mysafety insight

Intelligent Oxygen Control (IOC)

Clinical Information Leaflet

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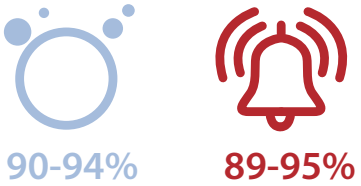
Oxygen requirements of the preterm neonates

Preterm infants have immature lungs at birth and often require supplemental oxygen for a prolonged period of time. Their nervous system is not fully developed either, often presenting apnoea of prematurity and a general respiratory instability that causes frequent drops in oxygen saturation (SpO_2) [1]. Arterial oxygen saturation is usually monitored by pulse oximetry and the fraction of inspired oxygen (FiO_2) is titrated to maintain the SpO_2 within a clinically intended range to minimize the exposure to hypoxemia and hyperoxemia. This requires frequent adjustments of the delivered FiO_2 by the healthcare professionals. These manual adjustments can be as frequent as 100 times per day. However, the safe target limits are commonly not achieved during routine care, with variable periods of time spent outside the intended SpO_2 target range. It has been shown that preterm infants spend only approximately half of the time within the clinically intended range of SpO_2, and around a quarter of the time above this range during routine neonatal intensive care [2, 3].

Oxygen therapy in neonates

In the preterm newborn, oxygen supplementation is essential for survival in patients with respiratory failure, and the need for supplemental oxygen is particularly frequent and prolonged among preterm babies. The need for supplemental oxygen in this population can extend from the initial stages of respiratory failure and convalescence to a more chronic dependence. In the last recent years, little has changed in terms of refining previous recommendations for oxygen saturation. Targeting lower saturations (85–89 vs. 91–95%) reduces risk of severe retinopathy of prematurity but at expense of increasing mortality. European guidelines recommendations in 2019 have therefore remained the same: targeting saturations between 90 and 94% by setting alarm limits between 89 and 95% [4].



Guideline recommendations for the treatment of neonates with oxygen therapy.

Long-term complications of exposure to altered levels of oxygen

An exposure of the neonate to a relative hyperoxic environment can cause an increase in the generation of reactive oxygen species (ROS). Preterm new-borns are particularly vulnerable to oxygen toxicity due to inadequate levels of antioxidant enzymes, and hence to decreased protection from oxidative injury of rapidly growing tissues. Alternating hypoxia and hyperoxia, like in episodes of oxygen desaturation, can also induce the accumulation of ROS [5]. Oxidative stress has the potential to damage multiple organ

systems, including the eyes, lungs, and intestines [6-8].

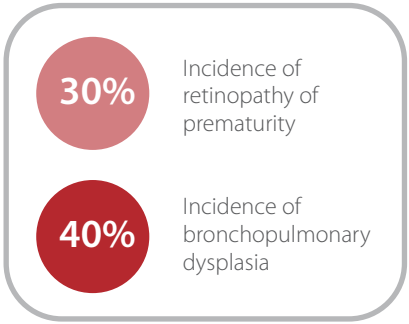
Episodes of hypoxia can occur as a result of immature lungs and apnoea of prematurity or due to inadequate ventilation or persistence of intrapulmonary arteriovenous shunts causing hypoxemia. Exposure to hypoxia have been associated with detrimental effects on the brain, pulmonary vasculature and other organs and tissues [9, 10].

Retinopathy of prematurity

One of the main causes of morbidity associated to hyperoxemia in extremely preterm infants is the retinopathy of prematurity (ROP). Its occurrence is known to be inversely proportional to gestational age and duration of oxygen exposure [11]. The incidence of ROP is increasing as higher numbers of premature neonates survive into infancy, particularly in developing countries. Some studies estimate the incidence among preterm birth infants to be over 30% [12]. ROP is a complication known to be increased by the prolonged use of supplemental oxygen from observations already published in the 1950s [6]. Continuous monitoring by pulse oximetry has allowed more frequent titration of the oxygen concentration administered and the establishment of safer limits to avoid the development of ROP [13].

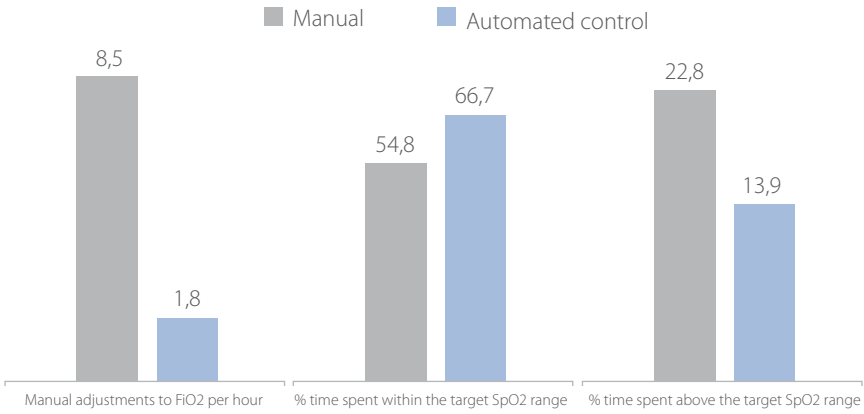
Bronchopulmonary dysplasia

The developing lung of the neonate is a perfect example of vulnerable tissue; the endothelial cells and the alveolar type II cells being especially susceptible to oxidative injury. Oxidative stress in these cells lead to cellular dysfunction, inactivation of surfactant, and impaired cell survival. Bronchopulmonary dysplasia (BDP) is a form of chronic lung disease that affects premature new-borns and infants and is attributed to the damage caused to the lungs by mechanical ventilation and long-term use of oxygen therapy. Both the airway and parenchyma of the lung can be affected [15]. Strategies to avoid this complication include the use of surfactant and antenatal corticosteroids, but despite of their widespread use as well as the advances in neonatal ventilation techniques, the incidence of BPD is reported to be relatively stable at approximately 40% of premature infants [14].



Most common morbidities in preterm infants as consequence of exposure to altered levels of oxygen.

A closed-loop oxygen control for a safer therapy



Comparative clinical study results for manual versus automated closed-loop O2 control systems.

Automated FiO_2 adjustment systems can help reducing workload of caregivers while improving outcomes for preterm neonates receiving invasive or non-invasive positive pressure respiratory support and supplemental oxygen. Metanalysis of several published clinical trials show important reductions in the number of adjustments of FiO_2 needed in automated systems when compared with manual systems, averaging 1.8 vs 8.5 times per hour [3]. The use of automated systems provides a significant improvement of the time spent in target saturations, being 66.7% of the time with automated systems vs 54.8% with the manual control. There is also a clear reduction in periods of hyperoxia and severe hypoxia in preterm infants receiving ventilatory support of 13.9% of the time with automated systems vs 22.8% with manually controlled [16].

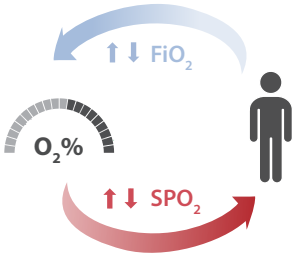
Safer and stable oxygen therapy with Intelligent Oxygen Control

Mindray's Intelligent Oxygen Control (IOC) achieves a closed-loop FiO2-SpO_2 by maintaining the baby' s saturation of oxygen within the predetermined range hence improving patient safety and reducing the workload of caregivers.

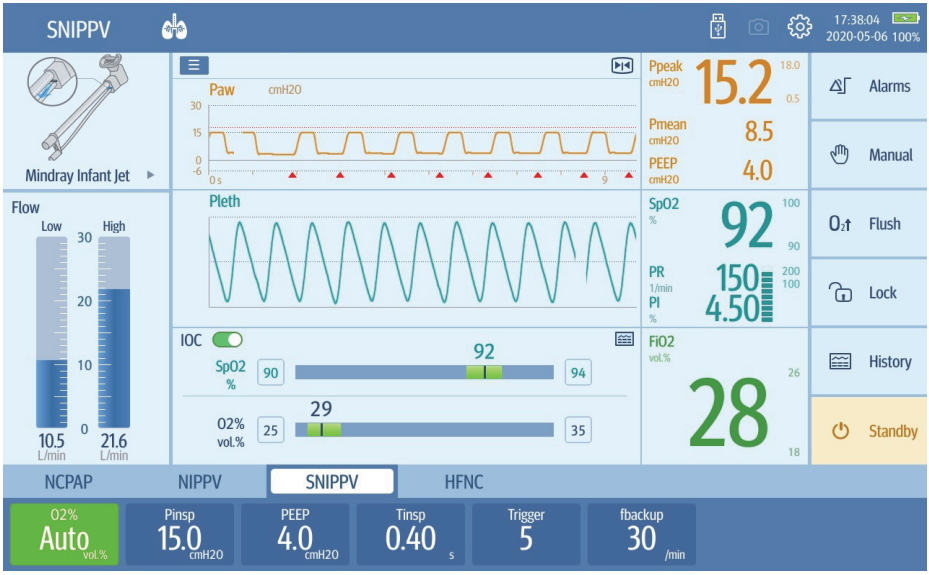
The system obtains the SpO_2 value through the built-in SpO_2 sensor and automatically adjusts the FiO_2 accordingly. As per consen -

sus guidelines, the default SpO_2 target is 90-94% and the FiO_2 range 21-35%, both can be adjusted otherwise.

IOC can be used in all ventilation modes, i.e. NCPAP, NIPPV, SNIPPV and HFNC for all kinds of patients needing ventilatory support. The system will pause and alert the healthcare professionals as a safety mechanism in cases when SpO_2 value might not be reliable. This might occur in circumstances like weak perfusion at the point of measurement, poor signal quality or if any alarm related to the position or integrity of the SpO_2 probe is triggered.



Intelligent Oxygen Control closed-loop system: an adaptative algorithm automatically adjusts FiO_2 value according to the real-time monitoring of SpO_2 maintaining this within the pre-set safe target.



Intelligent Oxygen Control (IOC) as shown in a Mindray ventilator screen.

Mindray' s Intelligent Oxygen Control technology achieves a closed-loop FiO_2-SpO_2 control by maintaining the baby' s SpO_2 within the predetermined range, hence improving patient safety and reducing the workload of caregivers.

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