



RIGEL MEDICAL
TESTED, TRUSTED... WORLDWIDE.

FloTest

USER MANUAL



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1 Introduction

Validity

This documentation is valid for the product: Rigel FloTest

You will find the name FloTest on the label at the back of your device.

Software and firmware version

This documentation applies to the following versions:

FloTest firmware – Version 1.2.000

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 such as ***Power*** and indicators on the display such as ***Settings*** are printed in boldface italics.

References to pages and sections

For references to pages and references, e.g. (4.5 Physical data), the symbol (XY) is used.

Version information

Issue date of this User Manual: **Release 02, 2023-03**

Subject to technical modifications without notice.

2 Intended use

This product is intended for testing and calibration purposes of medical – or other devices or systems that generate Air / O₂ / N₂ gas flows and / or gas pressures.

The device is intended for users who are trained in the use of measuring devices and who can carry out tests, repairs, calibrations, maintenance, and service work on medical or other devices. No dedicated training on this specific device is required.

The device can be used in:

- Hospital service departments
- Clinics
- Medical and non-medical devices manufacturing facilities
- Workshop / testing / laboratory facilities of independent service companies performing service and repair for medical and non-medical devices

FloTest is intended for use in an indoor test laboratory environment. 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 FloTest is intended for over-the-counter sale.

FloTest is the solution for measurements in the following areas:

- Flow (± 300 L/min)
- Volume (0L – 500000 L)
- Absolute pressure in the Flow channel (0.5 – 2 bar)
- Temperature in the Flow channel (-10 – 50 °C)



FloTest is a measuring instrument for testing and calibrating purpose on medical and non-medical devices or systems. It must not be used for patient monitoring. FloTest must not be used directly on patients or devices that are connected to patients.

This product is intended to be used at elevations of up to 5000 m operation altitude 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 emphasize important technical requirements.



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

3.2 Personnel



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

3.3 Responsibility and guarantee

The manufacturer accepts no responsibility or guarantee and will be exempt 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



- Report any serious incident that has occurred in relation to the medical device to the manufacturer ([8.6.2 Technical support](#)) and the authority having jurisdiction in their locale
- The device has user replaceable parts ([8.3 Preventive cleaning and servicing routines](#))
- Negligence of warning and error messages can lead to damage of the device
- The device including the measurement channel shall not be exposed to high level of volatile organic compounds (VOC). Doing so may lead to permanent offset of the humidity sensor.
- Only use original packaging in good condition for transport or storage
- The device must not be placed in a pressure chamber
- The device is not intended to measure flammable or combustible gases
- The device is not intended to measure liquids
- The device must not be connected to a telecom network
- The device must only be connected to approved equipment with CE, CSA, UL or other equivalent safety mark to ensure double insulation



Although the device meets high quality and safety standards and 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 not used in compliance with the intended use (improperly) or is misused. Therefore, please read this User Manual carefully and keep this documentation in a readily accessible place close to your device.

3.4 Service life

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

4 Specifications

4.1 Measurement parameters

Parameter		Value
Flow ¹ (4.13 Feature Set)	Range	±300 L/min
	Accuracy	FloTest: ±1.9 % or ±0.05 L/min
Volume	Range	0 L – 500000 L
	Accuracy	±2.25% or ±1mL (flow >2.5 L/min)
Absolute pressure in the Flow channel	Range	0.5 – 2 bar
	Accuracy	±10 mbar
Temperature ²	Range	-10 – 50 °C
	Accuracy	±1 °C

Accuracy valid

- between 10°C and 30°C (channel temperature)
- between 950 hPa and 1250 hPa
- zero offset calibration performed after warm-up
- for measurements performed within 4 h after last zero offset calibration at same ambient conditions

¹ Flow accuracy specified is valid under the above-mentioned general conditions and for an air flow in positive flow direction.

- Add 0.05 % of reading per 1 °C outside the range of 10 °C to 30 °C (channel temperature)
- Add 0.005 % of reading per 10 hPa above 1250 hPa
- Add 0.01 % of reading per 10 hPa below 950 hPa
- Add 0.05 % of reading per 10 % oxygen concentration above 21 %
- Add 0.2 % of reading for negative flow direction

Flow accuracy stated with gas (channel) temperature and ambient temperature within 10 °C of each other. Add 0.05 % of reading per 1 °C above 10 °C temperature difference.

² At flow rate ≥ 50 L/min, screen brightness ≤ 30 %, battery not charging

* Non-condensing

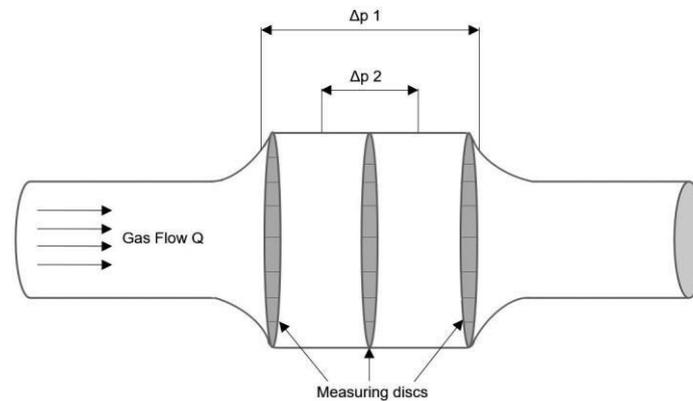


All flow and volume specifications are based on STP gas standard at 21.1 °C and 1013.25 mbar.

For all specifications with absolute and relative tolerances, the greater value applies (for example: ±1.9 % of reading or ±0.05 L/min absolute, whichever is greater).

4.2 Principle of flow measurement

Flow in the flow channel is determined by differential pressure measurement. To build up differential pressure Δp , a measuring disc is used to provide flow resistance. For flow rates > 50 L/min the differential pressure Δp_2 is used. For lower flows, the Flow- Meter uses Δp_1 to improve the accuracy at lower flow rates.



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

η : dynamic viscosity of the gas [Pa s]

ρ : gas density [kg/m^3]

c_1, c_2 : 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.

[\(4.8 Gas standards for flow and volume measurement\)](#)

Automatic battery operation in the event of a power failure.

4.3 Special function

- USB-A: for data recording and software updates
- USB-C: no communication, used only for charging
- RJ-10 (serial port) to stream measurement values and set up the device

4.4 Communication interfaces

Weight:	350 g
Size (l × w × h):	200 × 80 × 60 mm
Gas types:	Air, O ₂ , N ₂ and mixtures: Air/O ₂

4.5 Physical data

4.6 Calibration by user Offset calibration of the pressure and flow sensors (6.5.8 Zero offset calibration).

4.7 Operating data Degree of protection, against water and dust, according to IEC 60529: IP 20

The FloTest has 3 different modes:

- Battery operated
- Mains supplied / battery charging
- Switched off / storage

Please note the different ambient condition for the different modes. The allowed conditions for the Flow channel and the device enclosure are different.

Battery operated

Environment conditions	Allowed range
Temperature (flow channel / enclosure)	-10 – 50 °C (14 – 122 °F)
Air humidity (enclosure)	10 % – 90 % RH*
Absolute pressure in flow channel	50 kPa – 200 kPa
Atmospheric pressure	54 kPa – 120 kPa

Mains operated

Environment conditions	Allowed range
Temperature (flow channel / enclosure)	5 – 40 °C (41 – 104 °F)
Air humidity (enclosure)	10 % – 90 % RH*
Absolute pressure in flow channel	50 kPa – 200 kPa
Atmospheric pressure	54 kPa – 120 kPa

Switched off / storage

Environment conditions	Allowed range
Temperature (flow channel / enclosure)	-10 – 60 °C (14 – 140 °F)
Air humidity (flow channel / enclosure)	5 – 95% RH*
Absolute pressure in flow channel	50 kPa – 200 kPa
Atmospheric pressure	54 kPa – 110 kPa

* Non-condensing

4.8 Gas standards for flow and volume measurement

FloTest 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 FloTest:

Gas standard		Temperature	Pressure	Relative humidity
Ambient Temperature and Pressure	ATP	Current gas temperature	Current ambient pressure	Current gas humidity
Channel Temperature and Pressure	CTP	Current gas temperature	Current channel pressure	Current gas humidity
Standard Conditions USA	STP	21.1 °C (70 °F)	1013.25 mbar (760 mmHg)	0 %
Body Temperature and (Ambient) Pressure Saturated according to ISO 80601-2-12:2011	BTPS-A	37 °C (99 °F)	Current ambient pressure	100 %



Please refer to - (11 Measurement parameters and units). Here, you will also find the conversion factors for the units of measurement.

Input voltage of the power supply: 100 – 240 VAC (±10 %), 50 – 60 Hz, 0.6 A Output voltage of the power supply: 5 VDC, 3 .0 A

FloTest input voltage: 5 VDC, 2.5 A

The original power supply from IMT Analytics must be used for trouble-free and reliable operation. It is power tested and approved according to IEC 62368-1.

4.9 Power supply

4.10 Battery operation

Operating time during battery operation: at least 4 hours.

Charging the battery

A complete charging process takes about 4 hours in normal conditions. The service life of the battery is extended if the battery is not completely discharged. Do not store the device with a discharged battery. Optimal state of charge for long term storage is 80 %.



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



The device indicates visually and audibly when the battery must be charged. Please do not store the device if the battery is in a depleted state.

Caution: Complete depletion can damage the battery beyond repair!

4.11 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.

For the USB connection

V1.1 is used (12 Mbit)

For RJ-10 connection

If the device is to be actuated via the RS-232 interface, your dealer will be pleased to provide you with a detailed protocol.



The device is not intended for use outside a building.

Simplified EU Declaration of Conformity

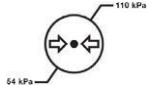
Hereby, IMT Analytics AG declares that the radio equipment type FloTest is compliant with Directive 2014/53/EU.

The full text of the EU declaration of conformity is available at the following internet address: <https://www.rigelmedical.com/gb/support/download/197/>

4.12 Device labels and symbols

The following labels and symbols can be found on FloTest, packaging or accessories:

Symbol	Description
	Warning notice
	Power button
	Alternating current
	Class II equipment
	For indoor use only
	Direct current
	Power input
	USB Port to connect an USB flash drive
IOIOI	Serial interface
	Conforms to CE Directives and Regulations
	Safety Mark for North America for FloTest
	Mark for proof of product compliance to North American safety st
	Manufacturer
	Date of Manufacture
	The operating instructions should be considered when operating t device
	Serial Number
	Waste Electrical and Electronic Equipment
	Conformity with Low Voltage Directive 2014/35/EU
	Mark for United Kingdom Conformity Assessment
	This equipment contains specified radio equipment that has bee to the Technical Regulation Conformity Certification under the Radi
UDI UDI Data  Matrix Code	Unique Device Identification (01) GTIN-No. (11) Production Date (21) Serial No.
	

Symbol	Description
	Catalogue number
	Keep dry
	Protect from sunlight
	Temperature for transport and storage
	Humidity range for transport and storage
	Atmospheric pressure for transport and storage

4.13 Feature Set

The FloTest available features.

FloTest	
Top cover	Grey
Flow measurement	± 300 L/min $\pm 1.9\%$ or ± 0.05 L/min
Volume measurement	available
Absolute pressure in flow channel	available
Differential pressure ports	not available
Temperature measurement	available
Humidity measurement	not available
Bluetooth	available
Statistic screen	not available

5 Start-up

5.1 Individual parts in the packaging

Picture	Description
 A blue rectangular flowmeter device with a digital display and a connector on the side.	FlowMeter
 A power supply unit with a power cord and several different types of power connectors.	Power supply
 A white, cylindrical protection filter with a central opening and a flange.	Protection Filter RT019
 A black folder containing several white calibration certificates with blue text and graphics.	Calibration certificate

5.2 Power supply

The power supply socket is located at the rear of FloTest.



The device can be disconnected from the mains by disconnecting the power supply. The power supply should therefore be easily accessible.

5.2.1 Supply voltage

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



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

5.3 Mechanical connectors

5.3.1 Protection Filter RT019

To protect the device against contaminants and particles in the flow channel, the Protection Filter RT019, must be used for flow measurements. Connect the Protection Filter RT019 to the flow channel inlet port before connecting the device under test.



Particles of dirt in the air can clog the measuring system and thus lead to incorrect measurements. The Protection Filter RT019 must be checked regularly ([8.3 Preventive cleaning and servicing routines](#)).

5.3.2 Flow channel

The flow channel can be used to perform gas flow measurements from -300 L/min to 300 L/min. The channel includes pressure and temperature sensors.



Measuring range & accuracy details: see chapter [\(4.1 Measurement parameters\)](#)



When working with relatively high humidity, ensure that condensation does not form in the unit! Water can irreparably damage the sensors!



The device including the measurement channel shall not be exposed to high level of volatile organic compounds (VOC). Doing so may lead to permanent offset of the humidity sensor.

5.4 Electrical interfaces

5.4.1 USB connection for charging

The USB-C port is used to connect the power supply. The port is located at the rear of the device.

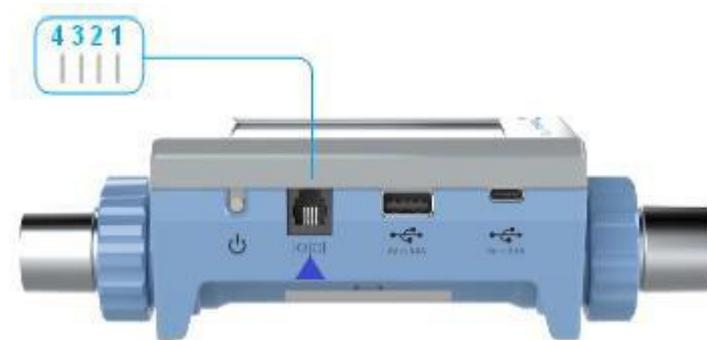


Rating: 5 V, 2.5 A

The device must only be connected to approved equipment with CE, CSA, UL or other equivalent safety mark to ensure double insulation.

5.4.2 RS-232

The RS-232 interface is used for remote monitoring or control.



Actuation of the RS-232 port takes place via a special RS-232 cable. If the device shall be actuated via the RS-232 interface, your dealer will be pleased to provide you with a detailed protocol.

FloTest pin assignment (RJ-10 connector): Pin 1 NC

Pin 2	RxD (Input of FloTest)
Pin 3	TxD (Output of FloTest)
Pin 4	GND

5.4.3 USB-A

The USB-A host connector can be used to connect a USB flash drive for data recording and software update.



Rating: 5 V, 0.5 A

The USB flash drive must comply with the following requirements.

- File system: FAT32
- Volume size: 0.5 – 32 GByte

USB hubs are not supported.

6 Operation

6.1 Switching the FloTest on and off

The FloTest is switched on and off using the power button on the rear of the device



6.2 Acoustic feedback

The FloTest provides a beep as acoustic feedback as follows:

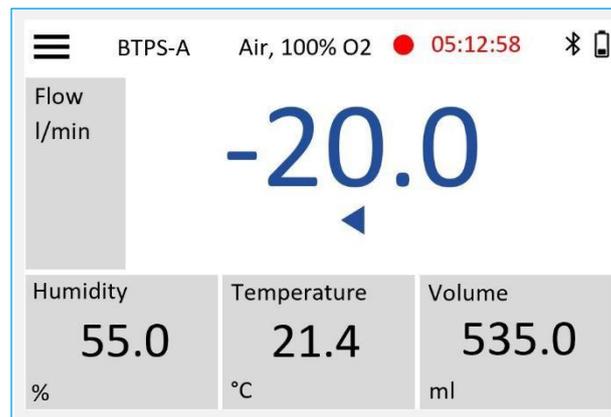
Event	Duration of beep	Number of beeps
Power on/off	Short	1
Battery state of charge falls below 20 %	Short	1
Battery state of charge falls below 10 %	Short	2
Battery state of charge falls below 5 %	Short	3
Device shuts down due to empty battery	Long	1
Info message	Short	1
Warning message	Medium	1
Error message	Medium	3

6.3 User control gestures

To operate the touch screen optimally and easily, use the gestures listed below

Gesture	Action	Function
	Tap	Tap an element once
<ul style="list-style-type: none"> • Selection of menu items • Change between Numerical view and Chart view 		
	Long press (> 0.5 sec.)	Tap and hold for one second
<ul style="list-style-type: none"> • Editing readings and curves 		
	Swipe	Drag your finger across the screen
<ul style="list-style-type: none"> • Change views on the measurement screen 		

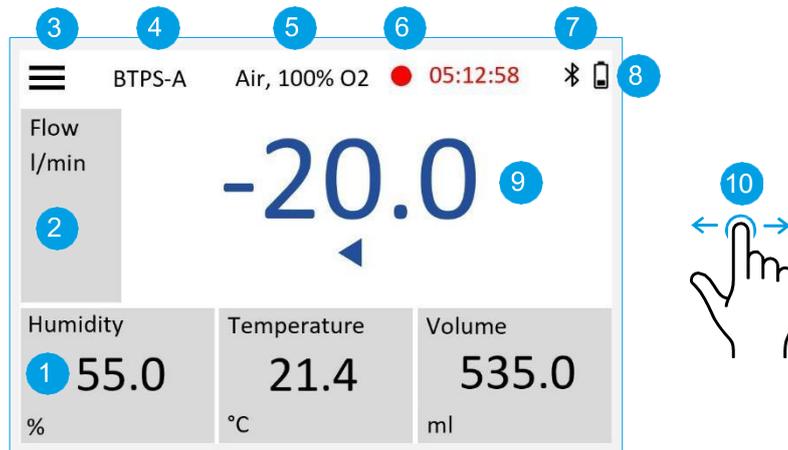
If the FloTest is switched on, the Measurement screen appears.



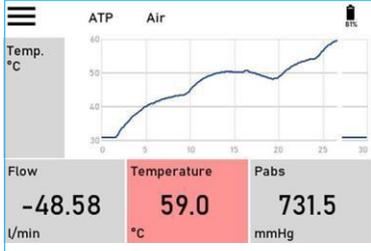
6.4 Screens

6.4.1 Measurement screen

The measurement screen is the starting point to operate the FloTest. The software version described in this User Manual displays the menu items listed below:

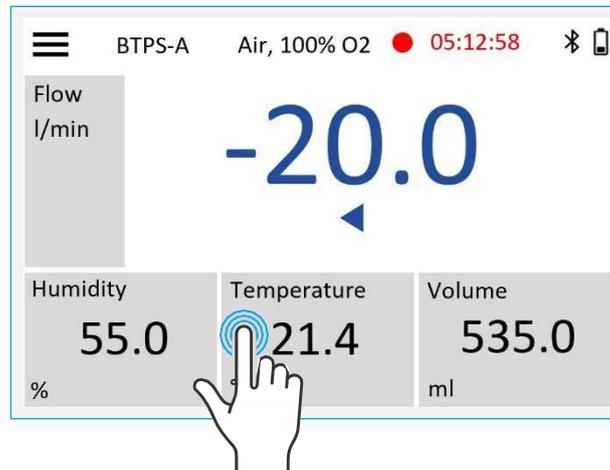


No.	Description	Action	
1	Value tiles Three different tiles can be configured individually with the following parameters: <ul style="list-style-type: none"> Measurement value (Updates every 1 sec.) Unit <div style="display: flex; justify-content: space-around; border: 1px solid #ccc; padding: 5px; margin: 10px 0;"> <div style="text-align: center;">Humidity 55.0 %</div> <div style="text-align: center;">Temperature 21.4 °C</div> <div style="text-align: center;">Volume 535.0 ml</div> </div> <p>If a value is outside of the specified measurement range, the background color will change to red:</p> <div style="display: flex; justify-content: center; border: 1px solid #ccc; padding: 5px; margin: 10px 0;"> <div style="text-align: center; background-color: #f08080; padding: 5px;">Temperature 59.0 °C</div> </div>	Long press: The parameter configuration menu opens	
2	Chart tile parameters	Shows the properties of the parameters: <ul style="list-style-type: none"> Name Unit 	Long press: The parameter configuration menu opens
3	Menu button	Shows the Menu	Tap: Overview of all sub menus opens (6.5 Menu)
4	Gas standard	Shows current configured gas standard	Tap: Selection of all gas standards opens
5	Gas type	Shows current configured gas type. Only for Air/O2: selection for O2 concentration is available.	Tap: Selection of all gas types opens
6	Recording status	Indicates if recording is active: <ul style="list-style-type: none"> Shown: Recording active Hidden: Recording inactive 	Tap: Recording menu opens
7	Bluetooth status	Indicates the status of the Bluetooth connection	

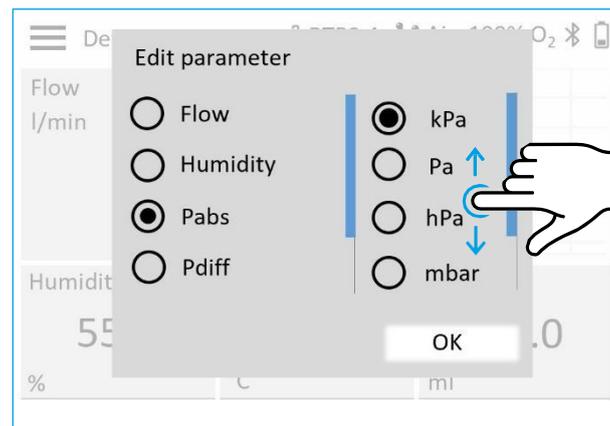
No.	Description	Action
8	<p>Battery level</p> <p>Indicates the battery level:</p> <ul style="list-style-type: none"> • Empty battery: No bar • Full battery: Full bar • Charging: A bolt symbol next to the battery 	
9	<p>Chart tile</p> <p>The Chart tile offers a Numerical view and a Chart view.</p> 	<p>If Numerical view is visible:</p> <ul style="list-style-type: none"> • Tap: Change to Chart view <p>If Chart view is visible:</p> <ul style="list-style-type: none"> • Tap: Change to Numerical view • Long press: Access slider to adjust the time axis

6.4.2 Configuration of the Measurement screen

The Measurement screen offers 1 chart tile and 3 value tiles which can be configured individually.



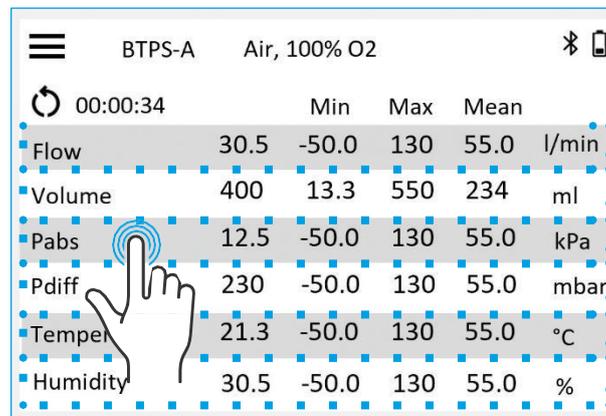
Long press the tile for 1 sec. to open the Edit parameter screen. Here you can select between all available values and units. Use the swipe up / down gesture to scroll through the lists of parameters.



All available values and units are listed in ([11 Measurement parameters and units](#))

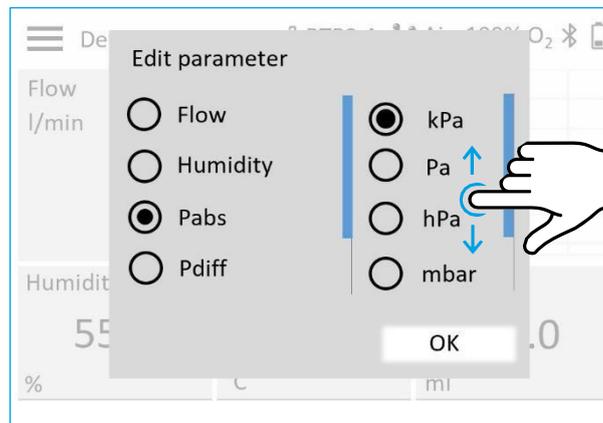
6.4.3 Configuration of the Statistic screen

For each row, long press for 1 sec. to select any measurement value.



	Min	Max	Mean	
Flow	30.5	-50.0	130	55.0 l/min
Volume	400	13.3	550	234 ml
Pabs	12.5	-50.0	130	55.0 kPa
Pdiff	230	-50.0	130	55.0 mbar
Temper	21.3	-50.0	130	55.0 °C
Humidity	30.5	-50.0	130	55.0 %

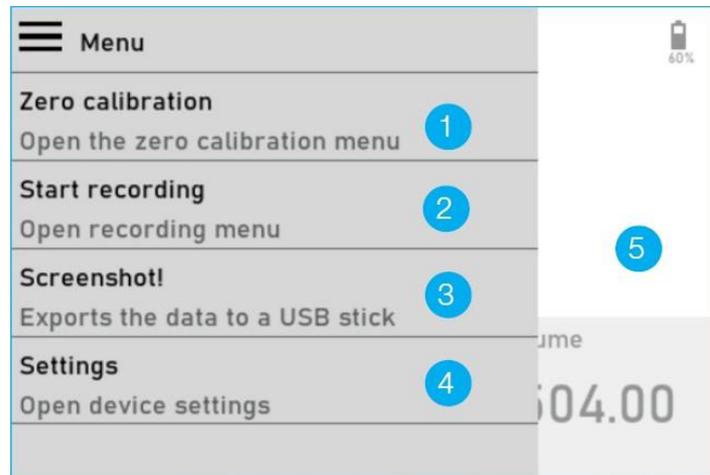
Long press on a row for 1 sec. to open the Edit parameter screen. Use the swipe up / down gesture to scroll through the lists of parameters.



All available values and units are listed in ([11 Measurement parameters and units](#))

6.5 Menu

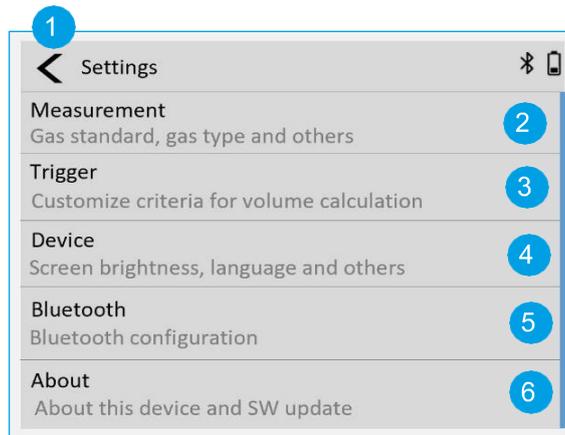
By tapping the **Menu** button, the sub menus are displayed:



No.	Description	Action
1	Zero Calibration Opens the sub menu zero calibration (6.5.8 Zero offset calibration)	Tap: The sub menu opens
2	Start Recording Opens the sub menu with the recording settings: <ul style="list-style-type: none"> • USB connection • Sampling interval • Recording duration Once the settings are made, the recording can be started by pressing the button "Start recording". The data is stored as comma separated value (CSV) file with ASCII encoding (Windows-1252 / ISO-8859-1 code page). Note: When a recording is active, this menu point changes its appearance as follows and opens the sub menu to stop the recording: 	If recording is inactive: <ul style="list-style-type: none"> • Tap: Sub menu of recording settings opens If recording is active: <ul style="list-style-type: none"> • Tap: Sub menu for stop recording opens
3	Screenshot! Exports a screenshot as Bitmap file (BMP) to a connected USB drive. Screenshot is only possible when a USB drive is connected.	Tap: Perform the Screenshot
4	Settings Opens the sub menu device settings: <ul style="list-style-type: none"> • Measurement • Trigger • Device • Bluetooth • About (6.5.1 Settings)	Tap: The sub menu opens
5	Close Menu Hides the overlaying Menu	Tap in the background: Hide the Menu

6.5.1 **Settings**

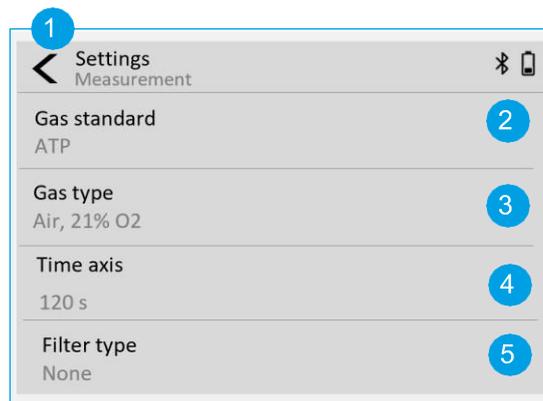
In the **Settings** menu, all device settings can be made:



No.	Description	Action	
	Back	Go back to the main Menu	
	Measurement	Opens the sub menu for the measurement settings: <ul style="list-style-type: none"> • Gas Standard • Gas Type • Time Axis • Filter Type (6.5.2 Measurement settings)	Tap: The sub menu opens
	Trigger	Opens the sub menu for the trigger settings: <ul style="list-style-type: none"> • Start/Stop Signal • Start/Stop Flow Threshold • Start/Stop Edge (6.5.4 Trigger settings)	Tap: The sub menu opens
	Device	Opens the sub menu for the device settings: <ul style="list-style-type: none"> • Screen Brightness • Screen Timeout • Language • Serial Interface • Factory Reset (6.5.5 Device settings)	Tap: The sub menu opens
	Bluetooth	Opens the sub menu for the Bluetooth configuration (6.5.6 Bluetooth settings)	Tap: The sub menu opens
	About	Opens the about screen with the following information: <ul style="list-style-type: none"> • Serial Number • Software Version • Calibration Interval • Last Device Message • Software Update (6.5.7 Software update)	Tap: The about screen opens

6.5.2 Measurement settings

The **Measurement** menu contains all measurement related settings:



No.	Description	Action
1	Back Go back to Settings menu	
2	Gas Standard Opens the gas standards settings with the following available choices: <ul style="list-style-type: none"> • STP • ATP • BTPS-A • CTP 	Tap: Selection of all gas standards opens
3	Gas Type Opens the gas type setting with the following available choices: <ul style="list-style-type: none"> • Air • Air/O₂, O₂ concentration, can be selected • N₂ 	Tap: Selection of all gas types opens
4	Time axis Opens a slider to adjust the time axis with the following available ranges: 2 sec., 5 sec., 10 sec., 15 sec., 30 sec., 60 sec., 120 sec.	Tap: Slider to adjust the time axis appears If the slider is opened: <ul style="list-style-type: none"> • Slide to the right: time range increases • Slide to the left: time range decreases
5	Filter type Opens the filter type setting with the following available choices: <ul style="list-style-type: none"> • None • Low • Medium • High (6.5.3 Filter type)	Tap: Selection of all filter types opens

 The selected gas type must match the measured gas. Improper setting of gas type or standard can lead to measurement errors up to 60%

6.5.3 Filter types

Numeric values for the graph are displayed when the screen is refreshed every 50 ms, but measurement takes place every 1 ms.

The sampling interval for measurement parameters is 1 ms. To reduce fluctuation of the reading and to make measurements easier to read, a filter can be applied.

The following four options are available:

- None (indication of the last reading without averaging)
- Low (average over 1 sec.)
- Medium (average over 2 sec.)
- High (average over 5 sec.)

Medium filter is the default setting.



This filtering of readings only impacts the values shown on the Flow- Meter display. During recording, only the raw and unfiltered readings are displayed.

6.5.4 Trigger settings

The **Trigger** menu contains all settings to configure the trigger



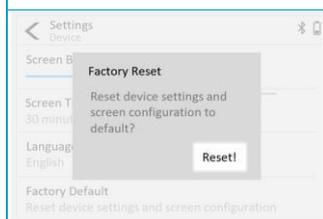
No.	Description	Action	
1	Back	Go back to Settings menu	
2	Start Signal	Opens the start signal setting with the following available choices: <ul style="list-style-type: none"> • Flow • Absolute Pressure (in Flow) • Differential Pressure 	Tap: Selection of start signal settings opens
3	Start Flow Threshold	Opens the start flow threshold configuration mask The unit of the corresponding measurement value is used and cannot be changed here. To change the unit, go back to the measurement screen and configure the measurement tile accordingly	Tap: Mask to increase (+) and decrease (-) the start flow opens
4	Start Edge	Displays the current setting of the start edge	Tap on toggle button: toggle between "Rising Edge" and "Falling Edge"
5	Stop Signal	Opens the start signal setting with the following available choices: <ul style="list-style-type: none"> • Flow • Absolute Pressure (in Flow) • Differential Pressure 	Tap: Selection of stop signal settings opens
6	Stop Flow Threshold	Opens the stop flow threshold configuration mask The unit cannot be changed here. For changing the unit go back to main menu and tap on the grey field.	Tap: Mask to increase (+) and decrease (-) the stop flow opens
7	Stop Edge	Displays the current setting of the stop edge	Tap on toggle button: toggle between "Rising Edge" and "Falling Edge"
8	Reset	Opens a window to perform the trigger factory reset (insert picture)	Tap on Reset! Device trigger configuration will be reset to factory defaults

6.5.5 Device settings

The **Device** menu contains all settings to configure the device:



No.	Description	Action	
1	Back	Go back to Settings menu	
2	Screen Brightness	Opens a slider to adjust the brightness of the screen with the following available choices: 10 %, 20 %, 30 %, 40 %, 50 %, 60 %, 70 %, 80 %, 90 %, 100 %	Tap: Slider to adjust the screen brightness appears If the slider is opened: <ul style="list-style-type: none"> • Slide to the right: screen brightness increases • Slide to the left: screen brightness decreases
3	Screen Timeout	Opens the screen timeout setting with the following choices: None, 1 minute, 5 minutes, 15 minutes, 30 minutes When the time since the last user input is longer than the screen timeout setting, the screen brightness is reduced to a low level to increase the battery runtime. Any tap on the screen restores the regular brightness level.	Tap: Selection of all screen timeout settings opens
4	Language	Opens the language setting with the following available choices: English, German, Spanish, French	Tap: Selection of all languages opens
5	Serial interface (RS-232)	Opens the serial interface (RS-232) setting with the following choices: IMT protocol, IMT fast protocol, IMT express protocol, TSI 5300 protocol	Tap: Selection of the serial interfaces (RS-232) opens
6	Factory Default	Opens a window to perform the factory reset	Tap on Reset! Device settings and screen configurations will be reset to factory defaults

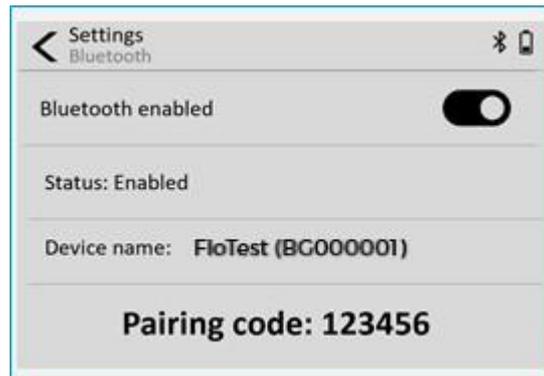


6.5.6 Bluetooth settings

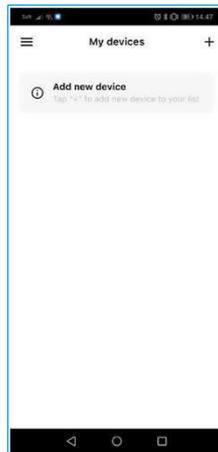
The FloTest App called IMT Analytics can be downloaded from the IMT Analytics website or from Google Play store or App store on your mobile device. Be sure, that Bluetooth is enabled.



In **Settings** menu on your FloTest select the sub menu **Bluetooth** to enable it. Pair your mobile device with your FloTest by entering the pairing code provided by the FloTest.



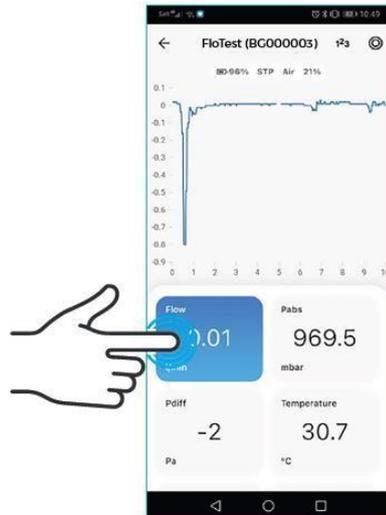
Choose the desired FloTest on the FloTest App to track the measurement values.



If connection is successful established the Bluetooth icon shown on your FloTest changed from Bluetooth enabled to Bluetooth connected:



In the FloTest App, a long press on a tile for 1 sec. opens the edit parameter screen. Use the drop-down menu to select parameters and units.



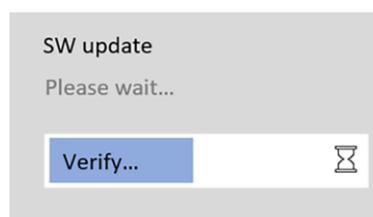
6.5.7 Software update

The software update file can be downloaded from the IMT Analytics website. A USB flash drive with FAT32 formatting is required to install new software.

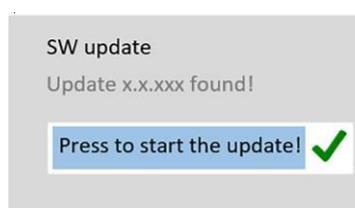
To update the FloTest software:

1. Copy the software update file to the root directory of a FAT32-formatted USB flash drive
2. Plug the USB flash drive into the USB-A host port
3. Switch on the FloTest
4. Tap the **Menu** button to open the main menu
5. Select **Settings**
6. Select **About**
7. Select **SW update**

The device verifies if a valid software update file is available on the connected USB flash drive. A progress bar is shown on the screen as follows:



If the verification was successful, the following message is shown on the screen:

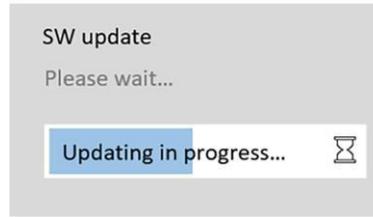




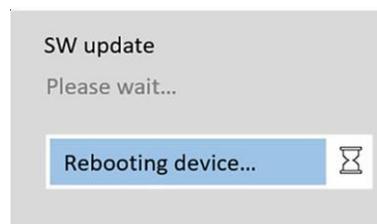
If the verification was unsuccessful, an error message is shown on the screen. See details about possible error messages below.

8. Tap ***Press to start the update!***

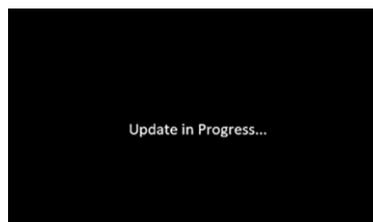
The software update starts. A progress bar is shown on the screen as follows:



Once the software update is loaded, the device reboots automatically. This is indicated on the screen as follows:



During the reboot, the screen turns white for a couple of seconds. After that, the following message is displayed on the screen:

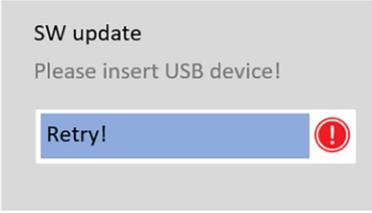
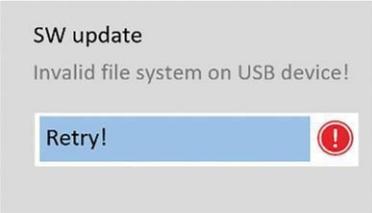
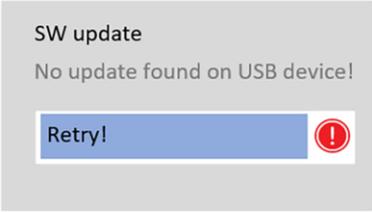
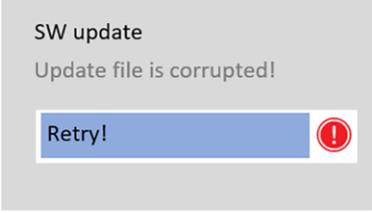


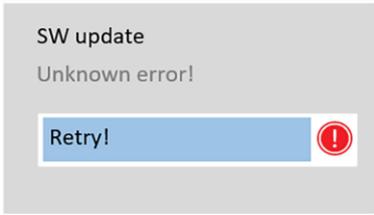
Once the update is completed, the measurement screen is displayed

9. Disconnect the USB flash drive from the FloTest

The device is ready for use

If the verification of a valid software update file was unsuccessful, one of the following error messages is shown on the screen:

Error message displayed	Troubleshooting
 <p>SW update Please insert USB device!</p> <p>Retry! </p>	<ol style="list-style-type: none"> 1. Tap Retry! to try it again 2. Ensure that a USB flash drive is connected to the USB-A host port (5.4 Electrical interfaces) 3. Ensure the battery charge is > 50% 4. Format the USB flash drive using the file system FAT32, then re-download the software update file from the IMT Analytics website, save the software update file named Flow- MeterUpdate.bin in the root directory of the USB flash drive, disconnect the USB flash drive from your computer safely (Eject) and try to install the software again 5. Repeat the process with a different USB flash drive
 <p>SW update Invalid file system on USB device!</p> <p>Retry! </p>	<ol style="list-style-type: none"> 1. Tap Retry! to try it again 2. Format the USB flash drive using the file system FAT32, then re-download the software update file from the IMT Analytics website, save the software update file named Flow- MeterUpdate.bin in the root directory of the USB flash drive, disconnect the USB flash drive from your computer safely (Eject) and try to install the software again 3. Repeat the process with a different USB flash drive
 <p>SW update No update found on USB device!</p> <p>Retry! </p>	<ol style="list-style-type: none"> 1. Tap Retry! to try it again 2. Ensure that a valid software update file named FlowMertUpdate.bin is in the root directory of the USB flash drive
 <p>SW update Update file is corrupted!</p> <p>Retry! </p>	<ol style="list-style-type: none"> 1. Tap Retry! to try it again 2. Ensure the USB flash drive is connected to the device while the software update verification is in progress 3. Format the USB flash drive using the file system FAT32, then re-download the software update file from the IMT Analytics website, save the software update file named Flow- MeterUpdate.bin in the root directory of the USB flash drive, disconnect the USB flash drive from your computer safely (Eject) and try to install the software again

Error message displayed	Troubleshooting
	<ol style="list-style-type: none">1. Tap Retry! to try it again2. Ensure the USB flash drive is connected to the device while the software update is in progress3. Format the USB flash drive using the file system FAT32, then re-download the software update file from the IMT Analytics website, save the software update file named Flow-MeterUpdate.bin in the root directory of the USB flash drive, disconnect the USB flash drive from your computer safely (Eject) and try to install the software again



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

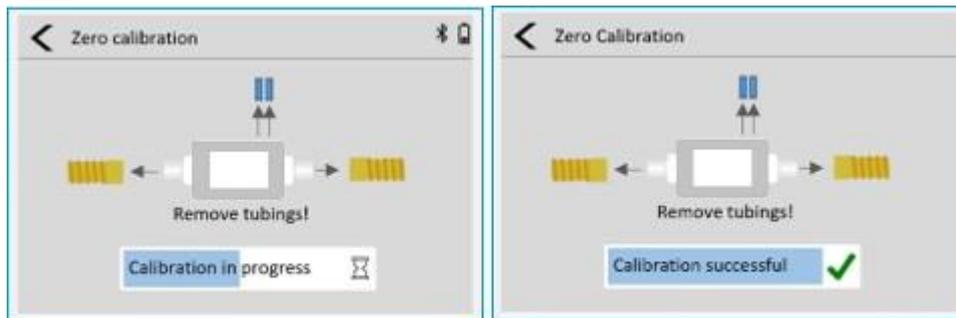


While installation is running, the device must not be switched off!

6.5.8 Zero offset calibration

Follow the procedure described below to achieve the most accurate readings:

- Perform the zero offset calibration when the FloTest has warmed up. Warm up takes approximately 30 minutes.
- To perform zero offset calibration, you must remove all connected tubes and protection caps from the device
- Tap on menu icon, select the sub menu **Zero Calibration**, and select: **Start Calibration**



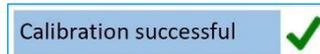
Calibration is running

The blue bar increases from left to right in 5 sec.



Results

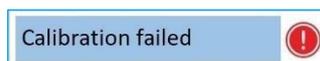
Calibration is successfully completed:



The device is now ready to use or

Calibration failed

The device is **not** ready to use.



If the calibration failed, ensure that all tubes and the protection caps are removed, and that there is no pressure or flow in the channel during zero offset calibration. In environments with high turbulence, close one of the flow ports using a protection cap.

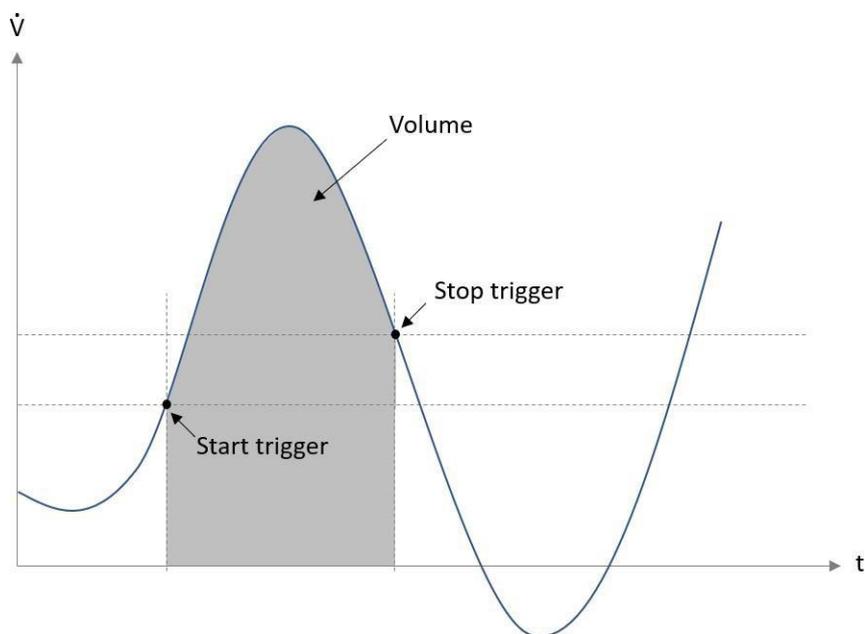


Be aware that the correct calibration of a medical device is an important process. Incorrect calibration may lead to patient harm and / or increase the treatment duration. In case the measurement values seem implausible, check the measurement setup and measurement equipment. When in doubt about the performance of the FloTest, send it back to the manufacturer for calibration and do not change any settings on the medical device.

7 Measuring volume

7.1 General principle

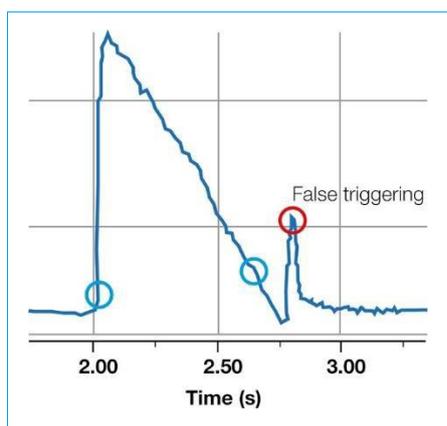
The FloTest measures volumes by integrating the flow between the start and stop trigger events. Flow, Absolute Pressure (in Flow) and Differential Pressure can be used as trigger source.



7.2 Finding the correct trigger values

If you set 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 analyze that characteristic by using the chart view on the device or record the data to a USB flash drive first. By analyzing the graph afterwards, the appropriate trigger settings can be determined.

The following example shows a flow curve with a potential problem:



The first two circles indicate the triggers that should be used to measure the volume of this event. However, after the event a small false signal is visible that can be caused for example by switching of valves. In this case a pressure trigger should be used.

8 Servicing and care

8.1 Guidelines for servicing and care

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



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

8.2 Notes about changing parts



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

8.3 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:

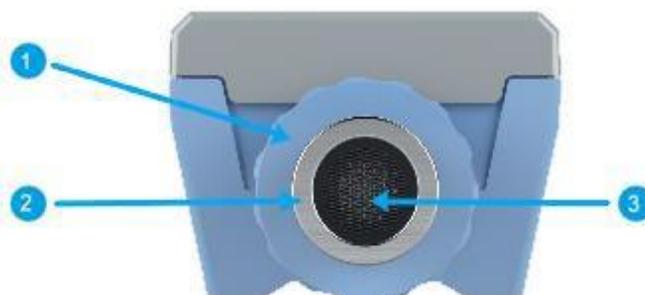
Every four weeks

For best accuracy, visually check the screens inside the flow ports. Inspect the screens for contamination by looking through each end of the flow channel

while pointing the other end of the flow channel at a light source.

If the screen is contaminated, clean it according to the following procedure:

- Unscrew the flow port retention nut **1**
- Remove the flow port connector **2** and the screen **3**
- Wash the screen under running water and dry it
- Reinsert the screen and flow port into the device
- Install and tighten the flow port retention nut





If the screen cannot be cleaned under running water, exchange it with a new one (9.2 Parts).

Note: If the flow channel was observed to be clean in the past, contamination can easily be recognized.

Every 12 months

Factory calibration ensures reliable measurement. To calibrate the FloTest by the manufacturer, visit the website www.easy-cal.com



Only use the spare parts recommended by the manufacturer (9 Accessories and spare parts).

8.4 Cleaning

For cleaning, only use agents which do not affect the functioning of the FloTest

- Flow channel: dry, compressed, and clean air
- Enclosure: soft, lint-free cloth, dry or moist (soap, mild cleaning agent or isopropyl alcohol)

For cleaning, do not use any solvent or chlorine based or abrasive detergents.

The device is not intended to be disinfected or reprocessed and shall therefore be kept clean.

Using incorrect cloths can cause scratches on the device.

8.5 Trouble shooting

Fault	Possible cause	Trouble shooting
FloTest not turning on	No power	Connect power supply, check voltage, check all connections, use a compliant power supply as described in the chapter specification
Error message: Sensor Failure!	Sensor defective or extreme environment condition Error code: xxxx	Follow allowed operation conditions and restart the device. If the error persists, contact the distributor or manufacturer for repair of the device
Error message: Battery not available!	Battery disconnected or defective	Restart the device and charge the battery for at least 2 hours. If the error persists, contact the distributor or manufacturer for repair of the device
Error message: Measurement not available	Measurement subsystem not responding	Restart the device. If the error persists, contact the distributor or manufacturer for repair of the device
Error message: Calibration overdue!	12 month since last calibration	Contact IMT Analytics for calibration: www.easy-cal.com

Fault	Possible cause	Trouble shooting
Error message: Calibration is due	11 months since last calibration	Contact IMT Analytics soon for calibration: www.easy-cal.com
Error message: Device over-heated	Channel temperature > 65 °C or Battery temperature > 60 °C or any other temperature > 75 °C	Move device to cooler environment to avoid damage. Any further increase in temperature will damage the device!
Error message: Channel pressure too high	Abs. Channel pressure > 2.05 bar	Reduce channel pressure below 2 bar absolute pressure to avoid damage. Any further increase in pressure will damage the device!
Error message: Ambient pressure too high	Abs. ambient pressure > 1250 mbar	Reduce ambient pressure below 1200 mbar absolute pressure to avoid damage. Any further increase in pressure will damage the device!
Error message: Ambient pressure too low	Abs. ambient pressure < 490 mbar	Increase the ambient pressure above 540 mbar absolute pressure to avoid damage. Any further decrease in pressure will damage the device!
Error message: External differential pressure too high	Ext DP sensor < -250 mbar or Ext DP sensor > 250 mbar	Reduce differential pressure to ± 250 mbar to avoid damage. Any further increase in pressure will damage the device!
The display values of the FloTest not match the device under test (DUT)	<ul style="list-style-type: none"> Flow channel dirty Calibration due Error in setup measurement 	<ul style="list-style-type: none"> Visually inspect the flow channel Contact IMT Analytics soon for calibration: www.easy-cal.com Check measurement setup
Touch screen not responsive	Software locked up	Hard reset the device. To do so: <ol style="list-style-type: none"> 1. Disconnect any cables including the power supply 2. Press and hold the power button for at least 10 sec. 3. Device will shut down and restart automatically

8.6 Contact If you have any questions or problems, please contact one of the departments listed below

8.6.1 Contact details

Rigel Medical
15-18 Bracken Hill
South West Industrial Estate
Peterlee
Co. Durham
SR8 2SW
United Kingdom

Tel: +44 (0) 191587 8730

Email: sales@rigelmedical.com

8.6.2 Technical Support

Email: support@rigelmedical.com

9 Accessories and spare parts

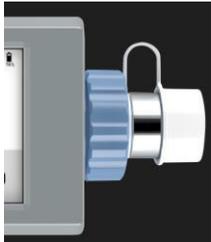
9.1 Ordering address

Rigel Medical
 15-18 Bracken Hill
 South West Industrial Estate
 Peterlee
 Co. Durham
 SR8 2SW
 United Kingdom

Tel: +44 (0) 191587 8730
 Email: sales@rigelmedical.com

9.2 Parts

Picture	Name	Article Number
	Power Supply including mains adapters for different countries	700.421.000
	Protection Filter RT019	302.531.000
	Flow Port Screen	700.412.000
	Adapter set	300.548.000
	RS-232 Interface Cable	302.075.000

Picture	Name	Article Number
 A grey carrying bag with a blue border and a handle. The text "IMT,Analytics" and "FlowMeter" is printed on the front.	Carrying Bag FloTest	700.422.000
 A close-up of a blue and white plastic cap with a small handle, attached to a grey device.	Flow Channel Protection Cap	302.780.000

10 Disposal

Disposal of the device is the operator's responsibility. Keep in mind the FloTest contains a Li-Ion battery and must be disposed of accordingly.

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.

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, waste material 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 environment or landscape.

11 Measurement parameters and units

11.1 Measurement parameters and units

11.1.1 Pressure readings

Measurement parameter	Designation	Units of measurement
Absolute pressure in flow channel	PAbs	mbar, inH ₂ O, cmH ₂ O, PSI, mmHg, hPa, kPa, Pa

11.1.2 Flow and Volume readings

Measurement parameter	Designation	Units of measurement
Flow	Flow	L/min, ft ³ /min
Volume	Volume	L, ml, ft ³

11.1.3 Temperature readings

Measurement parameter	Designation	Units of measurement
Temperature	Temperature	°C, K, °F

12 Wireless communication

FloTest contains a generation 5.1 Bluetooth module for wireless communication. The module complies with all requirements from EN 300 328 V2.2.2.

FCC ID: QOQGM210P

IC ID: 5123A-GM210P

The module is restricted to the following channels and output power.

Band	Lowest frequency	Highest frequency	Maximum power (EIRP) in dBm
2.4 GHz	2400 MHz	2483.5 MHz	10

FCC RF Radiation Exposure Statement:

This the equipment complies with FCC radiation exposure limits set forth for an un- controlled environment.

End users must follow specific operating instructions for satisfying RF exposure compliance:

- The transmitter meets the Mobile requirements at a distance of 20 cm and above from the human body, in accordance with the limit(s) exposed in the RF Exposure Analysis
- The transmitter also meets the Portable requirements at distances equal or above 5.3 mm*

Part 15 information to the user:

The equipment has been tested and found to comply with the limits of Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation.

This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in this installation.

If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna
- Increase the separation between the equipment and the receiver
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected
- Consult dealer or an experienced TV technician for help

NOTE: “Harmful interference” is defined in 47 CFR §2.122 by the FCC as follows: Interference which endangers the functioning of a radionavigation service or of other safety services or seriously degrades, obstructs, or repeatedly interrupts a radio communication service operating in accordance with [the ITU] Radio Regulations.

* The mechanical design of the FloTest ensures the distance to the transmitter is always equal or above 5.3 mm

13 Appendix

13.1 Abbreviations and glossary

A	
A	Ampere
B	
bar	1 bar = 14.50 psi
C	
°C	Degrees Celsius Conversion from Celsius (C) to Fahrenheit (F): $F = 9 \times C / 5 + 32$
cm	Centimeters
cmH ₂ O	Centimeters of water column
D	
dBm	Decibel-milliwatts
F	
°F	Degrees Fahrenheit Conversion from Fahrenheit (F) to Celsius (C): $C = (F - 32) \times 5 / 9$
ft ³	Cubic foot
ft ³ /min	Cubic foot per minute
G	
GHz	Gigahertz
GND	Ground
H	
Hz	Hertz (1 Hz = 1 / sec.)
h	Hour
hPa	Hectopascal
I	
IP	Protection class according to standard
inH ₂ O	Inches of water column
K	
K	Kelvin
kPa	Kilopascal
L	
L	Litre
L/min	Litres per minutes
M	
MB	Megabyte
mbar	Millibar
MHz	Megahertz
mL	Millilitre
mm	Millimetre
mmHg	Millimeters of Mercury
ms	Millisecond

P

Pa	Pascal
psi	Pounds per square inch (1 bar = 14.50 psi)

R

RH	Relative Humidity
RS-232	Serial interface
RJ-10 FCC	Connector for serial interface (telephone connector according to FCC registration, U.S. Federal Communications Commission; RJ = 'Registered Jack')

S

sec.	seconds
------	---------

V

\dot{V}	Flow
V	Volt
VAC	Volts Alternating Current
VDC	Volts Direct Current

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