Geratherm®
Respiratory

Ergostik

User Manual

Version 1.2.2

Date 17th October, 2014

1. Welcome to Blue Cherry

Thank you for choosing the Blue Cherry diagnostic platform, we are sure you will be very happy with your choice, and find the advanced functionality offered by Blue Cherry a great benefit in your diagnostic activities.

The Blue Cherry diagnostic platform offers its user a level of functionality which is unsurpassed, providing multiple diagnostic measurements from within a single software platform. Addition of further diagnostic measurements couldn't be easier: simply purchase the required hardware and plug it into a spare USB 2.0 port on the PC. The Blue Cherry system will recognise the new device and testing will become available within the diagnostic platform.

The Blue Cherry platform works well as a standalone device for the smallest of requirements, however expansion for the future is simple. The software has been designed to allow connection of multiple units to a single Blue Cherry Database to allow centralisation of data, for the purposes of reporting or statistical analysis, further with the ability to interconnect with many Hospital information systems using the HL7 format, the diagnostic system can be integrated into even the largest of requirements.

This document contains important information for the operation of Blue Cherry and Ergostik. We strongly recommend reading this manual carefully in order to avoid incorrect use or damage to the device. Geratherm Respiratory does not take responsibility for any direct or indirect damage to the Device, if it is not operated in accordance with this manual. Users must observe precautions, warnings and instructions.

Geratherm Respiratory does not take liability for mistakes in this documentation. The liability for direct or indirect losses related to the use of this document is excluded, as long as this is allowed by law.

This user manual is according to EN 60601-1 an integral part of the product. Geratherm Respiratory reserves the right to make changes to the contents without prior notice. All changes made are in accordance with the guidelines for manufacturing medical devices.

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2. Ergostik

2.1 Device description and scope of delivery

The Ergostik device is mainly used for CPET (Cardiopulmonary Exercise Testing). This investigation involves submaximal and maximal treadmill or bicycle exercise with continuous electrocardiographic monitoring and breath by breath determination of oxygen uptake and carbon dioxide output as well as spirometry. This allows determination of exercise capacity, peak heart rate, maximal oxygen consumption, anaerobic threshold, respiratory gas exchange ratio, and ventilatory equivalent for oxygen. Maximal oxygen consumption is the best indicator of maximal cardiac reserve and provides important prognostic information to guide the assessment and therapy of patients with heart failure as well as other cardiac conditions.

The Ergostik connects via USB to PC and consists of housing with integrated electronics, oxygen analyser, carbon dioxide analyzer and pump. For the flow measurement the proven Ergoflow flow sensor is used.
The Ergostik runs under the powerful Blue Cherry diagnostic software platform. The standard software is capable of measurements including CPET and Spirometry as well as Pre/post medication investigations and trend analysis. The software contains a powerful database for patient and test information. Ergostik together with Blue Cherry software has a modular design to allow the addition of further options in the future such as MVV or Pulse Oxymetry measurements.

The Ergostik is designed with versatility in mind, and can be used in many areas including Sport Medicine, Pulmonary Rehabilitation, Pre-operative assessment and Cardio Pulmonary Exercise Testing. It can be operated in a stationary or mobile way. Ergostik is not defined to check vital physiologic parameter. The following contraindications for CPET testing should be taken into account: Arrhythmia, resting BP higher than 180/100, severe respiratory insufficiency and other severe organic diseases.

A qualified physician should be present at all time during CPET testing.

The modular and flexible software concept allows user specific configuration of Blue Cherry. A User may add to the predefined medication list, select between different predicted equations sets and add further predicted equations, define new parameters, configure results table and change patient data input view.

Blue Cherry can be connected to office information software via a GDT interface. There are different export possibilities into Excel and XML. Using the standard Microsoft ®clipboard, all charts may be imported into standard software such as MS Word or MS PowerPoint.
Blue Cherry has a unique report interface allowing the preview and print of chosen numeric and Graphic data and the editing of curves retrospectively.

2.1.1 Scope of delivery

Ergostik includes the following components:

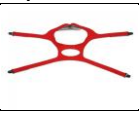
Component	Description
	**Ergostik** Cardiopulmonary exercise system
	**Blue Cherry Software CD** Modular diagnostic platform operating under Microsoft Windows environment
	**Quick user guide**
	**Flow Sensor** for measurement flow
	**Silicon Mouthpiece**
	**Noseclip**
	**Tubing set** Including flow double tube and gas sample line including filter and nafion line
	**Tube for gas calibration**

Component	Description
	**Power supply**
	**USB cable**
	**Silicone adapter** to connect flow sensor to calibration pump. Note user manual for indications for the conduct of the calibration.
 	**Ambistik including USB Dockingstation**

2.1.2 Accessories

The following accessories can be purchased from you dealer:

Component	Description	Part number
	**Face mask Large**	**10.813**
	**Face mask Medium**	**10.814**
	**Face mask Small**	**10.810**
	**Face mask Small**	**10.811**
	**Face mask Petit**	**10.825**
	**Face mask Pediatric Large**	**10.828**
	**Face mask Pediatric Small**	**10.827**

Component	Description	Part number
	Headgear M (for face mask Large, Medium and Small)	10.812
	Headgear S (for face mask Extra Small and Petit)	10.829
	Headgear (for face mask Pediatric Small and Pediatric Large)	10.826
	Maskadapter	10.815
	Mouthpiece including saliva tap	10.819
	Tubing set 2m	40.425
	Tubing set 4m	40.425-1
	Tubing set 6m	40.425-2
	Pressure reducer	10.821

2.1.3 Spare parts

The following spare parts can be purchased from your dealer:

Component	Description	Part number
	**Permapure tube and filter**	**40.424**
	**O2 Sensor**	**40.401**

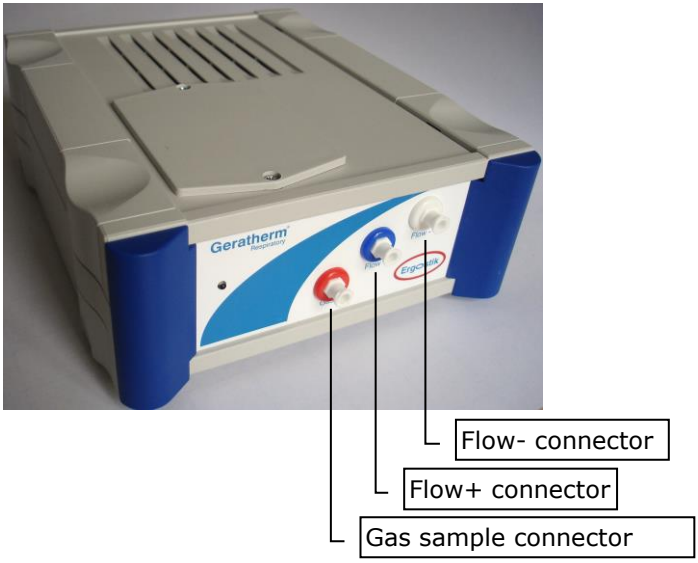
2.2 Setup

Before testing with the Ergostik the double pressure tube and the gas sample tube must be connected to the front panel and also to the Ergoflow flow sensor

Important additional information regarding the Blue Cherry software, calibration, disinfection and testing can be found in separate user manual. Attention should be paid to this information.

2.2.1 Connecting the tubes to the front panel

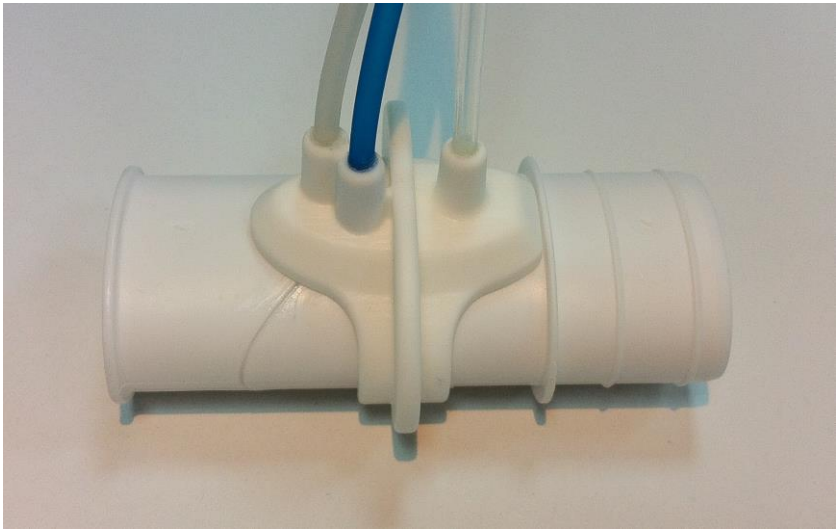
On the front side of the Ergostik device are three connectors for the connection of the pressure tubes. These connectors are colour coded to ensure correct connection of the tubes.



Always ensure that all tubes are connected securely. Place the connector from the hose onto the rear connector and turn in a clockwise direction to secure each connector,
turning counter clockwise will release each connection.

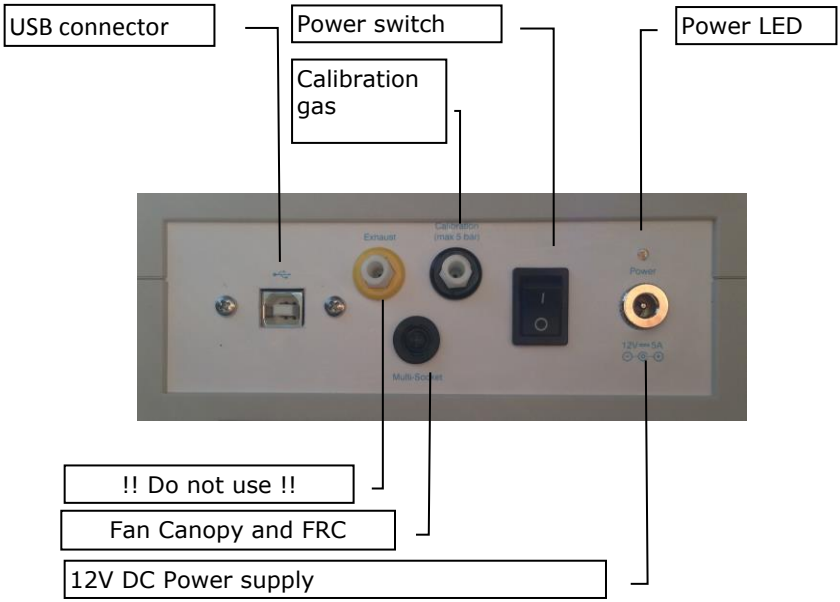
2.2.2 Flow Sensor connection

The double pressure tube and the gas sample tube should be connected to the flow sensor as illustrated in the following illustrations. Always ensure the tubes are firmly connected and are not bent.
Prior to testing connect a clean disinfected mouthpiece directly to the flow sensor.



2.2.3 Connection on the rear side of the Ergostik

Connect the black coded end of the calibration tube to the black connector on the rear side and the other end to the pressure reducer of the calibration gas cylinder.
Connect the USB hook up of the Ergostik device with a spare USB connector of the computer while using the provided USB cable.



Do not connect any tube to the yellow connector on the rear side of the device.

The maximum allowed pressure at the calibration gas connector is 5bar. A higher pressure can damage the device. We recommend to only use pressure reducer provided by Geratherm Respiratory which provide a fixed output pressure as well as fixed output flow of 2L/min.

2.2.4 Connect Ambistik

Connect first the USB connector of docking station with your computer and then Ambistik unit with the Data connector of your docking station. The power connector must not be used.

2.2.5 Switch-on Ergostik

Connect the power supply to the rear of the Ergostik then connect the power supply to a suitable power outlet. The device can then be switched on using the switch at the rear side of the unit.

The Ergostik may only be operated by using the provided power supply. See picture below.

Please ensure the power plug is easily accessible.

2.2.6 Switch-off Ergostik

The power switch on the back of the device allow to switch-off Ergostik unit. To separate from mains voltage the power cord need to be removed from power socket.

2.3 Security

2.3.1 General Security information

This manual is intended for medical technical personnel, familiar with the performance of Cardiopulmonary Exercise Testing procedures. Geratherm Respiratory recommend that users attend a certified training course. The instructions within this document are intended to describe the operation of the software and the handling of the equipment and should not be considered as training for the medical or technical personnel.

Before using the equipment users should read and understand this included user manual, paying attention to the operating instructions.

Geratherm Respiratory is responsible for the security and reliability of function of the Ergostik, as such only authorized personnel should perform changes or repairs to the system. Please consult your Geratherm Respiratory specialist service centre for any repairs. This equipment meets the requirements of VDE 0100

Geratherm Respiratory will not accept any warranty claims caused by the use of alternative accessories or consumables. Always use official Geratherm Respiratory products.

2.3.1.1 Norms and Guidelines

The Geratherm Respiratory products are manufactured in accordance with DIN EN ISO 13485. According to the European directive 93/42/EEC, Spirostik fulfils the requirements of annex II.
In addition the following norms are fulfilled:
- DIN EN 60601-1 (Medical electrical device)
- DIN EN 60601-1-1 (General safety requirements)
- DIN EN 60601-1-2 (EMV)
- DIN EN 60601-1-4 (Programmable electrical medical devices)
- DIN EN ISO 14971 (Risk management)
- DIN EN ISO 23747 (Peak Flow devices)

2.3.1.2 Electromagnetic compatibility

Strong radio transmitters should not be used close to the device. Do not use mobile phones and cordless phones close to the device. There may be an influence to medical devices. The interference resistance is 3V/m. Do not use a higher level close to the Ergostik.

2.3.2 Secure Use of the Ergostik

The Ergostik is a cardiopulmonary exercise system. It is highly recommend that the user observes all warning notices in order to ensure a safe use of the device.

The Ergostik should not be used in conjunction with multiple connection plug sockets or extension leads

Ergostik must only be used in combination with peripheral devices which fulfill the Norm DIN EN 60950 for office devices or the norm DIN EN 60601 for medical electrical devices. Always ensure the minimum requirements for the computer are met (see technical specification). Non-Medical devices should not be used close to a patient always ensure a minimum distance of 1.5m between patient and non-medical computer systems.

Flow sensors and pressure tubes must not be cleaned! Humidity inside the pressure tube may affect the accuracy of the measurement. Replace the pressure tube in case of contamination. Replace the flowsensor after each patient. Always observe instructions in the disinfection and cleaning section.

The User must not touch the patient and the signal output of the computer. The device should not be used in association with a mobile power strip or extension cable.

Large quantities of saliva and/or humidity in the flow sensor may impair the flow measurement. The flow sensor should be replaced in these conditions. In addition extreme temperature as well as extreme altitude may impair the flow measurement. Consider the site conditions indicated in the technical data.

Disconnect the device from power supply before cleaning. Wipe the housing and the PC using a soft cloth dampened with a non-abrasive cleaning solution and warm water. Remove excess fluids using a dry cloth.

For housing and PC use a surface wipe disinfection. Please see additional notes in section disinfection.

The device should not be exposed to water or operated in wet environments.

Ensure nothing can fall on the device; don´t put any objects on top of the device. There are no user serviceable components within the housing.

Never place the device on uneven or unsecured surfaces. Should the device case become damaged the unit should be returned for repair.

The device should not be used in dirty environments and wherever possible in a dust free environment.

This device must not be modified without the approval of the manufacturer

2.3.3 Cleaning and disinfecting the Mask, Mouthpiece and flow sensor

To protect both user and subject from cross contamination risk the mask, mouthpiece and flow sensor must be cleaned and disinfected after use. Further information on this subject can be found in the chapter cleaning and disinfection.

The nose clip is a single use item and must be disposed after use.

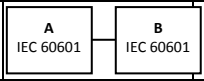
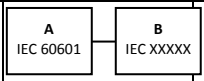
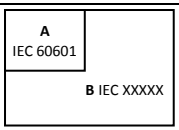
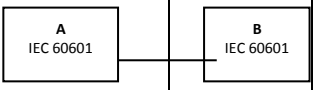
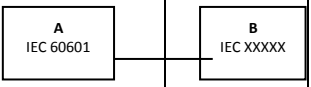
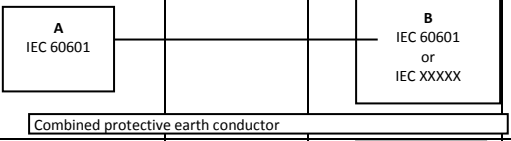
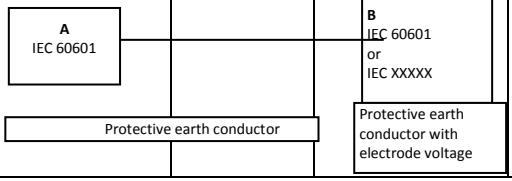
2.3.4 Combination with other devices

Connecting additional USB devices and high processor load can reduce the sample rate and therefore cause an error. We strongly recommend not connecting additional USB devices except mouse, keyboard and printer and not installing additional software. Please contact your local dealer for further information.

Always ensure all connections and cables are connected properly when using the Spirostik complete together with other devices. All connected devices must comply with legal regulations and the total leakage current must not exceed the maximum allowed valued specified in the Norm DIN EN 60601-1.

For some non-medical devices a higher case leakage current is allowed. Those higher limits can only be accepted outside patient area. It is essential to reduce the case leakage current, if such devices are used within patient area.

The Following table (source: DIN EN 60601-1-1, table BBB.201) explains the combination of medical electrical devices with non-medical electrical devices:

Situation	Medical used room		Non-medical used room	Possible solution
	Within patient area	Out of patient area		
resource A and B within patient area				
resource A and B within patient area				for B: additional protective earth conductor or safety transformer
Resource A is being power sourced by power source of resource B within patient area				for B: additional protective earth conductor or safety transformer
Resource A within patient area and resource B in medical used room				
Resource A within patient area and resource B in medical used room				See remarks below table
Resource A within patient area and resource B in a non-medical used room				See remarks below table
Resource A within patient area and resource B in a non-medical used room				for B: additional protective earth conductor or separator

2.3.5 Disposal

Ergostik contains electronic components, which must not be disposed of with domestic waste. Always ensure disposal is carried out in accordance with local directives.

2.3.6 Product Labelling

Example of typical product labelling:

SN: designates the serial number for the device.
The first 2 digits define the manufacturing year. The example 13 shows the device was manufactured in 2013.
The identifier |8|201| is a product specific code. The remaining digits define the device number of the Ergostik. In this example number 1.
REF: designates the part number for the Ergostik 40 400.

2.3.7 Used Symbols

The following table indicates all symbols used either on the product or within this manual.

Symbol	Explanation
	Pay attention to the user manual
	Intended to be used only in house (dry environment)
	Application component type BF according to DIN EN 60601-1
	Indicates single use device
	protection type II according to MDD
	Separate collection of electro and electronic devices
IPX0	Indicates no protection against dripping water
	Manufactured according RoHS directive 2002/95/EC
CE 0494	Geratherm Respiratory devices carry this CE no according to directive 93/42 ECC for medical devices and fulfil the requirements of annex II of the directive

2.4 Maintenance

The Ergostik has been designed to ensure it is a low maintenance device. Only minor maintenance is required to ensure trouble free operation.

Repair and maintenance should only be done by authorized service partner of Geratherm Respiratory.

2.4.1 Maintenance work and - interval

Interval	Maintenance work
Before each test	Check cable and tubing connections
After 50 to 100 Tests	Replace permapure tube and filter
After 12 months	Replace Oxygen cell and tubing set

2.4.2 Replace Oxygen cell

Oxygen measurement is performed using an oxygen analyser based upon the electro chemical principle. The Oxygen sensor will degrade with use and as such should be replaced at regular intervals to ensure continued quality of measurements. Geratherm Respiratory recommend changing this sensor after 12 months of use (this time may be reduced with increased testing).

The Oxygen sensor can be found underneath the below shown cover of the Ergostik housing. To exchange remove the cover and carefully remove the sensor detach the two tubes and the electrical connector from the ends and replace with a new sensor.

Replacement of the Oxygen cell should only be done by authorized service partner of Geratherm Respiratory. Please see technical manual for details.

Replacement Oxygen sensor may only be purchased from a local Geratherm Respiratory service partner.

2.4.3 Replacement of Nafion ® sampling line and filter

In order to improve life of the Oxygen sensor the gas sample taken during testing is dried. This is done using a sample filter and Nafion ® drying line, integrated into the gas sample tube. Both the filter and the Nafion ® tube should be replaced at regular intervals. A new sample tube is transparent but with use this tube will turn yellow and then brown in colour this change will reduce the effectiveness of the tube to dry the sample and it should be exchanged.

Geratherm Respiratory recommends that the in line filter is exchanged with the Nafion (R) tube.

Both items may only be purchased from a local Geratherm Respiratory service partner.

Saliva or high humidity within the tube can affect the measuring accuracy of the Ergostik. The tube and filter should be replaced in this case.

3. Warranty

3.1 General Description

Geratherm Respiratory assures that the device fulfils the technical data mentioned in the technical description and that this medical device is fee from material and manufacturing defects. This limited warranty is valid for 12 months from date of purchase. Within this period Geratherm Respiratory will repair or replace faulty products. The purchase date is equal to the delivery date, if purchased direct from Geratherm Respiratory, and respectively equal to installation date if purchased from a sales partner.

All service must be provided by Geratherm Respiratory or an authorized service partner of Geratherm Respiratory.
Geratherm Respiratory will not accept warranty claims on any unauthorised repairs.

3.2 Warranty exclusion

Warranty does not cover damage caused by the following:
- failure to meet the storage and transport conditions
- improper use, service or repair
- over or under voltage
- installation or use of external software
- connection with external devices
- use of the device outside the valid ambient conditions

3.3 Packing and shipping

In order to prevent damage caused by transport, devices must be shipped in the original packing. Damage during transport caused by improper packing will not be covered by Geratherm Respiratory.
We recommend insurance for all transport. Claims arising due to loss or damage are not covered by Geratherm Respiratory.

4. Technical Data Ergostik

Modifications are not permitted with this device

Technical Data:	Dimensions: Weight:	210 mm x 175mm x 75mm (L x w x h) 1120 g
Electrical data:	IP protection type: Protection class: Classification according to MDD: Application component type: PC interface: Power supply: Power consumption:	IPX0 IEC 529 II IIa 93/42/EWG date June 14th 1993 14.06.93 Appendix IX BF according to VDE 0750 (DIN EN 60601-1) USB 2.0 12V max. 5A <60 VA
Flow:	Flow sensor: Measuring principle: Measuring range: Measuring range ventilation: Resistance: Effective dead space: Flow resolution: Sample rate: Accuracy:	Ergoflow Differential pressure ± 16l/s 0 – 300l/min <0.12kPa/(l/s) <15l/s <20ml < 1ml/s 125 Hz ±3% or 20ml/s
Volume:	Measurement range: Accuracy:	0 – 20L ± 3% or 50mL
O2 Analyser:	Measurement principle: Measurement range: Accuracy: Resolution: T_{90}:	Electro Chemical cell 1 – 100% O2 0.1% 0.1% < 100 ms
CO2 Analyser:	Measurement principle: Measurement range: Accuracy: Resolution: T_{90}:	Infra-red absorption 0 – 13% CO2 0.1% 0.1% 28 ms
Operating conditions:	Temperature: Air humidity	+15°C to +40°C 10 to 90% (non-condensing)
Storage and Transport conditions:	Temperature: Air Humidity: Explosive conditions:	-10°C to +60°C 0 to 95% (non-condensing) Device should not be used in explosive or flammable atmospheres
Minimal requirements PC system:	Norm: Processor: RAM Memory: Hard disk: Monitor: Interface: Operating system:	DIN EN 60950 Pentium III compatible or higher 1Ghz or higher recommended 500 MHz minimum 512 MB RAM or higher 192 MB RAM minimum 1.5 GB or greater recommended 600 MB minimum free space required XGA (1024 x 768) or higher USB 2.0 recomended USB 1.1 minimum Windows XP SP2 or higher

5. Technical Data Pulstik

Modifications are not permitted with this device

Technical Data:	Dimensions: Weight:	76,5 mm x 30mm x 18,5mm (L x w x h) 20 g
Electrical data:	IP protection type: Classification according to MDD: Application component type: PC interface: Power supply: Power consumption: Transmitter frequency:	IPX0 IEC 529 IIa 93/42/EWG date June 14th 1993 14.06.93 Appendix IX BF according to VDE 0750 (DIN EN 60601-1) USB 2.0 Via USB port < 40 mA 2.4 GHz
Measurement range:	Pulse rate:	0 – 250 1/min
Operating conditions:	Temperature: Air humidity:	+5°C to +40°C 10 to 90% (non-condensing)
Storage and Transport conditions:	Temperature: Humidity: Explosive conditions:	-10°C to +50°C 0 to 95% (non-condensing) Device should not be used in explosive or flammable atmospheres
Minimal requirements PC system:	Norm: Processor: RAM Memory: Hard disk: Monitor: Interface: Operating system:	DIN EN 60950 Pentium III compatible or higher 1Ghz or higher recommended 500 MHz minimum 512 MB RAM or higher 192 MB RAM minimum 1.5 GB or greater recommended 600 MB minimum free space required XGA (1024 x 768) or higher USB 2.0 recommended USB 1.1 minimum Windows XP SP2 or higher