OxyGenie®

Inspired Oxygen Control

Automatic O_2 control for the SLE6000 ventilator

SLE

When the smallest thing matters

OxyGenie®: Works like Magic

OxyGenie®: Inspired Oxygen Control

Why Auto O_2?

Oxygen is one of the drugs most frequently used in neonates, often with the highest concentrations given to those with the least developed defence mechanisms to its potentially toxic side effects.

Even minor variations in blood oxygen levels may affect longer term outcomes such as mortality, retinopathy of prematurity (ROP) or necrotising enterocolitis (NEC) as has been shown in a number of recent studies [1].

In addition to the importance of closely maintaining an effective baseline target range, avoiding intermittent hypoxaemia or hyperoxaemia (e.g. a saturation of <80% or >95%) is equally important [2].

Decrease workloads

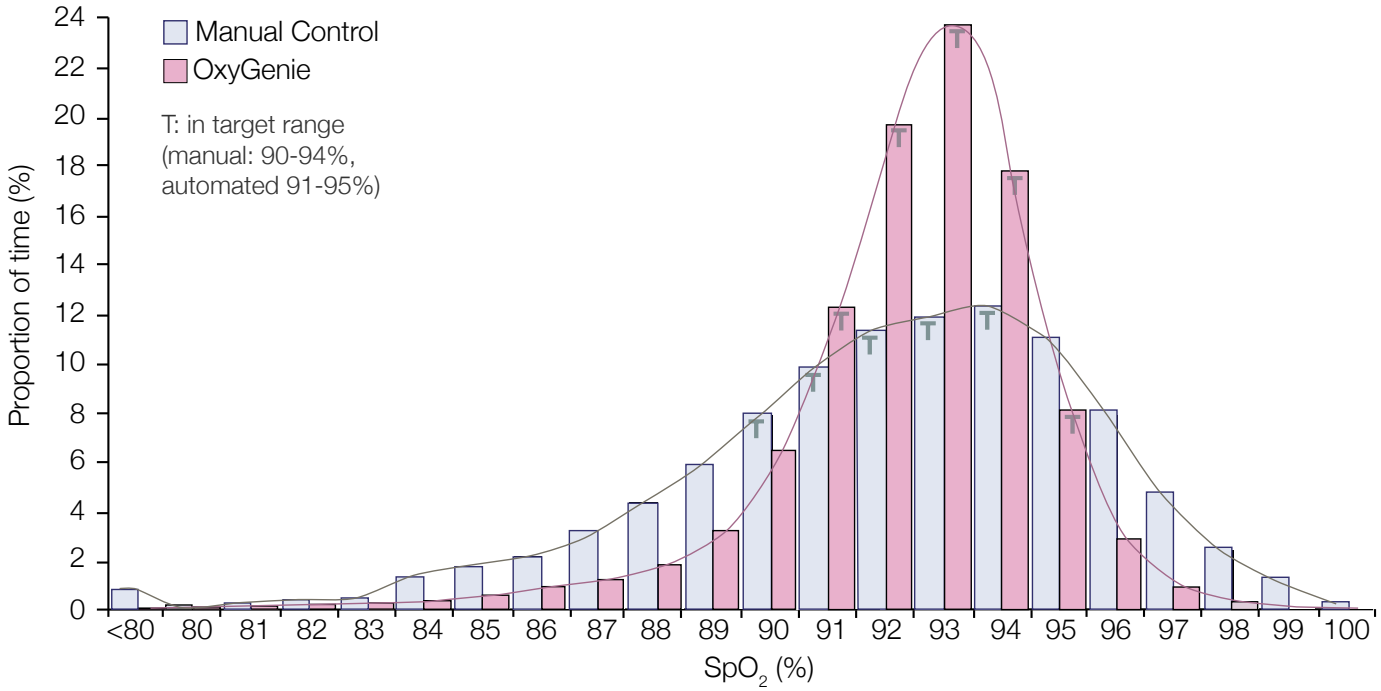
With the high workload medical staff caring for preterm infants often face, an automatic O_2 system that can help reduce the time spent adjusting the ventilator and allowing staff to spend more time caring for the patient would be invaluable.

The properties required for such control, however, are extensive: they should be able to respond to both a gradual change in oxygen requirements and sudden hypoxaemia, and should also be capable of avoiding the build-up of increasing fluctuations in FiO_2/SpO_2 during periods with changeable SpO_2 values. Infants with significant lung disease also need the algorithm to be responsive to their requirements.

The introduction of a reliable, accurate controller for oxygen would give a reduction in manual interventions enabling an improvement in efficiency of care.

OxyGenie®: Reducing your Workload

How does OxyGenie compare? Time in Target range. [3]



Graph (above) shows percentage of time SpO_2 is in range - comparing manual control with OxyGenie. [3]

OxyGenie

In 2016, SLE saw an Auto O2 system which really excited us.

It was responsive, safe and most importantly, effective.

It managed to maximise the time SpO_2 spent within a target range of 5%; it looked at many different inputs to determine an action; it analysed the inputs every second and could make as many changes as necessary and it reacted well when it experienced sudden changes in baby saturation.

Additionally, it had been shown to virtually eliminate prolonged episodes of both hyperoxaemia, and hypoxaemia [3].

We have incorporated this new system into a software module for the SLE6000 and we're calling it OxyGenie®, because it could make your wish for a stable saturation come true!

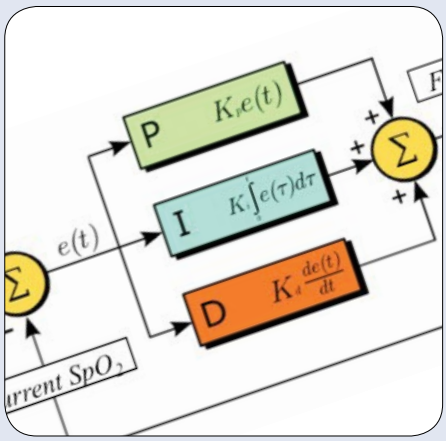
Reactive Algorithm

Developed at the University of Tasmania, in collaboration with the Royal Hobart Hospital, the OxyGenie software module uses a Proportional/Integral/Derivative algorithm which makes it responsive to SpO_2 deviations, allowing it to recognise serious instability and then be able to safely and quickly counteract it.

Peace of Mind

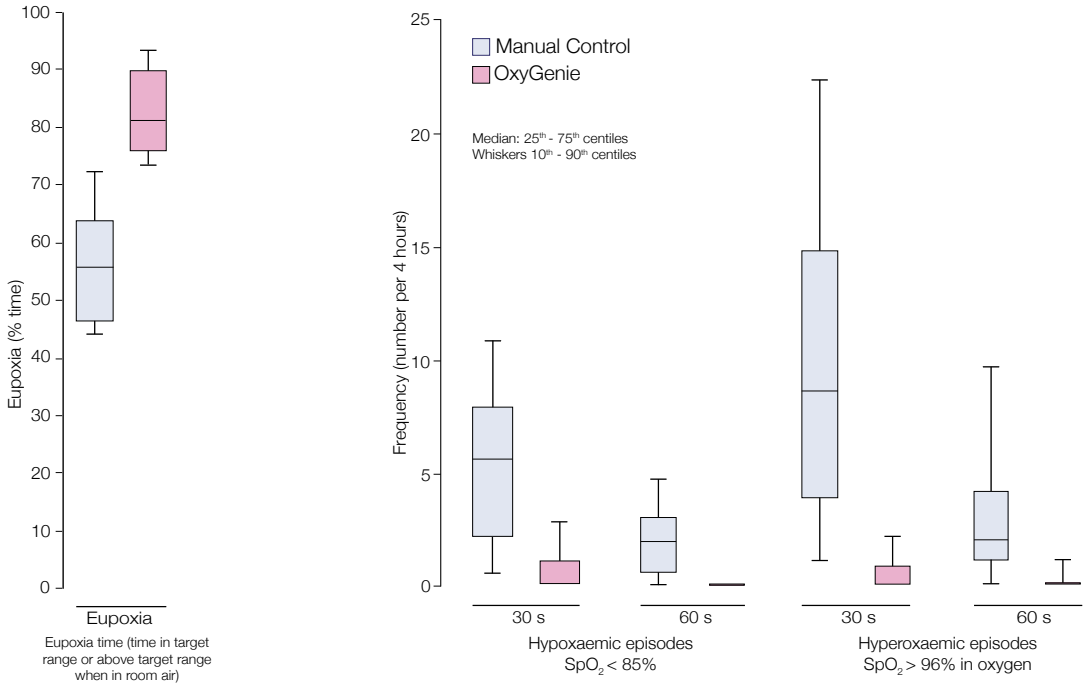
The new algorithm incorporates additional software that has a different response depending upon the severity of lung disease, plus target range attenuation and Severinghaus compensation.

The overall design of the software allows it to respond smoothly and effectively to both gradual and sudden changes in SpO_2.



OxyGenie®: Better than manual control

How does OxyGenie compare? Hypoxaemic and Hyperoxaemic episodes. [3]



Graph 1 (left): shows OxyGenie-treated babies spend more time in Eupoxia. (Time in target range or above target range when in room air). Note, there is no overlap in distribution.

Graph 2 (right): shows OxyGenie significantly reduces the number, duration and severity of hypoxaemic/hyperoxaemic episodes, and virtually eliminates severe episodes of 60 s or more [3].

What it means for you and your patients

Responsive

- The software reads the SpO_2 values at one second intervals and reacts within one second [4].
- 25% improvement in time within target range for SpO_2 [3]
- Reduced incidence of hypoxaemia and hyperoxaemia [3].
- No lock-out times [5].
- Uses Masimo™ SET system

Adaptive

- Target range attenuation (modifies sensitivity when nearer mid-point of range).
- Includes compensation for lung disease (modifies sensitivity in babies with higher reference FiO_2).
- Severinghaus compensation (Takes into account the non-linearity of PaO_2 - SpO_2 curve) and helps to reduce hyperoxaemic events [4].

Intuitive

- Decrease the required staff time in preterm infants with frequent desaturations.
- Works in all modes on the SLE6000 including NIV and HFOV.
- User adjustments per hour [3]:
  Manual mode - 2.3
  Auto O2 (OxyGenie) - 0.24

OxyGenie®

SLE6000: Ventilate with Confidence

SLE6000 Integration

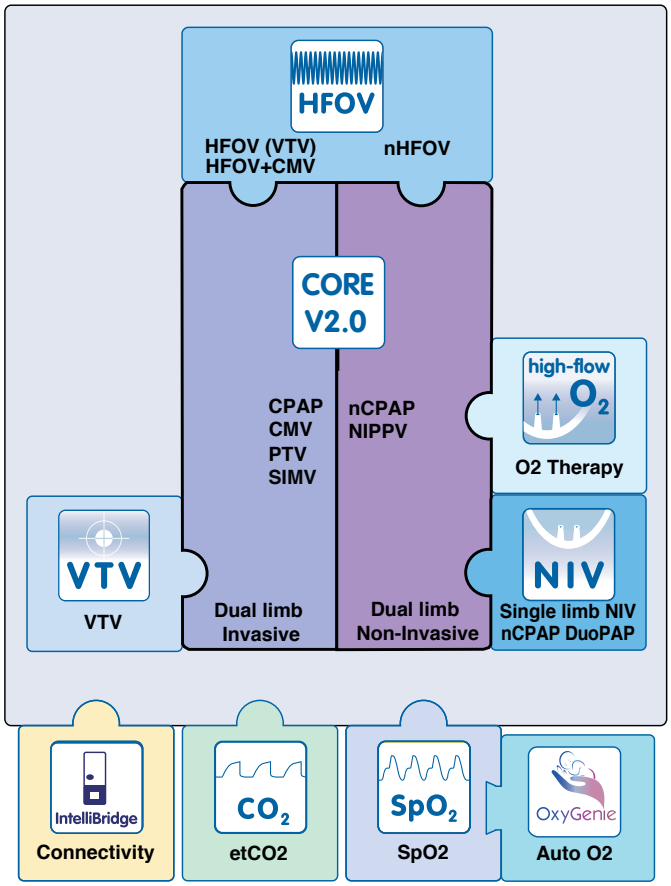
Various software and hardware modules can be added to the SLE6000 during production or at a later date as an upgrade.

To add OxyGenie to an SLE6000 requires the OxyGenie software module plus the SpO_2 module.

Integrating it into the SLE6000 also gives the caregiver a chance to observe the SpO_2 trend against the FiO_2 trend on the same time scales allowing easy correlation between cause and effect.

What's more, the integration is so seamless that only two additional controls are needed on the SLE6000's Lunar™ interface. There's one to set your target range (default 91-95%) and another to turn OxyGenie on and off.

OxyGenie®



References

[1] **Saugstad OD, Aune D.**
Optimal oxygenation of extremely low birth weight infants: a meta-analysis and systematic review of the oxygen saturation target studies. *Neonatology* 2014;105:55–63.

[2] **Poets CF, Roberts RS, Schmidt B, et al.**
Association between intermittent hypoxemia or bradycardia and late death or disability in extremely preterm infants.
JAMA 2015;314:595–603.

[3] **Plottier GK, Wheeler KI, Ali SKM, Sadeghi Fathabadi O, Jayakar R, Gale TJ, Dargaville PA.**
Clinical evaluation of a novel adaptive algorithm for automated control of oxygen therapy in preterm infants on non-invasive respiratory support.
Arch Dis Child Fetal Neonatal Ed 2017; 102: F37-F43.

[4] **Peter A Dargaville, Omid Sadeghi Fathabadi, Gemma K Plottier, Kathleen Lim, Kevin I Wheeler, Rohan Jayakar, Timothy J Gale**
Development and preclinical testing of an adaptive algorithm for automated control of inspired oxygen in the preterm infant
Arch Dis Child Fetal Neonatal Ed 2016;0:F1–F6.

[5] **Clarke, A., Yeomans, E., Elsayed, K., Medhurst, A., Berger, P., Skuza, E. and Tan, K. (2015)**
A randomised crossover trial of clinical algorithm for oxygen saturation targeting in preterm infants with frequent desaturation episodes.
Neonatology, 107 (2), 130-136.

Specifications and Part numbers

OxyGenie® Part Numbers

Part Number	Description
Z6000/CLP	OxyGenie® Auto O_2 software. (Requires SpO_2 software module to be already installed, plus SLE's $uSpO_2$ (Masimo™ SET) cable and sensors). *See below and separate data sheet.*

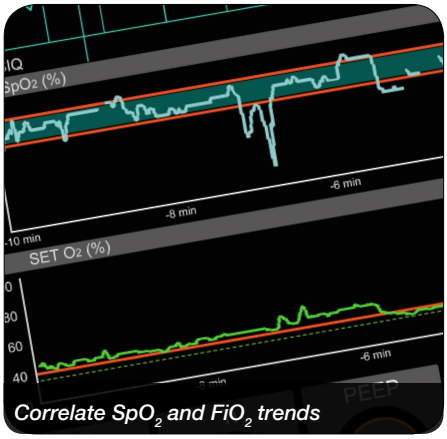
Specifications

Item	Description
Main software	Software control system that allows targeting of SpO_2 values by controlling FiO_2. Works in conjunction with Masimo™ software module and Masimo™ sensors to monitor SpO_2 values (bought separately)
Controls	Adds additional (start/stop) option to FiO_2 parameter controller. Range selector in SpO_2 utilities menu. Ranges are: 90 - 94%, 91 - 95% (default), 92 - 96%, 94 - 98% Manual override (timed, for 30 seconds)
Waveforms	Additional SpO_2 screen can show any one ventilation parameter plus plethysmogram and trends of SpO_2 and FiO_2.
Alarms	Alarms automatically set on SpO_2 software, corresponding with target range (1% above high and 1% below low). These can be manually set as well. Alarm indications shown in Alarm bar. Alarm level indicators on SpO_2 and FiO_2 graphs.
Indicator	Status panel (in bottom right-hand corner) shows OxyGenie status such as 'Auto', 'Manual Override' (with countdown) or 'Waiting for Signal'.
Trends	Trending information for SpO_2 and FiO_2 can be shown simultaneously. Up to 14 days of data are stored for each parameter.

Specifications subject to change without notice

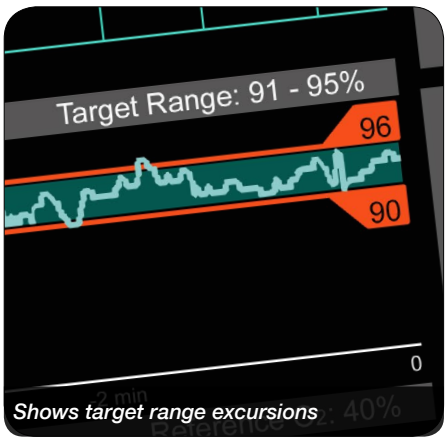
SpO_2 Part Numbers

Part Number	Description
Z6000/SPO	SLE6000 SpO_2 upgrade software module.
L6000/SP2/ KIT	SLE $uSpO_2$ cable (Masimo™ SET) (1.83 m) (includes LNCS® sample sensor starter kit).
Sensors	
LSPO2/2319	LNCS Inf-3 - Infant, SpO_2 adhesive sensor, 3 ft, 20/box
LSPO2/2320	LNCS Neo-3 - Neonatal, SpO_2 adhesive sensor, 3 ft, 20/box
LSPO2/2321	LNCS NeoPt-3 - Neonatal, SpO_2 adhesive sensor, 3 ft, 20/box
Accessories	
LSPO2/4089	RD to LNC Adapter cable, 3 ft. (to allow the use of Masimo RD sensors)



Correlate SpO_2 and FiO_2 trends

Large status indicator



Shows target range excursions

MASIMO SET®

OxyGenie®

Inspired Oxygen Control

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