PowerCube-Ergo Cardiopulmonary function testing

<u>Service Manual</u> <u>Ref.No. 03 140 0 046, rev.02</u> <u>Valid for PowerCube-Ergo-SSO / CASE</u>

- ENGLISH -

GANSHORN MEDIZIN ELECTRONIC



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Warranty

Only original GANSHORN parts may be utilized that have been listed in this documentation and in complementary documentation and that have been inspected and approved by GANSHORN. If non-original parts are used in GANSHORN devices, GANSHORN does not guarantee the safe operation and functioning of its products. In that case, the GANSHORN guarantee expires. No guarantee claims can be made in the case of damage resulting from utilization of non-original parts in GANSHORN devices.

GANSHORN regards itself as responsible for its products concerning safety, reliability, precision, and function only if:

- Assembly, installation, expansion, modification, adjustment, changes, and repairs have been carried out by GANSHORN or authorized GANSHORN partners
- The GANSHORN product has been employed in accordance with the operator instructions
- The GANSHORN product has been employed in accordance with the intended use.

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GANSHORN does not guarantee the flawless functionality of GANSHORN software programs in connection with any external software programs, and does not accept liability for malfunctions and/or their consequences.

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Copyright

All rights are reserved and retained by the manufacturer for products, circuits, processes, software programs, names, trademarks, and patents.

Documentation

Ref.No.	03 140 0 046
Valid for.:	PowerCube-Ergo-SSO, Ref.No. 03 337 0 210 and 03 337 0 238, Rev. D and higher
Related documents:	 Operating Instruction manual LF8 Operating Instruction manual PowerCube-Ergo

Copyright

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Revision history

Release date: 11 February 2009	Release number: Release 01/2009 Index a	Comment: Initial release
09 March 2009	Release 01/2009 Index b	Preface, modification of front cover
07 October 2009	Rev.01	Change of the release number Change of the ref. number system Revision of the English translation Modifications to REV.D (board layouts chapter 4) Modifications to Installation Assistant (chapter 5) Update Appendix B and D
23 November 2012	Rev 02	Update of the rear and front panels of the PowerCube according to IEC 60601-1 3 rd Edition and review of contents

The release number changes with every update for this documentation

General Notes

All GANSHORN documents correspond to the state of the underlying safety standards at the time of printing.

All illustrations in this documentation are provided as examples only. They may not necessarily reflect your equipment setup or data displayed. All pictured GANSHORN products and screen displays can deviate, due to technical changes.

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Update

This documentation is also regularly reviewed. Changes, technical improvements, as well as any typographical errors are taken into consideration in each following issue.

Technical changes/modifications made on the devices after the issue date are not contained in this documentation.

Changes/modifications performed on GANSHORN products that affect the hardware and software must be documented in a Medical Device Book.

The operator must be accordingly trained concerning the changes/modifications. This must subsequently be documented in the Medical Device Book.

In the case of non-observance, the manufacturer is not liable.

Intended Use, Documentation Purpose, Target Group and Safekeeping

System Description

The PowerCube-Ergo is a software-driven, cardio-pulmonary exercise system providing breath-by-breath measurements of flow, oxygen uptake, carbon dioxide production and optional heart rate. It measures the human response of increasing exercise with emphasis on the gas exchange and ventilation parameters. The results of the test can be displayed on a PC and can be printed after the test if a printer is connected to the PC.

Intended Use

The PowerCube-Ergo is intended for medical applications requiring a non-invasive assessment of the cardiopulmonary response to exercise or measurement of energy expenditure using indirect calorimetry. The PowerCube-Ergo is intended to be used on adults and adolescent patients.

The PowerCube-Ergo is intended to be used by trained operators under direct supervision of a licensed health care practitioner, in hospitals, clinics, physician offices and outreach centres.

The PowerCube-Ergo Ergospirometry module is intended for use with a personal computer system to run the measurement software, but also as part of a cardiopulmonary exercise testing system.

The PowerCube-Ergo, using LF8, is not meant to be used for any purpose other than those named herein. If it is used for purposes that do not meet its intended use, this is regarded as an unauthorized utilization!

WARNING	INTENDED USE
	If LF8 and the PowerCube-Ergo are used for purposes other than their intended use, a safe operation of LF8 and the PowerCube-Ergo is not possible! GANSHORN is not responsible for any personal and physical damage that results from non-intended utilization of LF8 and the PowerCube-Ergo; the operator is responsible! Protective measures Carefully read the documentation available in order to use LF8 and the PowerCube-Ergo in their intended applications! Obey all instructions contained in the documentation, especially the safety regulations and warning notices!

Documentation purpose

The purpose of this manual is to provide all the information necessary to enable the service engineer to efficiently locate and replace a faulty part or module. For details for the working with the PowerCube-Ergo please refer to the instruction manuals.

Target group

This documentation is for professional service technicians in health care techniques. These service technicians are expected to have working knowledge of medical state-of-the-arts, procedures, practices and terminology as required for completing this examinations. They are also expected to have working knowledge about working with the PowerCube-Ergo

Requirements for Installation, Maintenance and Service

- GANSHORN devices are only allowed to be installed, put into service and maintained in accordance with the actual regulations and standards.
- Medical electronic devices feature special safety requirements concerning electromagnetic compatibility and have to be installed and put into service according to the EMC-instructions of the accompanying documents.
- Portable and mobile HF-communication devices (e.g. mobile phones, DECT-phones etc.) may disturb medical electrical devices.

Interference may occur in the vicinity of equipment marked with the following symbol:



Requirements for Maintenance and Service Personnel

- Installation, initial operation, all changes, modifications, expansions, repairs, maintenance measures including safety control and metrological/safety control, and any other work on GANSHORN products may only be performed by GANSHORN or by an authorized GANSHORN partner.
- The enclosures of GANSHORN devices may only be opened by GANSHORN or by an authorized GANSHORN partner.
- If this device is modified appropriate inspection and testing must be conducted to ensure continued safe use of the device. After each maintenance control or other operation with the device or the system a metrological control and safety control is necessary. Each metrological control demands a succeeding safety control.

Definitions

Danger

Indicates an imminent hazard which, if not avoided, will result in death or serious injury

Warning

Indicates a potential hazard or unsafe practice which, if not avoided, could result in death or serious injury

Caution

Indicates a potential hazard or unsafe practice which, if not avoided, may result in minor personal injury or product/property damage

Example:

Level of seriousness	Kind of hazard
$\underline{\land}$	Text Text Text Text

For application instructions and other useful information

INFORMATION	
Text	
Text	
Text	

Action Instructions / Operating Steps

Explanation
 = Consequence / effect....

Lists

- Text.....
- Text.....

Cross Reference

Cross references are written as follows:

=> Chap. 1, Safety Regulations

Cross Reference to Possible LF8 Settings

(LF8 screen "system", see related "Operating instruction manual LF8 – software for pulmonary function testing"!)

Possible customizing in the LF8-settings is written as follows: Setup/register-card/register card line number (e.g. setup/general/64)

Keys and Buttons

Framed text indicates keys displayed on the user interface of the software, e.g. Start = software button labelled with "Start"

Square brackets indicate keyboard keys, e.g. <Alt> = keyboard key labelled with "Alt"

Equipment Identification

Every GANSHORN device has a unique serial number for identification. The serial number "SN" appears on the device label.

Equipment Symbols

For equipment symbols and their meaning please refer to

=> Instruction Manual PowerCube-Ergo, Preface!

Acronyms

ADC	analog to digital converter
ATS	American Thoracic Society
cm	centimeter
CMOS	complementary metal oxide semiconductors
CO2	carbon dioxide
CPU	processor unit
ERS	European Respiratory Society
HDD	hard disc drive
hPa	hectopascal
MCU	micro controller unit
m	meter
ml	millilitre
ms	millisecond
kg	kilogram
I	litre
02	oxygen
OS	operating system
PC	personal computer
Press.	pressure
PwC	PowerCube
RAM	main storage
S	second
Trans.	transducer

Chapter 1: Safety Regulations

Warning Notices

Definitions Service Relevant Warning Notices General Warning Notices Electrical Warning Notices Hygiene Specific Warning Notices Product Specific Warning Notices

Safety Regulations

Warning Notices

Definitions

The terms Danger, Warning, and Caution are used throughout this documentation and related documents in accordance to ANSI Z535.4 to point out hazards and to designate a degree or level of seriousness. Familiarize yourself with their definitions and significance. Hazard is defined as a source of potential injury to a person.

The safety notes presented in this documentation refer to the equipment in general. The order of the safety statements does not imply order of importance. Please refer also to

=> Instruction Manual PowerCube-Ergo, Chapter 2, Safety Regulations

Level of seriousness:

Danger	indicates an imminent hazard which, if not avoided, will result in death or serious injury
Warning	indicates a potential hazard or unsafe practice which, if not avoided, could result in death or serious injury
Caution	indicates a potential hazard or unsafe practice which, if not avoided, may result in minor personal injury or product/property damage

Service Relevant Warning Notices

DANGER	REQUIREMENT FOR SERVICE PERSONEL
$\underline{\mathbb{N}}$	Opening the PowerCube-housing as well as all changes, modifications, extensions, repairs, maintenance measures, and any other work on GANSHORN products including meteorological / safety checks may only be performed by GANSHORN or by an authorized GANSHORN partner.
	Only qualified service technicians that have been trained on repair and maintenance of the PowerCube are authorized to perform the procedures described in this manual!
DANGER	DISCONNECT FROM THE MAINS BEFORE ANY REPAIR WORK
$\underline{\mathbb{N}}$	Disconnect the PowerCube from the mains before starting any repair work. If checks and adjustments of the PowerCube-module can only be carried out by removing the cover AND when connected to the mains, it will be pointed out especially in the respective description. When performing these procedures be aware that parts inside the device may be current-bearing.
	ELECTROSTATIC DISCHARGE (ESD)
$\underline{\land}$	 The PowerCube contains electro-static sensitive electronic components; observe antistatic precautions for any maintenance procedure: The unit must be placed on an earthed antistatic mat Service personnel must be earthed and have to wear anti-static clothing/shoes when handling boards or components Comply with the international standard IEC 61340-5-1 Always use an antistatic bag when transporting boards or components

<u>Iways use</u> antistatic bag when transporting boards of components

General Warning Notices

WARNING	INTENDED USE
$\underline{\mathbb{N}}$	If LF8 and the PowerCube-Ergo are used for purposes other than its intended use, a safe operation of LF8 and the PowerCube-Ergo is not possible! GANSHORN is not responsible for any personal and physical damage that results from non-intended utilization of LF8 and the PowerCube-Ergo; the operator is responsible!
	Protective measures Carefully read the documentation available in order to use LF8 and the
	PowerCube-Ergo in their intended applications!
	Obey all instructions contained in the documentation, especially the safety regulations and warning notices!
WARNING	ORIGINAL GANSHORN PARTS
$\underline{\mathbb{N}}$	Patient safety, operator safety, measurement accuracy within the given limits and highest possible trouble free running of the GANSHORN device can only be ensured if GANSHORN parts are used for GANSHORN devices. So only original GANSHORN parts may be utilized those that have been listed in this documentation and in supplementary documentation and that have been inspected and approved by GANSHORN. If non-original parts are used in GANSHORN products, GANSHORN does not guarantee the safe operation and functioning of its products.
DANGER	AMBIENT CONDITIONS
	The ambient conditions described in the "technical specifications" for storage and operation have to be maintained. The GANSHORN device is not designed to be operated in explosion hazardous areas of medically used rooms. Explosion hazardous areas are formed when combustible anaesthesia products, skin cleansing, and skin disinfection products are used. Furthermore, the GANSHORN device is not designed for operation in a combustible atmosphere. Enriching the ambient air with more than 25% oxygen or nitrous oxide creates a combustible atmosphere. The GANSHORN device including the power supply is only licensed for being used in rooms designated for medical purposes.
WARNING	DEVICE LOCATION
	The GANSHORN device must be placed in a location where its correct functioning is not hindered. Avoid locations with thermal influences e.g. from direct insulation, heaters and air-conditioning. Prevent the device from drafts. The GANSHORN device must be placed in a location where the devices plugs and switches, on the front and back, are easily accessible without any problems, therefore not hindering the functionality.
CAUTION	OVERHEATING
\bigwedge	Devices can overheat and be damaged! Do not obstruct the device's air ventilation needed for cooling!

DANGER	INSTALLATION, UNINSTALLING
	All components of the GANSHORN device have to be switched off and disconnected from the mains for assembling and installation, as well as for uninstalling and disassembling.
	Installation and initial operation and any other work on GANSHORN products including meteorological / safety control may only be performed by GANSHORN or by an authorized GANSHORN partner.
DANGER	MODIFICATIONS, MAINTENANCE AND SERVICE
$\underline{\mathbb{N}}$	If the GANSHORN device is modified, appropriate inspection and testing must be conducted to ensure continued safe use of the device. After each maintenance check or other operation with the device or the system a metrological and safety check is necessary. Each metrological check demands a succeeding safety check.
	All changes, modifications, extensions, repairs, maintenance measures, and any other work on GANSHORN devices including meteorological / safety checks may only be performed by GANSHORN or by an authorized GANSHORN partner. Already changing the power supply is mentioned as a modification.
	DANGER OF INJURY - INSTALLATION
$\underline{\mathbb{V}}$	Wear protective gloves and safety shoes for installation and transport! In order to ensure maximum protection during transport, all GANSHORN devices are packed at the factory in suitable cartons and/or boxes with sufficient internal packing. Please observe the graphical symbols and the instructions on the packaging.
	DATA SAFETY
\wedge	In the case of a computer defect, the patient data, incl. measurement results, can go lost irrevocably!
<u></u>	Backup archives regularly to an external storage media (ZIP-drive, streamer, CD-ROM, recording system, etc.)!
	=> Instruction manual Software LF8, Chap. 4 Data Management!
WARNING	GAS MIXTURE CHECK
	Before using the gas mixture, the values of the individual gas components have to be checked with regard to the requirements of the measurement to be performed
WARNING	PRESSURIZED GAS BOTTLES
\bigwedge	Improper handling of gas bottles creates a potential danger for people and objects! The relevant regulations are to be observed! Secure the bottles, especially to avoid accidents! The content and filling condition must be clearly recognizable at all times!
	Gas bottle seals, connections and lines must be free of oil and grease! Have the gas bottle regularly inspected by an official inspection agency! The operator is liable! We recommend rented gas bottles. <u>Close the main cock whenever the gas bottle is not in use!</u>

WARNING	MAIN POWER SUPPLY
Λ	Utilize only the original, supplied mains power supply!
/!\	Using non-approved power supplies can be fatal!
WARNING	MULTIPLE SOCKETS
Λ	Infiltration of liquid and mechanical damage is possible! Do not lay moveable multiple outlets on the floor!
	Do not use extension cords together with multiple sockets!
$\overline{\cdot}$	Danger of life through electrical shock!
	If the GANSHORN device is used as a part of a system, it is not permitted to add
	other multiple sockets or extension cords to the system.
	If the GANSHORN device is used as a part of the system, the highest licensed charge is 1.000 W.
	It is not permitted to use the multiple sockets provided with the system to
	connect devices not being defined as parts of this system.
	To avoid any danger for patient and operator it is not permitted, to connect any
	electrical device that is not being a part of this system to the system's multiple
	sockets.
WARNING	ELECTRIC CIRCUIT / WALL SOCKET
Λ	All system devices must be connected to the same electrical circuit, otherwise the electrical safety of the system is not-existent!
	Devices, which are not connected to the same electrical circuit, must be
$\angle \cdot \land$	operated using galvanic separation (use a galvanic separated RS232 interface
	or separate insulation transformer)!
	To avoid all dangerous body currents, all parts of the system have to be plugged
	in via an insulation transformer (galvanic system separation device).
	It is not permitted to connect parts of a device directly to a wall socket.
WARNING	LAN
$\mathbf{\Lambda}$	It is the operator's duty, to observe all official and safety regulations if a PC-
/!\	system becomes integrated into an intranet.
$\overline{}$	
WARNING	ELECTROMAGNETIC COMPATIBILITY
	Medical electrical equipment needs special safety requirements concerning
/!\	electromagnetic compatibility and has to be installed and put into service
<u> </u>	according to the EMC-instructions of the accompanying documents
	Portable and mobile HF-communication devices (e.g. mobile phones, DECT- phones etc.) may disturb medical electrical devices.
	The manufacturer's declaration concerning electromagnetic compatibility
	has to be taken into account.
WARNING	INSTALLATION (EMC)
\wedge	Warning about the installation
/!\	The equipment/system should not be used adjacent to or stacked with other
\frown	
	equipment, and that if adjacent or stacked use is necessary, the
	equipment, and that if adjacent or stacked use is necessary, the equipment/system should be observed to verify normal operation in the

Electrical Warning Notices

WARNING	ELECTROMAGNETIC COMPATIBILITY – SPARE PARTS
$\underline{\mathbb{N}}$	It is not permitted to use any spare part for the GANSHORN device that has not been inspected and approved by GANSHORN. The use of accessories, transducers and wirings that are not mentioned in this documentation or accompanying documents, with exception of transducers and wiring available from GANSHORN as spare parts for internal components, may cause higher emission or lower resistance to jamming of the device or system.
WARNING	ELECTRIC SAFETY - CONNECTIONS
$\underline{\mathbb{N}}$	If a GANSHORN device has not been delivered as system, but combined to a system by a GANSHORN partner or the operator, they are considered as producer of the system and responsible for safety and complying with all applied standards. If a GANSHORN device is delivered as a system, it is prohibited to connect other devices that have not been defined as part of the system to the respective system.
	If the device and/or device data and/or device purpose change due to upgrade, reconstruction, repair, all labels and documents have to be updated accordingly. In any case the IEC 601-1-1/EN 60601-1-1 standard must be met.
WARNING	USE AS PART OF ECG-SYSTEMS

USE AS PART OF ECG-SYSTEMS

If a GANSHORN device has not been delivered as system, but combined to a system by the GANSHORN-partner or the operator, they are considered as producer of the system and responsible for security and meeting all applied standards.

Danger through electric shock, especially through missing equipment grounding! The insulation of the patient can be bridged by conducting components, thus cancelling the protective effect of the isolated inputs.

Pay special attention to ECG systems that all conductive parts (patient, plug, electrodes and transducer) that are connected to the patient input do not touch any other, grounded, conducting components!

Contact of neutral electrodes to ground potential is especially to be prevented

Hygiene Specific Warning Notices

DANGER	INSUFFICIENT HYGIENE – PATIENT AND PERSONNEL
\wedge	Insufficient hygiene endangers the patient and personnel!
$\overline{}$	Precautionary measures
	Clean and disinfect all contaminated parts completely before examining the next patient!
	Use single use disposables for best possible hygiene.
	Patients suspected of having tuberculosis or similar diseases should especially only be measured using single use disposables.
DANGER	INSUFFICIENT HYGIENE – EXECUTION OF MEASURES
\wedge	The efficiency of all cleaning measures depends on selecting suitable methods and carefully execution!
	Precautionary measures Be familiar with the state-of-the-art in infection control in pulmonary function testing and valid norms, rules, and recommendations for hospital hygiene and prevention of infection.
	Read the hygiene instructions of these instruction manual and related documents thoroughly and comply with the detailed instructions given in these

=> Instruction Manual PowerCube-Ergo, Chapter 8, Hygiene

DANGER
Λ
/!\

HYGIENE – ELECTRONIC PARTS

HYGIENE – DESINFECTION MEDIA

documentations

Never clean electronic devices like the PowerCube module by submerging it in water or liquid solution. Prevent liquid from penetrating the device housing. Protect the device from penetrating liquid.

WARNING



Use only cleaning and disinfection media and methods tested and released for

use by GANSHORN. Observe the cleaning and disinfection media user manual, especially the recommendations concerning area of application, stated concentrations, and

recommendations concerning area of application, stated concentrations, and required reaction time. Observe also the instructions concerning storage and the necessary protective measures when handling the media.

Incorrectly applied disinfection media, especially in wrong concentrations or combinations with other products, can be ineffective or damage the material and cause discoloration, material fatigue, cracks, broken parts or other damage.

Chapter 2: System description

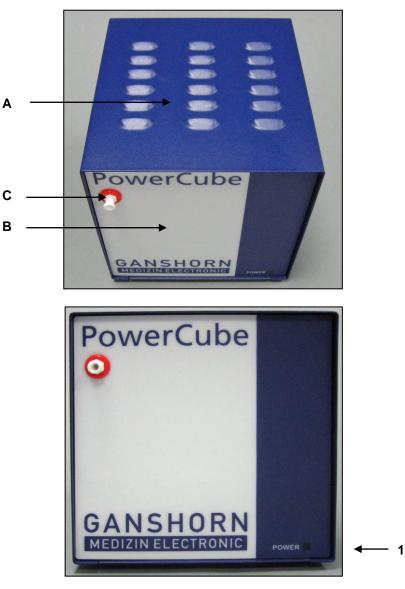
Component Description PowerCube-Ergo Description of Elements, Indicators and Connections of the PowerCube-Ergo Functional Block Diagram Tubing Block Diagram

Component Description PowerCube-Ergo

The configuration of an ergospirometry system depends on the individual components, e.g.:

Description	Function
PowerCube-Ergo	Measurement module containing e.g. pressure transducers, gas analyzers, gas suction pump, ambient
	pressure sensor
Plug-in Power-supply	(see technical data)
RS232 connection (Optoisolator or RS232 connection cable in some configurations)	Optoisolator, RS 232 connection for data transfer between PowerCube and PC, including 4.000 V isolation
Pressure reducer	For calibration gas supply (technical specifications see customer information "Measurement and calibration gas")
Tubing with pneumotach, face mask, mouth- pieces etc.	Patient side accessories
PC-System	(technical specification see instruction manual)
ECG / pulse belt	Provides heart rate, necessary for the calculation of some ergospirometry parameters
Electrode application unit	Accessories for ECG
Ergometer / treadmill	Provides controlled workload for individual test protocols

Description of Elements, Indicators and Connections of the PowerCube-Ergo



Pict.: PowerCube-Ergo with SSO, front

Pos.	Description	Function
А		Housing
В		Front panel
С	Gas calibration socket	Connection for the gas alimentation during the gas calibration (Ergo Calibration) Red: PowerCube-SN A1, B1
1	POWER	Power indicator PowerCube switched on = indicator on the front lights up



Pict. PowerCube-Ergo SSO-Sensor: tubing, rear

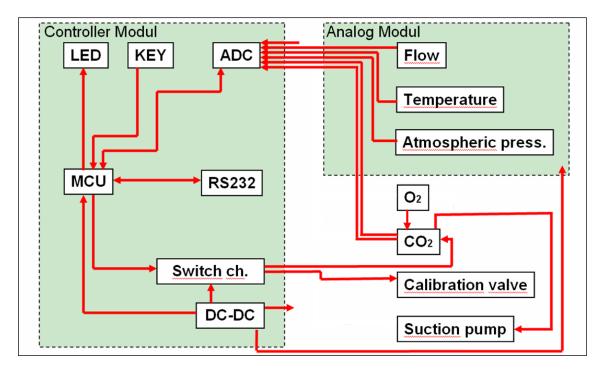


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Pict.: PowerCube-Ergo SSO-Sensor: connections, rear

Pos.	Description	Function
1	Flow – (blue)	Socket for patient tubing from the pneumotach, patient side
2	Flow + (white)	Socket for patient tubing from the pneumotach, device side
3	M-Gas-IN (red)	Socket for patient tubing from gas analysis / gas drying tube
4	Cal-Gas-IN (yellow)	Socket for calibration gas connection tube (yellow) from the manometer of the calibration gas bottle
5	Cal-Gas-OUT (green)	Calibration gas output – has to remain open!
6	Out	Exhaust, connection for the sound absorber
А	Power	Main power switch
		$\dot{\bigcirc}$ = Off: power indicator on the front goes out \odot = On: power indicator on the front lights up
В	Puls	Not used
C	SpO2	Socket for the connection of the Pulse Oximetry unit
D	ROS02	Not used
E	RS232	Optoisolator, RS 232 connection for data transfer between PowerCube and PC
F	DC-IN	Plug in power supply
G	Temp.	Plug for temperature sensor
		(remains on the device after the initial installation)
	Diff Flow +, Diff Flow –, PM	(Not used)

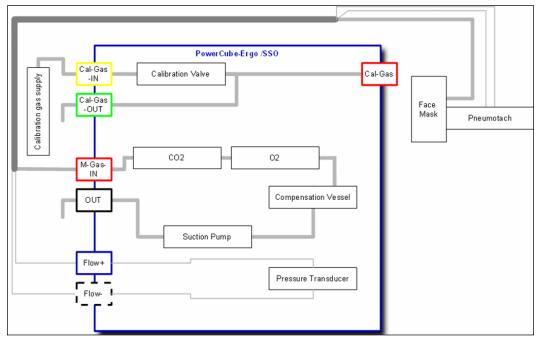
Functional Block Diagram



Pict.: Functional block diagram PowerCube-Ergo

Pos.	Description	Function
	Controller Module:	
	MCU with firmware	Control unit
	RS232 interface	Connection PowerCube-PC (control, data transfer)
	DC-DC module	Internal power supply,
		generates the different necessary voltages
	Switch ch.	Switch channels, control of the actuators i.e. suction pump, calibration valve, O2-analyser
	LED	Status control of the PowerCube (front panel)
	Button	Start / Stop-button (only for portable use)
	ADC	Conversion of analog signals (flow, temperature, ambient
		pressure, O2, CO2) to digital signals
	Analog Module:	Measurement transducer and signal amplification
	Pressure transducer	Differential pressure measurement, flow measurement
		from patient tubing /pneumotach
	ambient temperature sensor	Ambient temperature measurement for BTPS correction
	ambient pressure sensor	Ambient pressure measurement for BTPS correction
	Additional components:	
	n.n.	Processing external signals (optional)
	O2-Analyser (SSO-Sensor)	Gas analysis
	CO2-Analyser	Gas analysis
	Suction pump	Assures sample gas flow
	Compensation vessel	Assures constant sample gas flow
	Calibration valve	Calibration gas supply for gas calibration

Tubing Bock Diagram



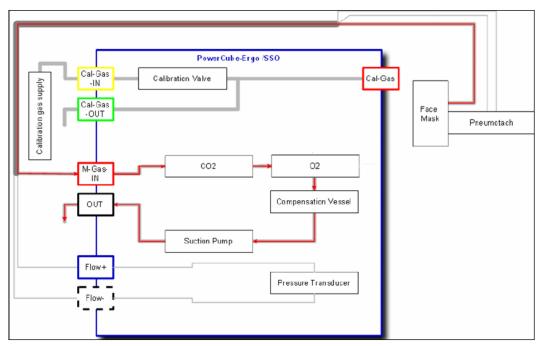
Pict.: Block diagram PowerCube-Ergo, tubing general

Gas flow to the analyzers during ergospiromety measurement

The suction pump assures the gas flow inside the tubing and the PowerCube. It sucks the gas sample (measurement gas)

- from the gas connectors of the face mask / mouth piece
- through the gas drying tube / patient tube
- through both gas analyzers (O2, CO2)
- through the compensation vessel

The gas sample leaves the PowerCube through the suction pump and the sound absorber



Pict.: Block diagram PowerCube-Ergo, gas flow during an ergopirometry-measurement (Red: gas sample, measurement gas)

Gas flow to the analyzers during gas calibration with <u>open</u> calibration gas valve:

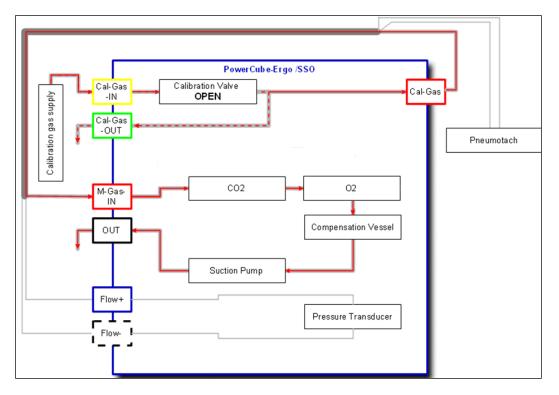
When the calibration valve is opened,

- the pressure reducer provides calibration gas coming from the calibration gas bottle
- through the calibration gas connection tube
- through the Cal-gas-in-socket
- to the calibration gas valve
- into the T-piece
- through the second end of the T-piece and the Cal-gas-out-socket into the room air

The suction pump sucks the gas sample (calibration gas)

- from the third end of the T-piece
- through the calibration gas socket on the front of the PowerCube
- through the gas drying tube / patient tube
- through both gas analyzers (O2, CO2)
- through the compensation vessel

The gas sample leaves the PowerCube through the pump and the sound absorber



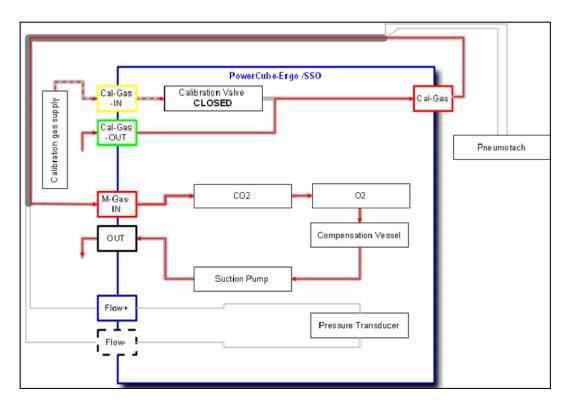
Pict.: Block diagram PowerCube-Ergo, gas flow during a ergo-calibration (gas calibration), calibration valve open (Red: gas sample from calibration gas. Dashed line: calibration gas)

Gas flow to the analyzers during gas calibration with <u>closed</u> calibration gas valve:

When the calibration gas valve is <u>closed</u>:

- The calibration gas supply is blocked (no gas consumption)
- The suction pump sucks ambient air (gas sample) from the Cal-gas-out-socket

The further gas circuit remains the same



Pict.: Block diagram PowerCube-Ergo, gas flow during a ergo calibration (gas calibration), calibration valve closed (Red: gas sample from ambient air. Dashed line: calibration gas)

Technical Data PowerCube-Ergo

General	
Software	LF8 32 bit for Windows®
Classifications	
Device classification	Active medical product, class Ila
Application section	Type BF
Corrections	
F/V processing	ERS or ATS
Inspiratory volume	BTPS (environment module)
quantities auto correction	
Gas volume	STPD (environment module)
Computer interface	
Signal transmission	4 kV optoisolator RS232-interface, 57 600 Baud
Flow measurement	
Measurement principle	Pneumotachograph with variable orifice
Measuring range	$0 \text{ to } \pm 18 \text{ l/s}$
Accuracy	<pre>< ± 3% or 50 ml/s (the larger value applies)</pre>
Needracy	PEF: \pm 5% or 150 ml (the larger value applies). Meets ERS/ATS standards
Resolution	10 ml/s
Volume measurement	Digital Integration
Range	Not limited, graphical display 0 to 10 l
Resolution	10 ml
Accuracy	± 0.1% O2
O2-Measurement	10.170 02
Measurement principle	Solid state oxygen SSO (zirconia)
Measuring range	10 to 21% O ₂
Resolution	0.01% O2
Rise time (10-90 time)	<100 msec
Accuracy	± 0.1% O ₂
CO2-Measurement	± 0.176 02
Measurement principle	Ultrasonic
Measuring range	0 to 15 % CO ₂
Resolution	0.01% CO2
Rise time (10-90 time)	<100 msec
Accuracy	± 0.1% CO ₂
Power supply PowerCube-Erg	
Power supply PowerCube-Erg	Egston E2DFMW3
•	•
Protection class	
Voltage output	24 VDC
Current output	1.25 A
Primary voltage range	100 to 240 VAC; 50 to 60 Hz; 620-380 mA
Ambient conditions, Operation	
Ambient temperature	+15 to + 35 °C
Relative humidity	30 to 80 % (non condensing)
Atmospheric pressure	700 to 1050 hPa
Max. warm-up time	30 min
Max. temp. gradient	3°C / hour
Ambient conditions, storage a	
Ambient temperature	-20 to +50°C
Relative humidity	10 to 90 % (non condensing)
Atmospheric pressure	600 to 1,050 hPa
Dimensions [W x H x D]	
PowerCube-Ergo	Approx. 15x 15 x 15 cm
Weight	
PowerCube-Ergo	Approx. 2.4 kg

Chapter 3: Disassembly

Warning Notices

Physical Overview General Tools and Accessories for PowerCube Maintenance

How to Remove the Cover from the Base Assembly How to Remove the Electronic Unit (Controller Module and Analog Module) How to Split the Electronic Unit into Electronic unit Holder, Controller Module and Analog Module

How to Remove / Replace the Suction Pump

How to Remove / Replace the CO2 Analyzer

How to Remove / Replace the O2 Analyzer

Disassembly

Warning notices

DANGER	REQUIREMENT FOR SERVICE PERSONEL
$\underline{\mathbb{N}}$	Opening the PowerCube-housing as well as all changes, modifications, extensions, repairs, maintenance measures, and any other work on GANSHORN products including meteorological / safety checks may only be performed by GANSHORN or by an authorized GANSHORN partner.
	Only qualified service technicians that have been trained on repair and maintenance of the PowerCube are authorized to perform the procedures described in this manual!
DANGER	DISCONNECT FROM THE MAINS BEFORE ANY REPAIR WORK
$\underline{\land}$	Disconnect the PowerCube from the mains before starting any repair work. If checks and adjustments of the PowerCube-module can only be carried out by removing the cover AND when connected to the mains, it will be pointed out especially in the respective description. When performing these procedures be aware that parts inside the device may be current-bearing.
CAUTION	ELECTROSTATIC DISCHARGE (ESD)
$\underline{\land}$	 The PowerCube contains electro-static sensitive electronic components; observe antistatic precautions for any maintenance procedure: The unit must be placed on an earthed antistatic mat Service personnel must be earthed and have to wear anti-static clothing/shoes when handling boards or components Comply with the international standard IEC 61340-5-1

• <u>Always use an antistatic bag when transporting boards or components</u>

Physical Overview

The PowerCube housing consists of two metal shells. The base assembly contains all electronic parts of the PowerCube. The cover is connected to the base shell with a cable for potential equalization.

For removing some components it is necessary to remove other components first. This is mentioned in the description of the respective procedure

General

- To prevent devices from scratching, abrasion or other damage, always place it on a clean, soft and antiskid ground for any maintenance procedures
- When removing the cover, take care not to place any strain on the equalization cable. Ensure that it is not bended or twisted. If necessary, unplug it for repair (Faston-plug). Take care to plug it again and not to squeeze it when putting the cover on the base assembly
- Proceed carefully when removing and replacing connectors. Never use force. Never strain cable assemblies
- Always perform the processing steps in the given order
- After repair allow for warm-up time before adjustments and tests

This chapter shows how to remove and replace modules that are considered as spare parts. The instructions show:

- The requirements for removing / replacing the module
- Necessary tools for removing / replacing and functional testing
- Removal and replacement procedures

It is possible to remove /exchange the following modules:

- Electronic unit complete (Analog Module and Controller Module)
- Controller Module
- Analog Module
- Mounting plate
- Electronic board holder
- CO2-Analyzer
- O2-Analyzer (SSO)
- Suction pump
- Calibration valve
- Compensation vessel

Tools and Accessories for PowerCube Maintenance

- Philips screwdriver PH1
- Torx TX10
- Fork wrench (metric size 5 and 5.5)
- Side cutter
- Flat bladed screwdriver 1.2 x 60
- Cable tie

Additional equipment for adjustment procedures:

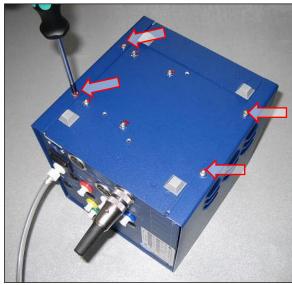
- Manometer 0-10 mbar (accuracy: 0.5% of the maximal readings)
- Flowmeter 0-1.5 l/min (accuracy: 5% of the maximal readings)
- Multimeter (DC: range 1 mV to 30V, accuracy 0.15% of maximal readings)
- COM98IO / PowerTool Software (automatically installed with LF8 installation)

How to Remove the Cover from the Base Assembly

The cover is secured on the base assembly with four screws; Access to these screws is gained from the lower surface of the unit. To remove the cover:

- 1) Switch off the PowerCube, unplug all cables, connectors and tubes
- 2) Turn the unit upside-down and place it on a clean, soft and antiskid ground.
- 3) Remove the four outer screws
- 4) Turn the PowerCube upright and remove the cover by spreading the side panels of the cover
- 5) If necessary, unplug the equalization cable

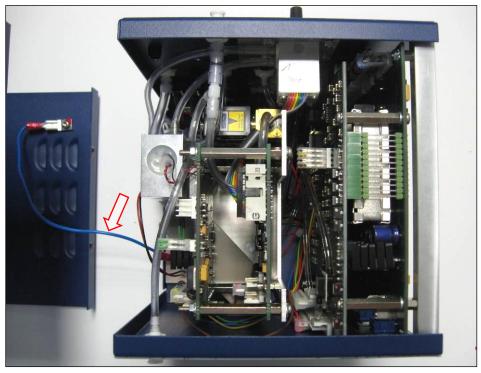
To close the PowerCube perform the same steps backwards



Pict.: Removing the screws



Pict.: Removing the cover



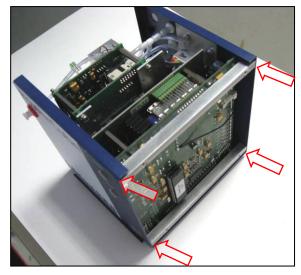
Pict.: PowerCube inner, with equalization cable between base assembly and cover

How to Remove the Electronic Unit (Controller Module and Analog Module)

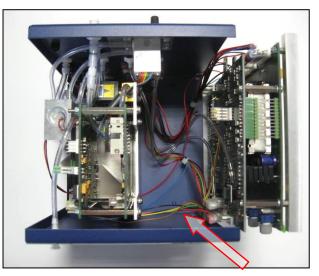
- 1) Remove the cover correctly from the base assembly
- 2) Unscrew the electronic unit holder by removing the four marked screws. Be aware, that two screws are located under the front panel; Lift the front panel carefully do not bend it!
- 3) When flapping the electronic unit outwards unplug the CO2-Analyser cable from the connector of the electronic unit
- 4) Flap down the electronic unit
- 5) Carefully disconnect cables and tubes from the electronic unit. Disconnect also electrical connections that are soldered

After replacement of one or both modules of the device, please perform:

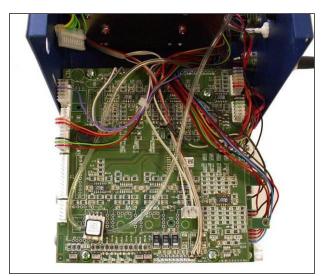
- 1) Suction flow adjustment (see chapter 6, Troubleshooting, checks and adjustments)
- 2) Volume calibration of the pneumotach "Blendenspirozeptor"
- 3) Gas calibration



Pict.: removing the screws



Pict.: Remove CO2-Analyser-cable



Pict.: Flapping down the electronic unit



Pict.: electronic unit

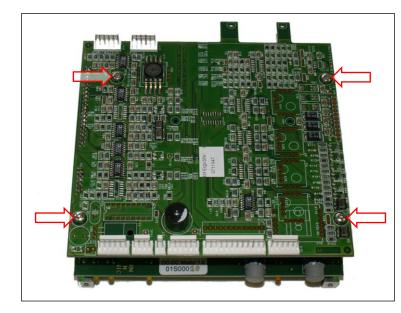
How to Split the Electronic unit into Electronic Unit Holder, Controller Module and Analog Module

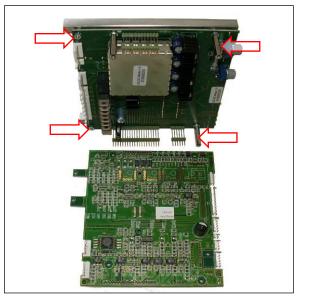
- 1) Remove the electronic unit correctly from the PowerCube
- 2) Unscrew the four screws connecting the elements
- 3) Detach the two circuit boards carefully
- 4) To detach the electronic unit holder from the Controller Module, unscrew the two screws at the left and the two bolts at the right

To assemble the modules again perform the same steps backwards

After replacing one or both modules of the device, please perform:

- 1) Suction flow adjustment (see chapter 6, Troubleshooting, checks and adjustments)
- 2) Volume calibration of the pneumotach "Blendenspirozeptor"
- 3) Gas calibration





Pict.: Electronic unit with attachment screws

Pict.: Controller Module (above) and Analog Module (below)

How to Remove / Replace the Suction Pump

- 1) Remove the cover correctly from the base assembly
- The suction pump tubes remain attached to the pump, do not remove!
- 2) Detach the suction pump tubes
 - a. from the compensation vessel (tube coming from pump connector "V") and
 - b. from the OUT-socket in the PowerCube's rear panel (tube coming from the pump connector "P")
- 3) Cut the cable tie holding the suction pump and unplug the pump cable from the Controller module
- 4) Withdraw the suction pump

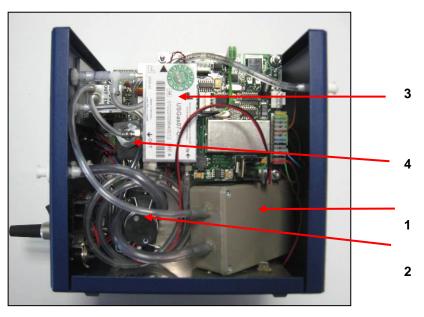
To assemble the modules again perform the same steps backwards

Please take care to ensure the correct flow direction of the suction pump when connecting the tubing:

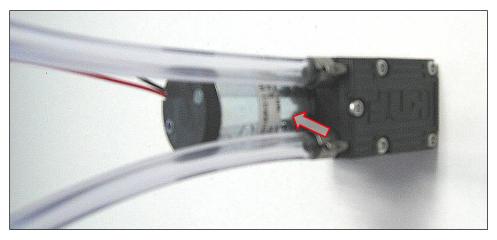
- a. To the OUT-socket in the PowerCube's rear panel connect the tube coming from the Pmarked side of the suction pump (P=pressure)
- b. To the Compensation vessel connect the tube coming from the V-marked side of the suction pump (V=vacuum)

After replacement of the suction pump please perform

1) Suction flow adjustment (see chapter 6, Troubleshooting, checks and adjustments)



Pict.: PowerCube-Ergo, inner lateral: with compensation vessel (1) and suction pump (2). Other components: CO2-Analyser (3) and calibration valve (4)



Pict.: PowerCube-Ergo, membrane suction pump, "▶"mark

How to Remove / Replace the CO2-Analyzer

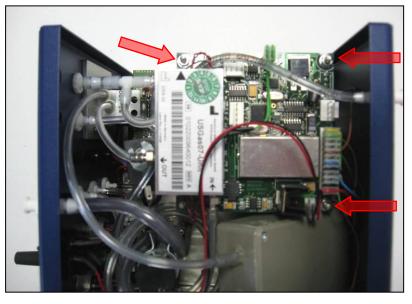
- 1) Remove the cover correctly from the base assembly
- 2) Remove the electronic unit correctly including removing the CO2-sensor cable
- 3) Flap out the compensation vessel to make the CO2-sensor accessible
- 4) Remove all tubes from the CO2-Analyzer
- 5) Unscrew the three attachment screws and withdraw the CO2-Analyser from the montage plate

To assemble the modules again perform the same steps backwards Please take care to ensure the correct flow direction when connecting the tubing:

- a. To the IN-socket of the CO2-Analyzer connect the thick tube coming from the M-gas-INsocket in the PowerCube's rear panel
- b. To the OUT-socket of the CO2-Analyzer connect the thick tube coming from compensation vessel

After replacement of the CO2-Analyser please perform:

- 1) CO2-Offset adjustment (see chapter 6, Troubleshooting, checks and adjustments)
- 2) CO2-Gain adjustment
- 3) Gas calibration



Pict.: PowerCube-Ergo, inner lateral

How to Remove / Replace the O2-Analyser

- 1) Detach the cover correctly from the base assembly
- 2) Remove the electronic unit correctly
- 3) Remove the CO2-Analyzer correctly
- 4) Unplug the signal cable from the O2-Analyser
- 5) Unscrew the three distance bolts that couple the O2- and CO2-Analyser to the montage plate

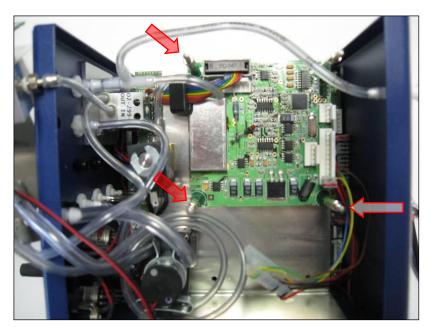
To assemble the modules again perform the same steps backwards Please take care to ensure the correct flow direction when connecting the tubing:

- a. To the IN-socket of the O2-Analyzer connect the thin tube coming from the M-gas-INsocket in the PowerCube's rear panel
- b. To the OUT-socket of the O2-Analyzer connect the thin tube coming from compensation vessel

To assemble the modules again perform the same steps backwards

After replacement of the O2-Analyser please perform:

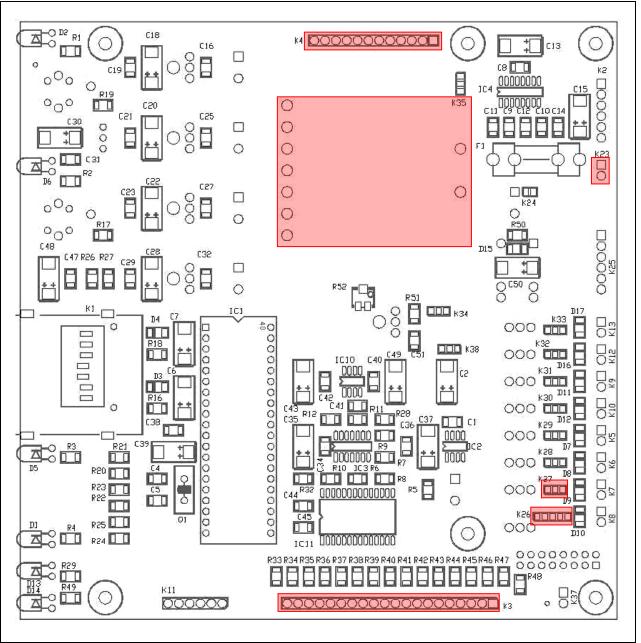
- 4) O2-Offset adjustment (see chapter 6, Troubleshooting, checks and adjustments)
- 5) O2-Gain adjustment
- 6) Gas calibration



Pict.: PowerCube-Ergo, inner lateral: O2-Analyzer board (dashed line) with attachment bolts

Chapter 4: Circuit Diagrams and Board Layouts

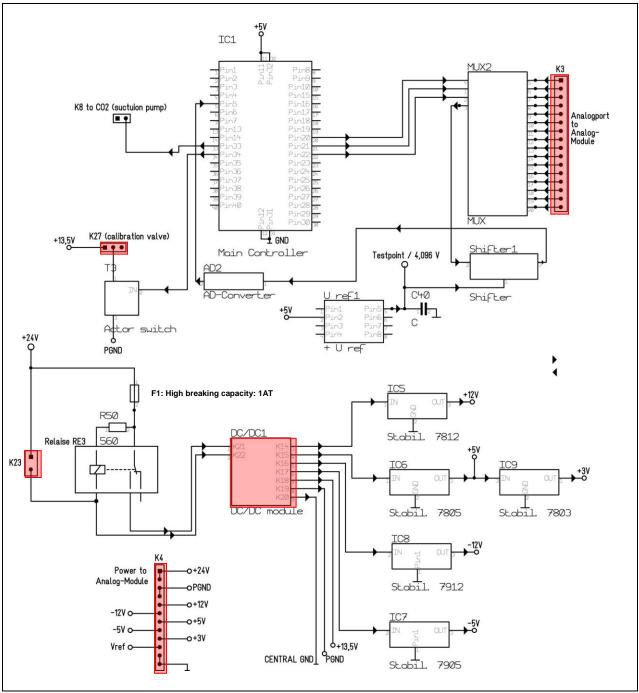
Controller Module 1.3 – Board Layout Controller Module 1.3 – Circuit Diagram Analog Module 1.3 – Board Layout Analog Module 1.3 – Circuit Diagram



Controller Module 1.3 – Board Layout

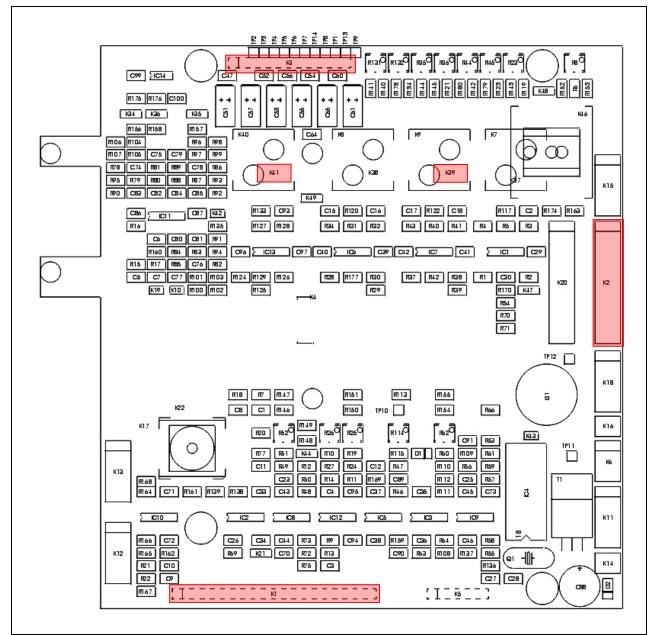
Pict.: Controller Module 1.3 with connectors (red)

Controller Module 1.3 – Circuit Diagram



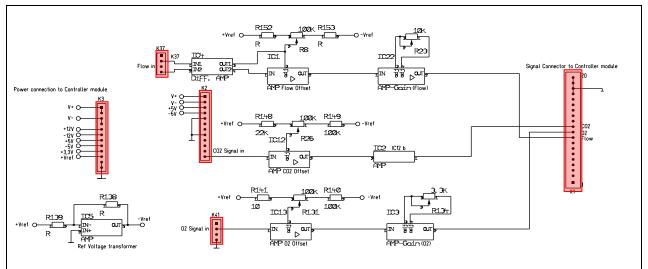
Pict.: Controller Module 1.3 with connectors (red)

Analog Module 1.3 – Board Layout



Pict.: Analog Module 1.3 with connectors (red)

Analog Module 1.3 – Circuit Diagram



Pict.: Analog Module 1.3 with connectors (red)

Chapter 5: Software

Installation

Updates for LF8

De-installation of LF8

De-installation of the BDE / the PDF Creator

Allocation of External Ergospirometry Parameters

Installation

Please use the GANSHORN Installation Assistant for every installation.

Before performing the installation, please ensure

- The correct connection of all parts of the system
- The correct installation of the operating system of the installation PC
- Warm-up-time

After having performed the installation and before performing measurements with the devices, please ensure

- Check of the correct COM-port
- Check or entry of the ambient parameters
- Volume calibration of the pneumotach "Blendenspirozeptor"

=> Instruction manual Software LF8, Appendix A, Calibrations and Tests

• Gas calibration of the PowerCube-Ergo

=> Instruction Manual PowerCube-Ergo, Chapter 5, Calibrations and tests, Ergo calibration (O2/CO2)

- If necessary: Allocate external devices or check the parameter allocation
- If necessary: Perform customized settings (customer data for report header, input of system specific data into the LF8-system, etc.)
- We strongly recommend to perform a system-printout and a security backup of the LF8installation folder.
- Warm-up-time

After the first successful test measurement, store and print out the test measurement, then input the system specific data into the LF8-system

- Go into the LF8-system (Setup)
- Click below at the right on Service
- •
- Enter the password "123ge456" and confirm with OK Please handle this password confidentially for service purpose only!
- Select the register card "System" and enter system-specific data, customer name, PCspecifications, peripherie, PC, ergometer etc. Under "Remarks" input installed programs
- Click on close to switch back to the general setup settings
- Click on Print Setup to print out the most important setup settings (approx. 3-4 pages) and keep it for service purposes

Updates for LF8

Please use the GANSHORN Installation Assistant for every update.

We strongly recommend to perform a security backup of the actual LF8-installation folder before starting the update.

INFORMATION

Please keep care, that some files are overwritten that may be customized: *.frm, texte.*, messwert.*, messwert2.*). For further information about the LF8-files see

=> Instruction manual Software LF8, Chapter 4, Data Management!

After having performed the installation and before performing measurements with the devices, please ensure

- Check or entry of the ambient parameters
- Volume calibration of the pneumotach "Blendenspirozeptor"

=> Instruction manual Software LF8, Appendix A, Calibrations and Tests

Gas calibration of the PowerCube-Ergo

=> Instruction Manual PowerCube-Ergo, Chapter 5, Calibrations and Tests, Ergo calibration (O2/CO2)

- If necessary: Allocate external devices or check the parameter allocation
- If necessary: Perform customized settings (customer data for report header, input of system specific data into the LF8-system, etc.)
- We strongly recommend to perform a system-printout and a security backup of the complete LF8-installation folder after the update
- Warm-up-time

De-installation of LF8

For de-installation erase the installation directory of LF8 (e.g. C:\lf8) completely with all sub-directories. This removes LF8 completely from the PC. No registries are made into other files, into the Windows[®] registry or in any ini-files during installation.

De-installation of the BDE / the PDF Creator

To remove the BDE and the PDF-Creator (automatically installed in version LF8.5G and higher) use the Windows[®] "Control Panel/Software" or "Control Panel/Add or Remove" programs

Allocation of External Ergospirometry Parameters

For the input of external parameters into the LF8-program it is necessary to define the source, i.e. the device sending measured data to the LF8 program.

As there are different possibilities, these parameters have to be allocated depending on the complete system. For these settings, go into the "Ergospirometry-configuration" of the measurement program "ergospirometry"

=> Instruction Manual PowerCube-Ergo, Chapter 6.6, Ergospirometry

- From the measurement program "Ergospirometry" click on edit
- Perform the desired settings

=> Appendix A: Allocation of Ergospirometry-Parameters

• In the column "Parameter allocation" select the desired parameter and allocate the data source for this parameter in the column "Devices"

VC 2,0-	cales <u>H</u> ardware Limits Cal	culation Load Training		D
-,-	Parameter allocation		Ergometer	
1,7.	Parameter	Devices	BOSCH602.BIK] el
1,3-	ECG VO2	Not present	BGA	am
1,0-	VCO2 VE Heart Rate		BGA	, =
0,7.	Respiratory rate Act. load Pred. load	C Peripheral device (RS232)		
0,3-	PETO2 PETCO2	⊂ Bicycle (RS232)	ECG VET_16.ECG	
	BPsys BPdia Pa02	C ECG (RS232)	[PEI_IGEOU	
0,0-	PaCO2 Pred. speed Pred. elevation	C Windows program		
02 [%	1	I		
35-1	I Heart rate from QRS t	rigger.		
30-8 25-6				
20-4		✓ OK 🗙 Car	ncel	

Pict. Ergospirometry configuration, register card "Hardware"

Pos.	Description	Function description
	Parameter allocation	Allocation of the individual parameters for each device (Data source)
	- Parameter	List of all Ergospirometry parameters that are available for device allocation (devices)
	- Devices	List of all devices available as data source for the corresponding parameter
	- Heart rate from QRS trigger	For setting whether the signal for the "Heart rate" parameter should be generated by the QRS trigger or not
	- Devices	Selection of the corresponding device driver for connection of ergometer, BGA- and/or ECG system via the serial interface
	Ergometer	Selection of the corresponding device driver for the ergometer
	BGA	Selection of the corresponding device driver for the BGA system
	ECG	Selection of the corresponding device driver for the ECG system

Click on OK

- = The modifications are stored
- = The program switches back to the Ergospirometry program

Click on Cancel

- = The modifications are not stored
- = The program switches back to the Ergospirometry program

Chapter 6: Troubleshooting, Checks and Adjustments

General

Trouble Shooting

Flow Chart for Error Analysis "No Data Communication with PowerCube" Flow Chart for Error Analysis "Error while Determining the Base Line" Flow Chart for Error Analysis "Invalid Volume Calibration – Drift" Flow Chart for Error Analysis "Gas Calibration – Delay Flow Chart for Error Analysis "Gas Calibration – Offset for O2/CO2 too high/ too low"

Flow Chart for Error Analysis "Generally Implausible Ergospirometry"

Checks and Adjustments

Service Program COM98IO How to Select Measurement Channels for Check and Adjustment How to Select Switch Channels for Adjustment and checks

Adjustments

General Layout Analog Module 1.3 Layout Controller Module 1.3 Adjustment of the O2 Analyzer Adjustment of the CO2 Analyzer Adjustment of the Sensor Flow PF1 Adjustment of the Suction Flow (Suction Pump) Adjustment of the Calibration Gas Pressure Regulator

Troubleshooting, Checks and Adjustments

WARNING

CARRYING OUT TROUBLESHOOTING



Troubleshooting should only be performed by trained GANSHORN personnel or an authorised GANSHORN distributor. If a problem is to arise, please contact the Service personnel.

General

The PowerCube was designed for simple and rapid repair of defective parts. In most cases on-board-repair is not necessary because modules can be replaced completely.

Nevertheless it is recommended to perform a complete function test to avoid repair that is not necessary. In case of malfunctioning of the device we recommend:

- If malfunctioning occurs after a new installations check the installation parameters
- Before the function check close all running programs and switch off the system completely. Check the complete system especially concerning mechanical damage of:
 - Electrical lines
 - Tubing
 - Enclosures
 - Operator and display elements
 - Connection to external system components
 - Connection to the main power

Check if all system components are connected to each other correctly.

- Switch on the system and start the software
 - Perform all necessary calibrations and check the previous calibrations (calibration trend)
 - \circ $\,$ Perform a test measurement or check reports for unusual measurement results
 - Read error messages carefully; they often give hints about the error source

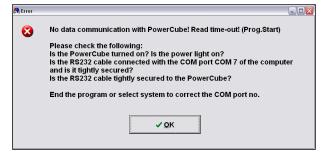
If the error source cannot be found, check the device for defective parts. To make trouble shooting easier, this chapter gives you some flow charts for service diagnosis. In case of more than one possibility, try them in the given order and perform the respective check after each step!

After exchange of defective parts, please always perform the necessary adjustments and tests, as well as a complete calibration of the system.

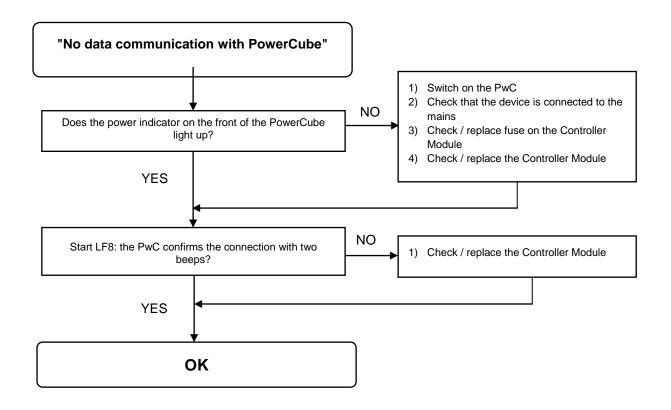
If you have removed parts for functional checks, don't forget to attach them (or their spare parts) again, even if it is not mentioned in the flow charts.

Trouble Shooting

Flow Chart for Error Analysis "No Data Communication with PowerCube"







Flow Chart for Error Analysis "Error while Determining the Base Line"

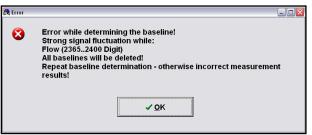
For general information about the base line determination please refer also to

=> Instruction manual Software LF8, Appendix A, Tests and calibrations, Determining the zero-point/base line!

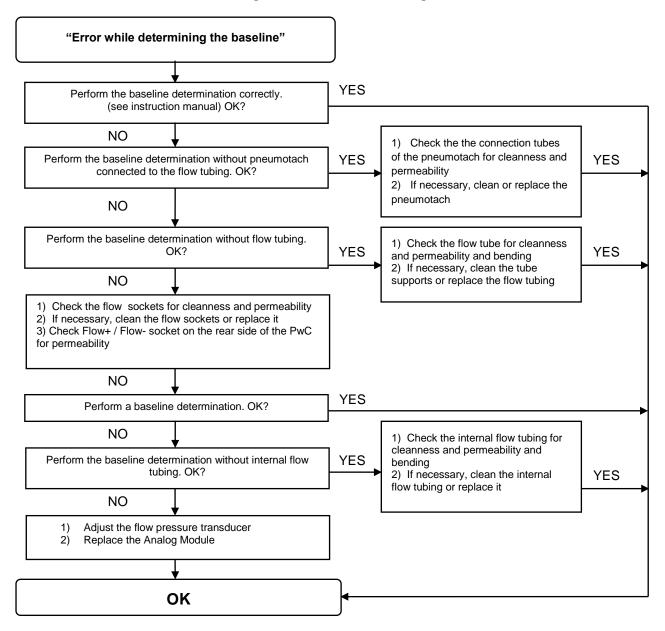
DANGER

DISCONNECT FROM THE MAINS BEFORE ANY REPAIR WORK

Disconnect the PowerCube from the mains before starting any repair work. If checks and adjustments of the PowerCube-module can only be carried out by removing the cover AND when connected to the mains, it will be pointed out especially in the respective description. When performing these procedures be aware that parts inside the device may be current-carrying.

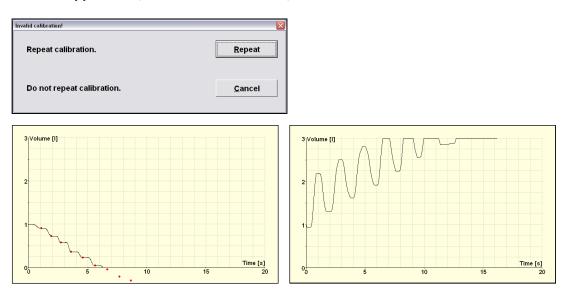


Pict.: Error message "Error while determining the baseline"

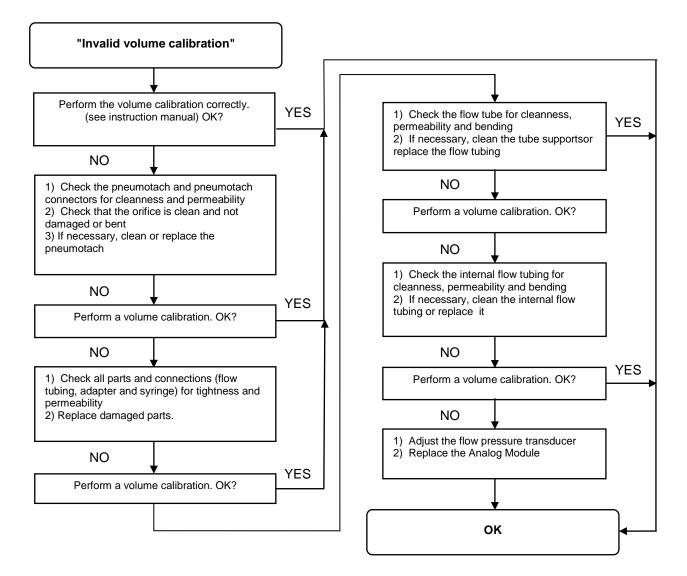


Flow Chart for Error Analysis "Invalid Volume Calibration – Drift "

For general information about the volume calibration please refer also to => Instruction manual Software LF8, Appendix A, Tests and calibrations, Volume calibration



Pict.: Error message "invalid calibration", examples



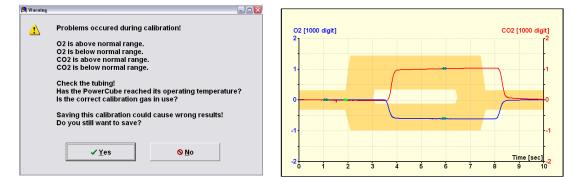
Flow Chart for Error Analysis "Gas Calibration – Delay"

DANGER

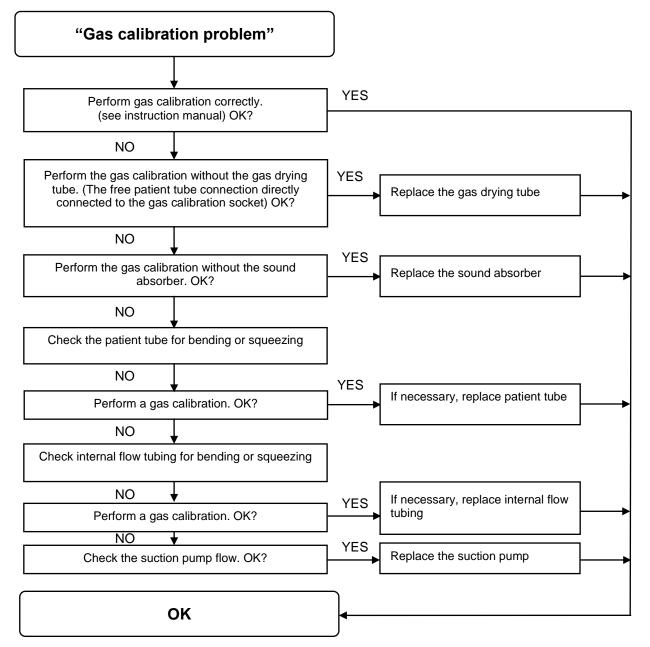
DISCONNECT FROM THE MAINS BEFORE ANY REPAIR WORK

 \bigwedge

Disconnect the PowerCube from the mains before starting any repair work. If checks and adjustments of the PowerCube-module can only be carried out by removing the cover AND when connected to the mains, it will be pointed out especially in the respective description. When performing these procedures be aware that parts inside the device may be current-carrying.



Pict.: Error message "gas calibration problem", example

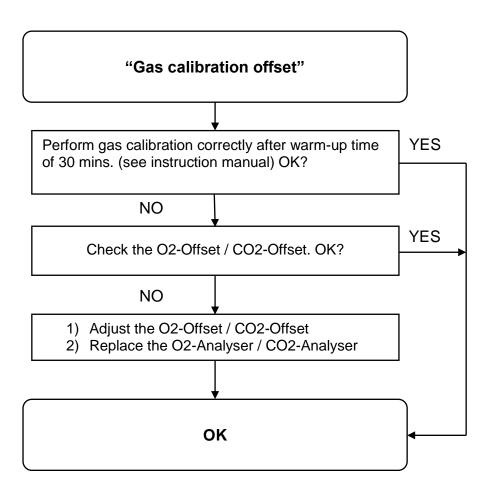


Flow Chart for Error Analysis "Gas Calibration-Offset for O2/CO2 too High/ Low"

٠	Check the actual calibration factors for O2- and/or CO2-Offset
---	--

Cal. no.	-11	-10	-9	-8	-7	-6	-5	4	-3	-2	-1	Actual
CalDate			22.08	17.02	17.02	10.07	11.07	12.07	19.07	19.07	19.07	19.07.07
CalTime			14:37	11:45	12:57	15:17	08:50	11:22	07:57	10:23	10:25	11:06
02-Factor [Digit/%]			109	128	127	122	0	117	182	124	119	0
02-Offset [Digit]			32	23	23	-130	-1832	-230	-78	-200	-150	-1048
CO2-Factor [Digit/%]			339	231	228	233	77	231	196	234	232	246
CO2-Offset [Digit]			4	4	5	126	-28	-338	-366	-446	-381	413

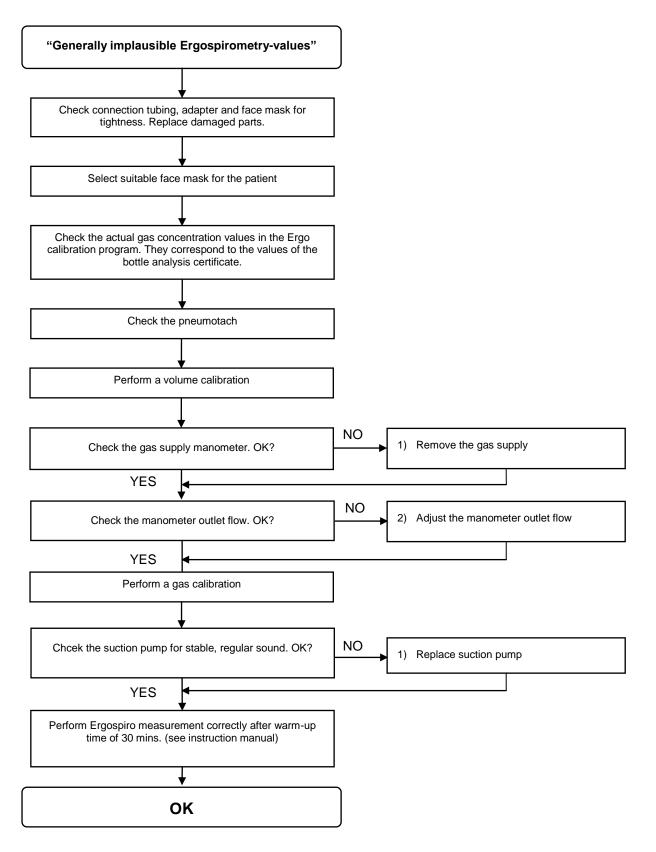
Pict.: Calibration gas table, ergo calibration (gas calibration)



Flow Chart for Error Analysis "Generally Implausible Ergospirometry Values"

For general information about Ergospirometry measurements and possible error sources please refer also to

=> Instruction Manual PowerCube-Ergo, Chapter 6.6, Ergospirometry, Improve the quality of Ergospirometry measurement!



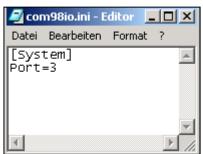
Checks and Adjustments

Service program COM98IO

Every LF8-installation performs automatically an installation of the COM98IO into the LF8-installation directory (main directory). COM98IO allows checking separately the different channels of the PowerCube.

To work with this service program,

- open the file "com98io.ini" in the LF8-installation directory. Use the program "Windows notepad" or "Editor"
- Enter the correct COM-port for the check: "Port=X" "X "means the used PowerCube-COM port



Pict.: COM98IO.ini-window

- Close the file and store the modifications.
- Start the COM98IO program by clicking on "com98io.exe" in the LF8-installation directory and select PowerCube as hardware
- Open the drop-down menu "Control" and click on "Start"
 - = The control measurement starts
 - = The window "com98io-info" gives actual numeric measurement values for every channel
 - = Use the measurement values for check or adjustment purpose

🏶 COM98IO V2.4 :-main-	: COM	1, 11	5200, 8, 1,	keine	Parität, Flag	ys: 1
Control Switch Channels	View	Print	Adjustment	Save	Stabilitätstes	t
StartCard StopCard	F5 F6					
Start	F7					
Stop	F8					
Measure with Card			COM98IO- CH6=2046	INFO	×	
✓ Ros 00 (off) Ros 01 (10Hz with Card) Ros 10 (10Hz without Card Ros 11 (15Hz))		CH7=2046 CH7=2046 CH8=2050 F CH9=2046 (CH10=2046)2=20,9	3%	
IgnoreStopFlag			CH11=2046 CH12=2046			
			CH13=2046		•	

Pict.: CO98IO, Pull-down-menu "Control"

How to select measurement channels for check and adjustment

- Click on register card "Channels"
 - = the list of all measurement channels is displayed on the screen
 - select the desired channel(s) for graphical display on the screen
 - = The more channels that are selected, the smaller the scales become
 - = The actual measurement value is displayed as red curve
 - = The COM98IO-Info-Window gives numeric values

🏶 COM98IO 🛛 ¥2	2.4 :-main-: COM 1,	115200, 8, 1, keine Parität, Flags: 1
Control Switch	Channels View Pri	nt Adjustment Save Stabilitätstest
	🗸 СНО	
	✓ CH1	
	✓ CH2	
	🗸 СНЗ	
	✓ CH4	
	✓ CH5	
	✓ CH6	CH6=2045
	✓ CH7	CH7=2046
	✓ CH8	CH8=2051 Flow=0,0I/s
	✔ СН9	CH9=2046 02=20,9%
	✓ CH10	CH10=2046 CO2=10,0%
	✓ CH11	CH11=2047
	✓ CH12	CH12=2046
	✓ CH13	CH13=2046
	✓ CH14	
	✓ CH15	
	CHallon F11	
	CHalloff F12	

Pict.: COM98IO, Drop-down menu "Channels"

How to select switch channels for adjustment and checks

- Click on "Switch"
 = the list of all switch channels is displayed on the screen
- Select the desired channel(s) for functioning

The selected switches activate the hardware (e.g. suction pump, calibration valve)
 The COM98IO-Info-Window gives simultaneously numeric values of the measurement channels

🎄 COM	9810 ¥2.4 :-main-:C	COM 1, 115200, 8, 1, keine Parität, Flags: 1
Control	Switch Channels Vi	iew Print Adjustment Save Stabilitätstest
	SW0	
	SW1	
	SW2	
	SW3	
	SW4	COM98IO-INFO
	SW5	CH2=2046
	SW6	CH3=3737
	SW7	CĤ4=2048
	SW all on F9	CH5=3436 T=22,3°C
	SW all off F10	CH6=2047
		CH7=2046
		CH8=2051 Flow=0,0I/s
		CH9=2046 02=20,9%
		CH10=2046 CO2=10,0%
		CH11=2046

Pict.: COM98IO, Drop-down menu "Switch"

Overview: Measuring and switching channels of the PowerCube Ergo

Measurement	Signal
Channel	
0	
1	
2	
3	Ambient pressure
4	
5	Temperature
6	
7	
8	PF1 (Flow)
9	
10	CO2-Analyzer
11	
12	O2-Analyzer (SSO)
13	
14	
15	

Switch Channel	Ergo
0	Suction pump
1	Calibration valve
2	
3	
4	
5	
6	
7	O2-reset

Adjustments

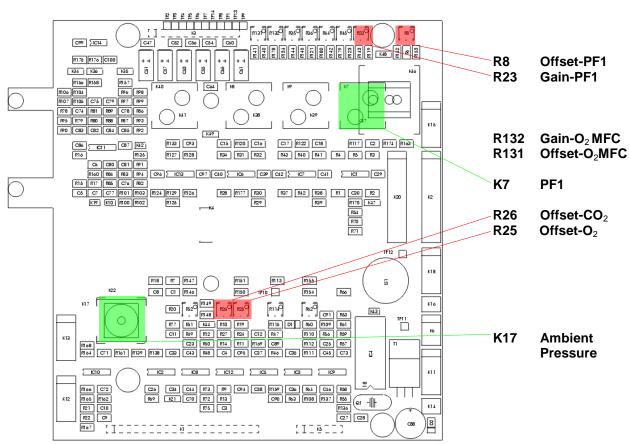
General

- Respect for all adjustments for gas analyzers or pressure transducer the 30-min-warm-up time
- Open COM98IO for monitoring of the desired channel(s)

DANGER	REQUIREMENT FOR SERVICE PERSONEL
$\underline{\mathbb{N}}$	Opening the PowerCube-housing as well as all changes, modifications, extensions, repairs, maintenance measures, and any other work on GANSHORN products including meteorological / safety checks may only be performed by GANSHORN or by an authorized GANSHORN partner.
	Only qualified service technicians that have been trained on repair and maintenance of the PowerCube are authorized to perform the procedures described in this manual!
DANGER	DISCONNECT FROM THE MAINS BEFORE ANY REPAIR WORK
$\underline{\mathbb{N}}$	Disconnect the PowerCube from the mains before starting any repair work. If checks and adjustments of the PowerCube-module can only be carried out by removing the cover AND when connected to the mains, it will be pointed out especially in the respective description. When performing these procedures be aware that parts inside the device may be current-carrying.
	ELECTROSTATIC DISCHARGE (ESD)
\triangle	 The PowerCube contains electro-static sensitive electronic components; observe antistatic precautions for any maintenance procedure: The unit must be placed on an earthed antistatic mat Service personnel must be earthed and have to wear anti-static clothing/shoes when handling boards or components Comply with the international standard IEC 61340-5-1

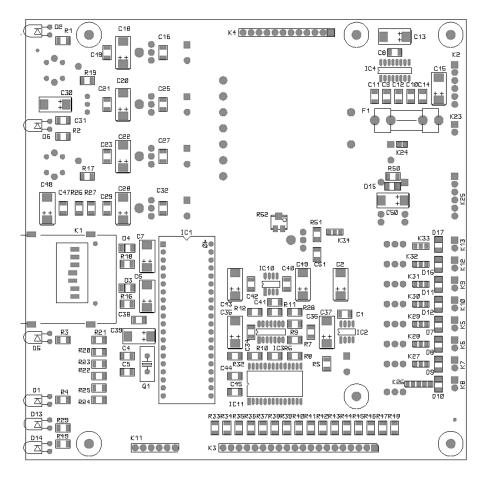
• Always use an antistatic bag when transporting boards or components

Layout Analog Module 1.3



Pict.: Analog Module 1.3 with pressure transducer (green) and potentiometer (red)

Layout Controller Module 1.3



Pict.: Controller Module 1.3

Adjustment of the O2-Analyzer

Preparation

- Connect patient tube correctly to PowerCube as for a gas calibration
- Ensure correct calibration gas supply
- With COM98IO switch on the suction pump channel

Gain

- Adjust the O2-offset to 2625 Digit (allowable deviation ±20 Digit)
 - With COM98I0 switch the O2-Reset switch channel for one second on and then off again.
 - Adjust potentiometer R131 on the Analog Module 1.3
 - Adjust offset until COM98IO show the value of 2625 Digit for the measurement channel (2625 Digit, allowance ±20 Digit)
 - With COM98I0 switch the calibration valve-channel on
- Adjust potentiometer R132 on the Analog Module 1.3
- Adjust gain until COM98IO shows a difference of x Digit to the actual offset-value (∆ x Digit, allowance ±50 Digit) as x = (20.9 (actual O2-concentration of the calibration gas) x 125
- With COM98I0 switch the calibration valve-channel off

Offset

- With COM98I0 switch the O2-Reset switch channel for one second on and then off again.
- Adjust potentiometer R131 on the Analog Module 1.3
- Adjust offset until COM98IO show the value of 2625 Digit for the measurement channel

Adjustment of the CO2-Analyzer

Due to the technique of the PowerCube-CO2-Analyser it is not necessary to adjust the gain, which is configured on the CO2-PCB. Only the offset has to be adjusted.

Preparation

- Perform the adjustment after at least 30 minute system warm-up time
- Connect patient tube correctly to PowerCube as for an Ergospirometry measurement

Offset

- Adjust potentiometer R26 on the Analog Module 1.3
- Adjust offset until COM98IO show the value of 1048 Digit for the measurement channel (1048 digit, allowance ±20 Digit)

Gain check

- Check gain with calibration gas (switch 0 & 1 in COM98IO) Gain = Δ 1000 Digit (± 50 Digit)
- With COM98I0 switch the calibration valve-channel on
- COM98IO should show for gain a difference of 1000 Digit to the actual offset-value (△ 1000 Digit, allowance ±50 Digit)
- With COM98I0 switch the calibration valve-channel off
- If gain is out of range, it is possible that the CO2-Analyzer has to be replaced

Adjustment of the Sensor Flow PF1

Offset

Avoid pressure on the flow pressure transducer (e.g. flow coming from the blue / white flow tubing socket on the rear of the PowerCube) during the offset-adjustment

- Adjust potentiometer R8 on the Analog Module 1.3
- Adjust offset until COM98IO show the value of 2048 Digit for the measurement channel (2048 Digit, allowance ±50 Digit)

Gain

- Supply 6.25 mbar pressure to the blue OR the white flow tubing socket on the rear of the PowerCube
- Adjust Potentiometer R23
- Adjust gain until COM98IO shows a difference of 1000 Digit to the actual offset-value (∆ 1000 Digit, allowance ±20 Digit)
- Repeat this procedure for the second flow tubing socket

Adjustment of the Suction Flow (Suction Pump)

Preparation

- Connect patient tube correctly to PowerCube as for an Ergospirometry measurement
- With COM98IO switch on the suction pump channel

Adjustment

- Adjust potentiometer R52 on the Controller Module 1.3
- Adjust the flow until flow meter shows the value of 1.0 l/min (allowance ± 0.1 l/min)
- With COM98IO switch off the suction pump channel

Adjustment of the Calibration Gas Pressure Regulator

The outlet flow of the pressure reducer should be 1.2 l/min but minimum 0.1l/min more than the measurement suction flow of the pump.

For details of the installation and adjustment of the calibration gas supply please refer to

=> Instruction Manual PowerCube-Ergo,

- Chapter 5, Calibrations and tests, Ergo calibration (O2/CO2)!
- Appendix: Customer information Measurement and calibration gas!

Chapter 7: Spare Parts

Spare Part List PowerCube-Ergo-SSO (GE CASE-ES)

GE Ref.No.	Gas analyzers (for exchange only, please send back the original parts)
2044244-001	O2-Analyzer (SSO) PowerCube-Ergo (incl. assembly auxiliaries)
2044244-002	CO2-Analysator PowerCube-Ergo (incl. assembly auxiliaries)
	Electromechanical parts
2044244-003	Side-stream sampling pump MB for PowerCube-Ergo
2044244-004	Calibration valve incl. PVC-tube 2x1 (20 cm) and two attached connection
	tubes (KP7011) for PowerCube-Ergo (incl. assembly auxiliaries)
	PCBs (for exchange only, please send back the original parts)
2044244-005	Analoge Module PowerCube-Ergo-SSO (incl. assembly auxiliaries)
2044244-006	Controller Module PowerCube-Ergo incl. DCDC-Module and PIC
	(incl. assembl.aux.)
2044244-036	Anacom Module SPO2
	Mechanical parts
2044244-007	Electronic unit holder PowerCube (PU: 2) (incl. assembly auxiliaries)
2044244-008	Mounting plate PowerCube-Ergo/Body/Diff (incl. assembly auxiliaries)
2044244-009	Compensation vessel PowerCube-Ergo/Body/Diff
2044244-010	Stands for PowerCube (PU: 4)
	Internal cables
2044244-011	Internal cable set incl. power switch (KP7001) for PowerCube
	(incl. assembl.aux.)
2044244-012	External RS232 cable, 2 m (KP7003) for PowerCube
	(incl. assembly auxiliaries)
2044244-013	Connection cable CO2-Analysator (KP7004) for PowerCube-Ergo
	(incl. assembl.aux.)
2044244-014	Internal temperature sensor (KP7005) for PowerCube
	(incl. assembly auxiliaries)
	Internal equalization cable cover (KP7008) for PowerCube
2044244-016	Internal electronic unit pulse receiver (KP7009) for PowerCube-Ergo
	(incl. assembly auxiliaries)
2044244-017	Internal electronic unit SPO2 (KP7139) for PowerCube-Ergo-SPO2
2044244-018	Internal connection cable AnaCom-Module - Analog-Module (KP7014)
	for PowerCube-Ergo-SPO2
	Internal equalization cable mounting plate (KP7018) for PowerCube
	Internal equalization cable housing (KP7019) for PowerCube
2044244-021	
	Ergo-SSO
2044244-022	Connection cable SSO-Signal Controller-Module / Analog-Module (KP7040)
	for PowerCube-Ergo-SSO
2044244-036	Internal connection cable RS232 (KP7002)
0044044.000	Internal tubes
	Internal flow-tubing set (SP7001) for PowerCube with pneumotach
	Internal gas calibration tubing set (SP7006) for PowerCube-Ergo A1, B1
2044244-025	Internal measurement tubing set ergospirometry (SP7025)
	for PowerCube-Ergo-SSO
2044244 202	Other spare parts
	Complete housing, GE-health for PowerCube-Ergo-SSO, (incl. assembl.aux.)
2044244-027	
2044244 000	(incl. assembl. aux.)
2044244-028	Cover, standard blue (RAL 5013) for PowerCube-Ergo-SSO
2044244 022	(incl. assembl.aux.)
	Front panel PowerCube, standard blue
	Rear panel PowerCube-Ergo/Spiro, standard blue
	External temperature sensor 6 cm (KP7006) for PowerCube
	External temperature sensor 70 cm (KP7026) for PowerCube
2044244-033	Power supply PwC 100–240VAC, 24VDC,

Appendix

Appendix A: Allocation of Ergo Parameters

Appendix B: Working Procedure AA MTK 70_03 for PowerCube Ergo-SSO

Appendix C: Checklist PP MTK 70_03 for PowerCube Ergo-SSO

Appendix A: Allocation of Érgospirometry Parameters

Ergospirometry configuration, register card hardware: settings for PowerCube-Ergo with PC-ECG, if the complete system (including ergometer / treadmill) is controlled by the ECG

Parameter	Not present	ErgoScope (analog)	Peripheral device(RS232)	Bicycle (RS232)	ECG (RS232)	Windows- Program
ECG	X					
VO2		Х				
VCO2		X				
VE		Х				
Heart rate						Х
Resp. rate		Х				
Act. Load						х
Pred. load						x
PET02		х				
PETCO2		X				
BDsys						х
BDdia						Х
PaO2	Х					
PaCO2	Х					
Speed						Х
Grade						Х
SpO2	Х					
Distance	х					
HR from QRS- Trigger	x					

Working procedure AA MTK 70_03	Ambit: Technical Support	Ganshorn Medizin
Working procedure for PowerCube Ergo /SSO Rev E	Revision: Rev01 30.11.2012	Electronic GmbH

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Flow PF1 Gain	3
Ergo suction flow	
Ergo pressure reducer outlet flow	5
O ₂ -cell T10/T90 time	5
O ₂ Offset	
O ₂ Gain (with Ergo-calibration gas)	5
CO ₂ Offset	
CO ₂ Gain (with Ergo-calibration gas)	6
9. System calibration	6
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Working procedure AA MTK 70_03	Ambit: Technical Support	Ganshorn Medizin
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Application area:

PowerCube-Ergo with Art.No: 033370210, 033370238 For options further checks might become necessary

Basic remark:

This check procedure must be carried out within a preventive maintenance and as checkout procedure after repair.

1. Examinee

Enter in the checklist the serial numbers of all parts that are checked.

2. Check conditions

The check conditions are the same as the measurement conditions. Avoid ambient condition fluctuations during at least 24 h before the check. Check, if actual ambient conditions correspond to ambient condition in the LF8-Calibration-program/ambient condition

3. Test equipment

Please note the requirements for test equipment. Use only test equipment with the allowed measuring range and which are calibrated accordingly to their manufacturer's guidelines (see chapter "Necessary tools and equipment")

4. Calibration gas

The gas specifications and requirements for checks are the same as for calibrations during running operation. The actual values have to be entered correctly in LF8.

5. Deviations, establishments and evaluation

Experienced deviations which can not be repaired immediately must be noticed. Differences can cause that some parts of the system or the complete system is not allowed to use till restoration since carried out. If necessary the complete check must be repeated. The evaluation shows the current state of the tested system.

6. Visual check

Perform visual check of the complete system for damages, failures, contamination, wrong / insufficient connections (tubes, connectors) etc.

7. Software settings

Before the check, assure correct software settings (ambient conditions, calibration gas etc.)

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8. Electronics

Functional check of the switching and measurement channels in COM98IO: Check the pressure sensors with pos. und neg. pressure; the higher differences have to be noted.

Test procedures for gas sensors have to be carried out with running suction pumps and complete tubing.

Attention: While adjustment do not breath into the system!!!

channel	Ergo
0	(SpO ₂)
1	
2 3	
3	Pressure(amb)
4	
5	Temp.
6	
7	
8	PF1
9	
10	CO ₂
11	(Puls Digi.)
12	O ₂
13	(Puls Ana.)
14	
15	

switch	Ergo
0	Pump Ergo
1	Cal. Valve
2	
3	
4	
5	
6	
7	

Switching channels

Check all used switching channels.

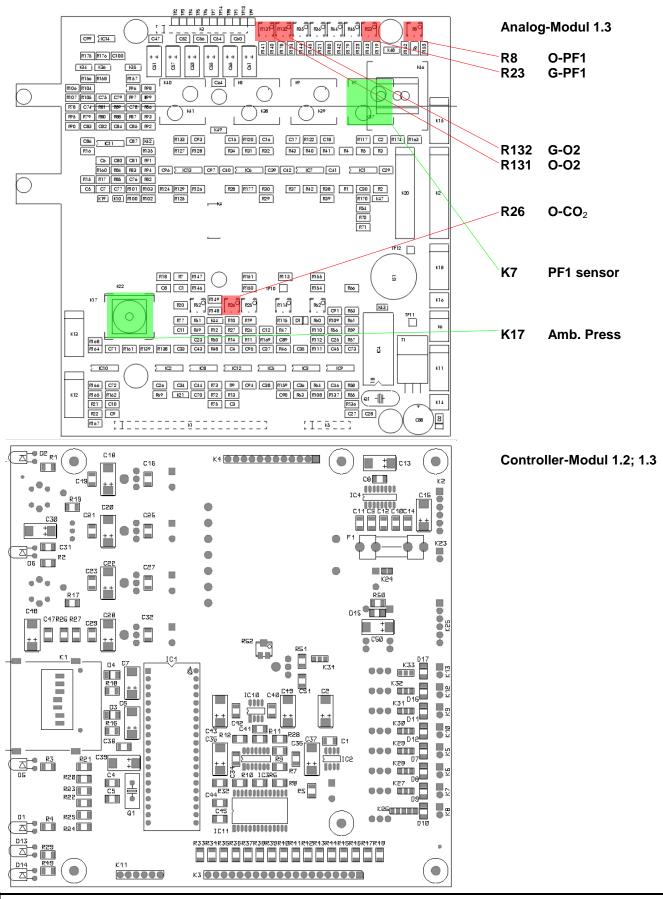
Flow PF1 Offset

Check Flow PF1 in COM98 I/O. **Adjustment:** Trim Flow PF1channel with potentiometerR8 on Analog-Modul 1.3

Flow PF1 Gain

Impinge pressure to sensor K7 and check value in COM98I/O. **Adjustment:** Impinge pressure and adjust Channel Flow PF1with potentiometer R23 on Analog-Modul 1.3

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Ergo suction flow

Switch on suction pump and measure the flow at the patient tube incl. gas drying tube. The suction flow is automatically controlled by the CO2 sensor.

Ergo pressure reducer outlet flow

Attention: Before starting this test check all connections being under pressure for solid and tight mounting.

Remove the calibration gas tube from the PowerCube rear side (yellow), open the gas bottle and check the outlet flow via flow meter (bottle pressure \geq 10 Bar).

O2-cell T10/T90 time

Prepare the PowerCube like for the gas calibration and open gas bottle.

Close the LF8 or COM98IO and start PowerTool V1.3: the windows GANSHORN-Hardware (Control), Switch (Switch) and Scan Timing (View) must be screened.

Select in window GANSHORN-Hardware "PwC" and the used COM port. Start the PwC via button 🗵 .

Activate in window Switch Channel 0.

Select in window "Scan Timing" the "Messmodus" "Ergogas-

Anstiegszeiten" and set at Measure channel the respective measurement channel for O_2 , Set at "Switch channel" the number for the Cal. Valve. All the othe settings can be remained like set automatically (Schaltzyklen Anzahl: 5; Zyklus-Abstand: 7000ms; Ein/Aus-Abstand: 3500ms). For viewing all needed parameters sometimes the scan timing window must be maximized.

Click the button "Start measurement" for begin the automatically performed test. Note the T10/T90 values from "Einschalten Mittelwert" and "Ausschalten Mittelwert" in the protocol.

If one of those values is out of the allowable range then the oxygen sensor must be replaced.

O2 Offset

Activate the switch for suction pump and switch on the O_2 reset for 1 second. Adjust the O_2 -Offset via R141 on the (Analog-Modul 1.3)

O2 Gain (with Ergo-calibration gas)

Activate the switches for the suction pump Ergo and the Cal. valve and check the indicated value in COM98IO.

Attention: The Gain depends from the used calibration gas and the O₂-cell. **Calculation:** Δ Digit(Gain)=((20,9%O₂)-(O₂ concentration gas bottle))*125 Adjustment: Adjust the Gain via R140 on the (Analog-Modul1.3)

CO₂ Offset

Switch on the Ergo suction pump and check the value in COM98IO. **Adjustment:** Set the value via potentiometer R26 (Analog-Modul 1.3) with running suction pump.



СОМ1 •

O SpiroJet O

O:

0. 1: 2: 3: 4: 5: 6:

Working procedure AA MTK 70_03	Ambit: Technical Support	Ganshorn Medizin
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CO₂ Gain (with Ergo-calibration gas)

Remark: Not applicable for PwC-Ergo with option Cardiac output

Activate the switches for the suction pump Ergo and the Cal. valve and check the indicated value in COM98IO.

Attention: The Gain depends from the used calibration gas and the CO₂-cell. The Gain is not adjustable!

9. System calibration

Perform a complete calibration of the device and note down the calibration factors in the protocol. Add to the check documentation hardcopies of all successfully performed calibrations.

Volume calibration

Calibrate the pneumotach "Blendenspirozeptor" with a suitable calibration syringe. Check the pneumotach for reliance on different flows. When calibrating the pneumotach with different speed (standard, double and half) drift is allowed only in the one / in the same direction.

Gas calibration

Perform the gas calibration like described in the operating instruction manual.

10. Self test

Perform all possible measurements by yourself. Print out the measurement results and add it to the check documentation.

11. Neccessary tools and equipment

- Screwdriver TX10
- Thermometer: 10 to $40^{\circ}C \pm 1^{\circ}C$
- Barometer: 900 to 1055 hPa ± 10hPa
- Hygrometer:
 20 to 90 % RH ± 5 % RH
- Flowmeter
 [e.g. Rota 1,5 l/min ± 10%]
- Pressure tester [e.g. HalstrupWalcher Kal200] 0 to 10 mbar, ± 0,1%

- SMD potentiometer screwdriver
- Multimeter [z.B. Fluke 175] 0 to 30 VAC ± 0,4%
- Calibration syringe [e.g.1 000 ml]
- 5mm allen wrench
- Phillips-tip screwdriver size 1
- Tamper evident seal

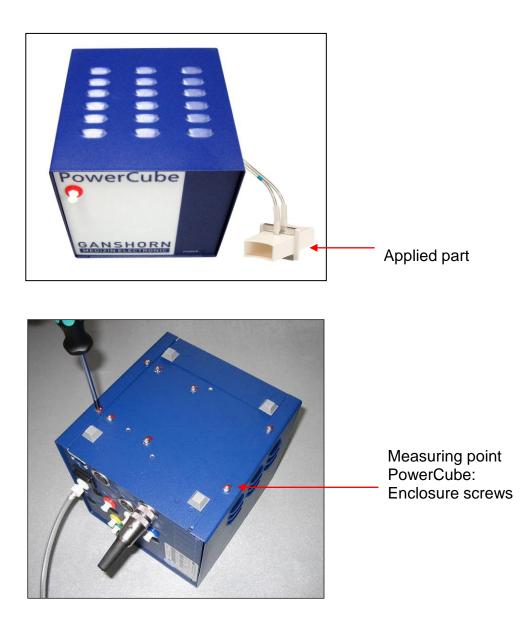
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ELECTRICAL SAFETY CHECKS

Electrical safety checks must be performed in a period of 12 month and after repair.

Product Safety Class: 2 BF

Applied part: Pneumotach "Blendenspirozeptor" (no current measurable because this part and its connection to the PowerCube enclosure is not conductive)



Checklist PP MTK 70_03	Ambit: Technical Support	Ganshorn Medizin Electronic GmbH
Checklist for PowerCube Ergo /SSO Rev E	Revision: Rev01 30.11.2012	

1. Examinee

Date:			Examiner:					
Date.								
System:			Company:					
		Accessorie			S/N			
Options:								
Last check:								
		Reason of	this check:					
Next check:		Preventive	Maintenanc	e 🗆	Check after F	Repair		
This check is only to	be carried out from authori	zed persons (N	IPBetreibV §	§11)!		-		
All following parame supply voltage of 23	ters have to be checked und	ler ambient co	nditions allo	wed for	measurement	use an	d wi	ith a
Respect the warm-up	o time of 30 minutes!							
The pressure sensor	s must be checked with pos	a. und neg. pres	ssure; the hi	igher dev	viation applies	s!		
2. Check ambient co								
	ance from +15 °C to +35 °C							С
Rel. humidity ; tole	rance from 30% to 80%						%	o o
Ambient pressure;	tolerance from 700 hPa to 1	050 hPa					h	Pa
3. Test equipment								
Multimeter	Туре:			S/N	:			
Flowmeter	Туре:			S/N	:			
Pressure tester	Туре:			S/N	:			
Thermometer	Туре:			S/N	:			
Barometer	Туре:			S/N	:			
Hygrometer	Туре:			S/N	:			
4. Test and calibration	on gas							
Ergo; 15,9% O ₂ 4.5	, 5% CO ₂ 4.5, Rest N ₂ 4.5		0 ₂	CO ₂	Use-by da	ite:		
5. Deviations, Establ	ishments and Evaluation							
						_		
						Y	es	No
				Test	t passed			
Date of t	est:	Signature (examiner):					
User		Use	er					
Function / departm	ent:	Name /	Signature:					

Checklist PP MTK 70_03	Ambit: Technical Support	Ganshorn Medizin
Checklist for PowerCube Ergo /SSO Rev E	Index: Rev01 30.11.2012	Electronic GmbH

6. Visual checks				n.a. nOK OK
Tubes and connectors (not bent, connected tightly, not damaged)				
Gas drying tube (not bent, connected tightly, not damaged)				
Pneumotach "Blendenspirozeptor" is clean, not damaged				
7. Software settings				n.a. nOK OK
Enter actual ambient conditions				
Check and adjust actual altitude				m
Cal. gas values entered correctly (Ergo Gas Ca	libration)			
8. Electronic				n.a nOK OK
Check switching channels				
Flow; Offset (2048 Digit), tolerance (± 50 Digit)				Digit
Flow; Gain at 6,25 mbar (∆ 1000 Digit), toleranc	e (±20 Digit)			Digit
PwC-Ergo:				
Ergo suction flow; measured at mask (0,5-0,7 l/min)				l/min
Ergo pressure reducer; outlet flow (1,2 l/min) (min. 0,1 l/min more than PowerCube suction flow)				l/min
O ₂ -Zelle T10/T90 rising time (<200 ms)				ms
O ₂ -Zelle T10/T90 drop-out time (<200 ms)				ms
O ₂ ; Offset with running suction pumps, (2625 Digit), tolerance (±20 Digit)				Digit
O₂; Gain (Calibration gas Ergo) with running pump (△ -625 Digit), tolerance (±50 Digit)				Digit
CO ₂ ; Offset with running suction pump (1048 Digit), tolerance (±20 Digit)				Digit
CO ₂ ; Gain (Calibration gas Ergo) with running pump (△ 1000 Digit), tolerance (±50 Digit)				Digit
9. System calibration				n.a. nOK O.K
Volume Calibration: Standard Sensor; Diff. in/e	ex			
Standard Sensor not dependent from different flows				
Ergo Gas Calibration				
Ergo Gas Calibration	O ₂ - Factor	O ₂ - Offset	CO ₂ - Factor	CO ₂ - Offset
11. Self test				n.a. nOK OK
Patient measurement o.k?				

Checklist PP MTK 70_03	Ambit: Technical Support	Ganshorn Medizin	
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ELECTRICAL SAFETY CHECKS:

Perform electrical safety checks when indicated. Record measurement values in your debrief. NOTE: The following values apply to 120/240VAC

STEP		CONDITION	UTT- ON	RESULT	Leakage Current limit in micor amps *UL 60601-1
A	Earth Leakage Current		in μA		UL
1.	Forward polarity	NC		Pass/Fail	500 µA
2.	Reverse polarity	NC		Pass/Fail	500 µA
3.	Neutral open, forward	SFC		Pass/Fail	1000µA
4.	Neutral open, reverse	SFC		Pass/Fail	1000µA
В	Enclosure Leakage Current		in μA		
1.	Forward polarity	NC		Pass/Fail	100 µA
2.	Reverse polarity	NC		Pass/Fail	100 µA
3.	Neutral open, forward	SFC		Pass/Fail	500µA
4.	Neutral open, reverse	SFC		Pass/Fail	500µA
С	Patient Leakage Current		in μA		
1.	Forward polarity	NC		Pass/Fail	10µA
2.	Reverse polarity	NC		Pass/Fail	10µA
3.	Neutral open, forward	SFC		Pass/Fail	50µA
4.	Neutral open, reverse	SFC		Pass/Fail	50µA

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D	Patient leakage current Mains on applied part		in μA		
1.	Forward polarity Neutral closed	SFC		Pass/Fail	5000µA
2.	Reverse polarity Neutral closed	SFC		Pass/Fail	5000µA

NC = Normal Condition SFC = Single Fault Condition

*Countries recognizing IEC standards use IEC values. Countries recognizing UL standards use UL values.



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