CERTIFIER® FA PLUS
TEST SYSTEM

OPERATOR'S MANUAL

P/N 1980560, REVISION H
JULY 2013

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Caution

TSI flowmeters are **not** medical devices under FDA 510(k) and in no situation should be used for human measurements.

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b. Pumps are warranted for hours of operation as set forth in product or operator's manuals;
c. Parts repaired or replaced as a result of repair services are warranted to be free from defects in workmanship and material, under normal use, for 90 days from the date of shipment;
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Trademarks

Certifier® is a registered trademark of TSI Incorporated.

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1 Introduction

The Certifier® Flow Analyzer (FA) Test System is a multi-functional pneumatic tester designed specifically for the medical industry. Specific measurements for ventilator testing are programmed and include flows, volumes, pressures, oxygen concentration, and breath timing. The Certifier® FA Plus Test System is designed for hospital, home care, field service, and laboratory settings.

Certifier® FA Test System components include:

- **Interface Module:**
  The keypad and touch screen display allow you to select test measurements and units for display. The Interface Module connects to the High or Low Flow Module.
- **High Flow Module:**
  Measures air, oxygen (O_2), nitrogen (N_2) and carbon dioxide (CO_2) flow rate over a range of 0 to 300 standard liters per minute (0 to 40 standard L/min for CO_2). A 150 PSI (10 Bar) gauge transducer, a barometric pressure transducer, and a 150 cm H_2O differential pressure transducer are also in the High Flow Module.
- **Low Flow Module:**
  Measures air, O_2, N_2, CO_2 and nitrous oxide (N_2O) flow rate over a range of 0.01 to 20 standard L/min with greater accuracy than the High Flow Module at low flow rates.
- **Oxygen Sensor:**
  Used with the High Flow module, allows the High Flow Module to measure O_2 concentration and other measurements for any mixture of air and O_2.

You can connect or disconnect the flow modules and oxygen sensor at any time during normal operation without interrupting the operation of the instrument.

Lithium-Ion batteries or an AC adapter can be used to power the test system.

WARNING

- To avoid the risk of explosion, do ***not*** use in the presence of flammable anesthetic gases.
- Only TSI qualified and trained service technicians are authorized to service the Certifier® FA Test System.

Caution
▪ To avoid inaccurate test readings, do ***not*** obstruct tubing or inlet or exhaust ports, and always use dry gas. ▪ To avoid damage to the Certifier® FA Test System components, always use bacteria filters upstream of the flow modules, and always cap flow module ports when not in use. ▪ The Certifier FA Plus is ***not*** a medical device under the Medical Device Directive or FDA 510(k) and in no situation should be used for human measurements.

1.1 Parts List

Carefully unpack the test system components from the shipping container. Check the individual parts against the packing list and notify TSI immediately if anything is missing or damaged. Table 1 summarizes the Certifier® FA Test System components and part numbers shown in Figure 1, 2, and 3.

Figure 1. Certifier® FA Test System High Flow Standard Kit (4080)

Table 1. Certifier® FA Test System Parts List

Item No.	Description	Replacement Part Number	Quantity
High Flow Standard Kit (part number 4080)			
1	Interface Module[a]	4088	1
2	High Flow Module[b]	4081	1
3	Bacteria filter, 22-mm × 22-mm male/female, for use with High Flow Module	1602341	1
4	Adapter, 22-mm × 6-mm (for interfacing High Flow Module to Low Flow filter)	1102091	2
5	Adapter, 15-mm ID × 22-mm OD	1102093	1
6	Airway pressure fitting with screen	1611330	1
7	Pressure tubing, silicone, ⅛-in. ID × ¼-in. OD × 48-in. (3.2 mm ID × 6.4 mm OD × 122 cm)	3002053	1
8	Velcro strap for use on High Flow Module	2913133	1
9	Adapter, high pressure port	1611221	1
10	Cable, flow module	1040219	1
11	Soft carrying case	1319289	1
12	Power supply 90/260 VAC to +12 VDC	2613237	1
13	Stylus	1319420	2
14	Certifier® FA Test System Operator's Manual	1980560	1
15	Battery—Lithium-Ion SBL-160	1208056	1
16	Connector, four types: AC NORTH AM./IEC320, right angle AC EURO/IEC320, right angle AC UK/IEC320 fuse, right angle AC AUST/IEC320, right angle	 1302013 1302014 1302015 1302025	 1 1 1 1
17	SD flash memory card	1500108	1
18	Protective Rubber boot for Interface module	6001503	1

Item No.	Description	Replacement Part Number	Quantity
19	Computer Cable—USB standard A to mini B	1303754	1

[a] If ordering a 4088 for replacement, items 10 through 19 are included.

[b] If ordering a 4081 for replacement, items 3 through 9 are included

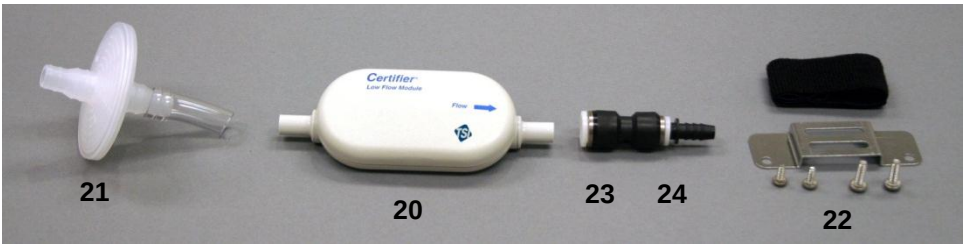

Figure 2. Certifier® FA Test System Low Flow Module Kit (4082)

Item No.	Description	Replacement Part Number	Quantity
Low Flow Module Kit (optional—part number 4082)			
20	Low Flow Module	4082	1
21	Bacteria filter, for use with Low Flow Module	1602342	1
22	Mounting bracket (includes bracket, screws, and Velcro strap)	1040044	1
23	Coupling, ⅜ inch tube	1601180	1
24	Adapter, ⅜ inch tube to ⅜ inch barb	1601179	1

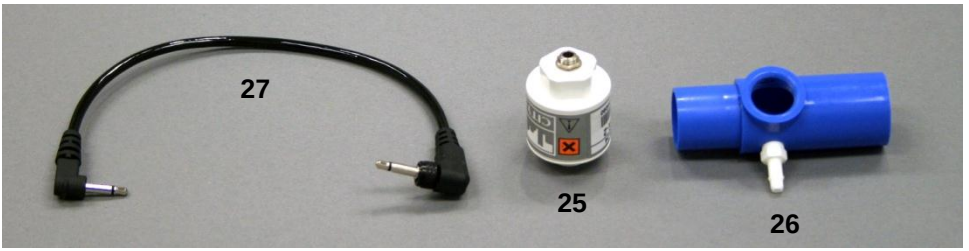

Figure 3. Certifier® FA Test System Oxygen Sensor Kit (4073)

Item No.	Description	Replacement Part Number	Quantity
Oxygen sensor kit (optional—part number 4073)			
25	Oxygen sensor	2917019	1
26	Threaded tee	1313118	1
27	Oxygen sensor cable	1303741	1

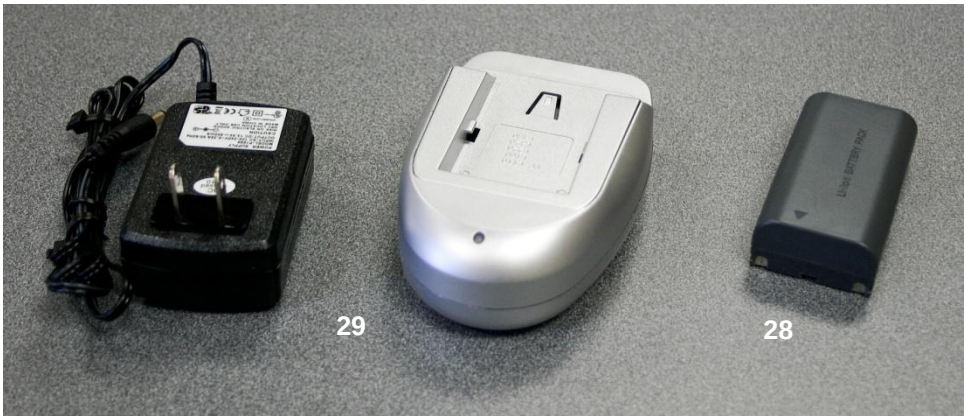

Figure 4. Certifier® FA Test System Extra Battery and Charger Kit (1208061)

Item No.	Description	Replacement Part Number	Quantity
Extra Battery and Charger Kit (optional kit – part number 1208061)			
28	Battery—Lithium-Ion SBL-160	1208056	1
29	Battery Charger kit	1208059	1
Other accessories (optional)			
	Printer Cable—USB mini A to standard B	1303860	

1.2 Glossary

These labels, terms, and symbols appear on the Certifier® FA Test System:

Refer to manual: see *Certifier® FA Test System Operator's Manual* for important information.

CE marking of European Conformity for the Low Voltage Directive (LVD) and the Directive for Electromagnetic Compatibility (EMCD).

WEEE Directive Label (Waste Electrical and Electronic Equipment). *(Item must be recycled properly.)*

1.2.1 Symbols on Display

Warning symbol. Touch symbol for explanation.

Flow module is working in unidirectional mode. The module is not detecting a significant amount of negative flows. When testing ventilators, unidirectional flow is used when the flow module is connected to the To Patient line

Flow module is in bi-directional flow mode. For ventilators bi-directional flow is used when the module is between the Y fitting and the test lung.

Battery status symbol. This symbol will indicate how much the battery charge is left. When no bars are showing instrument will shut off within minutes.

Battery charging symbol.

Start graph or start displaying data on main parameter screen.

Pause graph or pause data being displayed on main parameter screen

See Available Measurement Parameters in Table 3 for definitions of measurement symbols and abbreviations that appear on the Certifier FA+ display.

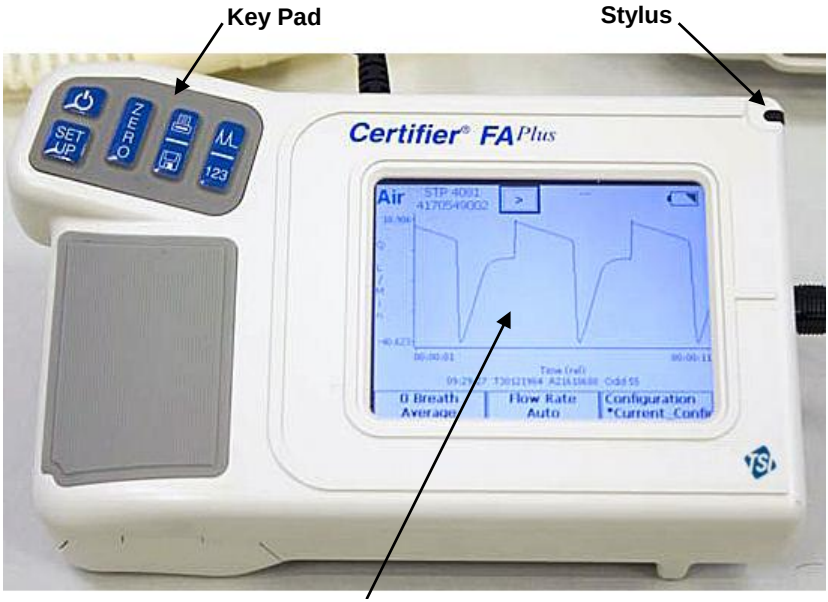

Figure 5. Interface Module

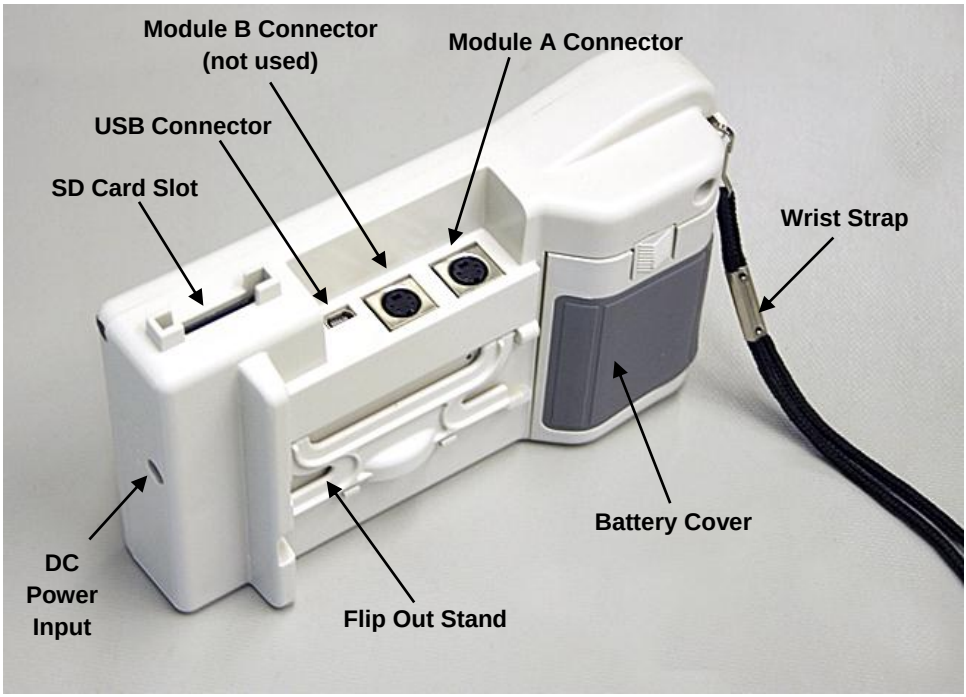

Figure 6. Back of Interface Module

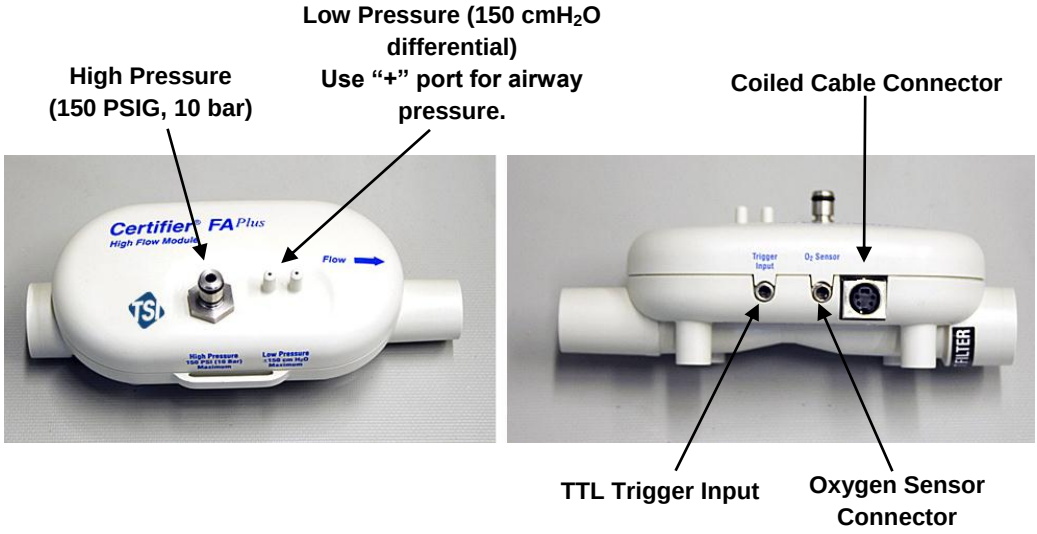

Figure 7. High Flow Module
(arrow on module indicates positive flow direction)

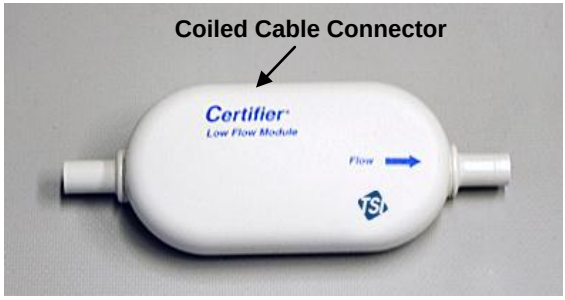

Figure 8. Low Flow Module

Figure 9. Oxygen Sensor Kit

2 Setup and Operation

Follow these steps to set up the Certifier® FA Test System:

Caution
To avoid damage to the Certifier® FA Test System components, ***always*** use bacteria filters upstream of the flow modules, and ***always*** cap flow module ports when not in use.

1. Install battery if not already installed. Connect AC adapter to DC power source connector if desired. The battery will charge in the instrument when the AC adapter is plugged in. Fully charge the battery overnight before using with battery alone.
2. Install SD flash memory card into card slot on top of the interface module. This step is necessary only if planning to log data.
3. Connect the Interface Module to a flow module (Figure 10). To remove the cable, pull its locking connector (not the cable) from the Interface Module.

Figure 10. Connecting the Interface Module to a Flow Module

Refer to the manufacturers test procedure for the device under test for specific instructions on where to connect the Certifier® FA Plus flow module. The manufacturer of the device under test will also specify which operating parameters to test.

4. Install the flow module into the test circuit. Align the flow direction arrow on the flow module with the positive direction of flow through the circuit; for ventilator testing the arrow should point towards the test lung or away from the “To Patient” port on the ventilator.

Figure 11. Installing a Flow Module into the Circuit for Measuring Bi-directional Flow
(flow direction Arrow should be towards test lung)

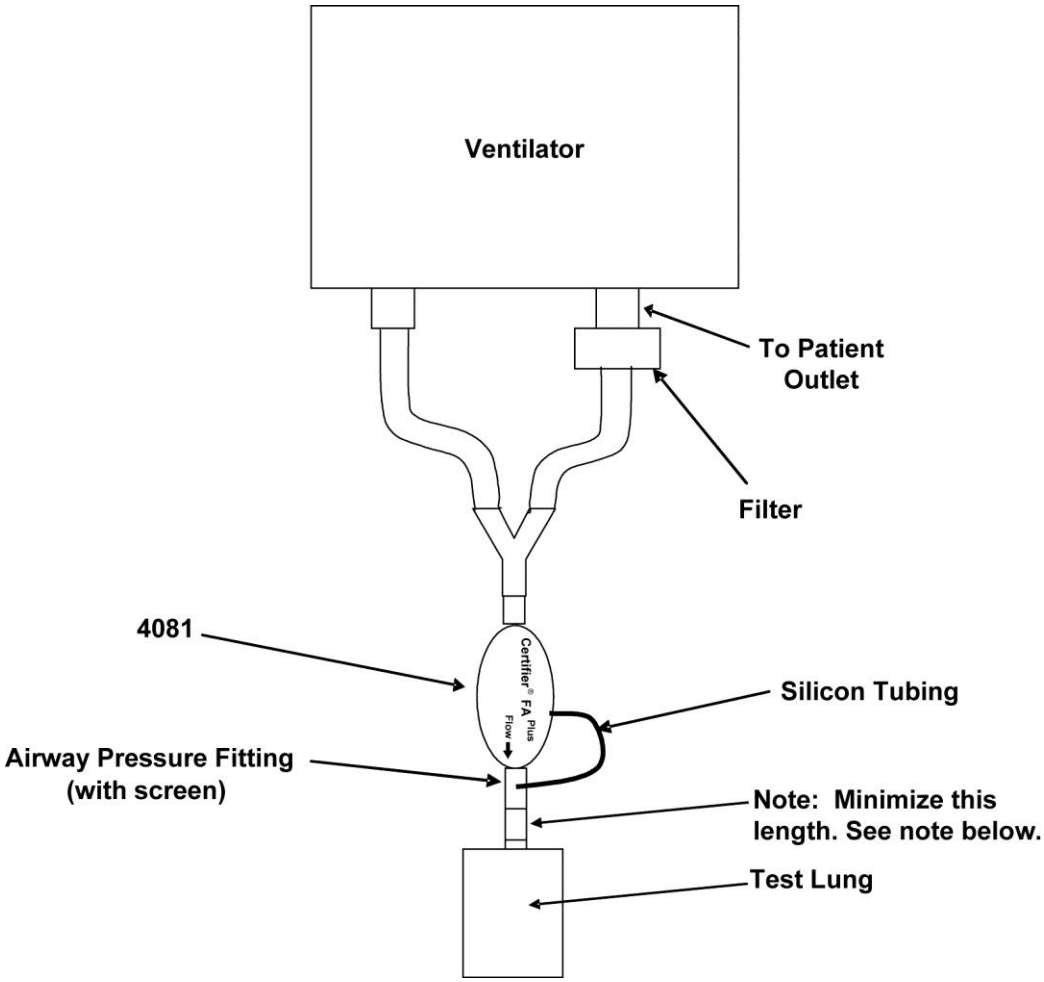

Figure 12. Test Circuit for Bi-Directional Flow

Note: If using a test lung with a built in restrictor or a separate restrictor, place the airway pressure fitting at least 15 cm of the 22 mm tubing between the restrictor and the flow module. If this is not done, the flow direction sensor may not work properly.

The low flow module is used for testing oxygen concentrators and other low flow devices. It is not designed for testing ventilators.

The low flow module includes a push-to-fit tube fitting. To install, push tubes into coupling. To remove fittings, press or pry ring towards the coupling body with a small screwdriver while pulling coupling away from flow module.

Figure 13. Removing Coupling

2.1 Keypad Functions

Figure 14. Interface Module Keypad

Table 2. Keypad Functions

Key	Primary Function
	**On/OFF** key
	**Zeroing Key**—Press this key to zero the high and low pressure transducers.
	**Print/Save Key**—Press this key to print and/or save data. See Print/Save section (pg. 29) in this manual for more information.
	Press this key to switch between the Parameter Screen and Graph Screen.
	Press this key to perform setup on the instrument.

2.2 Power up

If the device under test is running and creating flow or pressure, temporarily remove the flow module from the test circuit during power up. This allows the flow direction sensor on the high flow module to auto calibrate.

Press the **I/O (on/off)** key on the Interface Module to power up the Certifier® FA Plus Test System (the Interface Module powers all of the attached Certifier FA Test System components). At power up, the Interface Module shows information in this sequence below. After this, return the flow module into the test circuit.

1. Logo screen appears on display for several seconds.
2. One of two types of screens will appear on the display: **Graph Screen** or **Parameter Screen** (see Figures 15 and 16).
3. Wait 1 minute for pressure transducers and flow sensor to warm-up.
4. Perform the pre-test calibrations described in section 2.4.
5. Perform test per the device manufactures procedure (or other appropriate procedure).

If the AC adapter is plugged into the instrument, the battery charging symbol  will appear on the display.

2.3 Display Navigation

The main two screens are the Parameter Screen and the Graph Screen.

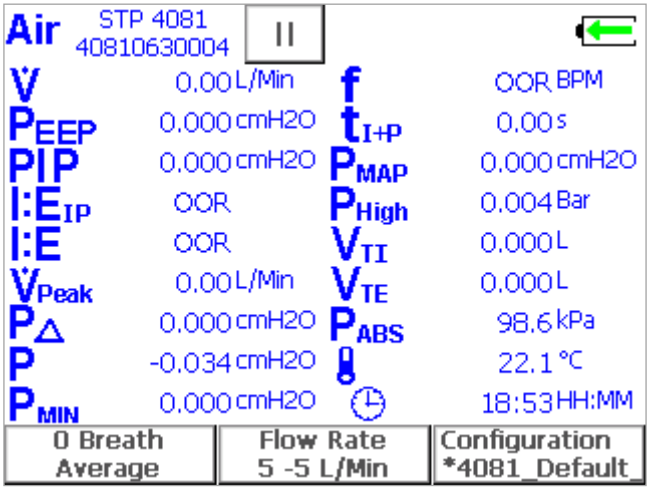

Figure 15. Example of Parameter Screen

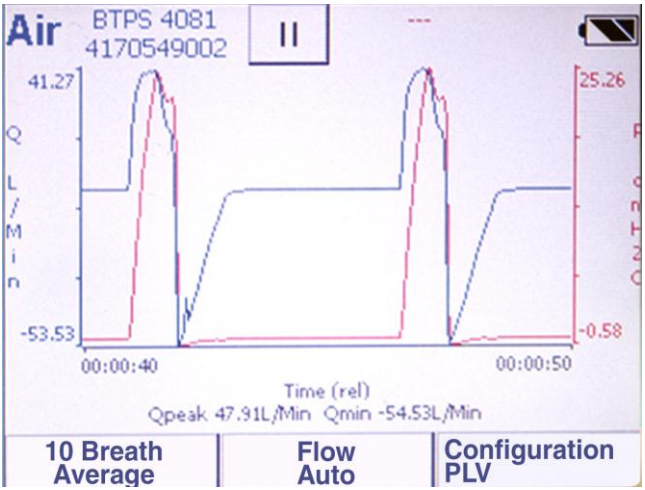

Figure 16. Example of Graph Screen

By touching on the active areas of the Parameter Screen, you can change the configuration of the display by choosing which parameters to monitor, units of measure, gas calibration, gas conditions, averaging, and triggering. You can also save the display configuration to a file or load a previously saved configuration.

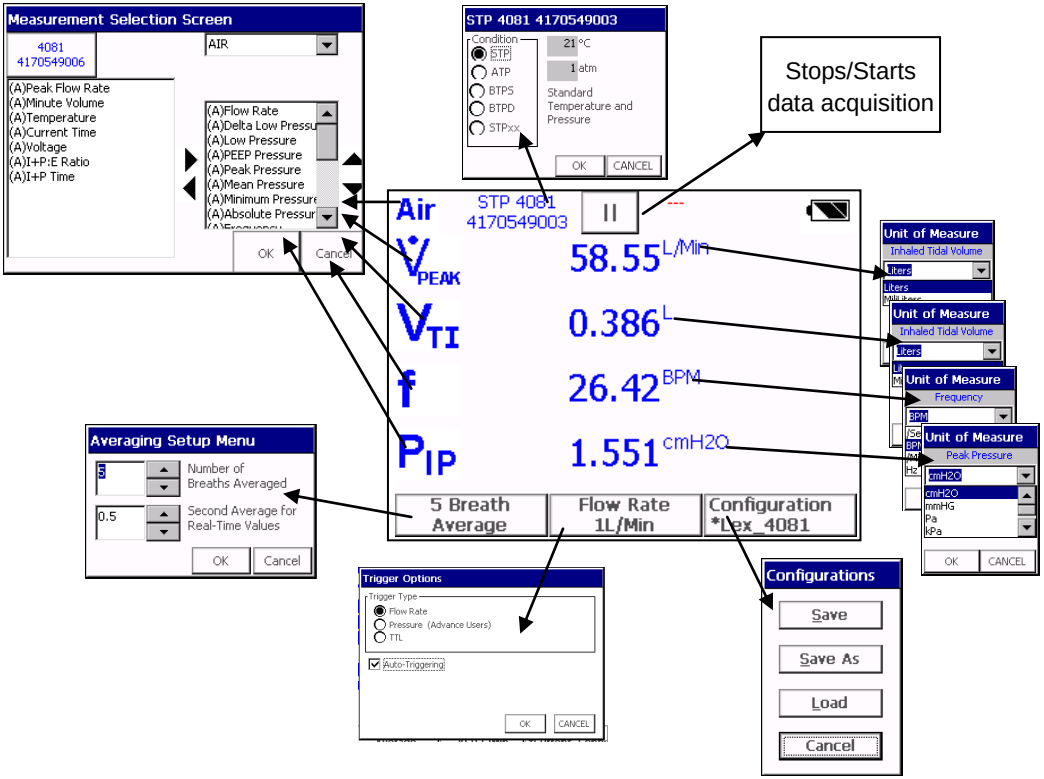

Figure 17. Parameter Screen Features

By touching on the active areas of the Graph Screen, you can change the configuration of the display by choosing which parameters to plot on the Graph, units of measure, gas calibration, gas conditions, averaging, triggering, x and y axis scale. You can also save the display configuration to a file or load a previously saved configuration.

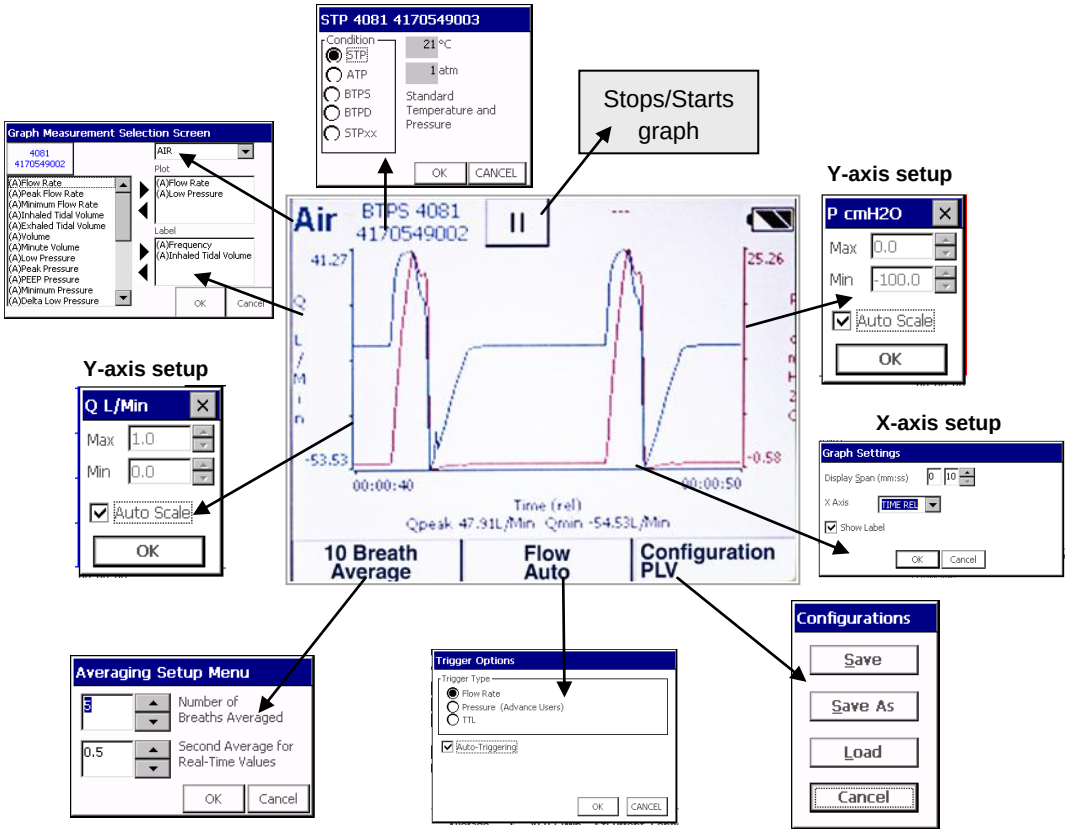

Figure 18. Graph Screen Features

2.3.1 Measurement Selection

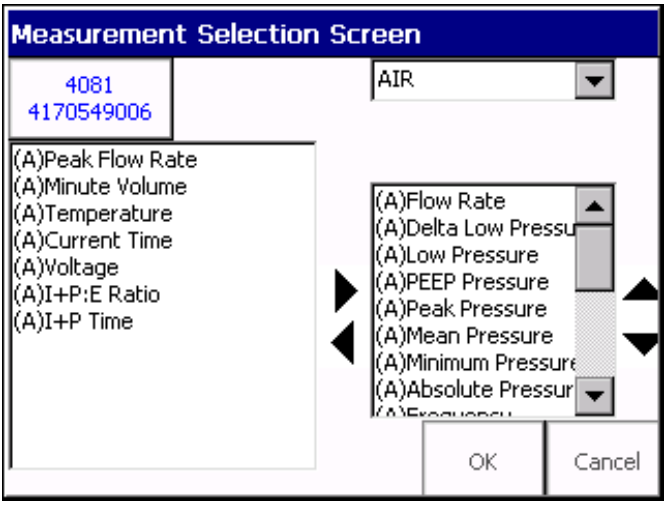

Figure 19. Measurement Selection Screen

- To add a parameter to the Parameter Screen, touch the parameter and then touch the right direction arrow. The available parameters change depending on what module is attached.
- To remove a parameter from the Parameter Screen, touch the parameter and then touch the left direction arrow.
- To move a parameter higher on the Parameter Screen, touch the parameter and then use the up and down direction arrows.
- To change the gas calibration used, touch the gas dropdown list and select the desired gas.

Note: If the gas selection Air/O_2 Mixture is selected but no oxygen sensor is plugged into the Model 4081 high flow module, then the high flow module will use the internal air calibration only. No corrections for oxygen concentration will be made if the oxygen sensor is not plugged into the flow module.

2.3.2 Graph Measurement Selection

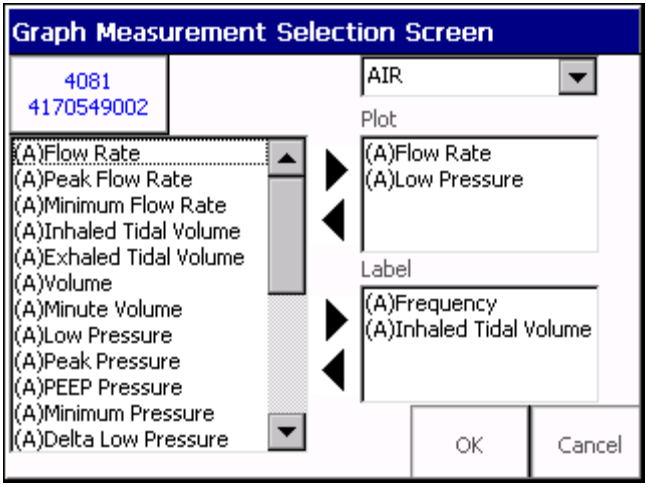

Figure 20. Graph Measurement Selection Screen

- To add a parameter to Graph, touch the parameter on the left and then touch the top right direction arrow. Only two parameters can be graphed at one time. The available parameters change depending on what module is attached.
- To remove a parameter from the graph, touch the parameter and then touch the top left direction arrow.
- To change the gas calibration used, touch the gas dropdown list and select the desired gas.
- To add a parameter to the label section below the graph, touch the parameter and then touch the bottom right direction arrow. Only four parameters can be in this section.
- To remove a parameter from the Parameter Screen, touch the parameter and then touch the bottom left direction arrow.
- After clicking **OK**, a prompt will appear to enter the units of measurement.

Note: Up to two parameters may be graphed simultaneously; whereas up to four parameters may be viewed simultaneously on the Graph page.

2.3.3 Available Measurement Parameters

Table 3. Parameters (parameter list changes depending on module attached)

$\dot{V}$	Flow Rate. "Q" is used on the Graph Screen.	P_{High}	High pressure transducer (4081 only)
$\dot{V}_{Peak}$	Peak Flow Rate—Peak Inhaled Flow Rate. "Qpeak" is used on the Graph Screen.	P_{ABS}	Absolute pressure in flow tube. If flow tube open to atmosphere, then this is also the **barometric pressure**
$\dot{V}_{MIN}$	Minimum Flow Rate—In Bi-Directional Mode this is the Negative of the Peak Exhaled Flow Rate. "Qmin" is used on the Graph Screen.	O_2	Oxygen concentration (with both 4081 and 4073 only)
V_{TI}	Inhaled tidal volume		Temperature of gas (accurate for flows above 5 L/min)
V_{TE}	Exhaled tidal volume (4081 only)	f	Frequency—Breath rate
V	Real-time volume (graphing only)	t_I	Inspiratory time
MV	Inhaled minute tidal volume	t_{IP}	Inspiratory pause time (4081 only)
P	Low pressure transducer—Airway pressure (4081 only)	t_{I+P}	Inspiratory time including the pause time
PIP	Peak Inspiratory pressure (4081 only)	t_E	Expiratory time
P_{EEP}	Peak End Expiratory Pressure (4081 only)	I:E	I to E ratio
P_{MAP}	Mean Airway Pressure (4081 only)	$I:E_{IP}$	I to E ratio which includes inspiratory pause time
P_{MIN}	Minimum low Pressure (4081 only)		Time of day
P_{Δ}	Delta low pressure—Delta airway pressure (4081 only)		

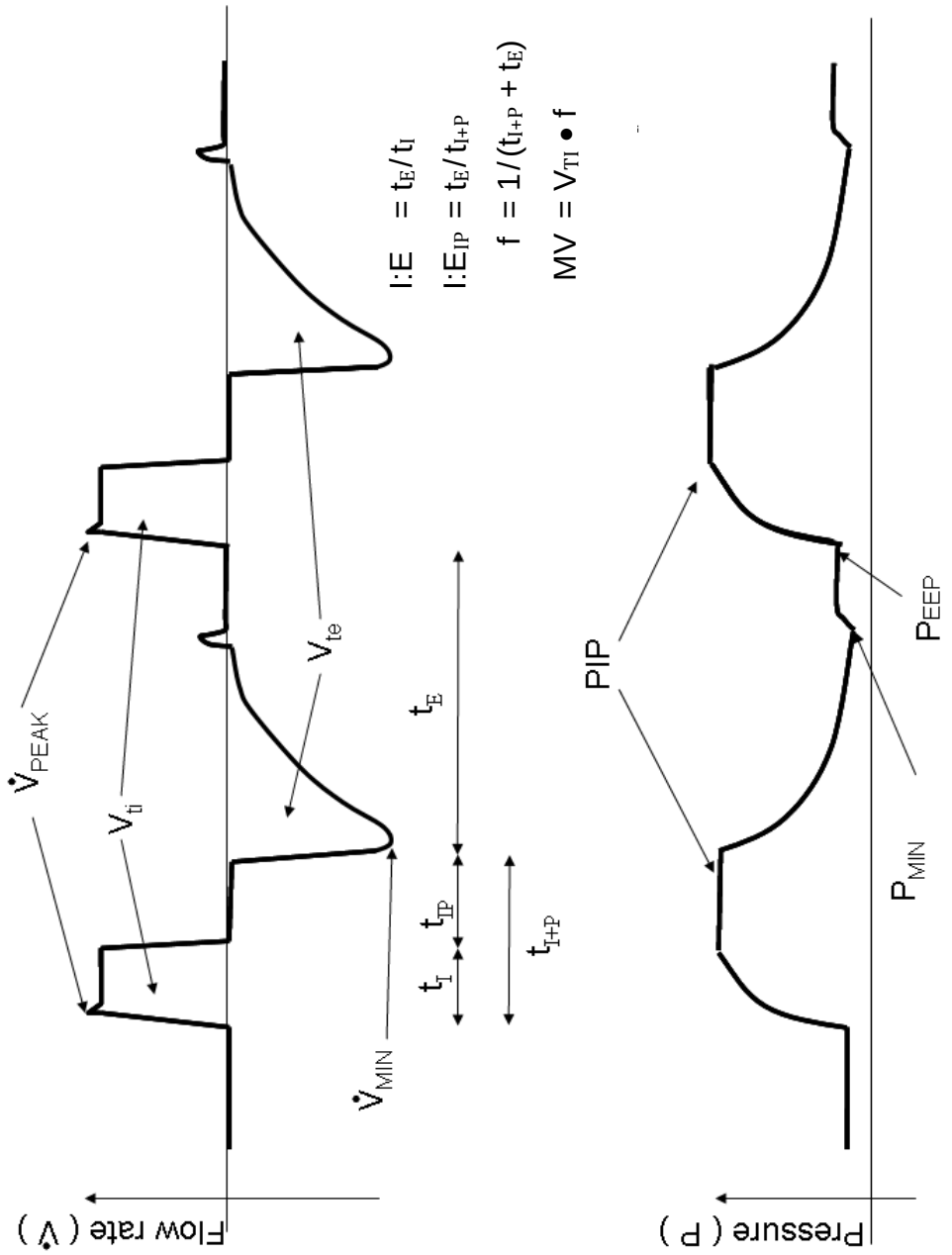

Figure 21. Parameter Definitions

2.3.4 Gas Conditions Selection Box

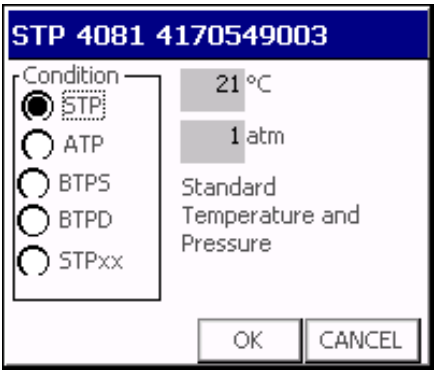

Figure 22. Gas Conditions Selection Box

STP	**Standard Temperature and Pressure**. The gas flow rate and volumes are displayed in terms of what the gas flow rate and volume would be if the gas was 21°C and 1 atmosphere (101.3 kPa) of pressure.
ATP	**Actual Temperature and Pressure**. The gas flow rate and volumes at the actual temperature and pressure of the gas.
BTPS	**Body temperature and Pressure Saturated**. The gas flow rate and volumes are displayed in terms of what the gas flow rate and volume would be if the gas was changed to 37°C, the actual pressure, and also saturated with water vapor.
BTPD	**Body temperature and Pressure Dry** The gas flow rate and volumes are displayed in terms of what the gas flow rate and volume would be if the gas was changed to 37°C, but maintaining the actual pressure.
STPxx	**User defined Standard Conditions**. The gas flow rate and volumes are displayed in terms of what the gas flow rate and volume would be if the gas was at the conditions entered in the boxes to the right.

2.3.5 Averaging Setup Menu

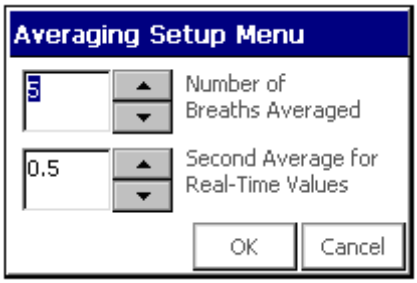

Figure 23. Averaging Setup Menu

Number of Breaths Averaged	All breath parameters are averaged over the selected number of breaths.
Second Average for Real-Time Values	All displayed transducer measurements are averaged over the selected number of seconds. Transducer measurements include: flow, low pressure, high pressure, absolute pressure, oxygen concentration, and temperature.

2.3.6 Breath Trigger Types

This screen defines how the start of the inspiratory breath cycle and the expiratory breath cycle are detected. Under most circumstances, it is recommended that the auto-trigger be used.

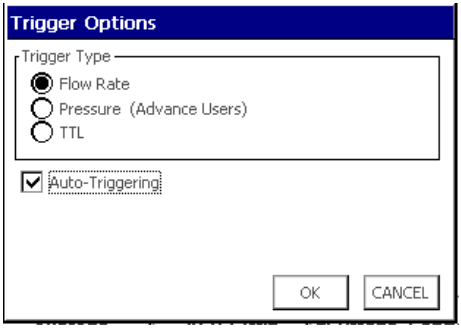

Figure 24. Trigger Options Menu

Flow Rate	Start and end of the breath is determined by the specified flow rate. If Auto-Triggering is selected, instrument tries to determine trigger levels. In some cases you may need to manually select the flow rates by looking at the flow waveform on the Graph Screen.
Pressure	Start and end of the breath is determined by the specified pressure levels. Positive slope changed through the first value is used for the start of inspiratory and a negative slope through the second value is used for the start of expiratory. ***Note**: This trigger type is intended to give advance users additional setup options for special circumstances, such as achieving basic breath measurements from high frequency ventilators or other setups in which flow rate or auto triggering are non-ideal.*
TTL	Start and end of the breath is determined by a TTL voltage signal given at the connector on the High Flow Module labeled “Trigger Input”. This is only available for the 4081 High Flow Module. The connector is a 3.5 mm mono audio jack plug.

2.3.7 Flow Triggering

If auto-triggering is not providing reasonable results, consider using either manual flow or manual pressure triggering. To use manual flow triggering, select the flow radio button and uncheck the "Auto-Triggering" checkbox. Similarly, to use manual pressure triggering, select the pressure radio button. For a breath to be detected, trigger settings must be set appropriately for the waveform of interest. There are two suggested methods for determining the appropriate start and end trigger values: 1) switch the Certifier FA Plus Test System to the graphing screen and observe the flow or pressure readings at the start and the end of inspiration and 2) observe the flow and pressure wave form from the ventilator being tested. For robust flow and pressure triggering always set the "End Trigger" level lower than the "Start Trigger". For example, a manual flow trigger setting may be +5 L/min for a start trigger and -5 L/min for an end trigger setting. These numbers can be optimized based upon your specific application.

2.3.8 Saving/Loading Configurations

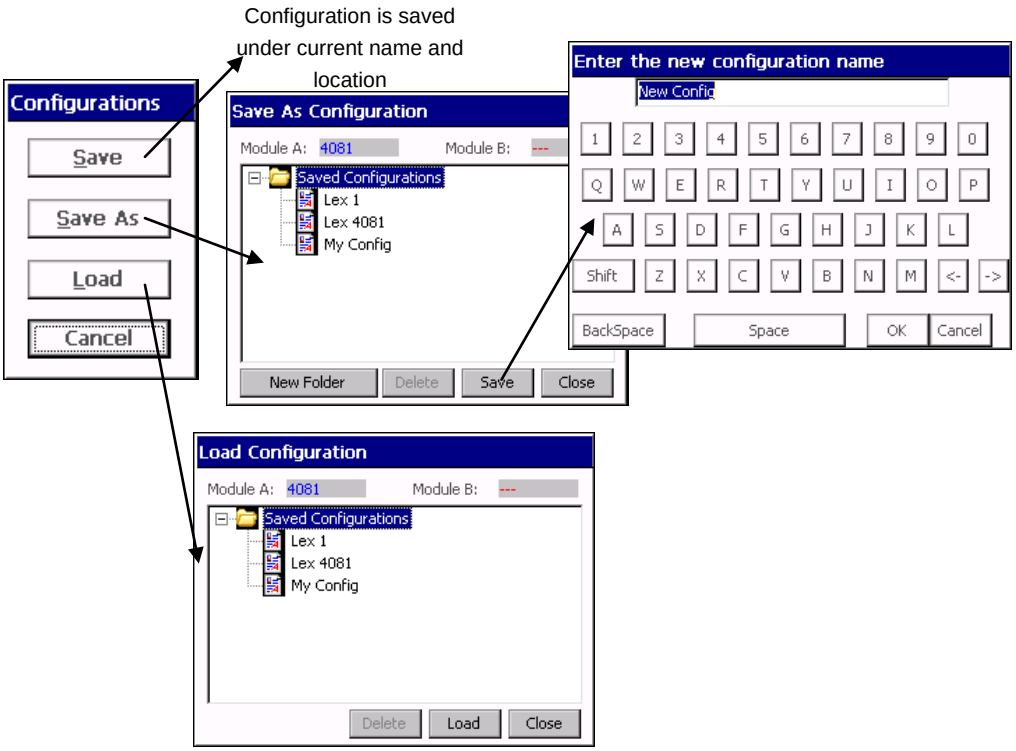

Figure 25. Configuration Save Screen

Configuration of the values displayed, gas, conditions, triggering, and graph setup can be saved and recalled. This allows the user to save configurations for different equipment.

See section 2.3.10.1 to learn how to transfer configuration files from one instrument to another using the SD memory card.

2.3.9 Print/Save Button

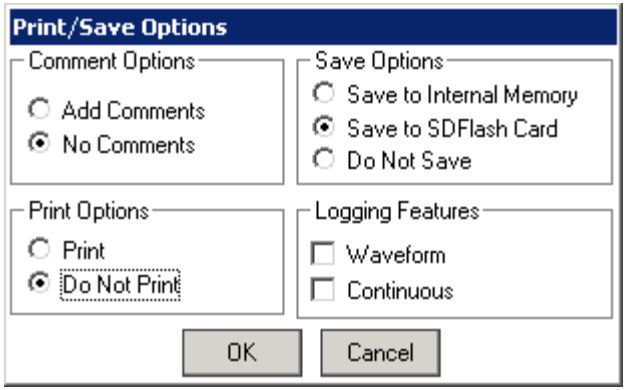

Figure 26. Print/Save Options Screen

If the **Print/Save** button is pressed while viewing the Parameter Screen, the "Print/Save Options" screen will appear. By selecting the various options on this screen you will be able to:

- Print the current data record without saving to a file.
- Print the current data record and also save it to a file in a single operation.
- Save the current data record to a file without printing.
- Select **Waveform** logging function. This feature saves 15 seconds of "raw" flowmeter data at a rate of 1 millisecond/reading to a file (requires an SD Flash memory card).
- Select **Continuous** logging function. This mode logs the Parameter Screen data into a file at intervals of approximately 1 second until you command the logging to stop (requires an SD Flash memory card).

When printing or saving, you can add custom comments to your data by selecting the **Add Comments** option. When that option is selected, an on-screen keyboard appears, allowing you to enter your comment text.

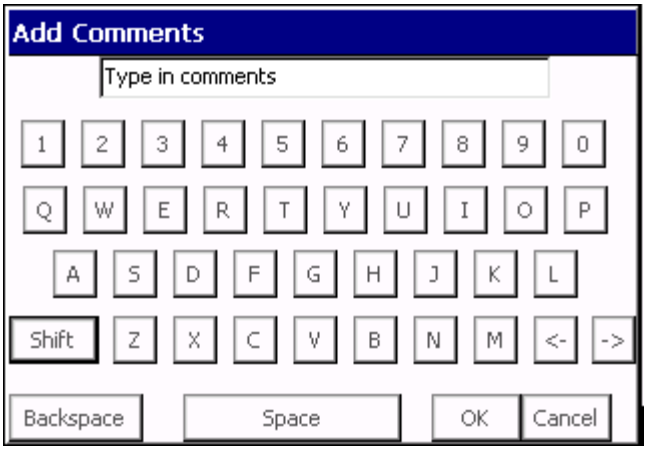

Figure 27. Add Comments Screen

If the **Print/Save** button is pressed while viewing the Graph Screen, you will be able to Save the currently displayed Graph data to a file to either the built-in Internal Memory or to an SD Flash card inserted into the SD Card slot. You cannot print the Graph or the Graph data and you cannot print or save a screen shot of the graph.

To retrieve data from the Certifier test system, simply connect the device to a PC using an USB standard A to mini-B cable. Use the Setup function “Select Mass Storage Target” (see section 2.3.10 “Setup Key”) to choose whether the host PC will access the Certifier test system’s built-in memory, or an SD Flash card inserted in the card slot of the Certifier test system.

All data files exported from Certifier test system use the ASCII character set and "comma separated value" (CSV) format. This is a format that most spreadsheet and database applications can import. See Advanced Features Menu for selecting file delimeters other than commas.

2.3.9.1 Waveform Logging

The Waveform Logging feature logs 15 seconds of raw flowmeter data into a file on a SD Flash card. The logging rate is about once per millisecond. The data is exported into “comma separated value” (CSV) format, readable by many common spreadsheet and database applications. See Advanced Features Menu for selecting file delimeters other than commas.

The Waveform logging feature requires an SD Flash card.

To initiate Waveform logging:

- Press the **Print/Save** button on the Certifier test system keypad.
- Select **Waveform** from the **Logging Features** section.
- You may choose to **Add Comments** if you would like to annotate the data.
- Click **OK**, add comments (if selected) and name the file.
- The Certifier test system will collect 15 seconds of flowmeter waveform data and then save it into the file.

Access the data by connecting the Certifier test system to a host computer via USB, or by removing the SD Flash card from the Certifier test system and inserting it into a card reader attached to a host computer.

2.3.9.2 Continuous Logging

The Continuous Logging feature will log snapshots of the same data being displayed on the Certifier Parameter Screen and log it into a file on an SD Flash card. The logging rate is once per second. Only data displayed on the Certifier Parameter Screen will be logged. See section 2.3 on how to add or remove parameters. The data is exported into "comma separated value" (CSV) format, readable by many common spreadsheet and database applications. See Advanced Features Menu for selecting file delimeters other than commas.

The Continuous logging feature requires an SD Flash card.

To initiate Continuous logging:

- Press the **Print/Save** button on the Certifier test system keypad.
- Select **Waveform** from the **Logging Features** section.
- You may choose to **Add Comments** if you would like to annotate the data.
- Click **OK**, add comments (if selected) and name the file.
- The Certifier test system will continue to log data until the **Print/Save** button is pressed again or until the SD Flash card fills up.

Access the data by connecting the Certifier test system to a host computer via USB, or by removing the SD Flash card from the Certifier test system and inserting it into a card reader attached to a host computer.

Note: If the pause button was pressed prior to continuous logging, a slight delay may be noticed in the start of the data acquisition.

2.3.10 Setup Key

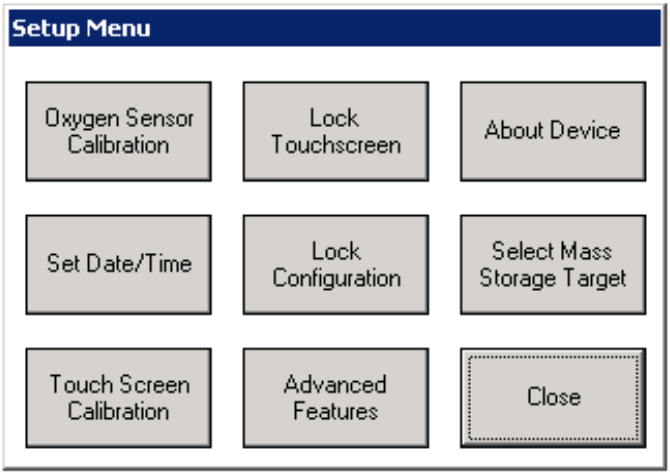

Figure 28. Setup Menu

- **Oxygen Sensor Calibration**
  See required pre-test section of this manual.
- **Set Time/Date**
  Sets the current time and date.
- **Touch Screen Calibration**
  Calibrates the touch screen of the interface module. Follow the instructions on the display.
- **Lock Touch Screen**
  Disables the touch screen once the Setup Menu is closed. To enable the touch screen, press the Setup button.
- **Lock Configuration**
  Disables the saving of configurations. The user will be able to load existing configurations and change the current configuration, but not save it.
- **Advanced Features**
  See section 2.3.10.1 for a complete list of advanced features which can be accessed through this menu.
- **About Device**
  Displays information about the Certifier Interface Module and any connected flow module.

- **Select Mass Storage Target**
  When the Certifier test system is connected to a host computer via USB interface, it appears to the host as a "mass storage" device, similar to a "memory stick" or “thumb drive”. This function allows you to select whether the host can access the Certifier's Internal Memory or an SD Flash memory card. The Certifier test system supports SD flash cards up to 1 GB in size. Restart the Certifier whenever a change if made when selecting between internal flash RAM and SD flash card.

2.3.10.1 Advanced Features

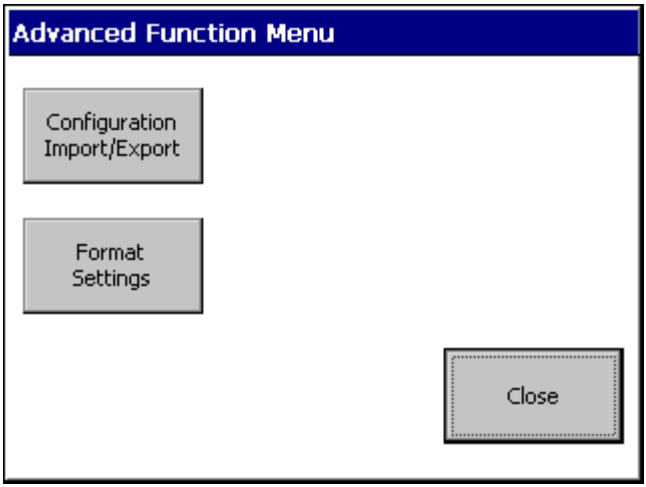

Figure 29. Advanced Function Menu

2.3.10.1.1 Configuration Import/Export

This feature enables you to both download and upload configuration files to and from the SD card. This is convenient when multiple Certifier FA+ units are in use where the configuration files from one unit can be transferred to multiple Certifier units. This eliminates the need to generate configuration files for each instrument.

This feature requires an SD card to be inserted in the instrument. If it is desired to view the configuration file on a PC, be sure the Select Mass Storage Device setting is configured to SD card as mentioned in section 2.3.10.

Press **Export** button to export the configuration file to the SD card.

Press **Import** to import the configurations from the SD card.

Notes about exporting configuration files:

- All data is saved to a single file called CertifierConfigurations.dat. If this file already exists on the SD card, it will be overwritten each time the Export command is executed.
- It is not possible to generate a user-selectable filename for the exported configurations.

Notes about importing configuration files:

- Importing a configuration which already exists under the same name in the Certifier memory will cause the configuration in memory to be overwritten.
- Importing a configuration file will not erase existing configuration files which already exist in memory but under a different configuration name.
- This feature is not designed for creating configuration files on a PC. The feature is primarily designed to transfer configuration files from one instrument to another.

2.3.10.1.2 Format Settings

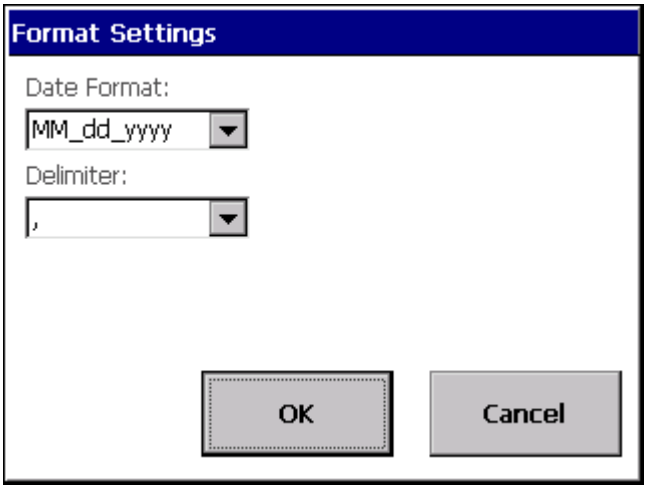

Figure 30. Format Settings Screen

Different formats of the date can be selected from this menu. This information is used in the file save mode as part of the filename and also stored internally within the file.

Different data delimeters used in the file save function can be selected through this menu. This allows for greater flexibility for importing data in different regions of the world.

Caution

- To ensure accurate measurements, wait one minute for the Certifier® FA Test System to warm up. If environmental conditions have changed significantly, more time may be necessary.
- To avoid damage to the Certifier® FA Test System components, ***always*** use bacteria filters upstream of the flow modules, and ***always*** cap flow module ports when not in use.
- If liquid has penetrated any of its components, do ***not*** use, and return to the factory for calibration.

2.4 Required Pre-test Calibrations

2.4.1 Low Flow Module

2.4.1.1 None required

2.4.2 High Flow Module

2.4.2.1 Zeroing the Flow Direction Sensor

The model 4081, High Flow Module, has a sensor that is used to detect the direction of flow. This sensor will normally auto-zero if there is no flow for a fraction of a second. If it is unable to do this at power-up or at least every 10 minutes, a ⚠ appears on the screen. Touch the symbol on the display for an explanation of the warning. To manually zero the direction sensor, remove the High Flow Module from the flow source and cover one end of the flow tube for a couple of seconds.

2.4.2.2 Low-Pressure and High-Pressure Transducer Zeroing

Check the Low-pressure transducer zero and a High pressure transducer zero by disconnecting the pressure tubing from the flow module *before each pressure measurement after initial power up* to ensure the most accurate readings. If the low or high pressure is not reading zero, perform the following steps to zero the transducers.

1. Disconnect the pressure tubing from the low and high pressure ports.
2. Press the ZERO key.
3. "Pressure Transducers Zeroing" appears on the display for one second. If the transducers do not see a steady pressure or near zero pressure, an error appears.
   NOTE: The barometric pressure transducer does ***not*** require a zero calibration.

2.4.2.3 Oxygen Sensor Calibration

Follow these steps *daily* and following an altitude change or sensor replacement to calibrate the oxygen sensor:

1. Power up the Certifier® FA Test System with the High Flow Module and oxygen sensor attached, allow one minute to warm up.
2. Press the 

key and select the “Oxygen Calibration” box on the display. Follow the directions on the screen. Note that either an “air only” or an “air and 100% oxygen” calibration can be done. The two point air/100% oxygen calibrations provide the best accuracy.

   Note: The numeric value displayed during the stabilization process does not necessarily represent the actual oxygen concentration. This numeric stabilization value is there for you to determine if it is changing or not. Once the reading stops changing then it is time to advance to the next step in the oxygen sensor calibration process.

3 Troubleshooting

Table 4 lists the symptoms, possible causes, and recommended corrective actions for problems you may encounter with the Certifier® FA Test System. If the symptom is not listed, or if none of the recommended corrective actions solve the problem, please visit our website at http://service.tsi.com or contact TSI Customer Support at (800) 874-2811 or 651-490-2811.

Table 4. Troubleshooting the Certifier® FA Test System

Symptom	Possible Cause	Corrective Action
Interface Module won't turn on, or turns on and off.	Batteries are depleted or not installed.	Connect AC adapter or install charged batteries.
Measurements are not displayed even though Interface Module is turned on.	Flow module is not connected to Interface Module.	Connect flow module to Interface Module. If connected, disconnect and then reconnect.
Measurements are not changing or graph is not updating.	Pause ⏸ button was pressed.	Press the **Play** ▶ button at the top of the screen.
"OOR" is shown on display.	Measurement is out of range.	Check range for displayed measurement, and only make measurements within that range.
Flow rate does not read zero when no gas flowing (Especially when set to N_2O or CO_2).	Meter was not purged with gas displayed on the Interface Module.	Purge meter with gas displayed on Interface Module or press gas select key to change to desired gas.
Unable to disconnect flow module from Interface Module.	Pulling on the cable rather than the connector.	Pull the locking connector (not the cable) to disengage connector lock.

Symptom	Possible Cause	Corrective Action
Volume, minute volume, peak flow, peak pressure, PEEP, respiratory rate, or I:E ratio measurement are not updated or incorrect.	Less than two consecutive full breaths have been supplied to flow module, or flow is not supplied as a breathing waveform. Auto-trigger not optimized for current waveform. Airway restrictor causing flow disturbance next to flow module. Flow condition causing oscillations in the waveform.	Wait for at least two consecutive full breaths to be supplied to the flow module. Ensure that flow is supplied as a breathing waveform. Manually set flow trigger level. Use the TSI Airway pressure fitting which contains the screen between the flow module and the test lung (see Figure 12). Minimize length of tubing between the test lung and the airway pressure fitting.
I:E ratio or I time readings do not appear correct.	It is possible the inspiratory pause function is turned on inside the ventilator.	Select the I time parameter T_{I+P} and ratio parameter $I:E_{IP}$ to be on the display when the inspiratory pause feature is activated on the ventilator. See section 2.3.3 for a description of the difference between T_I and T_{I+p}. Another option is to turn off the inspiratory pause feature on the ventilator.
Can't zero low-pressure or high pressure transducer.	Transducer is connected to a pressure source.	Disconnect pressure tubing from flow module and then zero low-pressure transducer.
Can't zero barometric pressure transducer.	Barometric pressure transducer does not require a zero calibration.	Resume normal system operation.

Symptom	Possible Cause	Corrective Action
Oxygen sensor calibration fails.	21% oxygen and/or 100% oxygen not supplied for calibration. Oxygen sensor is expired. Non-steady flow or tidal flows used.	Verify that calibration gases are 21% oxygen and 100% oxygen and repeat calibration. Replace oxygen sensor. Use constant flow rates to supply calibration gas.
Pressure trigger gives erroneous results.	Pressure signal supplied to high-flow module not correct.	Change source of pressure signal. Pressure trigger optimized for use with high-frequency ventilators.
Host computer not able to view internal memory or SD flash memory.	Certifier test system was not restarted after selecting mass storage target location.	Turn Certifier off and then on again.

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4 Maintenance

4.1 Recharging the Batteries (as required)

The batteries can be charged internally by connecting the AC adapter or they can be charged externally with the optional battery charger. The fastest charging method is to charge the battery in the instrument with the instrument turned off. The Certifier FA Plus uses SBL-160, Lithium Ion Batteries, which are available from many battery supply houses or TSI. Charging time is approximately 4 to 6 hours.

4.2 Replacing the Oxygen Sensor

The oxygen sensor will function for one or more years of normal operation if use begins before the expiration date. Replace the oxygen sensor every year or two of normal use, or if the sensor cannot be calibrated or sensor readings are erratic.

4.3 Cleaning (as required)

Table 5 summarizes recommended cleaning methods for Certifier® FA Test System components.

Table 5. Cleaning Recommendations

Component	Cleaning
▪ Interface Module ▪ Flow modules ▪ Carrying cases ▪ Oxygen sensor ▪ Oxygen sensor cables	Clean exterior as required with a clean cloth and isopropyl alcohol, hydrogen peroxide (3%), or ammonia (15%).
▪ Tee ▪ Adapters	Steam autoclave after contact with any non-sterile breathing circuit components, and discard if any damage is visible.
▪ Single use filters (High and Low Flow Modules)	Discard after contact with any non-sterile breathing circuit components or if damage is visible.

4.4 Factory Calibration (recommended yearly)

Certifier® FA Test System flow modules are designed for one year of normal use following each factory calibration.

If the test system has been dropped or liquid has penetrated any of its components, do ***not*** use, and return to the factory for calibration.

Recalibrated flow modules come with a certificate of calibration and a summary of performance before and after the calibration. A factory calibration consists of pressure transducer calibration over the full range of pressures and calibration over the full range of flows. All calibration datum are stored in the flow modules, so the Interface Module does **not** require calibration. Therefore, it is not necessary to return the Interface Module for factory calibration.

Follow the steps in **Section 4.5** to return Certifier® FA Test System flow modules for factory calibration.

4.5 Return Procedure

Follow these steps to return Certifier® FA Test System flow modules for factory calibration:

1. Obtain a Return Material Authorization (RMA) number using our online RMA form at rma.tsi.com or contact one of the following offices to make service arrangements.
2. Package the flow modules carefully to avoid damage during shipping.
   NOTE: It is ***not*** necessary to return the Interface Module for factory calibration.

U.S. & International

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Website: www.tsiinc.co.uk

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Fax: +49 241-52303-49
E-mail: tsigmbh@tsi.com
Website: www.tsiinc.de

5 Specifications

NOTE: Specifications are subject to change without notice.

5.1 Physical

Dimensions	Interface module: 17.3 cm × 10.5 cm × 4.5 cm (6.8 in. × 4.1 in. × 1.8 in.) High Flow Module: 15 cm × 6.7 cm × 6.1 cm (5.9 in. × 2.7 in. × 1.4 in.). Low Flow Module: 12.7 cm × 5.1 cm × 2.8 cm (5.0 in. × 2.0 in. × 1.1 in.).
Flow connectors	High Flow Module: • Flow inlet: 22-mm female ISO taper. • Flow outlet: 22-mm male ISO taper. Low Flow Module: • Flow inlet: 3/8-in. • Flow outlet: 3/8-in.
Weight	Approximately 0.7 kg (1.5 lb), interface with high flow module and cable.

5.2 Environmental

Temperature	Operating: 5 to 40°C (41 to 104°F). 15 to 80% relative humidity from 5 to 31°C decreasing linearly to 15 to 50% relative humidity at 40°C. Storage: -40 to 70°C (-40 to 158°F) at 10 to 90% relative humidity, non-condensing
Atmospheric Pressure	Operating: 57.1 to 106 kPa (8.28 to 15.37 psia). Storage: 15000 meters
Conditions	Indoor Use Operating Altitude up to 4000 m (13,000 ft) Pollution degree I or II

5.3 Power

Battery Life	3 to 6 hours typical
Battery Type	Lithium-Ion SBL160
AC Adapter	12 VDC 1A Minimum

5.4 Data Transfer and Storage

Internal Memory	1 MB (500 typical records)
External Memory	SD Flash Card. Supports up to 1 GB cards.

5.5 Test Measurements (See notes at end of section. See **Table 3** for symbol definitions.)

Measurement	High Flow Module	Low Flow Module
Flows	$\dot{V}$ $\dot{V}_{Peak}$ $\dot{V}_{MIN}$	
Range	-200 to +300.0 SLPM air, oxygen, and nitrogen -40 to +40 SLPM carbon dioxide 0 to 300 air/oxygen mixture	0.01 to 20.00 SLPM air, oxygen, nitrogen, carbon dioxide, and nitrous oxide
Accuracy	Air and oxygen: ±2% of reading or ±0.075 standard L/min, whichever is greater Nitrogen and carbon dioxide: ±3% of reading or ±0.075 standard L/min, whichever is greater Air/Oxygen mixture: ±4% of reading or ±0.100 standard L/min, whichever is greater	Air and oxygen: ±2% of reading or ±0.010 standard L/min, whichever is greater Nitrogen and carbon dioxide: ±3% of reading or ±0.010 standard L/min, whichever is greater Nitrous oxide: ±4% of reading or ±0.025 standard L/min, whichever is greater
Volumes	V_{TI}	
Range	0.01 to 10 L STP	0 to 10 L STP
Accuracy	Air and oxygen: ±2% of reading plus 0.020 L Air/oxygen mixtures: ±4% of reading plus 0.020 L STP	Air and oxygen: ±2% of reading or ±0.010 L, whichever is greater Nitrous oxide: ±4% of reading or ±0.010 L STP, whichever is greater

Measurement	High Flow Module	Low Flow Module
Volumes V_{TE}		
Range	0.01 to 10 L STP	Not applicable
Accuracy	Air and oxygen: ±3% of reading plus 0.030 L Air/oxygen mixtures: ±4% of reading plus 0.040 L STP	Not applicable
Minute Volume MV		
Range	0.01 to 100 L STP	0 to 10 L STP
Accuracy	±3% of reading	±3% of reading
Times t_I t_{IP} t_{I+P} t_E		
Range	0.04 to 30 seconds	0.04 to 30 seconds
Accuracy	2% of reading or ±0.01 seconds, whichever is greater	2% of reading or ±0.01 seconds, whichever is greater
I:E Ratios I:E $I:E_{IP}$		
Range	1:100.0 to 100.0:1	1:100.0 to 100.0:1
Accuracy	±4% of reading typical	±4% of reading typical
Respiratory Rate f		
Range	1 to 1500 breaths per minute	1 to 1500 breaths per minute
Accuracy	±2% of reading or 0.1 BPM, whichever is greater	±2% of reading or 0.1 BPM, whichever is greater
Low Pressures P PIP P_{EEP} P_{MAP} P_{MIN} P_{Δ}		
Range	-25.0 to 150.0 cmH_2O. (-18.4 to 110 mmHg)	Not applicable
Accuracy	±0.5% of reading or ±0.15 cmH_2O (0.15 mmHg), whichever is greater	Not applicable

Measurement	High Flow Module	Low Flow Module
High Pressure P_{High}		
Range	-10 to 150.0PSIG (-0.7 to 10 bar)	Not applicable
Accuracy	±1% of reading or 0.1 PSI (±7 mbar), whichever is greater.	Not applicable
Absolute Pressure P_{ABS}		
Range	375 to 1200 mmHg (500 to 1600 mbar)	375 to 1500 mmHg (500 to 2000 mbar)
Accuracy	±8 mmHg (±11 m bar)	±8 mmHg (±11 mbar)
Oxygen Concentration O_2		
Range	21 to 100%	Not applicable
Accuracy	2% concentration	Not applicable.
Temperature		
Range	5 to 40°C	5 to 40°C
Accuracy	±1°C When flow rates are above 2 L/min	±1°C When flow rates are above 2 L/min

Measurement	High Flow Module	Low Flow Module

NOTES

1. Standard conditions are defined as 21.1°C (70°F) and 101.3 kPa (14.7 psia).
2. Flow and volume accuracy is applicable at these standard conditions (see note 1).
3. For the High Flow Module the temperature of the gas and the ambient air must be within ±10°C (±18°F) of each other and the gas must be less than 30% relative humidity at 21.1°C (70°F).

   For the Low Flow Module the temperature of the gas and the ambient air must be within ±5°C (±9°F) of each other and the gas must be less than 30% relative humidity at 21.1°C (70°F).
4. Flow and volume accuracy de-rating: ±0.075% of reading per 1°C (1.8°F) away from 21.1°C (70°F); ±0.015% of reading per 1.03 kPa (0.15 psia) above 101.3 kPa (14.7 psia); ±0.022% of reading per 1.03 kPa (0.15 psia) below 101.3 kPa (14.7 psia); ±0.07% of reading per 1% relative humidity above 30% relative humidity. The Low Flow Module has an additional flow rate accuracy de-rating of 0.0003 standard L/min per 1°C (1.8°F) and 1 kPa away from 21.1°C (70°F) and 101.3kPa.

5.6 Calibration Recommendations

Flow Modules	Start with factory calibration every year for use under normal conditions using the filter(s) provided.
Interface Module	No calibration required.
Oxygen Sensor	Check Daily, calibrate as needed.

5.7 Compliance and Approvals

Complies with these standards:	• EN 55011 (1991) Class B, CISPR 11 (1990) Class B, FCC (CFR 47, Part 15) Class B: Emissions, Radiated and Conducted. • EMC Directive 89/336/ECC, EN 61326-1 (1997 plus Amendment A1 1998), IEC 1000-4-2 (1995), EN 61000-4-2, IEC 1000-4-3 (1995), EN 61000-4-3: Immunity.

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Appendix A Data File Formats

Parameter Screen Single Sample and Continuous Logging Data Format

Raw Text Example:

```
Filename:,\NV1FLASH\EXAMPLE.csv
Comments:,Custom comments  here
Configuration:,*Current Configuration
Module A Model:,4081
Module A SN:,40810705010
Trigger Type:,Flow Rate
Start Trigger:,Auto
End Trigger:,Auto
Module A Conditions:,STP
Module A Gas:,AIR
Data Section:,,Module A,Module A,Module A
,,Flow Rate,Low Pressure,PEEP Pressure
Date,Time,L/Min,cmH2O,cmH2O
27/12/2007,12:03:20,0.00,-0.256,0.000
```

As Formatted By spreadsheet application:

Filename:	\NV1FLASH\EXAMPLE.csv			
Comments:	Custom comments here			
Configuration:	*Current Configuration			
Module A Model:	4081			
Module A SN:	40810705010			
Trigger Type:	Flow Rate			
Start Trigger:	Auto			
End Trigger:	Auto			
Module A Conditions:	STP			
Module A Gas:	AIR			
Data Section:		Module A	Module A	Module A
		Flow Rate	Low Pressure	PEEP Pressure
Date	Time	L/Min	cmH2O	cmH2O
27/12/2007	12:03:20	-19.2	-0.256	0

Notes:

- When Continuous logging is used, each additional reading is given on a separate, appended text line.
- Parameter value columns are formatted in the same order that they have been configured on the display screen.

Parameter Screen Waveform Logging Data Format

Waveform Logging collects a 15-second snapshot of "raw" data from the connected flow module. An example of the data collected in waveform logging is shown below.

Raw Text Example (waveform logging):

```
Raw Samples   Feb. 3 2011 19:39:43   90000 values   Comments: CUSTOM COMMENTS
Flow Std. lpm   Temperature °C   Pressure kPa   High Pressure PSI   Directional Pressure Counts   Low Pressure cmH2O
22.708          24.218          99.463         -0.365              43882                         10.922
22.75           24.22           99.489         -0.329              43931                         10.912
22.655          24.218          99.489         -0.315              43928                         11.034
22.808          24.207          99.463         -0.338              44159                         10.987
22.876          24.223          99.409         -0.242              44181                         10.973
22.769          24.223          99.463         -0.397              43925                         10.969
22.708          24.218          99.46          -0.461              44098                         11.058
22.726          24.22           99.489         -0.315              43778                         11.025
22.718          24.22           99.476         -0.324              43896                         10.969
22.655          24.213          99.476         -0.265              43270                         11.025
22.613          24.223          99.476         -0.26               43979                         11.147
22.721          24.22           99.463         -0.306              43887                         11.053
22.692          24.228          99.451         -0.388              43720                         11.025
22.659          24.223          99.483         -0.324              43764                         11.063
22.537          24.223          99.502         -0.365              43652                         11.119
[15,000 data points total]
```

Graph Screen Data Format

The Graph Display data is formatted as 2 (1 parameter on Graph) or 3 (2 parameters on Graph) columns of text. The first column is the X axis (relative time), the second and third columns will contain the Graph data.

```
X          Q L/Min       P cmH2O
Total graph time: 10 seconds.
0          -0.421556     0.673527
0.041      -0.197457     0.678888
0.082      -0.095008     0.693449
0.123      -0.043302     0.699908
0.1639     -0.027286     0.712823
0.2049     -0.027088     0.723274
0.2459     -0.022927     0.730932
0.2869     -0.019958     0.736425
0.3279     -0.019294     0.738421
0.3689     -0.022878     0.740417
0.4098     -0.024059     0.744878
0.4508     -0.030267     0.744917
0.4918     -0.034957     0.747344
0.5328     -0.040919     0.74523
0.5738     -0.046022     0.740886
0.6148     -0.04976      0.749106
0.6557     -0.049111     0.743039
0.6967     -0.049844     0.742413
[up to 244 data points]
```

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