

Oxygen Assist Module (OAM) – Clinical FAQ's

Index

<i>Settings and Features.....</i>	<i>1</i>
<i>OAM behavior.....</i>	<i>3</i>
<i>Display, Monitoring, Troubleshooting...4</i>	

Settings and Features

What does the Exit Override setting mean?

You can override the OAM-set O₂ delivery at any time by using the Precision Flow control knob. The OAM will go into an 'Override mode', stop the control and allow the delivery of the clinician's set O₂. After the set "Revert to Auto" time it will take over automatic control again.

Why can't I change the set time?

You can't change time or date within an active case as this would cause issues with the case file. If you want to change time and date you need to go to MANUAL mode and end the case. Please be aware, this will make you lose the ability to view this patient's trend data, as you have started a new case.

Why do you offer different Patient populations to choose from?

The 4 different patient populations allow for different default settings in regard to SpO₂ target value, SpO₂ target range, backup O₂ and O₂ alarm limit. The controller algorithm operates the same way in all patient populations.

Is it a problem if I chose the wrong patient population and for example treat a Neonate in Infant setting?

No, this is not an issue at all. You simply need to make sure that all your therapy settings such as SpO₂ target value, SpO₂ target range, backup O₂ and O₂ alarm limit are appropriately set.

Can I adjust my OAM Patient settings while the device is in Auto Mode?

Yes, you can adjust all OAM settings by simply clicking the value on the touch screen and adjusting it with the blue control knob.

Why do I have to use two probes? Why can't the OAM serve as my SpO₂ monitor as well?

The OAM is not a monitor and does not provide SpO₂ alarms. Pulse oximetry is a technology which is heavily vulnerable for interferences. You experienced it yourself, sometimes your monitor displays SpO₂ values that clearly do not match your clinical interpretation and you decide to reposition or replace the SpO₂ sensor. The OAM is a computer and not a monitor or an intelligent human. If you hand over this responsibility to a computer, it is recommendable to have a second probe for SpO₂ monitoring. If you identify a large difference between the two readings (OAM and Monitor) you look to investigate which one has the interference and re-position the probes accordingly.

What is the difference between the target SpO₂ and the target range (upper and lower limit)?

The controller uses the single SpO₂ target value only to drive the controller and take decisions on the delivered O₂. The Target range is for graphical and numerical display only. The light blue target range bar is visible on the HOME and TREND screens. Additionally, a Time in Range is calculated and displayed on the TREND screen.

Why is there a 2 minutes delay on the SpO₂ signal loss alarm?

We aim to reduce noise as well as disturbing alarms whilst delivering a reliable and safe oxygen therapy. SpO₂ interferences and brief loss in signal quality are very common clinical issues. If each loss in signal would trigger an alarm this would probably cause significant alarm fatigue.

If the signal gets lost for less than 2 minutes the last calculated O₂ is delivered. If the signal loss expands to over two minutes the OAM will alarm and go to its Fallback mode.

OAM is to be used in conjunction with normal patient monitoring, which would appropriately alarm for high/ low SpO₂ during this time.

Settings and Features (continued)

How should I set the backup O₂?

This is totally up to the clinicians' discretion and depending on the individual patient. It is necessary to re-visit this setting a couple of times a day and always if the mean O₂ increases or decreases significantly.

Will the OAM mask if a patient is deteriorating?

The OAM will increase Oxygen when the patient's SpO₂ drops. To mitigate the risk of missing a change in the patient's stability, it is critical to set an O₂ Alarm. With an O₂ alarm set, the clinician will be alerted as soon as the patient requires more O₂ than the limit for more than 2 minutes. This O₂ alarm will signify a patient's deterioration in the absence of an SpO₂ alarm, which helps mitigate the risk of missing a change in the patient's stability. .

Being fully automated means giving up control. What options do I have to take back manual control?

At any time, you can override the O₂ by simply using your Precision Flow controller knob. The override will automatically return to Auto after the set time (usually 30 seconds - set in SYSTEM - 'Revert to AUTO'). If you want to take over control for a longer period of time, go to PATIENT screen and switch to Manual mode.

Why is there a 2-minute delay on the O₂ alarm limit?

Our proprietary control algorithm is designed to try to keep patients as close as possible to the clinician set SpO₂ target value. In order to achieve this, it makes frequent or large adjustments, albeit generally of a very short duration. This could result in unnecessary alarms. The 2-minute alarm delay was based on clinician feedback, targeting reduction in noise and prevention of alarm fatigue.

How should I set the O₂ alarm limit?

This is totally up to the clinician's discretion. Out of experience, Neonatologists set this approximately 10-15% above the mean O₂; adult clinicians usually use a larger delta. It is necessary to re-visit this setting a couple of times a day and additionally if the mean O₂ increases or decreases significantly. The O₂ alarm limit is an important clinical alarm threshold that deserves attention.

Can the OAM be used to transfer Patients (on the VTU)?

Yes, the runtime of the OAM built in battery is 4h. When using a PF HiVNI version that provides power via the HDMI port, on a transfer the OAM will be powered by the VTU battery and the runtime of the full VTU setup (including OAM) will be displayed on the VTU user interface. Important to note, transferring patients may cause frequent SpO₂ interferences.

Does it matter whether the probe is pre- or post-ductal?

Pre- and post-ductal SpO₂ can be different. It is a clinical consideration that needs to be made when setting targets and deciding on probe positioning.

Can the OAM be connected to my EMR system?

The OAM already has the required Hardware built in, we will be working on software to accommodate the data export to your EMR System. As soon as available a local Vapotherm partner will provide this software update to you.

Does OAM always need an external power supply?

Connected to Precision Flow Classic and Precision Flow Plus OAM needs an external power supply as provided in the UKIT. Connected to Precision Flow Hi-VNI no external power supply is needed – the OAM can be powered via the blue communication cable.

Can the OAM be connected to my central patient monitoring?

The OAM already has the required Hardware built in, we will be working on software to accommodate the data export to your monitoring System. As soon as available a local Vapotherm partner will provide this software update to you.

Settings and Features (continued)

Can I use OAM with other respiratory support devices than Precision Flow?

No, OAM is designed, developed and optimized to function with Precision Flow Classic, Plus and Hi-VNI.

Is there any restrictions in terms of age or bodyweight?

No, OAM can be used on humans of all ages and weights.

Can I use standard SpO₂ probes with my OAM?

OAM has either Masimo or Nellcor SpO₂ technology built in. For Nellcor the probes used need to be Oximax compatible. For Masimo, RD SET can be used with the standard cable, LNCS sensors can be used using an adapter or a replacement LNCS cable. Please also consult the Masimo/ Nellcor IFU included in your OAM IFU.

Is the data recorded, can I retrospectively view or download the recorded case file data?

Data is recorded and stored internally. It cannot be reviewed on screen. A csv-file can be downloaded and analyzed using third party software such as Excel.

OAM behavior

I observed the controller pushing the O₂ up very high and then quickly decreasing it again. Was this a malfunction or an erroneous decision of the OAM?

No, it wasn't. 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 short 10 second cycle time, the OAM can make large but short adjustments

Why can't I limit the delivered O₂?

The delivered O₂ is set based on the algorithm calculations considering the SpO₂ readings. Of clinical importance and with effect on morbidity and mortality is oxygenation (SpO₂) not so much oxygen delivery (FiO₂). To limit O₂ might risk having an under oxygenation when more Oxygen would be needed. Hypoxemia is most likely of higher risk than Hyperoxia.

Does the algorithm learn from the patient's dynamics? Does signal loss such as during a probe site change impact this learning?

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.

What do you mean by the algorithm operates on a 10 second cycle?

The algorithm makes a decision every 10 seconds. At the end of each of those 10 second cycles the set target value is compared to the current SpO₂ reading and the algorithm decides whether or not a change in O₂ delivery is required.

Does the flowrate or changing the flowrate show up on the OAM display?

No. The OAM controls the FiO₂ and does not control flowrate. Current therapy and monitor values are displayed as you are used to. Flow, O₂ and Temperature on the Precision Flow display, SpO₂, RR etc. on your patient monitor.

Is OAM likely to affect (positively or negatively) BPD?

Due to a lack of studies in this space, recently there is no data available that would show any effect of OAM on BPD. What we know is that OAM increases time in range while decreasing time above and below range. We also know, hyperoxia (time above range) is associated with a higher risk for BPD.

OAM behavior (continued)

What will happen in the case of an apnea?

It is very important to use separate SpO₂ monitoring. The OAM cannot differentiate – it will recognize the desaturation and increase the O₂. In parallel the patient monitor will alarm and alert the clinician. As soon as the baby re-starts breathing and the SpO₂ comes back up, OAM will start decreasing the O₂ again.

From experience I know that sometimes babies self-correct after desaturating. Wouldn't it make sense for the OAM to wait before it increases O₂?

OAM is a computer utilizing a control algorithm to keep patients as much time as possible within a target range. The quick reaction of OAM in terms of adjustment of O₂ is designed to maximize this time in target range, even for these otherwise brief desaturations which are self-resolving.

Will I lose awareness of how my patient behaves in certain circumstances (i.e., post-feeds etc.)

The way of monitoring and making yourself aware will change. By using the O₂ alarm limit, external SpO₂ monitoring and regularly reviewing the TREND screen the required information can be captured.

Can the OAM be used in the first few minutes of life?

The OAM can be used on patients requiring HVT, and can control oxygen to set target levels of as low as 80% SpO₂. It is a clinical decision as to whether such control is appropriate for the baby.

Why can't I set a target value below 80%?

The target value setting is limited to 80% because SpO₂ technology only provides sufficient accuracy above 80%.

Which type of patients benefit the most?

In the published Reynolds Study, every single patient enrolled had a higher time in range while in AUTO mode. There were patients with a steeper improvement and some with a smaller improvement, but all patients improved their time in target range.

Can I change the averaging time for the pulseoximetry?

No, the averaging time is fixed with Masimo OAM to 8 seconds and with Nellcor OAM to "normal" (6-7 seconds)

How shall I deal with care interventions or kangaroo care? Does the OAM need to go to MANUAL

The OAM is designed to adjust Oxygen according to the measured SpO₂ quickly and effectively. Obviously, a stable performance is based on availability of a valid SpO₂ signal. During manipulation and movement SpO₂ signal can be intermittently weak. OAM has a designed reaction algorithm to deal with this situation. Many clinicians have reported to value the OAM helping to keep their patients in range particularly during cares, ambulation and kangaroo care.

If I am weaning my patient off the PF and trial a pause in high velocity therapy (leaving it in run-mode on the lowest setting) what should I do with OAM?

We would suggest leaving the OAM on as well and toggle the mode to MANUAL. Trends can provide important information to the clinician and the settings and trends do not get lost in case the patient needs to be re-started on PF and OAM.

Display, Monitoring, Troubleshooting

What does the mean O₂ tell me?

The mean O₂ is the average O₂ delivered, always referring to the screen you currently look at. On the Home screen (i.e., set to 60 Minutes) the Mean O₂ is the average O₂ of this particular period of time. We would recommend utilizing the average O₂ using the 60-minute screen for your hourly O₂ documentation on your observational charts.

Display, Monitoring, Troubleshooting (continued)

Why is the SpO₂ display so small?

If you want to check for the patient's SpO₂ your standard patient monitor is the device to look at. The OAM is a controller, not a monitor.

The reason why we display the SpO₂ on the OAM display is to allow you to compare the OAM SpO₂ reading with your monitor SpO₂ reading in order to confirm accuracy.

Where can I see the currently delivered O₂?

The currently delivered O₂ is displayed on the screen of the Precision Flow. This O₂ value is prone to frequent changes due to the agility of the OAM. For documentation of your O₂ on your observation charts, as well as to get a sense of the mean O₂ requirement of your patient, we suggest using the Mean O₂ displayed on the OAM Home screen. Make sure when using this you are aware of the window it is set to (2, 15 or 60 Minutes)

What do I do if I have a huge mismatch in SpO₂ readings?

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.

How often should I adjust the O₂ alarm limit or the Backup O₂?

Beginning of each shift, on a regular basis i.e., every 4h and whenever the stability state of the Patient changes

Why is the SPO₂ reading differently on the OAM compared to my SATS monitor?

There always may be differences from measurement due to different sites, probes, movement etc. But also:

- If you are using different SpO₂ Technologies (Masimo & Nellcor for example) the different SpO₂ processing algorithms can result in different SpO₂ values
- If you are using the same technology (Nellcor Monitor and Nellcor OAM) the reading should be pretty accurate and similar on both devices. If this is not the case, the issue is around probe positioning, perfusion or probe age etc.
- If you are using Masimo on both devices there still can be differences due to different processing algorithms as Masimo algorithms have changed over time

It looks like the unit can administer 100% Oxygen in automatic control.

Yes, it can. OAM does not have an upper or lower limit for the O₂. The OAM does, however, have an O₂ alarm, which is set by the clinician. It will alert the clinician to any periods longer than 2 minutes above that clinician-set alarm limit.

What happens when the SpO₂ probe falls off or the signal is weak? Does this cause a risk for over oxygenating?

The utilized Pulsoximetry technologies (Masimo and Nellcor) have internal algorithms to detect a valid SpO₂ signal. Do they identify a signal as non-valid, OAM proceeds as if the signal was lost.

For the first two minutes of signal loss the last calculated O₂ will be delivered and a silent alert message informs the clinician.

After 2 minutes of signal loss the silent alert turns into an audible alarm and a Fallback mode is activated.

Fallback mode chooses the greatest of three possible fallback O₂ values:

- The clinician's set Backup O₂
- The mean O₂ of the last 3 automated settings
- The mean O₂ since started Auto mode

How can I avoid falsely low SpO₂ reading during probe site changes?

Consider disconnecting the probe from the cable, change probe site, reconnect cable to probe.

Should the SpO₂ on the OAM be documented alongside monitor SpO₂?

The OAM is not a monitor, it is a controller. We suggest you regularly check that the reading of OAM matches with your monitor reading.