

Guide for using the Oxygen Assist Module (OAM)

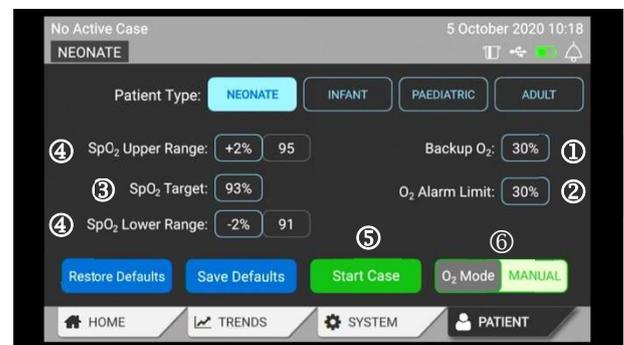
Choice of baby

- ⇒ Baby on Vapotherm Precision Flow in supplemental oxygen and requiring manual adjustment in response to SpO₂ fluctuations.
- ⇒ Baby is >28/40 gestation and more than 7 days old.

A: Before starting automated control

- ⇒ Hot swap the baby's Vapotherm circuit to a Precision Flow with an OAM attached.
- ⇒ Titrate flow, temperature and FiO₂ manually to patient requirements.
- ⇒ Attach the second SpO₂ probe and turn on the OAM.
- ⇒ Adjust the Patient Screen settings (SpO₂ Target ③, Backup O₂ ① & O₂ Alarm Limit ②)

Setting	Preterm	Term
Patient Type	Neonate	Infant
Backup O₂ ①	at current FiO ₂	at current FiO ₂
O₂ Alarm Limit ②	10% above current FiO ₂	10% above current FiO ₂
SpO₂ Target ③	93%	96%
Target Range ④	91 – 95%	94-98%



B: Settings guide

- ① **Backup O₂** *“The FiO₂ you want to deliver when signal is lost”*
If the SpO₂ signal gets lost, the last calculated O₂ is delivered for 2 minutes. After 2 consecutive minutes of signal loss the OAM will alarm and go to its 'Fallback mode' (see IFU for details), one option of which is the set backup O₂.
- ② **O₂ Alarm Limit** *“The threshold of FiO₂ you want to be notified of”*
This is a critical alarm that is used to alert the clinician once the patient requires more O₂ than the set limit for more than 2 consecutive minutes. This O₂ alarm will signify a patient deterioration in the absence of an SpO₂ alarm, which helps mitigate the risk of missing a change in the patient's stability.
- ③ **SpO₂ target** - The OAM uses the SpO₂ target value to drive the controller and make decisions on the delivered O₂. It can be set between 80-100%.
- ④ **SpO₂ target range** - The SpO₂ target range is for graphical display only. The light blue target range bar is visible on the HOME and TREND screens to allow visual judgement of the patient's SpO₂ stability.

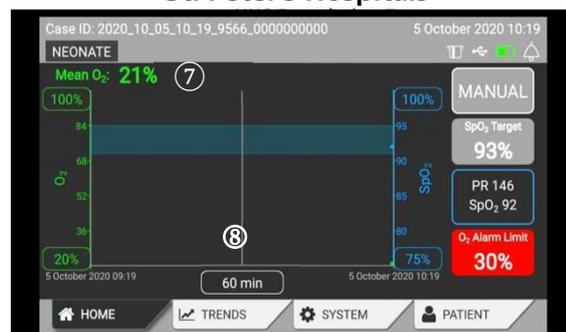
**ANY ISSUES, PLEASE CONTACT
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TO WATCH
TRAINING
VIDEO SCAN



C: Starting automated control

- ⇒ After checking and adjusting all patient settings, press Start Case ⑤.
- ⇒ Check correlation between patient monitor and OAM SpO₂. This should be ≤3%.
- ⇒ If this is not achieved, the SpO₂ probe(s) need be repositioned/replaced, or sites changed.
- ⇒ Start AUTO mode ⑥.



D: Recommended Monitoring frequency

Hourly

Record SpO₂ from patient monitor on observation chart and re-check correlation of SpO₂
Record Mean O₂ ⑦ from Home screen set to 60min ⑧

At start of shift and every 4 hours

- ⇒ Check and adjust backup and alarm settings (Backup O₂ & O₂ Alarm Limit)
- ⇒ After SpO₂ probe site changes – recheck SpO₂ correlation between OAM & monitor.
If variance >3% reposition probe(s).
- ⇒ If discrepancy persists, switch OAM from AUTO to MANUAL mode and alert the Sister in Charge, and/or a doctor familiar with the OAM. Changing one or both SpO₂ probes may be considered. If this does not resolve the issue, **please DO NOT turn the OAM off.** Continue to run in Manual mode to allow review of the trend data.

E: Additional Information

OAM makes large and frequent changes to the FiO₂, is this correct?

The OAM control algorithm is tuned to maintain the patient as close as possible to the set target SpO₂. In order to achieve this and based on its 10 second cycle time, the OAM can make large and frequent adjustments to the FiO₂. The behaviour and performance of the OAM (investigated in a clinical trial¹) was able to keep babies in target range for 80% of time (vs 49% in manual control)

The OAM and the monitor SpO₂ do not match up – what shall I do?

The issue will most likely be the probes, the probe positioning, patient movement, an open duct or differences in limb perfusion. We recommend working with your SpO₂ probes: adjust them, change sites or replace them until you get a good match of the SpO₂ readings.
Should this be impossible or outside your currently available resources we suggest turning the OAM into MANUAL mode, control the O₂ setting manually and return to AUTO mode once you have had success in matching up the SpO₂ readings.

Why do I have to use two probes?

The OAM is not an SpO₂ monitor and does not provide SpO₂ alarms.
Pulse oximetry is a technology which is heavily vulnerable for interferences. Having two probes helps to validate the information by identifying differences between the two readings (OAM and Monitor). If a large difference is shown it should be solved by repositioning the probes, checking probe age or changing probe site. Auto mode should not be used until the mismatch between the two readings is settled.

What is the 'Exit Override' setting?

You can override the OAM at any time by using the Precision Flow control knob. The OAM will go into an 'Override mode' and deliver the clinician's chosen FiO₂. After the set "Exit Override" time it will revert back to automatic control again.

Does the algorithm learn from the patient's dynamics?

The algorithm integrates short term past behaviour into its calculations. Signal loss does not impact this as the OAM recognizes signal loss and pauses the algorithm until the next valid SpO₂ is recognized.

Is tight control really better for my patient?

Hypoxemia increases the risk for NEC, death and neurodevelopmental impairment whereas hyperoxia increases the risk for ROP and lung damage. The OAM showed significant reduction of time in hyperoxia as well as hypoxemia when compared with manual control.

¹Randomized cross-over study of automated oxygen control for preterm infants receiving nasal high flow; Reynolds et al. 2018.