

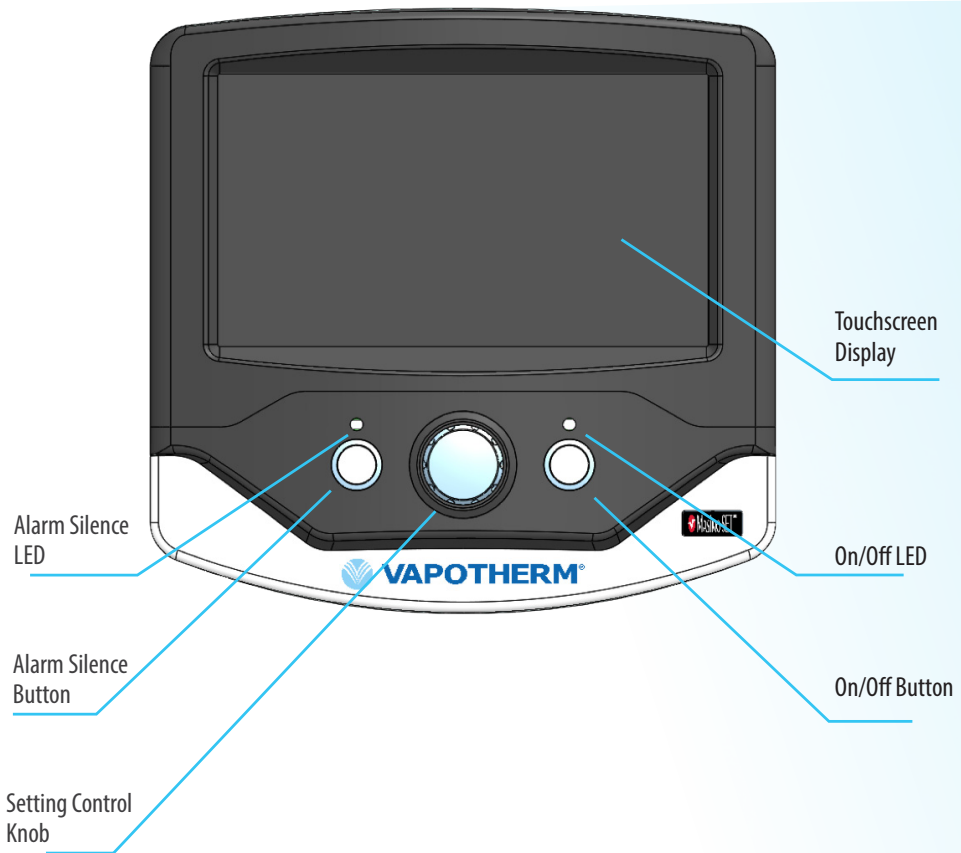


VAPOTHERM®

Oxygen Assist Module

for Vapotherm Precision Flow® Systems

QUICK REFERENCE GUIDE



This guide provides you with basic instructions on how to set up and operate the Vapotherm Oxygen Assist Module for Precision Flow® Systems. Before operating the Vapotherm Precision Flow® with the Oxygen Assist Module, please review the Instructions for Use which can be found at our website vtherm.com/pference.



SILENT ADVISORY MESSAGES

ALARM/ALERT MESSAGE	ACTION
%O₂ at user set %O₂ limit*	Increase %O ₂ Alarm Limit, or enter MANUAL mode
Battery Backup In Use	Oxygen Assist Module is in Battery Mode. When external power is lost, the module will automatically switch to Battery Mode
Battery Low	Plug the Oxygen Assist Module into external power
Check Precision Flow	Clear Precision Flow alarm and ensure it is in Run Mode with both Air and O ₂ sources present
Check SpO₂*	See the alert message on screen for additional information. Reconnect sensor with good signal or replace SpO ₂ sensor or patient cable
Local Storage is Low	Delete Previous Case Files from Local Storage
Local Storage is Full	Delete Previous Case Files from Local Storage
SpO₂ Target > 95%	Change SpO ₂ Target to 95% or Below
SpO₂ Target < 85%	Change SpO ₂ Target to 85% or Above
Time Near Expiration	Insert new Time Card before time expires or End Case

* These Silent Advisory Messages will become Medium Priority Alarms if not corrected after 2 minutes.

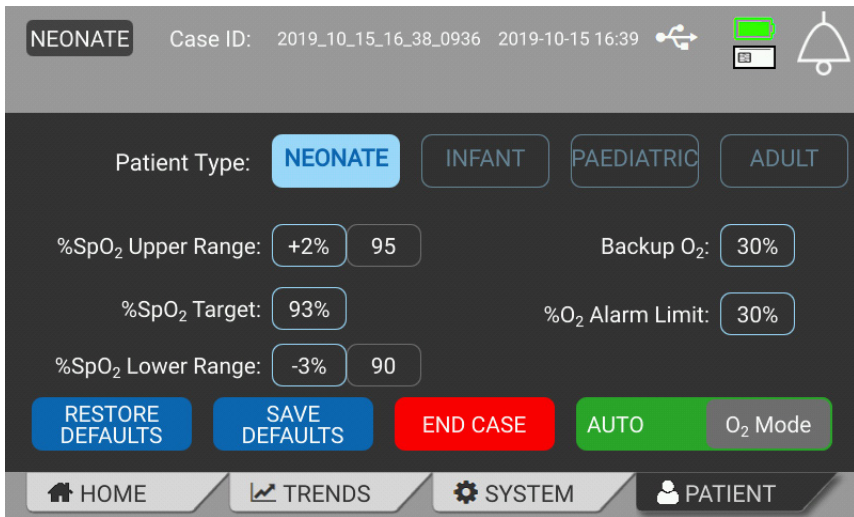
MEDIUM PRIORITY ALARM MESSAGES

ALARM/ALERT MESSAGE	ACTION
Battery Low - Shutdown Imminent	Plug Oxygen Assist Module into external power
Check SpO₂	See the alert message on screen for additional information. Reconnect sensor with good signal or replace SpO ₂ sensor or patient cable
Insert Time Card or End Case	Time Card expired or removed. Insert Time Card or End Case
Precision Flow Communication Error	Restore Precision Flow Connection, enter MANUAL Mode, or End Case
Precision Flow Invalid Software Version	Restore Precision Flow Connection or End Case and Update Precision Flow Software
SpO₂ Communication Error	Alert may self-correct. If not, enter MANUAL Mode, or End Case
System Reset - Check Settings	Check settings. Press any key, touch screen or turn setting control knob

A full list of Alarms and Advisory Messages can be found in the Vapotherm Oxygen Assist Module Instructions for Use.

SYSTEM SET-UP

- ▶ Connect Oxygen Assist Module to Precision Flow and ensure the Precision Flow is in RUN mode and shows a GREEN LED light
- ▶ Connect the SpO₂ patient cable to the Oxygen Assist Module. Attach the sensor to the patient cable and apply the sensor to the patient
- ▶ Plug Oxygen Assist Module into external power and power on
- ▶ On the System screen, check settings
- ▶ On the Patient screen, check settings. Select parameters with the touchscreen and rotate the blue Setting Control Knob to adjust the value.
- ▶ Start Case
- ▶ Press the O₂ Mode AUTO button to begin automatic mode once the patient is in a stable SpO₂ state.



INDICATIONS, WARNINGS AND CAUTIONS

Primary Indications:

The Oxygen Assist Module is an optional module used only with the Vapotherm Precision Flow and is indicated for on-demand titration of oxygen into warm humidified breathing gases delivered to spontaneously breathing patients based on continuous non-invasive monitoring of blood oxygen saturation.

The Oxygen Assist Module is intended to treat pediatric (including neonatal) and adult patients in monitored clinical environments.

Incorporation of SpO₂ into the Precision Flow with the Oxygen Assist Module does not eliminate the need for separate and independent patient monitoring indicated by the Precision Flow system labeling.

Patients on high velocity nasal insufflation receiving supplemental oxygen are acute and appropriate clinical vigilance should be observed by the care team. Additional patient monitoring including pulse oximetry is necessary if the Precision Flow is used to give supplementary oxygen.

Oxygen Assist Module Packaging contains:

Oxygen Assist Module Unit	Quick Reference Guide	
Power Cord	Pole Mount Assembly	Masimo SpO ₂ Patient Cable and Training Kit

DOWNLOAD DATA

- ▶ Insert USB Drive
- ▶ On the System screen, select Case Data and enter PIN
- ▶ Choose which Case file or files to download and press Download button
- ▶ Once data is saved, press OK and remove USB Drive
- ▶ As needed, delete Case files to clear Local Storage

SHUT DOWN


- ▶ On the Patient screen, End Case
- ▶ To power down, press the On/Off button to turn off, then disconnect the module from AC power
- ▶ Wipe down with Super Sani-Cloth® to clean and disinfect between patients

The screenshot shows the NEONATE patient screen. At the top, it displays 'NEONATE' and 'Case ID: 2019_10_15_16_38_0936 2019-10-15 16:41'. Below this is a yellow message bar that says 'This is an alarm or advisory message'. The main display area is split into two sections. The left section shows a trend display for %O₂ with a scale from 20% to 100% and a blue line graph showing a dip from 84% to approximately 75% around 16:40. The right section shows 'AUTO O₂ Mode' with 'SpO₂ Target 93%' and 'PR 80 %SpO₂ 94'. Below the target is a red box for '%O₂ Limit 30%'. At the bottom, there is a navigation bar with icons for HOME, TRENDS, SYSTEM, and PATIENT. Numbered callouts 1-8 point to: 1. Patient Type Indicator (NEONATE), 2. Trend Display, 3. Patient ID, Time and Date Display, 4. Alarm Silence Indicator (bell icon), 5. Message Display, 6. %O₂ Mode (Auto; Manual), 7. Parameter Boxes (press to call up menus), and 8. Menu Keys.

1 Patient Type Indicator	5 Message Display
2 Trend Display	6 %O ₂ Mode (Auto; Manual)
3 Patient ID, Time and Date Display	7 Parameter Boxes (press to call up menus)
4 Alarm Silence Indicator (crossed when silenced)	8 Menu Keys

GENERAL WARNINGS

- ▶ For use only on spontaneously breathing patients. The Precision Flow with or without the Oxygen Assist Module is not life supporting.
- ▶ Incorporation of SpO₂ into the Precision Flow with the Oxygen Assist Module does not eliminate the need for separate and independent patient monitoring indicated by the Precision Flow system labeling. Patients on high velocity nasal insufflation receiving supplemental oxygen are acute and appropriate clinical vigilance should be observed by the care team. Additional patient monitoring including pulse oximetry is necessary if the Precision Flow is used to give supplementary oxygen.
- ▶ Do not initiate automatic oxygen delivery with the Oxygen Assist Module until the patient's SpO₂ is stable.

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May be patented. www.vapotherm.com/patents
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