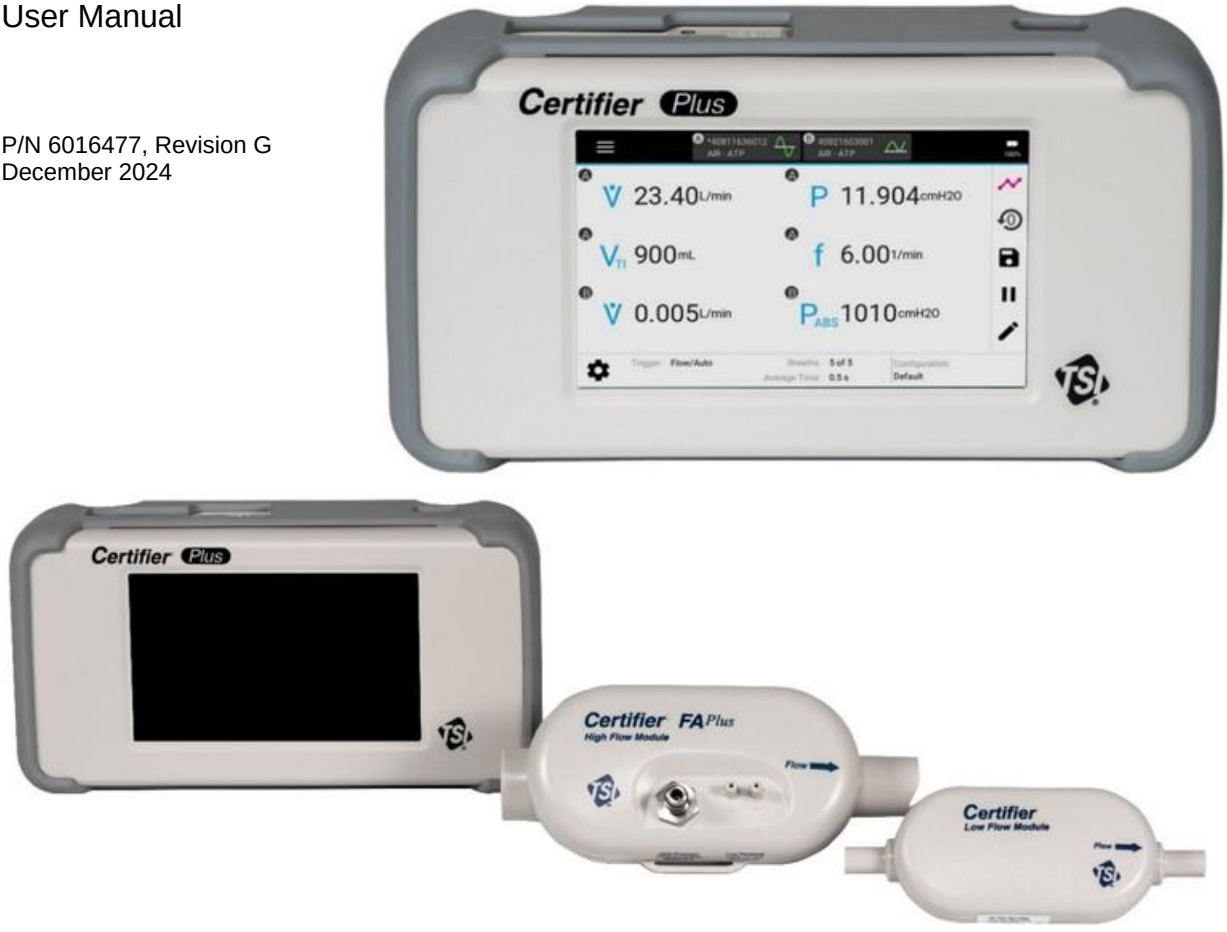
Certifier™ Plus Flow Analyzer Test System

Models 4089, 4081, 4082

User Manual

P/N 6016477, Revision G
December 2024



Start Seeing the Benefits of Registering Today!

Thank you for your TSI® instrument purchase. Occasionally, TSI® releases information on software updates, product enhancements and new products. By registering your instrument, TSI® will be able to send this important information to you.

http://register.tsi.com

As part of the registration process, you will be asked for your comments on TSI products and services. TSI's customer feedback program gives customers like you a way to tell us how we are doing.

Warranty

Address

TSI Incorporated / 500 Cardigan Road / Shoreview, MN 55126 USA

WARNING

TSI® Certifier Flow Analyzers employ a heated platinum sensor. They **SHOULD NOT** be used with flammable or explosive gases or mixtures.

TSI® 4081 and 4082 Flow Modules are not designed for use with anesthesia gas other than nitrous oxide. Only the anesthesia gas measurement accessory is designed for use with anesthetic gases.

CAUTION

TSI® Certifier Flow Analyzers are not medical devices under FDA 510k and in no situation should they be utilized for human respiration measurements.

ATTENTION

As indicated by the WEEE Symbol on the case of the Interface Module and the cases of the flow modules, this product should not be discarded as unsorted waste but must be sent to separate collection facilities for recovery and recycling.

Limitation of Warranty and Liability *(effective May 2024)*
(For country-specific terms and conditions outside of the USA, please visit www.tsi.com.)

Seller warrants the goods, excluding software, sold hereunder, under normal use and service as described in the operator's manual (version published at the time of sale), to be free from defects in workmanship and material for the longer period of either **2 years** (24 months) or **the length of time specified in the operator's manual/warranty statement provided with the goods or made available electronically (version published at the time of sale)**, from the date of shipment to the customer on shipments that occur on or after May 15, 2023. A warranty period of 12 months applies to all instruments shipped prior to May 15, 2023. This warranty period is inclusive of any statutory warranty. This limited warranty is subject to the following exclusions and exceptions:

.

a. Hot-wire or hot-film sensors used with research anemometers, and certain other components when indicated in specifications, are warranted for 90 days from the date of shipment;

b. Pumps are warranted for hours of operation as set forth in product or operator’s manuals (versions published at the time of sale);

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;

d. Seller does not provide any warranty on finished goods manufactured by others or on any fuses, batteries or other consumable materials. Only the original manufacturer's warranty applies;

e. This warranty does not cover calibration requirements, and Seller warrants only that the goods are properly calibrated at the time of its manufacture. Goods returned for calibration are not covered by this warranty;

f. This warranty is **VOID** if the goods are opened by anyone other than a factory authorized service center with the one exception where requirements set forth in the operator's manual (version published at the time of sale) allow an operator to replace consumables or perform recommended cleaning;

g. This warranty is **VOID** if the goods have been misused, neglected, subjected to accidental or intentional damage, or is not properly installed, maintained, or cleaned according to the requirements of the operator's manual (version published at the time of sale). Unless specifically authorized in a separate writing by Seller, Seller makes no warranty with respect to, and shall have no liability in connection with, goods which are incorporated into other products or equipment, or which are modified by any person other than Seller.

h. New parts or components purchased are warranted to be free from defects in workmanship and material, under normal use, for 90 days from the date of shipment.

The foregoing is **IN LIEU OF** all other warranties and is subject to the **LIMITATIONS** stated herein. **NO OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS FOR PARTICULAR PURPOSE OR MERCHANTABILITY IS MADE**. **WITH RESPECT TO SELLER'S BREACH OF THE IMPLIED WARRANTY AGAINST INFRINGEMENT, SAID WARRANTY IS LIMITED TO CLAIMS OF DIRECT INFRINGEMENT AND EXCLUDES CLAIMS OF CONTRIBUTORY OR INDUCED INFRINGEMENTS. BUYER'S EXCLUSIVE REMEDY SHALL BE THE RETURN OF THE PURCHASE PRICE DISCOUNTED FOR REASONABLE WEAR AND TEAR OR AT SELLER'S OPTION REPLACEMENT OF THE GOODS WITH NON-INFRINGING GOODS.**

TO THE EXTENT PERMITTED BY LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE LIMIT OF SELLER'S LIABILITY FOR ANY AND ALL LOSSES, INJURIES, OR DAMAGES CONCERNING THE GOODS (INCLUDING CLAIMS BASED ON CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) SHALL BE THE RETURN OF GOODS TO SELLER AND THE REFUND OF THE PURCHASE PRICE, OR, AT THE OPTION OF SELLER, THE REPAIR OR REPLACEMENT OF THE GOODS. IN THE CASE OF SOFTWARE, SELLER WILL REPAIR OR REPLACE DEFECTIVE SOFTWARE OR IF UNABLE TO DO SO, WILL REFUND THE PURCHASE PRICE OF THE SOFTWARE. IN NO EVENT SHALL SELLER BE LIABLE FOR LOST PROFITS, BUSINESS INTERRUPTION, OR ANY SPECIAL, INDIRECT, CONSEQUENTIAL OR INCIDENTAL DAMAGES. SELLER SHALL NOT BE RESPONSIBLE FOR INSTALLATION, DISMANTLING OR REINSTALLATION COSTS OR CHARGES. No Action, regardless of form, may be brought against Seller more than 12 months after a cause of action has accrued. The goods returned under warranty to Seller's factory shall be at Buyer's risk of loss, and will be returned, if at all, at Seller's risk of loss.

Buyer and all users are deemed to have accepted this LIMITATION OF WARRANTY AND LIABILITY, which contains the complete and exclusive limited warranty of Seller. This LIMITATION OF WARRANTY AND LIABILITY may not be amended, modified or its terms waived, except by writing signed by an Officer of Seller.

Service Policy
Knowing that inoperative or defective instruments are as detrimental to TSI attention to any problems. If any malfunction is discovered, please contact your nearest sales office or representative, or call TSI's Customer Service department at (800) 680-1220 (USA) or (001 651) 490-2860 (International) or visit www.tsi.com.

Trademarks
TSI and TSI logo are registered trademarks of TSI Incorporated in the United States and may be protected under other country's trademark registrations. REDEL is a registered trademark of Interlemo Holding S.A. Luer-Lok is a registered trademark of Becton Dickinson. Velcro is a registered trademark of Velcro IP Holdings LLC. Phillips is a trademark of Phillips Screw Company.

Contents

(This page intentionally left blank)

CHAPTER 1

Introduction and Parts Identification

Introduction

The Certifier™ Plus Gas Flow Analyzer Test System is a portable, 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™ Plus Flow Analyzer is designed for use in hospital, field service, home care, manufacturing, research, and laboratory settings.

The Certifier™ Plus Test System components include:

Interface Module

The interface module connects to and powers the high flow and low flow modules. The model 4089 Interface Module works with existing 4081 High Flow and 4082 Low Flow Modules. The coiled cable used to connect the flow and interface modules has been updated to a REDEL®-style connector for the 4089 side while the flow module end retains the same 4-pin min-DIN connector. The display on the interface module is used to control the Certifier Plus system and display measurement readings.

High Flow Module

Measures air, oxygen (O_2), nitrogen (N_2) and carbon dioxide (CO_2) flow rate over a range of -200 to +300 standard liters per minute (0.01 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. A High Flow Module (model 4081) along with an Interface Module (model 4089) make up the model 4080 Certifier Plus System.

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. The Low Flow Module kit (model 4082) is an optional accessory for the 4080 Certifier Plus System. For testing anesthesia workstations, a 4082 Low Flow Module can be purchased and used in conjunction with a 4089 Interface Module to measure N_2O gas flows.

Oxygen Sensor

Connected to the high flow module, the oxygen sensor enables the measurement of oxygen concentration as well as air and oxygen mixtures. The Oxygen Sensor kit (model 4073) is an optional accessory for the 4080-S Certifier Plus system standard kit, but it is included as part of the model 4080-F system full kit.

Anesthesia Sensor

An external infrared sensor that connects directly to the breathing circuit to provide real-time gas concentrations of carbon dioxide (CO_2), nitrous oxide (N_2O), and the anesthetic agents halothane, enflurane, isoflurane, sevoflurane, and desflurane. The Anesthesia Sensor Kit (model 4093) is an optional accessory for the Certifier™ Plus and Certifier™ Pro test systems. Refer to the Anesthesia Sensor Kit User Manual for more detailed information.

CAUTION

- To avoid inaccurate test readings, **DO NOT** obstruct the tubing or inlet or outlet ports, and always use clean, dry gas.
- To avoid damage to the Certifier™ Plus test system components, always use an inlet filter upstream of the flow modules, and always cap flow module ports when not in use.
- The Certifier™ Plus test system **IS NOT** a medical device under the Medical Device Directive or FDA 510(k) and in no situation should be used for human measurements.

(continued on next page)

List of Standard Components

Carefully unpack the test system components from the shipping container. Check the individual parts against the packing list and notify TSI® immediately if any parts are missing or damaged.

Certifier™ Plus High Flow Test System, Standard Kit (Model 4080-S)

Item Number	Description	Replacement Part Number	Qty.
1	Interface Module[a]	4089	1
2	High Flow Module[b]	4081	1
3	Inlet Filter, HEPA, 22 mm x 22 mm M/F (for use with 4081 High Flow Module)	1602341	1
4	Adapter, high pressure port	1611221	1
5	Adapter, 22 mm x 6 mm (to connect 4081 to Low Flow Filter)	1102091	2
6	Adapter, 15 mm ID x 22 mm OD	1102093	1
7	Airway pressure fitting with screen	1611330	1
8	Pressure tubing, silicone, 1/8-inch ID x 1/4-inch OD x 48 in.	3002053	1
9	Velcro® strap for use on High Flow Module	2913110	1
10	Flow module cable, REDEL® straight plug to 4-pin mini-DIN	130384	1
11	Carrying case (13.8 x 9.5 x 8.1 inch, 35 x 24 x 20.5 cm)	130389	1
12	Power supply 100/240 VAC to +12 VDC 2.1 mm plug, includes plug set with NA, UK, EU, CN, SAA connectors	130400	1
13	Battery, 4 cell Lithium-Ion 7.2 V 6.4 AHr (pre-installed)	130385	1
14	Protective cover, Certifier™ Plus Interface Module	130392	1

[a] If ordering a 4089 Interface Module Kit for replacement, items 10 through 14 are included.

[b] If ordering a 4081 High Flow Module Kit for replacement, items 3 through 9 are included.

Certifier™ Plus High Flow Test System, Full Kit (Model 4080-F)

Item Number	Description	Replacement Part Number	Qty.
1	Interface Module[a]	4089	1
2	High Flow Module[b]	4081	1
3	Inlet Filter, HEPA, 22 mm x 22 mm M/F (for use with 4081)	1602341	1
4	Adapter, high pressure port	1611221	1
5	Adapter, 22 mm x 6 mm (to connect 4081 to Low Flow Filter)	1102091	2
6	Adapter, 15 mm ID x 22 mm OD	1102093	1
7	Airway pressure fitting with screen	1611330	1
8	Pressure tubing, silicone, 1/8-inch ID x 1/4-inch OD x 48 in.	3002053	1
9	Velcro® strap for use on High Flow Module	2913110	1
10	Flow module cable, REDEL® straight plug to 4 pin mini-DIN	130384	1
12	Power supply 100/240 VAC to +12 VDC 2.1 mm plug, includes plug set with NA, UK, EU, CN, SAA connectors	130400	1
13	Battery, 4 cell Lithium-Ion 7.2 V 6.4 AHr (pre-installed)	130385	1
14	Protective cover, Certifier™ Plus Interface Module	130392	1
20	Certifier Oxygen Sensor Kit	4073	1
24	RAM Mounting Kit for Interface + Flow Module	130399	1
29	Adapter, 22 mm F to 22 mm F, straight	130373	1
30	Adapter, 15 mm M to 22 mm F, pediatric cuff	130374	1
31	Deluxe carrying case, fitted (19 x 14.75 x 6.5 inches)	130393	1
32	Test Lung, adult, 1.0L	130396	1
33	Stylus, capacitive touch	130370	1

[a] If ordering a 4089-F Interface Module Kit for replacement, items 1, 10, 12-14, 20, 24, and 29-33 are included.

[b] If ordering a 4081 High Flow Module Kit for replacement, items 2 through 9 are included.

List of Accessory Kits

Certifier™ Plus Low Flow Module Kit (Model 4082)

Item	Description	Part Number	Qty.
16	Low Flow Module	4082	1
17	Inlet Filter, HEPA, 3/8 to 1/2-inch barb, plus 3/8-inch tubing	1602342	1
18	Coupling, 3/8-inch tube	1601180	1
19	Adapter, 3/8-inch tube to 3/8-inch barb	1601179	1

Certifier™ Oxygen Sensor Kit (Model 4073)

Item	Description	Part Number	Qty.
21	Oxygen Sensor Cell	2917019	1
22	Oxygen Sensor Coupling	1313118	1
23	Oxygen Sensor Cable	1303741	1

Anesthesia Sensor Kit (Model 4093)

Item	Description	Part Number	Qty.
A	Anesthesia Sensor Cell (with DB-9 connector cable)	130386	1
B	Anesthesia USB Serial Converter	130402	1
C	Anesthesia Airway Adapter, Adult/Pediatric	130403	1

Refer to the Anesthesia Sensor Kit User Manual for more detailed information.

Mounting Kit, for Certifier™ Plus Interface Module (PN 130398)

Item	Description	Part Number	Quantity
25	Adapter Plate for Interface Module, sheet metal	227098	1
26	RAM Double Socket Arm	130371	1
27	RAM Tough-Claw Small Clamp Base with Ball	130372	1

Mounting Kit, for Certifier™ Plus Interface and Flow Module (PN 130399)

Item	Description	Part Number	Quantity
26	RAM Double Socket Arm	130371	1
27	RAM Tough-Claw Small Clamp Base with Ball	130372	1
28	Adapter Plate for Interface + Flow Module, sheet metal (Attach either a 4081 high flow or 4082 low flow module)	227099	1

Flow Resistor Kit (PN 130395)

Flow resistors are calibrated airway adapters used to simulate nominal levels of resistance. Resistors can be used to demonstrate or test changes in airway resistance. The Flow Resistor Kit adapters can be cleaned and sterilized.

The kit includes three resistors: Rp5, Rp20 and Rp50.

Certifier™ Connector Kit (PN 130391)

Item	Description	Part Number	Quantity
5	Adapter, 22 mm x 6 mm (to connect the 4081 to Low Flow Filter)	1102091	2
6	Adapter, 15 mm ID x 22 mm OD	1102093	1
7	Airway pressure fitting with screen	1611330	1
29	Adapter, 2 2mm F to 22 mm F, Straight	130373	1
30	Adapter, 15 mm M to 22 mm F, Pediatric Cuff	130374	1

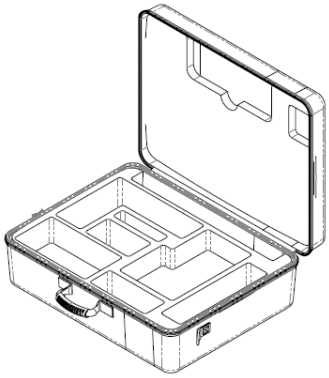
Mobilize™ Integration Chip (PN 130401)

Plug-in dongle that enables the Certifier™ Plus Flow Analyzer to wirelessly communicate with the Mobilize™ mobile application developed by Pronk Technologies®. The Mobilize™ app runs on iOS devices to capture real-time data from the Certifier™ Flow Analyzer and provide some instrument control.

Run user-defined or manufacturer recommended checklists, wirelessly acquire test data, and automatically generate test reports from the Mobilize™ app. Mobilize™ app includes an integrated barcode scanner for asset management, optional CMMS connectivity, and more.

®Pronk Technologies is a registered trademark of Pronk Technologies, Inc. Sun Valley, CA

Other Optional Accessories

Description	Part Number	Image
Deluxe Carrying Case, Fitted for the Certifier™ Plus Flow Analyzer (19 x 14.75 x 6.5 inches 48 x 37.5 x 16.5 cm)	130393	
Test Lung, Adult, 1.0L, includes elbow connector (15 mm ID x 22 mm OD)	130396	
Test Lung, Pediatric, 0.5L, includes one elbow connector and two straight connectors with Luer-Lok® ports and locks, connectors include a variable leak adjustment to demonstrate patient-trigger function or to simulate an airway leak.	130397	
Computer Cable, RS-232, USB-A to 9-Pin D-sub (6 ft), includes null modem adapter	130379	
Computer Cable, USBC to USBA, screw lock (2m), screwdriver USB cable is used to communicate with the Certifier™ Flow Analyzer from a computer. Contact TSI® for more information prior to purchase.	130382	
Fitting, Push to Connect, 3/8 to 5/16 inch (for use with 4082 Low Flow Module)	130394	
Anesthesia Airway Adapter, Infant	130404	

CHAPTER 2

Flow Analyzer Overview

Instrument Overview

4089 Interface Module, Back

4089 Interface Module, Front

1.	Flow Module Connector (A)	7.	Screw hole for USB-C cable lock
2.	Flow Module Connector (B)	8.	Tilt Stand
3.	DC Power Input (2.1 mm barrel jack)	9.	Cable Retainer
4.	Power Button (On/Off)	10.	Mounting holes (2), threaded M4
5.	USB-A Connectors (2)	11.	Touchscreen Display
6.	USB-C Communications Output	12.	Protective Cover

4081 High Flow Module, Back

4081 High Flow Module, Front

1.	Interface Module Connector	4.	Mounting Holes (threaded #8-32)
2.	O_2 Sensor Input	5.	Low Pressure Ports (± 150 cmH_2O) Connect to “+” port for airway pressure
3.	TTL Trigger Input	6.	High Pressure Port (150 PSIG, 10 bar)

4082 Low Flow Module

1.	Interface Module Connector	2.	Mounting Holes (threaded #6-32)

NOTICE
The Model 4080-F test kit is designed to include everything needed to test the pneumatics of mechanical ventilators. To expand to other applications, such as testing anesthesia workstations, the model 4082 Low Flow Module kit can be added.

Operation Overview

Flow Modules

You can connect or disconnect Certifier™ Flow Modules from the Certifier™ Interface Module at any time during normal operation without having to reboot the instrument or change settings. Flow modules can be connected to either of the flow module ports (A or B) on the interface module. Two flow modules can be connected and operated through the interface module at the same time, by connecting two of the same Flow Modules (ex. 4081 and 4081) or two different Flow Modules (ex. 4081 and 4082).

End Caps

TSI® Flow Analyzers measure flow utilizing an exposed thermal flow sensor that is highly sensitive to foreign matter and particles within the gas flow. TSI® supplies end caps for both the high flow module and low flow module and recommends that flow module ends be capped when not in use.

CAUTION

To avoid damage to the Certifier™ Plus Test System components, always cap the ends of the Flow Modules when not in use.

Lithium Ion Batteries

The model 4089 Certifier Plus Interface Module utilizes a 4-cell lithium ion battery pack which can provide up to 8 hours of continuous operation from a full charge. The battery pack is calibrated and installed into the 4089 Interface Module at the factory. The battery pack is rechargeable and can be charged internally by providing power to the Certifier Interface Module via the AC power adapter. The Certifier Plus batteries cannot be charged externally from the instrument.

Supplying Power

The Certifier Plus Interface Module provides power to any Certifier Plus Flow Modules when connected via the coiled cable connector. The interface module can be powered by internal Lithium-Ion batteries or an AC power adapter can be used. Refer to Chapter 7 of this manual for the Certifier Plus power supply specifications.

If the AC adapter is delivering power to the Certifier Interface Module with the battery is installed, the battery symbol on the display will contain a lightning bolt to indicate that the battery is being charged. If the AC adapter is powering the instrument but no battery is installed, a question mark symbol will appear within the battery symbol.

NOTICE

When running the Certifier Plus test system on battery power without an AC connection, the device will shut down automatically if the battery charge reaches 5% in order to prevent battery damage from occurring.

Power Button LED States

The power button contains an LED that changes state and color depending on the condition of the Certifier Plus instrument. If the Certifier™ Plus test system is running with the battery installed while connected to power via the power cable, the power button will display the following LED states:

- Blinking red: 0–10% battery charge
- Solid red: 10–20% battery charge
- Solid green: >20% battery charge

If the Certifier™ Plus test system is turned off with the battery installed while connected to power via the power cable, the power button will display the following LED states:

- Solid yellow: Battery is charging
- Blinking yellow: Battery is full, no charging needed

If no battery is installed and the Certifier™ Plus test system is connected to power via the power cable, the power button will display a solid green LED when the instrument is powered on. The power button will not display any LED status if the Certifier™ test system is turned off and no power is connected.

Touchscreen Display

The Certifier Plus Interface Module utilizes a 5-inch color, capacitive touchscreen display. The Certifier graphical user interface (GUI) is designed to be operated using your fingers; however, a capacitive-touch stylus can also be used as an alternative. Press with your fingers lightly on the display for optimal touchscreen operation.

To operate the Certifier Plus test system, touch any on-screen element that you would like to change. Between 1 and 18 measurement parameters can be displayed on screen at one time, and the display will automatically adjust the font and positioning of the text based on the number measurements selected. The display brightness can be adjusted in the **Settings** option of the Certifier Plus user interface.

User Configurations

A user configuration is a collection of setting values for the measurements, units, gas type and conditions, triggering, and graph settings that can be saved and recalled at a later time. This allows you to save and load different test setups for specific models of equipment or to ensure test setups conform with organizational standards or personal preference.

There is no limit to the number of user configurations that can be stored in the internal memory of the Certifier Plus Flow Analyzer. Configurations can be exported from either USB-A port on the 4089 to a USB mass storage device. Exported user configurations can then be imported onto other model 4089 Certifier Plus or model 4090 Certifier Pro instruments. Exported configurations can also be sent as email attachments.

Hardware Setup

User configurations are specific to the module(s) connected to the Certifier interface at the time in which the configuration was created, referred to as the hardware setup. To display and load saved configurations, the Certifier Flow Analyzer needs to be in the same setup as the saved configuration(s). When exported, the file extension of the configuration is based on its recorded hardware setup.

File extensions for exported configurations are based on the Certifier™ hardware setup as follows:

- P = primary
- S = secondary
- 1 = 4081 module
- 2 = 4082 module
- M+ = Masimo anesthesia sensor

File Extension	Certifier™ Hardware Setup
.P1	One 4081 connected to either port
.P2	One 4082 connected to either port
.P1S1	Two 4081s are connected
.P2S2	Two 4082s are connected
.P1S2	4081 (primary) and 4082 (secondary) connected

File Extension	Certifier™ Hardware Setup
.P1M+	One 4081 connected to either port and anesthesia sensor connected
.P2M+	One 4082 connected to either port and anesthesia sensor connected
.P1S1M+	Two 4081s and anesthesia sensor connected
.P2S2M+	Two 4082s and anesthesia sensor connected
.P1S2M+	4081 (primary), 4082 (secondary), and anesthesia sensor are connected
.NONE	No modules are connected

If a 4081 high flow module is connected to the Certifier™ Plus Flow Analyzer, it will automatically act as the primary trigger to start and end the breaths. If both connected flow modules are the same model (ex. two 4081s or two 4082s) then the flow module connected to the A port of the 4089 interface module will act as primary and control the breath triggering.

Legacy configuration files from the discontinued model 4088 Certifier™ FA+ interface module have a .cfp file extension and use a different file format than the 4089 interface module uses. When importing a legacy configuration (.cfp) file onto a 4089, the Certifier™ Flow Analyzer will attempt to convert the configuration to the new file format.

Data Acquisition and Export

The Certifier™ Plus Flow Analyzer is capable of logging measurement data and capturing screenshots. Files are saved to the internal memory of the Certifier Flow Analyzer and can be exported through either of its two USB-A ports. Saved measurement data is exported as .csv files and screenshots are exported as .png files.

The Certifier Plus Flow Analyzer offers the following data acquisition options:

Option	Description
Snapshot	Saves a screenshot image and the data currently displayed, either from the **Parameter** screen or **Graph** screen. Upon executing a snapshot, the Certifier Flow Analyzer will create two files, an image file (.PNG) for the screen capture and a data file (.CSV) with a single data point.
Continuous Log	Captures data for the measurements currently selected on screen. The sampling rate at which data is collected can be set from 1 second to 10 minutes. The collection time can be set from 15 seconds to up to five days (120 hours) of continuous logging.
Waveform Log	Records raw sensor data at high resolution for flow rate, low pressure, high pressure, absolute pressure, temperature, and oxygen concentration (if connected). The sampling rate for waveform logging is fixed at 1 ms (1000 Hz), and you can specify the collection time from 15 to 60 seconds.

USB Communications

Saved measurement data, screen captures, and user configurations are stored on the internal memory of the model 4089 Certifier Plus Interface Module. You can export saved data and configurations via USB flash drive from either of the two USB-A ports located on the top of the interface module.

Certifier Flow Analyzers are capable of establishing wired communications with a computer over a direct USB link utilizing an NDIS driver and USB computer cable. Once a connection is established, serial interface commands can be used to communicate with the Certifier instrument. A one-time purchase is required to acquire the NDIS driver and command set manual. Contact TSI® for more information on wired communications to a computer.

Wireless communications with third party mobile applications can be enabled with the purchase of an integration chip. The pre-programmed integration chip is inserted into a USB-A port of the Certifier instrument which allows mobile devices to acquire real-time data from the Certifier instrument via BLE connection.

Measurements and Units

Available Measurement Parameters

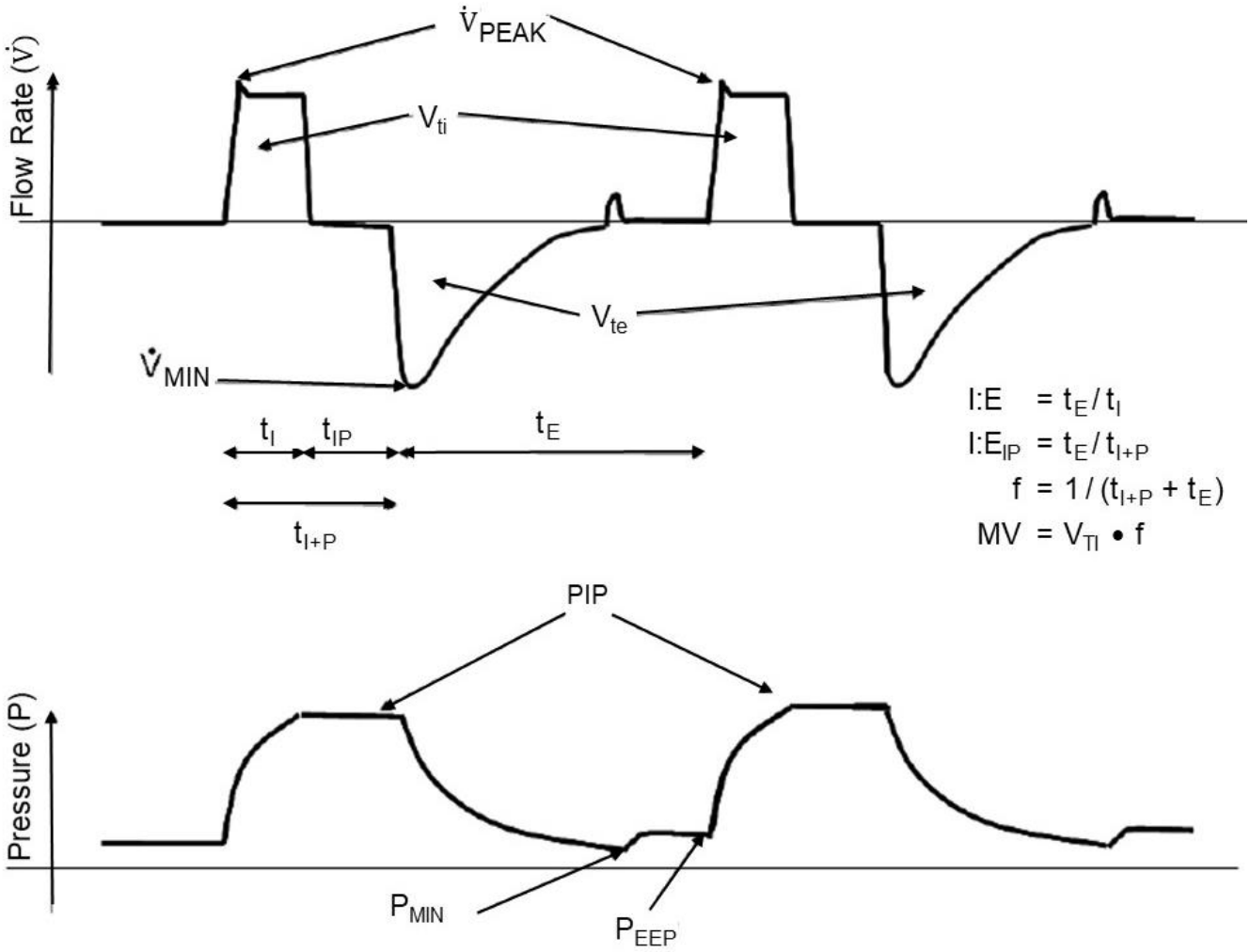
The list parameters available for selection is dependent on the model of the connected flow module.

Symbol	Description	Symbol	Description
$\dot{V}$	Flow rate	P_{PLAT}	Plateau pressure – pressure at the end of the inspiratory phase during no flow (4081 only)
$\dot{V}_{PEAK}$	Peak flow rate – Peak inhaled flow rate	P_{HIGH}	High pressure measurement (4081 only)
$\dot{V}_{MIN}$	Minimum flow rate – the negative of the peak exhaled flow rate in a bi-directional test circuit.	P_{ABS}	Absolute pressure in flow tube. Equals barometric pressure if flow tube is open to atmosphere.
$\dot{V}_{\Delta}$	Flow rate delta – the numerical difference in flow rates.	O_2	Oxygen concentration measurement (4081 with 4073 only)
$\dot{V}_{\Delta\%}$	Flow rate delta percent – the difference in flow rates by %.	T	Flow tube temperature measurement.
V_{TI}	Inhaled tidal volume	f	Breath frequency
V_{TE}	Exhaled tidal volume	t_I	Inspiratory time
V	Real-time volume	t_{IP}	Inspiratory pause time
MV	Inhaled minute tidal volume	t_{I+P}	Inspiratory time including pause time
P	Low pressure measurement (4081 only)	t_R	Inspiratory rise time – amount of time from the start of breath to the max flow rate
PIP	Peak inspiratory pressure (4081 only)	t_E	Expiratory time
P_{EEP}	Peak end expiratory pressure (4081 only)	I:E	Inspiratory to Expiratory ratio
P_{MAP}	Mean airway pressure (4081 only)	$I:E_{IP}$	Inspiratory to Expiratory ratio including pause time
P_{MIN}	Minimum low pressure (4081 only)	C_{STAT}	Static compliance – calculated as Tidal volume / (plateau pressure – PEEP)
P_{Δ}	Delta low pressure – Delta airway pressure (4081 only)	🕓	Time of day
LR	Leak rate – calculated as change in low pressure over the set Average Time		

Available Units of Measurement

Measurement	Factory Default Units	Optional User-Selectable Units
$\dot{V}$, $\dot{V}_{PEAK}$, $\dot{V}_{MIN}$	L/min	mL/min, mL/s
V_{TI}, V_{TE}, V, MV	L	mL, L
P, PIP, P_{EEP}, P_{MAP}, P_{MIN}, P_{Δ}, P_{PLAT}	cmH_2O	kPa, Pa, hPa, mbar, mmHg, inH_2O, PSI
P_{HIGH}	PSI	kPa, bar
P_{ABS}	kPa	cmH_2O, Pa, hPa, mbar, bar, mmHg, PSI, inH_2O
LR	cmH_2O/s	kPa/s, Pa/s, hPa/s, mbar/s, mmHg/s, PSI/s, inH_2O/s
C_{STAT}	mL/cmH_2O	L/H_2O, mL/mbar, L/mbar
O_2	% oxygen	-
T	^oC	^oF
f	BPM	Hz
t_I, t_{IP}, t_{I+P}, t_E, t_R	s	–

Measurement Parameter Definitions



(This page intentionally left blank)

CHAPTER 3

Flow Analyzer Setup

Getting Started

Power On/Off

Press the power button on the 4089 Interface Module once to turn the instrument on. With the device powered on, press the power button once to begin the controlled shutdown procedure. The controlled shutdown will count down for 15 seconds before shutting the instrument down. During the countdown procedure, buttons are displayed to provide the options to either shut down the instrument immediately or to cancel the shutdown.

Initialization and Warm-Up

Upon pressing the power button, the Certifier™ Plus Interface Module will display a TSI® splash screen and progress bar during the bootup process. The initialization process takes approximately 40 to 45 seconds to complete. Wait for 1 minute after initialization has completed to allow for the pressure transducers and flow sensor to warm-up.

NOTICE

To ensure accurate measurements, wait one minute for the Certifier™ Plus Flow Analyzer to warm up after powering on the instrument with flow module(s) connected. If environmental conditions have changed significantly, more time may be necessary.

Instrument Setup

Connect/Disconnect Flow Modules

Connect flow modules to either port (A or B) on the top of the interface module. Flow modules can be connected or disconnected with the interface module powered on or powered off. To remove the coiled cable from the either the interface module or flow module, pull from the cable's locking connector shell and not from the cable itself.

If the Certifier™ Flow Analyzer is powered on when a flow module is connected/disconnected, the interface will recognize the action and restart its application. This process takes approximately 25 to 30 seconds to complete, after which the Certifier™ Flow Analyzer will be ready for normal operation.

Either one or two flow modules can be connected to the interface module at a time. Connect the flow module to either port on the interface module. Upon connecting or disconnecting a flow module, the interface will display a message while application restarts. To remove the coiled cable from the flow module, pull its locking connector shell (not the cable) from the flow module.

Connect Inlet Filter

TSI® Certifier™ Flow Analyzers measure utilizing an exposed thermal flow sensor that is highly sensitive to foreign matter and particles within the gas flow. TSI® supplies inlet filters for both the high flow module and low flow module. TSI® recommends that an inlet filter be used on flow modules at all times when operating the Certifier instrument.

CAUTION

To avoid damage to the Certifier Plus Test System components, always use inlet filters upstream of the flow modules.

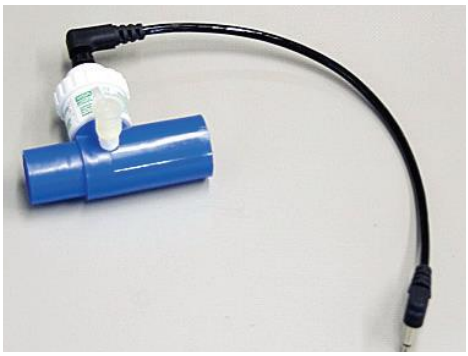
Connect the Low Pressure Measurement

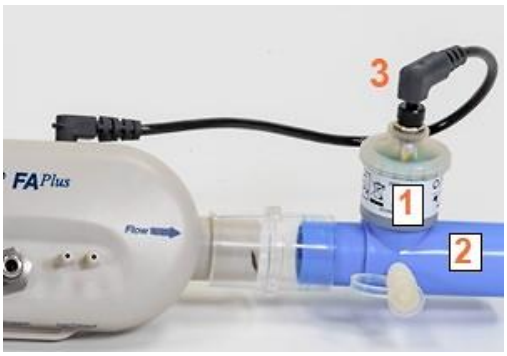
Low pressure is available from the 4081 high flow module only.

To connect the oxygen sensor kit, attach the airway pressure fitting with screen (1) to the outlet of the flow module. Cut a length of silicon tubing (2), connect one end of the tubing to the barb on the airway pressure fitting, and connect the other end of the tubing to the (+) port of the flow module.

Connect the Oxygen Sensor

The model 4073 Oxygen Sensor kit connects to 4081 High Flow Modules only. You can connect or disconnect an oxygen sensor at any time without interrupting the operation of the instrument. Prior to use, oxygen sensors should be field calibrated daily. The oxygen sensor should also be field calibrated following a change in altitude.





To connect an oxygen sensor, unpackage the oxygen sensor cell (1) and screw it into the airway coupling (2). Attach the airway coupling (2) to the outlet of the high flow module and insert the end of the sensor cable (3) containing the nut into the top of the O_2 sensor cell. This end of the sensor cable can be screwed into the oxygen sensor cell. Connect the other end of the sensor cable to the input jack labeled “O2 Sensor” located on the top of the high flow module.

Breath Triggers

The Certifier™ Plus Flow Analyzer uses triggers to define start of the inspiratory and expiratory cycles. Triggers are based on the flow rate, pressure, or from a TTL voltage signal. The Certifier™ Flow Analyzer is set as its trigger default to automatically detect the breath cycles (using flow rate), but you can also set your own start and end trigger values. Under most circumstances, it is recommended to use the Auto Trigger feature.

In manual trigger mode, you select values for the start and end of the breath. A positive slope through the first value is used for the start of inspiratory and a negative slope through the second value used for the start of expiratory. To determine manual flow trigger values, it can be helpful to view the Flow Rate waveform on the Graph screen.

You have the option to set start and end triggers manually based on pressure. To determine pressure trigger values, it can be helpful to view the Low Pressure waveform on the Graph screen. The pressure trigger is intended to give advanced users additional setup options for testing high frequency ventilators or other setups in which flow rate or auto-triggering are not ideal.

Start and end of the breath can also be triggered by a TTL voltage signal given at the connector on the Certifier™ Plus 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.

If a 4081 high flow module and 4082 low flow module are both connected to the interface module, the 4081 high flow module will always control breath triggers for the instrument regardless of the port to which it is connected. If both connected flow modules are the same model (ex., two 4081s or two 4082s) then the flow module connected to the A port will control triggering.

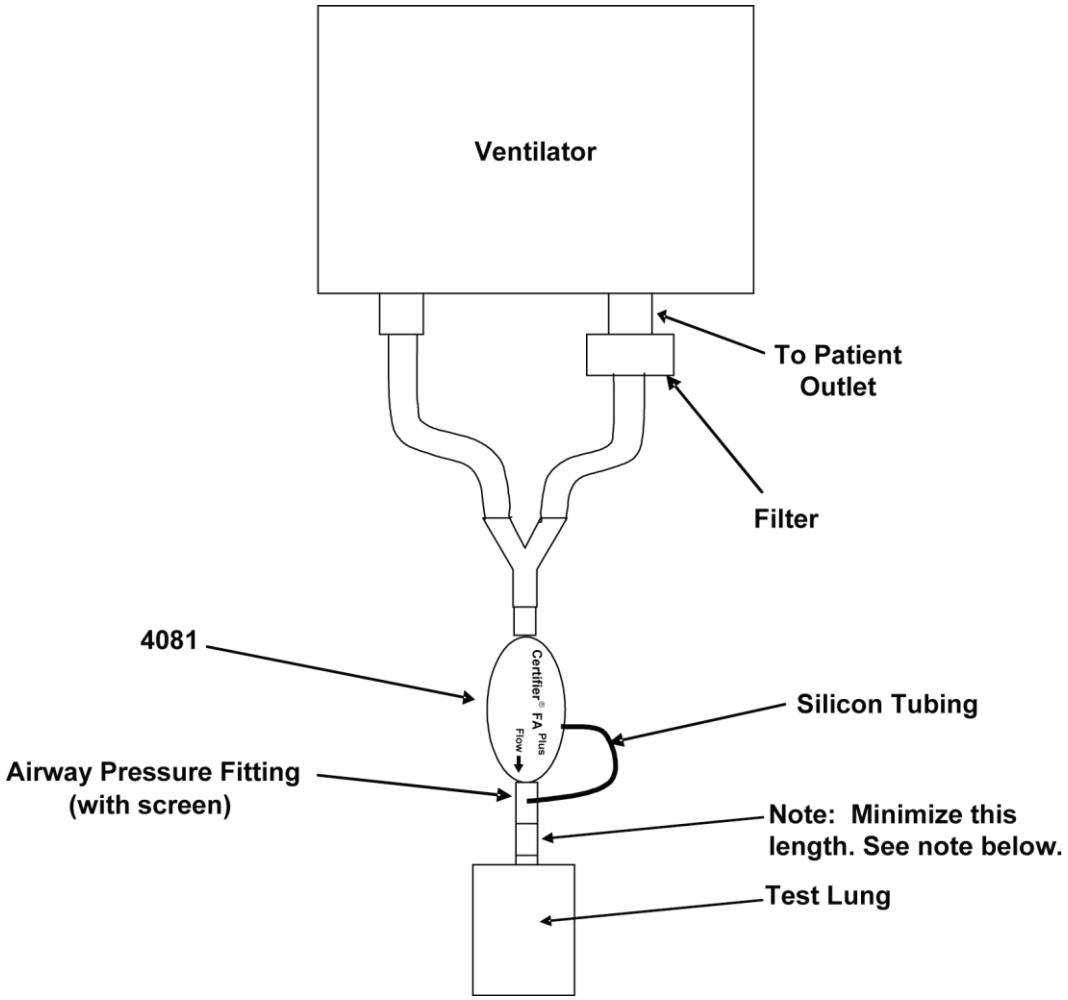
Connect the Certifier™ Plus High Flow Module to a Ventilator

Follow the steps below to connect the Certifier™ Plus 4081 High Flow Module to a bi-directional test circuit such as a mechanical ventilator:

1. Connect the high flow module to the interface module using a coiled cable connector. To remove the coiled cable from the flow module, pull its locking connector shell (not the cable) from the flow module.
2. Connect an inlet filter to the upstream end of the Certifier™ Plus High Flow Module.

3. Connect the AC adapter to the DC power input of the Certifier Plus Interface Module. The battery will charge in the instrument when the AC adapter is plugged in. The instrument can also be operated on battery power without a wired power connection.
4. Press the power button to turn on the Certifier Plus Flow Analyzer. After bootup has completed, wait 1 minute for the pressure transducers and flow sensor to warm up.
5. Perform pre-test checks including zeroing the 4081 pressure transducers and calibrating the oxygen sensor (if applicable). Refer to the Pre-Test Checks section for detailed instructions.
6. Install the flow module into the test circuit between a Y-fitting and a test lung. 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. Refer to the manufacturer's test procedure for the device under test for specific instructions on where to connect the Certifier Plus Flow Module.
7. Connect the low pressure measurement and oxygen sensor (if applicable) to the flow module. Refer to the Instrument Setup section for low pressure and oxygen sensor setup instructions.
8. Configure the Certifier Plus Flow Analyzer settings from the interface display as desired for the instrument under test. If available, a saved configuration specific to the model under test can be loaded at this time. The manufacturer of the device under test will specify the settings and measurement parameters in which to test.

9. Perform testing per the device manufacturer's procedure (or other appropriate procedure). The manufacturer of the device under test will specify the testing requirements and pass/fail criteria.



Test circuit for bi-directional flow

NOTICE
If using a test lung with a built-in restrictor or a separate restrictor, connect the airway pressure fitting with less than 15 cm length 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.

Connect the Low Flow Module

The 4082 low flow module is used for testing flow in oxygen concentrators and other low flow devices. It is not designed for testing ventilators.

Unidirectional mode symbol. The module is not detecting significant negative flow. When testing ventilators, unidirectional mode is used when the flow module is connected to the "**To Patient**" line.

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

Pre-Test Checks

Low Flow Module

Flow Measurement

To ensure proper operation of the system for safety, ensure the 4082 flow calibration is valid. If the calibration due date is approaching or past according to the factory attached label, return the flow module to TSI® for calibration. To do a quick check, disconnect the flow module from the breathing circuit and cap the ends, wait 1 minute and then observe the flow reading. If the flow rate does not measure 0.000 ± 0.010 liters/min, return the flow module to TSI® Incorporated for calibration.

High Flow Module

Flow Measurement

To ensure proper operation of the system for safety, ensure the 4081 flow calibration is valid. If the calibration due date is approaching or past according to the factory attached label, return the flow module to TSI® for calibration. To do a quick check, disconnect the flow module from the breathing circuit and cap the ends, wait 1 minute and then observe the flow reading. If the flow rate does not measure 0.000 ± 0.010 L/min, return the flow module to TSI® Incorporated for calibration.

Flow Directional 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 the directional sensor has not automatically zeroed within 10 minutes, a warning symbol "!" will appear. To manually zero the directional sensor, remove the high flow module from the flow source and cover one or both ends of the flow tube for 2-3 seconds. *No indication is given by the flow analyzer during this process.*

Low-Pressure and High-Pressure Transducer Zeroing

Check the low-pressure transducer zero and 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 pressure and high pressure ports.
2. Press the zero icon.
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.

NOTICE
Barometric pressure transducers **DO NOT** require a zero calibration.

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™ Plus test system with the high flow module and oxygen sensor attached, allow one minute to warm up.
2. Navigate to the **Settings** menu and select “**Oxygen Sensor**”. Follow the directions on the screen. Either an “air only” or “air and 100% oxygen” calibration can be done. The two point air and 100% oxygen calibration provides the best accuracy.

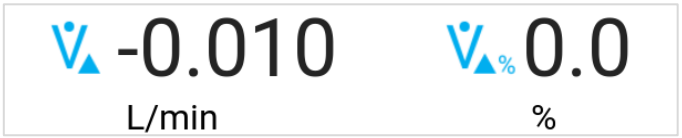
NOTICE
The numeric value displayed during the stabilization process does not necessarily represent the actual oxygen concentration. This numeric stabilization value is there for you to determine if it is changing or not. Once the reading stops changing then it is time to advance to the next step in the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

Flow Compare

Compare flow measurement readings between two TSI® Flow Modules to provide a quick “go/no-go” indication of the flow accuracy. Connect any two model 4081 or 4082 Certifier Plus flow modules and select the Flow Rate Delta or Flow Rate Delta Percent parameters.

The Flow Rate Delta parameter (shown below left) displays the difference in readings in a discreet value. The Flow Rate Delta Percent parameter (shown below right) displays the difference in flow rate readings as a percentage.

NOTICE
A flow rate greater than 2.5 L/min should be used with the flow compare feature.



CAUTION
▪ To ensure accurate measurements, wait 1 minute for the Certifier™ Plus Flow Analyzer to warm up. If environmental conditions have changed significantly, more time may be necessary. ▪ To avoid damage to the Certifier™ Plus Test System components, **ALWAYS** use inlet 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.

CHAPTER 4

Touchscreen Operation

Display Interface Overview

The two primary screens on the **Dashboard** of the Certifier™ Plus Flow Analyzer are the **Parameter Screen** and the **Graph Screen**. The top, bottom, and right bars are always present on both screens. Edits made to the instrument through any of these bars apply to the entire instrument regardless of the screen in which you make changes from.

Parameter Screen

1.	Menu	8.	Parameter/Graph Screen Toggle
2.	Module Cards	9.	Zero Pressure Sensors
3.	Module Indicator	10.	Save Data and/or Snapshots
4.	Battery Indicator	11.	Pause/Play Display
5.	Measurement and Units	12.	Edit Measurements and/or Units
6.	Triggers/Averaging Settings	13.	Warnings and Errors Notifications
7.	User Configurations		

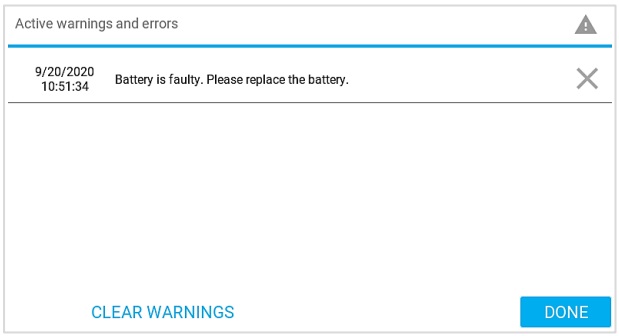
Option	Description
1. **Menu**	Press to access **Manage Data**, **Configurations**, **Settings**, and **Device Information** screens.
2. **Module Cards**	A card is generated for each module connected to the interface and displays the serial number, currently set gas type and conditions, and flow direction indicator for the connected module. Press a flow module card to view information or edit the gas type or gas condition settings for that particular module. If two flow modules are connected, an asterisk (*) will indicate which flow module is being used for triggers and breath averaging.

Option	Description
3. **Module Indicator**	If more than one module is connected, a letter (ex. A, B) is displayed in each module card. These letters are used to signal from which connected module the measurements being selected and displayed are coming from.
4. **Battery Indicator**	Displays the current charge remaining between 0 to 100%. A lightning bolt symbol will be shown inside the battery icon if the Certifier™ Plus battery is actively charging. An exclamation point will be shown inside the battery icon if the Certifier™ Plus Flow Analyzer is powered but no battery is connected.
5. **Measurements and Units**	Displays the selected measurement parameters and their current readings in their selected units. Press either the measurement symbol, reading, or units to edit. Editing includes adding, removing, or reordering measurements as well as editing the units of measurement. Refer to the table in Measurements and Units for a complete list of selectable measurement parameters.
6. **Triggers/Averaging Settings**	Used to set the breath triggers, breath averaging, and time average for real-time values. Access these instrument settings by pressing the gear icon or by pressing directly on the value to be edited. If two flow modules are connected, an asterisk (*) will be displayed in the module card of the flow module that is controlling the triggers.
7. **Configurations**	Displays the name of the configuration that is currently loaded. An asterisk (*) will appear in front of the name if the currently loaded configuration has been edited by the user. Press the configuration name or label on the display to access the screen to rename, save, load, delete, export, or import configuration files.
8. **Parameter/Graph Screen Toggle**	Press to toggle the Certifier™ dashboard between the **Parameter** screen and **Graph** screen.
9. **Zero Pressure Sensors**	Touch to zero the low pressure and high pressure measurements in any connected flow modules. High/low pressure is available in 4081 High Flow Modules only.
10. **Save Data**	Press to log measurement data or to save a screen capture.
11. **Pause Display**	Touch to pause either the **Parameter** or **Graph** screen from updating data on the display. Even while paused, the instrument will continue to make measurements. When paused the pause icon will change into a play icon; press the play icon to resume updating the display.
12. **Edit Measurements**	Press while on the **Parameter** screen to add, remove, or reorder selected measurements and their units.
13. **Warnings and Errors Notifications**	If the Certifier™ Plus Flow Analyzer generates a warning or an error, a yellow triangle with an exclamation point will be displayed in this area. Click on this icon to open the Active Warnings and Errors screen which provides you with descriptions of the issue(s).

Warnings and Errors

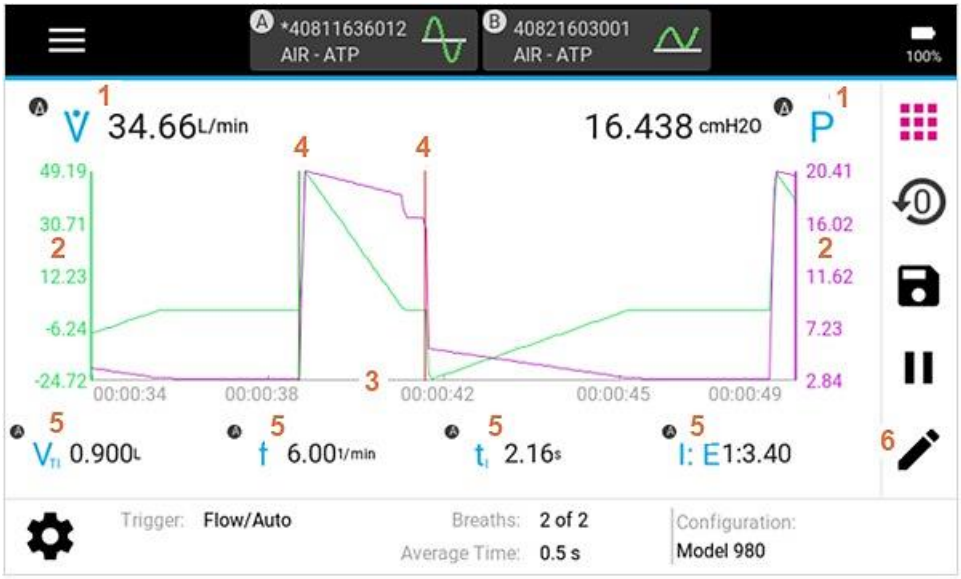
Descriptions of any active warnings or errors can be viewed in the Active Warnings and Errors screen. Errors are shown highlighted in red, whereas warnings are not highlighted. You can clear warnings manually in this screen if desired. Errors can only be cleared if you take appropriate steps to resolve the error state or if the Certifier™ Plus Flow Analyzer is powered down. It is possible that an error may shut down the Certifier™ Plus Flow Analyzer automatically if the error state is not resolved.

Possible warnings and errors displayed on the Certifier™ Plus Flow Analyzer include:



- Battery missing
- Battery faulty
- Battery is too cold to run
- Battery is too hot to run
- Battery is too cold to charge
- Battery charge is full
- Battery level is low
- Battery level is too low, powering down
- Continuous data log warning
- Continuous data log stopped
- Low disk storage space
- Failed to export to USB drive
- Error opening data log of snapshot
- Flow sensor has not been zeroed in 10 minutes

Graph Screen



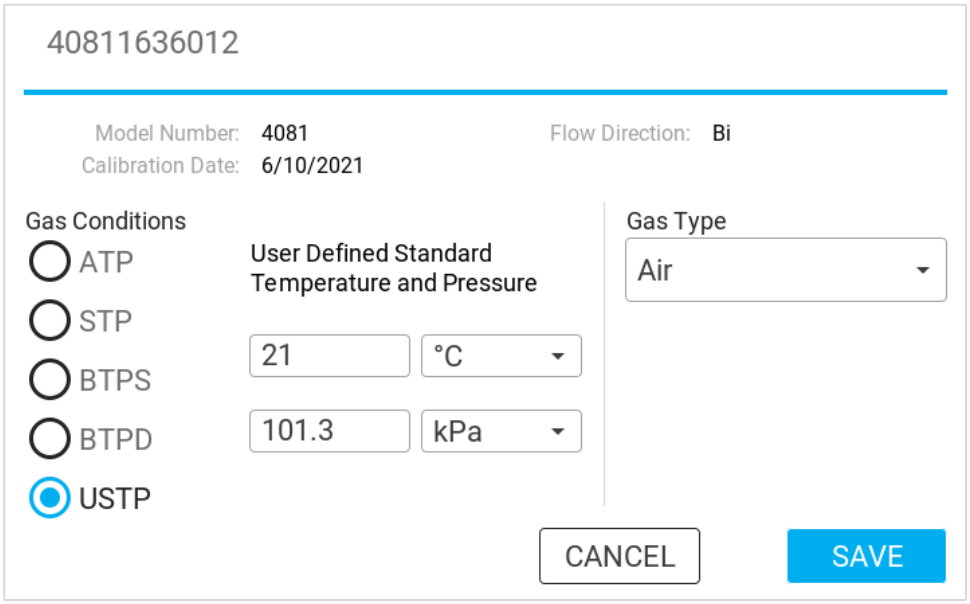
1. Plotted Measurements	4. Trigger Indicators
2. Y-Axis	5. Real-time Measurements
3. X-Axis	6. Edit Graph

Option	Description
1. **Plotted Measurements**	Displays current values for the selected measurements and their units and plots the measurement on the graph. Press either the measurement symbol, reading, or units to edit elements of the graph screen.
2. **Y-Axis**	Scaling is displayed in the same units as those selected for the plotted measurement. The color of the axis matches the color of the corresponding measurement parameter. With 2 measurements plotted, a second Y-axis will be displayed on the right side of the graph, colored for that measurement. The Y-axes are not clickable.
3. **X-Axis**	Scaling is displayed in seconds of time for all plotted measurements. The X-axis is not clickable.
4. **Trigger Indicator**	If enabled, the trigger timing being used by the Certifier™ Flow Analyzer to define the breath cycles will be shown on the graph as vertical lines. The first (green) line indicates the start of the inspiratory breath phase, and the second (red) line indicates the start of the expiratory breath phase.
5. **Real-time Measurements**	Up to four measurements can be selected to display their real-time values beneath the graph. Press on the measurements or units to edit the graph screen.
6. **Edit Graph**	Press while on the **Graph** screen to edit elements of the graph including plotted measurements and units, axis scaling, display span, trigger time, and displayed measurements.

NOTICE
See the Parameter Screen section above for descriptions of screen elements not included here.

Module Cards

A module card is generated at the top of the dashboard for each flow module connected to the Certifier™ interface. Upon pressing a module card, you will be able to view and edit settings related to that particular module.



Option	Description
Serial Number	Of the connected flow module, shown as the heading of the module card.
Model Number	Of the connected flow module (ex. 4081).
Calibration Date	Date of last factory calibration for the connected module.
Flow Direction	Indicates if the connected module makes Uni- or Bi-directional flow measurements.
Gas Type	Displays the selected gas and enables you to change the gas type.
Gas Condition	Displays the selected gas condition and enables you to change the gas condition.

Gas Type options available on the Certifier™ Plus Flow Analyzer:

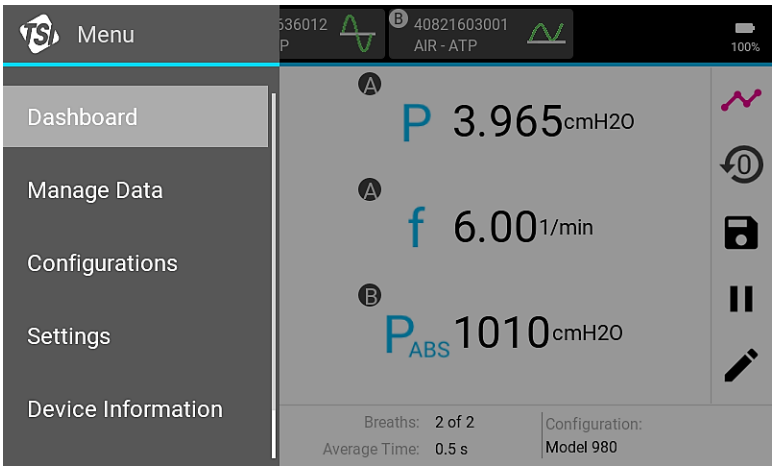
- Air
- Oxygen
- Air-Oxygen Mix (with oxygen sensor connected to high flow module)
- Carbon Dioxide
- Nitrogen
- Nitrous Oxide (with low flow module only)

Gas Condition options available on the Certifier™ Plus Flow Analyzer:

Option	Description
ATP	**Actual Temperature** and **Pressure**. The gas flow rate and volumes at the actual temperature and pressure of the gas. ATP is the default gas condition.
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.
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.
USTP	**User 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 at the temperature and pressure conditions specified by the user.

Menu Screen

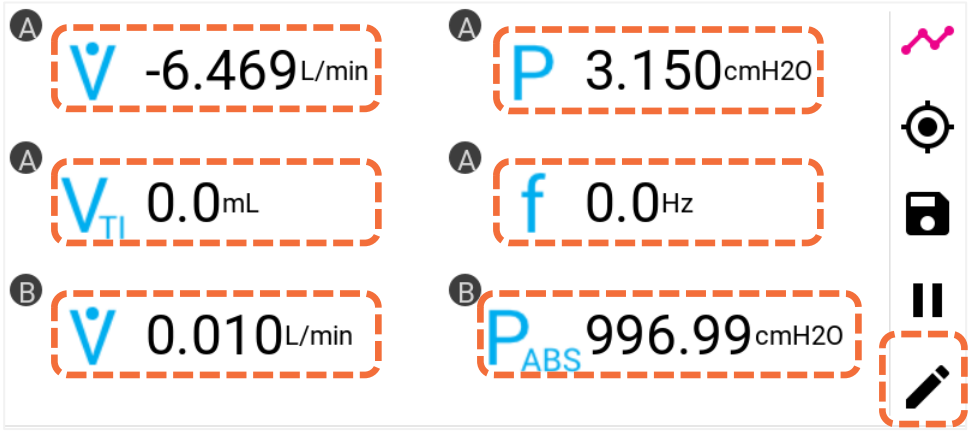
The menu can be accessed from either the **Parameter** screen or **Graph** screen.



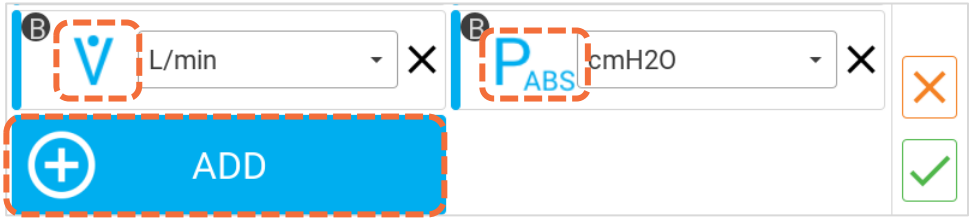
Menu	Description
Dashboard	Closes the **Menu** options and returns you to the previous screen.
Manage Data	Enters screen where you can organize, preview, export, and delete saved data.
Configurations	Used to save, load, export, import, rename, and delete Certifier™ configuration files.
Settings	Access general, date, time, and display brightness settings or calibrate an oxygen sensor.
Device Information	Displays model, serial number, firmware version and last calibration date for the interface module plus any connected modules.

Measurements and Units

From the **Parameter** screen, access the measurement selection screen by pressing on any of the currently displayed measurement symbols, readings, or units of measurement, or by pressing the pencil icon in the right navigation bar.

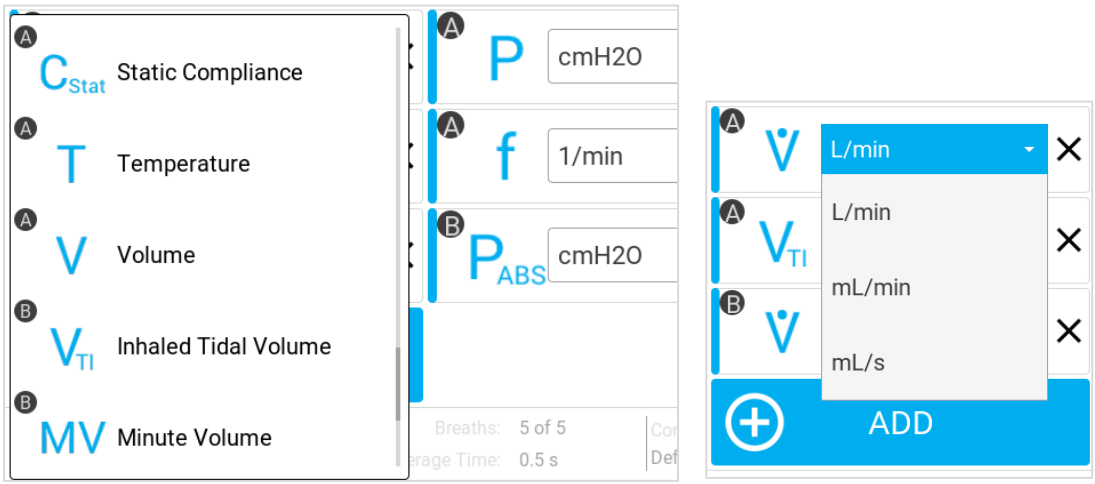


Press the **(+) ADD** tile to select an additional measurement, or press the measurement symbol of a currently selected measurement to change that measurement parameter.

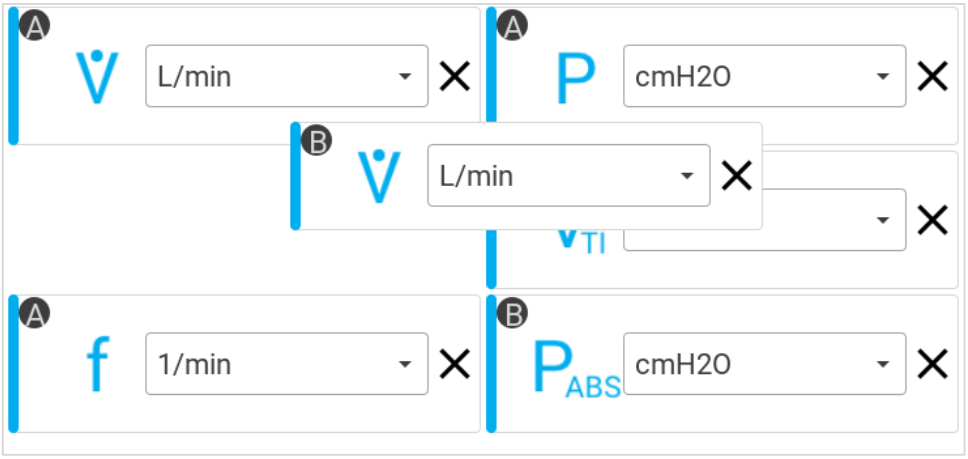


Once pressed, a list of available measurements will be displayed in alphabetical order (see below left). If more than one module is connected, then a letter (ex. A, B) will indicate which module the measurement is coming from. Swipe up and down to scroll through the list options, tap to select.

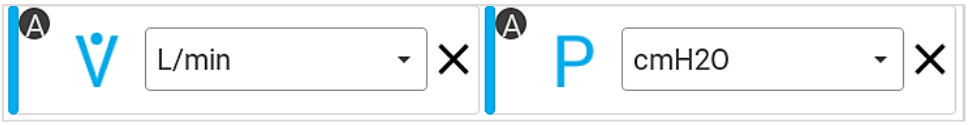
To change the units of measurement for a parameter, press on the currently selected units to access a drop-down list of available alternatives (see below right). Refer to the table Available Units of Measurement to see all the available units for each measurement.



To reorder the selected measurements, press and hold a measurement tile to be able to drag it around the display. The other tiles will adjust on the screen as the tile is being dragged, release the tile once the desired position has been reached.



To remove a measurement from being displayed on the **Parameter** screen, press the **X** located next to the units for that measurement.



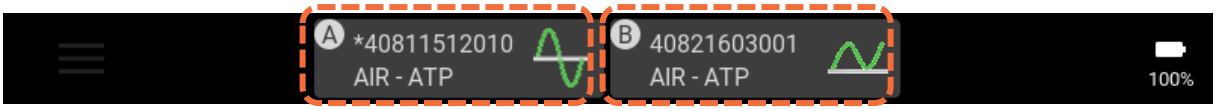
Press the orange **X** button in the right navigation bar at any time to disregard all changes and return to the **Parameter** screen.

Press the green ✓ checkmark button in the right navigation bar to save changes and returns you to the **Parameter** screen.

Gas Type and Gas Condition

The active gas type and gas condition is displayed on the individual flow module cards located in the top black bar on the screen. Press anywhere on a module card to view and edit the settings for that particular connected module.

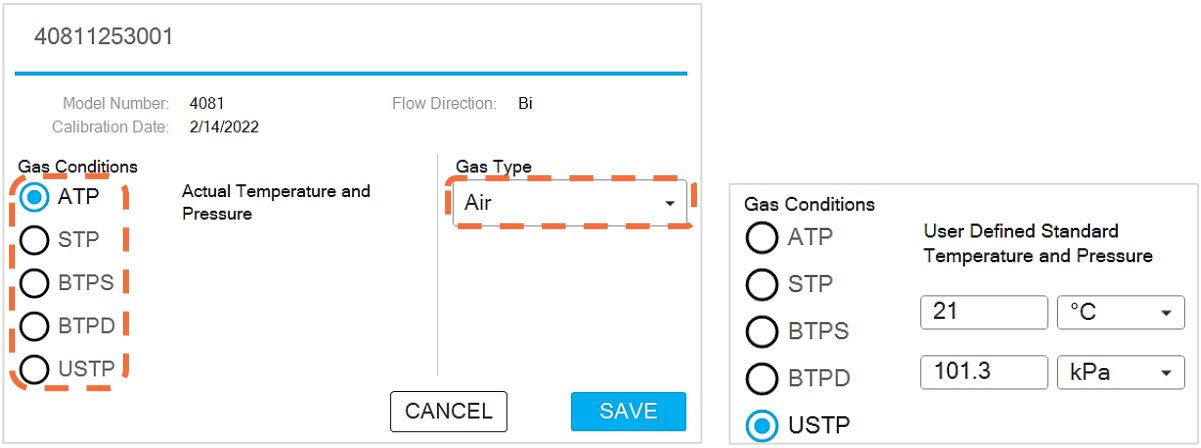
NOTICE
If two flow modules are connected, an asterisk (*) will be displayed in the module card to indicate that flow module is being used for triggers and breath averaging.



The module card (shown below left) displays the serial number, model, calibration date, and flow direction for the connected flow module. The flow direction indicates whether the connected module measures gas flows with bi- or uni-directional functionality.

Press the **Gas Type** field to display the list of available gases and to select a gas.

Press the radio buttons to select a **Gas Condition** to apply to the flow measurements.



To specify your own temperature and pressure values and apply those conditions to gas flow measurements, select the **USTP** gas condition option (shown above right).

Press the **SAVE** button to apply changes to the gas type or gas conditions. Press **CANCEL** to disregard changes and return to the previous screen.

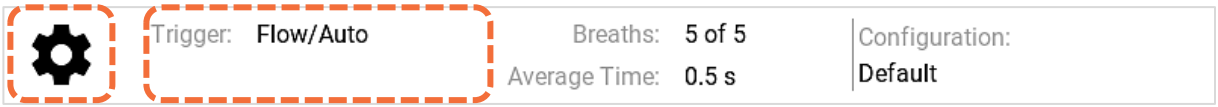
Gas condition options available on the Certifier™ Flow Analyzer:

Option	Description
ATP	**Actual Temperature** and **Pressure**. The gas flow rate and volumes at the actual temperature and pressure of the gas. ATP is the default gas condition for the Certifier™ Flow Analyzer.
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.
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.
USTP	**User 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 at the temperature and pressure conditions specified by the user.

Breath Triggers

Triggers are used to detect the start of the inspiratory and expiratory breath cycles. Triggers can be based on the flow rate, pressure, or from a TTL voltage signal. The Certifier™ Flow Analyzer can automatically detect the breath using the flow rate. You can also manually set your own start and end trigger values using the flow rate or low pressure.

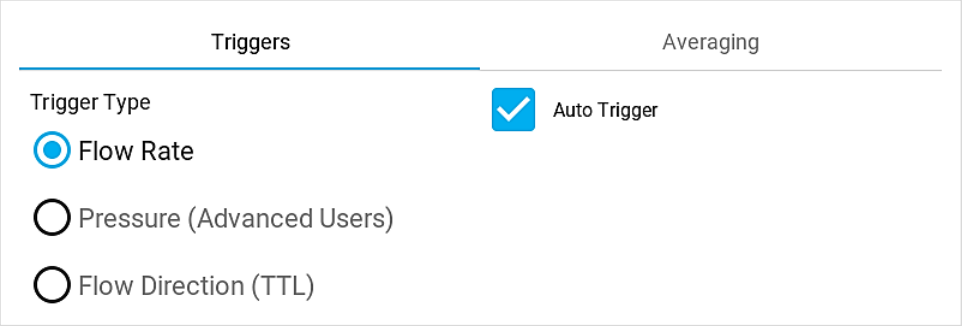
Access the Triggers screen by pressing on the currently selected trigger or the gear icon from the dashboard of the Certifier™ Flow Analyzer. Triggers can also be accessed through the Menu by selecting Settings and then the Triggers and Averaging option.



Flow Rate – Auto Triggers

The Certifier™ Flow Analyzer default is to trigger automatically using the flow rate. Under most circumstances, it is recommended to use the **Auto Trigger** feature. In Auto Trigger mode, the Certifier™ Flow Analyzer will use the flow rate to detect the waveform and automatically assign the start of the inspiratory phase and expiratory phase for each breath.

NOTICE
The Graph Screen can display trigger timing indicators so that you may see the approximate values that the Certifier™ Flow Analyzer is using for triggers.

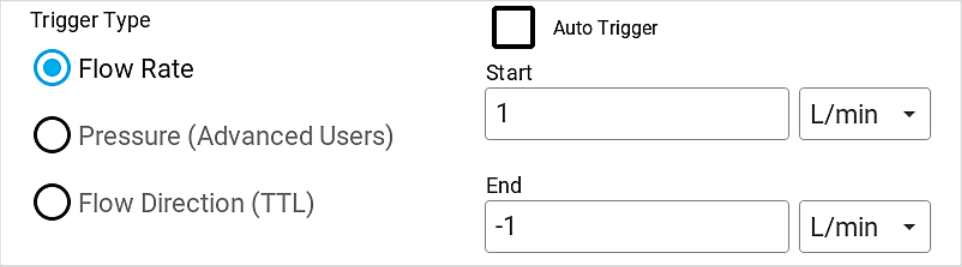


If two flow modules are connected (ex. 4081 and 4082), the 4081 high flow will always control triggers. If both connected flow modules are the same model (ex. two 4081s or two 4082s), then the flow module connected to the A port will control triggering. An asterisk (*) will be displayed before the serial number in the module card of the flow module that is controlling the triggers.

Flow Rate – Manual Triggers

If auto-triggering is not providing reasonable results, consider using manual flow triggering. Press the **Auto Trigger** box to unselect it and be able to specify flow rate values for the start and end of the breath. A positive slope through the first value is used for the start of inspiratory and a negative slope through the second value used for the start of expiratory. For robust triggering, always set the "**End**" level lower than the "**Start**" level.

To optimize manual flow trigger values, it can be helpful to view the **Flow Rate** waveform plotted on the Certifier™ **Graph** screen or observe the flow waveform from the ventilator being tested. Refer to section Editing the Graph Screen for more information on graphing waveforms.



Pressure – Manual Triggers

This trigger type is intended to give advanced users additional setup options for testing high frequency ventilators or other setups in which flow rate or auto-triggering are not ideal.

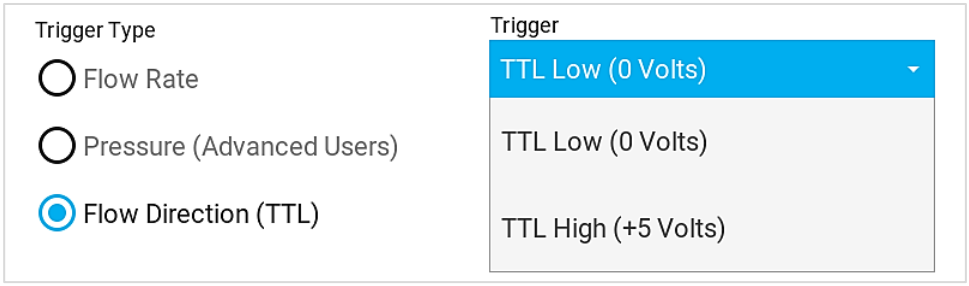
NOTICE
Auto-triggering is not available for pressure.

To trigger using the low pressure, select the **Pressure** radio button option. A positive slope through the first value is used for the start of inspiratory and a negative slope through the second value used for the start of expiratory. For robust triggering, always set the "**End**" level lower than the "**Start**" level.

To optimize manual pressure trigger values, it can be helpful to view the **Low Pressure** waveform plotted on the **Graph** screen or observe the pressure waveform from the ventilator being tested. Refer to section Editing the Graph Screen for more information on graphing waveforms.

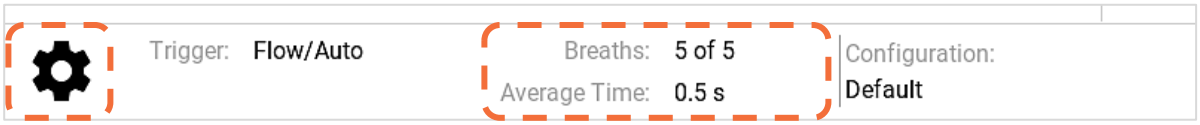
TTL Trigger

The start and end of the breath can also be triggered by a TTL voltage signal given at the connector on the Certifier™ Plus 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. To trigger using TTL voltage, select the **Flow Direction** (TTL) radio button option and select the TTL voltage.



Averaging

Access the **Averaging** screen by pressing on the area around the **Breaths** and **Averaging Time** fields or gear icon located at the bottom of the screen. Averaging can also be accessed through the Menu by selecting **Settings** and then the **Triggers** and **Averaging** option.

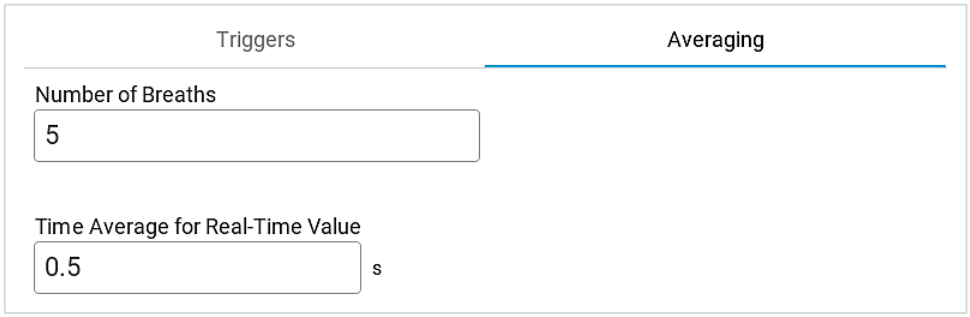


Number of Breaths

This setting specifies the maximum number of breaths over which to average the breathing parameter measurements. For example, if the number of breaths is set to 5, but only 3 breaths have been detected so far, all 3 breaths will be used in calculating the breathing parameters. In the same scenario, if 7 breaths have been detected, only the most recent 5 breaths would be used in the calculations. To specify the number of breaths, touch the input field and enter a whole number ranging from 1 to 10 breaths.

Time Average for Real-Time Values

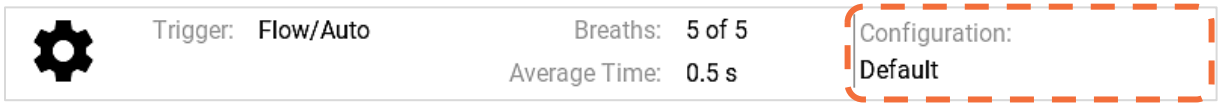
The time average sets the rate at which real-time values are averaged and updated on the display. For example, with a time average value of 0.5 second, the incoming data is averaged over a 0.5 second period and updated on the display every 0.5 seconds. Real-time values include measurements for flow rate, low pressure, high pressure, absolute pressure, oxygen concentration, and temperature. To specify the time average, touch the input field and enter a value ranging from 0.5 to 10 seconds.



Using Configurations

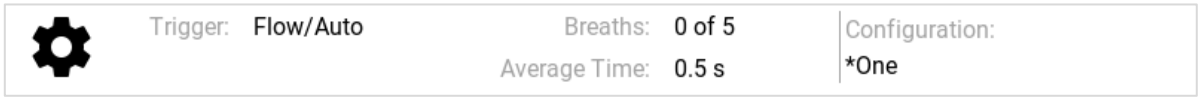
A configuration is a collection of Certifier™ settings that can be saved to internal memory and later recalled. This allows you to save and use specific setups to test different equipment, to comply with organizational test standards, or for personal preferences. Configurations record the measurements and units selected, gas calibrations, gas conditions, triggers and averaging, and graph setup.

The active configuration is displayed at the bottom right of the **Parameter** and **Graph** screens. Access the **Configurations** screen by pressing anywhere in the Configuration area in the bottom right corner of the screen. **Configurations** can also be accessed through the Menu by selecting the **Configurations** menu option.



NOTICE

An asterisk will be displayed in front of the configuration name to indicate that the settings have been changed and differ from what is saved in the original configuration. The asterisk will be removed if the Certifier™ Flow Analyzer is changed back to the original configuration settings or if the configuration is reloaded. You also have the option to save the current settings and changes, either overwriting the currently loaded configuration or creating a new configuration.

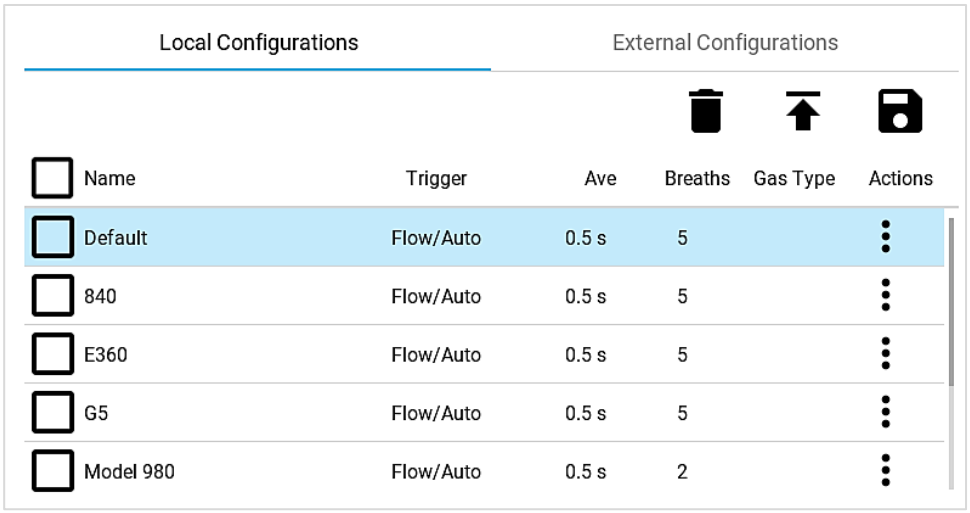


Managing Configurations

The Local Configurations tab lists all the individual configuration files saved in the Certifier™ Plus Flow Analyzer's internal memory. The Certifier Plus can save an unlimited number of user configurations. The currently loaded configuration will be highlighted blue in the list (ex. Default). Swipe up and down on the list to scroll through the files.

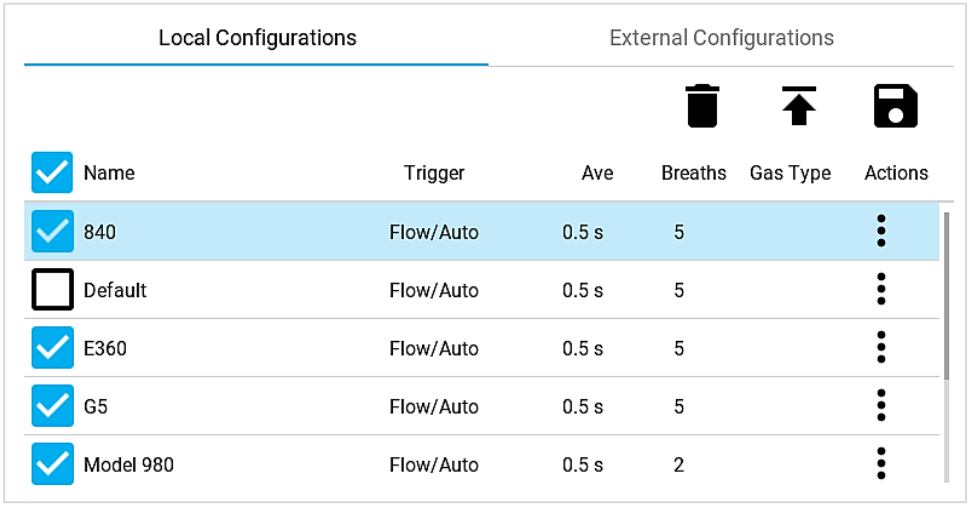
User configurations are specific to the module(s) connected to the Certifier interface at the time in which the configuration was created, referred to as the hardware setup. Saved configurations will only be displayed in the Local Configurations tab if the Certifier Flow Analyzer has the same hardware setup that it had at the time in which the configuration was created. See User Configurations on page 2-4 for more information about the hardware setup.

The 3-dot icons provide the options to **Rename**, **Save**, **Load**, **Export**, or **Delete** individual configuration files. Press the 3-dot icon of individual configuration file rows to perform an action.



The check boxes are used to select multiple files so you may export or delete more than one configuration at a time. Press a check box to select and press again to deselect. Press the checkbox in the **Name** column heading to select all configuration files.

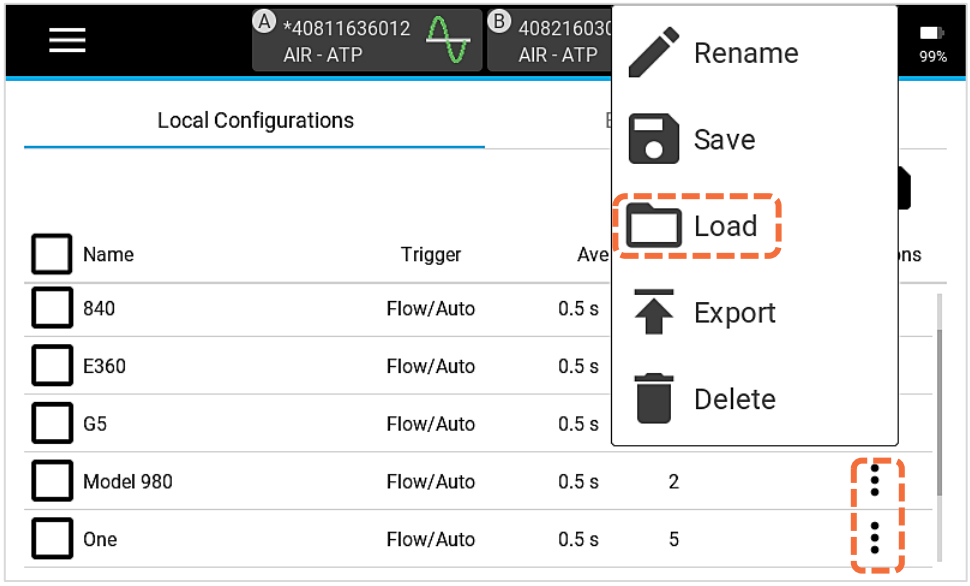
NOTICE
The Default configuration file **cannot** be overwritten, renamed, exported, or deleted.



Loading Configurations

Locate the configuration in the list under **Local Configurations** and press the 3-dot icon for the file row. Select the **Load** option from the pop-up menu.

NOTICE
Only one configuration can be loaded and active on the Certifier™ Flow Analyzer at a time, the check boxes are not used for loading configurations.

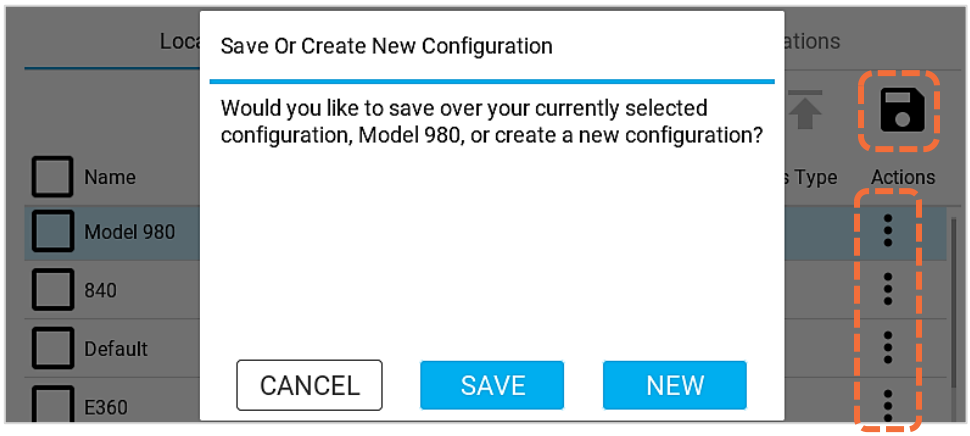


Saving Configurations

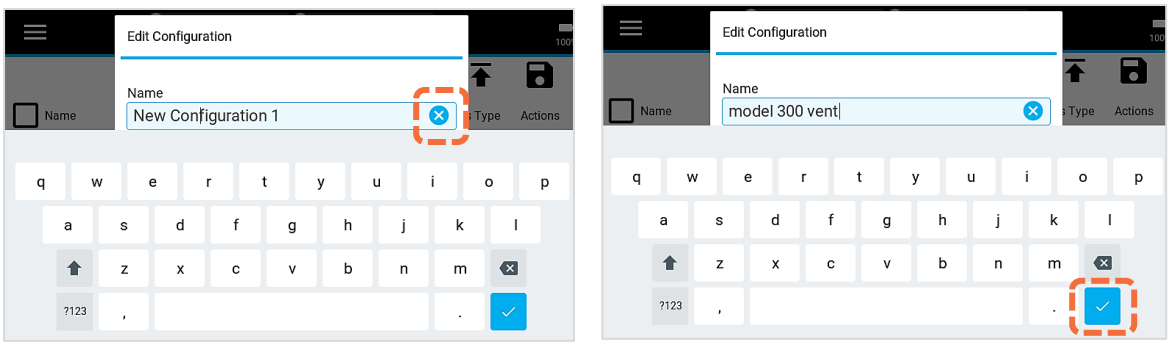
To save the current Certifier™ Plus Flow Analyzer setup as a configuration, navigate to the **Local** tab of the **Configurations** screen and click the save (disk) icon. A pop-up screen provides the options to overwrite the active configuration [**SAVE**] or to create a new configuration [**NEW**].

NOTICE
Only one configuration file can be saved at a time, and that the check boxes are not used for saving configurations.

As an alternative, from the **Configuration** screen you can choose to save your current setup by overwriting an existing configuration on the Certifier™ Plus Flow Analyzer. Locate the configuration to be overwritten and press the corresponding 3-dot icon. A pop-up screen will ask for confirmation before overwriting the selected configuration file.



If you choose to create a new configuration to save the setup, the Certifier™ Flow Analyzer will generate a new configuration named “**New Configuration**”. To rename the new configuration, press the 3-dot menu and select the **Rename** option. Press on the text field in the **Edit Configuration** pop-up screen to bring up the onscreen keyboard. Press the blue and white **X** to the right of the configuration name to clear the text in the name field. After editing the name, press the white on blue ✓ checkmark button in the bottom right of the keyboard.



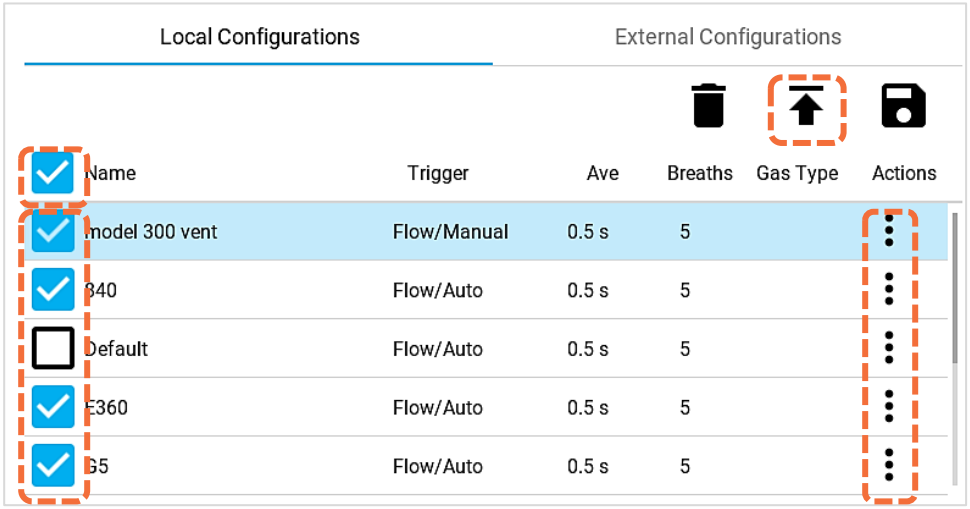
Exporting Configurations

Configurations are stored in the internal memory of the Certifier™ instrument and can be exported through either of the two USB-A ports located on the top side of the 4089 Interface Module. To export one or more configurations, insert a USB flash drive into the Certifier™ Flow Analyzer and navigate to the **Local** tab of the **Configurations** screen. Any existing Certifier Flow Analyzer configurations stored on the USB flash drive will be displayed in the **External Configurations** tab.

To export a single configuration, either click on the 3-dot menu of that particular configuration file and select the **Export** menu option, or check the corresponding box and press the export icon (up arrow).

To export more than one configuration, press the check box for each configuration file or press the checkbox in the **Name** column heading to select all configuration files.

NOTICE
The Default configuration file **cannot** be exported, renamed, overwritten, or deleted.



After configurations have been exported, you can navigate to the **External Configurations** tab to confirm that configuration files have successfully exported to the inserted USB drive. Exported configuration files can be attached in emails and imported into other Certifier™ Plus instruments.

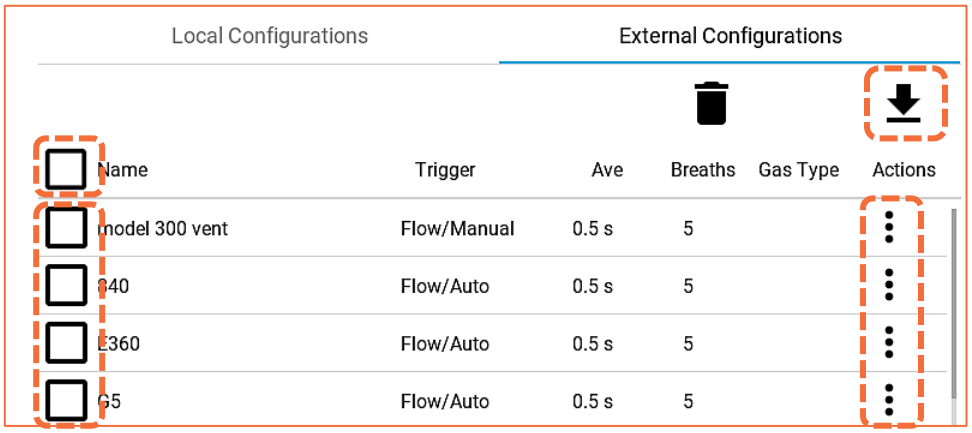
When exported, configuration files will have a file extension based on the hardware setup of the Certifier™ Flow Analyzer when the configuration was originally created. See User Configurations on page 2-4 for more information about hardware setups and file extensions for exported configuration files.

Importing Configurations

The Certifier™ Plus Flow Analyzer can import configurations from a USB flash drive inserted into either of the two USB-A ports located on the top side of the 4089 Interface Module. The Certifier™ Flow Analyzer will recognize any configuration files and display them in the **External Configurations** tab.

To import a single configuration, either click on the 3-dot menu of that particular configuration file and select the **Import** menu option, or check the corresponding box and press the export icon (down arrow).

To import more than one configuration, press the check box for each configuration file or press the checkbox in the **Name** column heading to select all configuration files.

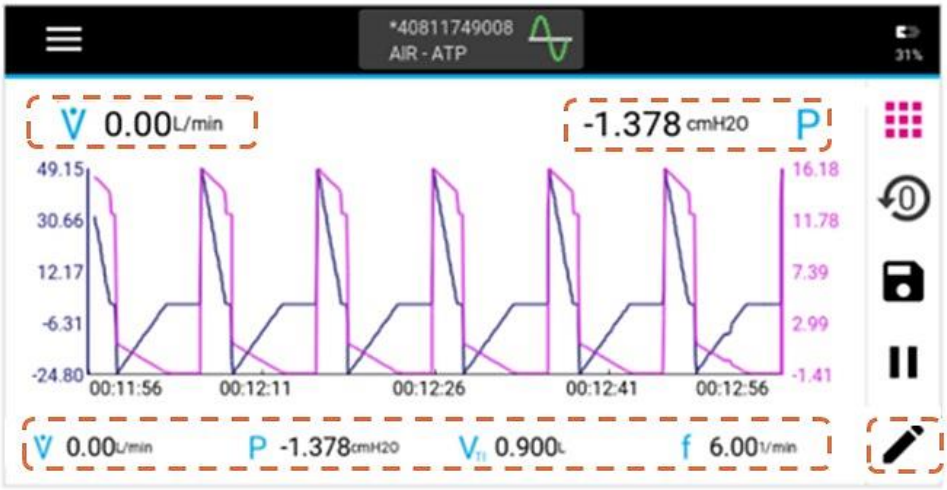


NOTICE

Configuration files from a model 4088 Certifier™ FA+ interface module are not compatible with the Certifier Plus and Certifier Pro instruments. Users would need to perform a one-time replication of the settings on a Certifier Plus or Certifier Pro Flow Analyzer and save the new configuration.

Editing the Graph Screen

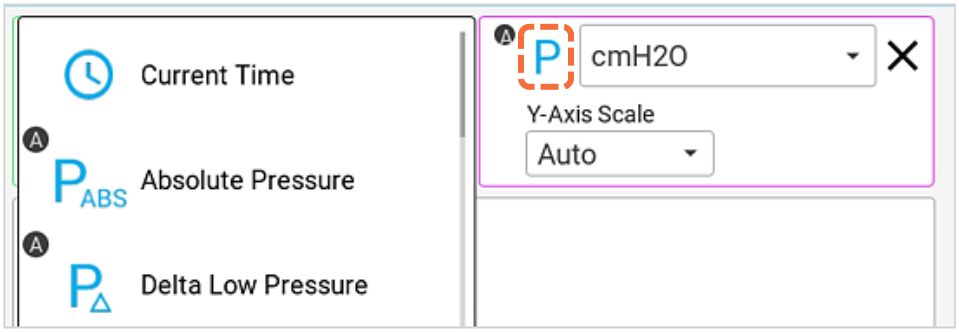
From the **Graph** screen, press on the pencil icon or on any displayed measurement symbols, readings, or units to access the edit graph screen.



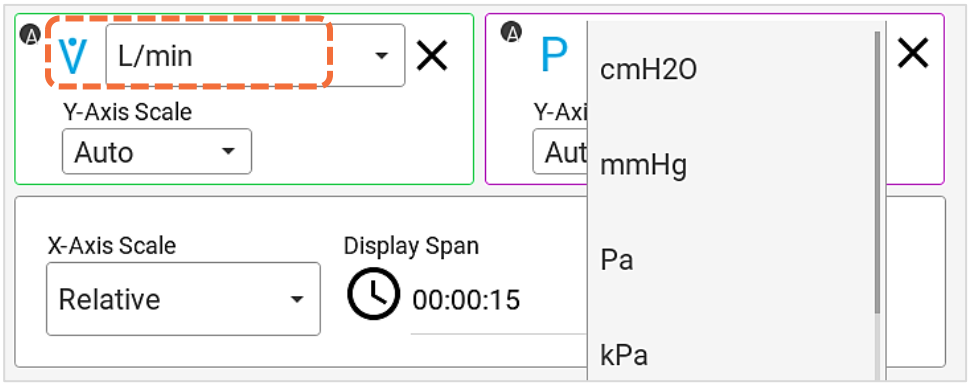
Plotted Measurements

Either 1 or 2 measurements can be plotted on the graph at a time. The primary measurement is displayed on the left side of the screen and the secondary measurement on the right. The color of the borders around the plotted measurements in the edit screen correspond to the colors shown for the Y-axes and traces on the graph.

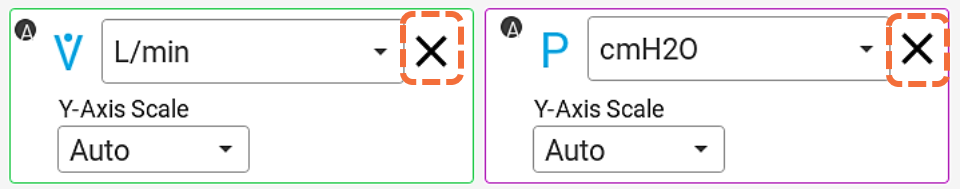
To change a measurement parameter, press on the measurement symbol to display a list of available measurements in alphabetical order (see below left). If more than one module is connected, then a letter (ex. A, B) will indicate which module the measurement is coming from. Swipe up and down to scroll through the list options, and tap to select.



To change the units of measurement for a plotted measurement, press on the current units to access a drop-down list of available alternatives. Refer to the table Available Units of Measurement to see all the available units for each measurement.



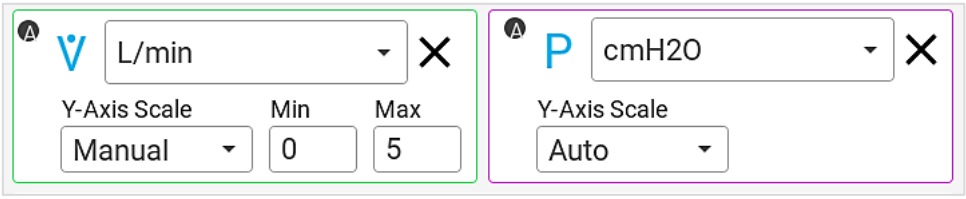
To remove a measurement from being plotted on the graph, press the **X** located next to the units for that measurement.



Y-Axis Scaling

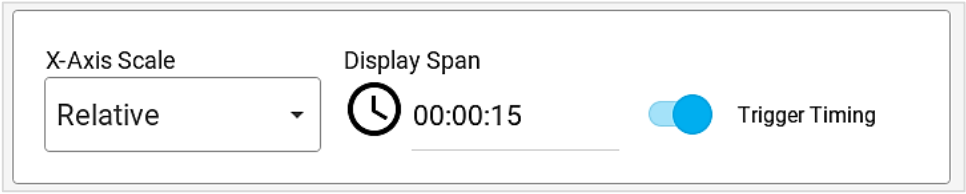
Scaling for the Y-axis is displayed in the same units as those selected for the plotted measurement. The color of the borders around the Y-Axis Scales in the edit graph screen correspond to the colors shown for the Y-axes and traces on the graph.

The Y-axis is set to scale automatically as the default. With auto-scaling, the graph will automatically adjust the Y-axis minimum and maximum values. You can choose manual scaling for Y-axes and input the minimum and maximum values to be displayed on the graph. The values input for manual **Min** and **Max** use the same units of measurement as the plotted parameter.

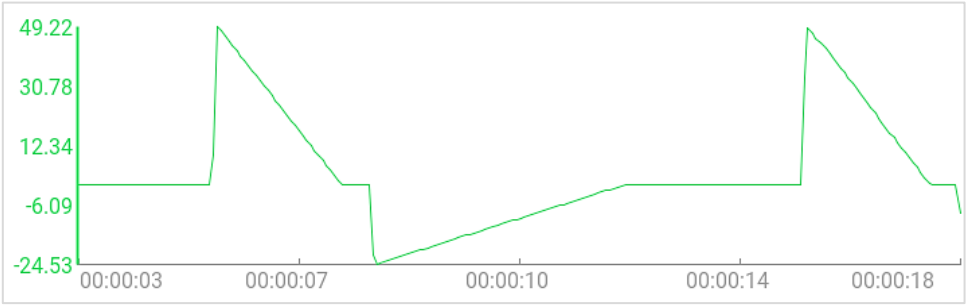


X-Axis Scaling

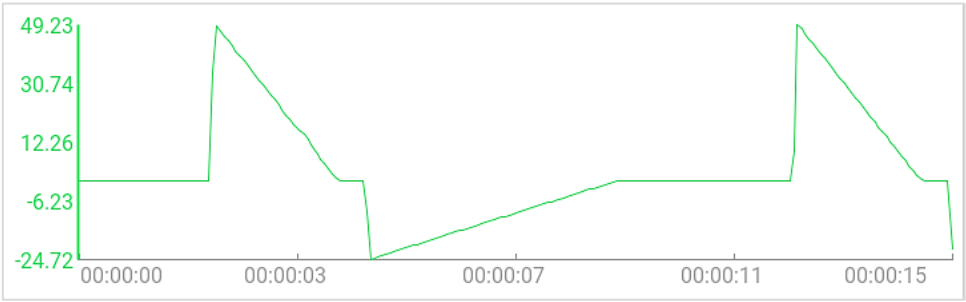
The X-axis is displayed in seconds of time for all plotted measurements. The **Display Span** specifies the length of time to display data on the graph at one time. The display span ranges from 1 to 60 seconds with the default set as 15 seconds.



The **Relative X-Axis Scale** option sets the X-axis to count in seconds and use that value as the maximum for graph. For example, with the **Relative** option selected and a display span of 15 seconds, the graph X-axis will count 00:00:15, 16, 17, 18, etc. as the maximum and 15 seconds less 00:00:00, 01, 02, 03, etc. as the minimum values on the graph.

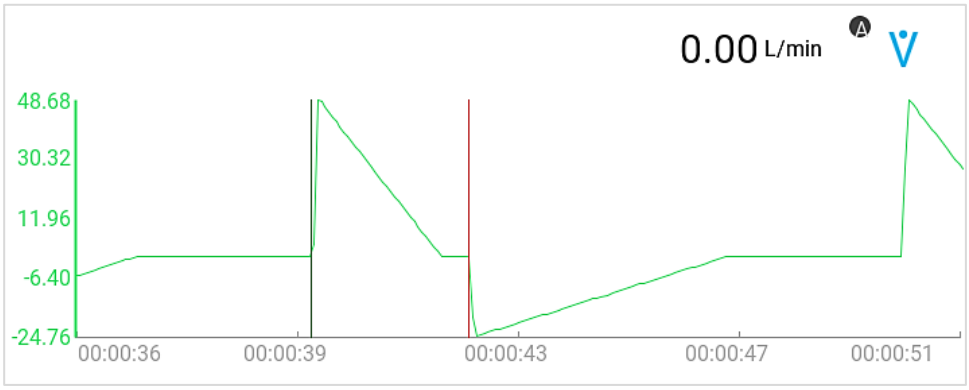


The **Span** option does not count the time and retains the beginning and end of the display span. For example, with the **Span** option selected and a display span of 15 seconds, the graph will show 00:00:00 as the minimum and 00:00:15 as the maximum for the X-axis.



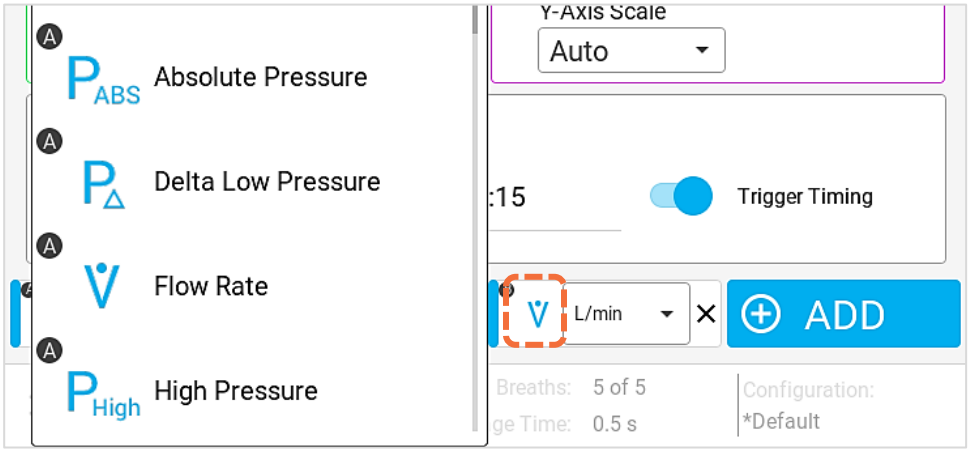
Trigger Indicators

When enabled, the trigger timing being used by the Certifier™ Flow Analyzer to define the breath cycles will be shown on the graph as vertical lines. The first (green) line indicates the start of the inspiratory phase, and the second (red) line indicates the start of the expiratory phase of the breath cycle.

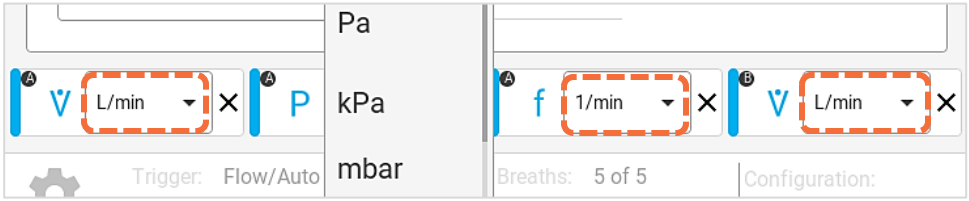


Real-Time Measurements

Up to four measurements can be selected to display their real-time values beneath the graph. To change a measurement parameter in the edit graph screen, press on the measurement symbol to display a list of available measurements in alphabetical order (see below left). If more than one module is connected, then a letter (ex. A, B) will indicate which module the measurement is coming from. Swipe up and down to scroll through the list options, and tap to select.



To change the units of measurement for a parameter, press on the currently selected units to access a drop-down list of available alternatives (see below right). Refer to the table Available Units of Measurement to see all the available units for each measurement.



To reorder the selected real-time measurements, press and hold a measurement tile to be able to drag it left or right along the bottom of the display. The other tiles will adjust on the screen as the tile is being dragged, release the tile once the desired position has been reached.

To remove a measurement from being displayed on the **Parameter** screen, press the **X** located next to the units for that measurement.

Press the orange **X** button in the right navigation bar at any time to disregard all changes and return to the **Parameter** screen.

Press the green ✓ checkmark button in the right navigation bar to save changes and return you to the **Parameter** screen.

Zeroing and Calibration

Zero Pressure Sensors

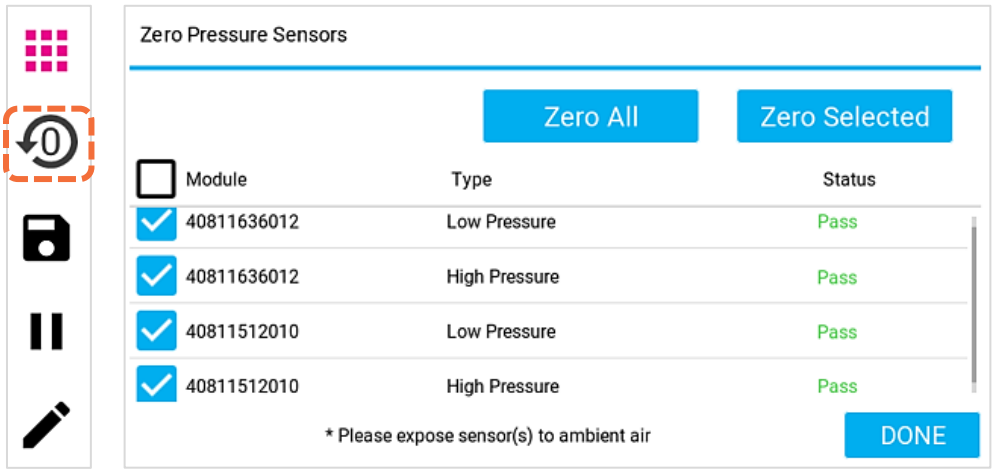
The Certifier™ Plus 4081 High Flow Module contains embedded low pressure and high pressure sensors. TSI® recommends zeroing these transducers before each pressure measurement to ensure the most accurate readings.

NOTICE
If two 4081 Flow Modules are connected to the 4089, the pressure transducers for both modules are simultaneously able to be zeroed.

To zero the pressure sensors, perform the following steps:

1. Disconnect any pressure tubing from the low pressure and high pressure ports to expose the sensors to the ambient air.

2. Press the zero icon located in the right navigation bar of the Certifier™ display (see below left).
3. Select the sensor(s) to be zeroed by checking their boxes and press the **Zero Selected** button, or press the **Zero All** button to select and zero all pressure sensors.



After zeroing, a status is displayed for each connected pressure sensor to indicate the result of the zero process. The pressure sensors can be zeroed more than once by you while in the **Zero Pressure Sensors** screen. Press the **DONE** button to return to the Certifier™ dashboard screen.

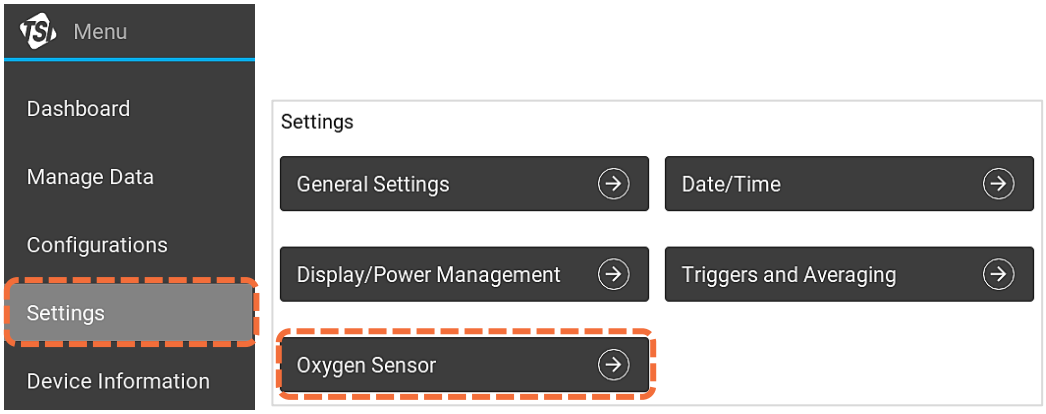
NOTICE
The barometric pressure sensor (used for absolute pressure measurements) **does not** require zeroing and; therefore, this sensor is not displayed in the **Zero Pressure Sensors** screen.

Calibrate Oxygen Sensor

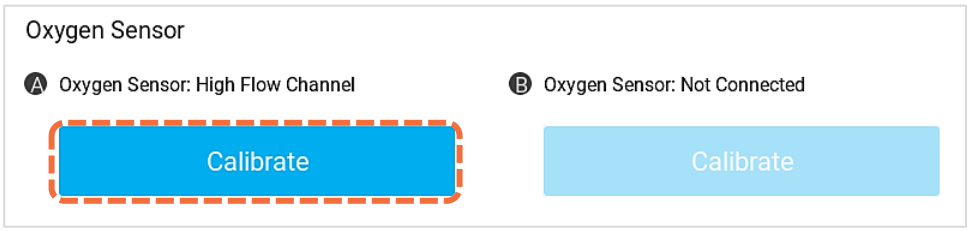
An oxygen sensor can be connected to the 4081 High Flow Module to provide real-time oxygen concentration measurements. TSI® recommends the oxygen sensor be field calibrated on a daily basis as well as after replacing the oxygen sensor cell or after a change in altitude.

To field calibrate an oxygen sensor, perform the following steps:

1. Power up the Certifier™ Plus Test system with the high flow module and oxygen sensor connected, and allow one minute for the Certifier™ Flow Analyzer to warm up.
2. On the Certifier™ display, press the **Menu** icon and select the **Settings** option. From the **Settings** screen, select the **Oxygen Sensor** option.



3. In the **Oxygen Sensor** screen, the Certifier™ Flow Analyzer will display any connected oxygen sensors. Press the **Calibrate** button and follow the on-screen directions to complete the calibration process.



4. Either an “air only” or “air and 100% oxygen” calibration can be done. The two point air and 100% oxygen calibration provides the best accuracy.
5. When exposing the oxygen sensor to ambient air or 100% oxygen gas, it is recommended that the flow rate be anywhere from 4 to 9 liters per minute.

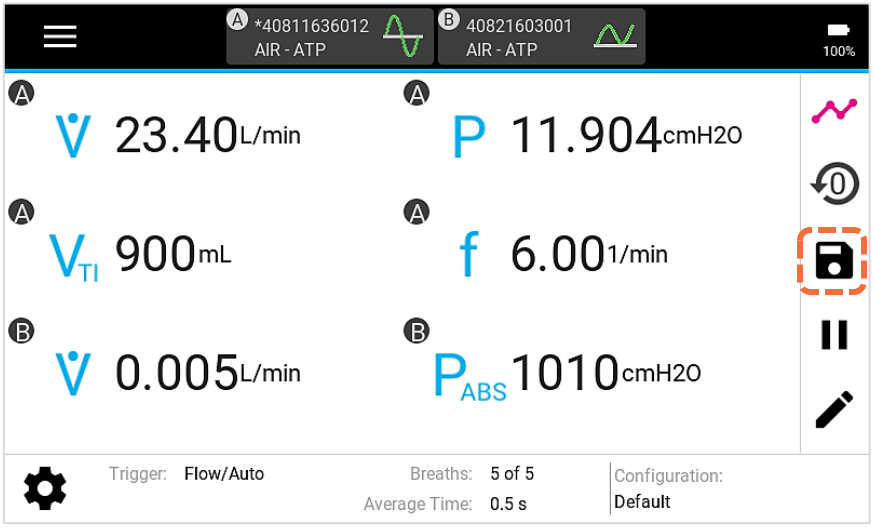
NOTICE
The numeric value displayed during the stabilization process does not necessarily represent the actual oxygen concentration. This numeric stabilization value is there for you to determine if it is changing or not. Once the reading stops changing then it is time to advance to the next step in the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

Data Logging and Export

The Certifier™ Plus Flow Analyzer is capable of logging measurement data and capturing screenshots. Files are saved to the internal memory of the Certifier™ Flow Analyzer and can be exported through either of its two USB-A ports. Saved data is exported as .csv files and screenshots are exported as .png files.

Data Acquisition

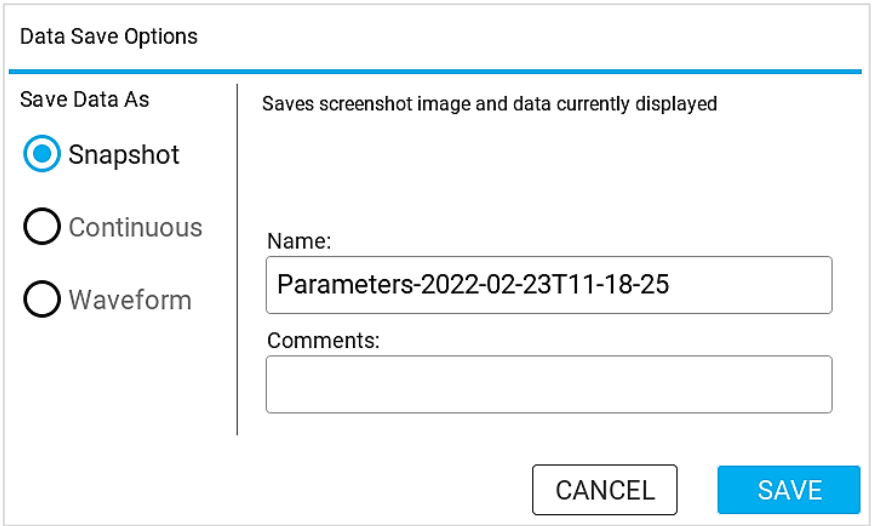
Press the save icon (disk image) in the right navigation bar to access the **Data Save Options** screen. Upon pressing the save icon, the Certifier™ Flow Analyzer will automatically pause the display from updating while you choose between taking a snapshot, continuous logging, or waveform logging.



Snapshot

The Snapshot feature saves a screenshot image as well as saves the data currently displayed on the screen, either from the **Parameter** screen or **Graph** screen. Upon executing a snapshot, the Certifier™ Flow Analyzer will create two files, an image file for the screen capture and a data file with a single data point.

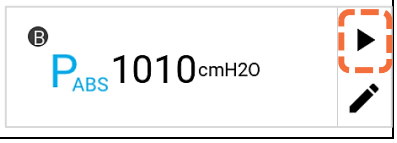
With the **Snapshot** option selected, a name is generated for the file using the screen being saved on, either “Parameters” or “Graph”, followed by the current date and time. You can save with this name or edit the **Name** field to input a custom name. You can input comments that will be attached to the saved file.



NOTICE

After pressing the **SAVE** button, the Certifier™ Flow Analyzer will return to the previous screen with the display still paused. Press the play button (triangle icon) in the right navigation bar to resume updating the display.

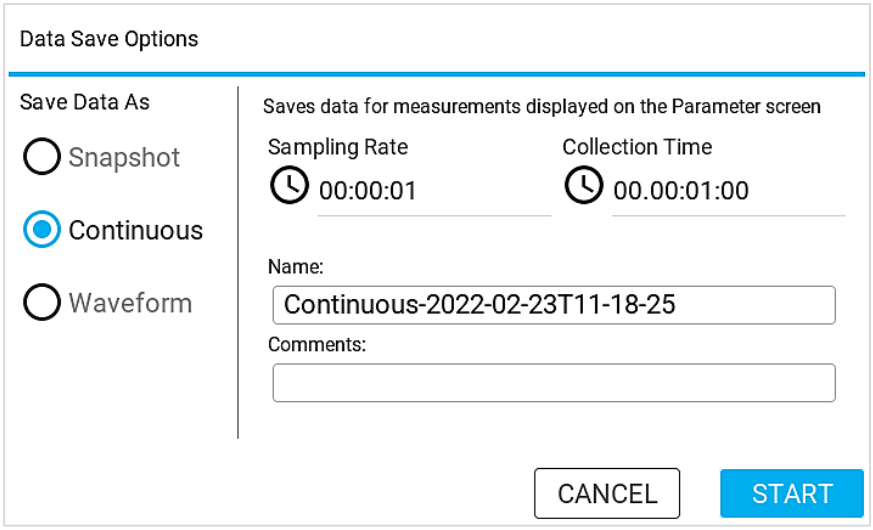
Pressing the **CANCEL** button from the **Data Save** screen will return you to the previous screen and automatically resume updating the display.



Continuous Logging

Continuous logging initiated from the **Parameter** screen will save data for the measurements currently selected on screen. Initiated from the **Graph** screen, Continuous will save data for the plotted graph measurements. The sampling rate at which data is collected can be set from 1 second to 10 minutes. The collection time can be set from 15 seconds to up to 5 days (120 hours) of continuous logging.

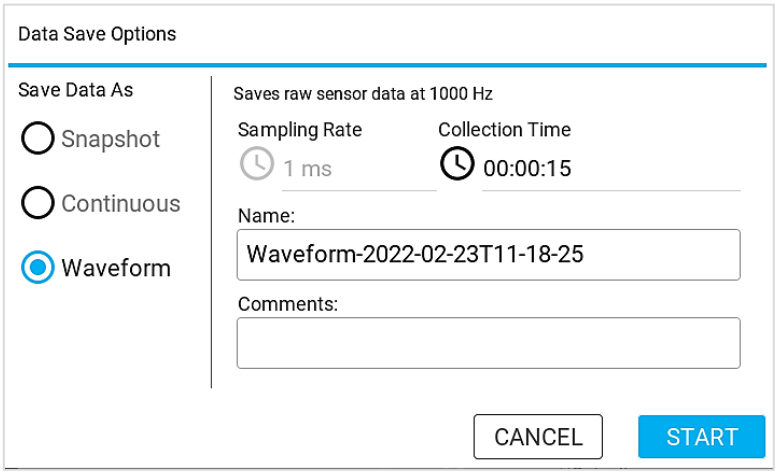
With the **Continuous** option selected in the **Data Save** screen, a name is generated for the file using "**Continuous**" followed by the current date and time. You can save with this name or edit the Name field to input a custom name. You can input comments that will be attached to the logged file. Press **START** to initiate logging, press **CANCEL** to disregard saving data and return to the previous screen.



Waveform Logging

Waveform logging is used to record raw sensor data with high resolution. Waveform logs include data for flow rate, low pressure, high pressure, absolute pressure, temperature, and oxygen concentration (if connected) regardless of the screen from which logging was initiated. The sampling rate for waveform logging is fixed at 1 ms (1000 Hz). You can set the collection time from 15 to 60 seconds.

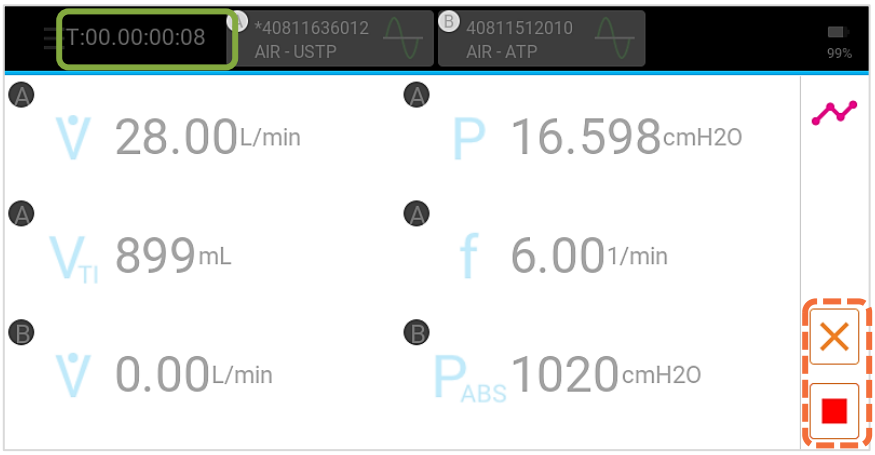
With the **Waveform** option selected in the **Data Save** screen, a name is generated for the file using "**Waveform**" followed by the current date and time. You can save with this name or edit the **Name** field to input a custom name. You can input comments that will be attached to the logged file. Press **START** to initiate logging, press **CANCEL** to disregard saving data and return to the previous screen.



Cancel/Stop an Active Log

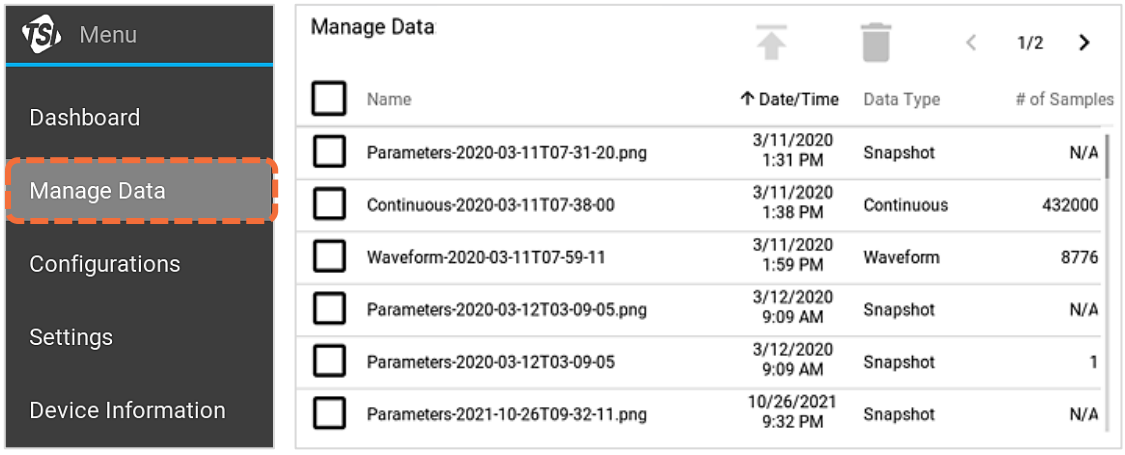
The Certifier™ display is disabled while actively collecting data from a **Continuous** or **Waveform** log, and you can only toggle between the **Parameter** and **Graph** screens during this time. The collection time remaining is shown counting down on the left side of the header bar (circled in green below). During active logging the right navigation bar will populate buttons for you to cancel or stop logging (circled below in red). Once logging has completed, the Certifier™ flow analyzer creates a log file and the display will become re-enabled.

To cancel the active data log, press the top **X** button in the right navigation bar. Cancelling will end the active log and disregard any data saved up to that point. To stop the active data log, press the bottom red square button in the right navigation bar. Stopping will end the active log and create a log file with the data saved up to that point.



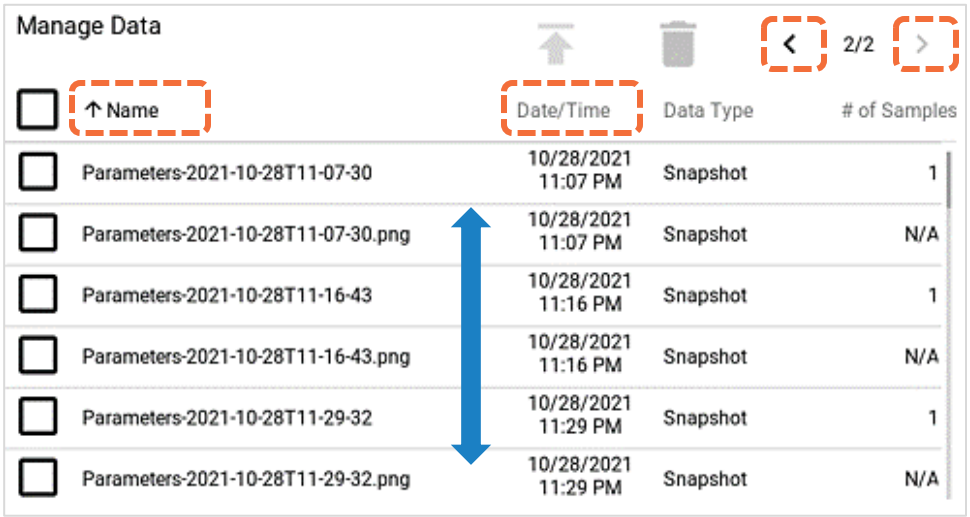
Managing Data

Saved screenshots and data log files are stored in the internal memory of the Certifier™ Plus Flow Analyzer and can be viewed from the **Manage Data** screen. Access the **Manage Data** screen by pressing the **Menu** and selecting the **Manage Data** menu option. From this screen you can preview, export, or delete screenshots and saved files.



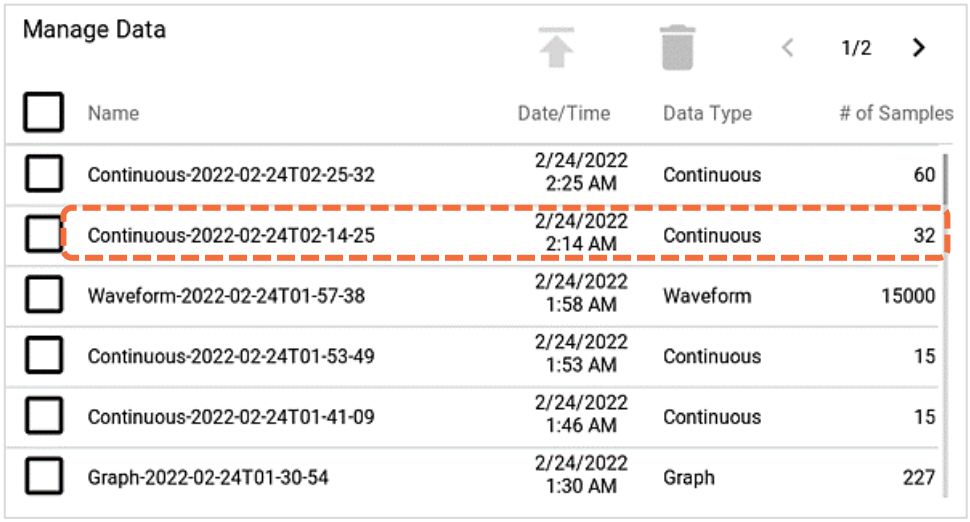
The **Manage Data** screen lists all the individual saved data files and screenshots available to the user. The **Data Type** column corresponds to the Certifier™ logging options and files are labeled as either **Snapshot**, **Continuous**, **Waveform**, or **Graph**. The **# of Samples** column denotes the number of data points collected for each file and equals the sampling rate multiplied by the collection time.

Press on the **Name** heading or **Date/Time** heading to order the list of saved files by that column value in either ascending or descending order. Swipe up and down on the screen to scroll through the list of files. If there is more than one page of saved files, press the arrows in the upper right of the screen to tab through the different pages.

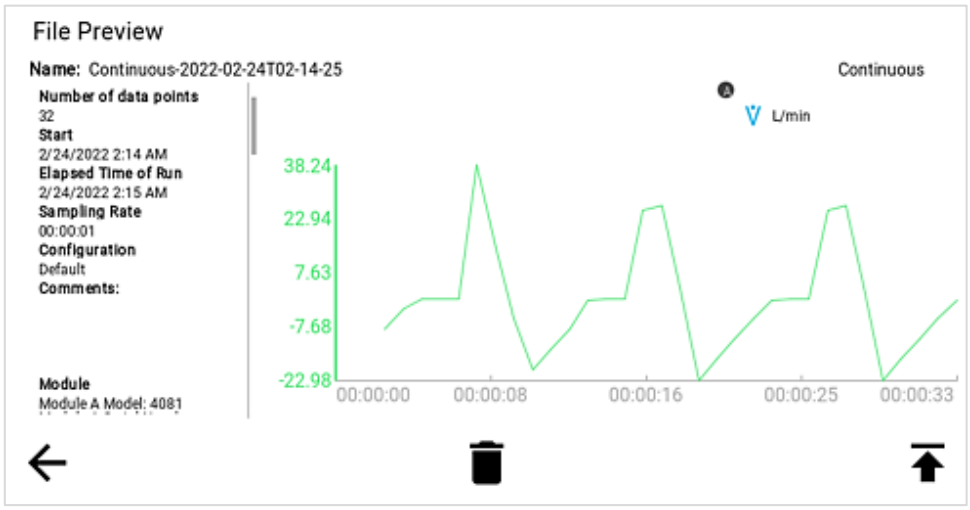


Preview Saved Files

You can preview screenshots and data logs from the Certifier™ Plus display prior to exporting. To do this, press anywhere on the row of the file you want to view.



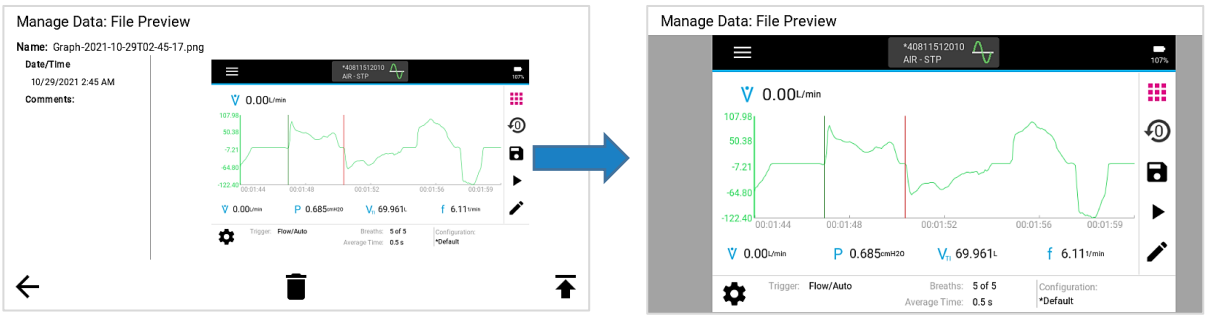
In the **File Preview** screen, you can preview screen captures or logged data in graph form. For data log files, the preview screen displays the number of data points collected, log start time, total logging time, sampling rate, the active configuration, comments, and the module from which the data came from. Screen capture file previews include the file name, date and time of capture, and any comments.



Saved files can also be deleted or exported from within the **File Preview** screen using the buttons on the bottom of the screen. Press the left arrow icon to return to the **Manage Data** screen. Press the garbage can icon to delete the currently previewed file, press the up arrow icon to export the currently previewed file.

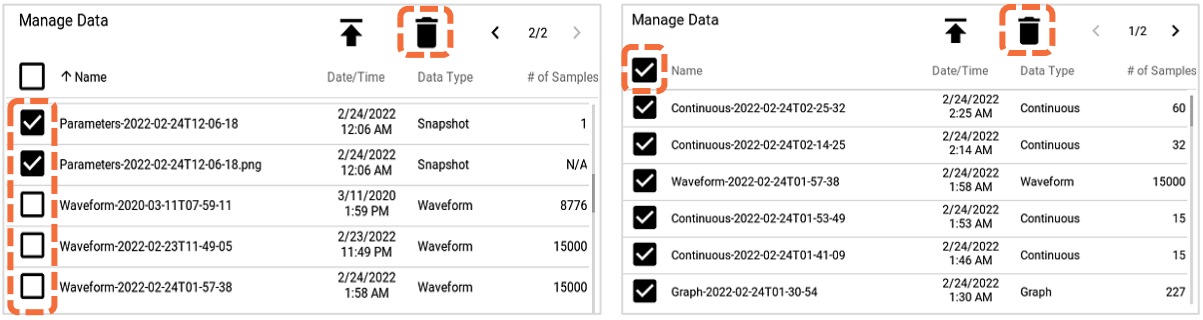
NOTICE
A USB flash drive **must** be inserted into the Certifier™ Plus Flow Analyzer to export a saved file.

Press on the image in the **File Preview** screen to increase its size for easier viewing. Press on the image again to return the expanded image to its original size.



Delete Saved Files

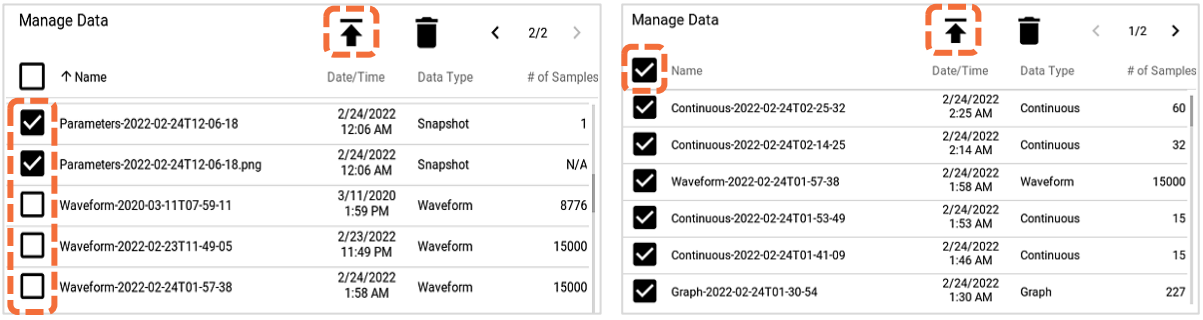
In the **Manage Data** screen, use the check boxes to select one file or multiple files. Press a check box to select and press again to deselect. Click the check box in the heading to select all files. Press the delete button (garbage can icon) to delete selected files; the Certifier™ Plus Flow Analyzer will ask to confirm the deletion.



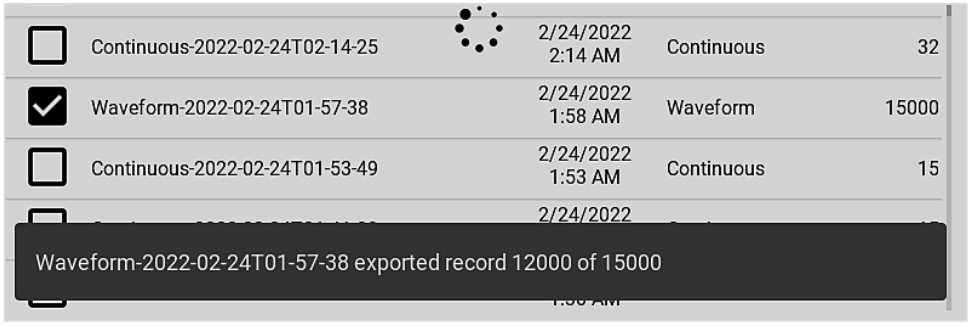
Exporting Data

Saved screenshots and data log files can be exported through either of the two USB-A ports located on the top side of the 4089 Certifier™ Plus Interface Module. To export one or more saved files, insert a USB flash drive into the Certifier™ Flow Analyzer and navigate to the Manage Data screen. Press on an individual file row in the Manage Data screen to preview the file on screen prior to exporting through USB.

Use the check boxes to select one file or multiple files. Press a check box to select, and press the box again to deselect. Click the check box in the heading to select all files. Press the export button (up arrow icon) to export selected files.



While actively exporting files, a loading icon will appear and the export progress is shown in the bottom screen bar. The Certifier™ Flow Analyzer will provide notification when the export has completed.



Snapshots are exported as .png image files and data is exported as .csv files. The delimiter for data export can be set as comma, pipe, semicolon, or tab delimited. Select the **Export Delimiter** in the **General Settings** page of the **Settings** menu option.

Viewing Exported Data

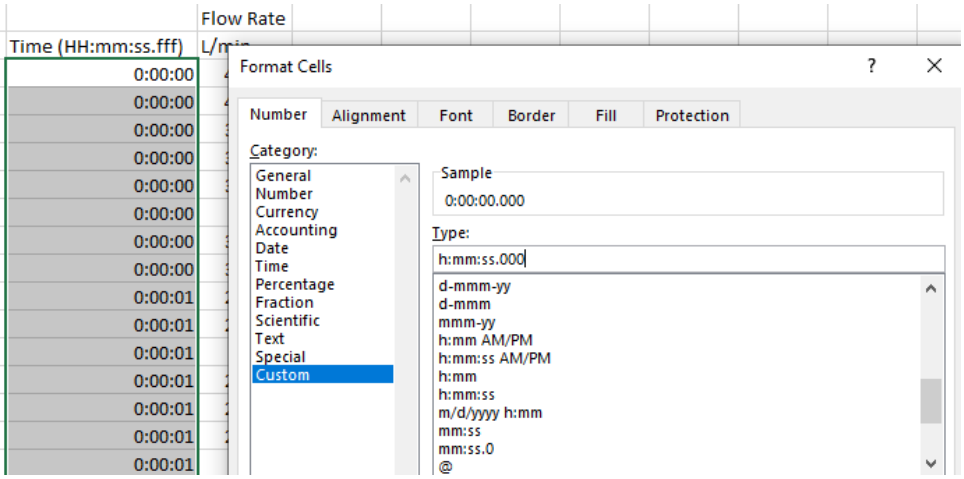
Exported .csv files can be opened and viewed within Microsoft® Excel® or an equivalent spreadsheet program. See Appendix A for examples of exported data formats for Snapshots, Continuous, and Waveform data logs.

NOTICE

The cell in the "Time" column will need to be reformatted in order to display properly. To format:

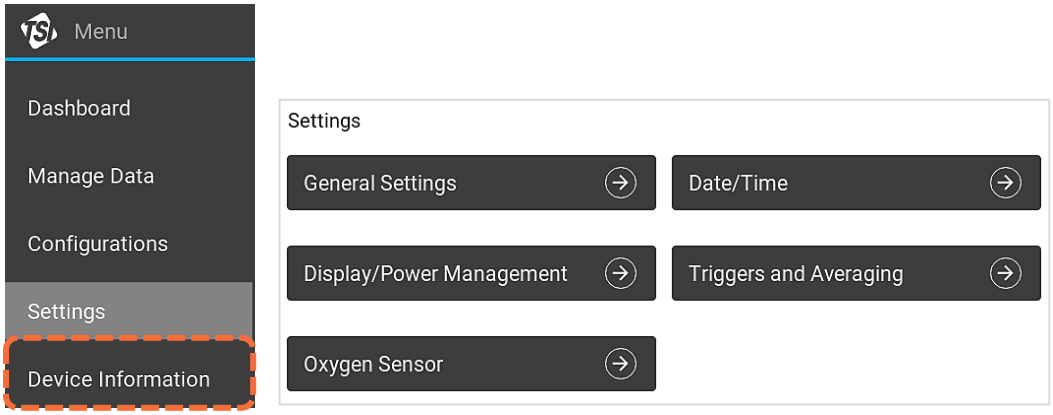
1. Select all the data in the column.
2. Select "**Format Cells**."
3. Choose the **Custom** category.
4. Select **h:mm:ss** as the Type.

To include millisecond data as part of the Time column cells, enter ".000" after the hh:mm:ss in the Type field.



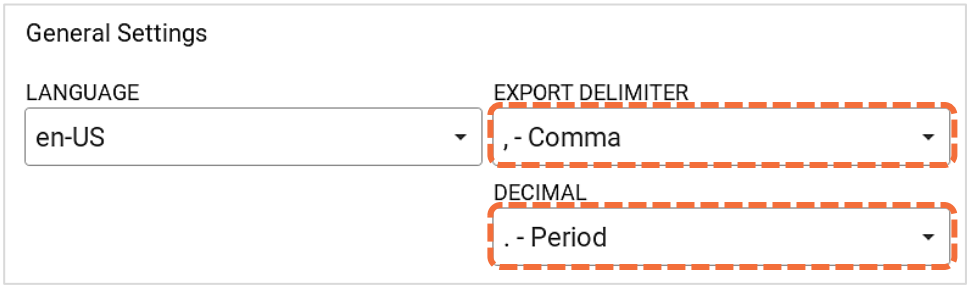
Device Settings

Access the device settings by choosing the **Settings** option from the **Menu** drop-down. From this screen, you can select which functional settings to view and adjust.



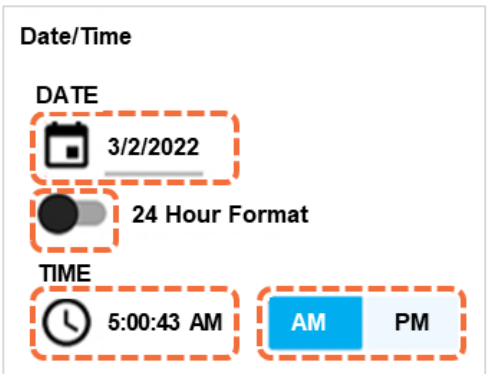
General Settings

In this screen you can set the **Export Delimiter** and **Decimal** format for the Certifier™ instrument. The export delimiter is used to specify how exported data is separated on the .csv file. The export delimiter can be set to comma, pipe, semicolon, or tab. The decimal specifies whether a period or a comma is used for the decimal mark. Press on the fields to edit their values. The language cannot be changed.



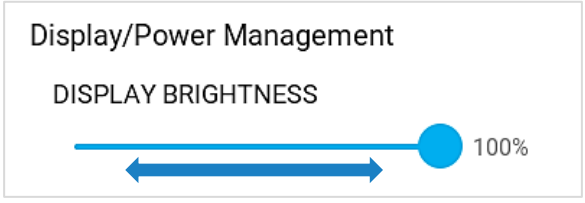
Date/Time

You can set the time, date, and date format for the Certifier™ instrument. Press on the fields to edit their values. Press the toggle to switch to 24-hour format, press again to return to 12-hour format. Select between **AM** and **PM** time.



Display/Power Management

You can adjust the display brightness to your preferred brightness including dimming the brightness in order to conserve power. Press on the gray scroll bar or drag the blue circle indicator to set the brightness level.



Triggers and Averaging

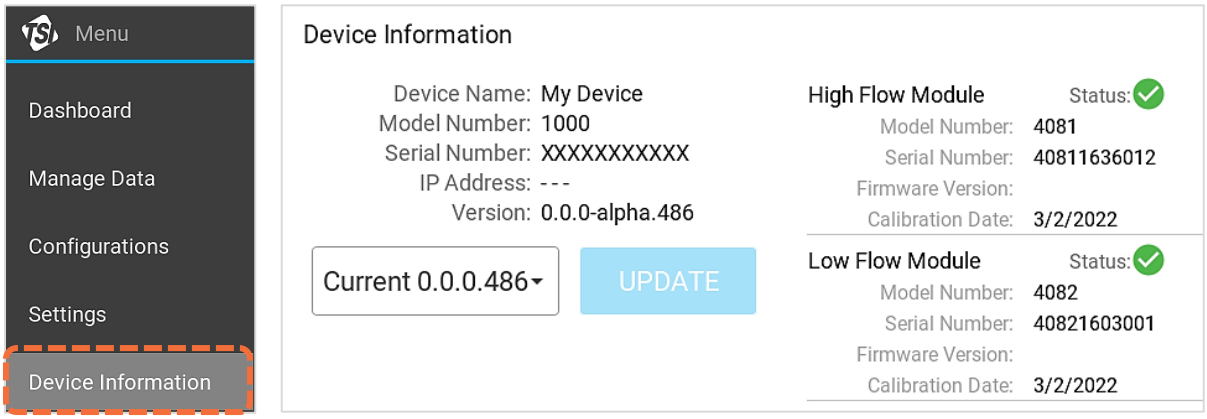
You can navigate to the triggers and averaging settings through the menu screen as an alternative to accessing these settings from the dashboard screens. Refer to the Breath Triggers and Averaging sections for detailed instructions.

Oxygen Sensor

In the **Oxygen Sensor** screen is where you can field calibrate their connected oxygen sensor(s). Refer to the section Calibrate Oxygen Sensor for oxygen calibration instructions.

Device Information

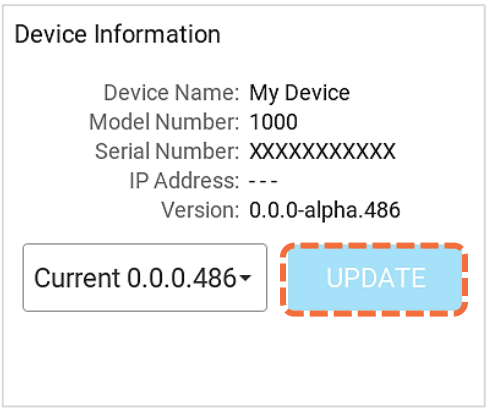
The device information screen displays information about the Certifier™ Interface Module and any connected flow modules. Access this screen by selecting the **Device Information** option from the menu drop-down.



Update Firmware

The firmware version for the 4089 Interface Module is displayed in the device information screen. You can perform field firmware updates to the interface module, but not the flow modules.

To update firmware, download the latest firmware version from tsi.com and save the file to a USB mass storage drive. Insert the USB drive into either of the USB-A ports on the Certifier Interface Module and press the **UPDATE** button on the screen.



CHAPTER 5

Troubleshooting

The table below lists the symptoms, possible causes, and recommended corrective actions for problems that may be encountered while operating the Certifier™ Plus system. If the symptom is not listed or if none of the recommended corrective actions solve the problem, contact technical support at technical.services@tsi.com or customer support at 800-680-1220 or 651-490-2860 for assistance.

Symptom	Possible Cause	Corrective Action
Interface module will not turn on, or turns on and off.	Batteries 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 the interface module.	Connect flow module to interface module. If connected, disconnect and then reconnect
Measurements not changing or graph is not updating.	The display is paused.	Press the play icon in the right navigation bar.
“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 change the gas type on the Certifier™ test system to the 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.
Pressure trigger gives erroneous results.	Pressure signal supplied to high-flow module is not correct.	Change source of pressure signal. Pressure triggers are optimized for use with high-frequency ventilators.
Volume, minute volume, peak flow, peak pressure, PEEP, frequency, or I:E ratio measurements are not updated or incorrect.	Less than two consecutive full breath have been supplied to the flow module or flow is not supplied as breath waveform.	Wait for at least two consecutive full breaths to be supplied to the flow module.
	Auto-trigger is not optimized for the current waveform.	Ensure that flow is supplied as a breathing waveform. Manually set the flow trigger levels.
	Airway restrictor is causing flow disturbance next to the flow module.	Use TSI® airway pressure fitting which contains a screen between the flow module and test lung.
	Flow condition is causing oscillations in the waveform.	Minimize the length of tubing between the test lung and the airway pressure fitting.

Symptom	Possible Cause	Corrective Action
I:E ratio or I time readings do not appear correct.	It is possible the inspiratory pause function is turned on inside the ventilator.	Display the I time, T_{I+P}, and $I:E_{IP}$ ratio when the inspiratory pause is activated on the ventilator. Or turn off the inspiratory pause feature on the ventilator.
Cannot zero low pressure or high pressure sensors.	Sensor is connected to a pressure source.	Disconnect the pressure tubing from the flow module and then re-zero the pressure sensors.
Cannot zero barometric pressure sensor.	Barometric pressure sensor does not require a zero calibration.	Resume normal system operation.
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% and 100% O_2 and repeat calibration. Replace oxygen sensor. Use constant flow rates to supply calibration gas.
Saved configurations are missing from the Local Configurations tab.	Current Certifier™ hardware setup is different from the hardware setup that was used to create the configuration.	Adjust the Certifier™ hardware setup until it matches the setup of the configuration file. Refer to page 2-4 for more information.
Unable to export configurations or log files to removable USB drive.	USB drive is not recognized by the Certifier™ Flow Analyzer.	Reformat the USB drive to FAT32 format. Reformat even if the drive shows FAT32 already.
Battery will not charge with the instrument plugged in to power.	Battery has discharged beyond minimum charge level.	Unplug power adapter, plug back in, and charge for 10 minutes. Repeat until normal charging behavior is observed.

CHAPTER 6

Maintenance

Recharging the Battery

The fastest charging method is to charge the internal batteries with the Certifier™ Plus Flow Analyzer Test System turned off. With new batteries and the Certifier™ instrument turned off, the charging time to go from empty to a full charge is approximately 4 hours. When connected to AC power, the Certifier™ Plus Flow Analyzer will charge the internal batteries during operation; however, the time to full charge will be extended. The batteries cannot be charged externally from the Certifier Flow Analyzer.

The Interface Module can be powered by internal Lithium-Ion battery or an AC power adapter can be used. If the AC adapter is delivering power to the Certifier Interface Module and the battery is installed, a lightning bolt symbol will be displayed in the battery icon to indicate active battery charging.

Replacing the Battery

The Certifier Plus Flow Analyzer comes with the battery pre-installed into the 4089 Interface Module. The battery will function for four or more years with normal operation of the Certifier Plus test system. To remove or install a battery, a Philips-head screwdriver is required.

To remove a battery from the Certifier Plus Flow Analyzer:

1. Turn the Certifier Interface Module off and disconnect any cables.
2. Remove the protective cover (if attached).
3. Remove the cover on the back side of the Certifier case by unscrewing the 3 screws.
4. Disconnect the battery pack by unplugging the pigtail connector from the Certifier Flow Analyzer.

To install a battery into the Certifier™ Plus Flow Analyzer:

1. Turn the Certifier™ Interface Module off and disconnect any cables.
2. Remove the protective cover (if attached).
3. Plug the battery pigtail connector into the Certifier™ Plus Flow Analyzer.
4. Place the battery pack into the back cavity of the Certifier Plus Flow Analyzer.
5. Attach the back cover by screwing in the 3 Phillips® screws.

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. Refer to the Calibrate Oxygen Sensor section for detailed sensor calibration instructions.

Cleaning the Flow Analyzer

The table below summarizes TSI® Incorporated's recommended methods for cleaning the primary components of the Certifier™ Plus test system.

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%). Remove dust, particles, and fibers from the flow module sensors with clean, dry compressed air.
▪ Tee ▪ Flow 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.

WARNING

DO NOT submerge any Certifier™ Flow Analyzer components and **NEVER** run liquids through the flow modules. **NEVER** touch the flow sensor mounted inside the flow module as it will break upon contact.

Factory Calibration (recommended annually)

To maintain a high degree of confidence in the measurements made by the Certifier™ Plus Flow Analyzer, TSI® recommends that 4081 high flow and 4082 Low Flow Modules be returned to TSI® Incorporated for re-calibration every 12 months following initial factory calibration.

The 4089 Interface Module does not contain any sensors and does not need to be returned to TSI® for routine calibration or maintenance.

NOTICE
Any alternative Certifier™ Plus Flow Module may be used with the Certifier™ Plus interface display module in order to remain “up” at all times.

All re-calibrated flow modules are returned from TSI® with a certificate of calibration and a summary of performance before and after the calibration. A calibration consists of pressure calibrations over the full range of pressures and flow calibration over the full range of flows. All calibration data is stored in the flow modules. The interface module does not contain any factory calibration information.

Return Procedure

Follow these steps to return a Certifier™ Plus Flow Module or Interface Module to a TSI® service center for calibration and/or repair service:

1. Obtain a service request number by completing a “Service Request” form online at tsi.com/service, or contact one of the TSI® offices listed below to make the arrangements.
2. Register an account with TSI® or create the service request as a guest.
3. The Service Request form will provide instructions and the TSI address for returning the equipment.
4. Package the Certifier™ Plus Flow Analyzer components carefully to avoid damage during shipping. *Note that it is not necessary to return the interface module for calibration.*

TSI Incorporated
500 Cardigan Road
Shoreview, MN 55126 USA

Phone: +1-800-680-1220 (USA)
E-mail: technical.services@tsi.com

TSI GmbH
Neuköllner Strasse 4
52068 Aachen
GERMANY

Telephone: +49 241-52303-0
E-mail: tsigmbh@tsi.com

TSI Instruments Ltd.
Stirling Road
Cressex Business Park
High Wycombe, Buckinghamshire
HP12 3ST
UNITED KINGDOM

Telephone: +44 (0) 149 4 459200
E-mail: tsiuk@tsi.com

TSI Instruments Singapore Pte Ltd
150 Kampong Ampat
#05-05 KA Centre
SINGAPORE 368324

Telephone: +65 6595-6388
Fax: +65 6595-6399
E-mail: tsi-singapore@tsi.com

TSI Instrument (Beijing) Co., Ltd.
Room 504-505 5/F, Block D
Chang'An Mills, South Wuyi Theater Road
Shijingshan District, Beijing,
CHINA 100043

Telephone: +86-10-8219 7688
Fax: +86-10-8219 7699
E-mail: tsibeijing@tsi.com

(This page intentionally left blank)

CHAPTER 7

Specifications

Note that specifications are subject to change without notice.

Physical

Dimensions	Interface Module: 8.1 x 4.2 x 2.9 inches (20.5 x 10.6 x 7.3 cm) High Flow Module: 5.9 x 2.6 x 0.4 inches (15 x 6.7 x 6.1 cm) Low Flow Module: 5 x 2 x 1.1 inches (12.7 x 5.1 x 2.8 cm)
Flow connectors	High Flow Module: ▪ Inlet: 22 mm female ISO taper. ▪ Outlet: 22 mm male ISO taper. Low Flow Module: ▪ Inlet: 3/8 inch tube ▪ Outlet: 3/8 inch tube
Weight	Interface module is 1.9 pounds (0.85 kg) Total: 2.4 pounds (1.1 kg) for interface and high flow module plus cable

Environmental

Temperature	Operating: 5 to 40 °C, Humidity: -20 to 35 °C Dew Point, non--condensing Storage: -40 to 70 °C, Humidity: -40 to 35 °C Dew Point, non-condensing
Atmospheric Pressure	Operating: 57.1 to 106 kPa Storage: 15000 meters
Conditions	Indoor Use, Operating Altitude up to 4000 m Pollution degree I or II

Power

Battery Life	8 hours under typical usage (with 1 flow module connected)
Battery Type	Lithium-Ion, proprietary form factor, 7.2 V 6.4 AHr
AC Adapter	12 VDC, 3A minimum

Compliance

The Certifier™ Plus Test System includes the following marks, compliance, and FCC statements:

- CE mark, UKCA mark, ETL Listed mark, RCM mark, and RoHS compliance.
- Per FCC 15.19(a)(3) and (a)(4) This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.
- Per FCC 15.21, The user manual or instruction manual for an intentional or unintentional radiator shall caution the user that changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Measurements

See additional notes listed at the end of the specifications.

Measurement[1]	High Flow Module (4081)[2]	Low Flow Module (4082)[3]
Flows	$\dot{V}$, $\dot{V}_{PEAK}$, $\dot{V}_{MIN}$	
Range	-200 to +300 SLPM air, oxygen, nitrogen, and air/oxygen mixtures -40 to +40 SLPM carbon dioxide	0.01 to 20 SLPM air, oxygen, nitrogen, carbon dioxide, and nitrous oxide
Accuracy[4]	**Air, Oxygen**: ±2% of reading or ±0.075 SLPM, whichever is greater **Nitrogen, Carbon dioxide**: ±3% of reading or ±0.075 SLPM, whichever is greater **Air/Oxygen mixture**: ±3% of reading or ±0.1 SLPM, whichever is greater	**Air, Oxygen**: ±2% of reading plus ±0.008 SLPM **Nitrogen, Carbon dioxide**: ±3% of reading plus ±0.01 SLPM **Nitrous oxide**: ±3% of reading plus ±0.025 SLPM
Inspiratory Volumes	V_{TI}	
Range	0.001 to 10 liters	0.001 to 10 liters
Accuracy[4]	**Air, Oxygen:** ±2% of reading plus ±0.02 liters **Air/Oxygen mixtures, Nitrogen, Carbon dioxide:** ±3% of reading plus ±0.02 liters	**Air, Oxygen:** ±2% of reading plus ±0.005 liters **Nitrous oxide, Nitrogen, Carbon dioxide:** ±3% of reading plus ±0.005 liters
Expiratory Volumes	V_{TE}	
Range	0.001 to 10 liters	Not available
Accuracy[4]	**Air, Oxygen:** ±2.5% of reading plus ±0.02 liters **Air/Oxygen mixtures, Nitrogen, Carbon dioxide:** ±3% of reading plus ±0.04 liters	Not available
Minute Volume	MV	
Range	0.001 to 100 liters	0.001 to 100 liters
Accuracy[4]	±3% of reading plus ±0.02 liters	±3% of reading plus ±0.005 liters
Real-Time Volume	V	
Range	0.001 to 100 liters	0.001 to 100 liters
Accuracy[4]	±3% of reading plus ±0.02 liters	±3% of reading plus ±0.005 liters
Timing	t_I t_{IP} t_{I+P} t_E t_R	
Range	0.04 to 30 seconds	Not available
Accuracy	2% of reading or ±0.01 second, whichever is greater	Not available
I:E Ratios	I:E I:E_{IP}	
Range	1:100 to 100:1	Not available
Accuracy	±4% of reading	Not available

Measurement[1]	High Flow Module (4081)[2]	Low Flow Module (4082)[3]
Respiratory Rate	f	
Range	1 to 1500 breaths per minute	Not available
Accuracy	±2% of reading or ±0.1 BPM, whichever is greater	Not available
Low Pressures	P PIP P_{EEP} P_{MAP} P_{MIN} P_{Δ} P_{PLAT}	
Range	-25 to 150.0 cmH_2O	Not available
Accuracy	±0.5% of reading or ±0.15 cmH_2O, whichever is greater	Not available
Leak Rate	LR	
Range	±30 cmH_2O/s	Not available
Accuracy	±0.5% of reading or ±0.2 cmH_2O/s, whichever is greater	Not available
High Pressure	P_{High}	
Range	-10 to 150.0 psig	Not available
Accuracy	±1% of reading or ±0.1 psi, whichever is greater	Not available
Absolute Pressure	P_{ABS}	
Range	50 to 200 kPa	50 to 200 kPa
Accuracy	±0.7% kPa	±0.7% kPa
Static Compliance	C_{Stat}	
Range[5]	0.01 to 1000 mL/cmH_2O	Not available
Accuracy	±3% or ±1 mL/cmH_2O, whichever is greater	Not available
Oxygen Concentration	O_2	
Range	21 to 100%	Not available
Accuracy	±2% of reading	Not available
Temperature	T	
Range	5 to 40 °C	5 to 40 °C
Accuracy	±1 °C when flow rate is above 2 liters/min	±1 °C when flow rate is above 2 liters/min

NOTES:

1 Standard conditions are defined as 21.1 °C (70 °F) and 101.3 kPa (14.7 psia). Flow and volume accuracy are applicable at these standard conditions. SLPM = standard liters per minute

2 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).

3 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 accuracies are stated at 21.1 °C (70 °F), 101.3 kPa (14.7 psia), and <= 30% RH

- Add an additional ±0.075% of reading per 1 °C (1.8 °F) away from 21.1 °C (70 °F)
- Add an additional ±0.015% of reading per 1 kPa (0.15 psia) above 101.3 kPa (14.7 psia)
- Add an additional ±0.022% of reading per 1 kPa (0.15 psia) below 101.3 kPa (14.7 psia)
- Add an additional ±0.07% of reading per 1% relative humidity above 30% relative humidity

5 Must develop at least 7 cmH_2O of pressure to obtain a valid static compliance measurement.

(This page intentionally left blank)

APPENDIX A

Data Export Formats

Snapshot Data File from the Parameter Screen

File Name:	Parameters-2021-06-10T09-39-27.csv						
Data Type:	Parameter						
Number of data points:	1						
Comments:	No Comments						
Configuration:	V500						
Module A Model:	4081						
Module A Serial Number:	40811636012						
Trigger Type:	Auto Trigger						
Breath Average:	5						
Breath Average Time:	0.5 s						
Gas Condition A:	ATP						
Gas Type A:	Air						
Data Section		Module A	Module A	Module A	Module A	Module A	Module A
		Flow Rate	Low Pressure	Inhaled Tidal Volume	Frequency	Inspiratory Time	I:E Ratio
	Time (HH:mm:ss.fff)	L/min	cmH2O	mL	1/min	s	cmH2O
	00:00.0	28.25	19.517	900	6	2.16	3.4

NOTICE

Snapshots of the Parameter screen capture a single data point for all selected measurements.

Snapshot Data File from the Graph Screen

File Name:	Graph-2021-06-10T09-40-48.csv	
Data Type:	Graph	
Number of data points:	303	
Comments:	No Comments	
Configuration:	V500	
Module A Model:	4081	
Module A Serial Number:	40811636012	
Trigger Type:	Auto Trigger	
Breath Average:	5	
Breath Average Time:	0.5 s	
Gas Condition A:	ATP	
Gas Type A:	Air	
Data Section		Module A
		Flow Rate
	Time (HH:mm:ss.fff)	L/min
	0:00:00.000	41.6595
	0:00:00.066	40.1154
	0:00:00.132	38.5713
	0:00:00.198	37.0272
	0:00:00.264	35.4831
	0:00:00.330	33.939

NOTICE

Snapshots of the Graph screen capture data for the selected measurements currently plotted in the graph.

Continuous Log file (Initiated from the Parameter Screen or Graph Screen)

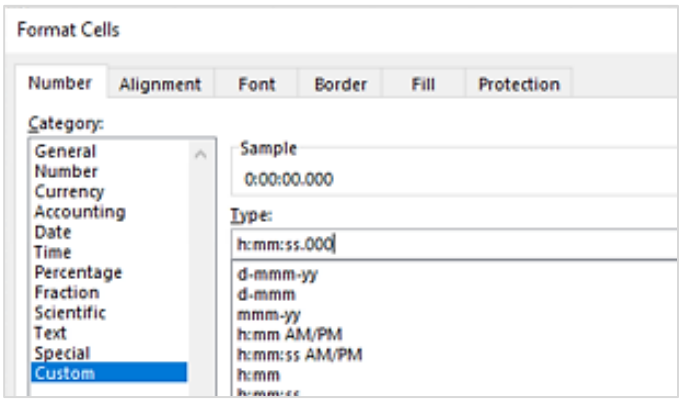
File Name:	Continuous-2021-06-10T09-41-37.csv						
Data Type:	Continuous						
Number of data points:	30						
Comments:	No Comments						
Configuration:	V500						
Module A Model:	4081						
Module A Serial Number:	40811636012						
Trigger Type:	Auto Trigger						
Breath Average:	5						
Breath Average Time:	0.5 s						
Gas Condition A:	ATP						
Gas Type A:	Air						
Data Section		Module A	Module A	Module A	Module A	Module A	Module A
		Flow Rate	Low Press	Inhaled Ti	Frequency	Inspirator	I:E Ratio
Date (M/d/yyyy)	Time (HH:mm	L/min	cmH2O	mL	1/min	s	cmH2O
6/10/2021	42:13.8	0	2.888	900	6	2.16	3.4
6/10/2021	42:14.8	0	2.851	900	6	2.16	3.4
6/10/2021	42:15.8	37.26	19.902	900	6	2.16	3.4
6/10/2021	42:16.8	13.86	18.902	900	6	2.16	3.4
6/10/2021	42:17.8	-7.17	13.004	900	6	2.16	3.4
6/10/2021	42:18.8	-19.85	4.931	900	6	2.16	3.4
6/10/2021	42:19.8	-14.04	4.35	900	6	2.16	3.4
6/10/2021	42:20.8	-8.22	3.769	900	6	2.16	3.4
6/10/2021	42:21.8	-2.41	3.187	900	6	2.16	3.4
6/10/2021	42:22.8	0	2.906	900	6	2.16	3.4
6/10/2021	42:23.8	0	2.888	900	6	2.16	3.4
6/10/2021	42:24.8	28.57	13.95	900	6	2.16	3.4
6/10/2021	42:25.8	25.52	19.4	900	6	2.16	3.4
6/10/2021	42:26.8	2.71	17.833	900	6	2.16	3.4
6/10/2021	42:27.8	-22.75	5.221	900	6	2.16	3.4
6/10/2021	42:28.8	-16.93	4.64	900	6	2.16	3.4
6/10/2021	42:29.8	-11.12	4.058	900	6	2.16	3.4
6/10/2021	42:30.8	-5.31	3.477	900	6	2.16	3.4
6/10/2021	42:31.8	-0.15	2.957	900	6	2.16	3.4
6/10/2021	42:32.8	0	2.906	900	6	2.16	3.4
6/10/2021	42:33.8	0	2.869	900	6	2.16	3.4

Waveform Log file (Initiated from the Parameter Screen or Graph Screen)

File Name:	Waveform-2021-06-10T09-47-00.csv						
Data Type:	Waveform						
Number of data points:	15000						
Comments:	No Comments						
Configuration:	V500						
Module A Model:	4081						
Module A Serial Number:	40811636012						
Gas Condition A:	ATP						
Gas Type A:	Air						
Data Section		Module A	Module A	Module A	Module A	Module A	Module A
		Flow Rate	Low Press	Absolute	Oxygen C	Temperat	High Pressu
	Time (HH:mm:s	L/min	cmH2O	kPa	%	Â°C	PSI
	0:00:00.000	-6.96613	3.642762	100.123	0.005569	20.123	85.1367
	0:00:00.001	-6.96032	3.64218	100.123	0.005722	20.123	85.1367
	0:00:00.002	-6.9545	3.641599	100.123	0.005569	20.123	85.1367
	0:00:00.003	-6.94869	3.641017	100.123	0.005569	20.123	85.1367
	0:00:00.004	-6.94288	3.640436	100.123	0.005646	20.123	85.1367
	0:00:00.005	-6.93706	3.639854	100.123	0.005569	20.123	85.1367
	0:00:00.006	-6.93125	3.639273	100.123	0.005722	20.123	85.1367
	0:00:00.007	-6.92543	3.638691	100.123	0.005569	20.123	85.1367
	0:00:00.008	-6.91962	3.63811	100.123	0.005646	20.123	85.1367
	0:00:00.009	-6.91381	3.637528	100.123	0.005569	20.123	85.1367
	0:00:00.010	-6.90799	3.636947	100.123	0.005569	20.123	85.1367
	0:00:00.011	-6.90218	3.636365	100.123	0.005569	20.123	85.1367
	0:00:00.012	-6.89636	3.635784	100.123	0.005646	20.123	85.1367
	0:00:00.013	-6.89055	3.635202	100.123	0.005646	20.123	85.1367
	0:00:00.014	-6.88474	3.634621	100.123	0.005646	20.123	85.1367
	0:00:00.015	-6.87892	3.634039	100.123	0.005569	20.123	85.1367
	0:00:00.016	-6.87311	3.633458	100.123	0.005569	20.123	85.1367
	0:00:00.017	-6.86729	3.632876	100.123	0.005646	20.123	85.1367
	0:00:00.018	-6.86148	3.632295	100.123	0.005646	20.123	85.1367
	0:00:00.019	-6.85566	3.631713	100.123	0.005722	20.123	85.1367
	0:00:00.020	-6.84985	3.631132	100.123	0.005493	20.123	85.1367
	0:00:00.021	-6.84404	3.63055	100.123	0.005646	20.123	85.1367
	0:00:00.022	-6.83822	3.629969	100.123	0.005646	20.123	85.1367

NOTICE

The cells in the “Time” column will need to be reformatted in order to display millisecond data. properly. To format the cells, select all the data in the column, select “**Format Cells**,” choose the **Custom** category, select h:mm:ss as the Type, and enter “.000” after the h:mm:ss in the Type field.



(This page intentionally left blank)

Knowledge Beyond Measure.

TSI Incorporated – Visit our website **www.tsi.com** for more information.

USA	**Tel:** +1 800 680-1220	**India**	**Tel:** +91 80 67877200
UK	**Tel:** +44 149 4 459200	**China**	**Tel:** +86 10 8219 7688
France	**Tel:** +33 1 41 19 21 99	**Singapore**	**Tel:** +65 6595 6388
Germany	**Tel:** +49 241 523030		

P/N 6016477 Rev. G Printed in U.S.A.