

Oxygen Reserve Index (ORI™)

The First Noninvasive & Continuous Parameter to
Provide Insight into Oxygen Reserve in Patients
Receiving Supplemental Oxygen



Limitations of Current Approaches to Assess Oxygenation

- > 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 monitor levels of hyperoxia but this requires blood gas analysis that is intermittent and delayed.
- > Between invasive sampling, changes in PaO2 cannot be assessed and therefore unexpected hypoxia or unintended hyperoxia can occur.

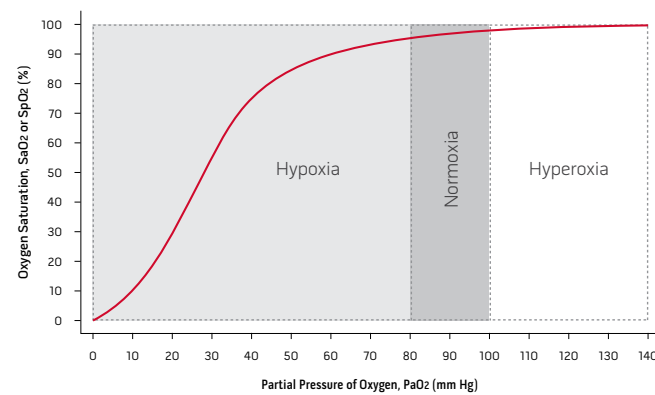
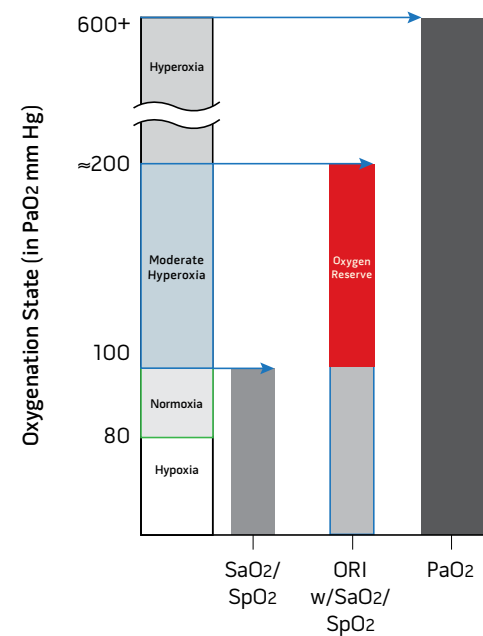


Figure 1. The oxyhaemoglobin dissociation curve illustrates the relationship between SaO2/SpO2 and PaO2

Oxygen Reserve Index

- > 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.
- > When utilized 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.
- > ORI is an index that is intended to supplement, not replace, SaO2/SpO2 and PaO2 measurements.



*ORI is an index that is intended to supplement, not replace SaO2/SpO2 and PaO2

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 Clinical Application

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

EXAMPLE OF ORI DURING INTUBATION IN A HIGH-RISK PEDIATRIC SURGERY

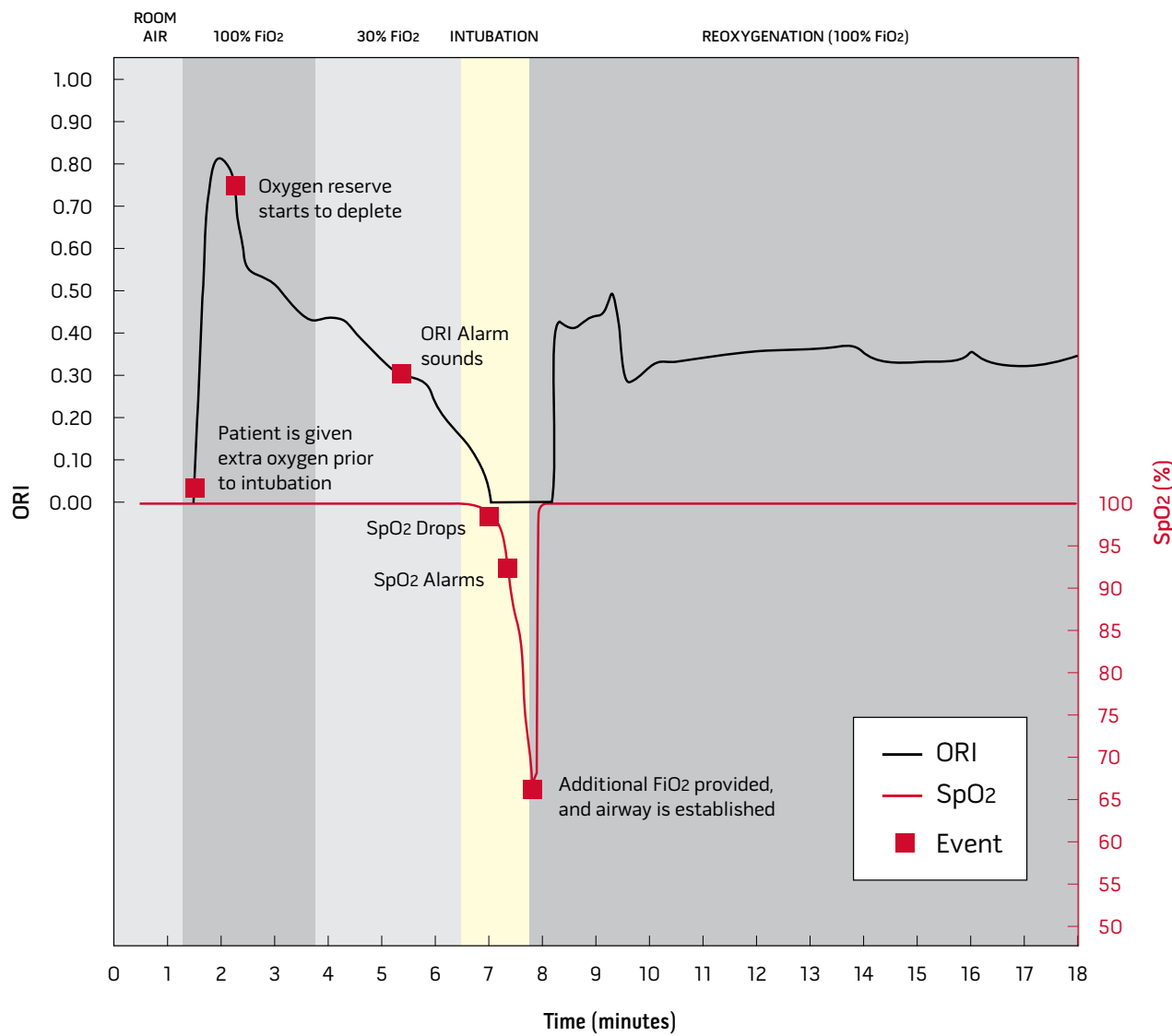


Figure 3. ORI levels drop prior to SaO2 lower FiO2 administration and intubation, and rise during re-oxygenation

PRODUCT DISPLAY

When used with a rainbow adhesive sensor, ORI can be displayed on Root® with an ORI-enabled Radical-7® with the latest MX-5 circuit board.



PRODUCT SPECIFICATIONS

ORI range.....	0.00 to 1.00
ORI Accuracy.....	≥85% sensitivity and ≥80% specificity to a PaO2 value <150 mm Hg
ORI Alarms	Trending, Low Limit

TECHNOLOGY PLATFORM

Masimo rainbow SET® is a noninvasive monitoring platform featuring Masimo SET® Measure-through Motion and Low Perfusion™ pulse oximetry with the option to measure multiple additional blood constituents and physiologic parameters.

- | | | |
|----------------------------|----------------------------------|---|
| > Oxygen Saturation (SpO2) | > Oxygen Content (SpOC™) | > Acoustic Respiration Rate (RRa®) |
| > Pulse Rate (PR) | > Pleth Variability Index (PVI®) | > Respiration Rate from the Pleth (RRp™)* |
| > Perfusion Index (PI) | > Methemoglobin (SpMet®) | > Oxygen Reserve Index (ORI™)* |
| > Total Hemoglobin (SpHb®) | > Carboxyhemoglobin (SpCO®) | > Fractional Oxygen Saturation (SpfO2™)* |

The Root Patient Monitoring and Connectivity also supports measurement expansion through Masimo Open Connect™ (MOC-9™) ports, including:

- > SedLine® brain function monitoring
- > Capnography and gas monitoring
- > O3™ regional oximetry*



MOC-9 ports

*Regulatory Notice:

The following new features/products are CE Mark and are not currently available for sale in the United States:

- > Respiration Rate from the Pleth (RRp)
- > Oxygen Reserve Index (ORI)
- > Fractional Oxygen Saturation (SpfO2)
- > O3 Regional Oximetry

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

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