# analyser the art of measuring



User Manual CITREX H3

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# **1** Introduction

**CITREX H3** was developed in order to measure flow and various pressures and thus calculate various ventilation parameters. CITREX H3 is a compact, mobile and easy-to-operate measuring instrument. The device was developed in order to calibrate gas flows and pressures by simple means. With the oxygen option it is possible to measure oxygen concentrations.

The descriptions and instructions in this manual refer to the product CITREX H3. In this User Manual the unit "sL/min" is based on ambient conditions of 0°C and 1013.25 mbar in accordance with DIN 1343.

This documentation applies to the following versions:

CITREX H3 software:4.4.000CITREX H3 hardware:4.0

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

Subject to technical modifications without notice.



To avoid possible injuries, please read all the safety instructions before you use the product.



The device is not intended for use outside a building.

# 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 equipment. The user of the device has received training on how to use medical equipment and can perform repairs, maintenance and servicing on medical devices. CITREX H3 can be used in hospitals, in clinics, at device manufacturers or at independent service companies that perform repairs or servicing operations on medical devices.

CITREX H3 is intended for use in a 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 measuring instrument CITREX H3 is intended for overthe-counter sale.

With CITREX H3 you have the solution for measurements in the following areas:

- Flow
- Pressure
- Volume
- Ambient pressure
- Temperature

In addition, various ventilation parameters can be measured:

- Ventilation rate
- Time
- Ratio
- Tidal volume
- Minute volume
- Peak flow
- Pressure
- Trigger



CITREX H3 is a measuring instrument for checking and calibrating ventilators and anaesthetic equipment. It must not be used for patient monitoring. During patient treatment by the ventilator it is not allowed to connect to CITREX H3.

It is not allowed to measure liquids with CITREX H3.

# **3** Safety instructions

#### 3.1 Representation of hazards, cautions and notes

Please read all the safety instructions carefully before you use CITREX H3.

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 to prevent damage of any kind, as well as useful tips and information for handling the device, will be indicated by the following icon:



#### 3.2 Personnel

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:

Work on and with CITREX H3 may only be performed by persons

who have undergone appropriate technical training and have the

- Fail to use the device in accordance with its intended use.
- Disregard the specifications.

necessary experience.

- Tamper with the device in any way (conversions, modifications or the like).
- 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.

#### 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 Symbol explanation

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The symbols listed below may appear on the packaging material, on the device rating plate and in the User Manual of the CITREX H3 measuring instrument.

•	USB interface
SN BBXXXX	Serial number
	Ethernet interface
Ċ	On/Off button
	SD card
¥	Fragile contents
Ţ	Keep dry
Ĩ	Read the User Manual
X	The device must not be disposed of in household waste
CE	The device is CE approved
$\triangle$	Caution: observe the safety instructions in the User Manual
s	Reusable packaging
	Manufacturer's specification and date of manufacture
×	Keep away from heat
2°02+	Temperature range for storage and transport
	CSA monogram with C/US indicator
	Direct current

Table 1: Symbol explanation

# 5 Start-up

	CITREX H3
	Power supply plug with country-specific adapters
	USB cable
2 GB ►	MicroSD card
	Dust filter RT019
	Network cable

Table 2: Scope of delivery

#### 5.1 Power supply

CITREX H3 can be operated from the mains or from the integrated battery.

Power can be supplied via the USB port (Mini-B) on the top of CITREX H3. Use the power supply unit included to charge the battery or operate the device via the USB port. You will find more information about power supply in the section "Electrical interfaces".

During the charging process a green battery symbol is lit on the front.

Please connect the power supply unit included to a voltage of 100 VAC to 240 VAC with a frequency of 50 Hz to 60 Hz.



Figure 1: Power supply



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. When operating CITREX H3 via the USB port only use the original power supply unit included!

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

Caution: depletion can damage the battery beyond repair!

#### 5.2 Mechanical connectors

#### 5.2.1 Flow channel

The flow channel can be used bidirectionally. The positive flow direction is from left to right, viewed from the front of the device. The measurements of volume, flow, gas temperature, oxygen (option) and channel pressure are taken in the flow channel. The values, and the ventilation parameters calculated from them, can be displayed on the screen. You will find the relevant setting options in the section "Operation".

Flow (air)	Measuring range	± 300 sL/min
	Accuracy	$\pm 2\%$ of reading or $\pm 0.1$ sL/min
Volume	Measuring range	0-10sL
	Accuracy	$\pm 2\%$ of reading or $\pm 0.02  sL$
Temperature	Measuring range	0-50°C
	Accuracy	$\pm 1.75\%$ of reading or $0.5^{\circ}C$
Oxygen	Measuring range	0-100%
	Accuracy	±1% O <sub>2</sub>
Pressure in flow	Measuring range	–50 – 150 mbar
channel		
	Accuracy	$\pm 0.75\%$ of reading or $\pm 0.1$ mbar



Figure 2: Flow channel

#### 5.2.2 Oxygen sensor (option)

CITREX H3 can be fitted with an oxygen sensor. The option is enabled using the configuration tool. You will find further information on the configuration tool in the section "Configuration tool".

After enabling, oxygen concentration can be measured in the flow channel. To do so, an oxygen sensor is screwed into the appropriate port. The oxygen sensor has to be connected to the measuring instrument using the cable included. The following steps explain how to install and replace the oxygen sensor.



Figure 3: Oxygen sensor holder

Measuring range	0-100%
Accuracy	±1% O <sub>2</sub> (absolute)

#### 5.2.3 Installing the oxygen sensor

1. Remove the protective cap from the sensor port of the device.



Figure 4: Protective cap



2. Screw the oxygen sensor clockwise into the appropriate port. Make sure the sensor seals off the port and there is no leak.

Figure 5: Screwing in the oxygen sensor

3. Connect the cable included to the oxygen sensor by pushing the cable into the hole at the top of the sensor until the cable locks into place. Connect the other end of the cable to CITREX H3 by inserting it into the hole provided, which is labelled "O<sub>2</sub>".



Figure 6: Oxygen sensor cable

 Perform an oxygen calibration. The calibration procedure is described in the section "Calibration". Calibration ensures that the measured values of the new sensor are correct.

#### 5.3 Electrical interfaces

A INT. Analytics

Figure 7 shows the available electrical interfaces of CITREX H3.

Figure 7: Electrical interfaces

1	MicroSD	The firmware of CITREX H3 is stored on the microSD card.	
	card slot	It also contains customised configurations.	
2	O <sub>2</sub> interface	The optional oxygen sensor is connected to CITREX H3 via	
		the $O_2$ interface. You will find further information on this in	
		the section "Oxygen sensor".	
3	USB port	The USB port is used to operate the device from the mains	
		power supply and to charge the device battery. It is a "USB	
		Mini-B port".	
4	Ethernet	The Ethernet interface is used to configure the device and it	
		is used as a data interface.	

Table 3: Description of electrical interfaces

#### 5.4 Change CITREX battery

The battery of CITREX H3 can be changed by the user. To do so, undo and remove the two screws on the back of the device. Then the battery can be removed and replaced. Check whether the new battery has been inserted properly. For this purpose the terminals must be opposite one another.



Figure 8: Change battery

# 6 **Operation**

This section describes how to use the device and what possible uses there are.

6.1 Switching the device on/off The device is switched on and off at the On/Off button. Figure 8, section "User controls", shows where this button is located on the device. To switch CITREX H3 on you must press the On/Off button briefly. You will hear an audible signal. To switch the device off you must press the On/Off button for about 1 second. If the device can no longer be controlled, you have the option of pressing the On/Off button for about 6 seconds. The device is then forced to shut down.

6.2 Screen lock Press the context button on the side of the device for 2 seconds. The screen shows a message indicating that the screen is locked. To unlock the screen, press and hold down the context button or one of the four buttons on the front for 2 seconds.

# 6.3 Dim screen If the device is not operated by the user, the display of CITREX H3 shuts down after about one minute and the four buttons start to flash. As soon as a button is pressed, the screen comes on again.

The setting for how long it takes until the display is dimmed can be customised using the configuration tool. You will find further information on this in the section "Configuration tool".

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#### 6.4 User controls

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Figure 9: User controls

1	Change, Edit
2	Context button; long press: key lock on/off
3	On/Off button
4	Menu button; zero point adjustment
5	Charge indicator
6	Flow direction indicator
7	Screen
8	Display readings and scroll forward
9	Malfunction indicator
10	Display readings and scroll back

Table 4: User controls

6.5 Settings

With the × button you access the "Settings" menu. By pressing the button more than once you can view the various settings of the measuring instrument.

#### 6.5.1 Info display

This display provides information about the owner, the company, the next recommended calibration, the software version and the hardware revision. Settings concerning the owner can be edited with the configuration tool.

CITREX H3	
Owner:	John Bio
Company:	IMT Analytics
Next Calib.:	May 2018
Software:	4.1.000
Hardware:	4

Figure 10: Info display

#### 6.5.2 Battery indicator

The battery indicator informs you about the level of the battery charge.



Figure 11: Battery indicator

#### 6.5.3 Ethernet interface

Here it is possible to make various settings for the network connection. With the O button you can choose between the options "DHCP Client", "Default" and "Configured". The setting does not have to be confirmed and it is enabled as soon as it is visible on the screen. More information about the settings is available in the section "Web server".



Figure 12: Ethernet interface

#### 6.5.4 Trigger

With the trigger settings the start and end points of a ventilation parameter are defined. Two preset triggers are available. With the O button you can select the trigger "Adult" or "Pediatric". The trigger settings do not have to be saved and they are enabled as soon as they are displayed on the screen. It is possible to differentiate between flow trigger, pressure trigger and external trigger.

The settings can be changed with the configuration tool. You will find further information on this in the section "Configuration tool".

Trigge Adult	r	
Start: Flow: End: Flow:	rising 3.0 l/min falling -3.0 l/min	60ms 60ms

Figure 13: Trigger

The preset trigger settings are defined as follows.

	Adult	Pediatric
Start	3L/min	1 L/min
	Rising edge	Rising edge
Stop	–3L/min Falling edge	– 1 L/min Falling edge
Delay	60 ms	60ms
Base flow	0L/min	0 L/min

Table 5: Trigger settings

#### 6.5.5 Gas standard

The CITREX H3 measuring instrument can convert gas flow and volume readings to various gas standards and display them. Care must be taken to ensure that on the measuring instrument the same gas standard is set as the one on the device being tested. With the  $\bigcirc$  button you can switch between the various gas standards. As soon as a gas standard is displayed, it is enabled. There is a list of available gas standards in the Appendix in the section "Gas standards for flow and volume readings".



Figure 14: Gas standard

#### 6.5.6 Gas type

Under this menu item the gas type to be measured can be set. With the  $\bigcirc$  button you can switch between gas types. The gas type indicated is enabled and does not have to be saved. In the section "Gas type" there is an overview of available gas types. Gas types with adjustable oxygen concentrations, e.g. "Air O<sub>2</sub> manual", can be changed with the configuration tool.



Figure 15: Gas type

#### 6.5.7 Gas humidity

The gas humidity of the gas being measured can be set. This has an impact on gas flow measurement. With the  $\bigcirc$  button the gas humidity can be changed in steps of 10. The value is enabled as soon as it is displayed on the screen.



Figure 16: Gas humidity

#### 6.5.8 Oxygen calibration (optional)

Oxygen calibration is only available if the oxygen option has been enabled. The process of oxygen calibration is described in the section "Calibration". With the  $\bigcirc$  button you can choose between one-point calibration and two-point calibration. Press the  $\triangle$  button to start calibration.



Figure 17: O2 calibration

#### 6.6 Numerical readings

With the D button on the front of CITREX H3 you can display the various numerical readings. If you press more than once, the view on the screen changes. The different views can be configured by web server. The web server and how to make the settings are explained in the section "Web server".



Figure 18: Numerical readings

1	Gas Standard	The measured volume readings or gas flow readings can be displayed with various gas standards. There is a list of standards in the Appendix in the section "Gas standards for flow and volume readings".
2	Trigger signal	The icon appears as soon as a trigger condition is fulfilled. This means that the time of appearance of the indicator is identified as the start of inspiration. The indicator appears for 0.5 seconds. If this signal is not displayed, the trigger settings should be adjusted for the current ventilation mode.
3	Gas type	The gas type currently set is displayed as text. It can be customised on the device under Settings.
4	Reading	This shows the current reading in the selected unit of measurement.
5	Measurement parameter	Indicates the measurement parameter currently selected. Meas- urement parameters can be changed in configuration; see section "Configuration tool".
6	Measuring Unit	Indicates the unit of measurement currently selected. Units of meas- urement can be changed in configuration; see section "Configuration tool".

Table 6: Numerical values

#### 6.7 Filter

The screen of CITREX H3 is refreshed every 0.5 s. The recording of readings takes place every 5 ms. Since CITREX H3 can record and display readings very quickly, it is advisable to filter the readings. This is performed using a mean value. The extent to which a reading is filtered can be set using the configuration tool.

The following filters are available:

- No filter (indication of the last value measured without any threshold)
- Low (mean above 240 ms)
- Medium (mean above 480 ms)
- High (mean above 960 ms)

#### 6.8 Change parameters and units

The "high" filter is set by default.

If the context button ( $\blacksquare$ ) is pressed twice in succession, "Edit Mode" is enabled. This is indicated by a red icon on the screen. The parameter or unit in the red frame can be changed with the  $\Box$  icon or the O icon. The  $\Delta$  icon allows you to jump to the next element. If the context button or the × button is pressed once, you exit "Edit Mode"



# 7 Calibration

#### 7.1 Zero point

The various calibration options with CITREX H3 are described in this section. To avoid incorrect measurements you must adhere to the procedures described here.

This adjustment is necessary if indication of the channel pressure sensor ( $P_{channel}$ ) or a flow through open connection ports shows a value greater or less than zero. This can occur if there are considerable temperature fluctuations, or after the warming-up time. Zero calibration resets all values to zero. To perform zero calibration you must remove all connected tubes from the device. Press the × icon and keep it pressed for approx. 3 seconds. The screen shows a message "Zero Offset – Calibrating, please wait".



Figure 19: Zero calibration



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.



During zero calibration there must be no pressure being applied to a connection port, and care must be taken to ensure that there is no flow through the flow channel.

#### 7.2 Oxygen (O<sub>2</sub>) 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 and takes about four minutes. Calibration can be selected by pressing the × button more than once.

#### 7.2.1 Calibration with air

Calibration is only available if the oxygen option has been enabled. Make sure air is flowing through the flow channel at a rate of at least 30 L/min. To start calibration, press the  $\times$  button until you see the menu item

"O<sub>2</sub> Calibration". With the  $\bigcirc$  button you can switch between air and air and oxygen (O<sub>2</sub>). Select the  $\bigcirc$  button until "Air" appears on the screen in green letters. To start calibration, press the  $\triangle$  button. It takes about 120 seconds before calibration is completed.



Figure 20: Screen displays "Calibration Air"

#### 7.2.2 Calibration with oxygen and air

For calibration of the oxygen cell with oxygen and air a gas flow of 30 L/min is used in each case. Press the × button until you see the menu item "O<sub>2</sub> Calibration". With the O button you can switch between air and air and oxygen (O<sub>2</sub>). Press the O button until the screen shows "O<sub>2</sub> and Air" in green letters. To start calibration, press the  $\Delta$  button. Calibration for air and oxygen takes 120 seconds for each one.



Figure 21: Screen displays "Calibration Oxygen and Air"

#### **Connecting the device** 8

The measurement setup for CITREX H3 has an impact on flow measurement. To obtain results that are as accurate as possible, comply with the instructions in this section. It is important to ensure that the tubing in the measurement setup does not have any radii, kinks or dents. You are also recommended to always use the dust filter included.



The measured gases must be free of oil, grease and dust.

#### 8.1 General measurement setup

The general measurement setup applies to gas flow measurement. The RT019 filter included and a short piece of tubing must be used. This ensures laminar flow to the flow sensor unit. The filter also prevents dust, oil and grease from contaminating the CITREX H3 measuring instrument and thus prevents discrepancies in measurement results. The measurement setups shown below are dependent on the direction of gas flow being measured.



Figure 22: General measurement setup

The measurement setups listed below are unsuitable and produce inaccurate measurement results. Kinks, tees and angle pieces should be avoided in the flow channel. They cause turbulence in the gas being measured and hence inaccurate or incorrect measurement results.

Bad setup: Kinks, tees, angle pieces at the device inlet



Figure 23: Bad setup

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# 8.2 Measurement setup for checking ventilators

CITREX H3 is ideal for checking ventilators. The best measurement results are achieved with the measurement setup shown below. Make sure the test lung is connected to the grey aluminium connection port of CITREX H3.



Figure 24: Measurement setup for checking ventilators

# 9 Configuration tool

The configuration tool can only be used with Microsoft Internet Explorer.

9.1 PC minimum requirements Microsoft® Silverlight 5 or higher

Windows x86 or x64 (64-bit mode only supports IE) 1.6 GHz or higher with 512 MB RAM

Macintosh (Intel based) Intel Core Duo 1.83 GHz or higher with 512 MB RAM

Microsoft® Windows® 10, 8.1, 8, Windows Server 2012, 7, 7 SP1, Windows Server 2008 SP2, Windows Server 2008 R2 SP1, Vista

Macintosh OS 10.6 (Intel based), MacOS 10.7 - 10.11 (Intel based)

Ethernet network connection

Screen resolution 1024 × 768 (1280 × 1024 recommended)

9.2 Web server
The Ethernet port on CITREX H3 enables access to the device via a network. Settings can be made on the device via the web browser using the so-called configuration tool. The oxygen option can also be enabled with the web server. The prerequisite for using the web server is an installed Internet Explorer with Microsoft Silverlight 5.

There are three different setting options to establish a connection between CITREX H3 and a computer. Tap the  $\times$  button until the "Ethernet" menu item appears. You will find a description of the settings in the following sections.

#### 9.2.1 Default

These are default settings that cannot be changed. These settings are recommended in order to establish a direct connection to the computer via an Ethernet cable. The configuration on CITREX H3 is as follows:

IP Address: 192.168.1.1 Subnet Mask: 255.255.255.0

To establish a connection, the network settings on the computer must be changed. For this purpose open the network settings of the computer, which are located in the Control Panel. Then open the "Internet Protocol Version 4 (TCP/IPv4)" settings. Enter an IP address between 192.168.1.2 and 192.168.1.255 and subnet mask 255.255.255.0 in the form on the screen.

Now open Internet Explorer and enter IP address 192.168.1.1 in the address field. The connection to CITREX H3 is established.

#### 9.2.2 Configured

This setting option is suitable for connecting CITREX H3 to a network that does not have a DHCP server. Define an IP address and a subnet mask using the configuration tool on CITREX H3. Then the device can be connected up to the network and be accessed using the defined IP address via Internet Explorer.

#### 9.2.3 DHCP

To connect CITREX H3 to a DHCP server, first connect CITREX H3 to the network. In the "Ethernet" menu select the setting "DHCP". With the IP address shown on the display it is possible to establish a connection to CITREX H3 via Internet Explorer.

#### 9.2.4 Enable oxygen option

With the PC, establish a connection to CITREX H3, as described above. The enable code obtained can be entered in the "Software Options" menu. The code is device-dependent and only has to be entered once.



Figure 25: Enable oxygen option

# 10 Servicing and care

Careful servicing in compliance with the instructions is essential for ensuring that CITREX H3 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.



The servicing operations listed below may only be performed by persons who are familiar with CITREX H3. All further repair work may only be performed by authorised trained professionals. Please also observe the information issued by the various manufacturers.

# 10.1 Preventive cleaning and servicing operations

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.

#### 10.1.1 During operation

Use of the filter included in order to protect the device against contamination. Make sure the device is only used inside a building.

#### 10.1.2 Every 4 weeks

Check the bacterial filter for soiling. For this purpose the pressure drop above the filter must be measured. The pressure drop must not exceed a value of 2 mbar at a flow of 60 L/min. Otherwise the filter must be replaced.

#### 10.1.3 Every 12 months

Factory calibration and servicing to ensure reliable measurement; it may only be performed by IMT Analytics or an authorised partner.

To have CITREX H3 calibrated at the manufacturer's, IMT Analytics, visit the website <u>www.imtanalytics.com/easycal</u>

The EasyCal service makes it possible for users to have CITREX H3 calibrated and adjusted quickly and easily. The annual servicing procedure is also performed.

# **11 Accessories and spare parts**

On the website <u>www.imtanalytics.com</u> you will find the original spare parts and other products from IMT Analytics.

#### Ordering address:

IMT Analytics AG Gewerbestrasse 8 CH-9470 Buchs, Switzerland

Tel:+41 (0) 81 750 67 10Email:sales@imtanalytics.comOrders can also be placed in our Webstore.

**11.1 Accessories table** 

#### Options

305.056.000	Oxygen sensor with activation code
305.055.000	Warranty extension (plus 2 years) CITREX H3

#### Service

0011100	
000.000.017	Calibration & Servicing CITREX H3
000.000.022	ISO17025 Calibration & Servicing CITREX H3
000.000.018	Receiving inspection of CITREX H3
305.054.000	Triple Calibration & Servicing Package for CITREX H3

#### Accessories & Consumables

300.548.000	Adapter set
301.997.000	Car adapter for CITREX
302.077.000	Laminar inlet pipe
304.161.000	Black protective pouch for CITREX
304.161.001	Red protective pouch for CITREX
304.161.002	Blue protective pouch for CITREX
301.851.000	MicroSD memory card
301.655.000	Blind plug for oxygen connector (rubber)
302.178.000	Blind plug for oxygen connector (solid)
301.624.000	Oxygen sensor with mono jack
302.531.000	Bacterial filter RT019
304.714.000	CITREX stand

#### Spare parts

opuro purto	
301.936.000	Carrying case for CITREX H4
301.625.000	Battery for CITREX
301.563.000	Network cable
301.673.000	USB cable for CITREX
301.653.000	Oxygen sensor cable
304.578.000	Power supply plug for CITREX
302.780.000	Flow channel protective cap

Table 7: Accessories

# **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.

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 Directives and approvals**

- CE
- CAN/CSA-C22.2 No. 61010-1-12
- UL Std. No. 61010-1 (3rd Edition)
- IEC 61010-1 2010
- IEC 61326-1 2012
- ETSI EN 301 489-17 V3.1.0
- FCC Part 15, Subpart B, Digital Devices, Emission Class B

#### **CE Declaration of Conformity**

#### 2014/35/EU (LVD)

DIRECTIVE 2014/35/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits tested according to EN61010-1:2010

#### 2014/30/EU (EMC)

DIRECTIVE 2014/30/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility tested according to EN61326-1:2013

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# **14 Specifications**

#### 14.1 Measurement parameter

#### Flow and pressure measurement Measuring range Accuracy

#### Air and N<sub>2</sub>

Flow measurement	±300 sL/min***	±2% * or ±0.1 sL/min **
Temperature compensated	Yes	
Ambient pressure compensated	Yes	
Channel pressure compensated	Yes	–50 – 600 mbar

#### O<sub>2</sub>/air mixtures

Flow measurement	±300 sL/min***	±2%* or ±0.1 sL/min**
Temperature compensated	Yes	
Ambient pressure compensated	Yes	
Channel pressure compensated	Yes	–50 – 600 mbar

#### N<sub>2</sub>O/O<sub>2</sub> mixtures

Flow measurement	±80 sL/min ***	±4%* or ±0.3sL/min**
Temperature compensated	Yes	25-30°C
Ambient pressure compensated	Yes	
Channel pressure compensated	Yes	–50 – 600 mbar

#### Pressure

In flow channel	–50–150 mbar	±0.75% * or ±0.1 mbar **
Barometer	500-1150mbar	±1%* or ±5mbar**

Table 8: Measurement parameters

Additional readings	Measuring range	Accuracy
Oxygen concentration (pressure compensated ≤ 150 mbar)	0-100%	$\pm 1\% O_2^{**}$
Gas temperature****	0-50°C	±1.75%* or ±0.5°C**
Gas type	Air, O <sub>2</sub> , Air/O <sub>2</sub> , N <sub>2</sub> O/O <sub>2</sub>	
Gas Standard	ATP, ATPD, ATPS, AP21, STP, STPH, BTPS, BTPS-A, BTPD	

#### Units of measurement

Flow	L/min, L/s, cfm	
Pressure	bar, mbar, cmH <sub>2</sub> O, mmHg, inH <sub>2</sub> O	

Table 9: Additional readings

It is the larger tolerance that applies: \* Tolerance in relation to the reading \*\* Absolute tolerance

\*\*\* In this User Manual the unit sL/min is based on ambient conditions of 0°C and 1013.25 mbar (DIN1343)
\*\*\*\* CITREX H3 measures the gas temperature inside the measurement channel. While CITREX H3 is warming up, the temperature of the measurement channel, and hence also the temperature of the gas inside the measurement channel, rises at the same time. The measurement channel volume is relatively small, even for relatively high volumetric flows (e.g. PIF @ 60L/min). If the temperature of the gas on entering CITREX H3 is compared with gas temperature in the measurement channel, it becomes evident that the temperature in the measurement channel is higher. Therefore the temperature of the gas entering the

CITREX H3 measurement channel should not be expected to equal the temperature displayed on the screen because the temperature displayed is measured inside the CITREX H3 measurement channel.

Ventilation parameters Measuring Accuracy range Rate Breaths/min 1-1000 breaths/ ±1 breath or ±2.5% \*\* min Time Ti 0.05-60s ±0.02s Ratio I:E 1:300-300:1 ±2.5%\* Tidal volume V<sub>ti</sub> ±2%\* or ±0.20mL (>6sL/min)\*\*  $\pm 10 \, \text{sL}$ Minute volume Vi 0-300 sL/min ±2.5%\* Peak flow Insp./exp. ±300 sL/min  $\pm 2\%$  \* or  $\pm 0.1$  sL/min \*\* Pressure P<sub>Peak</sub>, P<sub>Mean</sub>, 0-150 mbar ±0.75%\* or ±0.1 mbar\*\* PEEP Trigger Adult, Pediatric, Flow, Pressure

Table 10: Ventilation parameters

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#### **General information**

Screen	1.7" colour display
Interfaces	Ethernet
AC input	100–240 VAC (50/60 Hz)
Battery operation	4 hours
Dimensions (W $\times$ D $\times$ H)	11.4 × 7 × 6 cm
Weight	0.38 kg
Calibration interval	Once a year
Memory card	Yes

#### **Operating data**

Ambient temperature	15–40°C (59–104°F)
Air humidity	10-90% RH
Ambient pressure	783–1150mbar
Storage and transport conditions	–10–60°C (14–140°F) at 5–95% RH
Degree of soiling	Degree of soiling 2, to IEC 61010-1

Table 11: General information and operating data

It is the larger tolerance that applies: \* Tolerance in relation to the reading \*\* Absolute tolerance

\*\*\* In this User Manual the unit sL/min is based on ambient conditions of 0°C and 1013.25 mbar (DIN1343).

14.2 Gas type	The gas type measured must agree with the setting on CITREX H3. Please select the correct gas type in the settings.		
	The following gas types are available for selection:		
	<ul> <li>Air 100%</li> <li>Air/O<sub>2</sub>-Man. Air/oxyger fault is 10</li> <li>Air/O<sub>2</sub>-Auto. (optional) Air/oxygen internal oxy</li> <li>N<sub>2</sub>O/O<sub>2</sub>-Man. Nitrous ox</li> </ul>	100% Air/oxygen mixture according to manual input; the de- fault is 100% O <sub>2</sub> Air/oxygen mixture according to sensor measurement of internal oxygen cell Nitrous oxide / oxygen mixture according to manual	
	Standard conditions are understood to mean defined conditions for pressure perature and, in some cases, humidity, which constitute the basis for convert flow actually measured. Therefore it is essential to check which standard co the value displayed will relate to. The standard currently set is indicated on the numerical display.		
	A gas type that has not been selected properly and a gas s ard that has not been selected properly can lead to measur of up to 20%.		
14.3 Power supply	Input voltage of the power supply unit Supply voltage Power input	100–240 VAC, 50–60 Hz 5 VDC 2.5–6 W	
14.4 Battery operation	Operating time in battery operation	4 hours*	
	Charging the battery	A complete charging process takes 5 to 8 h, depending on which connection port is used for charging. The service life of the battery is extended if the battery is charged completely only after a prompt by the device.	

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\* This operating time is reached in non-networked operation (i.e. the interfaces are not in use or they are switched off)

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# **15 Appendix**

15.1 Principle of flow measurement

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



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

 $\eta:$  dynamic viscosity of the gas [Pa s]

p: gas density [kg/m<sup>3</sup>]

c1, c2: device-specific constants (channel geometry)

#### **Dynamic viscosity**

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

Triggers are used to define start and end points of cyclical signals. With regard to pressure and flow curves the trigger makes it possible to determine inhalation and exhalation. The resulting information constitutes the basis for ventilation parameter calculation. If the trigger is not set properly or if it is not possible to detect a trigger, the ventilation parameters will be calculated incorrectly or not at all.



Figure 26: Trigger

15.2 Trigger

#### 15.2.1 Flow trigger

On CITREX H3 a flow trigger can be set. When the set flow is reached, the trigger is activated. In this context it is essential to specify whether at the start and end of a cycle the trigger is to be activated by a rising edge or a falling edge. Flow measurement in the flow channel serves as the trigger source. CITREX H3 can be operated bidirectionally.

#### 15.2.2 Pressure trigger

In the case of a pressure trigger it is the pressure measured in the flow channel that serves to activate measurement. Whereby the direction of flow is of no consequence.

#### 15.2.3 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 constant discharge of 3 L/min, those 3 L/min are not included in the inspiratory volume. The 3 L/min can be entered as a trigger setting so they will not be taken into account.

#### 15.2.4 Delay

With a delay it is possible to filter out signal errors or noise and prevent false triggering. As a result, a trigger is only activated if the set trigger level continues to apply after the delay time. If the trigger level is no longer reached after the delay time, no trigger is activated. The delay time can be set.



Figure 27: Delay

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#### 15.3 Measurement parameters and units

Pressure readings	Measurement parameter	Designation	Units of measurement
	Ambient pressure Pressure in flow channel high	P atmo. P Channel	mbar, bar, inH2O, cmH2O, mmHg
Flow readings	Measurement parameter	Designation	Units of measurement
	Flow	Flow	L/min, cfm, L/s
Meteorological readings	Measurement parameter	Designation	Units of measurement
	Temperature	Temp.	°C, K, °F
	Oxygen content (option)	O <sub>2</sub>	%
	Volume	Volume	mL, L, cf
Gas concentrations	Measurement parameter	Designation	Units of measurement
	Gas concentration	Gas concentration	%
Ventilation parameters	Measurement parameter	Designation	Units of measurement
	Positive end-expiratory pressure Mean pressure Maximum pressure	PEEP P <sub>mean</sub> P <sub>Peak</sub>	mbar, bar, inH₂O, cmH₂O, mmHg,
	Inspiratory minute volume Inspiratory/expiratory peak flow	Vi PF <sub>insp</sub> /PF <sub>Exp.</sub>	L/min, cfm, L/s,
	Inspiratory volume Ventilation rate Inspiratory/expiratory ratio Inspiratory time	Vti Rate I:E T <sub>i</sub>	mL, L, cf Breaths/min s

Table 12: Measurement parameters and units

#### 15.4 Gas standards for flow and volume readings

CITREX H3 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 CITREX H3.

Gas Standard	Abbrevia- tion	Pressure	Temperature	Relative humidity
Ambient Temperature and Pressure	ATP	Current ambient pressure	Current gas temperature	Current gas humidity
Ambient Temperature and Pressure Dry	ATPD	Current ambient pressure	Current gas temperature	0%
Ambient Temperature and Pressure Saturated	ATPS	Current ambient pressure	Current gas temperature	100%
Ambient Pressure at 21°C	AP21	Current ambient pressure	21.0°C (70°F)	Current gas humidity
Standard Conditions USA	STP	1013.25 mbar (760 mmHg)	21.0°C (70°F)	0%
Standard Conditions USA Humid	STPH	1013.25 mbar (760 mmHg)	21.0°C (70°F)	Current gas humidity
Body Temperature and Pressure, Saturated	BTPS	Current ambient pressure + channel pressure	37.0°C (99°F)	100%
Body Temperature and (Ambient) Pressure Saturated according to ISO 80601-2-12:2011	BTPS-A	Current ambient pressure	37.0°C (99°F)	100%
Body Temperature and Pressure Dry	BTPD	Current ambient pressure + channel pressure	37.0°C (99°F)	0%

Table 13: Gas standards for flow and volume readings

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#### 15.5 Conversion factors

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Value	Equivalent		
1 mbar	0.001	bar	
	100	Pa	
	1	hPa	
	0.1	kPa	
	0.75006	torr	(760 torr = 1 atm.)
	0.75006	mmHg	(at 0°C)
	0.02953	inHg	(at 0°C)
	1.01974	cmH <sub>2</sub> O	(at 4°C)
	0.40147	inH <sub>2</sub> O	(at 4°C)
	0.01450	psi, psia	
1 bar	1000	mbar	
	0.1	Pa	
	1000	hPa	
	100	kPa	
	750.06	torr	(760 torr = 1 atm.)
	750.06	mmHg	(at 0°C)
	29.53	inHg	(at 0°C)
	1019.74	cmH₂O	(at 4°C)
	401.47	inH₂O	(at 4°C)
	14.50	psi, psia	

Table 14: Conversion factors

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