EMS Healthcare

TOM-2 Total Oxidizer Monitor w/Mitigation

Operators Manual

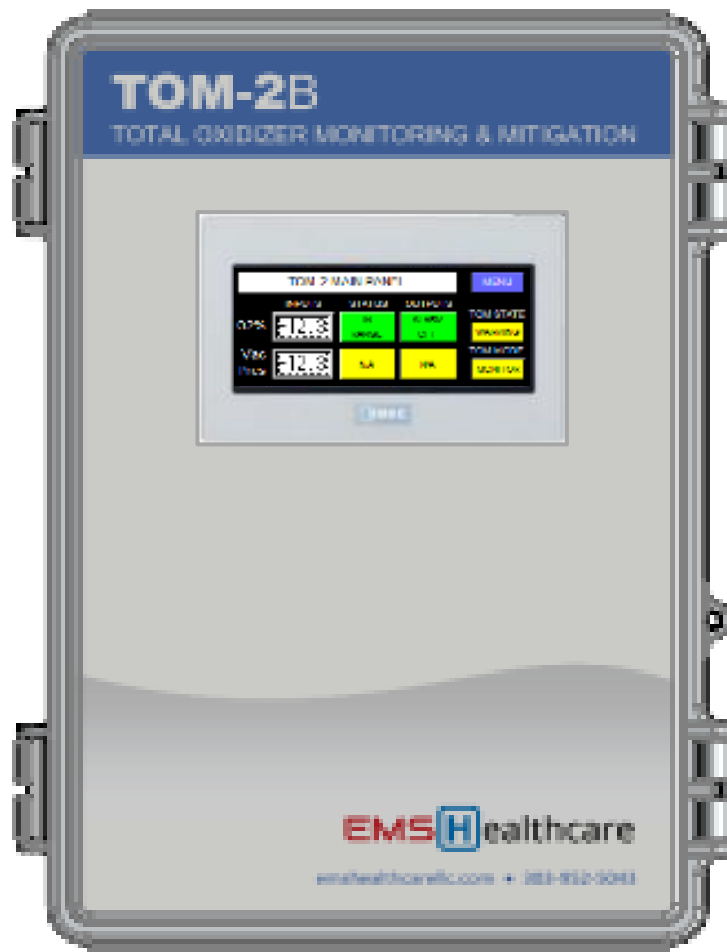**For Part Number TOM-2095A and TOM-2095B**

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System Overview

With the introduction of NFPA 99 2012 edition came an entirely new requirement for medical-surgical vacuum systems that are also used for Waste Anesthetic Gas Disposal (WAGD). For these combined-use systems, the NFPA now requires the total concentration of oxidizers (oxygen and nitrous oxide) be maintained below 23.6 percent or the materials, lubricants, and sealants within the vacuum pump be inert to these oxidizers for new installations (reference section 5.1.3.8.1.2. (2)). The NFPA 99 2018 edition imposes this requirement on all (existing and new) combined-use vacuum systems and the 2021 edition removes nitrous oxide from the requirement.

The *TOM-2* Total Oxidizer Monitor (patent pending) from EMS Healthcare, LLC is a gas monitoring and mitigation system that's ideal for the continuous regulation of oxygen below the limit of 23.6 percent in combined-use vacuum systems. The heart of the monitoring & mitigation system is a PLC that interfaces to an oxygen sensor, a vacuum transducer, and a control valve. The unit monitors oxygen concentration and vacuum pressure and take appropriate action based on these input parameters. The PLC will operate a valve plumbed to a regulated gas source (e.g., carbon dioxide or nitrogen) or ambient air to maintain levels below the critical threshold of 23.6%. Maintaining system vacuum pressure is always prioritized over oxygen levels; as long as vacuum pressure remains acceptable, increasing oxygen levels to the vacuum pump inlet will be mitigated.

Models

The *TOM-2* is available in two models. The TOM-2A (part number TOM-2095A) performs oxygen monitoring only while the TOM-2B (part number TOM-2095B) performs both oxygen monitoring and mitigation and is recommended for use in facilities where oxygen concentrations may exceed the NFPA 99 threshold of 23.6%. Both TOM-2A and TOM-2B continuously monitor and log total oxygen concentration in order to provide periodic reports for compliance purposes.

Both models feature a zirconium oxide O2 sensor with a life span of 10 years of continuous operation. Sensor behavior is very stable under nominally changing environmental conditions of temperature, pressure, and humidity. Because of its stability, the sensor requires only periodic testing to verify the sensor remains calibrated for accuracy.

System Specifications

| Part Number		TOM-2095A	TOM-2095B
Description		Oxygen monitoring, alarm relay output, data logging	Oxygen monitoring and mitigation, vacuum pressure monitoring, alarm relay output, data logging
Performance	**Response Time**	Within 1 second of any change in oxygen levels	
	Accuracy	± 0.5% of FS	
	Repeatability	± 1% of reading	
	Operating Temp	-40° to 122°F (-40° to +50°C)	
	Humidity	0 – 98% RH, non-condensing	
	Data Logging	Oxygen concentration readings logged every 10 seconds	Oxygen concentration and Vacuum Pressure readings logged every 10 seconds
	Alarm Output	2-wire dry contact, normally closed (open on alarm of 23.6% O2)	
Oxygen Monitoring	**Range**	0 – 95% oxygen concentration	
	Sensor Connection	1" NPT male adapter with KF25 quick disconnect (10 ft cord to control unit)	
Vacuum Pressure Monitoring	**Range**	N/A	0 – 30 in Hg, vacuum range
	Sensor Connection	N/A	¼" NPT male threaded connection (10 ft cord to control unit)
Gas Mitigation	**Gas Type**	N/A	Carbon dioxide, nitrogen or ambient air (with included muffler)
	Gas Pressure	N/A	5 – 10 psig (operating pressure range at valve inlet port
	Gas Connection	N/A	½" NPT female threaded connection
	Valve Power	N/A	Power supplied by control unit (10 ft cord to control unit)
Electrical	**Voltage Source**	110-120 VAC, 60 Hz	
	Power (max)	13 Watts	19 Watts
Physical (Control Unit)	**Dimensions**	8" (W) x 12" (H) x 6" (D)	
	Weight	6.5 pounds (2.9 kg)	10.0 pounds (4.5 kg) including solenoid valve and vacuum transducer
	Enclosure Type	NEMA 1,2,4,4X rated, polycarbonate, indoor/outdoor use	

System Installation

Facility Requirements
TOM-2 installation must be performed by a qualified technician trained by EMS Healthcare LLC.

The TOM-2A comes pre-wired with an oxygen concentration monitoring sensor on a 10-foot cable for installation into the facility vacuum system. Additionally, the TOM-2B comes pre-wired with a vacuum pressure sensor on a 10-foot cable and a solenoid-operated mitigation valve on a 10-foot cable for installation into the facility vacuum system.

The TOM enclosure should be mounted on or near the vacuum pump skid to allow installation of the sensors and valve into the facility vacuum system as indicated in the diagram below. See Specifications for enclosure dimensions.
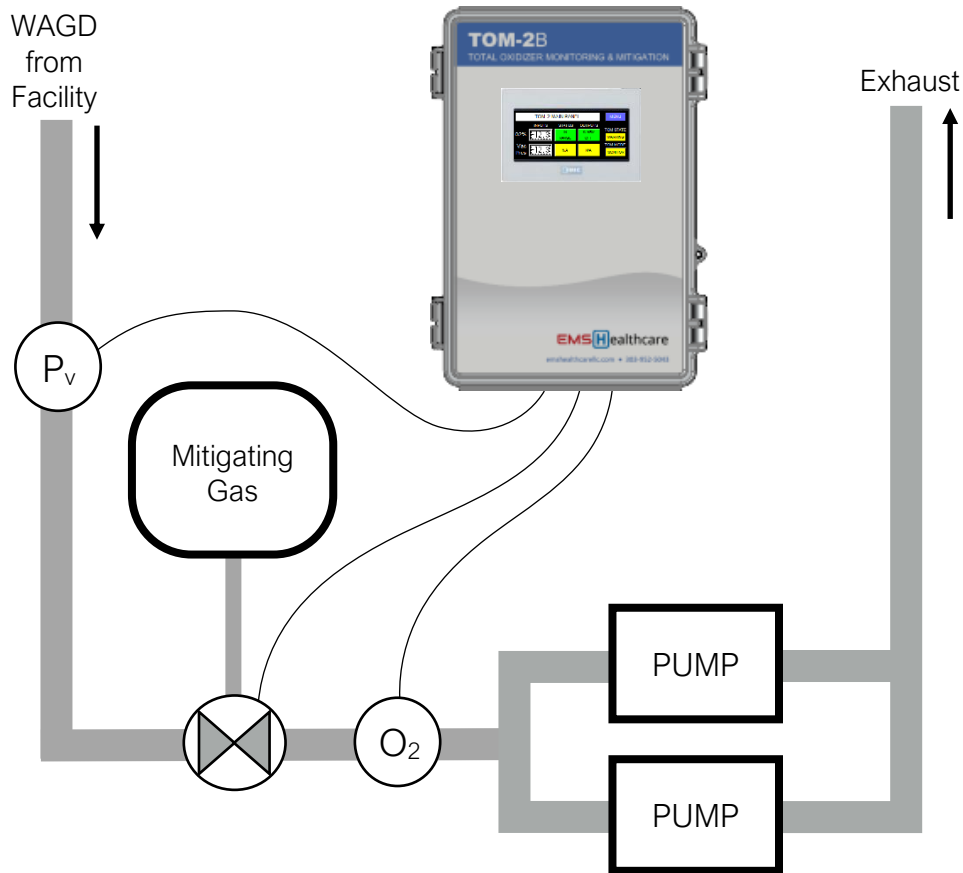

NOTE: In the TOM-2095B configuration, the mitigating valve must be installed at least 1 foot upstream of the O2 sensor to allow proper mixing of the mitigation gas. The vacuum transducer must be installed at least 1 foot upstream of the mitigating valve to monitor patient-side vacuum levels during mitigation.
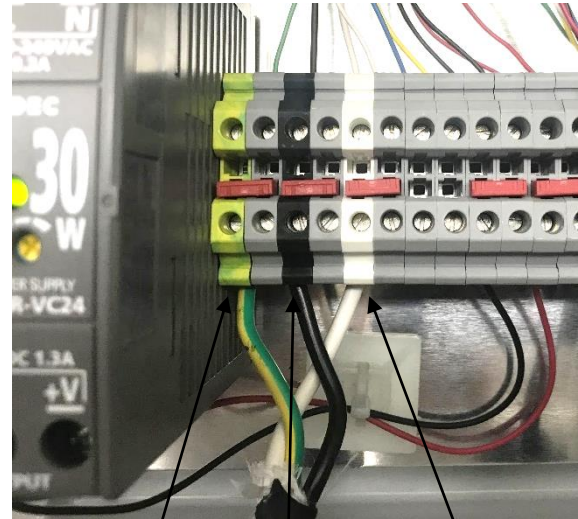
Facility Wiring

Electrical installation must be performed by a qualified electrician.

1. **TOM-2 Power input** - The TOM-2A and -2B require 110VAC electrical power (2-conductor plus ground) wired into it. The power input connections are to be made at terminal blocks inside the unit enclosure.
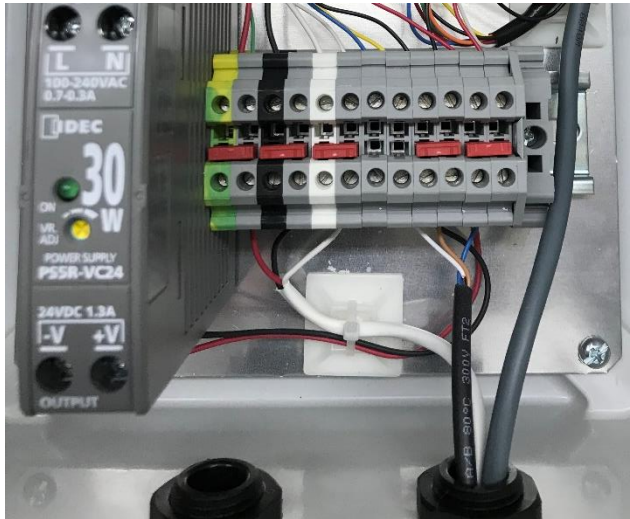
Insert 110VAC power input
wiring thru left wiring port

Ground Wire to
Green Terminal

Neutral Wire to
White Terminal

Hot Wire to
Black Terminal

2. **O2 Alarm Relay Output** – The TOM-2A and -2B both provide an O2 Alarm relay output (2-wire dry contact, normally closed) that can be wired to the facility master alarm panel. This relay output will open when an O2 Alarm is indicated (23.6% O2 is exceeded) or when a loss of 110VAC power to the unit occurs.

3. **O2 Warning Relay Output** – The TOM-2A and -2B both provide an O2 Warning relay output (2-wire dry contact, normally closed) that can be wired to the facility master alarm panel. This relay output will open when an O2 Warning is indicated (22% O2 is exceeded – this value can be adjusted) or when a loss of 110VAC power to the unit occurs.

Q2 and COM2 are the **O2 Warning** relay output

Q1 and COM1 are the **O2 Alarm** relay output
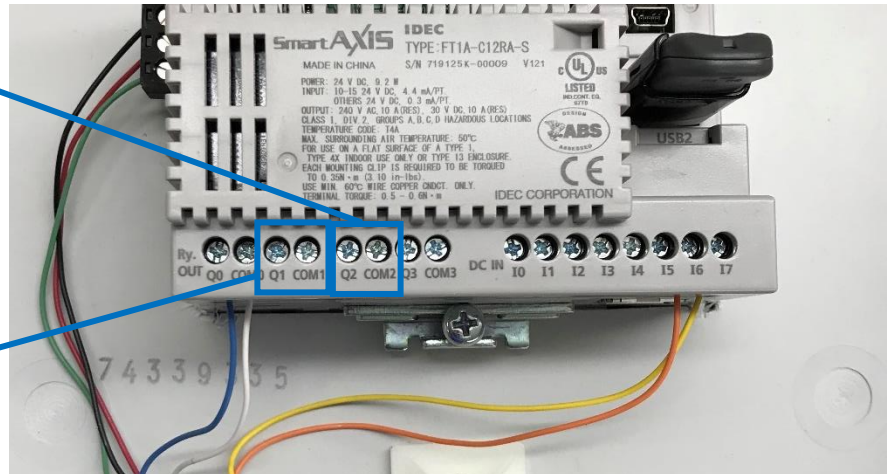
Mitigating Gas

When utilizing the TOM-2B configuration, the mitigation of high oxygen levels can be implemented with ambient air, carbon dioxide gas, or nitrogen gas.

For in-patient facilities, the combined WAGD systems typically have large system volumes such that, when oxygen is introduced into the system, its contribution to the overall percentage of gases is small and easily mitigated by dilution in the total system volume or by introduction of a small amount of mitigating gas. Therefore, ambient air is suggested as the mitigating gas for these in-patient facilities. The TOM-2095B comes equipped with an air inlet filter/muffler on the solenoid valve for installations where ambient air will be used. After installation, if the system shows recurring O2 alarms with ambient air mitigation, carbon dioxide or nitrogen may be required as a mitigating gas.

For out-patient facilities and surgery centers, the rise rate and peak level of oxygen concentration in the system during facility use can be much higher than what is seen in an in-patient facility due to smaller system volumes. Therefore, it is suggested that these facilities use carbon dioxide or nitrogen as a mitigating gas to more rapidly respond to increasing oxygen levels detected by the TOM-2. See the Specifications page for gas connection sizing and acceptable pressure input levels if carbon dioxide or nitrogen gas will be used.

The mitigating gas valve should be installed at a point where all vacuum system input is consolidated to one line upstream of the vacuum pumps. Larger valve sizes (3/4" and 1") are available if the vacuum pump system requires higher flow.

Initial Power Application

On initial application of 110VAC power following system installation, the system will power up with initial settings entered from the factory. The touch screen on the front cover of the unit will power on and show the TOM-2 MAIN PANEL. Verify that the following steps occur automatically:
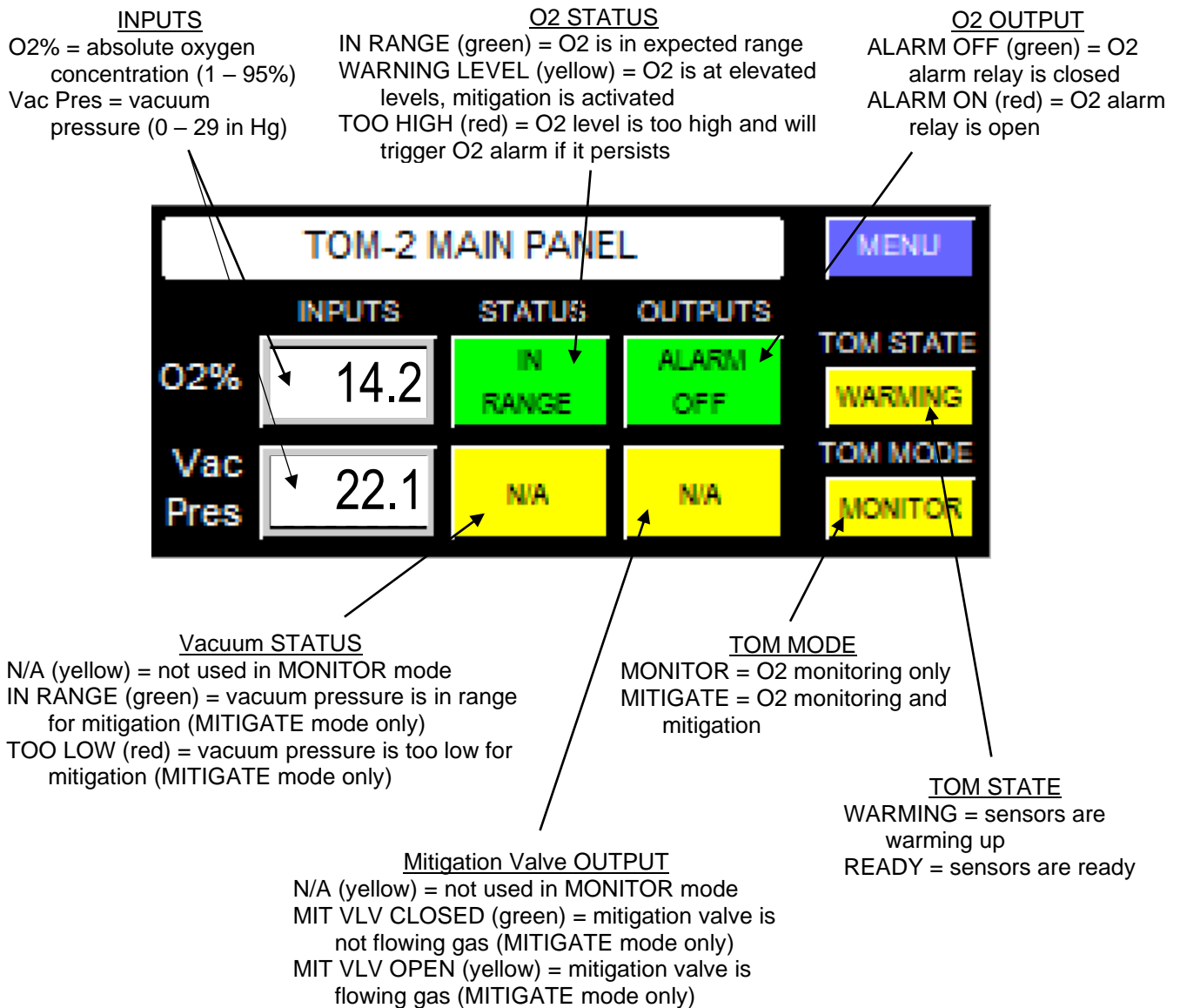
1. TOM STATE indicates "WARMING" and then transitions to "READY" after about 2 minutes.

2. Once TOM STATE indicates "READY", O2% measurement is displayed

3. TOM MODE indicates "MONITOR" or "MITIGATE".

4. MAIN screen displays "N/A" for vacuum pressure status and mitigation valve output when TOM MODE indicates "MONITOR". When TOM MODE indicates "MITIGATE", these displays will become active.

Once the unit is operational, the installer should baseline the O2 sensor concentration for the facility location and altitude. This is done by exposing the sensor to ambient air for at least 2 minutes and recording the concentration reading. This baseline reading can then be used to ensure the O2 sensor is not drifting during annual maintenance checks. Refer to "Periodic Sensor Calibration" under the **System Maintenance** section in this manual for the calibration process.

TOM-2 MAIN Screen

INPUTS
O2% = absolute oxygen
    concentration (1 – 95%)
Vac Pres = vacuum
    pressure (0 – 29 in Hg)

O2 STATUS
IN RANGE (green) = O2 is in expected range
WARNING LEVEL (yellow) = O2 is at elevated
    levels, mitigation is activated
TOO HIGH (red) = O2 level is too high and will
    trigger O2 alarm if it persists

O2 OUTPUT
ALARM OFF (green) = O2
    alarm relay is closed
ALARM ON (red) = O2 alarm
    relay is open

Vacuum STATUS
N/A (yellow) = not used in MONITOR mode
IN RANGE (green) = vacuum pressure is in range
    for mitigation (MITIGATE mode only)
TOO LOW (red) = vacuum pressure is too low for
    mitigation (MITIGATE mode only)

TOM MODE
MONITOR = O2 monitoring only
MITIGATE = O2 monitoring and
    mitigation

TOM STATE
WARMING = sensors are
    warming up
READY = sensors are ready

Mitigation Valve OUTPUT
N/A (yellow) = not used in MONITOR mode
MIT VLV CLOSED (green) = mitigation valve is
    not flowing gas (MITIGATE mode only)
MIT VLV OPEN (yellow) = mitigation valve is
    flowing gas (MITIGATE mode only)

System Operation

System Configuration

The TOM-2B provides a touch screen display interface that allows the user to monitor system operations and adjust configuration settings as needed. The MAIN screen (as shown above) allows access to Settings, Calibrations, real-time data trending, and the O2 Alarm Reset by pressing MENU on the display. Always press MAIN once settings are viewed or modified to return to the main screen.

MENU Screen

Settings

Access to this screen is password protected to prevent unauthorized personnel from changing system settings after initial system installation.

The Settings screen (below) enables the operator to modify settings for the TOM-2 mode (monitor or mitigate), O2 warning and alarm limits, solenoid valve operation setpoints (TOM-2B only), and vacuum alarm limit (TOM-2B only).
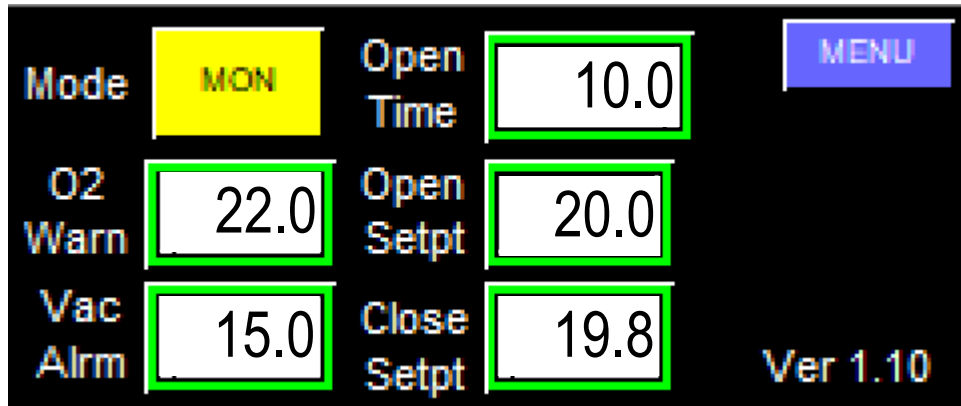
SETTINGS Screen

1. Monitor/Mitigate Mode - The system operates in monitor or mitigation modes. The Settings screen shows MON or MIT depending on the setting.
   a. Press MON (monitor mode) to change setting to MIT (mitigation mode); likewise, press MIT to change back to MON. The selected setting will remain active even after a power reset.
   b. In monitor mode, the system only monitors oxygen levels and provides O2 warning and alarm indications. In this mode, only the O2 sensor input is required and active.
   c. In mitigation mode (TOM-2B only), the system monitors oxygen and vacuum pressure levels and mitigates high O2% by opening a mitigating gas valve. In this mode, the O2 sensor input, vacuum pressure input, and solenoid valve output are required and active. Once selected, mitigation mode will remain selected even after a power reset.

2. Limits – This section describes the limits and recommended settings based on the type of facility the unit is installed in. All settings will remain active even after a power reset.
   a. O2 Warning
      i. Initial value for the warning is 22.0% O2 and can be adjusted by the operator. This setting can be modified by touching the value window (a pop-up window will appear to adjust the value; once a new value is input, press ENTER).
      ii. When the warning limit is exceeded (value is higher than limit), WARNING LEVEL in yellow is indicated under O2 STATUS on the MAIN screen; otherwise, it displays IN RANGE in green.
      iii. When the warning limit is exceeded, the O2 Warning relay output will remain ON (relay is open) until the O2 value drops below the limit. When this occurs, the O@ STATUS will display IN RANGE and the O2 Warning output relay will close.
   b. O2 Alarm
      i. The value for the alarm is set at 23.6% O2 as dictated by NFPA 99 and cannot be adjusted by the operator.
      ii. When the alarm limit is exceeded with persistence (value is higher than limit for a sustained period of time), the O2 OUTPUT ALARM ON in red is set on the MAIN screen; otherwise, it displays ALARM OFF in green.

      iii. When O2 ALARM ON is indicated, the O2 Alarm relay output will remain latched ON (relay is open) until the operator resets it.

      iv. To reset the O2 Alarm, select MENU and then press ALARM RESET. Then press MAIN to return to the main screen and verify that the O2 OUTPUT indicator is ALARM OFF in green.

c. Vacuum Alarm (TOM-2B, Mitigation mode only)

      i. This alarm is only used internally by the O2 mitigation algorithm in order to prioritize vacuum system pressure over O2 mitigation. If the vacuum system pressure ever falls below this minimum pressure limit, all O2 mitigation activity will be disabled until vacuum pressure returns to a value above the minimum limit. There is no relay output from the device for this alarm because the vacuum system controller already has such an alarm.

      ii. Initial value for the alarm is 15.0 in Hg and can be adjusted by operator. This setting can be modified by touching the value window (a pop-up window will appear to adjust the value; once a new value is input, press ENTER).

      iii. When the alarm limit is exceeded (pressure falls BELOW the limit), Vacuum STATUS on the MAIN screen indicates TOO LOW in red; otherwise, it displays IN RANGE in green. The indicator will automatically return to IN RANGE once the vacuum pressure is within limits.

d. O2 Mitigation (TOM-2B, Mitigation mode only)

      i. O2 Mitigation is only enabled when vacuum system pressure is above the Vacuum Alarm minimum limit (factory default setting is 15.0 in Hg). The operator can adjust mitigation valve Open Setpoint, Close Setpoint, and Open Time settings based on facility vacuum system design. These settings should be adjusted to provide sufficient time for the mitigation process to affect the oxygen levels and avoid an O2 alarm situation. The factory default settings have been evaluated under test and should be acceptable for use in most facilities.

      ii. The initial Open Time is set at 10 seconds. This setting can be modified by touching the value window (a pop-up window will appear to adjust the value; once a new value is input, press ENTER).

      iii. Initial Open Setpoint is 20.0% O2 and can be adjusted by operator. This setting can be modified by touching the value window (a pop-up window will appear to adjust the value; once a new value is input, press ENTER).

      iv. Initial Close Setpoint is 19.8% and can be adjusted by the operator. This setting can be modified by touching the value window (a pop-up window will appear to adjust the value; once a new value is input, press ENTER).

      v. Mitigation operation - when the Open Setpoint is exceeded (O2% value is higher than setpoint), MIT VLV OPEN in yellow is indicated on the MAIN screen; otherwise, it displays MIT VLV CLOSED in green.

         1. Solenoid valve output is activated for a time period specified by the Open Time setting.

         2. Once the Open Time expires and the O2% is confirmed to be below the Close Setpoint, the valve is closed.

         3. If O2% level remains above the Open Setpoint after the Open Time expires, the valve will remain open until the O2% level drops below the Open Setpoint AND the Close Setpoint.

4. If vacuum pressure level falls below the minimum vacuum level setting when O2 mitigation is active, the solenoid valve output will be immediately deactivated and remain deactivated until vacuum level rises above the minimum limit (plus 0.5 In Hg for valve on/off hysteresis).

e. O2 Monitoring
    i. The TOM-2 continuously monitors O2% levels against the warning and alarm limit thresholds.
    ii. If the system detects an O2% above the O2 Alarm limit for a sustained period of time, the system will open the O2 Alarm relay, sending an indication to the Master alarm panel if this relay output is wired to the facility panel. If this situation occurs, the facility should develop a procedure to physically monitor the vacuum system pumps, inspect the O2% reading on the TOM-2 and, if the reading is below the O2 alarm limit of 23.6%, attempt to reset the O2 alarm. Then contact the TOM-2 installation agency for further evaluation of the system to understand the cause and determine whether TOM-2 setting adjustments are required.

Sensor Calibration

Access to this screen is password protected to prevent unauthorized personnel from changing system settings after initial system installation.

CALIBRATION Screen
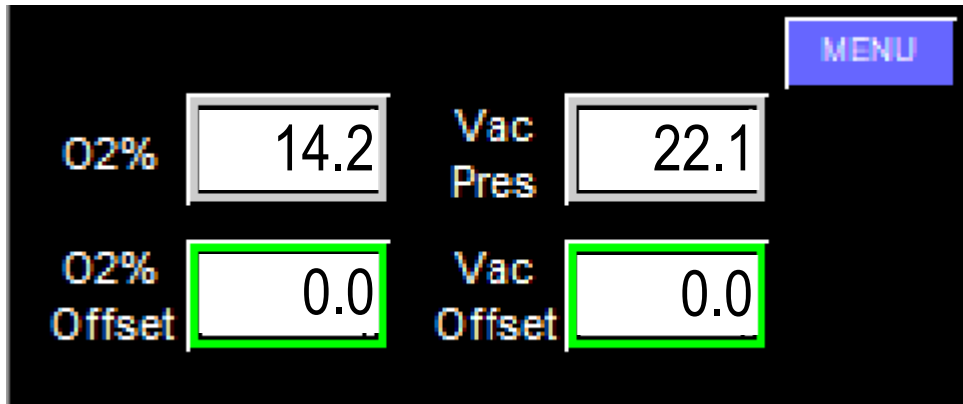
1. O2 Sensor Calibration
   This screen allows for O2 sensor calibration as part of regular TOM-2 system maintenance. Calibration should only be performed by qualified personnel trained by EMS Healthcare LLC.
   a. O2 sensor OFFSET can be adjusted up/down from default of 0.0

2. Vacuum Pressure Calibration
   This screen allows for vacuum pressure sensor calibration as part of regular TOM-2 system maintenance. Calibration should only be performed by qualified personnel trained by EMS Healthcare LLC.
   a. Vacuum pressure sensor OFFSET can be adjusted up/down from default of 0.0

O2 Alarm Reset

To reset the O2 Alarm, select MENU on the MAIN screen, then press ALARM RESET once the O2% reading is verified to be below the O2 alarm limit. Then press MAIN to return to the main screen and verify that the O2 ALARM OFF in green is indicated.

Data Trend

From the MAIN screen, press MENU and then press TREND to view O2% for the system in a graphical plot. The screen will show a graph of O2% data from the data log. After 60 seconds, the screen will revert back to the MAIN screen automatically. The operator can scroll through previous data using the arrows provided.

Data Logging

The TOM-2 system utilizes a real-time logging function that writes data directly to an attached thumb drive (provided with the unit) containing sufficient memory to record more than one year's worth of data. O2% and Vacuum Pressure data in engineering units are logged every ten (10) seconds to provide a time history of the vacuum system oxygen and pressure levels for review.

The data stored in the thumb drive can be reviewed by removing the thumb drive from the unit, inserting the drive into the USB port of a laptop computer, and importing the data as a CSV into an Excel spreadsheet. Some manipulation of the data may be required.
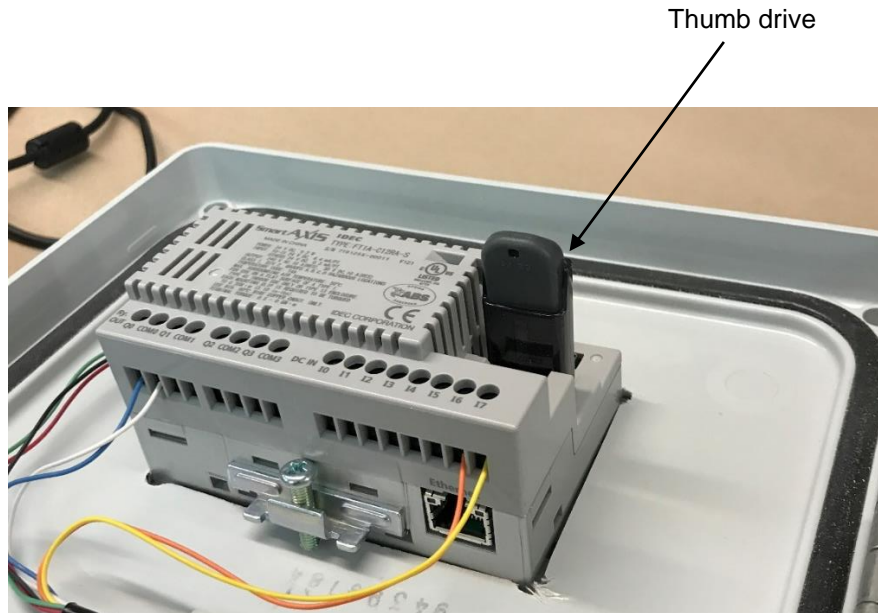
Thumb drive

System Maintenance

Annual Compliance Reporting

EMS Healthcare recommends downloading the time history log from the thumb drive on an annual basis to provide the facility a report of oxygen concentration compliance to the NFPA 99 requirement.

In support of this recommendation, EMS Healthcare will provide a new thumb drive to the local service agent or the facility for replacement of the existing thumb drive (around the anniversary of installation). The existing thumb drive should be sent to EMS Healthcare annually for data retrieval, evaluation, and producing a facility report.

Periodic Sensor Calibration

EMS Healthcare recommends checking the O2 sensor on an annual basis to verify sensor accuracy. This check can be conducted during the same visit when the time history log is downloaded from the unit. The sensor assembly comes equipped with a KF25 vacuum flange, quick-disconnect clamp, and a manual ball valve to facilitate easy removal from the facility vacuum system in order to perform this check.

To check the O2 sensor, first move the ball valve at the O2 sensor to full close in order to isolate the sensor from the vacuum system. Then disconnect the sensor using the quick disconnect clamp, being careful to collect the centering ring during removal. Leave the sensor in ambient air for at least 2 minutes and then verify the O2% is reading the same as the baseline reading taken at initial system startup (refer to Initial Power Application under System Installation). If the sensor is not at this value, adjust the O2 sensor offset value (refer to O2 Sensor Calibration under System Operation) to re-calibrate it.

Once the O2 sensor has been verified, it should be re-installed into the sensor port using the centering ring and quick-disconnect clamp. Be sure to move the ball valve back to full open after re-installing the sensor.

System Troubleshooting

O2 Concentration at Vacuum Pressure

The O2 sensor is designed to measure O2 concentrations relative to the ambient pressure at the time the sensor was manufactured. When exposed to lower pressures due to vacuum conditions, the sensor will count fewer O2 molecules and produce an O2 concentration relative to ambient pressure. While the fractional oxygen content in the ambient gas remains relatively constant, the O2 concentration being reported by the sensor will decrease at pressures lower than ambient and increase at pressures higher than ambient as it calculates absolute oxygen content relative to ambient.

Password Screen

To enter the password, use the arrow keys to move the cursor to the alpha-numeric character and then press "enter" to add the character to the sequence. Do this to enter every character in the sequence. Once the password has been entered, move the cursor to the "OK" key and press "enter" to accept the password. Once the password has been entered, all screens that require the password will be open to the operator. After 10 minutes of inactivity on the IDEC, the password-protected screens will require the password to be re-entered.

Changing limits to test the Warning and Alarm

To test the O2 Warning indicator and relay without access to the O2 sensor to adjust O2 levels, the O2 Warning limit setting can be adjusted in order to trigger an O2 Warning (see System Operations > Settings > 2.a O2 Warning for details). Note: in order to trigger the relay, the Mitigation Valve Close Setpoint (see System Operations > Settings > 2.d.iv for details) must also be adjusted in order for the relay to change state.

LOGA02 Data Table

LOGA02 Value	TOM-2 State	Not Applicable (Relay 3)	O2 Warning (Relay 2)	O2 Alarm (Relay 1)	Mitigation Valve (Relay 0)
7	Elevated O2 levels below the Warning limit, mitigation is active	0	1	1	1
6	Normal O2 levels, mitigation is not active	0	1	1	0
5	Alarm limit exceeded, O2 level is back to normal, mitigation remains active	0	1	0	1
4	Alarm limit exceeded, O2 level is back to normal, mitigation is not active	0	1	0	0
3	Warning limit exceeded, mitigation is active	0	0	1	1
2	*Not a valid state*	0	0	1	0
1	Alarm limit exceeded, mitigation is active	0	0	0	1
0	*Not a valid state*	0	0	0	0

Under normal conditions, a value of "6" is expected. During elevated oxygen conditions, a value of "7" and/or "3" is expected if mitigation demand is sufficient for the elevated levels of oxygen. If mitigation cannot keep up with the elevated oxygen levels, then a value of "1" or "4" or "5" may be recorded.

Since the O2 Alarm relay is latched, once it is set it will remain set. Therefore, once normal conditions return, a value of "4" will be recorded instead of "6" until the O2 Alarm is manually reset (see "O2 Alarm Reset")