CORTEX
Medizin · Sport · Fitness

Calibration Manual

Product no. 931-00-264 / Revision a / 2017-10-20

for the devices:

- MetaMax® 3B
- MetaMax® 3X
- MetaLyzer® 3B-R2
- MetaLyzer® II

with the software:

- MetaSoft® Studio

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Dear User!

We are grateful for the trust you place in us by purchasing this product.

The **CORTEX "Professional" calibration set** contains the necessary equipment for the calibration of your CORTEX spiroergometry system and its accessories. Read this manual through carefully.

Please also read all other manuals that familiarize you with the workings and the functions of the hard- and software before operating your CORTEX spiroergometry system for the first time. This involves the following documents:

- **Hardware manual** (MetaLyzer® 3B/II or MetaMax® 3B) – describes use and handling of your device, including all safety instructions and hygienic measures.
- **Software manual** (MetaSoft® Studio) – explains the integration of devices and leads you through the operation of the software.
- **Installation manual** – explains the system requirements, the installation and the update of the MetaSoft® Studio software.

In case of questions or issues we are glad to help you. For service you can trust, contact your CORTEX retail/service partner or CORTEX directly:

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1 Calibration

▶ Note

You receive your spiroergometry device already pre-calibrated from the factory. A corresponding calibration protocol is part of the scope of delivery.

Before you use your spirometry system for your measurement, you have to calibrate the **flow sensor** (usually Triple-V volume sensor) and the **gas sensors** (O_2 and CO_2) regularly. This synchronizes your spirometry system with the environmental conditions, such as pressure, humidity etc. and assures that your device works precisely.

Always carry out the air pressure calibration first; then the volume calibration, and lastly the gas calibration!

Also adhere to the **calibration procedures** as well as the **warmup times** for your CORTEX spiroergometry device before beginning the calibration to assure a consistently high accuracy of measurement!

⊡ **Tip!** The calibration procedures apply to stable environmental conditions!

Tab. 01: Calibration procedures and warm-up times of the CORTEX spiroergometry device

Calibration type	Calibration procedure	Warm-up time
Air pressure	**semi-annually**, recalibration is only necessary if the deviation ≥ 10mbar	15 Minutes
Flow sensor	**1x daily** or before each test, as well as after the exchange of the turbine	15 Minutes
Gas sensors (O_2 and CO_2)	**1x monthly** or: ▪ before the start of a longer measurement run ▪ in the case of increased precision requirements ▪ after every air pressure calibration	45 Minutes

1.1 Prepare calibration

1.1.1 Calibration set and accessories

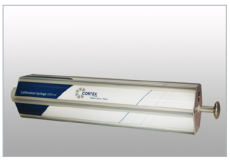
The following components are part of the scope of delivery of the **"Professional" calibration set** (complete) with **item no.: 010-01-793**:

Fig. 01:
Scope of delivery/ accessories CORTEX Professional calibration set

Depending on the calibration type you will require the following (accessory) parts that are part of your CORTEX spiroergometry system and/or that you can order readily from CORTEX:

Accessories	Description	Item no.
	MetaLyzer® 3B/II	220-01-702/ 210-01-702

Tab. 02:
Calibration accessories

Accessories	Description	Item no.
	MetaMax® 3B/3X	130-01-702/ 140-01-702
	Sample line (about 100 cm Nafion)	*upon request* *depending* *on device*
Flow Sensor Calibration		
	CORTEX-calibration pump 3 l	010-00-083
	Triple-V-Volume sensor (Flow sensor)	*upon request* *depending* *on device*
Gas calibration		
	Calibration gas bottle, 1.2 l (with 15 % O_2, 5 % CO_2, the rest N_2) *(or gas from third party supplier)*	010-00-005
	Gas-on-demand- valve with adapter	010-00-898

Accessories	Description	Item no.
	Adapter for CORTEX sample gas bottle	010-00-072
	Tube adapter (for calibration with gas from third party supplier)	010-01-897

1.2 Perform the calibration

Before beginning the calibration you first have to apply a few settings in the software. To do this, open the submenu CALIBRATION/SETTINGS in the MetaSoft® Studio **Toolbox**.

1.2.1 Preparations in the software

The settings that you apply here are effective in carrying out the calibration in the Toolbox as well as also in the MetaSoft® Studio:

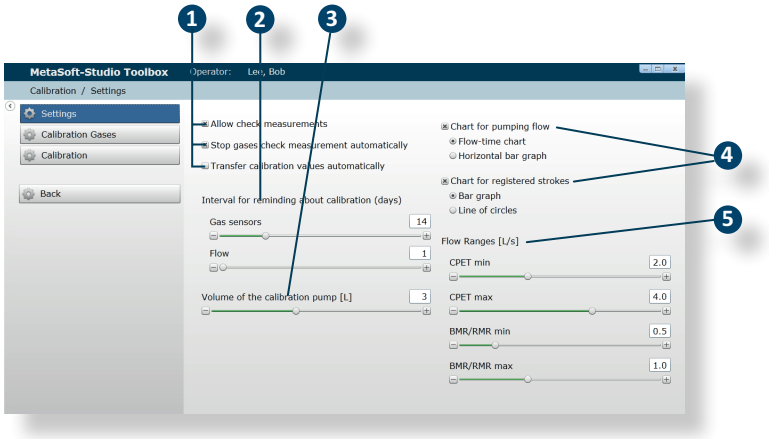


Fig. 02:
Settings in the MetaSoft® Studio Toolbox

Define which functions (check measurement etc.) you want to select/ deselect by clicking on the option buttons ☒ in the upper area ❶ (➡Fig. 02).

Specify the cycle of the calibration memory using the slider or by direct entry under INTERVAL FOR REMINDING ABOUT CALIBRATION (DAYS) ❷.

In the next step also enter the VOLUME OF THE CALIBRATION PUMP ❸ that you use.

NOTICE	The volume of the calibration pump should correspond approximately to the maximum respiratory volume that is expected during the test with the patient (e. g. maximum effort test: 3 l, resting test: 1 l).

In CHART FOR PUMPING FLOW or CHART FOR REGISTERED STROKES ❹ you select the chart for performing the flow sensor calibration that you feel most comfortable with (➡*see*Toolbox submenu: CALIBRATION/ CALIBRATION, Menu FLOW SENSOR). Enter in each case the minimum and maximum limit value for the pump flow in litres/sec for the appropriate measurement (spirometry vs. resting measurement) under FLOW RANGES ❺.

Save your settings at the end by clicking on [SAVE].

Calibration gas management

You can set up or edit your calibration gases in the submenu CALIBRATION/CALIBRATION GASES.

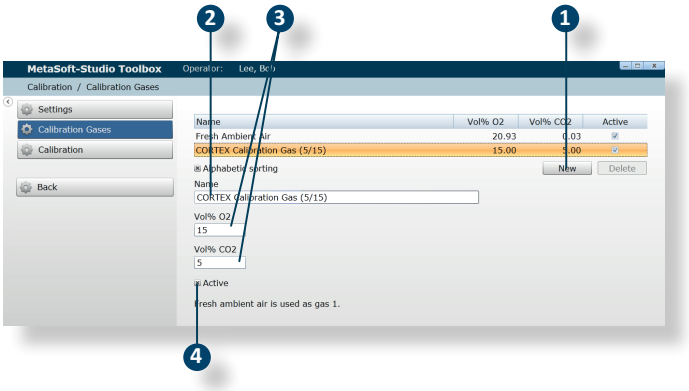


Fig. 03: Managing the calibration gases in the MetaSoft® Studio Toolbox

By clicking on [NEW] ❶ (➡Fig. 03) you set up a new device configuration. Provide an informative description under NAME ❷.

Under Vol%02 and Vol%CO2 ❸ enter in each case the gas concentration values for O_2 and CO_2. You usually find them on the label of your calibration gas bottle.

In the last step you define whether the calibration gas should be set to ACTIVE by clicking on the option button ☒ ❹.

⊡ **Tip!** Only 2 gases may be set to “active”! Usually the definition for one of the gases is always *Fresh Ambient Air*.

Manage the flow sensors

Prior to the calibration you have to set up the flow sensors you use in the Toolbox submenu TEST EQUIPMENT/FLOW SENSORS. For further details, refer to the MetaSoft® Studio manual.

1.2.2 Air pressure calibration

NOTICE	Under certain conditions (e.g. high elevation) air pressure calibrations have to be performed regularly! Please note the instructions in chapter 1 (➡Tab. 01).

First measure the current air pressure with your digital CORTEX barometer or a similar reference barometer.
Now open the Toolbox submenu CALIBRATION/CALIBRATION.

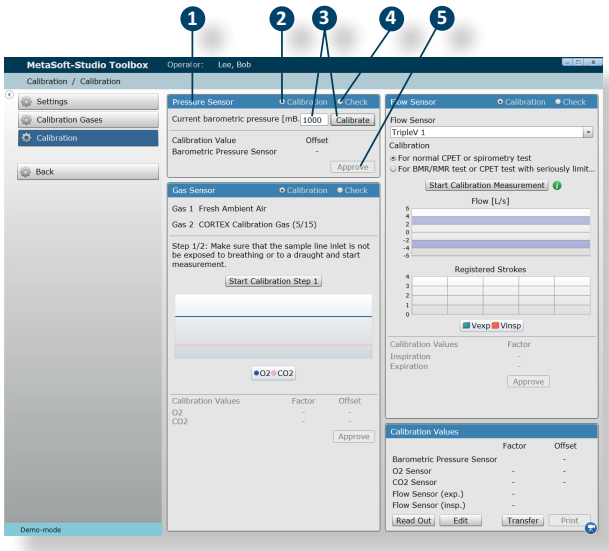


Fig. 04:
Air pressure calibration

In the menu PRESSURE SENSOR ❶ (➡ Fig. 04) first select the option button ⊙ CALIBRATION ❷ and enter the air pressure you measured under CURRENT BAROMETRIC PRESSURE ❸. Then click on [CALIBRATE] ❸.

The new offset value is shown under "Offset".

You can verify this value by clicking on ⊙ CHECK ❹. You finish up the air pressure calibration by clicking on [APPROVE] ❺.

1.2.3 Calibrate the flow sensor

NOTICE	Observe the calibration routines and warm-up times of the CORTEX spiroergometry device specified in chapter 1(➡Tab. 01)!

⊡ **TIP!** Interactive step-by-step instructions are also available in the video tutorials. To do this, click in the Toolbox submenu in the lower right on the video symbol and then on [FLOW SENSOR]. Alternatively you can open the video tutorial directly in MetaSoft® Studio. To do this, click in the Patient centre in the control bar (bottom) on CALIBRATE FLOW SENSOR. The module for the calibration opens. Now click on the video symbol in the control bar .

Calibration setup

Required accessories:
- CORTEX CPET device
- Calibration pump
- Flow sensor
- Sample line

Fig. 05: Calibration setup for MetaLyzer®

Fig. 06: Calibration setup for MetaMax®

Connect the flow sensor and sample line with your CORTEX spiroergometry device (MetaLyzer® or MetaMax®) as shown in the figures above (➡Fig. 05/Fig. 06).

Then check whether your device is plugged into a power outlet and turn it on.

⊡ **TIP!** Observe the specified warm-up times for your device (➡Tab. 01).

Remove the sample line from the flow sensor (if still connected) and seal the opening with the small, black plug (part of the scope of delivery of the flow sensor) (➡Fig. 07)!

Then plug the flow sensor into the opening provided in the calibration pump for that purpose (➡Fig. 08).

Fig. 07: Close opening for sample line

Fig. 08: Connect flow sensor with calibration pump

Perform flow sensor calibration

Now open the Toolbox submenu CALIBRATION/CALIBRATION.

Depending on which settings you have selected in the Toolbox submenu CALIBRATION/SETTINGS either the CHART FOR PUMPING FLOW is the FLOW-TIME CHART or the HORIZONTAL BAR GRAPH and as the CHART OF THE REGISTERED PUMP STROKES the BAR GRAPH or the LINE OF CIRCLES is displayed (➡Fig. 09/Fig. 10).

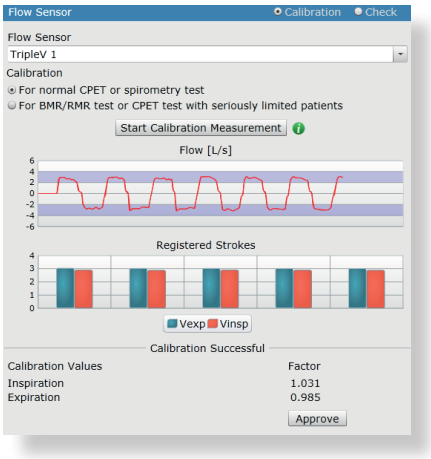


Fig. 09: Flow time chart and bar graph

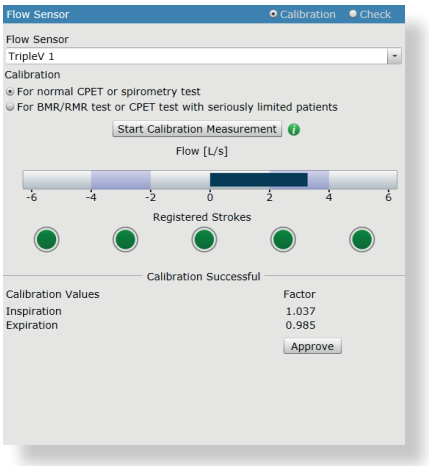


Fig. 10: Horizontal bar graph and line of circles

⊡ **TIP!** In the Toolbox submenu CALIBRATIONS/SETTINGS you can also combine FLOW TIME CHART with LINE OF CIRCLES as well as also the HORIZONTAL BAR GRAPH with the BAR GRAPH .

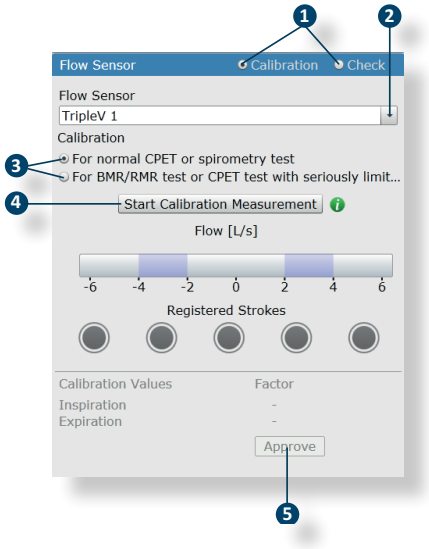


Fig. 11:
Calibrate the flow sensor

In the menu FLOW SENSOR first select the option button ⊙ CALIBRATION ❶ (➡Fig. 11). You can verify this value by clicking on the option button ⊙ CHECK. Then select in the selection menu under FLOW SENSOR ❷ the flow sensor that is mounted on the pump (e.g. Triple V1). By clicking on the appropriate option button ⊙ ❸ under CALIBRATION, you then define whether you want use the flow sensor for the spiroergometric test or the resting measurement (BMR/RMR-Test).

Now pick up the calibration pump (with the mounted flow sensor), click on [START CALIBRATION MEASUREMENT] and start pumping.

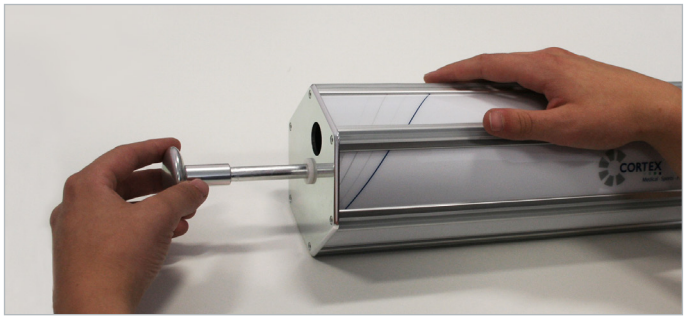


Fig. 12:
Pumping with the CORTEX calibration pump

NOTICE	Observe the calibration routines and warm-up times of the CORTEX spiroergometry device specified in chapter 1 (➡Tab. 01)!

MetaSoft® Studio recognizes automatically whether each pump cycle has been carried out correctly. You may possibly have to perform more than 5 pump cycles until the required strokes have been recognized.

Tips for pumping correctly:

- Make sure that you slide the pump piston evenly and continuously from one stop to the other.
- Carry out the pump cycles without pause and do not dwell at the stop of the pump.
- Make sure that the minimum and maximum pump strokes (at the pump stop) are within the violet-shaded area (chart display) (➡Fig. 13/Fig. 14).

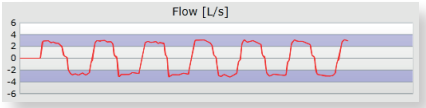


Fig. 13: Pump strokes in the flow time chart

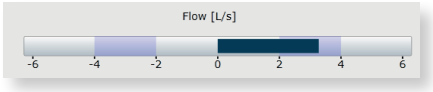


Fig. 14: Pump strokes in the horizontal bar graph

The flow sensor calibration stops automatically once all 5 required (pump) strokes have been completed, and you hear an acoustic signal (➡Fig. 15/Fig. 16).

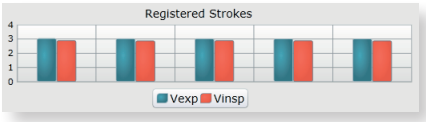


Fig. 15: 5 Registered strokes in the bar graph

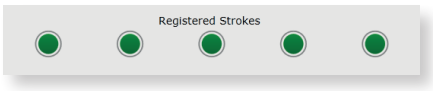


Fig. 16: 5 Registered strokes in the lines of circles

After successful flow sensor calibration the values for inspiration and expiration are displayed. Click on [APPROVE] ❺ (➡Fig. 11).

1.2.4 Gas sensor calibration

NOTICE	Observe the calibration routines and warm-up times of the CORTEX spiroergometry device specified in chapter 1 (➡Tab. 01)!

- **TIP!** Interactive step-by-step instructions are also available in the video tutorials. To do this, click in the Toolbox submenu in the lower right on the video symbol and then on [GAS SENSOR]. Alternatively you can open the video tutorial directly in MetaSoft® Studio.
- To do this, click in the Patient centre in the control bar (bottom) on CALIBRATE GAS SENSOR. The module for the calibration opens. Now click on the video symbol in the control bar .

Calibration setup

Required accessories (➡Tab. 02):
- CORTEX spiroergometry device
- Gas-on-demand valve (with hose piece)
- Adapter (for CORTEX sample gas bottle)
- Wrench (nominal size 22 mm)
- CORTEX sample gas bottle or third party calibration bottle
- Sample line
- Tube adapter and tube set (with calibration with third party gas)

Prepare gas-on-demand valve

NOTICE	Instead of the previous gas savers or the automatic gas calibrator only the gas-on-demand valve is now used for the gas sensor calibration!

Depending on the gas bottle used, you have to prepare the gas-on-demand valve for use.

1. Use of the CORTEX sample gas bottle

Now pick up the gas-on-demand valve, the adapter as well as the wrench (➡Fig. 17).
Screw the adapter on to the gas-on-demand valve and tighten it with the wrench (➡Fig. 18). Make sure that the two parts do not jam in the process!

NOTICE	Gas can escape if the gas-on-demand valve and the adapter are not connected correctly!

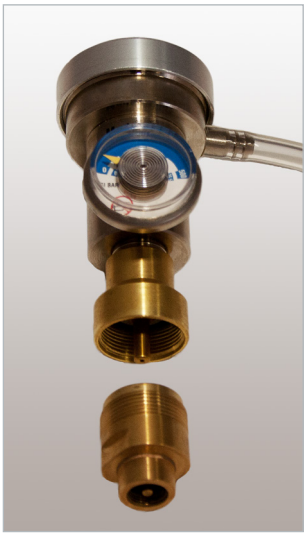


Fig. 17: Gas-on-demand-valve and adapter

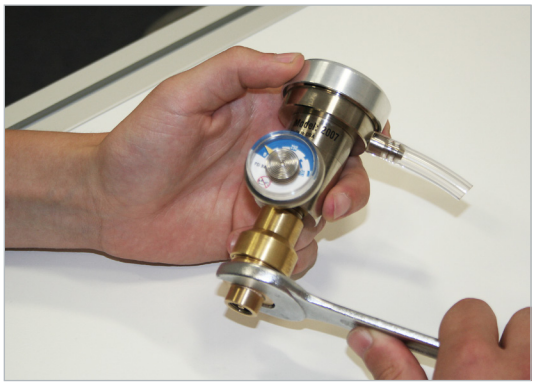


Fig. 18: Tighten adapter with wrench

Now pick up the CORTEX sample gas bottle and the gas-on-demand valve (with the adapter that was just screwed on). Place the CORTEX sample gas bottle on a flat surface and screw the adapter that is connected with the gas-on-demand valve carefully and straight on to the thread of the CORTEX sample gas bottle (➡Fig. 19) until you hear a brief, soft hissing.

Fig. 19: Screw the gas-on-demand valve on to the CORTEX sample gas bottle

Fig. 20: Readout on the pressure valve displays 12 bar or 250 PSI an.

NOTICE	The screw process can jam if not handled expertly. This can damage the thread, which can cause gas to escape! Leave the gas-on-demand valve and adapter screwed together after the first application, even if you want to remove the gas-on-demand valve from the sample gas bottle: The gas will empty into the sample gas bottle only if the adapter remains on the sample gas bottle!

If used correctly, the readout on the pressure valve will display 12 bar or just 250 PSI (➡Fig. 20).

Now just plug the end of the sample line into the tube piece on the gas-on-demand valve (➡Fig. 21).

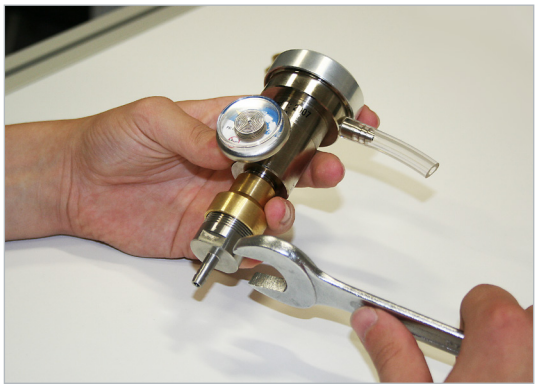
Fig. 21:
Connect sample line with the tube piece on the gas-on-demand valve

2. Use with third party calibration gas

If you are not using calibration gas by CORTEX you have to use a **tube adapter** (➡Tab. 02) for the connection of the gas-on-demand valve to your gas bottle. You can order it from your local CORTEX retail/service partner or directly from CORTEX under the **item no. 010 01 897**.

Now pick up the gas-on-demand valve. Screw the hose adapter on to the gas-on-demand valve. Tighten it then with the wrench (➡Fig. 22).

Fig. 22:
Screw the tube adapter together with the gas-on-demand valve



The tube adapter and tube delivered can be delivered to you already pre-assembled from the factory upon request. If this is not the case, plug the end of the tube into the tube adapter (➡Fig. 23):

Fig. 23:
Plug tube into tube adapter

NOTICE	The gas can escape later if tube adapter and gas-on-demand valve are not screwed together correctly!

Plug the other tube end firmly into the pressure reducing valve ❶ (➡Fig. 24) of your gas bottle.

Now open the gas bottle carefully. Then adjust the pre-pressure at the pressure reducing valve to a maximum of 1-2 bar:

Fig. 24:
Calibration setup
Gas sensor calibration

Now just plug the end of the sample line into the hose piece on the gas-on-demand valve (➡Fig. 24). Connect the other end of the sample line to your CORTEX spiroergometry device.

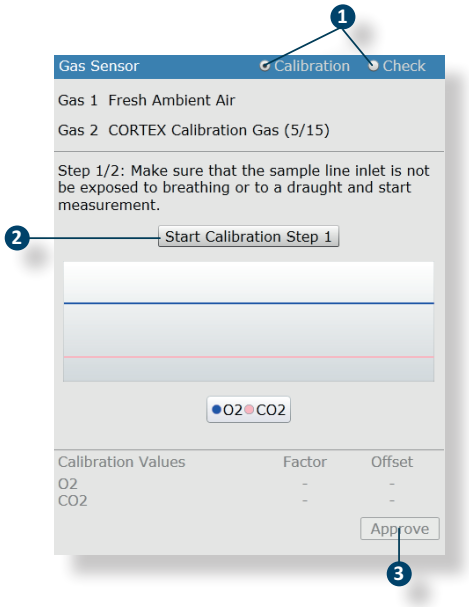
Perform gas sensor calibration

Now open the Toolbox submenu CALIBRATION/CALIBRATION.

NOTICE	Before you start the gas calibration you must have set up your calibration gases in the Toolbox submenu CALIBRATION/CALIBRATION GASES and set them to ACTIVE! Realize that you can only set 2 gases to active, where gas 1 has to already be reserved for “Fresh ambient air” (➡ch. 1.2.1)

You perform the gas calibration in 2 steps.

Fig. 25:
Gas sensor calibration step 1



Calibration step 1 | In the menu GAS SENSOR select the option button ⊙❶ CALIBRATION (➡Fig. 25) . You can verify the values by clicking on the option button CHECK .

Always perform the gas calibration with fresh air first. In that case “Fresh ambient air” must be set up as gas 1 (➡ch. 1.2.1).

NOTICE	Be certain that the sample line is not exposed to direct respiratory air or draft because the measurement results could otherwise be falsified! Prior to the calibration the room should be well ventilated with fresh air!

Clicking on [START CALIBRATION STEP 1] ❷ starts the calibration with the surrounding air. Wait until the calibration has finished; this takes about 2 minutes and is indicated by an acoustic signal.

Calibration step 2 | Clicking on [START CALIBRATION STEP 2] starts the calibration with the gas used set to “active” (e.g. CORTEX calibration gas). Wait until the calibration has finished; this takes about 2 minutes and is indicated by an acoustic signal.

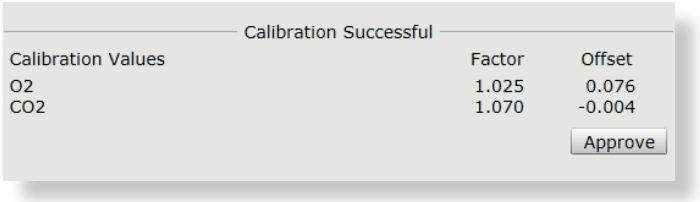


Fig. 26:
Gas sensor calibration successfully completed

Once the gas sensor calibration is complete, a window opens with the message: CALIBRATION SUCCESSFUL (➡Fig. 26)! The currently measured values (O_2 and CO_2) are displayed. To finish, click on [APPROVE].

You can [READ OUT], [EDIT], [TRANSFER] and [PRINT] the calibration values.

⊡ **TIP!** The reading out and editing of calibration values can for example be necessary if values from a faulty calibration were transferred to the device, and a previous state is to be reestablished.

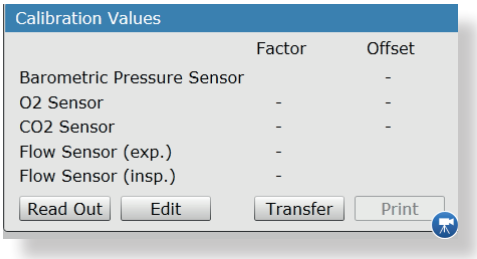


Fig. 27:
Edit calibration values

By clicking on [READ OUT] (➡Fig. 27) the calibration values currently stored in the device are transferred to MetaSoft® Studio so that you can manually modify or reenter them by clicking on [EDIT]. To store the new values in the device, click on [TRANSFER]. If you want to create a calibration protocol, click on [PRINT].

1.2.5 Calibration in MetaSoft® Studio

Instead of in the MetaSoft® Studio-Toolbox, you can also perform the calibration directly in MetaSoft® Studio. For this purpose there are each 2 buttons available in the control bar in the Patient Centre, as well as in the Test preparation module.

We recommend the later way because you can quickly set up configurations here in the software.

1.3 Cleaning and service

Exchanging the CORTEX sample gas bottle

The CORTEX sample gas bottle that came with the **"CORTEX Professional calibration set"** should be sufficient for about 15 gas sensor calibrations. The bottle is a single use item. Dispose of it through appropriate recycling centres once the gas is used up. You can reorder the sample gas bottle anytime at your CORTEX retail/service partner, or directly from CORTEX.

Cleaning and exchanging the hose set

If properly used, the tubes that are part of the **"CORTEX Professional calibration set"** do not have to be cleaned. Should they nonetheless become contaminated, clean them with distilled water and dry them at ambient temperature.

NOTICE	We recommend replacing the tubes every 12 months - at the latest, however, if they exhibit damage. For that reason inspect the tubes before every use!

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Legal notice