analyser

the art of measuring

User Manual
FlowAnalyser PRO

IMT Analytics

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Table of contents

1 Introduction

Validity
This documentation is valid for the product with the designation:

- FlowAnalyser PF-300 PRO, REF 700.300.000
- MultiGasAnalyser OR-703, REF 500.041.000

You will find the name FlowAnalyser PRO on the rating plate on the side of the device.

Software and firmware version
This documentation applies to the following versions:
FlowAnalyser PRO firmware – version 4.16.000

In the case of older or newer versions there may be minor discrepancies in relation to this User Manual.

Designations used in this User Manual
Buttons and indicators on the display.
Buttons such as ***Power*** and indicators on the display such as ***Change Settings*** are printed in boldface italics.

References to pages and sections
For references to pages and references, e.g. (→4.1.6 Physical data), the symbol (→XY) is used.

Version information
Issue date of this User Manual: **Release 02, 2022-02**
Subject to technical modifications without notice.

2 Intended use

This product is intended for testing and calibration purposes on medical devices or systems that generate gas flows or gas pressures. That includes ventilators and anaesthetic machines. The user of the device has received training on how to use medical equipment and can perform repairs, maintenance and servicing on medical devices. The device can be used in hospitals, in clinics, at device manufacturers or at independent service companies that perform repairs or servicing on medical devices. FlowAnalyser PRO is intended for use in a laboratory environment. The device must be placed in a position that the display is readable by the user without impairment. It may only be used outside the nursing sector. It must not be used directly on patients or devices that are connected to patients. The measuring instrument FlowAnalyser PRO is intended for over-the-counter sale.

FlowAnalyser PRO is the solution for measurements in the following areas:

- Flow (-300 – 300 L/min)
- Ultra Low Flow (-1 – 1 L/min)
- Volume
- High Differential pressure (-250 – 250 mbar)
- Low Differential pressure (-10 – 10 mbar)
- High pressure/Vacuum (-1 – 10 bar)
- Ambient Pressure (500 – 1240 mbar)
- Oxygen (0 – 100 vol %)
- Temperature (0 – 50 °C)
- Humidity (0 – 100 %)
- Channel Pressure (-50 – 160 mbar)

In addition, various ventilation parameters can be measured:

- Inspiratory tidal volume, expiratory tidal volume
- Inspiratory minute volume, expiratory minute volume
- Volumen
- Post-Inspiratory Pause %Tp
- Breath Rate
- I:E
- Inspiratory time, expiratory time
- Inspiratory hold time, expiratory hold time
- P_{peak}
- P_{mean}
- $P_{plateau}$
- PEEP
- PF Insp (inspiratory peak flow)
- PF Exp (expiratory peak flow)
- Ti/T_{cyc}
- C_{stat}

FlowAnalyser PRO is a measuring instrument for checking and calibrating ventilators and anaesthetic machines. It must not be used for patient monitoring. During patient treatment by the ventilator it is not allowed to connect to FlowAnalyser PRO.

Using the device for patient monitoring, the following contra indications can occure:

- contamination of the device
- contamination of the patients lung
- loss of ventilation performance
- increase of dead value

This product is intended to be used at elevations of up to 3000 MASL in buildings.

3 Safety instructions

3.1 Representation of hazards, cautions and notes

This User Manual uses the representation below to specifically draw attention to residual risks during intended use and emphasise important technical requirements.

Information and/or instructions and prohibitions shall be observed to prevent damage of any kind.

3.2 Personnel

Work on and with FlowAnalyser PRO may only be performed by persons who have undergone appropriate technical training and have the necessary experience.

3.3 Responsibility and guarantee

The manufacturer accepts no responsibility or guarantee and will exempt itself from liability claims accordingly if the operator or any third parties:

- fail to use the device in accordance with its intended use
- disregard the specifications
- tamper with the device in any way (conversions, modifications, etc.)
- operate the device with accessories that are not listed in the associated sets of product documentation.

Although the device meets high quality and safety standards and it has been constructed and tested according to the current state of the art, it is not possible to rule out the risk of injuries with serious consequences if the device is used in non-compliance with the intended use (improperly) or is misused. Therefore please read through this User Manual carefully and keep this documentation in a readily accessible place close to your device.

If you have received the device in a damaged packaging please contact the office listed below.

Customer service
Email: customerservice@imtanalytics.com

If you be aware of an incident please contact the office listed below.

Technical support
Tel: +41 (0)81 750 67 10
Email: techsupport@imtanalytics.com

3.4 Service life

The maximum service life of the device has been specified as 10 (ten) years, provided it is handled properly in accordance with this User Manual.

4 Specifications

4.1 Measurement parameters

4.1.1 Measuring instrument values[1]

Flow	Range Accuracy	-300 – 300 L/min*** ± 1.65 %* or ± 0.04 L/min (for 10 – 40° C)**
Ultra Low Flow	Range Accuracy	-1 – 1 L/min*** ± 1.65 %* or ± 0.01 L/min (for 10 – 40° C)**
Volume	Range Accuracy	0 – 1000 L ± 1.75 %* or ± 0.10 mL
Pressure (at flow)	Range Accuracy	-50 – 160 mbar ± 0.5 %* or ± 0.1 mbar**
High Differential pressure	Range Accuracy	-250 – 250 mbar ± 0.5 %* or ± 0.1 mbar**
Low Differential pressure	Range Accuracy	-10 – 10 mbar ± 1 %* or ± 0.01 mbar**
High pressure and Vacuum	Range Accuracy	-1 – 10 bar ± 1 %* or ± 7 mbar**
Ambient pressure	Range Accuracy	500 – 1240 mbar ± 1 %* or ± 5 mbar**
Oxygen	Range Accuracy	0 – 100 vol % ± 1 vol %**
Temperature	Range Accuracy	0 – 50 °C ± 1.75 %* or ± 0.5 °C**
Humidity	Range Accuracy	0 – 100 % RH*** ± 3 % RH** from 10 % RH to 80 % RH ± 5 % RH** for <10 % RH and > 80 % RH

[1]Standard litres per minute (converted to STP conditions of 21.1°C and 1013 mbar)

* Tolerance related to the measured value
** Ablsoute tolerance, with steady air flow
*** Non-condensing

4.1.2 Ventilation parameters

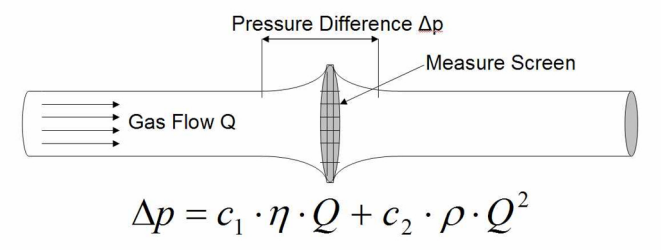
Vti, Vte	Tidal volume of inspiration and expiration	Range Accuracy	0–60 L ± 1.75 %* or ± 0.10 mL
Vi, Ve	Minute volume of inspiration and expiration	Range Accuracy	0–300 L/min ± 1.75 %* or ± 5 ml/min
Ti	Inspiratory time	Range Accuracy	0.01–60 s ± 0.01 s
Te	Expiratory time	Range Accuracy	0.01–90 s ± 0.01 s
Ti/T_{cyc}	Ratio of inspiratory time to time of a respiratory cycle	Range Accuracy	0–100 % ± 5 %*
P_{peak}	Peak inspiratory pressure	Range Accuracy	0–160 mbar ± 0.75 %* or ± 0.10 mbar**
P_{mean}	Mean airway pressure	Range Accuracy	0–160 mbar ± 0.75 %* or ± 0.10 mbar**
I:E	Inspiratory/expiratory time ratio	Range Accuracy	1:300 – 300:1 ± 2 %*
PEEP	Positive end-expiratory pressure	Range Accuracy	0–160 mbar ± 0.75 %* or ± 0.10 mbar**
Rate	Ventilation rate	Range Accuracy	0–2000 bpm ± 1.0 %** or ± 1bpm
PF_{Insp}	Peak flow during Inspiration	Range Accuracy	-300–300 L/min ± 1.65 %* or ± 0.04 L/min**
PF_{Exp}	Peak flow during Expiration	Range Accuracy	-300 – 300 L/min ± 1.65 %* or ± 0.04 L/min**
C_{stat}	Static lung compliance	Range Accuracy	0–1000 mL/mbar ± 3 %* or ± 0.01 mL/mbar**
$P_{plateau}$	Inspiratory pause pressure	Range Accuracy	0–160 mbar ± 0.75 %* or ± 0.10 mbar**
%TP	Post-Inspiratory Pause “%TP” (=Inspiratory hold time/Inspiratory time)	Range Accuracy	0–100 %TP ± 0.1 %TP
Ti_{Hold}	Insp. hold time	Range Accuracy	0–60 s ± 0.01 s
Te_{Hold}	Exp. hold time	Range Accuracy	0–90 s ± 0.01 s

* Tolerance related to the measured value

** Ablsoute tolerance, with steady air flow

4.1.3 Principle of flow measurement

Flow in the flow channel is determined by differential pressure measurement. To build up differential pressure a plastic screen is used to provide flow resistance.



$$\Delta p = c_1 \cdot \eta \cdot Q + c_2 \cdot \rho \cdot Q^2$$

η: dynamic viscosity of the gas [Pa·s]
ρ: gas density [kg/m³]
c1, c2: device-specific constants (channel geometry)

Dynamic viscosity

The viscosity of a medium is its resistance to the flow and shear of the current. Viscosity is extremely dependent on temperature. The viscosity of a medium is slightly dependent on the pressure and moisture content of the medium.

Density

Density is the unit for the mass per unit volume of the medium. Density is very dependent on pressure and temperature.

The impact of ambient conditions is hence the reason why flow is occasionally converted to standard conditions.
(→4.2 Gas standards for flow and volume measurement)

4.1.4 Special functions

Automatic battery operation in the event of a power failure

4.1.5 Communication interfaces

USB, RS-232 port for firmware download, remote control functions and connection to MultiGasAnalyser OR-703 (optional), trigger input (digital) for external trigger.

4.1.6 Physical data

Weight:	3.2 kg
Size (l × w × h):	312 × 233 × 130 mm
Gas types:	Air, O_2, N_2O, He, N_2, CO_2 and mixtures: Air/O_2, N_2O/O_2, He/O_2

4.1.7 Calibration by user

Offset calibration of the pressure and flow measurements. Calibration of the oxygen sensor.

4.1.8 Operating data

Operating Humidity:	10–95 % RH (non-condensing)
Operation Temperature:	15–40 °C (59–104 °F)
Operating ambient pressure:	540–1100 hPa
Storage ambient pressure:	540–1100 hPa
Storage and transport conditions:	-10–60 °C (14–140 °F) 5–95 % RH (non-condensing) Keep dry und keep away from sunlight.
IP classification:	IP21
Installation categorie:	Class II

4.2 Gas standards for flow and volume measurement

FlowAnalyser PRO converts the flow and volume readings measured in the device to match the conditions of the standard selected. The following gas standards are supported by FlowAnalyser PRO:

Gas standard		Temperature	Pressure	Relative humidity
Ambient Temperature and Pressure	ATP	Current gas temperature	Current Ambient pressure	Current gas humidity
Ambient Temperature and Pressure Dry	ATPD	Current gas temperature	Current Ambient pressure	0 %
Ambient Temperature and Pressure Saturated	ATPS	Current gas temperature	Current Ambient pressure	100 %
Ambient Pressure at 21 °C	AP21	21.0 °C (70 °F)	Current Ambient pressure	Current gas humidity
Standard Temperature and Pressure at 0 °C	STPD0	0.0 °C	1013.25 mbar (760 mmHg)	0 %
Standard Temperature and Pressure at 20 °C	STPD20	20.0 °C	1013.25 mbar (760 mmHg)	0 %
Standard Temperature and Pressure at 21 °C	STPD21	21.0 °C	1013.25 mbar (760 mmHg)	0 %
23 °C/1013mbar	23/1013	23 °C (73.4 °F)	1013.25 mbar (760mmHg)	0 %
Standard Conditions USA	STP	21.0 °C (70 °F)	1013.25 mbar (760 mmHg)	0 %
Standard Conditions USA Humid	STPH	21.0 °C (70 °F)	1013.25 mbar (760 mmHg)	Current gas humidity
Body Temperature and Pressure Saturated	BTPS	37 °C (99 °F)	Current ambient pressure and channel pressure (Flow)	100 %
Body Temperature and (Ambient) Pressure Saturated according to ISO 80601-2-12:2011	BTPS-A	37 °C (99 °F)	Current ambient pressure	100 %
Body Temperature and Pressure Dry	BTPD	37 °C (99 °F)	Current ambient pressure and channel pressure (Flow)	0 %
Body Temperature and (Ambient) Pressure Dry	BTPD-A	37 °C (99 °F)	Current ambient pressure	0 %
Standard condition according to DIN 1343	0/1013	0 °C (32 °F)	1013.25 mbar (760 mmHg)	0 %
Standard condition according to ISO 1-1975 (DIN 102)	20/981	20 °C (68 °F)	981 mbar (736 mmHg)	0 %

Please use allways standard condition STP for ultra low flow measurements.

Gas standard		Temperature	Pressure	Relative humidity
API Standard Conditions	15/1013	15 °C (60 °F)	1013.25 mbar (14.7 psia)	0 %
Cummings Standard	25/991	25 °C (77 °F)	991 mbar (500 ft altitude)	0 %
20 °C/1013 mbar	20/1013	20 °C (68 °F)	1013.25 mbar (760 mmHg)	0 %
Normal Temperature and Pressure	NTPD	20.0 °C (68 °F)	1013.25 mbar (760mmHg)	0 %
Normal Temperature and Pressure, Saturated	NTPS	20.0 °C (68 °F)	1013.25 mbar (760mmHg)	100 %
Ambient Pressure at 25 °C	AP25	25.0 °C (77 °F)	Current Ambient pressure	Current gas humidity

In this User manual the unit L/min is based on ambient conditions of 0 °C and 1013 mbar (DIN 1343).

Please refer to Appendix B: Measurement parameters and units. There you will also find the conversion factors for the units of measurement.

4.3 Power supply

Input voltage of the power supply unit: 100–240 VAC, 50–60 Hz, 2.0 A
Output voltage of the power supply unit: 24 VDC, 2.7 A
PF-300 PRO input voltage: 24 VDC, 2.5 A
Power supply protection class: Class I

Only use the power supply unit and cable provided!

4.4 Battery operation

Operating time in battery operation: 16 hours
Operating time in battery operation with MultiGasAnalyser: 13 hours

Charging the battery
A complete charging process takes 8 h. The service life of the battery is extended if the battery is charged completely only after a prompt by the device.

The device indicates visually and audibly when the battery has to be charged. Please do not store the battery in the depleted state.

Caution: depletion can damage the battery beyond repair!

4.5 Directives and approvals

- IEC 61010-1
- IEC 61326-1

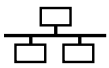
- CAN/CSA-C22.2 No. 61010-1-12
- UL 61010-1 3rd Edition

The device is classified as Pollution Degree 2.
The device is classified as Overvoltage Category II.

> The device is not intended for use outside a building.

4.6 Device labels and symbols

The following labels and symbols can be found on FlowAnalyser PRO and its packaging:

Symbol	Description
	Stand-by
	Alternating current
	Class II equipment
	For indoor use only
	Direct Current
	Ethernet network connector
	USB Port to connect an USB Stick
	Serial Interface
	Port to communicate with a computer
	Battery
	Conforms to CE Directives and Regulations
	Safety Mark for North America for PF-300 PRO
	Safety Mark for North America for Power Supply
	Manufacturer

Symbol	Description
	The operating instructions should be considered when operating the device
	Caution is necessary when operating the device
	Do not dispose with household waste
SN	Serial Number
REF	Reference Number
	Temperature range for transport and storage
	Humidity range for transport and storage
	Atmospheric pressure für storage and transport
	Keep dry
	Protect from sunlight
UDI UDI Data Matrix Code (e.g.): 	Unique device identifier (01) GTIN-No. (10) Batch Code (11) Production Date (21) Serial No.
IP21	Protection class according to standard
Trigger IN	Trigger interface, maximum 24V, 60 mA

4.7 PC minimum requirements

Intel® Pentium® 4 2.4 GHz
(Intel® Core TM2 Duo recommended)
Microsoft® Windows® XP, Vista, 7, 8 (32 bit / 64 bit)
Microsoft® .NET Framework 3.5 or higher
128 MB RAM (512 MB recommended)
160 MB storage space on hard disk (full installation) CD-ROM drive
Monitor 800 × 600 (1024 × 768 recommended)

5 Start-up

5.1 Individual parts in the packaging

	FlowAnalyser PRO
	Power supply
	USB cable
	Calibration certificate
	Filter
	Adapter set

5.2 Power supply

The power supply socket is located at the back of FlowAnalyser PRO.

The device can be disconnected from the mains using the power cord. The cord should therefore be easily accessible.

5.2.1 Supply voltage

The mains voltage of the power supply unit included is 100–240 VAC at 50–60 Hz.

Before switching on, make sure the operating voltage of the power supply unit agrees with the local mains voltage.
You will find this information on the rating plate on the back of the power supply unit.

Only operate FlowAnalyser PRO with the original power supply unit included!

5.3 Mechanical connectors

5.3.1 Filter

To protect the device against soiling due to contaminants and particles in the air the filter included must be used for flow measurement. Connect the filter on the flow channel port between the tube and the device (→9.2. Connecting to the ventilator).

Particles of dirt in the air can clog the measuring system and thus lead to incorrect measurements. The filter must be checked regularly (→10.3 Preventive cleaning and servicing routines).

5.3.2 Adapter set

The adapters enclosed help to connect the test specimen to FlowAnalyser PRO. Minimising dead volume and differences in the diameter of the flow stream helps to increase the accuracy of measurement. When using the Ultra Low Flow channel, the positive connector of the differential pressure sensor is used for pressure measurements. With the tee enclosed and the connecting tube the relevant ports can be connected to one another.

5.3.3 Flow Channel

The Flow channel can be used to perform gas flow measurements from -300 to 300 L/min. Additionally the channel includes sensors for pressure, temperature, humidity and oxygen concentration.

Measuring range: -300 – 300 L/min
Accuracy: ± 1.65 % of reading or ± 0.04 L/min

If work is being performed at a relatively high level of air humidity, care must be taken to ensure that no condensation forms in the device. Water can damage the sensors beyond repair!

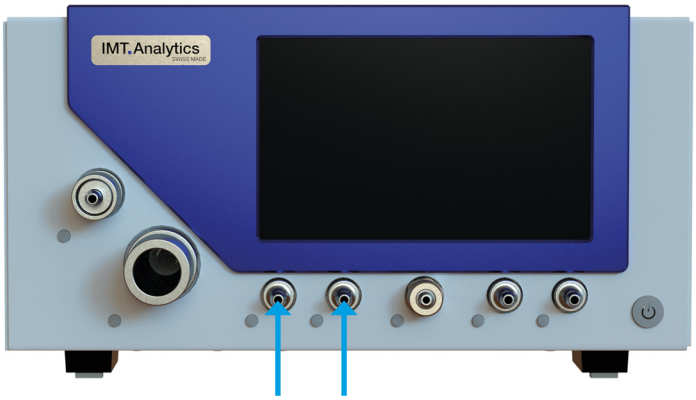
5.3.4 Ultra Low Flow

The Ultra Low Flow measurement can be used to measure very low gas flows in a range of -1 to 1 L/min

Measuring range: -1 – 1 L/min
Accuracy: ± 1.65 % of reading or ± 0.01 L/min

5.3.5 Low Differential pressure

The Low Differential pressure connectors can be used for differential pressure measurements with low pressures.



Measuring range: -10 – 10 mbar
Accuracy: ± 1 % of reading or ± 0.01 mbar

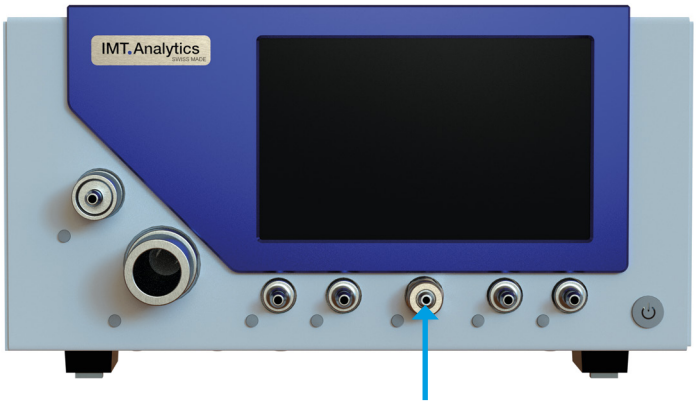
5.3.6 Differential pressure

The differential pressure connectors can be used for differential pressure measurements.

Measuring range: -250 – 250 mbar
Accuracy: ± 0.5 % of reading or ± 0.1 mbar

5.3.7 High pressure and Vacuum

The high-pressure port can be used for measuring pressures from -1 to 10 bar. If a DISS-O_2 connector is required for the port, an appropriate adapter can be ordered.

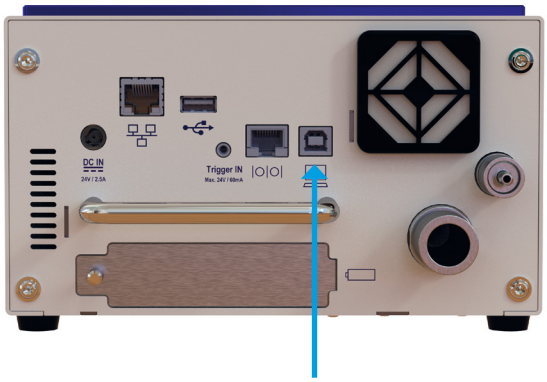


Measuring range: -1 – 10 bar
Accuracy: ± 1 % of reading or ± 7 mbar

5.4 Electrical interfaces

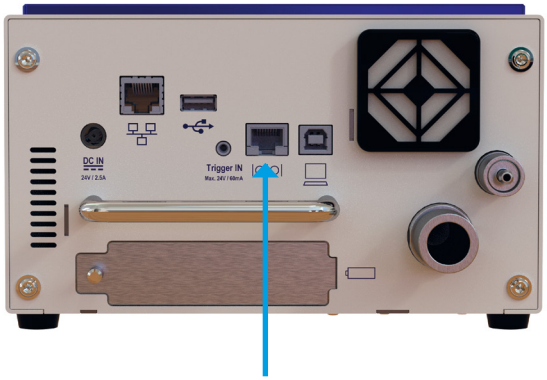
5.4.1 USB to Computer

The USB port is used for connecting FlowAnalyser PRO to a PC. The port is located at the back of the device.



5.4.2 RS-232

The RS-232 interface is used for remote monitoring or control and for connecting to a MultiGasAnalyser OR-703.



Actuation of the RS-232 port takes place via a special RS-232 cable.

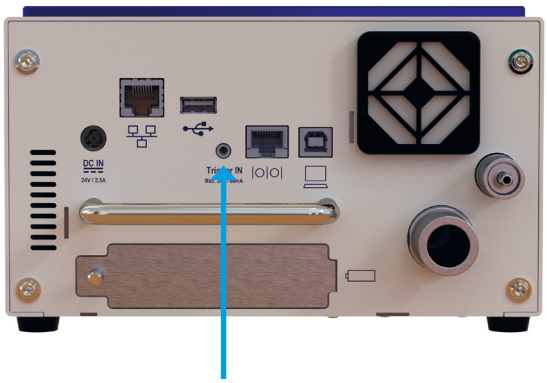
If the device is to be actuated via the RS-232 interface, various data protocols are available.

FlowAnalyser PRO pin assignment (RJ-45 connector):

Pin 1	+5 VDC
Pins 4, 5	GND
Pin 7	TxD
Pin 8	RxD
Pins 2, 3, 6	No connection

5.4.3 External Trigger

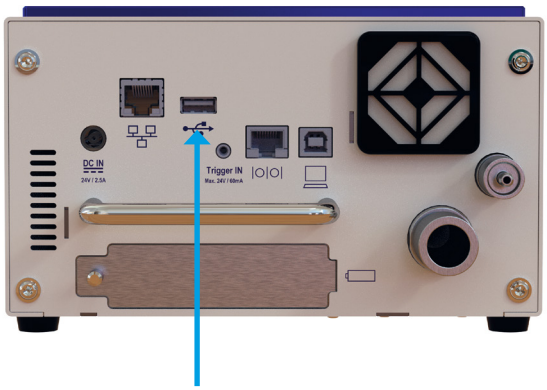
The external trigger interface is used to start and stop volume measurement and to determine ventilation parameters using an external signal. The input is electrically isolated.



Maximum 24V and 60 mA to be used on external trigger interface.

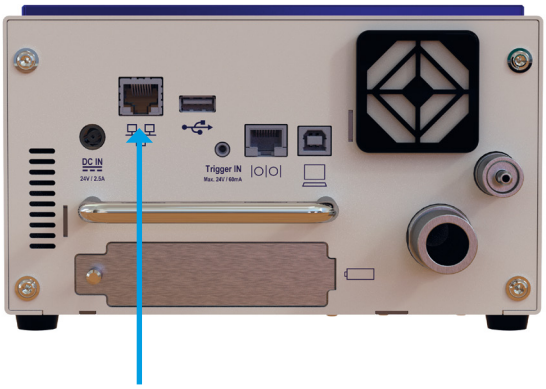
5.4.4 USB

The USB Host Connector can be used to connect a memory stick for data logging and also for firmware upgrade.



5.4.5 Ethernet

The Ethernet connector allows to connect the device to a LAN. The device will provide an embedded web server.



6 Operation

6.1 Switching the device on and off

Check that all the cables and tubes are connected properly and check compliance with the specifications (→5 Start-up)

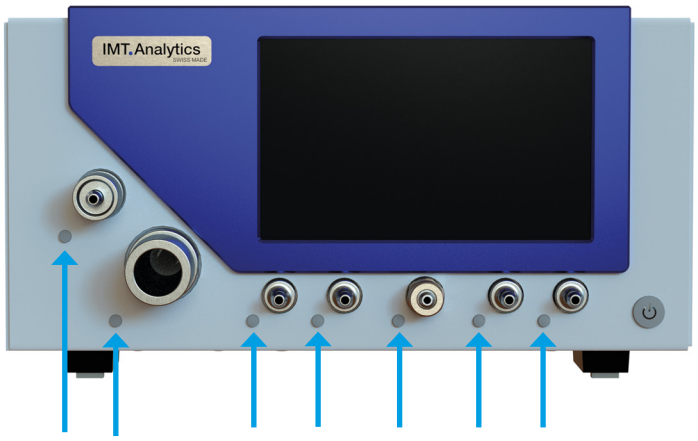
The device can be turned on and off using the power knob on the front of the device.

6.2 The Start screen

If FlowAnalyser PRO is switched on, the welcome screen appears.

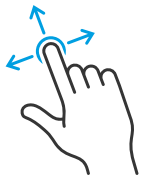
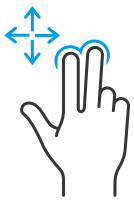
6.3 Direct Access controls (DAC)

Next to each mechanical port there is a Direct Access Control button (DAC). Information associated with the mechanical port, e.g. measurement parameters, value range, present reading, is shown on the display by pressing the relevant DAC. An LED in each DAC indicates whether the relevant port on the display screen is activate



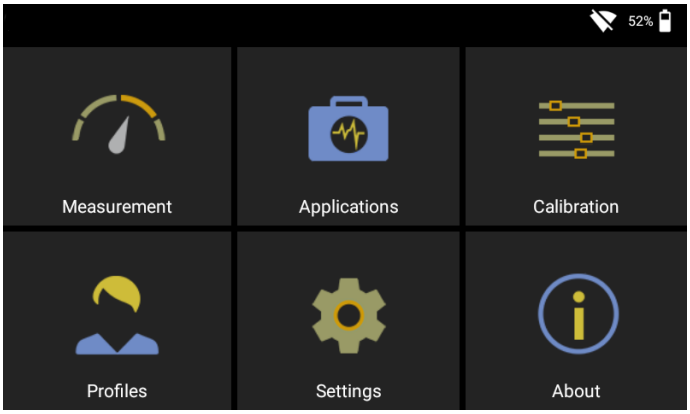
6.4 User control gestures

To be able to operate the multi-touch screen optimally and easily you have various gestures at your disposal.

Gesture	Title	Action	Function
	Tap	Tap an element once.	• Increase in readings and measurement curves • Selection of menu items • Perform measurement on the graphical measurement curves
	Hold down	Press and keep pressed for one second.	• Editing readings and curves • Editing files and profiles
	Swipe	Drag your finger across the screen.	• Change views on the measurement screen • Unlock screen • Shut down device
	Move by dragging	Tap an element, drag it to the position required and let go there.	Move a reading.
	Pinch close or pinch open	Move thumb and index finger together or move them apart.	Zoom in or out on measurement curves.
	Drag with two fingers	Place index finger and middle finger on object and drag.	Moving of measurement curves when the measurement curve is paused.

6.5 Main menu

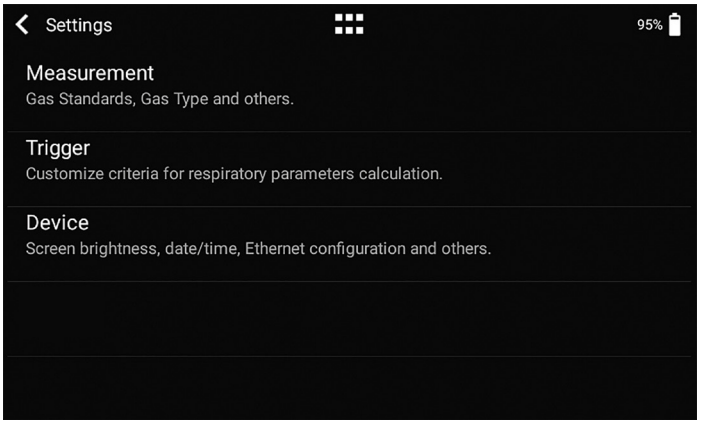
The main menu is the starting point for operation of FlowAnalyser PRO. The software version described in this User Manual displays the menu items listed below.



Measurement	This is where the measured pressures, flows and ventilation parameters are displayed. There are graphical and numerical methods of representation available. They can be freely configured by the user. You will find more information on this in sections 6.7 and 6.8.
Settings	All device-specific representations are configured in this menu item. The options available are explained in section 6.6.
Calibration	Zero-point calibration and oxygen sensor calibration can be called up with this menu item. You will find details on how to perform calibration in section 7.
Profiles	With FlowAnalyser PRO you have the option of creating profiles to suit your particular requirements. You can load, edit and create functions in this menu item.
Applications	With the menu item Applications you are offered custom applications. If you are in need of such a solution, please contact IMT Analytics at: sales@imtanalytics.com
About	This menu item saves user information and device information.

6.6 Settings

In the menu item ***Settings*** all the settings can be defined.



6.6.1 Measurements

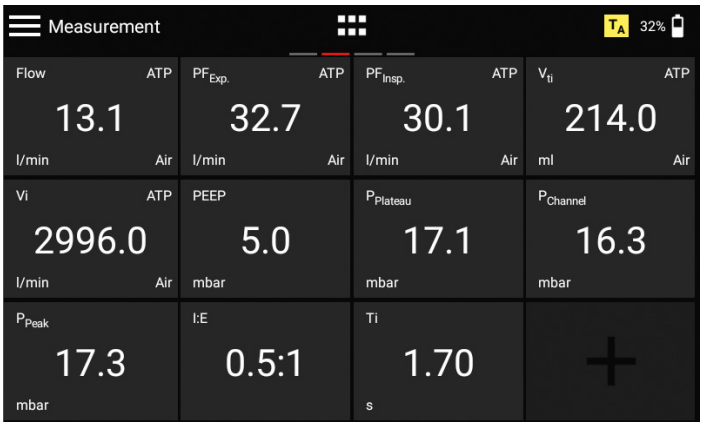
Measurement settings contain all the settings to configure measurements. Here you can set the gas standard, gas type, gas humidity and pressure compensation. In addition, this setting also makes it possible to configure the filter type and the ventilation parameter pressure source.

Gas standard	FlowAnalyser PRO supports various gas standards. The gas standards are listed under 6.12 Gas type and standards.
Gas type	The gas that is to be measured must be set on FlowAnalyser PRO. O_2 gas mixtures that are referred to as “automatic” are calibrated using the oxygen cell. You will find a complete list of gas types in the section 6.12 Gas type and standards.
Dynamic Pressure Compensation	The Dynamic Pressure Compensation setting only affects the displayed PChannel value. When the Dynamic Pressure Compensation setting is enabled, a virtual pressure is calculated, lying downstream in the device (hence the measurement is independent from the orientation of the device.). This replicates the behaviour of the FlowAnalyser PRO. When the Dynamic Pressure Compensation setting is disabled, the displayed pressure value is the value which is measured by the pressure sensor in the flow channel.
Filter type	To make the parameters easier to read the readings are filtered. Readings are recorded every 1 ms. The following four options are available: • None (100 ms) • Low (250 ms) • Medium (650 ms) • High (1000 ms)
Ventilation parameter pressure source	Ventilation parameters require a pressure measurement for calculation. The pressure value from the “$P_{channel}$” sensor is used by default. Optionally both differential pressure sensors P_{diff} low and P_{diff} high can be selected for automatic calculation.

In the menu sub-item ***Measurement*** the settings are made for gas type, gas standard, gas humidity and pressure compensation source. FlowAnalyser PRO provides three different trigger settings. The associated settings can be found in the sub-item ***Trigger***. You will find the settings concerning the device in the sub-menu ***Device***. That contains various adjustment options for the screen, device settings and the various interfaces.

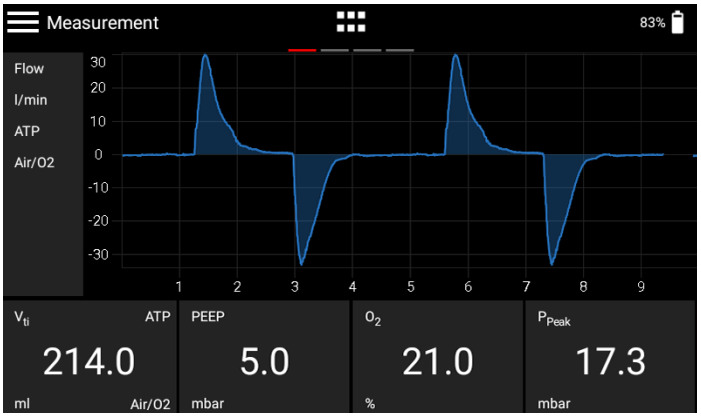
6.7 Numerical readings

You can display all the readings in FlowAnalyser PRO numerically or graphically. In the Appendix (13.2 Measurement parameters and units) you will find an overview of the available readings and parameters. To access edit mode, tap a measurement tile once.



6.8 Graphical readings

Each reading or parameter can be represented by a measurement curve. To edit the value, tap the name of the reading. In the full-screen view you have the option of changing the parameter, the unit of measurement, the gas standard and the gas type. With the pause button you can also freeze the curve and perform measurements on it.



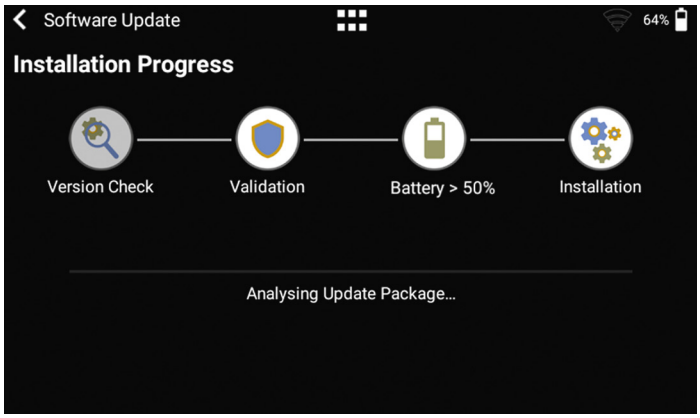
6.9 Software update

To provide the device with a new software version a USB stick is required. Firstly, format a USB memory stick with the FAT32 format. Then copy the installation file to the storage medium and plug the latter into the USB Host port with the USB adapter included. Now start the device and in the sub-menu ***About*** go to ***Software Update***. Follow the instructions on the screen.

The installation of new software takes about 10 minutes.

During installation make sure the battery charge is at least 50 % or the device is plugged into the power supply with the power supply unit included.

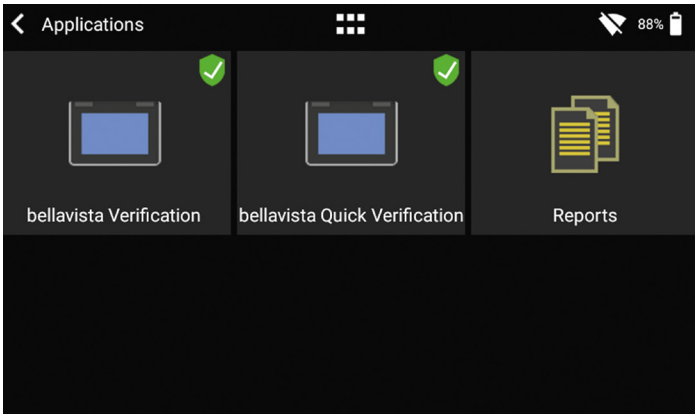
While installation is running, the device must not be switched off!



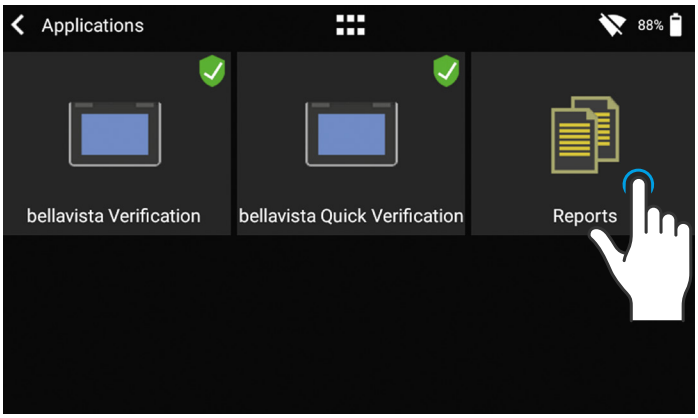
6.10 Applications

Under the menu item ***Applications*** you can store custom programs and device-specific programs. These are designed to simplify and support the testing of various devices. At the moment you will find two applications on the device, which each create a test report at the end of a test process and save it in the form of a PDF file.

An application with the “Verified” icon indicates that the program has been verified by the manufacturer of the device.



The menu item ***Reports*** contains the various test reports in the PDF format. The reports can be viewed, deleted or exported. These functions are located in the context menu at top left. To export the test reports a USB stick with the adapter included must be plugged into the USB Host port on the device.



If you require for your device an application tailored to your particular needs, please contact sales@imtanalytics.com.

6.11 Gas type and standards

Depending on the gas that is to be measured, the corresponding gas type must be set on FlowAnalyser PRO beforehand.

The following gas types are available for selection:

- Air (100 %)
- Air/O_2-Man.
  (Air/oxygen mixture according to manual input. The default is 100 % O_2)
- Air/O_2-Auto.
  (Air/oxygen mixture according to sensor measurement of internal oxygen cell)
- N_2O/O_2-Man.
  (Nitrous oxide/oxygen mixture according to manual input. The default is 100 % O_2)
- N_2O/O_2-Auto.
  (Nitrous oxide/oxygen mixture according to sensor measurement of internal oxygen cell)
- Heliox (21% O_2)
- He/O_2-Man.
  (Helium/oxygen mixture according to manual input. The default is 100 % O_2)
- He/O_2-Auto.(Helium/oxygen mixture according to the sensor measurement of internal oxygen cell)
- N_2 (100 %)
- CO_2 (100 %)

Leakage occurring with inhalation anesthesia (e.g. N_2O) is known to not provide adequate protection from anesthetic gases with natural ventilation. Therefore, suitable (ventilation-) technical measures must be observed in rooms where the performance with anesthetic gases takes place.

By pressing ***Change*** you can switch between the various requirements and ***Save*** applies the value selected. In the case of mixtures with manual input of O_2 concentration the latter can be adjusted in addition.

Standard conditions are understood to mean defined conditions for pressure, temperature and, in some cases, humidity, which constitute the basis for converting the flow actually measured. Therefore it is essential to check which standard condition the value displayed relates to.

The standard currently set is indicated on the numerical display.

If you press ***Change*** a plus and a minus appear, so you can switch between the various requirements. ***Save*** applies the value selected.

A gas that has not been selected properly and a gas standard that has not been selected properly can lead to measuring errors of up to 20 %.

6.12 Filter

The display of FlowAnalyser PRO is refreshed every 0.2 seconds but measurement takes place every 1 ms. Without a filter the current reading is shown every time the screen display is refreshed.

Since a measurement always has a certain amount of noise, it is useful, over a certain time, to average the readings recorded at a very high speed. This can be accomplished with the filter function.

The following filters are selectable:

- None (100 ms)
- Low (250 ms)
- Medium (650 ms)
- High (1000 ms)

A high filter is used by default.

By pressing ***Change*** you can switch between the various filters with the arrow buttons and ***Save*** applies the filter selected.

This filtering of readings only has an impact on the values shown on the display of FlowAnalyser PRO. In the FlowLab software it is always the raw, unfiltered readings that are displayed.

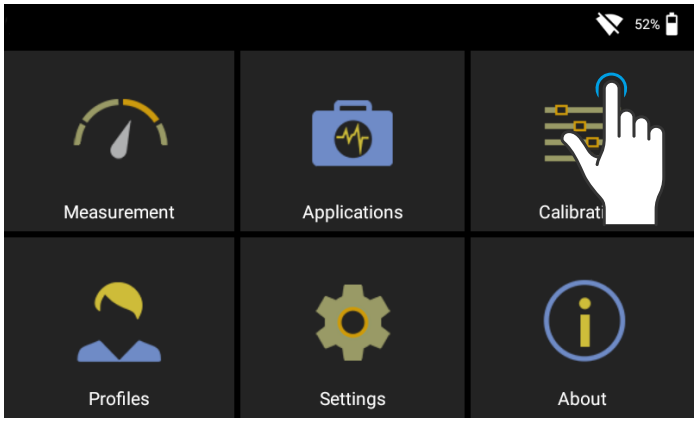
7 Calibration

The various calibrations of FlowAnalyser PRO are described in this section. To avoid incorrect measurements you must adhere to the procedures described here.

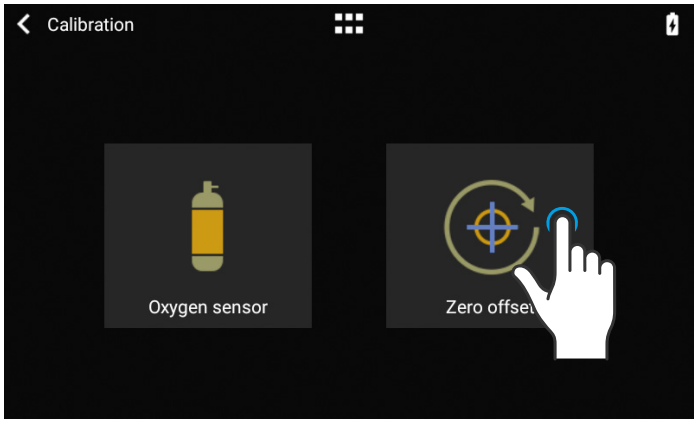
7.1 Zero point

Zero calibration must be performed as soon as FlowAnalyser PRO has warmed up. To perform zero calibration you must remove all connected tubes from the device.

In the main menu, tap the ***Calibration*** icon.



In the Calibration sub-menu tap the ***Zero Offset*** icon. Follow the instructions on the screen and tap ***Start***. After successful calibration a confirmation appears. The device is now ready for use.



When you have switched on the device, individual displays may deviate slightly from the zero point until operating temperature has been reached. Zero calibration should never be performed with the device cold. Warming-up time is approx. 10 minutes.

7.2 Oxygen (O_2) calibration

There are two different methods of calibrating the oxygen cell. The variant in which the oxygen cell is calibrated with air only takes about two minutes. The second variant consists of calibrating the oxygen cell with air and 100 % oxygen. This so-called two-point calibration adjusts the oxygen sensor more accurately. Calibration can be called up under ***Calibration*** and then ***Oxygen Sensor***.

7.2.1 Calibration with air only

Make sure air is flowing through the flow channel at a rate between 20 and 30 L/min. Then press ***Start Air Calibration*** and follow the instructions on the screen. The entire process takes about two minutes. At the end of the process a message appears confirming that calibration was successful, or an error message appears.

7.2.2 Calibration with oxygen and air

In this calibration, the requirement is oxygen (100 %) and air at a flow between 20 and 30 L/min. In the first step, the sensor is subjected to oxygen calibration. For this purpose connect the device to a gas flow source with an oxygen flow between 20 and 30 L/min and press ***Start Oxygen Calibration***. Follow the instructions on the screen. In the second step you must connect air with a gas flow between 20 and 30 L/min. The entire process takes about four minutes.

8 MultiGasAnalyser OR-703

8.1 Description

MultiGasAnalyser OR-703 consists of a 10-channel infrared (NDIR) gas sensor, a barometric pressure sensor, a CPU and an RS-232 Interface.

This User Manual describes the specifications of the red model of MultiGasAnalyser OR-703. If you have any questions about the blue model, please contact our Technical Support.

The sensor can measure the following gas concentrations:

- Carbon dioxide (CO_2)
- Nitrogen oxide (N_2O)
- Halothane (HAL)
- Enflurane (ENF)
- Isoflurane (ISO)
- Sevoflurane (SEV)
- Desflurane (DES)

The concentrations of CO_2, N_2O and two of the five anaesthetic gases can be measured at the same time.

8.2 Usage

MultiGasAnalyser OR-703 is designed to perform, in conjunction with FlowAnalyser PRO, gas measurements for the calibration and testing of anaesthesia systems and facilities.

The sensor is **not** suitable for monitoring patients.

The sensor is **not** suitable in conjunction with applications that are parts of means of transport such as cars or aircraft.

8.3 Warning

MultiGasAnalyser OR-703 may only be used by professionally trained personnel.

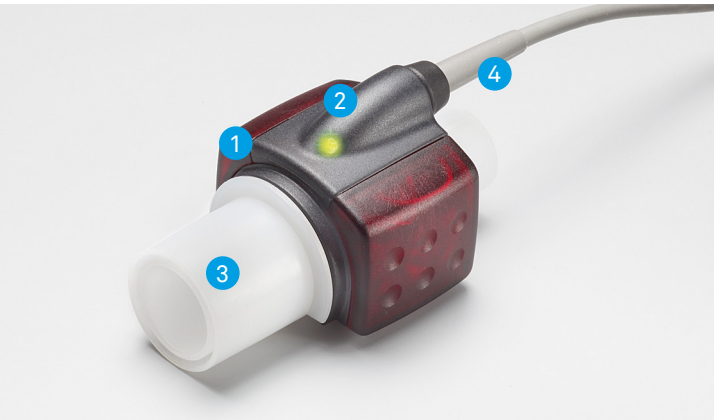
MultiGasAnalyser OR-703 may not be used with flammable anaesthetic agents.

Used airway adapters that have to be discarded must be disposed of in accordance with local waste disposal regulations for biologically contaminated liquids.

Measurements can be detrimentally affected by RF radiation, e.g., by cell phone communication.

Care must be taken to ensure that MultiGasAnalyser is only operated in an EMC-specified environment.

8.4 Principle



MultiGasAnalyser OR-703 consists of an OR sensor head 1, an O_2 sensor cell (optional) 2, an airway adapter 3 and a connecting cable 4.

The OR sensor head is located on the top of the airway adapter. The sensor head contains all the optical components that are required for measuring all the gases.

Since all the calibration data is stored in the relevant sensor head, it is possible to change the sensors without recalibration.

8.5 Connection

The OR sensor first has to be connected to the RS-232 input of FlowAnalyser PRO (at the back).

Attacked the OR sensor to the airway adapter from above. If it is in the correct position, the sensor will click into place. Wait 15 minutes before the first measurement until the sensor has warmed up.

A green LED indicates that the sensor is ready for operation.

8.6 LED signal

Continuous green light	System OK
Continuous blue light	Anaesthetic agent exists
Continuous red light	Sensor error
Flashing red light	Please check the adapter
Flashing green light	Calibration of the OR sensor

8.7 OR sensor calibration

Ambient air calibration of the infrared measurement should be performed at regular intervals and after any replacement of the airway adapter.

The need for ambient air calibration is indicated on the monitor by an alarm message "Calibration of OR Sensor!". (After calibration the message disappears).

Ambient air calibration can also be performed if an offset is found in the gas measurements. The gas measurements should be checked with a reference measuring instrument. Calibration is performed by attaching a new airway adapter to the OR sensor. The airway adapter must not be connected to the air circuit. Then the calibration procedure begins in the menu of FlowAnalyser PRO. If the sensor is in the correct position, it will click into place. Before continuing, please wait 30 seconds because the sensor has to warm up first.

If the airway adapter is being replaced, a zero calibration must be performed.

It is important to ensure that during calibration there is no flow through the airway adapter. For successful ambient air calibration it is essential to have ambient air conditions (21 % O_2 and 0 % CO_2)!

After calibration the readings should always be checked in order to obtain correct readings with certainty during subsequent measurements.

8.8 Servicing and care

MultiGasAnalyser is non-sterile. Autoclaving, sterilisation and immersion in liquid can cause serious damage to the sensor. The sensor can be cleaned with a cloth moistened with ethanol or isopropyl alcohol.

The airway adapter must be changed at least every 12 months. If MultiGasAnalyser is used in a sterile system, a new sterile adapter must be fitted.

Gas measurements should be checked regularly using a reference measuring instrument.

For this purpose IMT Analytics AG offers a service to recertify the measuring accuracy of the sensor.

8.9 Technical specifications

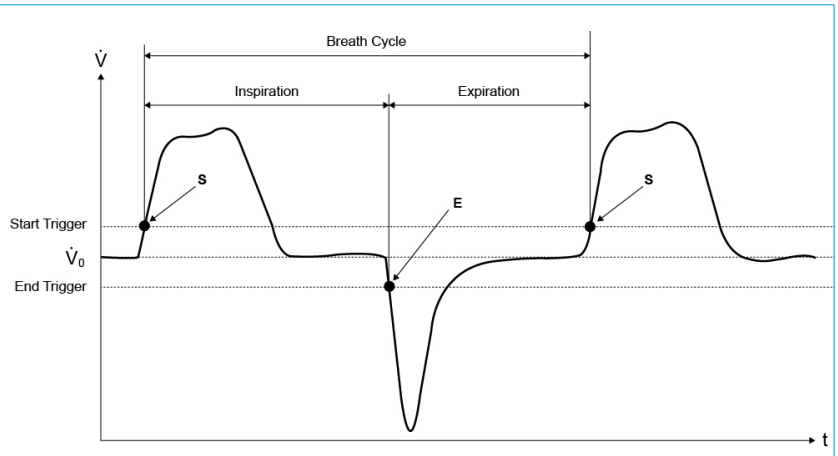
Physical data	Dimensions (L × W × H)		38 × 37 × 34 mm 1.49 × 1.45 × 1.34 inches
	Weight		<25 g (not including cable)
	Cable length		2.50 m ± 0.1 m
Ambient conditions	Operating temperature		10 – 40 °C, 50 – 104 °F
	Storage temperature		-40 – 70 °C, -40 – 158 °F
	Air humidity (operation)		10 – 95 % RH, non-condensing
	Air humidity (storage)		10 – 95 % RH, non-condensing
	Atm. pressure (operation)		525 – 1200 hPa (< 5211 m)
Accuracy specifications (under standard conditions)	**Gas**	**Area**	**Tolerance**
	CO_2	0 – 15 vol%	± (0.2 vol% + 2% of reading)
		15 – 25 vol%	unspecified
	N_2O	0 – 100 vol%	± (2% vol% + 2% of reading)
	HAL, ISO, ENF	0 – 8 vol%	± (0.15 vol% + 5% of reading)
		8 – 25 vol%	unspecified
	SEV	0 – 10 vol%	± (0.15 vol% + 5% of reading)
		10 – 25 vol%	unspecified
	DES	0 – 22 vol%	± (0.15 vol% + 5% of reading)
		22 – 25 vol%	unspecified
Rise times (@ 10 L/min)	CO_2 ≤ 90 ms N_2O, HAL, ISO, ENF, SEV, DES ≤ 300 ms		
Monitoring	Numerical measurement data and real time graph representation with FlowLab software.		

Deviations from gas setting stated. For example, 50 vol% helium typically reduces the CO_2 values by 6 %. This means that a measured mixture consisting of 5.0 vol% CO_2 and 50 vol% helium is equivalent to a measured concentration of (1 – 0.06) * 5.0 vol% = 4.7 vol% CO_2.

9 Measuring Ventilation Parameters

9.1 General

To measure ventilation cycles it is essential that FlowAnalyser PRO can read a ventilation cycle from the measured pressure and / or flow graphs. This is controlled using the triggers.



Correct definition of the start and stop triggers is therefore of major importance and it can have a considerable impact on the measurement results.

For triggering the ventilation cycles the set triggers are used.

It is therefore very important for the triggers to be set correctly before the measurement of ventilation parameters is started.

The start trigger is interpreted as the beginning of the inspiratory phase. The stop trigger is interpreted as the end of the inspiratory phase and as the beginning of the expiratory valve. Expiration continues until the next start trigger.

Automatic Trigger

The PF-300 PRO features an automatic trigger, which sets the limit to detect the inspiration and expiration automatically.

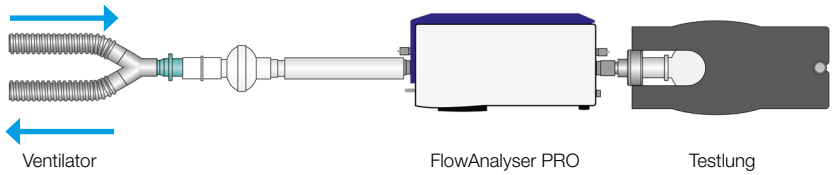
If the automatic trigger is selected, no further trigger settings are available.

For the automatic trigger to determine the limits reliably, the last 30–40 seconds of flow and pressure data is evaluated. Though the automatic trigger works very reliably, it may take up to 40 seconds to adapt to changed ventilation settings.

9.2 Connecting to the ventilator

Basically there are three different variants for how FlowAnalyser PRO can be connected to the ventilator:

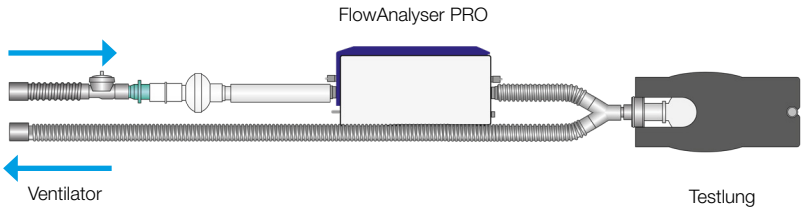
A: Downstream of the Y-piece



Note: It is advisable to have the inspiratory flow entering from the front (positive direction) and the expiration entering from the back (negative direction) of the unit.

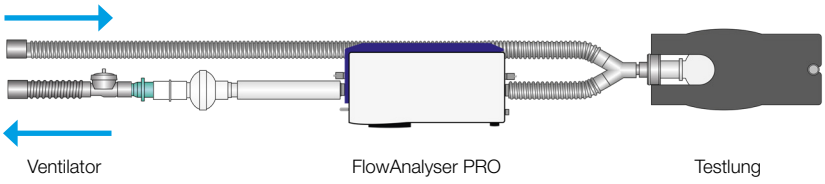
If this is not the case trigger settings have to be modified for proper breath detection. With default trigger settings inspiration becomes expiration and several parameters will be calculated wrongly or not at all.

B: In the inspiratory channel upstream of the Y-piece



Note: default trigger settings require modification.

C: In the expiratory channel upstream of the Y-piece



Note: default trigger settings require modification.

9.3 Standard trigger values

Since FlowAnalyser PRO is able to measure flows in both directions of flow, it makes sense to prefer connection variant A. With this measurement setup the flow is normally selected as the trigger parameter. For this reason the flow triggers are stored in the device as standard values and they can be restored at any time. The standard trigger values for the flow trigger in adult ventilation are as follows, for example:

- Start trigger: Flow > 3 L/min
- End trigger: Flow < -3 L/min

You will find the other standard values in the Operation section.

With connection variants B and C it is usually the pressure that is selected as the trigger signal. In this case the standard requirements are as follows:

- Start trigger: Pressure > 1 mbar
- End trigger: Pressure < 1 mbar

9.4 Base flow

Base flow is a constant flow that must not be included in volume calculation.

If, for example, a system has a defined leak, resulting in a continuous discharge of 3 L/min air, those 3 L/min are not included in the inspiratory volume. By entering

- Base flow: on 3.0 L/min

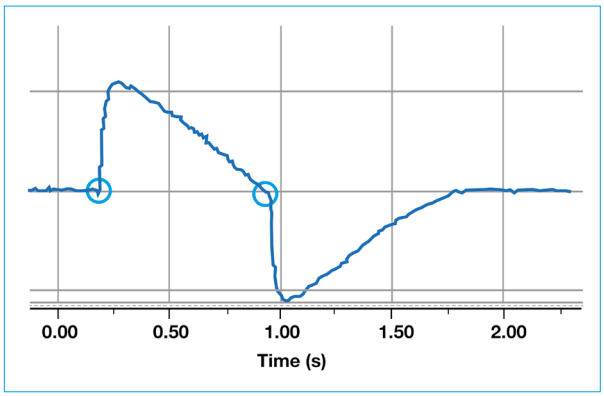
the volume calculation could be corrected in our example.

9.5 Finding the correct trigger values

If you are setting a trigger for the first time, it is important to know the characteristic of the signal that will be used for the trigger (flow or pressure). It is therefore advisable to analyse that characteristic with the FlowLab software first. Graphically it is then very easy to decide where the triggers should be placed.

In the following we will now show a few examples that also point to potential problems.

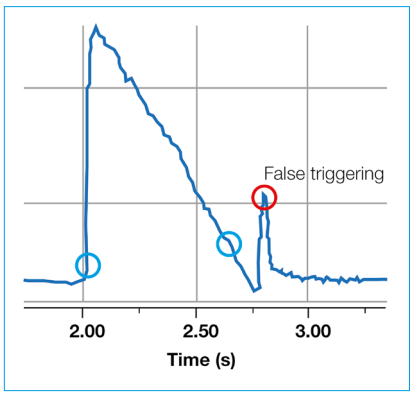
9.5.1 Flow curve downstream of the Y-piece



This example shows a flow curve downstream of the Y-piece. The standard triggers (> 3 L/min / < -3 L/min) can be used in this case without any problems.

In such a situation it is important to ensure that the trigger is significantly above the noise of the baseline or else false triggering can be caused.

9.5.2 Flow curve upstream of the Y-piece

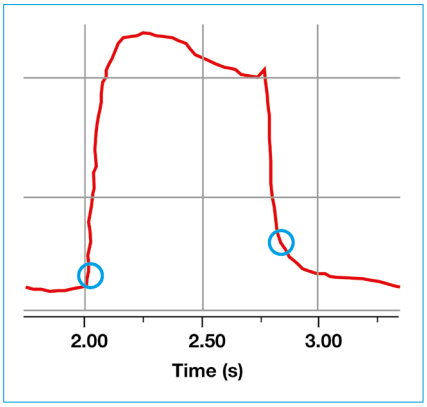


This graph shows the flow curve in the inspiratory channel upstream of the Y-piece. The first two circles indicate the triggers that should be used in this case.

The illustration above shows that at this measuring point after inspiration a small false signal is still visible which was generated by switching over the valves. This leads to false triggering!

Here the flow must not be used as a trigger! The pressure curve must be used instead (9.5.3 Pressure curve upstream of the Y-piece).

9.5.3 Pressure curve upstream of the Y-piece



Now here the standard triggers can again be used for the pressure curve:
(> 1 mbar / < 1 mbar).

Naturally it is also important to ensure that the trigger is significantly above the noise of the baseline. Otherwise the trigger value must be increased.

In the FlowLab software it is very easy to determine with the aid of the cursor where the trigger should be placed.

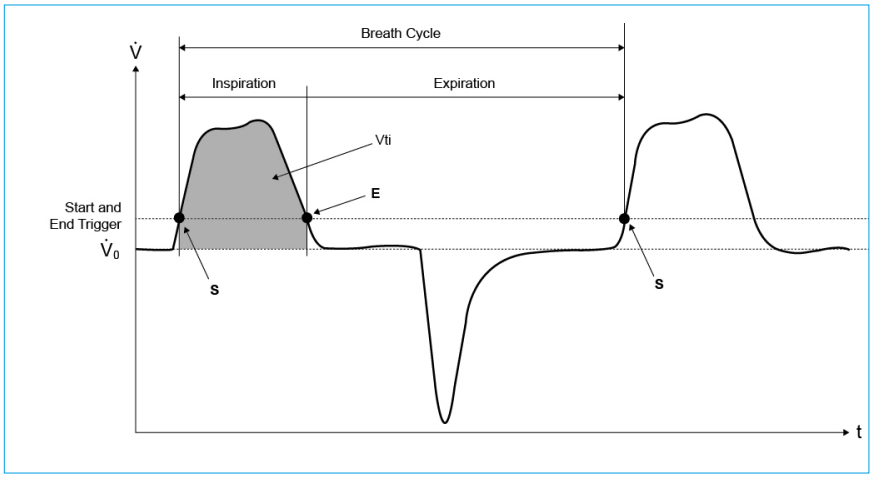
9.6 Special cases

Basically, in measuring technology it is always possible to deviate from the standard variant in order to achieve an even more accurate result. However, it must be borne in mind that with the settings discussed so far it is possible to achieve very accurate results that surpass the accuracy of all ventilators.

Measuring errors due to the system as a whole occur both in the ventilator and in FlowAnalyser PRO. However, the values indicated can vary because what was measured and compared may not be exactly the same.

9.6.1 Inspiratory volume Vti

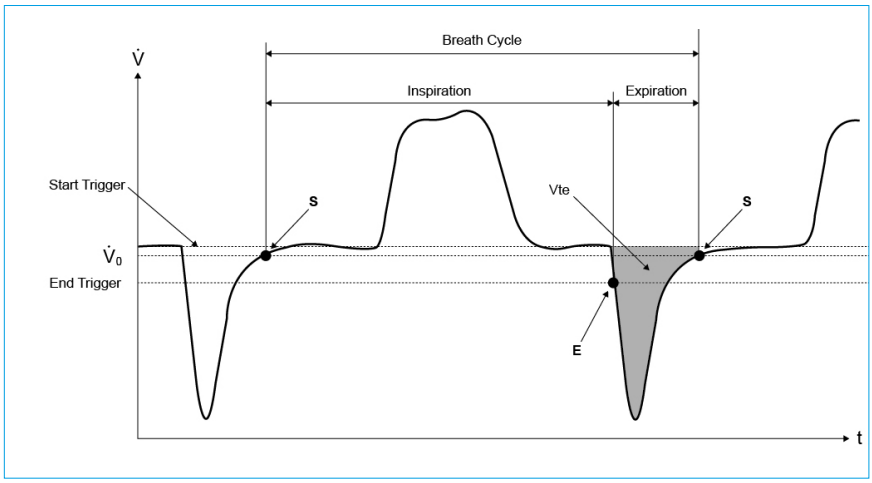
If the ventilation curve has a plateau or a pause, a very small flow can nevertheless be measured during that time. Many ventilators do not include these small flows in the calculation of Vti. With the following trigger settings this can also be prevented in FlowAnalyser PRO:



S on this chart represents the start trigger and E represents the end trigger.

9.6.2 Expiratory volume Vte

Here is the analog setting for Vte:



Here, the start trigger should be also placed at S and the end trigger should be placed at E.

9.6.3 Plateau/Pause

The FlowAnalyser PRO features an automatic inspiratory and expiratory plateau detection. A plateau is sometimes also called pause.

During the detected plateau, the ventilation parameters RatioTp, $P_{plateau}$, C_{stat}, Ti Hold and Te Hold are determined.

To detect a plateau, the flow must be small and the pressure must be stable. More specific, the flow must fall below a value in the range of 1 L/min to 3 L/min, depending on the respiratory mode.

At the same time, the pressure range during the plateau must not be bigger than 0.5 mbar.

10 Servicing and maintenance

10.1 Guidelines for servicing and care

Careful servicing in compliance with the instructions is essential for ensuring that FlowAnalyser PRO operates safely and efficiently. Only components recommended by the manufacturer may be used.

It is absolutely essential to comply with the guidelines and servicing instructions issued by the various manufacturers.

10.2 Notes about changing parts

The servicing operations listed below may only be performed by persons who are familiar with FlowAnalyser PRO. All further repair work may only be performed by authorised trained professionals. Please also observe the information issued by the various manufacturers.

10.3 Preventive cleaning and servicing routines

To ensure that your device operates with precision and reliability for as long as possible, it is essential to perform the following servicing routines regularly during the device is switched off:

During operation
Use of the filter included

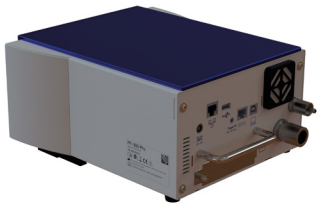
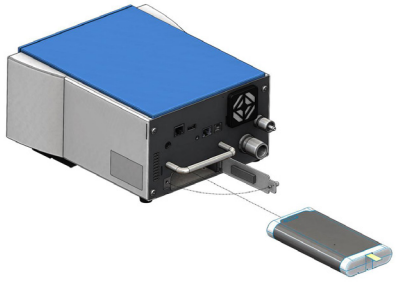
After each use
The outer surface of the device enclosure shall withstand wipe disinfection with a cloth moistened with ethanol or isopropyl alcohol.

Every four weeks
Visually check the protection filter for dust or contamination. Replace the filter if contamination is visible.

Every 12 months:
Factory calibration to ensure reliable measurement. To have FlowAnalyser PRO calibrated at the manufacturer's, IMT Analytics AG, visit the website www.imtanalytics.com/easycal

10.3.1 Replacing the battery

To replace the battery the battery cover must be opened:

	Turn counterclockwise
	Open carefully 90°
	Remove battery

Only use the spare parts recommended by the manufacturer (11 Accessories and spare parts).

The battery must not be replaced with a different type. Doing so may lead to a explosion, burn or fire hazard.

10.4 Contact

If you have any questions or problems please contact one of the offices listed below.

10.4.1 Manufacturer‘s name and address

IMT Analytics AG
Gewerbestrasse 8
CH-9470 Buchs
Switzerland

Tel: +41 (0)81 750 67 10
Email: sales@imtanalytics.com

10.4.2 Technical support

Tel: +41 (0)81 750 67 10
Email: techsupport@imtanalytics.com

11 Accessories and spare parts

11.1 Ordering address

IMT Analytics AG
Gewerbestrasse 8
CH-9470 Buchs
Switzerland

Tel: +41 (0)81 750 67 10
Email: sales@imtanalytics.com

11.2 Spare parts

Picture	Name	Article Number
	Battery Pack	700.348.000
	Power Supply	700.355.000
	Adaptor Set	300.548.000
	Power Cord EU 10A, 2.0 m	200.055.000
	Power Cord US 15A, 2.0 m	200.055.002
	Power Cord CH 10A, 2.0 m	200.055.003

12 Disposal

Disposal of the device is the operator's responsibility. The device can

- be delivered, carriage free and duty paid, to the manufacturer for disposal.
- be handed over to a licensed private or public collection company.
- be professionally broken down into its constituent parts by the operator and be recycled or disposed of in accordance with regulations.

Accessories and consumables must be disposed of in accordance with the relevant instructions for use. For information, contact your local environmental or regulatory agency, or an appropriate waste disposal company. In the case of self-disposal the disposal regulations are country-specific and are contained in relevant laws and ordinances. These codes of conduct must be obtained from the authorities responsible.

In this context, wastes must be recycled or destroyed

- without endangering human health
- without using processes or methods that harm the environment, especially water, air, soil, animals and plants
- without causing noise or odour nuisances
- without having a detrimental effect on the surroundings or landscape.

13 Appendix

13.1 Abbreviations and glossary

A	
A	Ampere
AC	Alternating Current
B	
bar	1 bar = 14.50 psi
Base flow	Base flow is a constant flow that must not be included in volume calculation.
C	
°C	Degrees Celsius Conversion from Celsius (C) to Fahrenheit (F): F = 9×C/5 + 32
Cstat	Static Compliance
D	
DC	Direct Current
DIN	Deutsche Industrienorm (German Industrial Standard)
DAC	Direct Access Control
E	
EMC	Electromagnetic Compatibility
F	
°F	Degrees Fahrenheit Conversion from Fahrenheit (F) to Celsius (C): C = (F-32)×5/9
G	
GND	Ground
H	
Hz	Hertz (1 Hz = 1 s-1)
HF	High Frequency
I	
IP	Protection class according to standard
I:E	Inspiratory/expiratory ratio
I	
L	Litre
LED	Light emitting diode
L/s	Litres per second
M	
Max, max	Maximum
mbar	Millibar (1 mbar = 10-3 bar)
Min	Minute
Min, min	Minimum
min.	At least
mm	Millimetre (1 mm = 10-3 m)
mL	Millilitre (1 mL = 10-3 L)

N	
nL/min	Standard litres per minute (converted to ambient conditions of 0°C and 1013 mbar)
P	
prox.	Proximal
psi	Pounds per square inch (1 bar = 14.50 psi)
Ppeak	Peak pressure
Pmean	Mean pressure
PEEP	Positive end-expiratory pressure
PF Insp.	Maximum flow during inspiration
PF Exp.	Maximum flow during expiration
Pplateau	Plateau pressure at the end of inspiration
R	
RH	Relative Humidity
RS-232	Serial interface
T	
$Ti//T_{cyc}$	Ratio of inspiratory time to time of a respiratory cycle
V	
V	Volt
VA	Apparent power input of the device
VAC	Volts Alternating Current
VDC	Volts Direct Current

13.2 Measurement parameters and units

13.2.1 Pressure readings

Measurement parameter	Designation	Units of measurement
Ambient pressure	pAtmo	mbar, bar, inH_2O, cmH_2O, psi, Torr, inHg, mmHg, hPa, kPa, Pa
Pressure high	P High	
Pressure in Flow channel	P Channel	
High Differential pressure	P Diff. High	
Low Differential pressure	P Diff. Low	

13.2.2 Flow readings

Measurement parameter	Designation	Units of measurement
Flow	Flow	L/min, mL/min, cfm, L/s, mL/s
Ultra Low Flow	Ultra Low Flow	L/min, mL/min, cfm, L/s, mL/s

13.2.3 Meteorological readings

Measurement parameter	Designation	Units of measurement
Temperature	Temp.	°C, K, °F
Humidity	Humid.	%
Oxygen content	O_2	%
Dew point	Dew point	°C, K, °F
Volume	Vol. HF	mL, L, cf

13.2.4 Gas concentrations

Measurement parameter	Designation	Units of measurement
Gas concentration	Gas concentration	%
Partial pressure	Partial pressure	mbar, bar, inH_2O, cmH_2O, psi, Torr, inHg, mmHg, hPa, kPa, Pa

13.2.5 Ventilation parameters

Measurement parameter	Designation	Units of measurement
Volume	Volume	mL, L, cf
Inspiratory to expiratory time ratio (I:E)	I:E	none
Post-Inspiratory Pause	RatioTp	%
Ratio Ti/T_{cyc}	RatioTiT_{cyc}	%
Positive end expiratory pressure	PEEP	mbar, bar, inH_2O, cmH_2O, psi, Torr, inHg, mmHg, hPa, kPa, Pa
Mean pressure	P_{mean}	
Maximum pressure	P_{peak}	
Plateau pressure	$P_{plateau}$	
Minute volume Expiration	Ve	L/min, mL/min, cfm, L/s, mL/s
Minute volume Inspiration	Vi	
Inspiratory peak flow	PF Insp.	
Expiratory peak flow	PF Exp.	
Expiratory tidal volume	Vte	mL, L, cf
Inspiratory tidal volume	Vti	mL, L, cf
Ventilation rate	Rate	bpm, b/min, Hz
Static lung compliance	C_{stat}	ml/mbar, l/mbar, ml/cmH_2O, l/cmH_2O
Inspiratory time	Ti	s, ms
Inspiratory hold time	Ti Hold	
Expiratory time	Te	
Expiratory hold time	Te Hold	
Peak Expiratory Flow	PF Exp.	L/min, L/s, cfm, mL/min, mL/s
Peak Inspiratory Flow	PF Insp.	

13.3 Index

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