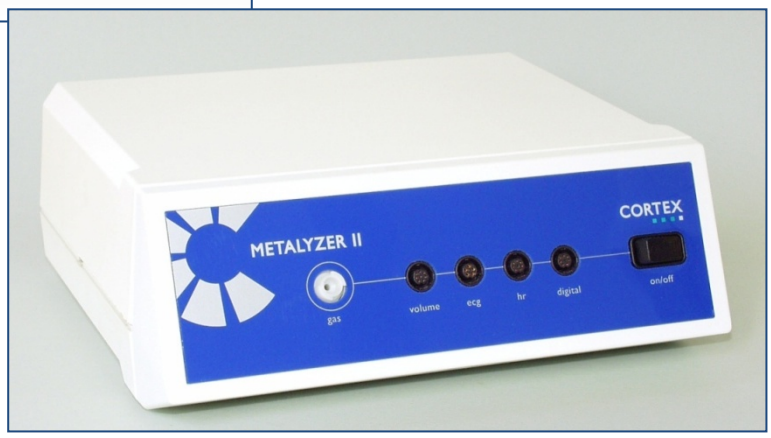
User Manual

MetaLyzer® 3B / MetaLyzer® II



CE 0124

Version ML 3B-R2 2.5.46 / ML II-R2 2.5.46
Manual Art.-No. 931-00-217 / Revision a / 2015-08-13

Dear User

We would like to thank you for putting your trust in us by purchasing our product.

This **Hardware Manual** contains comprehensive information about your equipment and describes how to set it up and use it properly, along with tips about hygiene and cleanliness.

The following documentation is also available for your Cardio Pulmonary Exercise Testing (CPET) system:

- **Installation Manual** - This explains the system requirements along with how to install and update the MetaSoft® software.
- **Software Manual** – This explains how to link devices and describes how to use and operate the MetaSoft® software.
- **Calibration Manual** – This provides a step-by-step guide to calibration so that you can ensure the measurements you perform with your system will be accurate.

We would be delighted to receive feedback from you as a user of the CORTEX system. Please do not hesitate to contact us with your comments and suggestions at any time.

Should you have any questions please contact your local CORTEX sales / service representative or get in touch with CORTEX directly.

We hope you enjoy using your system.

Your CORTEX Team

CORTEX Biophysik GmbH
Walter-Köhn-Str. 2d
04356 Leipzig
Germany

Tel. +49 (0)341 48 74 9-0
Fax +49 (0)341 48 74 9- 50

e-mail: info@cortex-medical.com
http://www.cortex-medical.com

Notation

Formatting attributes

Italics	Software / device responses
SMALL CAPS	Paths, windows, menus
BOLD CAPS	Buttons, keys, sockets
➲	Reference, link

Instructions

WARNING	Risk of life-threatening injuries and consequences which would be harmful to health
CAUTION	Material damage, consequences which would be harmful to health, injuries
NOTE	Functional restrictions
TIP	Recommendation

Table of Contents

1 Before you start

1.1 Introduction

This manual is intended for use with the following CORTEX products:

- **MetaLyzer® 3B - R2**
- **MetaLyzer® II - R2**
- **MetaSoft® Software**

It contains information about setting up and using your device.

Your MetaSoft® software manual describes how to use the MetaSoft® software in detail.

Please read all manuals associated with your product (see Page 2) carefully before starting to use your Cardio Pulmonary Exercise Testing (CPET) system. Should you have any questions please contact your local CORTEX sales / service representative or get in touch with CORTEX directly. Please keep this and your other manuals in a safe and easily accessible location.

1.2 Purpose of CORTEX CPET devices

CORTEX spiroergometry devices are used to perform cardio pulmonary exercise testing (CPET). During a CPET test a patient is subjected to a defined physical load over a period of 10-20 minutes. In that process measurement data of ventilation, gas exchance and heartrate are recorded and displayed.

For that the following precautions apply:

Only medically trained personal is permitted to perform a spiroergometry test (CPET) with CORTEX devices. It is not allowed to perform CPET tests with CORTEX devices in home environment. Furthermore CPET tests may be conducted only in enclosed spaces – with the exception of the mobile device MetaLyzer 3B, MetaLyzer 3 II and MetaLyzer X.

Before a load test a patient must be asked about his physical restrictions especially propensity to cardiovascular disease, hereditary diseases etc. Furthermore the patient has to be asked about medication he must take or he has taken in the past. The user bears the full responsibility for his decision if a patient is suitable to perform a CPET test.

The patient may perform a CPET test only with suitable clothing (which carries no risk of falling). Furthermore the patient should not have taken any alcohol or other stimulants themselves. Also, he shouldn't have eaten anything within the last 1.5 hours.

It is recommended to use CORTEX devices only with children from the age of 6 years. Against the use of CORTEX devices for younger children, there are no objections. In this case the user bears the special responsibility (e.g. special supervision).

With special attention to the burdens of pregnancy (e.g. avoid anaerobic exercise), the use of CORTEX devices is allowed with pregnant women. In this case the user bears the special responsibility.

1.3 Intended Use

CORTEX CPET devices may only be used in sense of its purpose. Every other use is not as intended and can cause damage for which the manufacturer accepts no liability. Only medical trained personal is allowed to use the CORTEX devices. Further the subsequently indications and contraindications must be observed. Intended use also includes the observance of the relevant instructions in the manuals with special attention to the safety instructions and all notes about hygiene and maintenence.

1.4 Indications

1. Internal medicine, general medicine, pediatrics, rehabilitation therapy and preventive medicine

    a) To define and analyze restrictions on maximum performance and maximum oxygen uptake in the case of a test subject who has dyspnea
    b) To control and monitor therapy, as well as to identify the benefit of a therapy (e.g. following rehab, balloon dilatation or a bypass operation)
    c) To identify shortcomings in general physical performance, to advise on possible changes to exercise and eating habits, to monitor and control the success of actions taken

2. Occupational medicine and assessment in the context of social medicine

    a) As a performance test in the context of an initial examination and subsequent monitoring tests in the field of occupational medicine, e.g. as would be appropriate for personnel working with breathing apparatus
    b) Assessment in the context of social medicine with regard to a reduction in ability to work or the issue of causality in relation to liability (circumstances giving rise to and the fulfillment of) in the case of pension claims submitted to an employers' liability insurance company

3. Sports medicine, occupational and performance physiology and flight and space medicine

    a) To identify performance levels and performance reserves

1.5 Contra-indications

Maximum Exercise Test and fat burning test

In these two tests, the test subject is exposed to physical stress. The following contra-indications are derived:

a) Cardiac insufficiency according to Study IV AHA, cardiac insufficiency at rest
b) Heart defects with pronounced right to left shunt
c) Pronounced pulmonary fibrosis
d) Pronounced chronic obstructive pulmonary disease and clear dyspnea at rest
e) Bronchial asthma with resistance > 1 kPa
f) Recent heart attack or stenocardia at rest
g) Recent embolism
h) Suspected myocarditis
i) Malignant hypertension
j) Serious (first degree) arrhythmia and AV blockages
k) First degree aortic stenosis
l) Known myocardial aneurysm
m) Acute infection (pneumonia, cholecystis, florid hepatitis, nephritis)
n) Acute thrombophlebitis

Side effects: Other than natural exhaustion and possible “muscle pain”, there are no other known side effects of exercise testing (maximum exercise test, fat burning test).
However, please be aware that the test subject ability to communicate with the physician or user will be restricted by wearing the mask and this can lead to subjective feelings of being under mental stress.

1.6 Safety instructions

Conditions of use

The electrical equipment installed in areas in which CPET systems are used must meet the requirements set out for medical areas (DIN VDE 0100 Part 710).

The device must always be kept in a dry and safe location (protected against dust, dirt, heat, cold and mechanical stress).

The system must not be operated in the vicinity of anesthetic compounds or other flammable gases (it is not a Class AP or APG device).

Requirements of personnel

Prior to operating the equipment, personnel must complete relevant training and read and understand the documentation included in the scope of supply.

The system must be operated by physicians and personnel who have completed training in medical engineering or sports science and are in possession of the requisite medical and medical engineering knowledge.

Safety of test subject

All non-medical equipment (e.g. monitors, PCs, etc.) must be located at least 1.5 m away from the test subject (see DIN EN 60601-1 und DIN EN 60601-1-1).

Before starting a test, check that the system is in full working condition. Defective parts must be replaced immediately. Should you have any questions please contact your local CORTEX sales / service representative or get in touch with CORTEX directly.

Although the mask is biocompatible, please check the test subject for skin redness / irritation and refrain from testing if necessary.

Ensure compliance with the cleaning and maintenance instructions set out in this manual.

Hygiene

Compliance with the hygiene and maintenance instructions set out in this manual is a prerequisite for the proper use of the system. The Triple V® volume sensor, the mask and the mask harness must be cleaned and disinfected prior to every test. The POLAR® transmitter belt must be cleaned for each test subject and disinfected if necessary.

Equipment safety

Defective or damaged parts, components or equipment must never be used and must be replaced immediately. The system must only be operated with the original desktop power supply included in the scope of supply (which has medical approval). Do not use any equipment housed in an open or damaged enclosure. The equipment must only be opened by individuals authorized to do so by CORTEX.

Mutual reactions

MetaLyzer® 3B and MetaLyzer® II meet the requirements of applicable electromagnetic compatibility (EMC) standards. This generally excludes mutual reactions with other devices. Strict compliance with the requirements of DIN EN 60601-1-1 is mandatory when using the system in conjunction or combination with other devices / systems.

Abnormally high electromagnetic sources can impair the equipment's function and functional reliability. You must follow the EMC instructions in the instructions for use for the other devices.

No other devices must be connected to multiple socket outlets (power strips) used to supply power to the CORTEX system. The maximum load on the multiple socket outlet must not

exceed 3500 W. Fit covers to the socket outlets. Multiple socket outlets must not be positioned on the floor or used with extension cables.

Accessories, add-on equipment, spare parts, consumables

The CPET system must only be used with accessories, add-on equipment, sensors and consumables supplied and approved by the manufacturer.
If you connect your own computer systems, bicycle ergometers and / or treadmills to the MetaLyzer® base system, it is your responsibility to ensure that this equipment meets the requirements of the standard for medical electrical equipment (DIN EN 60601-1 and DIN EN 60601-1-1). The bicycle ergometer and / or treadmill must be supported by the MetaSoft® software.
Do not add additional CORTEX equipment to the system cart (if you are using one) unless the corresponding mounts and brackets have been fitted. The system cart must not be expanded beyond the scope of supply available from CORTEX.

Computer and data security

Check your computer system regularly for viruses and shut your computer down properly in the event of error messages.
Backing up subject / test databases to an external data carrier (e.g. external disc drive, DVD…) on a daily basis will protect against data loss. We recommend that you back up your data prior to performing a software update.
A problem with your computer or a power failure could lead to all data being lost irretrievably!

Repairs

The CPET system and / or its component parts must only be repaired by an authorized CORTEX sales / service representative or by CORTEX directly. Repairs not carried out by authorized personnel can put personnel and test subjects at serious risk and CORTEX may invalidate the warranty / guarantee as a result.

Transport

CORTEX supplies the CPET system in a secure transport case with insert; this is to afford maximum protection to the equipment during transport. If the equipment has been exposed to temperatures below zero during transport, it must be acclimatized at room temperature for approx. 2 hours prior to being put into operation.

Disposal

Electrical and electronic equipment must not be disposed of in household waste. Consumers are obliged by law to take electrical and electronic equipment which has reached the end of its service life to designated public collection points or back to the point of sale. Specific requirements are set out by the applicable legislation in the country of use. Similarly, batteries must only be disposed of in designated containers.

Liability

CORTEX accepts no liability for damage caused by improper use and non-compliance with the instructions in the product documentation.

2 Technical specifications

2.1 MetaLyzer® basic device

MetaLyzer® 3B and MetaLyzer® II are stationary portable devices for CPET. MetaLyzer® 3B is a breath-by-breath device and MetaLyzer® II works in accordance with the mixing chamber measuring technique. Whilst the test subject is exercising on the bicycle ergometer or treadmill, both devices measure the levels of concentration of oxygen and carbon dioxide respired, along with ventilation and heart rate. The measured values obtained are transferred from the basic device to the PC, where they are analyzed using software.

2.1.1 Physical variables

Device	Size (L x W x H)	235 x 165 x 85 mm
	Weight	1110 g

2.1.2 Sensors

Volume sensor	Type	Triple V® Turbine, digital
	Range	0.05 - 20 L/s
	Resolution	7 mL
	Accuracy	± 2 %
	Resistance	≤ 0.1 kPA/L/s at 16 L/s
O_2 sensor	Type	Electrochemical cell
	Range	MetaLyzer® 3B: ≤ 25 vol%; MetaLyzer® II: ≤ 25 vol%;
	t_{90}:	MetaLyzer® 3B: 100 ms; MetaLyzer® II: 3 s
	Accuracy	0.1 vol%
CO_2 sensor	Type	ND infrared
	Range	0 - 13 vol%;
	t_{90}	100 ms
	Accuracy	0.1 vol%
Pressure sensor	Type	Silicon
	Range	500 - 1050 mbar
	Accuracy	1.8%
Heart rate	POLAR® heart rate monitor	

2.1.3 Ambient and usage conditions

Temperature	+10°C to +35°C
Humidity	0 - 99% (non-condensing)
Pressure	500 - 1050 mbar
Power supply	100 - 240 V AC, 50 - 60 Hz

2.1.4 Transport and storage

Transport

Temperature	-50°C to +70°C
Humidity	0 - 99% (non-condensing)
Pressure	400 - 1300 mbar

Storage

Temperature	+2°C to +30°C
Humidity	0 - 60% (non-condensing)
Pressure	400 - 1300 mbar

2.1.5 Device identification

This number indicates the device's year of manufacture.

2.2 Product safety

Directive	93/42/EEC: 14 June 1993
Standards	DIN EN 60601-1:1990 + A1:1993 + A2:1995 DIN EN 60601-1-1:2001 DIN EN 60601-1-2:2001 DIN EN 60601-1-4:1996 + A1:1999 DIN EN 14971:2007 DIN EN 980:2003 DIN EN 1041:1998
Conformity	Class II a (to 93/42/EEC; Annex IX)
Type	BF
Protection class	II
Degree of protection	IP 20

Not a Class AP/APG device. Suitable for continuous operation.

Safety instructions ➲ Chapter 1.6.
Disinfection instructions ➲ Chapter 7.

2.3 Quality management system

CORTEX operates successfully in accordance with a quality management system meeting the requirements of quality standards EN ISO 9001 and EN ISO 13485.

CE 0124 The device meets the requirements of Directive 93/42/EEC and can therefore bear the CE mark illustrated.

CORTEX is a member of the *Qualitätsring Medizinische Software* in Germany (an association of companies providing services and solutions for the medical sector).

3 MetaLyzer® basic device

3.1 View from the front

3.1.1 Tubing / cable connections and switches

Connection	Function
gas	Gas sample line connection
volume	Volume sensor connection
hr	Connection for Polar® heart rate monitor
ecg	Connection for ECG cable
digital	Digital interface for the connection of external devices
on/off	Switches the device on and off

3.2 View from the rear

3.2.1 Connections

Connection	Function
12 - 15 V/1.5 A DC	Connection for the external medical power supply
PC	Connection for the serial cable link to the PC
program	Download button to download the latest firmware

4 How to put the equipment into operation for the first time

Handling pin connectors and sockets

4.1 Handling electrical connectors and sockets

1. Turn the outer ring of the connector until the notch lines up with the groove.

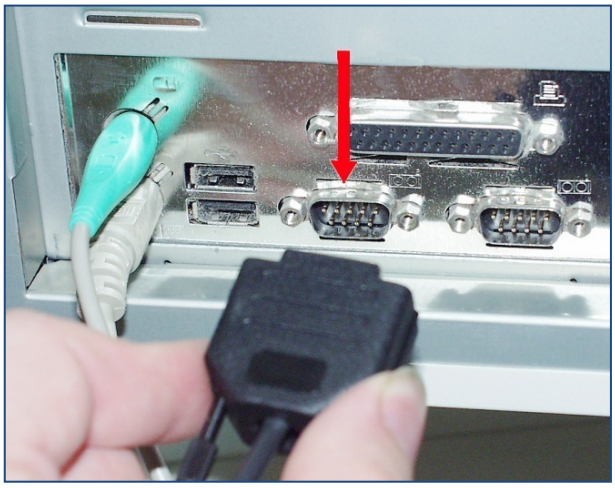
2. Then turn the connector so that the notch and groove on the connector line up exactly with those of the socket.

   CAUTION
   The connector must slide into the socket easily. If it does not, the plug-in connection might be damaged and must be repaired.

3. Turn the connector housing clockwise until it snaps into place.

PC connection cable

Connecting the PC connection cable to the device



Connecting the PC connection cable to the PC / Notebook

4.2 Connecting PC / Notebook

MetaLyzer® 3B / MetaLyzer® II is connected to a PC / Notebook using the connection cable included in the scope of supply.

1. Insert the small black connector on the PC connection cable into the **PC** port on the rear of the device (➲ Chapter 3.2).

CAUTION
The connector must slide into the socket easily. If it does not, the plug-in connection might be damaged and must be repaired.

2. Plug the serial connector on the PC connection cable into the serial port on your PC / Notebook.

Ergometer cable, serial

Connecting a workload device cable to a serial port

4.3 Connecting an bicycle ergometer / treadmill

The system supports the automatic control of numerous bicycle ergometers and treadmills.

1. Connect the workload device to the designated cable (serial cable). Follow the instructions issued by the manufacturer of the workload device.

2. Connect the other end of the serial cable to the serial port on your PC / Notebook.

NOTE
If your PC / Notebook only has one USB port, you will need to use a USB / serial cable adapter (Art.-No. 820-40-010).

Desktop power supply unit with mains cable

Connecting the power supply cable of the desktop power supply unit to the device

4.4 Mains connection

CAUTION
When connecting the mains power supply, please ensure compliance with the power supply specifications for operating conditions.

1. Connect the cable of the power supply desktop unit to your device (➲ Chapter 4.1).

   CAUTION
   The connector must slide into the socket easily. If it does not, the plug-in connection might be damaged and must be repaired.

2. Plug the mains power cable into the power supply desktop unit and the mains connector into the mains outlet.

WARNING
Only use the original desktop power supply unit included in the scope of supply to supply power to the device; this will protect your test subject against potential leakage currents.

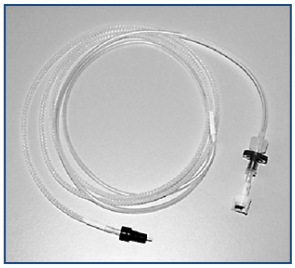
Triple® V volume sensor

Connecting the volume sensor

4.5 Connecting the volume sensor

Plug the connector on the Triple V® volume sensor into the **VOL** socket on the device (➲ Chapter 4.1).

CAUTION
The connector must slide into the socket easily. If it does not, the plug-in connection might be damaged and must be repaired.



Gas sample line

Connecting the sample line to the device

4.6 Connecting the gas sample line

CAUTION
The gas sample line must always be in perfect condition. A damaged gas sample line will interfere with the sensors.

Place the plastic connector of the gas sample line onto the **GAS** port on the front of the device and turn the connector clockwise until it snaps into place to secure it.

POLAR® receiver with cable

4.7 Connecting the POLAR® receiver to the device

Connecting the POLAR® receiver to the device

The POLAR® belt and receiver are the standard equipment used to measure heart rate.

Insert the black connector of the POLAR® receiver cable to the **HR** socket on the device (➲ Chapter 4.1).

CAUTION
The connector must slide into the socket easily. If it does not, the plug-in connection might be damaged and must be repaired.

Attaching the POLAR® receiver to the workload device

4.8 Attaching the POLAR® receiver to an bicycle ergometer / treadmill

Attach the POLAR® receiver to the bicycle ergometer / treadmill.

The front of the receiver must be pointing towards the HR belt worn by the test subject. For optimum data transmission between belt and receiver, the receiver and the belt must be kept between 60 and 80 cm apart.

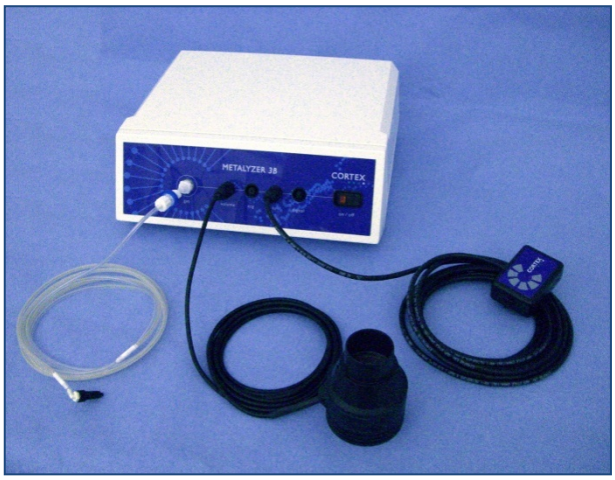
5 Getting ready for the test

This chapter will show you how to get ready to perform a test. Please refer to the software manual for information about preparing the software for testing.

5.1 Preparing the device

5.1.1 Calibrating the system

If you are using the device for the first time, all calibration routines (pressure, gas and volume calibration) will need to be completed. If you have previously used the device, you will simply need to complete a volume calibration routine prior to commencing the first test of the day (➲ Calibration Manual).



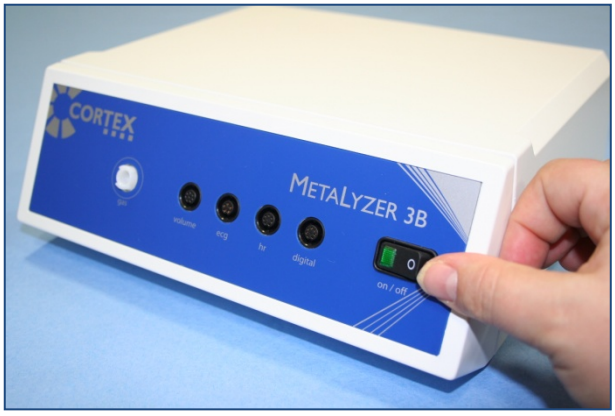
Checking the connections on the front of the device

5.1.2 Checking the connections

Prior to commencing testing, check that the following components have been connected correctly and are in perfect working condition:

- Volume sensor
- Gas sample line
- Polar® receiver cable
- Desktop power supply unit and mains cable
- PC connection cable

NOTE
We recommend only removing the gas sample line. The Triple V® volume sensor and the Polar® receiver cable only if you need to replace and / or clean them.



Switching the device on

5.1.3 Switching the device on

Switch your device on using the **ON/OFF** switch on the front panel.

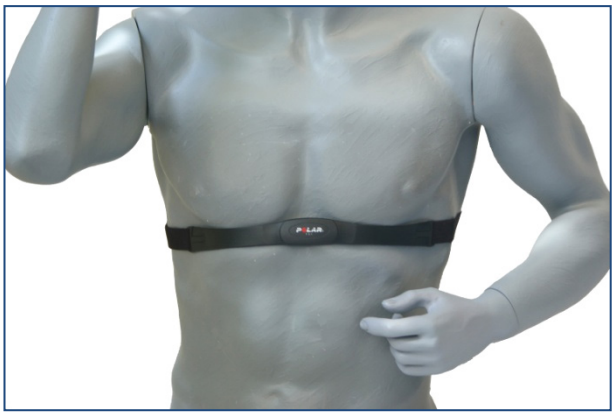
NOTE
Following power-up, the device will need at least 30 minutes to reach a stable operating temperature.

5.2 Preparing the test subject

Fastening the elastic strap on the POLAR® HR belt

5.2.1 Attaching the POLAR® HR belt

1. Fasten the elastic strap to the POLAR® HR belt.
2. For optimum skin contact, wet the grooved areas on the back of the POLAR® HR belt with a little electrode gel or water.



Fastening the Polar® HR belt to the chest

3. Fasten the POLAR® HR belt around the test subject's chest with the elastic strap as shown and fasten the other end of the elastic strap to the POLAR® HR belt as described above.
4. Adjust the elastic strap so that the POLAR® heart rate belt makes good contact with the skin.

Personal-Use Mask

Reusable Mask

5.2.2 Selecting a mask

1. Select a mask which is most likely to suit your test subject.
2. Press the mask gently onto the test subject's face and seal the opening with the palm of your hand.
3. Ask the test subject to breathe in and out against the mask. If air escapes to the sides of the mask, select a different size.

Fastening the lower and upper clips for the cap to the mask

Putting on the Reusable Mask and mask harness

5.2.3 Preparing the Reusable Mask by attaching the mask fasteners

1. Attach all four lower clips to the mask.
2. Attach the two upper clips of the mask harness to the mask clips.
3. Loosen the velcro straps slightly.
4. Once you have attached the clips as described above, place the mask over the test subject's head and position it onto the face.
5. Then fasten the lower clips of the mask harness to the mask.
6. Tighten the velcro straps so that the mask is sitting snugly and comfortably on the test subject's face.
7. Check that the mask is tight enough to prevent air escaping. To do this, press the palm of your hand onto the mask opening and ask the test subject to take shallow breaths in and out. If air escapes to the sides of the mask, tighten the velcro straps.
8. Now ask your test subject to take up the necessary position for testing.

Attaching the volume sensor to the mask

5.2.4 Attaching the volume sensor to the Reusable Mask

Insert the volume sensor into the designated opening of the mask. Do this by pulling the top section of the mask opening up with your thumb and index finger and inserting the volume sensor at an angle from below.

CAUTION
To prevent kinks, the connection for the gas sample line on the volume sensor should point upwards or 90° to the side. Never have the gas sample line pointing downwards!

TIP
You will find it easier to attach the volume sensor before fitting the mask to the test subject.

View from the front: Mask and mask fasteners

5.2.5 Preparing the Personal-Use Mask by attaching the mask harness

1. Loosen the elastic straps slightly.
2. Place the mask harness over the test subject's head.
3. Hold the mask over the test subject's face and slide the elastic strap of the mask harness under the tab at the bottom of the mask.
4. Slide the separate elastic strap under the tab at the top of the mask.
5. Fasten the separate elastic strap at the nape of the test subject's neck.
6. Tighten the elastic straps so that the mask is sitting snugly and comfortably on the test subject's face.
7. Now ask your test subject to take up the necessary position for testing.

Attaching the volume sensor to the mask

5.2.6 Attaching the volume sensor to the Personal-Use Mask

Insert the volume sensor into the designated opening in the mask. Do this by pulling the top section of the mask opening up with your thumb and index finger and inserting the volume sensor at an angle from below.

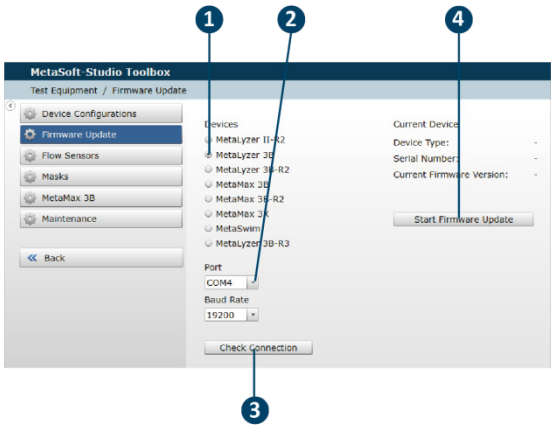
CAUTION
To prevent kinks, the connection for the gas sample line on the volume sensor should point upwards or 90° to the side. Never have the gas sample line pointing downwards!

TIP
You will find it easier to attach the volume sensor before fitting the mask to the test subject.

6 Firmware download

How to update your current firmware:

1. Connect your CPET device to the PC.
2. Switch your CPET device on.
3. Open the menu TEST EQUIPMENT / FIRMWARE UPDATE in the MetaSoft®Studio-Toolbox.



MetaSoft®Studio dialog: Firmware Update

MetaSoft firmware download: Pressing the program button

4. The MetaLyzer®3B device ❶ and the right port ❷ are automatically selected, if the MetaLyzer®3B device is connected and the device configuration is active.

   By clicking the Check Connection *button ❸ you can check, whether the right port is selected.*

5. Now click onto the Start Firmware Udate button ❹.

A message is diplayed, in which you will be prompted to put the device in the "download mode".

6. Switch out the device.
7. Press with a pen the **program** button on the device.
8. Turn on the device again, while pressing the **program** button.

   The device is now in download mode.

9. Click the OK button in the in MetaSoft®Studio displayed message.

   The progress of the download process will be displayed on the screen.

   The download process can take several minutes to complete.

7 Hygiene, maintenance & calibration routines

7.1 Introduction

This chapter contains requirements and instructions for cleaning, disinfecting and maintaining your device and its accessories. Compliance with the instructions outlined below is vital to long service life, reliable measurements and if any claims made under the terms of the warranty or guarantee are to be honored.

We recommend having your system inspected / serviced by your local CORTEX sales / service partner, or by CORTEX directly, **once a year**.

Please ask your local CORTEX sales / service partner, or contact CORTEX directly:

- For information about maintenance contracts
- If you think that parts might be defective or not in full working order
- If your system is defective
- If you need replacement parts and disposables

7.2 Cleaning, disinfection and maintenance intervals

Prior to every use

- Check the connection cable and the desktop power supply unit
- Check the tubings and tubing connections
- Check the housing incl. electrical connections and switches

On completion of every test

- Clean / disinfect the mask
- Clean the mask harness
- Clean and if necessary disinfect the POLAR® HR belt
- Clean the housing
- Check the connection cable and the desktop power supply unit
- Check the tubings and tubing connections
- Check the housing incl. electrical connections and switches

Every week

- Clean the housing

Every 6 months

- Replace the gas sample line

Every 12 months

- Device inspection (preventive maintenance)

Every 18 months

- Replace the oxygen sensor

7.3 Permissible cleaning and disinfection agents

We recommend using a mild ph-neutral cleaning agent to clean your system.
You can use standard household enzyme cleaners to remove protein deposits from the mask.
The following disinfectants have been tested and can be recommended for disinfecting the following parts:

- Metricide (Metrex Research Corp.) — Reusable Mask
- Gigasept® Instru AF (Schülke & Mayr GmbH) — All parts
- Descogen (Antiseptica chem. pharm. Produkte GmbH) — Volume sensor

7.4 Cleaning / Disinfecting the mask

The Reusable Mask comes into contact with the test subject and must be cleaned and disinfected immediately after every use.
The Personal-Use Mask and its harness are personal gear; in other words, each test subject has his or her own mask and harness. Both parts should be cleaned immediately after every use and can be disinfected if necessary. Test subjects usually clean their own gear.
The volume sensor needs to be removed before cleaning the mask.

TIP
To prevent saliva/sputum drying on the mask immediately after the test, soak the mask in water until it is cleaned / disinfected.

NOTE
Check the mask regularly for damage. If you find any evidence of damage, replace the mask.

1. Remove any heavy soiling with a damp sponge or cloth.

2. If necessary, soak the mask in a container of enzyme cleaner to shift protein deposits. Rinse the mask with clean water.

   CAUTION
   Follow the instructions provided by the manufacturer of the enzyme cleaner. Do not allow the mask to soak in the enzyme cleaner for more than 5 minutes (this is to avoid weakening and damage of the mask material).

3. Clean the mask thoroughly in warm water at a temperature of 20 – 45°C and using a mild pH-neutral cleaning agent. Rinse the mask out with clean water.

4. The Reusable Mask must be disinfected before every new test subject. We recommend disinfecting the Personal-Use Mask after every use.

   CAUTION
   Please follow the instructions for use and the warnings provided by the manufacturer of whichever disinfectant you are using. Rinse the mask out thoroughly following disinfection.

   For test subjects suffering from skin irritation, the re-useable mask can be disinfected using steam. The steam disinfection cycle must not exceed a temperature of 135°C and should last no longer than 15 minutes.

5. Dry the mask with a soft clean cloths and / or air.

7.5 Cleaning the mask harness

1. Clean the mask harness thoroughly in warm water at a temperature of 20 – 45°C and using a mild pH-neutral cleaning agent.

2. Rinse the mask harness out thoroughly in water.

3. Allow the mask harness to air-dry.

CAUTION
Check the mask harness regularly for damage. If you find any evidence of damage, replace the harness.

7.6 Cleaning the POLAR® belt

1. Rub the liquid (one of the cleaning or disinfecting agents listed above) onto the belt and in particular into the grooved areas on its rear.

   CAUTION
   During disinfection, please follow the instructions for use and the warnings issued by the manufacturer of whichever disinfectant you are using. Compliance with the instructions governing the strength of the disinfectant solution, its soaking temperature and soaking time is mandatory. The belt must be wiped off thoroughly following disinfection.

   CAUTION
   Liquid must never be allowed to flow into the belt as this could damage the electronics.

2. Clean the elastic strap thoroughly in warm water at a temperature of 20 – 45°C and using a mild pH-neutral cleaning agent.

3. Rinse the elastic strap out thoroughly in water.

4. Allow the elastic strap to air-dry.

7.7 Cleaning the device housing

1. Switch your device off and unplug it from the power supply.

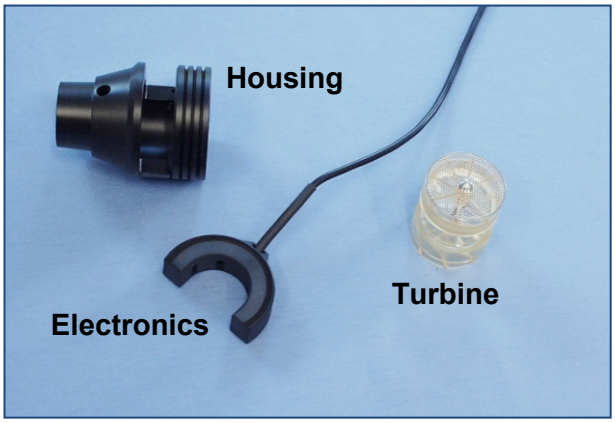
2. Detach all tubings and / or plug-in connectors from the device.

3. Using a cleaning agent approved for use in clinical applications or wet cloths, wipe the device clean.

CAUTION
Liquid must not be allowed to flow into the device (the electrical and tubing connections, as well as the switches, are at particular risk) as this could damage the electronics. If liquid does get into the device, you must have it checked by your local CORTEX sales / service partner, or directly by CORTEX, before putting it back into operation.

7.8 Cleaning / Disinfecting the volume sensor

The volume sensor must be cleaned and disinfected after every use. We recommend having spare volume sensors and turbines available should replacements be required. These can be purchased as accessories via your CORTEX sales / service partner or directly from CORTEX.



The components of the volume sensor

7.8.1 Dismantling the volume sensor

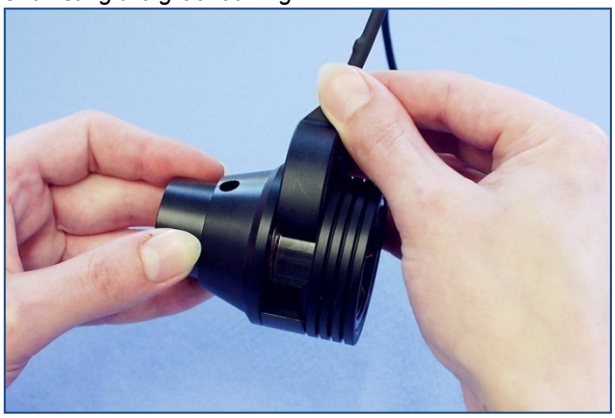
1. Remove the gas sample line from the volume sensor and then disconnect the sensor from the mask.

   The volume sensor comprises the following parts:

   - Housing
   - Turbine
   - Electronics with cable

2. Turn the grooved ring of the housing counterclockwise as far as it will go to detach the electronics.

Untwisting the grooved ring



Pulling out the electronics

3. Carefully pull the electronics out from the sensor housing.

Sliding the turbine out of the housing

4. Slide the turbine out carefully towards the wider opening of the housing.

5. Once you have dismantled the sensor, check the parts for mechanical damage (turbine, sieve, electronics housing, and cable connections).

7.8.2 Cleaning the volume sensor

1. Turbine:

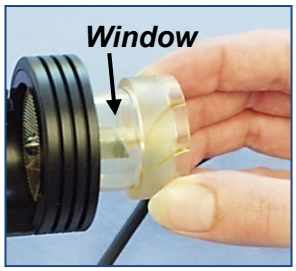
   - Rinse the turbine in warm distilled water (temperature no higher than 50°C).

     CAUTION
     Do not clean the turbine under running water as this will damage it.

   - Mix the components following the manufacturer's instructions and pour the solution into a suitably sized container.

   - Place the turbine fully into the disinfectant in order that its entire surface is disinfected. Cover the container whilst the turbine is soaking.

   - Rinse the turbine for at least a minute in water (distilled if possible) to remove any disinfectant residue.



   - The turbine is air-dried.

     CAUTION
     Do not use mechanical drying means (e.g. blow-dryer, paper or cloth) as these could introduce dust into the sensor.

     TIP
     The turbine can be used damp (only the window has to be dry).

2. Electronics:

   Should the electronics become soiled, they should only be wiped clean using a cleaning and disinfecting agent approved for use in clinical applications or disinfectant soaked cloths.

   CAUTION
   Moisture must not be allowed to get inside the housing.

3. Housing:

   Clean the housing using a mild pH-neutral cleaning agent in warm water (20 - 45°C), rinsing it thoroughly in clean water and allowing it to air-dry.

7.8.3 Assembling the volume sensor

The parts are assembled in reverse order. The side of the turbine with the sieve must point towards the mask adapter.

7.9 Inspecting the connection cable, connectors and housing

This inspection is carried out visually every time the device is powered up and checked for:

- Mechanical damage to cable insulation
- Breaks in cable / connectors
- Bent pins of plugs
- Mechanical damage to the housing

CAUTION
Defective parts must be replaced immediately. If you think that a part might be defect, please contact your local CORTEX sales / service partner or CORTEX directly.

7.10 Replacing the gas sample line

The gas sample line should be replaced every 6 months (based on standard use of 10 to 15 tests per week) as the drying characteristics in particular are prone to degradation.

CAUTION
The gas sample line must be replaced if it becomes discolored or blocked, or if it breaks. If you do not replace a line in this condition, condensate may accumulate in the sensors, causing damage and impairing measurement accuracy significantly.

Gas sample lines can be purchased via your CORTEX sales / service partner or directly from CORTEX.

7.11 Replacing the oxygen sensor

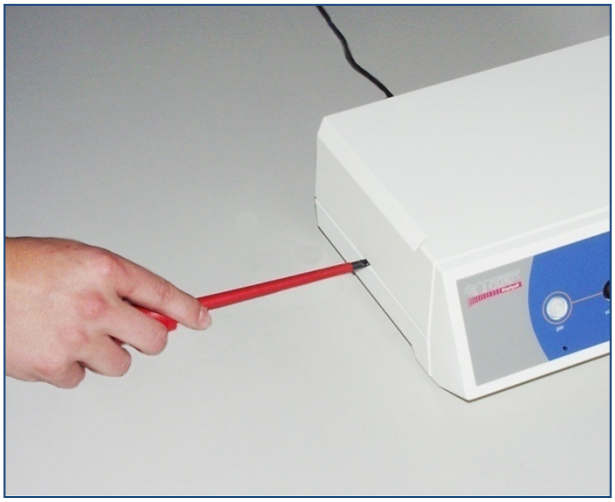
The oxygen sensor is an electrochemical cell which will need to be replaced approximately every 18 months. To exclude the possibility of incorrect measurements, the device is capable of self-diagnostics and will issue a warning via the software when the cell needs to be replaced.

For safety reasons, we recommend that you always have the oxygen sensor replaced by your local CORTEX sales / service partner or by CORTEX directly. If you wish to replace the sensor yourself, you must follow the instructions in this chapter.

7.11.1 Required accessories

- MetaLyzer 3B / MetaLyzer II oxygen sensor, sealed gas-tight
  Art.-No. 000-45-020

- Flathead screwdriver



Pushing the latches inward

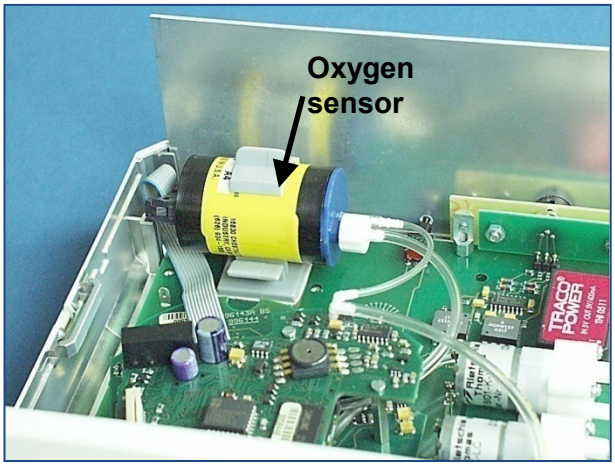
7.11.2 Removing the oxygen sensor

1. Switch your device off and unplug it from the power supply.

2. To open the device, use a flathead screwdriver to push the internal latches on the right and left-hand sides of the housing carefully inwards.

Opening the device housing

3. Carefully pull the top half of the housing up.



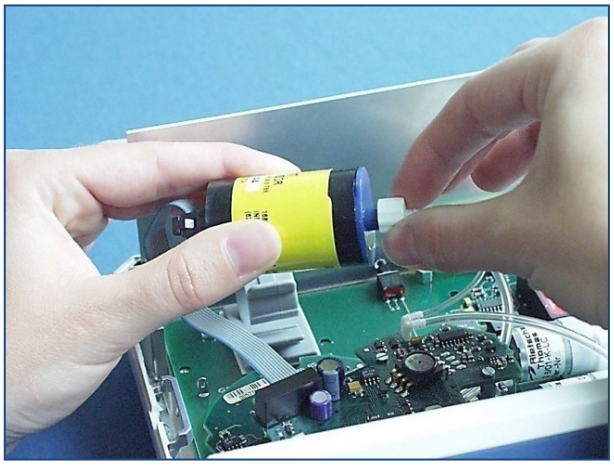
Position of the oxygen sensor in the device

Device with oxygen sensor following removal of the top half of the housing

Pulling out the oxygen sensor

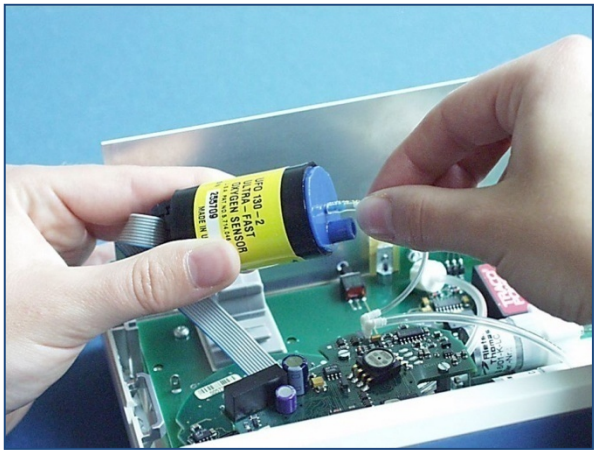
4. Start by removing the securing o-ring from the gray clamp holding the oxygen sensor (not illustrated here).

5. Then carefully pull the oxygen sensor out of the gray plastic clamp.



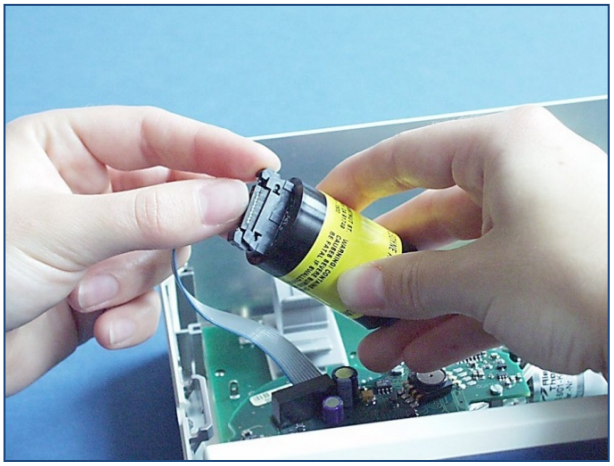
Unscrewing the tubing with the white screw cap

6. Unscrew the tubing with the white screw cap from the oxygen sensor.



Pulling the tubing without a screw cap

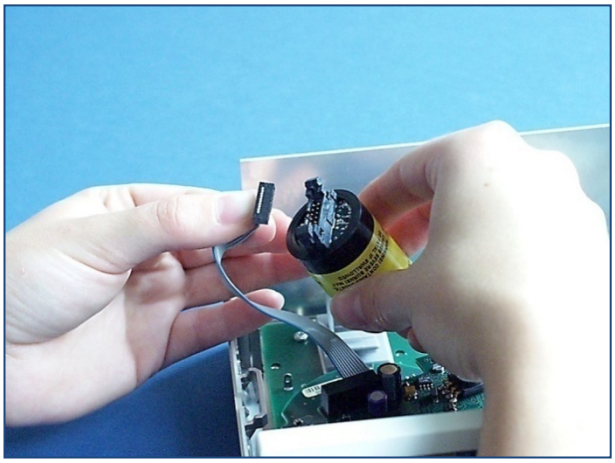
7. Pull the second tubing (without a screw cap) from the oxygen sensor.



Disconnecting the connector

8. To remove the connector from the oxygen sensor, push the interlocks on the left and right-hand sides of the black connector outwards.

9. Then pull the black connector off the oxygen sensor and lift the sensor out of the housing.

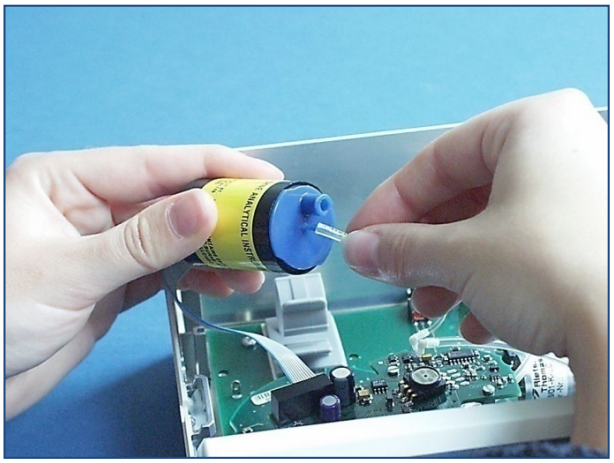


Reconnecting the electrical connector

7.11.3 Fitting the oxygen sensor

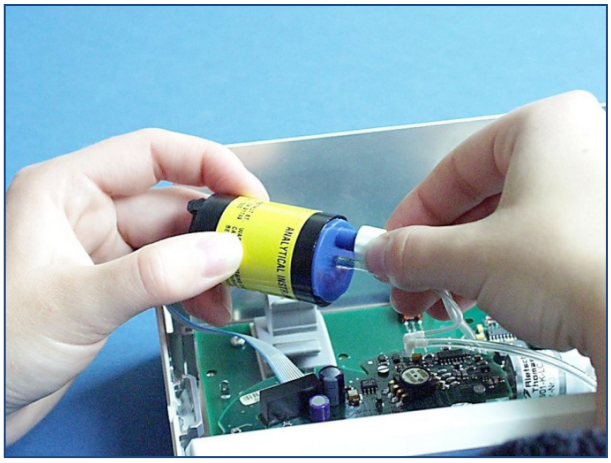
1. Plug the black connector into the socket on the oxygen sensor.

2. Close the latches on the left and right-hand sides of the connector (snap fitting).



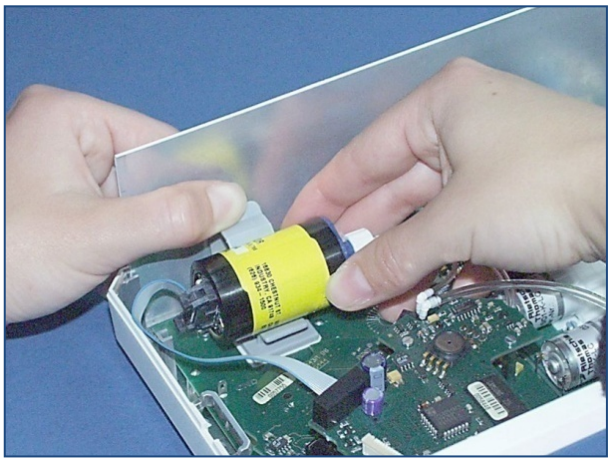
Connecting the tubing without a screw cap

3. Slide the tubing without a screw cap onto the oxygen sensor (small port). Check that the tubing is secure.



Hose with the white hose clamp

4. Screw the white screw cap of the second tubing tight to the larger port.



Fastening the oxygen sensor into place

5. Place the oxygen sensor back into the gray plastic clamp.

6. Then fit the o-ring to secure the oxygen sensor in the clamp and (the o-ring is not illustrated here).

Closing the device

7. Refit the top half of the housing to the device.

   CAUTION
   All tubings must be located inside the housing.

8. Then press down on the housing until you hear the two halves snap together.

NOTE
You will need to recalibrate the device after replacing the oxygen sensor (➲ Calibration guide).

7.12 Calibration routines

Please use your calibration guide to calibrate your MetaLyzer®.

NOTE
These calibration routines are only valid under stable operating conditions; in other words, if ambient conditions only change slightly between measurements.

	Calibration routine
Pressure sensor	Compare with ambient pressure every 6 months Recalibrate in the event of deviations in excess of 10 mbar
Volume sensor	At least once daily prior to the first test of the day or Whenever the turbine is replaced
Gas sensors (O_2 and CO_2)	At least once a month or • Prior to commencing a major series of measurements • Whenever accuracy requirements increase • Whenever the oxygen sensor is replaced • Whenever the pressure is calibrated

8 Possible errors and troubleshooting techniques

In the event of an error, your first source of information should always be this manual. Please refer to the instructions for troubleshooting in the other manuals and guides supplied with your products. If the error is not listed or if you are not able to rectify the fault, please contact your local CORTEX sales / service partner or CORTEX directly.

CAUTION
Do not try to repair defective parts yourself; this will invalidate their warranty!

Problem	Cause	Action
Device will not power up	Desktop power supply and / or power supply cables not connected correctly.	Check plug connectors in socket, appliance connector and device.
Condensate water is appearing in the gas sample line.	Gas sample line deteriorated.	Stop the test and shut down the device to avoid a total failure. Replace the gas sample line. Power up the device and let it run for approx. 5 hours under normal conditions (approx. 20 - 25°C and less than 60% humidity).
Oxygen uptake (V'O2) values are too low.	The gas sample line is blocked or leaking.	Replace the gas sample line. Art.-No. 220-02-003
	Incorrect calibration.	Perform calibration.
	Mask not tight.	Check tightness of mask.
All values are equal to 0 and breath detection has stopped.	The volume sensor electronics is defective.	Replace the electronic unit of the volume sensor. Art.-No. 200-01-009 or Send the defective electronic unit in for repairs.
	The turbine is defective.	Replace the volume sensor's turbine. Art.-No. 010-15-049
All values are deviating.	The mask is not tight.	Tighten the velcro straps of the mask harness.
	The wrong sized mask has been selected.	Select a suitable mask.

Problem	Cause	Action
No heart rate is showing.	The POLAR® heart rate chest belt has not been fitted correctly.	Tighten the elastic strap of the POLAR® heart rate chest belt or moisten the grooved areas on its rear with a little water or electrode gel.
	The POLAR® receiver is too far away from the POLAR heart rate chest belt.	Make sure that the receiver and the chest belt are located between 60 and 80 cm apart.
Software error messages		
Volume sensor defective or not connected.	Volume sensor has not been connected to device correctly.	Check the connection of the volume sensor cable. Check the cable and the contact pins for mechanical damage.
O_2 measurement has failed.	The O_2 sensor is deteriorated or the electronics has failed.	Replace the O_2 sensor.
The O_2 sensor is worn out.	O_2 sensor deteriorated.	Replace the O_2 sensor.
Condensate water is appearing in the gas sample line.	Nafion tubing is deteriorated.	Stop the test immediately and shut down the device. Replace the gas sample line. Power up the device and let it run for approx. 5 hours at 20 – 25°C and less than 60% humidity. Perform a two-point gas calibration routine prior to commencing the next test.
The ventilation values measured deviate significantly from the expected values.	Volume sensor has not been calibrated correctly.	Recalibrate the volume sensor.
	The volume sensor's turbine has sustained mechanical damage.	Replace the volume sensor.
	The volume sensor's turbine has become soiled.	Clean the turbine following the maintenance instructions in this manual.
Ventilation values are plausible but the V'O_2 or V'CO_2 values are zero or close to zero.	Gas sample line is not connected to the volume sensor.	Connect the gas sample line.

Problem	Cause	Action
Software error messages		
The gas values (V'O_2, V'CO_2, RER) measured deviate significantly from the expected values.	Zero point calibration has been carried out incorrectly or not at all.	Perform a zero point calibration routine.
	Gas sensors have not been calibrated correctly.	Perform a gas calibration routine.
	Gas sample line is leaking.	Replace the gas sample line.
Problems affecting zero point calibration		
Instable measured values during zero point calibration (measurement runs continuously and does not stop)	Breathing air interfering with gas sample line.	Make sure that the free end of the gas sample line is pulling unused fresh air during zero point calibration.
Measured values are stable but deviate significantly from standard values (e.g. 20.93% O_2 or 0.03% CO_2).	A gas calibration routine has not been performed recently enough.	Perform a gas calibration routine.
	O_2 sensor is deteriorated.	Replace the O_2 sensor.

9 Appendices

Appendix 1: Guidance and manufacturer's declaration to EMI

Appendix 2: System expansions and accessories

Appendix 3: Declarations of conformity

Appendix 4: Quality assurance certificates

Appendix 5: Quality assurance system certificate

9.1 Appendix 1: Guidance and manufacturer's declaration of EMI

Guidance and manufacturer's declaration – electromagnetic immunity		
The MetaLyzer 3B/II is intended for use in the eletromagnetic environment specified below. The customer or the user of the MetaLyzer 3B/II should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The MetaLyzer 3B/II use electromagnetic energy only for internal function. Therefore is the eletromagnetic emission very low and it is improbable, that devices in the neighbouring are influenced.
RF emissions CISPR 11	Class B	The MetaLyzer 3B/IIis suitable for use in all establishments include domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration – electromagnetic immunity			
The MetaLyzer 3B/II is intended for use in the electromagnetic environment specified below. The customer or the user of the MetaLyzer 3B/IIshould assure that it is used in such an environment. Disturbances because of a bad public power supply network cause, arise only in stationary mode of the MetaLyzer 3B/IIwithout internal battery.			
Immunity test	**IEC 60601 Test Level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±1 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV differntial mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5s	<5% U_T (>95% dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5s	By short voltage fluctuations or flicker emissions there is no changing of the measuring status.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	2 A/m	Influences of the supply frequency are nearly eleminated by the monitoring software with special filter technology.
Note: U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The MetaLyzer 3B/II is intended for use in the electromagnetic environment specified below. The customer or the user of the MetaLyzer 3B/II should assure that it is used in such an environment.			
Immunity test	**IEC 60601 Test Level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2,5 GHz	2 Vrms 2 V/m 80 MHz up to 1 GHz	Portable and mobile RF communi-cations equipment should be used no closer to any part of the MetaLyzer 3B/II, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** d = 1,2 √ P d = 1,2 √ P 80 MHz bis 800 MHz d = 2,3 √ P 800 MHz bis 2,5 GHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manu- facturer and *d* is the recommended separation distance in metres (m). Field strengths from fixed RF trans-mitters, as determined by an electro-magnetic site survey, a) should be less than the compliance level in each fre- quency range. b) Interference may occur in the vicinity of equipment marked with the following symbol: 
Note 1: At 80 MHz and 800 MHz, the higher frequency range applies. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the MetaLyzer 3B/IIis used exceeds the applicable RF compliance level above, the MetaLyzer 3B/IIshould be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the MetaLyzer 3B/II. b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Recommended separation distances between portable and mobile RF communications equipment and the MetaLyzer 3B/II

The MetaLyzer 3B/II is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the MetaLyzer 3B/II can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the MetaLyzer 3B/II as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter **W**	**Separation distance according to frequency of transmitter** **m**		
	150 kHz bis 80 MHz d = 1,2 √ P	**80 MHz bis 800 MHz** d = 1,2 √ P	**800 MHz bis 2,5 GHz** d = 2,3 √ P
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: To calculate of the recommend safety distance from transmitters in a frequency range from 80 MHz up to 2,5 GHz is an additional factor of 10/3 used, to reduce the probability that an unintentional inserted mobile/portable communicator device in the patient area take interferences.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and
reflection from structures, objects and people.

9.2 Appendix 2: System expansions and accessories

System options and accessories are available to expand the functional scope of your MetaLyzer® system. Please refer to your software manual for information about MetaSoft® software options.
Please address enquiries about general system accessories and replacement parts to your local CORTEX sales / service partner or to CORTEX directly.

System options	Description	Art.-No.
3-channel monitoring ECG (for MetaLyzer® 3B only)	ECG module for the recording and online display of ECG curves as well as heart rate during CPET. Uses Einthoven I-III leads.	670-01-003
CardioLyzer Ultra	PC-based 12-channel ECG for rest and stress ECGs with automatic control of workload device and blood pressure via the MetaSoft® software.	420-01-980
CBP 2000; Mobile blood pressure system	Mobile blood pressure system for measuring blood pressure automatically or manually (for mobile measurements with telemetric data transmission only).	650-01-990
Ipod External SpO2 module	Pulse oximeter and sensor in an all-in-one system - easy to use	671-01-001
Xpod External SpO2 module	This external oximetry module is easy to connect and comes complete with a wide range of ready-to-use sensors.	671-01-002
	Xpod ear clip option	671-01-007
	Xpod finger clip option	671-01-006
	Xpod forehead sensor option (incl. 10 caps and 20 stickers)	671-01-009
Calibration kit “Professional”	A high-quality calibration kit for calibrating pressure, gas and volume sensors. Comes complete with the assurance of optimum performance and measurement quality expected of CORTEX systems.	010-01-993
Calibration kit “Auto”	A high-quality calibration kit for calibrating pressure, gas and volume sensors (automatic gas calibration). Comes complete with the assurance of optimum performance and measurement quality expected of CORTEX systems.	010-01-995
Transport case for calibration kit	Transport case with insert (suitable for both calibration kits)	010-01-037

9.3 Appendix 3: MetaLyzer® 3B declaration of conformity

CORTEX
Medical · Sports · Fitness

DECLARATION OF CONFORMITY

Manufacturer **CORTEX Biophysik GmbH**
Walter – Köhn – Str. 2 d
D-04356 Leipzig
Germany

Product **METALYZER® 3B**

We declare in sole responsibility that the product named above complies with the following directives and standards:

Directives	**Issue / Issue Date**
93/42/EEC	05. September 2007
Standards	**Issue / Issue Date**
DIN EN 60601-1	2007
DIN EN 60601-1-2	2007

Additional Product Information

Class of Product: (in accordance with 93/42/EEC, Annex IX)	II a
Conformity Assessment Procedure:	93/42/EEC, Annex II
UMDNS Code / GMDN Code:	17-474 / 36146

Quality Management System

Quality Assurance System:	Directive 93/42/EEC, Annex II
Notified Body (Company / Identification Number, Address):	DEKRA Certification GmbH / 0124 Handwerkstr. 15, D-70565 Stuttgart, Germany

Validity

Serial No.:	ML3 947QYY0V – ML3 999QYY0V [nnn=sequential no.(inverse numbering: 947=749th device); Q=Quarter; YY=Year; V=Version)
until:	31. May 2013

Leipzig, 31. May 2012

Dr. Ralf Henker
Managing Director

Dr. Jürgen Kölner
Safety Officer for Medical Devices

Appendix 3 (continued): MetaLyzer® II declaration of conformity

CORTEX
Medical · Sports · Fitness

DECLARATION OF CONFORMITY

Manufacturer CORTEX Biophysik GmbH
Walter – Köhn – Str. 2 d
D-04356 Leipzig
Germany

Product METALYZER® II

We declare in sole responsibility that the product named above complies with the following directives and standards:

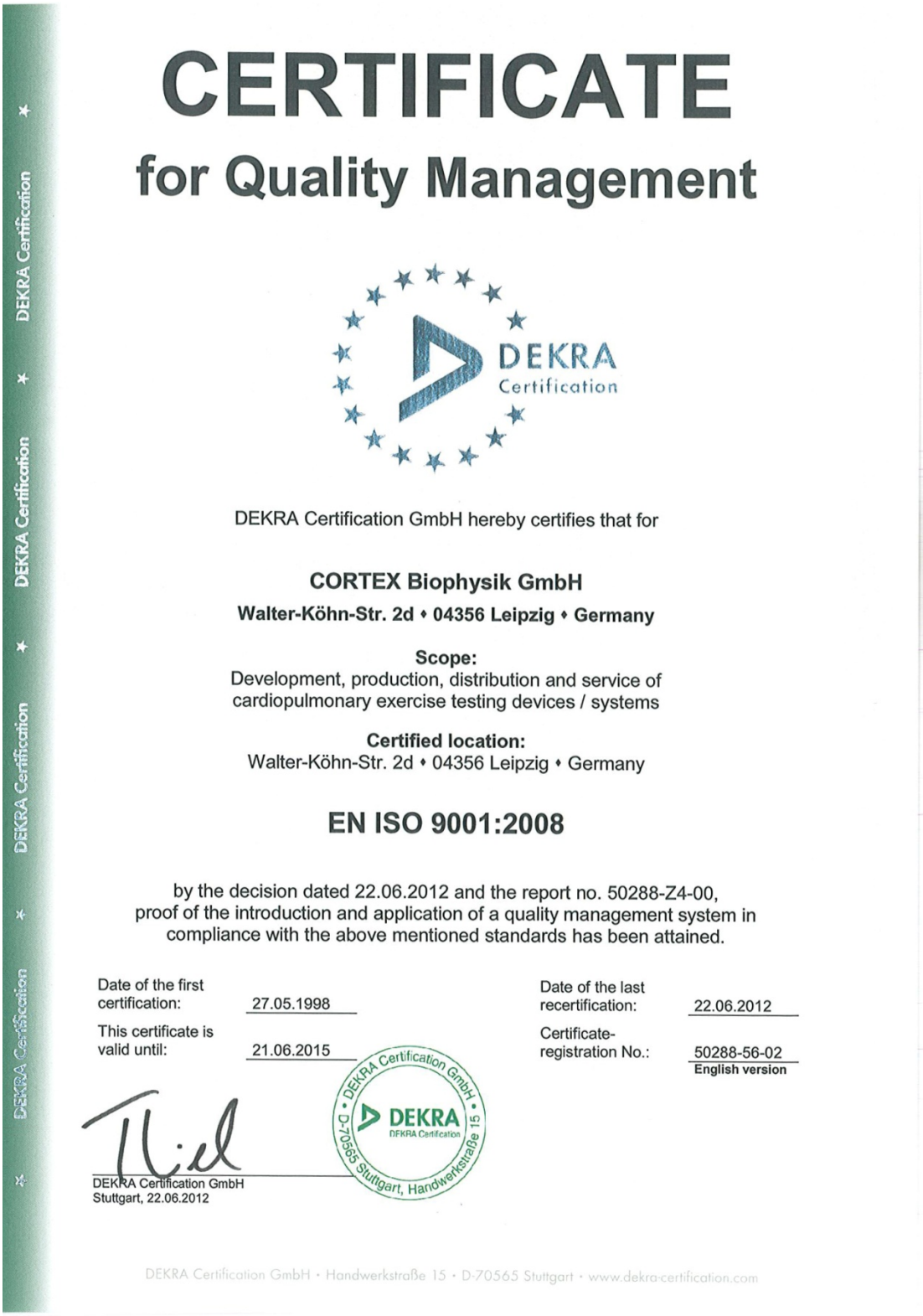
Directives	**Issue / Issue Date**
93/42/EEC	05. September 2007
Standards	**Issue / Issue Date**
DIN EN 60601-1	2007
DIN EN 60601-1-2	2007
Additional Product Information	
Class of Product: (in accordance with 93/42/EEC; Annex IX)	II a
Conformity Assessment Procedure:	93/42/EEC, Annex II
UMDNS Code / GMDN Code:	17-474 / 36146
Quality Management System	
Quality Assurance System:	Directive 93/42/EEC, Annex II
Notified Body (Company / Identification Number, Address):	DEKRA Certification GmbH / 0124 Handwerkstr. 15, D-70565 Stuttgart, Germany
Validity	
Serial No.:	ML 032QYYVV – ML 005QYYVV [nnn=sequential no.(inverse numbering: 032=230th device); Q=Quarter; YY=Year; VV=Version)
until:	31. May 2013

Leipzig, 31. May 2012

Dr. Ralf Henker
Managing Director

Dr. Jürgen Köllner
Safety Officer for Medical Devices

9.4 Appendix 4: Quality assurance certificates



DEKRA Certification

DEKRA Certification

DEKRA Certification

DEKRA Certification

DEKRA Certification

CERTIFICATE

for Quality Management

DEKRA Certification

DEKRA Certification GmbH hereby certifies that for

CORTEX Biophysik GmbH

Walter-Köhn-Str. 2d • 04356 Leipzig • Germany

Scope:
Development, production, distribution and service of cardiopulmonary exercise testing devices / systems

Certified location:
Walter-Köhn-Str. 2d • 04356 Leipzig • Germany

EN ISO 9001:2008

by the decision dated 22.06.2012 and the report no. 50288-Z4-00, proof of the introduction and application of a quality management system in compliance with the above mentioned standards has been attained.

Date of the first certification:	27.05.1998	Date of the last recertification:	22.06.2012
This certificate is valid until:	21.06.2015	Certificate-registration No.:	50288-56-02 English version

DEKRA Certification GmbH
Stuttgart, 22.06.2012

DEKRA Certification GmbH • Handwerkstraße 15 • D-70565 Stuttgart • www.dekra-certification.com

Appendix 4: Quality assurance certificates (continued)

DEKRA Certification

DEKRA Certification

DEKRA Certification

DEKRA Certification

CERTIFICATE

for Quality Management

DEKRA Certification

DEKRA Certification GmbH hereby certifies that for

CORTEX Biophysik GmbH

Walter-Köhn-Str. 2d • 04356 Leipzig • Germany

Scope:
Development, production, distribution and service of cardiopulmonary exercise testing devices / systems

Certified location:
Walter-Köhn-Str. 2d • 04356 Leipzig • Germany

EN ISO 13485:2003 + AC:2009

by the decision dated 22.06.2012 and the report no. 50288-Z4-00, proof of the introduction and application of a quality management system in compliance with the above mentioned standards has been attained.

Date of the first certification: 27.05.2003

This certificate is valid until: 21.06.2015

Date of the last recertification: 22.06.2012

Certificate-registration No.: 50288-08-01
English version

DEKRA Certification GmbH • D-70565 Stuttgart, Handwerkstraße 15 • DEKRA Certification

Akkreditiert durch
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
ZLG-ZQ-992.00.02-46

DEKRA Certification GmbH
Stuttgart, 22.06.2012

DEKRA Certification GmbH • Handwerkstraße 15 • D-70565 Stuttgart • www.dekra-certification.com

9.5 Appendix 5: Quality assurance system certificate

DEKRA Certification

DEKRA Certification

DEKRA Certification

DEKRA Certification

EC Certificate

For the Quality Assurance System according the directive 93/42/EEC, Annex II excluding section (4)

DEKRA Certification

As a notified body of the European Union, DEKRA Certification GmbH certifies, that the company

CORTEX Biophysik GmbH

Walter-Köhn-Str. 2d • 04356 Leipzig , Germany

applies a quality assurance system for the medical devices listed in the annex according to the directive 93/42/EEC annex II. The approval is based on the result of the re-certification audit report no. 50288-Z4-00, the decision dated 22.06.2012 and is only valid in connection with the successful performance of the annual surveillance audits.

Date of the first certification:	27.05.1998	Date of the last recertification:	22.06.2012
This certificate is valid until:	21.06.2015	Certificates registration No.:	50288-16-04 English version

DEKRA Certification GmbH • D-70565 Stuttgart, Handwerkstraße 15 • DEKRA DEKRA Certification

ZLG

Akkreditiert durch
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
ZLG-ZQ-992.94.16

Stuttgart, 22.06.2012
DEKRA Certification GmbH
Handwerkstraße 15, 70565 Stuttgart, Germany
Notified Body ID-number: 0124

DEKRA Certification GmbH • Handwerkstraße 15 • D-70565 Stuttgart • www.dekra-certification.com

10 Index

11 Trademarks

MetaLyzer and MetaSoft are registered trademarks of CORTEX Biophysik GmbH.

Microsoft and Windows are registered trademarks of the Microsoft Corporation.

Polar is a registered trademark of Polar.

Metricide is a registered trademark of Metrex Research.

Gigasept Instru AF is a registered trademark of Schülke & Mayr.

Descogen is a registered trademark of Antiseptica chem. pharm. Produkte.

Other trademarks are registered trademarks belonging to the relevant organizations or companies.

12 Legal notice

The information in this manual is subject to change at any time without prior notice.

CORTEX Biophysik GmbH (CORTEX) can provide no guarantee that the information made available in this document is complete, correct and up to date in every aspect. CORTEX reserves the right to change or expand the design and specifications without prior notice.

CORTEX will under no circumstances accept liability for actual, direct and indirect damage or damage caused by inability of use, data loss or possible loss of profit (whether due to non-compliance with contractual obligations, negligence or other impermissible conduct) as a result of the use of information and / or the delivery of products or the provision of services made accessible by this manual.

Photos, images and screenshots have been included solely for the purpose of illustration.

13 How to reach CORTEX

Via e-mail

Technical Support	support@cortex-medical.com
Product information	sales@cortex-medical.com

On the Internet http://www.cortex-medical.com

Via telephone and fax

Tel. +49 341 4 87 49-0
Fax +49 341 4 87 49-50

By mail

CORTEX Biophysik GmbH
Walter-Köhn-Str. 2d
04356 Leipzig
Germany

Your local CORTEX sales / service partner

We would like to wish you every success with your system.

Notes