreed (kick-off meeting) that tests of Task 1.5 with 6 babies should also include pilot tests with several stimulus.

In D2.1, the different stimulus and the related results are shown. In D2.2, the selected levels and the final stimulus to be used with the 36 babies (task 2.6) will be defined.

As it is explained in D2.1, the initial maximal stimuli was not enough, so it was increased before continue with tests to optimize the work an avoid the risk of not producing an arousal.

With an increased level of stimuli, the previous problem was solved and the pilot test were carried out with the following objectives:

- To obtain the required information related to task 1.5.
- To make pilot tests with several stimulus in order to optimize task 2.6 (tests with 36 babies) as it was agreed on the kick-off meeting.

The clinical trials within task 1.5 consisted of watching how the baby sleeps and how he reacts to the external stimuli applied to him by means of the mattress. A polysomnography was performed along the night to monitor the baby respiratory rate and EEG. Pressure was also measured with non-intrusive instrumentation. A list of the sensors used in these trials can be found in Table 1. Normal conductor gel will be applied to increase conductivity in order to improve the acquired EEG signals.

Table 1. Sensors used in pilot tests.

SENSOR	DESCRIPTION
Pressure	Pressure pad placed between the baby and the mattress.
Polysomnography: EEG, Respiratory Rate.	Sensors to measure the sleep of the baby.

A trained neurophysiologist in performing polysomnographies to infants was observing during all the trial to identify if an arousal is produced as a results of a applied stimuli.

Trial was divided into two parts. During the first one, the baby was just monitored. In the second one, the neurophysiologist applied different stimulus to the baby and observed his reactions. Test were developed during the night, the starting time was set according to the baby's sleeping habits.

The main objective was to find out the stimuli able to produce an arousal in the baby without waking him up. Familiars of the baby may decide to end the trial whenever they want.

This trial is totally innocuous to the baby and its protocol has been approved by the Ethics Committee of the Dr. Peset Hospital of Valencia.

The characteristics of the babies participating within this task are shown on Table 2.

Table 2. Characteristics of babies participating in the pilot tests.

ID	AGE (months)	WEEKS OF PREGNANCY (weeks)	WEIGHT (Kg)	HEIGHT (cm)	AGE OF THE MOTHER (Years)	TYPE OF BABY FEEDING
S1	4.5	41 (full term baby)	7.7	64	28	Breastfeeding
S2	6.4	40 (full term baby)	9	70	35	Artificial
S3	7.6	40 (full term baby)	7.8	71	35	Artificial
S4	4.5	39 (full term baby)	6.2	61	30	Artificial
S5	7	39 (full term baby)	6.3	64	36	Breastfeeding
S6	6.3	40 (full term baby)	8.9	72	30	Breastfeeding

3. Thresholds and patterns of the physiological signals

These limits were already described in D 1.1 and D1.2. In this section, when appropriate, they are completed with examples of real data coming from test with babies.

It is important to note that when literature review offered enough information, it was decided to not introduce an extra variable that would disturb the baby such as with skin temperature and pH. The aim was to keep the test as simpler as possible in order to make it easier for the participant babies.

Respiration as the key feature of the system was measured using a pressure pad in order to prove the viability to measure baby respiration by pressure. In addition, pressure with a respiration band was also measured.

3.1 Respiratory rate, movements and pressure.

Normal physical findings in a newborn include a respiratory rate of 40 to 60 breaths per minute. During rapid eye movement (REM) sleep, infants often exhibit irregular respirations with pauses of 5 seconds or less. In contrast, during non-REM or quiet sleep, a newborn's respiratory rate is 5 to 10 breaths per minute slower than in the awake or active (REM) sleep states.

Respiratory distress can be defined as tachypnea with respiratory rate greater than 60 breaths per minute, nasal flaring, chest retractions (intercostal, subcostal, and substernal), and expiratory grunting. Irregular or slow respiratory rates of less than 30 breaths per minute, particularly if associated with gasping, are a worrisome sign. [1]

The respiratory rate of preterm infants is greater throughout the first half of the year becoming essentially equalized by 8 months of age. The peak difference between preterm and full-term occurs at age 10 weeks, with the differences rapidly decreasing during the remainder of the first half-year. [2]

Table 3. Respiratory rate in preterm and full-term infants during quiet sleep [2]. Values are means ± SE. P < .05. P < .01.

Age (wk)	Respiratory Rate (Breaths/min)		
	Preterm	Full-term	Difference
2	41±4	36±2	5.3
4	46±4	35±2	10.6[1]
6	43±4	37±2	6.6
8	48±8	36±2	12.2
10	44±5	31±1	13.7[2]
12	42±5	30±1	12.1[2]
14	39±4	30±1	9.5[2]
16	39±4	31±1	7.7[1]
18	34±3	29±1	4.7
22	30±2	28±1	1.7
26	32±2	28±1	3.5
30	32±3	28±1	4.0
34	29±2	27±1	1.7
38	30±2	29±2	0.7

Age (wk)	Respiratory Rate (Breaths/min)		
	Preterm	Full-term	Difference
42	27±1	27±3	-0.1
46	28±2	27±2	1.1
50	27±3	25±1	2.1

The respiration signals of Figure 2 have been obtained using a pressure pad. Obtained signals have been sent to the consortium. The sampling rate used was 250 Hz.

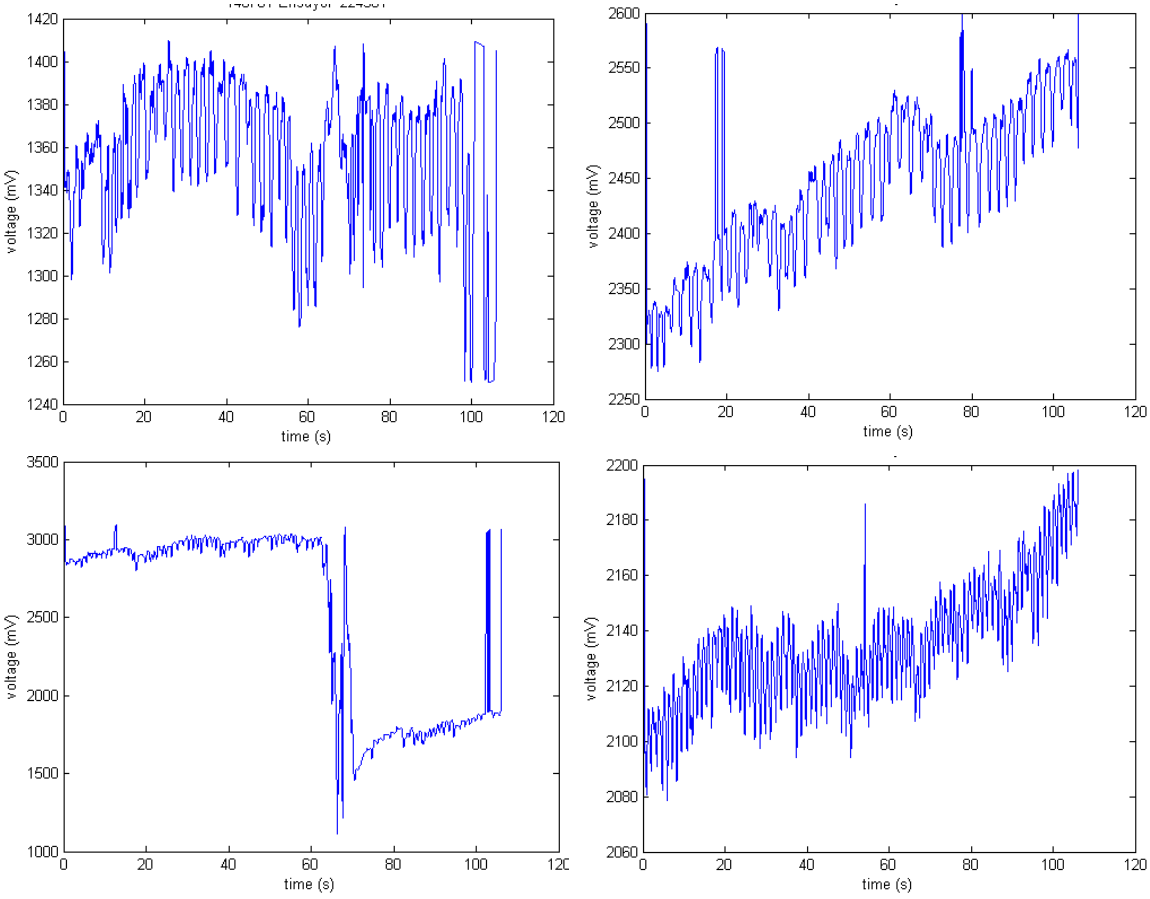

Figure 2. Respiration measured with a pressure pad.

In addition, PIN has provided some examples of real signals measured with a respiration band to be considered. The full set has been sent to the consortium but a few examples are also included below.

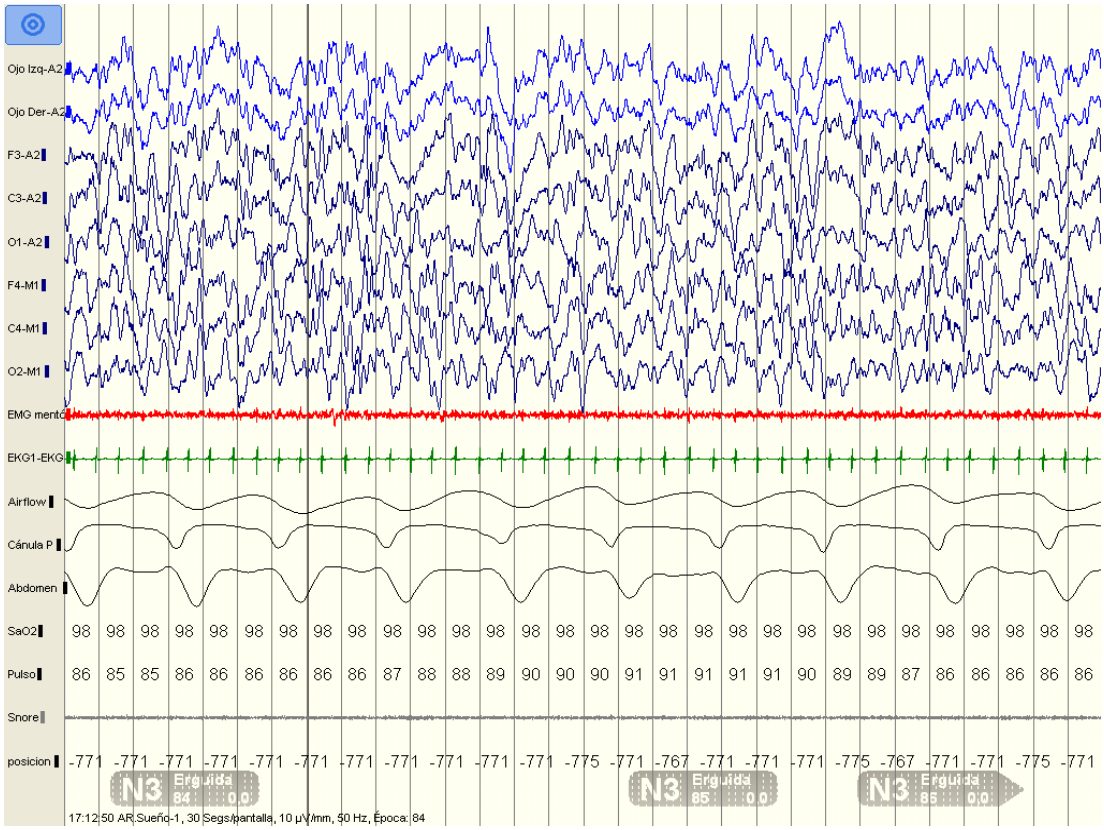

Figure 3. Normal respiration, 4 months, male, N3.

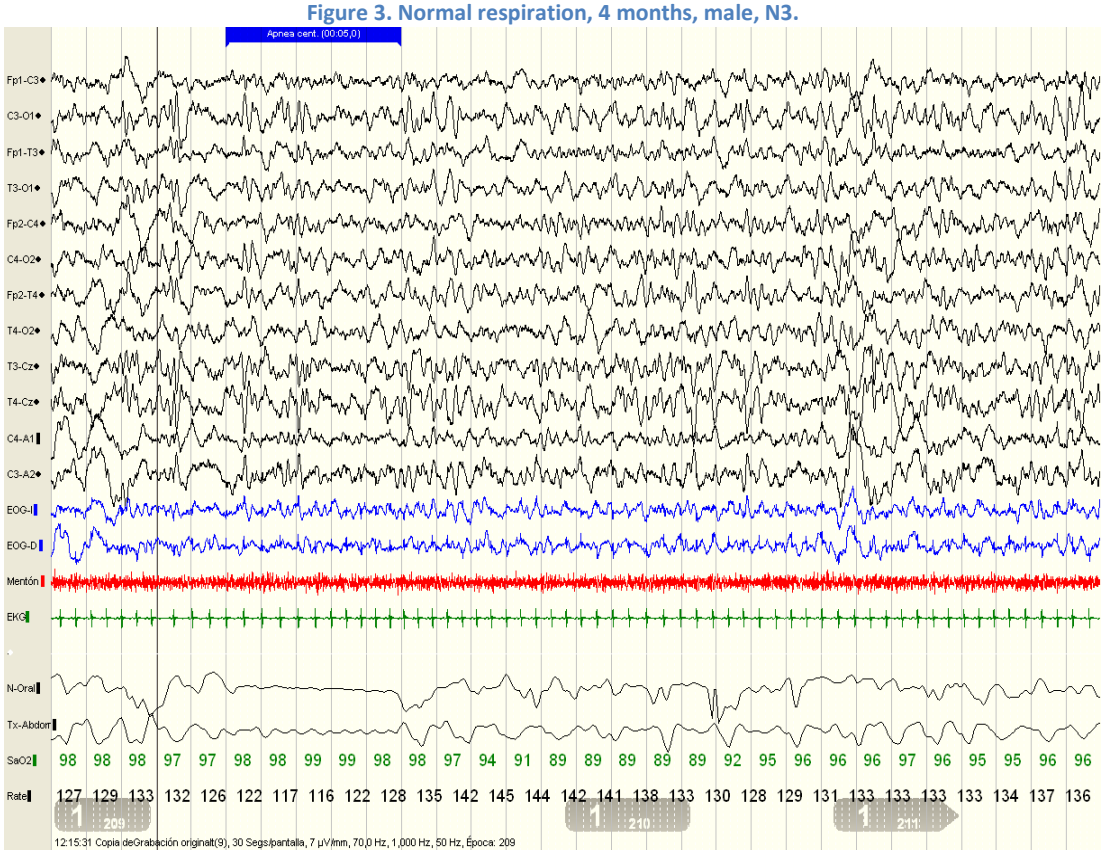

Figure 4. Apnea, 3 months, male.

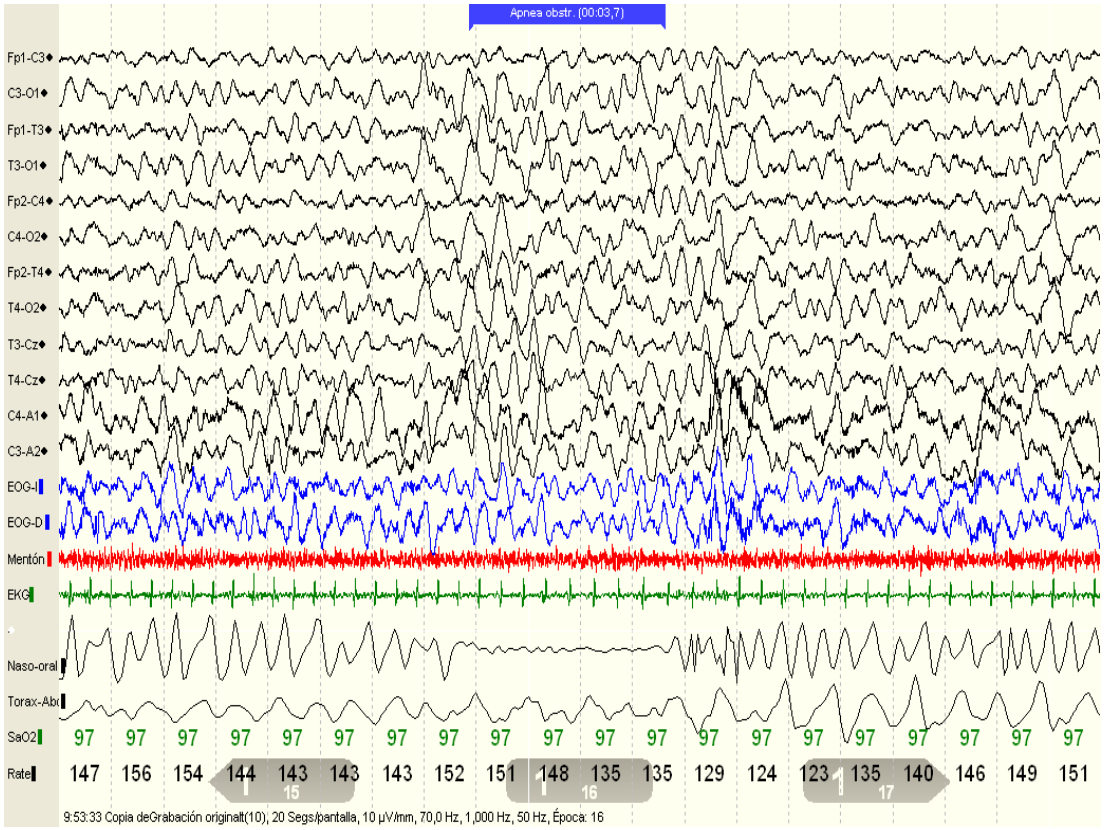

Figure 5. Apnea, 4 months, female.

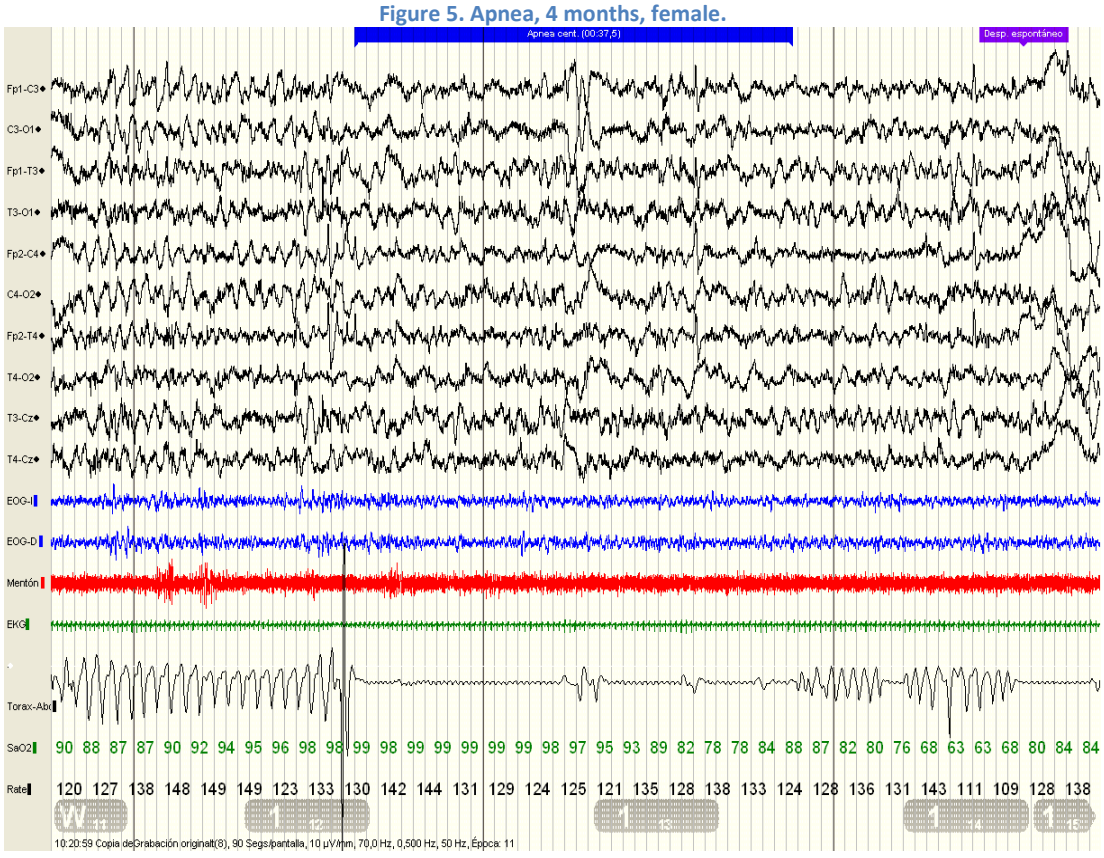

Figure 6. Apnea, 4 months, male (preterm of 25 weeks).

3.2 Skin temperature

There are differences of temperature in newborns throughout the 4 EEGsleep-defined states. Preterm babies have higher rectal temperatures than fullterm babies. Nevertheless, no significant variations have been found in skin temperature between preterm and fullterm.

There exist average skin temperature differences among all states. Specifically, for average skin temperature between mixed frequency active and tracé alternant quiet sleep. [3]

Table 4. Summary of temperature (ºC) data for preterm and full-term infants [3].

Variable	Mean		Standard deviation		Minimum		Maximum	
Preterm (n=34) / Full-term (n=25)	PT	FT	PT	FT	PT	FT	PT	FT
Mixed frequency active sleep								
Skin average	36.28	36.17	0.40	0.62	35.06	34.79	36.86	37.29
Skin variance	4.46	5.11	1.35	1.61	2.40	2.26	7.27	8.70
High voltage quiet sleep								
Skin average	36.27	36.10	0.44	0.73	34.97	34.29	36.95	37.28
Skin variance	4.36	4.92	1.53	1.42	1.94	2.56	7.53	9.00
Tracé alternant quiet sleep								
Skin average	36.19	36.05	0.41	0.69	35.06	34.37	36.84	37.35
Skin variance	4.24	4.91	1.38	1.52	1.81	2.10	7.14	8.85
Low voltage irregular active sleep								
Skin average	36.18	36.07	0.41	0.70	34.94	34.28	36.89	37.36
Skin variance	4.39	5.29	1.50	1.84	1.58	2.56	7.52	10.43

3.3. pH

Gastro-oesophageal reflux (GOR) is defined as the passage of gastric contents into the oesophagus due to inappropriate relaxation of the lower oesophageal sphincter. It occurs in 50% of neonates less than 3 months of age and usually resolves by 12 to 18 months of age. Around 20% of neonates with GOR will require medical intervention.

Oesophageal pH monitoring is not routinely recommended in neonates as 75% of GOR may be due to non-acid or weakly acidic reflux.

A reflux episode was defined as a lower oesophageal pH of < 4 for 15 seconds or longer. [4]

4. Performance needed by the biosensing textiles

The need performance need by the biosensing textiles has been updated and it is shown in Table 5.

Sampling rate used in the test was 250Hz. Reductions of sampling rate should be studied carefully.

Table 5. Sensor specifications.

Sensor	Pressure (position)	Pressure (breathing)	Temperature	pH of reflux
Signal and Unit	Mattress mapping Baby location and position ? ON/OFF (baby present or not)	Breathing frequency (Hz)	Skin temperature (°C)	pH (no unit) Threshold at 4 and 7.
Accuracy on the mattress	Enough to support the breathing sensor 1-5 cm Back or front position?	Depending on the sensor size (sensor resolution) Should be able to measure wherever the baby is	Enough to give the same temperature wherever the baby is. To be tested by CTB	Enough to give the same value wherever the baby is. The amount of liquid typically rejected will be considered.
Range of measurements (extreme values)	Baby weight 1.5 to 12.8 kg Size of the active area : 50 cm*70 cm Baby size : 52 to 70 cm	20 and 60/min are thresholds 1br every 3sec 20br/min = 0,33 Hz 80br/min = 1,33 Hz	Baby T° : 33 to 40 Check skin T°	Acid: 4 Alkaline: 8 [6] Number of episodes per hour: 2-4 [7]
Reliability	++	+++	+++	++
Signal sensitivity (which variation has to be detected)	Enough to support the breathing sensor	Really sensitive Sensitivity : 1 br/min = 16.66 mHz	0, 5 °C as an objective	Values lower than 4 and higher than 7.
Comfort	Low (integrated)	Low (integrated)	Medium	High (in contact)
Cost Acceptable	€€	€€€	€€	€
	Linked to reliability Depending on the amount of sensor			
Washing resistance (Y/N)	N Not in contact	N Not in contact	Y Encapsulated by a polymer	Yes definitely, not encapsulated Disposable sensor ?
Response time (s)	1sec	0,25 sec (max frequency)	1 min after first detection (initial warm up)	4 sec Drying time < 60 sec [7]

5 Conclusions

The aim of this deliverable is to define the patterns and thresholds that are used as the **textile biosensing requirements**. This requirements are described in **section 4**.

According to the DOW (task 1.5), **tests with 6 babies** in order to confirm and complete the patterns and thresholds **have been developed**. Protocol to perform these tests is shown in section 2 and results about patterns and thresholds are described in section 3.

In addition, in order **to optimize the development of Task 2.6** (test with 36 babies) by knowing before stimulus to be used in the design of experiments, **it was agreed (kick-off meeting) that tests of Task 1.5 with 6 babies should also include pilot tests with several stimulus**. The protocol and the babies participating are described in section 2 while the results related to stimulation parameters will be shown in D2.1. This part of the test has been very useful in order to defined a design of experiments (D2.2) to be perform within T2.6.

6. References

[1] Suhas M. Nafday, MD, MRCP(Ire), DCH; Christina M. Long, DO, AAP Textbook of Pediatric Care, American Academy of Pediatrics, 2008.

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[6] López-Alonso M, Moya MJ, Cabo JA, Ribas J, del Carmen Macías M, Silny J, Sifrim D., "Twenty-four-hour esophageal impedance-pH monitoring in healthy preterm neonates: rate and characteristics of acid, weakly acidic, and weakly alkaline gastroesophageal reflux.," *Pediatrics,* vol. 118, no. 2, pp. 299-308, 2006.