Design, development and experimental validation of a non-invasive device for recording respiratory events during bottle feeding

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Abstract— **In newborns, a poor coordination between sucking, swallowing and breathing may undermine the effectiveness of oral feeding and signal immaturity of Central Nervous System. The aim of this work is to develop and validate a non-invasive device for recording respiratory events of newborns during bottle feeding. The proposed device working principle is based on the convective heat exchanged between two hot bodies and the infants' breathing. The sensing elements are inserted into a duct and the gas exchanged by infants is conveyed into this duct thanks to an ad hoc designed system to be mounted on a commercial feeding bottle.**

Two sets of experiments have been carried out in order to investigate the discrimination threshold of the device and characterize the sensor response at oscillating flows. The effect of distance and tilt between nostrils and device, and the breathing frequency, have been investigated simulating nostrils and neonatal respiratory pattern.

The device has a discrimination threshold lower than 0.5 L/min at both 10° and 20° of tilt. Distance for these two settings does not affect the threshold in the investigated range (10-20 mm). Moreover, the device is able to detect breathing events, and to discriminate the onset of expiratory phase, during a neonatal respiratory task delivered by a lung simulator.

The results foster the successful application of this device to the assessment of the temporal breathing pattern of newborns during bottle feeding with a non-invasive approach.

I. Introduction

Thanks to the advances in technology and medical science, the mortality among preterm infants has dramatically decreased in the last decade. However, preterm infants often experience neurodevelopmental impairments. One of their main and earliest challenges is to independently orally feed. The attainment of a safe and successful oral feeding in fact requires the complex coordination between sucking, swallowing and breathing: any deficit in one of these functions may cause several risks to the newborn, such as aspiration, pneumonia or apnea. Besides, irregularities in the coordination of the feeding pattern may be a first indication of later neurodevelopmental and motor outcomes [1]. A coordinated cycle of nutritive sucking is expected to show a 1:1:1 relational pattern among sucking, swallowing and breathing, which is reported as an important developmental achievement for preterm immature infants. For this reason, the importance of monitoring and recording the events of sucking, swallowing and breathing has been confirmed through several studies over the last decades [2]. Understanding how preterm infants breathe during feeding represents an important step for the assessment of the infant's development. Concerning the recording of breathing events during neonatal feeding, scientific literature reports several non-invasive and invasive techniques [3,4]. The employment of invasive approaches is discouraged, especially in the case of preterm infants, in order to avoid additional stress [5]. Given that, more research effort is needed to design sensing solutions that can be easily embeddable on a common bottle for feeding [2,6,7], and that can be used to assess the temporal breathing pattern. Different flowmeters are employed to monitor respiratory patterns in newborns (i.e., pneumotachographs [8], orifice meters [9] and optical-based sensors [10,11]). In this work we propose a non-invasive device for recording newborns' respiratory events, designed to be embedded on a common feeding bottle. Its working principle is based on the heat transfer from the surface of two NPN transistors to the colder respiratory gas that hits them. The experimental validation has been carried out in order to assess the device feasibility to the monitoring of the temporal pattern of breathing while feeding. Experiments have been carried out to characterize the discrimination threshold and the device response at oscillating flows.

II. Theoretical Background

The working principle of the proposed device is based on the convective heat exchanged between the surface of two transistors heated by Joule phenomenon and the colder gas inhaled and exhaled by the infant. The relationship between the base-emitter voltage (V_{be}) and the base-emitter junction temperature (T_{be}^S), can be considered as linear in a wide range of temperature [12]:

$$V_{be}(T_{be}^S) \cong a + bT_{be}^S \qquad (1)$$

The coefficients *a* and *b* are constant, and *b* represents the thermal sensitivity of V_{be} (equal to -2 mV/K). In presence of flow with $T_f < T_{be}^S$, the transistor reaches an equilibrium temperature value lower than the one it experiences under

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steady state conditions. T_{be}^S can be obtained by the following equations:

$$I_C^2\, R_{CE} \cong h\, S\, (T_{be}^S - T_f\,) = Q \qquad (2)$$

where I_C is the collector current, R_{CE} is the equivalent collector emitter resistance, Q is the heat exchanged between the transistor and the gas, and S is the hit exchange surface.

The heat transfer coefficient (h) can be expressed by King's Law:

$$h = A + B\sqrt{\rho v} \qquad (3)$$

where A and B are two calibration constants, ρ is the fluid density, and v is the mean fluid velocity. Introducing (3) and (2) in (1) and solving for V_{be}, we obtain the relationship between V_{be} and v:

$$V_{be}(v) = a + b\left(\frac{Q}{S\left(A + B\sqrt{\rho v}\right)} + T_f\right) \qquad (4)$$

In order to discriminate the flow direction, two nominally identical NPN transistors have been used and mounted as shown in Fig. 1b. When transistor Tr1 is directly hit by the gas, transistor Tr2 is shielded by the PCB where it is soldered. In this case, the equilibrium temperature of Tr1 is lower than the one of Tr2, so the two V_{be} are different, and the difference ΔV_{be} can be expressed by:

$$\Delta V_{be}(v_1, v_2\,) = b\left[\frac{Q_1}{S\left(A + B\sqrt{\rho v_1}\right)} - \frac{Q_2}{S\left(A + B\sqrt{\rho v_2}\right)}\right] \qquad (5)$$

where v_1 and v_2 are the velocities of the gas hitting Tr1 and Tr2, respectively.

Under the condition of laminar flow, v_1 is equal to $2v$ and corresponds to the maximum velocity of the gas flowing within the duct. Assuming v_2 negligible, $Q_1 = Q_2 = Q$ and introducing in (5) the expression of the volumetric flow rate $F = \Omega v$, we obtain the following relationship:

$$\Delta V_{be}(F) = \pm b\left[\frac{Q}{S\left(A + B\sqrt{\rho\dfrac{2F}{\Omega}}\right)} - \frac{Q}{SA}\right] \qquad (6)$$

where Ω is the duct cross section. By grouping parameters in (6), we obtain (7)

$$\Delta V_{be}(F) = \pm k c\frac{\sqrt{F}}{A + c\sqrt{F}} \qquad (7)$$

with $k = \dfrac{bQ}{SA}$, $c = \dfrac{B\rho^2}{\Omega^2}$.

The sign of ΔV_{be} is determined by the direction of the gas flow.

III. Design and Manufacturing

Among several available possibilities, we have chosen two nominally identical NPN bipolar junction transistors (PBSS2515M by Philips), each one soldered on a PCB. The two PCBs have been positioned 1 mm apart in order to avoid the effects of heat conduction on the base-emitter junctions of the two transistors. The PCBs are inserted into a duct with a diameter equal to 10 mm, designed to be mounted on the ring of a commercial feeding bottle (Angled Well-Being Chicco, Artsana S.p.A) and to avoid direct contact with the infant.

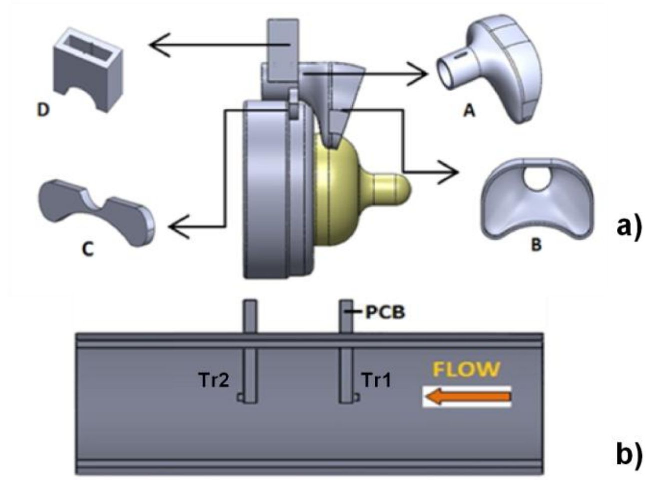

Figure 1. a) Assembly of mechanical components: (A) duct inserted into the air conveying system (B), (C) duct support, (D) PCBs support. b) Schematic representation of the sensing element.

One end of the duct is inserted into an air conveying system (Fig. 1a, A), designed to get a profile matching with the teat (Fig. 1a, B). Two mechanical supports have been designed: the first one holds the duct (Fig. 1a, C); the second one guarantees the PCBs placement at the chosen distance, in line with the duct axis and with the surface perpendicular to the flow direction (Fig. 1a, D). These mechanical components have been designed in SolidWorks and built using a rapid prototyping printer (Project 3000 by 3D Printer Inc.). The base and emitter voltages have been conditioned by an analog circuit providing an output, V_{out}, proportional to their difference.

IV. Experimental Set up

A. Discrimination threshold

In order to estimate the discrimination threshold of the device in different configurations, an experimental set-up simulating the infant's nostrils has been set (Fig. 2).

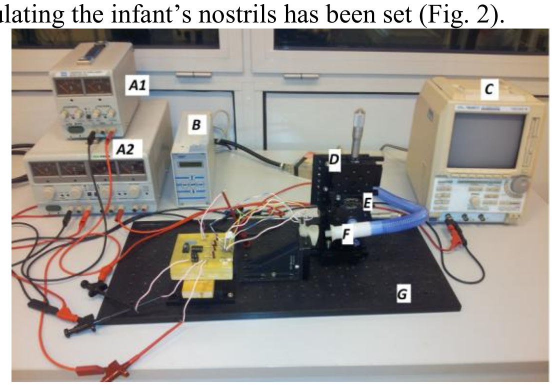

Figure 2. Discrimination threshold experimental setup: (A1) DC power supply for transistor, (A2) DC power supply for amplifiers, (B) Air flow controller, (C) Oscilloscope, (D) Micropositioners, (E) Tilt angle regulator, (F) Nostrils, (G) Optical table.

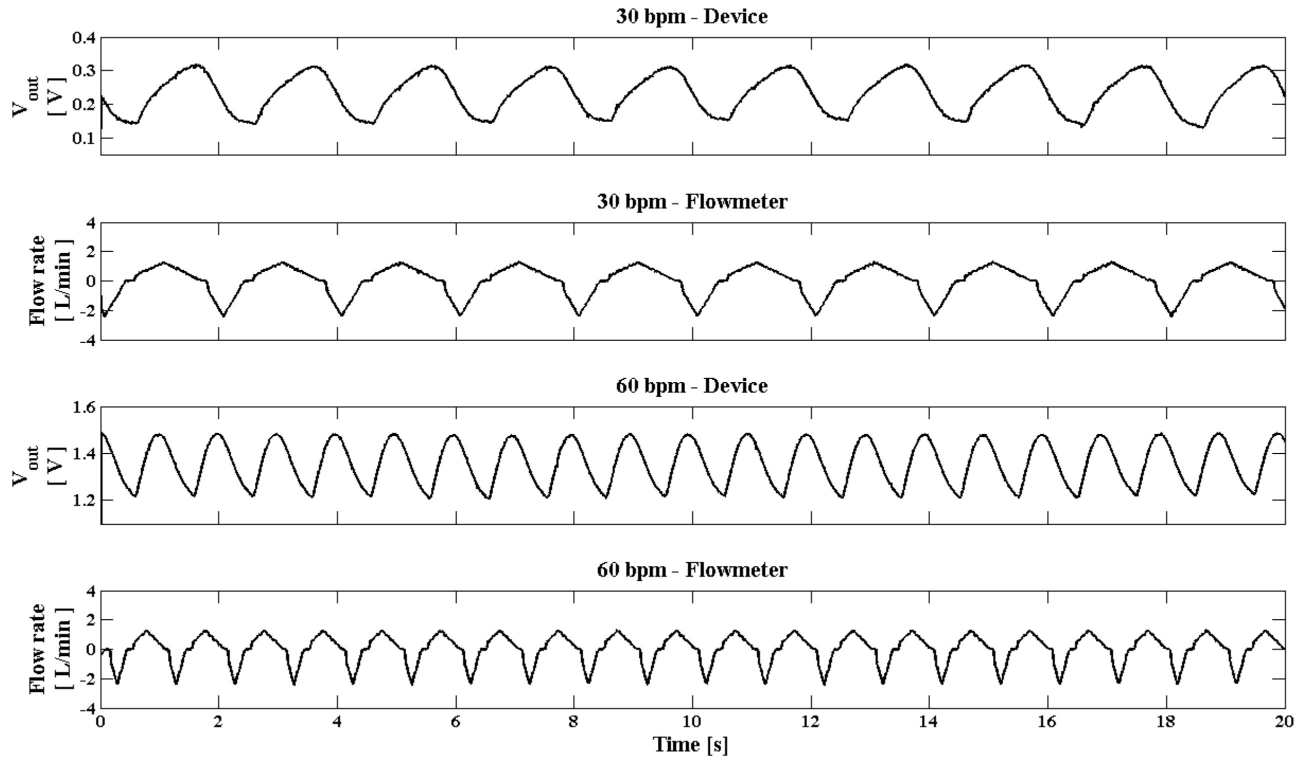

Figure 3. Device and flowmeter outputs at 30 and 60 bpm.

The infant's nostrils have been simulated through two pipes of 5 mm diameter; the distance between their centers was 8.5 mm [13]. The pipes have been inserted on a plastic base, which has been fixed to the end of a breathing circuit. This circuit is connected to a mass flow controller, which delivers constant flow rates (from 0.1 L/min to 0.5 L/min with step of 0.1 L/min; from 0.5 L/min to 2.5 L/min with step of 0.5 L/min; 3.5 L/min, 5 L/min, 6 L/min and 7 L/min). Flow rates caused a ΔV_{be} according to (7), recorded by an oscilloscope (Fig. 2, C). Two micropositioners have been used in order to allow horizontal and vertical movements of the nostrils. An angle regulator, connected to the micropositioners, has been used to allow the changes of the nostril tilt with respect to the axis of the duct.

B. Response to oscillating flows

We used an Active Lung Simulator (ALS) to deliver flows similar to a neonatal respiratory pattern. It is composed of four cylinder-pistons (2KS444P Airport Corporation, 15.5 cm^2 cross-section each) perpendicularly connected to a central spherical chamber, described in detail in [14,15]. Pistons are moved by four closed-loop DC brushless actuators (M-235.2DD Physik Instrumente). When the ALS delivers gas, it simulates the expiratory phase. In this case the fluid passes through a fast mono-directional flow meter (4121 TSI, accuracy of 2% of measured value, range of measurement up to 20 L/min, and response time of 4 ms), and then hits the transistors (Fig. 1b). During the simulation of inspiratory phase, the gas hits the device and then passes through the flowmeter. Flows and volumes generated by the ALS are measured by the flowmeter and used as reference.

V. VALIDATION PROCEDURES

Discrimination threshold has been assessed setting three different distances between the nostrils and the connector (10 mm, 15 mm and 20 mm) and three different tilt angles of the nostrils relative to the duct axis (10°, 20° and 30°). Angles bigger than 30° have not been investigated since the considered feeding bottle already has its own 30° tilt. The 10 mm minimum distance corresponds to the average distance between the nose and upper lip of the infant [16]; the 20 mm maximum distance is suggested by the geometry of the considered teat. Therefore, this range allows covering all the angles and distances which can occur during bottle feeding.

In order to characterize the device response at oscillating flows, experiments have been performed by simulating two different respiratory patterns: *i)* the first one was characterized by a respiratory rate of 30 bpm (0.5 Hz) and, ii) the second one by 60 bpm (1 Hz), in order to cover all the respiratory rates typical of neonatal ventilation during bottle feeding [17] (Fig. 3). For both the experiments a typical minute volume encountered in neonatal ventilation (i.e., 1.0 L/min) has been delivered [18]. The outputs of both flowmeter and device (V_{out}) have been sampled at 1 kHz and processed applying a 10-sample moving average filter (Fig. 3).

VI. RESULTS AND DISCUSSIONS

A. Discrimination threshold

Nine measures have been performed at each air flow rate and compared with those recorded in no flow conditions: the minimum flow rate with a resulting p-value < 0.05 (one-sample t-test) has been considered as the discrimination threshold. Table I reports the results for the different investigated configurations.

TABLE I. DISCRIMINATION THRESHOLD AT DIFFERENT CONFIGURATIONS

Distance [mm]	Threshold [L/min]		
	Tilt angle [°]		
	10	*20*	*30*
10	0.2	0.3	2
15	0.2	0.3	6
20	0.2	0.3	7

Experimental results show that the proposed device represents an interesting solution for the monitoring of respiratory events during bottle feeding. In fact, at 10° and 20°, the device is able to discriminate air flow rates smaller than 0.5 L/min at all the distances, which is the half of the infant's minimum expiratory peak value (1L/min [18]). A relevant decrease of performances is experienced at 30°, as the device presents a discrimination threshold equal to 2 L/min, 6 L/min and 7 L/min for a distance of 10 mm, 15 mm and 20 mm, respectively.

B. Response to oscillating flows

The signal from our device is delayed with respect to the one of the flowmeter. Considering 30 and 60 bpm, the delay is 80 ± 15 ms and 65 ± 16 ms, respectively. The mean duration of a single breath detected by the flow meter and our device is respectively 996 ± 19 ms and 994 ± 8 ms at 60 bpm, and 2007 ± 28 ms and 2007 ± 23 ms at 30 bpm. In both cases, the difference between the mean breath duration detected by the flowmeter and our device was not statistically significant.

Hence, the proposed system allows detecting the starting and the ending of all single breaths during oscillating flows having trends similar to typical neonatal respiratory acts.

VII. CONCLUSION

A non-invasive device for monitoring newborns' breathing pattern has been designed and developed in order to be easily integrated on a common feeding bottle.

The experimental validation has demonstrated that such sensing device has a discrimination threshold lower than 0.5 L/min in most of the investigated configurations, and that it is able to discriminate the respiratory acts.

Further work is required to implement a dedicated algorithm for identifying the onset of the inspiratory phase, and to extend the number of trials and the measurement range.

Summing up, the proposed device exhibits promising results, which foster its successful application to the assessment of the temporal breathing pattern of newborns during bottle feeding with a non-invasive approach.

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