

Oxygen Reserve Index (ORi™)

SUMMARY

Pulse oximetry (SpO₂) provides noninvasive and continuous visibility to arterial blood oxygenation in hypoxia (less than normal oxygenation) and normoxia (normal oxygenation) but cannot assess hyperoxia (higher than normal oxygenation). During supplemental oxygen administration, clinicians often use the partial pressure of oxygen (PaO₂) to assess hyperoxia but this requires blood gas analysis that is intermittent and delayed. Between invasive samples, changes in PaO₂ cannot be assessed and therefore unexpected hypoxia or unintended hyperoxia can occur.

ORi provides real-time visibility to oxygenation status in moderate hyperoxic range (PaO₂ of approximately 100 to 200 mm Hg). ORi is intended to supplement, not replace, SpO₂ monitoring and PaO₂ measurements. As an "index" parameter with a unit-less scale between 0.00 and 1.00, ORi can be trended and has optional alarms to notify clinicians of changes in a patient's oxygen status.

In patients receiving supplemental oxygen such as those in surgery, conscious sedation, or the intensive care unit, ORi may provide an advance warning of an impending hypoxic state or indication of an unintended hyperoxic state when used in conjunction with PaO₂ measurements. In this way, ORi may enable proactive interventions to avoid hypoxia and unintended hyperoxia.

Relationship Between Oxygen Saturation and Partial Pressure of Oxygen in the Blood

A patient's oxygen status can generally be classified into one of the following three categories¹:

- > Hypoxia (less than normal oxygenation)
- > Normoxia (normal oxygenation)
- > Hyperoxia (higher than normal oxygenation)

Arterial oxygen saturation (SaO₂) is defined as the percentage of haemoglobin molecules bound with oxygen and is measured by analysing arterial blood gas samples. Pulse oximetry provides a noninvasive and continuous monitoring of oxygen saturation (SpO₂) in the hypoxic and normoxic states but cannot assess hyperoxia (higher than normal oxygenation). The partial pressure of oxygen (PaO₂) is the pressure exerted by oxygen when dissolved in plasma. During supplemental oxygen administration, clinicians often use the partial pressure of oxygen (PaO₂) to assess hyperoxia, but this requires blood gas analysis that is intermittent and delayed. Between invasive samples, changes in PaO₂ cannot be assessed and therefore unexpected hypoxia or unintended hyperoxia can occur. The oxyhaemoglobin dissociation curve, shown in Figure 1, can be used to visually represent these ranges through the graphical relationship between SaO₂/SpO₂ and PaO₂.

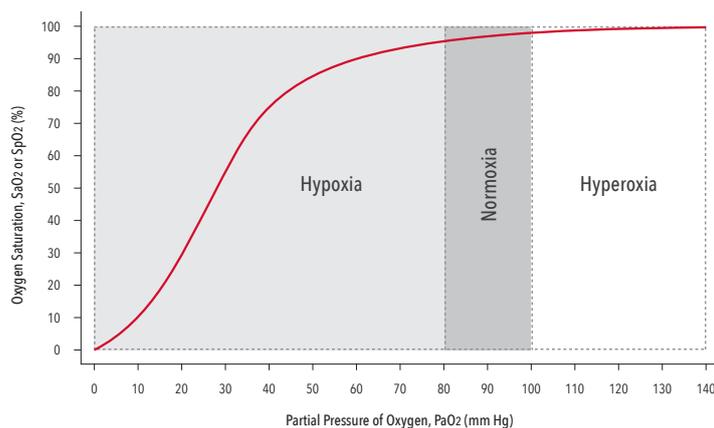


Figure 1. The oxyhaemoglobin dissociation curve illustrates the relationship between SaO₂/SpO₂ and PaO₂. SaO₂ and SpO₂ are not able to assess the hyperoxic range due to the flattening of the SaO₂/SpO₂ curve. PaO₂ can be used as an indication of oxygenation throughout all ranges; however, measurements are both intermittent and delayed.

Oxygen Reserve Index (ORi)

ORi is a noninvasive and continuous parameter intended to provide insight into a patient’s oxygen status in the moderate hyperoxic range (PaO₂ >100 and <200 mm Hg), which we define as a patient’s oxygen "reserve". ORi is an "index" with a unit-less scale between 0.00 and 1.00. ORi can be trended and has optional alarms to notify clinicians of changes in a patient’s oxygen reserve. ORi is an index that is intended to supplement, not replace SaO₂/SpO₂ and PaO₂. When utilised in conjunction with SpO₂ monitoring (as demonstrated in figure 2), ORi may extend the continuous and noninvasive visibility of a patient’s oxygen status into ranges previously unmonitored in this fashion.

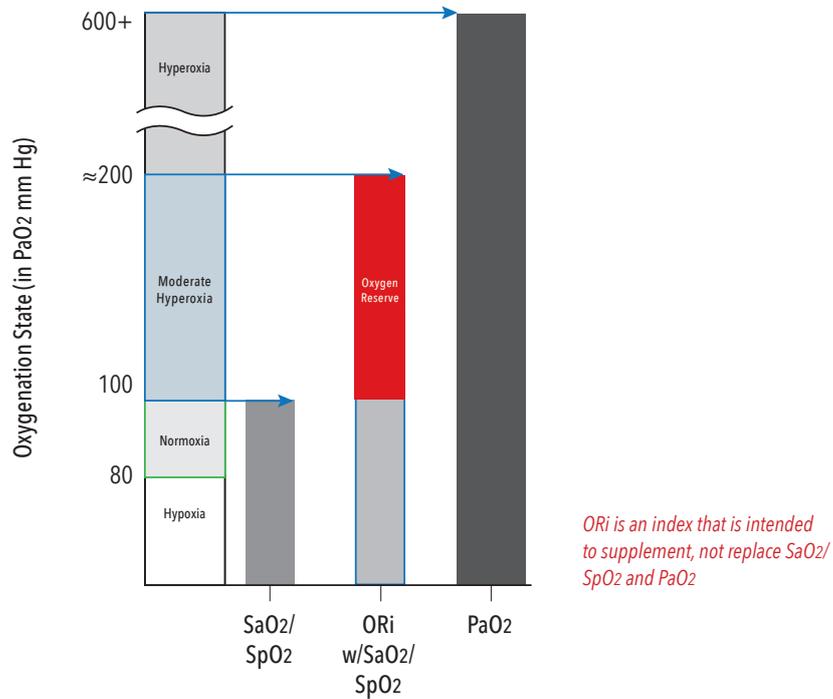


Figure 2. Range of oxygenation monitoring that can be assessed with SaO₂/SpO₂, ORi, and PaO₂. SaO₂/SpO₂ can assess hypoxia and normoxia, PaO₂ can assess all ranges of oxygenation, and SpO₂ with ORi provides real-time visibility from hypoxia to the moderate hyperoxic state.

ORi Operational Principle

The Fick principle relates oxygen consumption (VO₂) with cardiac output (CO), oxygen content of arterial blood (CaO₂), and deoxygenated venous blood (CvO₂).²

$$VO_2 = CO \times (CaO_2 - CvO_2)$$

Substituting the oxygen content equation for the arterial (CaO₂) and venous (CvO₂) blood, we are left with the following equation (where SvO₂ is the oxygen saturation in the venous blood and PvO₂ is the partial pressure of oxygen in the venous blood³):

$$VO_2 = CO \times ((SaO_2 \times tHb \times 1.34) + 0.003 \times (PaO_2)) - (SvO_2 \times tHb \times 1.34 + 0.003 \times (PvO_2))$$

This equation can be modified via oxygen saturation equations to the following:

$$VO_2 = CO \times (1.34 Hb \times (SaO_2 - SvO_2) + 0.003 \times (PaO_2 - PvO_2)) \text{ Equation 1}$$

The oxygen dissociation curve (Fig 1.) provides a relationship between SaO₂ and PaO₂ as given by the equation below.

$$\text{SaO}_2 = f(\text{PaO}_2) \text{ and } \text{SvO}_2 = f(\text{PvO}_2) \text{ Equation 2}$$

Substituting Equation 2 in Equation 1, we get:

$$\text{VO}_2 = \text{CO} \times (1.34 \times (f(\text{PaO}_2) - \text{SvO}_2) + 0.003 \times (\text{PaO}_2 - f^{-1}(\text{SvO}_2)))$$

Hence, for a constant oxygen consumption and cardiac output, SvO₂ is directly proportional to PaO₂, as f (defined in Equation 2) is an increasing function as shown in Figure 1. This results in the following relationship:

$$\text{SvO}_2 \propto \text{PaO}_2 \text{ for constant } \text{VO}_2, \text{CO} \text{ Equation 3}$$

Pulse oximeters work by measuring the absorption of pulsatile blood at the measuring site (finger). Pulsatile changes are observed at the arteries, capillaries, and, in a lesser degree, in the venules. A pulse oximeter absorption measurement at wavelength λ , denoted by $A(\lambda)$, is thus affected by both arterial and venous blood absorption changes.

$$A(\lambda) = A_a(\lambda) + \alpha A_v(\lambda) \text{ where } \alpha \ll 1 \text{ and } a \text{ is dependent on perfusion at the measurement site Equation 4}$$

In the absence of dyshaemoglobins:

$$A_a(\lambda) = \text{SaO}_2 \times A_a^{\text{O}_2\text{Hb}}(\lambda) + (100 - \text{SaO}_2) \times A_a^{\text{HHb}}(\lambda) \text{ Equation 5}$$

$$A_v(\lambda) = \text{SvO}_2 \times A_v^{\text{O}_2\text{Hb}}(\lambda) + (100 - \text{SvO}_2) \times A_v^{\text{HHb}}(\lambda) \text{ Equation 6}$$

where $A_a^{\text{O}_2\text{Hb}}$ is the absorption of oxy-haemoglobin in arterial blood.

$A_v^{\text{O}_2\text{Hb}}$ is the absorption of oxy-haemoglobin in venous blood.

A_a^{HHb} is the absorption of deoxy-haemoglobin (reduced) in arterial blood.

A_v^{HHb} is the absorption of deoxy-haemoglobin (reduced) in venous blood.

Substituting Equation 5 and Equation 6 into Equation 4:

$$A(\lambda) = (\text{SaO}_2 \times A_a^{\text{O}_2\text{Hb}}(\lambda) + (100 - \text{SaO}_2) \times A_a^{\text{HHb}}(\lambda)) + \alpha (\text{SvO}_2 \times A_v^{\text{O}_2\text{Hb}}(\lambda) + (100 - \text{SvO}_2) \times A_v^{\text{HHb}}(\lambda)) \text{ Equation 7}$$

Combining Equation 3 and Equation 7, we observe that $A(\lambda)$ changes as a function of PaO₂.

As PaO₂ increases beyond 100mm Hg, SvO₂ continues to increase, eventually saturating at around 200 mm Hg. This results in a change in $A(\lambda)$ and therefore makes it possible to detect changes in PaO₂ up to 200mm Hg.

ORi may be affected by factors such as VO₂, CO (as determined by Fick equation), pH, temperature, and the presence of dyshaemoglobins (oxyhaemoglobin dissociation curve) and the amount of perfusion (venous pulsation).

ORi Validation / Accuracy Specification

In an IRB-approved study conducted at Masimo per ISO-80601 guidelines, 11 healthy consenting adults underwent a variety of interventions to change their PaO₂ and SpO₂ levels. A total of 1,885 paired sets of both ORi and PaO₂ were collected. Mild hyperoxia was defined as a PaO₂ <150 mm Hg. Moderate hyperoxia was defined as PaO₂ ≥150 mm Hg. An ORi value of 0.3 provides ≥85% sensitivity and ≥80% specificity for a PaO₂ <150 mm Hg.

ORi Study in Surgical Pediatrics

In a recent study from the University of Texas Southwestern, researchers evaluated ORi in pediatric patients undergoing surgical procedures requiring intubation and general anaesthesia. The researchers reported that ORi provided an average 40 second advance notice before a patient reached an SpO₂ of 98%, and a 52 second advance notice before the a patient reached an SpO₂ of 92%.⁵ The authors concluded "For this reason, ORi's ability to measure changes in oxygen reserve and alarm during a rapid decrease could help clinicians respond with needed interventions sooner," and "The ORi alarm provides an increased warning time for avoiding potential hypoxia and could help in optimising the oxygenation before and during prolonged intubation."

ORi Clinical Application

In patients receiving supplemental oxygen such as those in surgery, conscious sedation, or the intensive care unit, ORi may provide an advance warning of an impending hypoxic state or indication of an unintended hyperoxic state when used in conjunction with PaO₂ measurements. In this way, ORi may enable proactive interventions to avoid hypoxia and unintended hyperoxia.

Example of ORi during intubation in high-risk paediatric surgery

As shown in Figure 5, ORi levels rise as FiO₂ levels are titrated up prior to intubation

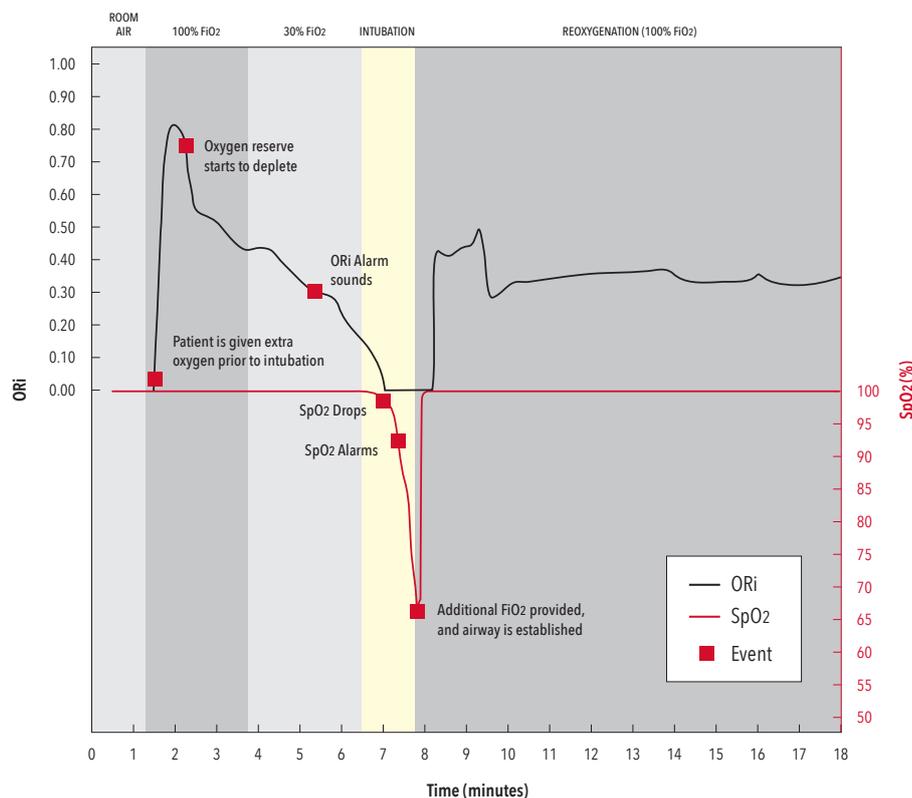


Figure 5. ORi levels drop prior to SaO₂ lower FiO₂ administration and intubation, and rise during re-oxygenation

References

¹ Fischbach FT, Dunning MB III, eds. (2009). Manual of Laboratory and Diagnostic Tests, 8th ed. Philadelphia: Lippincott Williams and Wilkins. ² Cuschieri J, Rivers EP, Donnino MW, Katilius M, Jacobsen G, Nguyen HB, Pamukov N, Horst HM. Central venous-arterial carbon dioxide difference as an indicator of cardiac index. *Intensive Care Medicine*. 2005; 31 (6): 818-22. ³ Mahutte CK1, Jaffe MB, Sassoon CS, Wong DH. Cardiac output from carbon dioxide production and arterial and venous oximetry. ⁴ Oxygen Reserve Index Blood Study, Test Report. Masimo Corporation, data on file, 2014. ⁵ Szmuk P, Steiner J, Olomu P, Dela Cruz BS, Sessler D. Oxygen Reserve Index: A New Noninvasive Method of Oxygen Reserve Measurement. *Proceedings of the American Society of Anesthesiologists*, 2014. BOC12.

Regulatory Notice:

ORi has obtained CE Marking and is not currently available for sale in the United States or Canada.

For professional use. See instructions for use for full prescribing information, including indications, contraindications, warnings, precautions and adverse events.

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