# Qualification of O2 dosing pacifiers



**Testing of medical devices done using artificial setups that simulate real-world environments can provide great first-hand knowledge, reproducibility and cost effective assessment of a device's performance. This application note summarizes how the FlowAnalyser PF-300 including Flowlab software, was used in a test setup for pre-validation of a medical device for oxygen administration.**

## Introduction

One way of administrating oxygen for infants, e.g. during recovery phase post-surgery, is through a nasal mask attached to a pacifier. The idea of using a pacifier for this purpose is to support the natural sucking reflex, and thereby soothe the infant, while providing oxygen. The mask is open, and just loosely covers the nose area, not to discomfort the infant. Pure oxygen (100% $O_2$) supplied by the mask is mixed with atmospheric air (21% $O_2$) as the infant breaths through the nose.

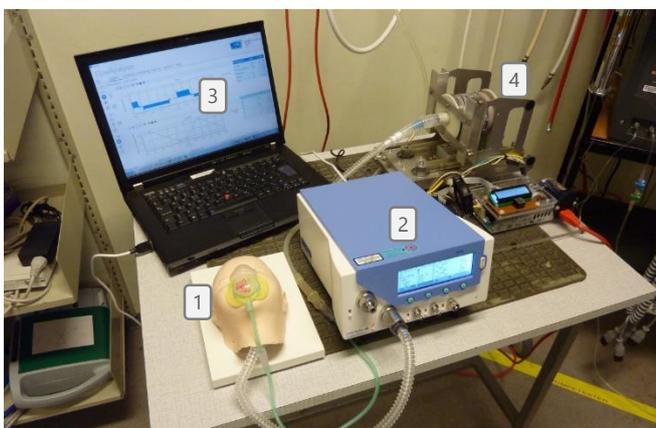The gas mixture, and thereby the infant's $FiO_2$, depends on:

- The infant's ventilatory pattern, like tidal volume, flow rate and I:E ratio.
- Placement of the nasal mask and the infant's anatomy.
- Flow rate of 100% oxygen administered by the nasal mask.

### Editorial

Scientific Note 20

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*Oxygen-dosing pacifier similar to the one being tested during the study.*

## Where does the PF-300 FlowAnalyser come into use?

We have used the PF-300, including the Flowlab software, for accessing the expected $FiO_2$ oxygen levels pre-clinically, when using the pacifier. Specifically we wanted to verify that the routines used with infants, involving oxygen administration, were safe in terms of avoiding high $FiO_2$ concentrations. A test setup has been developed which includes:



Using the high flow port of the PF-300 and the Flowlab software we display and log the ventilatory patterns of the Artificial lung on a breath by breath basis. With the integrated $O_2$ cell we display and log the resulting airway $O_2$ level.

After the lung has been active for some minutes, the $O_2$ level reaches a steady state value and gives a preclinical estimate of the $FiO_2$ mixture provided to the infant. Thus we have been able to make valuable reproducible firsthand tests when using a pacifier with mask for oxygen administration, thanks to the PF-300 and FlowLab software.

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1. *Test mannequin head, emulates the facial autonomy of an infant.*
2. *PF-300 inserted in series with the airway (between head / lung).*
3. *FlowLab for PF-300 data acquisition and analysis.*
4. *Artificial lung, enclosure formed by a ventilation hose with a port in one end. The ventilation hose can be compressed and expanded by a stepper motor powered drive. The drive is controlled by an Arduino board. With the lung we can emulate a variety of different ventilatory patterns.*