Clinical evaluation of a novel adaptive algorithm for automated control of oxygen therapy in preterm infants on non-invasive respiratory support

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SUPPLEMENTAL TEXT

METHODS

The device incorporating the algorithm for automated oxygen control was a stand-alone instrument consisting of a laptop computer, an automated air-oxygen blender and a data input/output device (USB-6008, National Instruments, Austin, USA) incorporating an analogue-digital (AD) converter. The controller received digital inputs from a standard cardiorespiratory monitor (Dräger Infinity, Dräger Medical Systems Inc, Notting Hill, Australia), including SpO_2 (Masimo oximetry probe, Masimo Corp, Irvine, California), heart rate determined from the electrocardiographic signal (HR_{ecg}), and plethysmographic heart rate (HR_{pleth}). SpO_2 averaging was set at fast (2-4 sec). FiO_2 was measured via a sensor in the proximal limb of the respiratory circuit (Teledyne), and input to the device via the AD converter. The desired value for FiO_2 derived from the algorithm was routed to a servomotor (model HS-322HD, Hitec RCD USA, Poway, USA) custom-mounted on an air-oxygen blender (Bird Ultrablender, Carefusion, Seven Hills, NSW), which allowed automatic rotation of the blender FiO_2 selection dial via a ringed gearing mechanism. The servomotor and gearing system had sufficient torque and precision to allow small adjustments to FiO_2 (minimum ±0.5%) to be made accurately and repeatedly. The servomotor also had a

low holding torque such that the blender dial could still be turned manually; such manual intervention was detected by a position sensor and resulted in a switch to a manual mode in which FiO_2 was no longer under automated control (see below). At the beginning of each study, the servomotor calibration was checked and if necessary altered.

The automated control algorithm consisted of a core PID component[1] with enhancements in the determination of the proportional, integral and derivative terms to suit application of a PID approach to automated oxygen control in the preterm infant. The enhancements of the proportional term included modulation based on severity of lung dysfunction, error attenuation while within the target range and error capping during hypoxia. Integral term enhancements included integrand magnitude capping, compensation for the non-linear PaO_2-SpO_2 relationship, and inhibition of integrand increase in room air.[2]

The PID algorithm code was within a loop iterating each second. The algorithm was thus designed to detect and respond to the rapid changes in oxygenation that are all-too-frequent in preterm infants. Value ranges for the PID coefficients were derived from extensive simulation studies using data from preterm infants,[3] allowing multiple permutations of different values for all coefficients to be examined.

Non-numeric SpO_2 values were treated as missing, as were SpO_2 values in which the values of HR_{ecg} and HR_{pleth} differed by >30 bpm. In the event of missing SpO_2 values, the FiO_2 was held at the current value. Full function of the algorithm resumed as soon as a valid signal was recovered.

During automated control, bedside staff could over-ride the control device by manually turning the blender FiO_2 dial. This signalled manual over-ride through the detection of a discrepancy between the set FiO_2 and the FiO_2 value detected by the position sensor within the servomotor. Once in manual over-ride, automated control resumed at the user-selected FiO_2 30 seconds after the last manual alteration to FiO_2. The device could also be locked in manual control mode by the research team on instruction from bedside staff if deemed necessary.

REFERENCES

1. Visioli A. *Practical PID control*. London: Springer Verlag, 2006.
2. Dargaville PA, Sadeghi Fathabadi O., Plottier GK, *et al*. Development and pre-clinical testing of an adaptive algorithm for automated control of inspired oxygen in in the preterm infant. *Companion paper submitted to ADCF&N* 2016.
3. Lim K, Wheeler KI, Gale TJ, *et al*. Oxygen saturation targeting in preterm infants receiving continuous positive airway pressure. *J Pediatr* 2014;164:730-736.

	Manual control	Automated control	P value*
SpO_2 below target range (no. of episodes per 4h)	71 (57-100)	43 (17-58)	0.024
SpO_2 below target range (episode duration, sec)	39 (30-42)	18 (14-21)	0.0005
SpO_2 <80% (no. of episodes of any duration per 4h)	3.4 (1.5-7.5)	0 (0-4.3)	0.0005
SpO_2 <80% (episode duration, sec)	20 (9.0-24)	0 (0-7.0)	0.0012
SpO_2 above target range (no. of episodes per 4h)	86 (70-113)	93 (59-121)	0.90
SpO_2 above target range (episode duration, sec)	43 (34-49)	19 (16-23)	<0.0001

Supplemental Table 1. SpO_2 deviations from the target range

Median (interquartile range). *Wilcoxon matched pairs test

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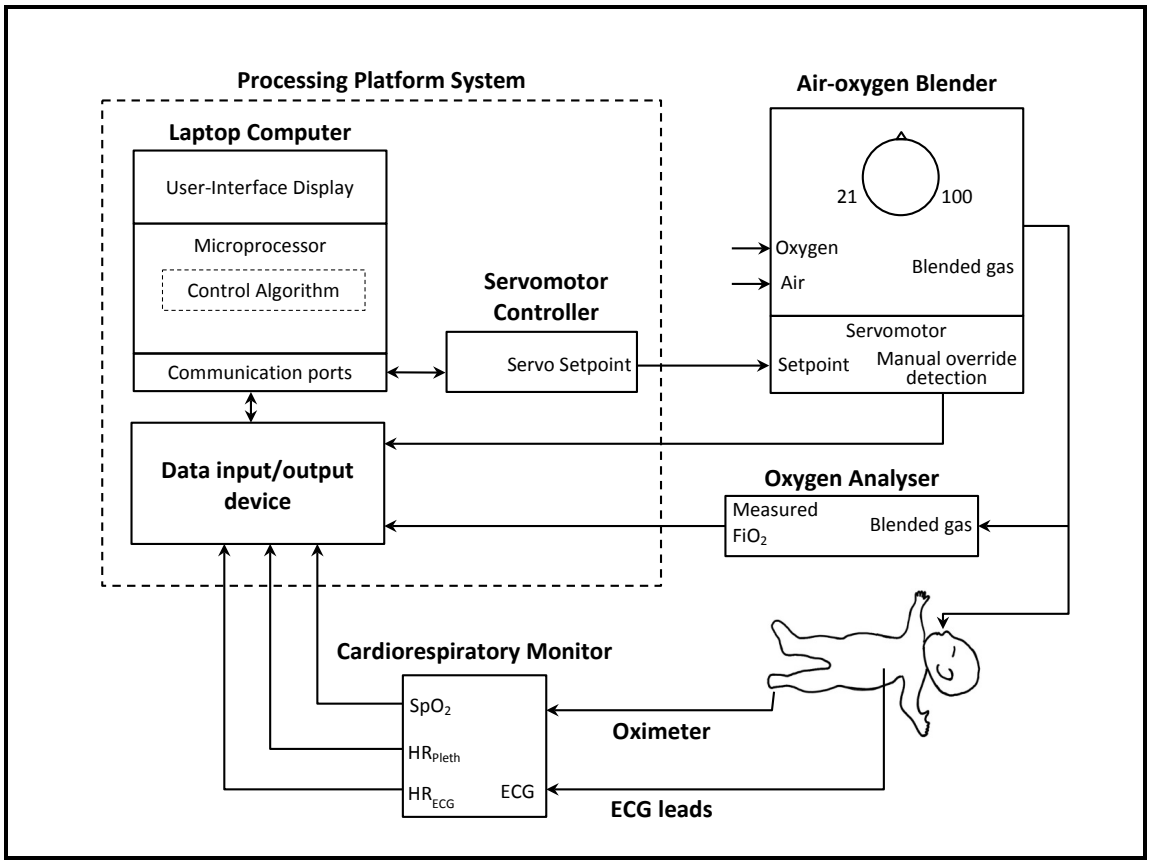
ONLINE FIGURE



Online Figure 1. Automated oxygen control system
Diagrammatic representation of the automated oxygen control device used in the study.