

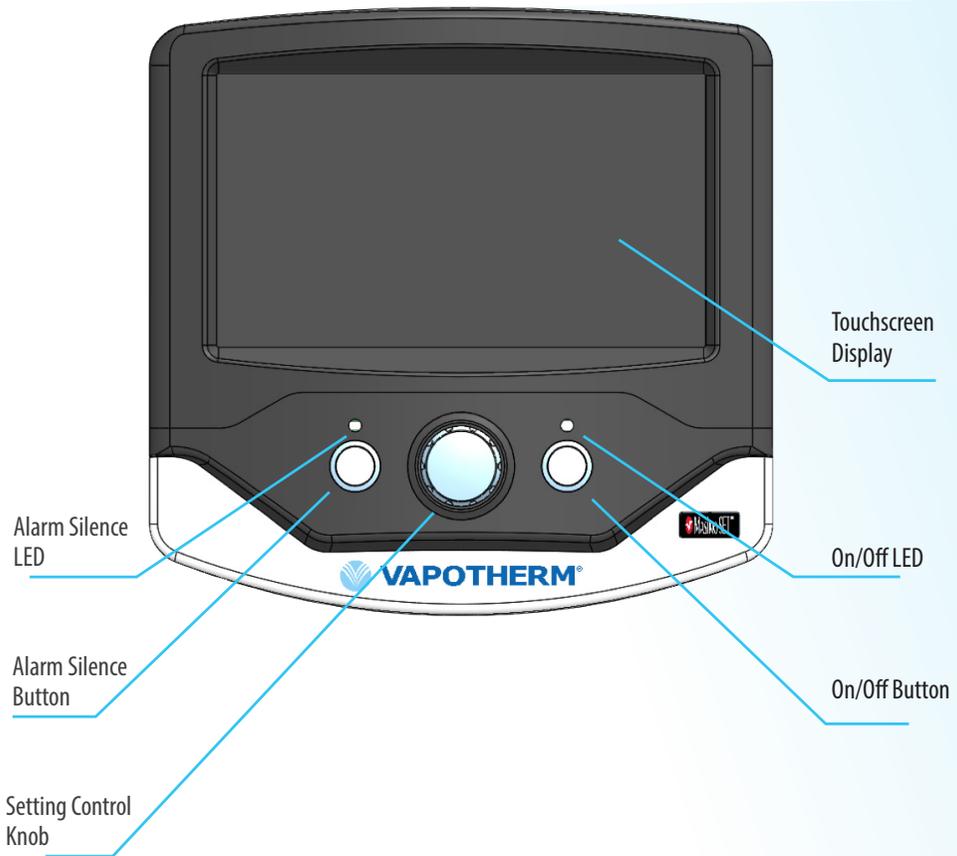


# VAPOTHERM®

## 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 [www.vapotherm.com](http://www.vapotherm.com).

## SILENT ADVISORY MESSAGES

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

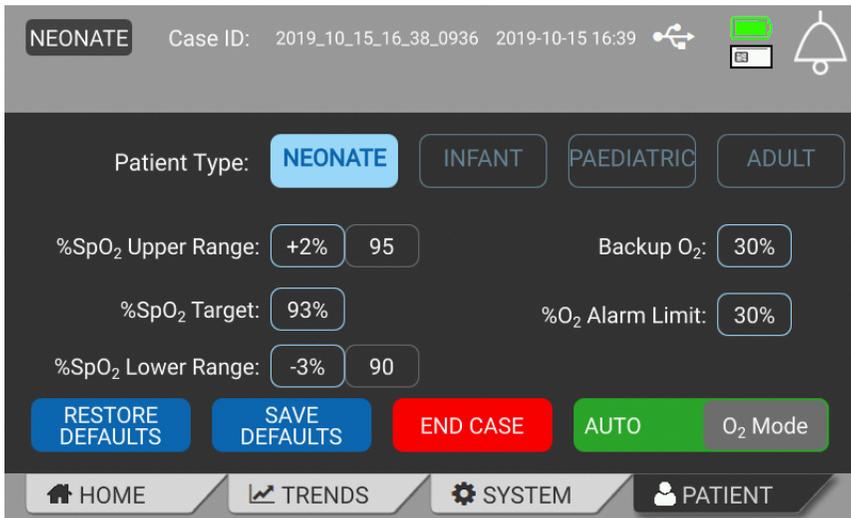
## MEDIUM PRIORITY ALARM MESSAGES

ALARM/ALERT MESSAGE	ACTION
<b>Battery Low - Shutdown Imminent</b>	Plug Oxygen Assist Module into external power
<b>Check SpO<sub>2</sub></b>	See the alert message on screen for additional information. Reconnect sensor with good signal or replace SpO <sub>2</sub> sensor or patient cable
<b>Insert Time Card or End Case</b>	Time Card expired or removed. Insert Time Card or End Case
<b>Precision Flow Communication Error</b>	Restore Precision Flow Connection, enter MANUAL Mode, or End Case
<b>Precision Flow Invalid Software Version</b>	Restore Precision Flow Connection or End Case and Update Precision Flow Software
<b>SpO<sub>2</sub> Communication Error</b>	Alert may self-correct. If not, enter MANUAL Mode, or End Case
<b>System Reset - Check Settings</b>	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 SpO<sub>2</sub> 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 O<sub>2</sub> Mode AUTO button to begin automatic mode once the patient is in a stable SpO<sub>2</sub> 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 SpO<sub>2</sub> 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	Instructions for Use	Quick Reference Guide
Power Cord	Pole Mount Assembly	Masimo SpO <sub>2</sub> 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' with a timestamp '2019-10-15 16:41'. A yellow banner reads 'This is an alarm or advisory message'. The main display features a trend graph for %O<sub>2</sub> (left y-axis, 20% to 100%) and SpO<sub>2</sub>% (right y-axis, 75% to 100%). The graph shows a blue line for SpO<sub>2</sub> and a green line for %O<sub>2</sub>. On the right, there are parameter boxes: 'AUTO O<sub>2</sub> Mode', 'SpO<sub>2</sub> Target 93%', 'PR 80 %SpO<sub>2</sub> 94', and a red '%O<sub>2</sub> Limit 30%'. The bottom navigation bar has 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 (yellow banner), 6. %O<sub>2</sub> Mode (AUTO), 7. Parameter Boxes, and 8. Menu Keys.

1 Patient Type Indicator	5 Message Display
2 Trend Display	6 %O <sub>2</sub> 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 SpO<sub>2</sub> 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 SpO<sub>2</sub> is stable.

 **VAPOTHERM, INC.**  
100 Domain Drive  
Exeter, NH 03833  
T: 603-658-0011  
USA

**Technical Support**  
T: 855 557 8276 USA  
+1 (603) 658-5121 International  
ts@vtherm.com

CE 0297

EC REP

RMS-UK Ltd.  
28 Trinity Road  
Nailsea, North Somerset BS48 4NU  
United Kingdom

