Geratherm® Respiratory

Spirostik

Serial numbers: xx|8|001|yyy and 2001xxxxx



Instructions for Use

Version: 6

Release date: 14. July 2021

Please read carefully and store in a place which is always accessible for future consultation!

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Foreword

Thank you for purchasing a medical device from Geratherm® Respiratory GmbH. Spirostik is part of our product family with solutions for cardiopulmonary function diagnostics which are operated using the common software platform BLUE CHERRY®. This means that you have the option of optimising the working processes in your practice using the networked application of further products from Geratherm® Respiratory GmbH, and to benefit from the simple use of our products.

1 General Information

All our medical devices are manufactured and tested in accordance with certified quality standards. This means that Spirostik fulfills the regulatory requirements for medical devices (class IIa).

This IFU is a component of the product in accordance with DIN EN ISO 60601-1. It should make it easier to familiarise yourself with Spirostik, as well as give you instructions about its intended use and safe operation.

This IFU has been written for healthcare professionals who are qualified to perform spirometric examinations.

The basic prerequisite for safe working with the Spirostik is to follow all the safety instructions given.

In addition to the notes in this IFU, the local accident prevention regulations and the national industrial safety regulations apply.

Read this IFU carefully and in its entirety before using Spirostik. For future reference, keep them in the immediate vicinity of the medical device, ready at hand for the user / operator and accessible at all times!
Please refer to the separate IFU of the BLUE CHERRY® software platform for pulmonary function diagnostics.

If, in spite of careful reading of this IFU, you require more information, please contact your specialist retail partner on site. You can obtain the contact details via a form provided by the manufacturer at www.geratherm-respiratory.com/login/.

1.1 Abbreviations

The following simplified style of writing and abbreviations are used hereinafter to make this IFU easier to read.

Instructions for Use	→ IFU
Geratherm® Respiratory GmbH	→ Manufacturer
Medical specialist personnel	→ User(s)
Personnel instructed in cleaning / maintenance work	→ Operator(s)

1.2 Explanations

For the safety of your patients, for your personal safety and to avoid damage to property, observe the meaning of the following explanations of symbols. These are divided into hazard levels. If several severity levels occur at the same time, the warning note for the highest level is always used.

The safety instructions are presented in accordance with DIN ISO 3864 following ANSI Z535.4 (American National Standards Institute).

DANGER	Indicates a directly hazardous situation. Not observing and not avoiding the situation will lead to death or severe injuries. The signal word DANGER is only used for extreme situations.
WARNING	Indicates a possibly hazardous situation. Not observing and not avoiding the situation may lead to death or severe injuries.
CAUTION	Indicates a possibly hazardous situation. Not observing and not avoiding the situation may lead to minor or moderate injuries.
Attention	Not observing this warning information may lead to faults or malfunctions of the Spirostik or may indicate that something in its environment may be damaged.
	Indicates places in the IFU which are relevant to the current topic but do not present any danger, or which simplify your handling of the Spirostik.

1.3 Symbols

Symbols displayed in this IFU, on the medical device itself and / or on its packaging are standardised symbols.

Symbol	Explanation
	**Follow the instructions for use!**
	**Applied part from type BF corresponding to DIN EN 60601-1** The applied part is in direct contact with the patient (BF: Body Floating). In order to comply with the limit value for the patient leakage current, the applied part is insulated from earth.
	**Only use indoors!**
IP20	**Protection type (safe environmental conditions)** IP2x: Protection of enclosure against ingress of solid foreign objects with a diameter greater than or equal to 12.5 mm and access to hazardous parts with finger. IPx0: No protection of enclosure against harmful ingress of water.
	**Do not dispose of the device along with general household waste!** It must be disposed of in a proper and correct manner via the specialist retail partner. By marking a device with this symbol, the manufacturer also declares that he fulfills all the requirements of the law on the distribution, return and environmentally friendly disposal of electrical and electronic devices. (Rechargeable) batteries must be taken to a central collection point for used batteries or to the manufacturer.

Symbol	Explanation
	**For single use only!** This symbol does not refer to the Spirostik itself, but to the consumable items used in connection with it. This is applied to the respective packaging and must be observed.
	**Batch number** This symbol identifies the batch or lot code given by the manufacturer. The code is placed adjacent to the symbol.
	**Serial number** This symbol identifies the serial number given by the manufacturer.
	**Catalog number** This symbol identifies the catalog number given by the manufacturer.
	**Manufacturer** This symbol identifies the manufacturer of a product.
	**Date of manufacture** This symbol indicates the date on which a product is manufactured.
	**Conformity mark** This symbol indicates conformity with health, safety and environmental protection standards for products sold within the European Economic Area (EEA). The additional four-digit number identifies the Notified Body involved in the conformity evaluation procedure of this product. In this case 0494 identifies SLG Prüf- und Zertifizierungs GmbH as Notified Body.
	**Caution, non-ionizing electromagnetic radiation** Precautions must be taken to avoid an unexpected effect of non-ionizing radiation.

Symbol	Explanation
	**Fragile, handle with care** The package contains a product that must be handled with appropriate care to prevent damage during transport and storage.
	**Keep away from rain** The package contains a product that must be protected from moisture during transport and storage.
	**Temperature limitation** The product can be safely transported, stored or operated within the specified temperature range.
	**Humidity limitation** The product can be safely transported, stored or operated within the specified humidity range.
	**Atmospheric pressure limitation** The product can be safely transported, stored or operated within the permissible atmospheric pressure.

1.4 Copyright

The manufacturer reserves all rights to this document and the information contained therein. No part of this document or the information contained herein may be reproduced or transmitted without the written consent of the manufacturer. All information or brand names of a third party contained in this document are subject to the copyright of that third party.

1.5 Limitation of Liability

The manufacturer emphasises the creation of accompanying documents for his products. Despite careful checking, errors or inaccuracies in this document version cannot be completely ruled out. The liability of the manufacturer for direct or indirect damages arising in connection with the present documentation is excluded to the extent permitted by law. Technical or content information in this document is subject to change at any time and without notice. Should any questions arise, please contact your authorised specialist retailer or the manufacturer directly.

2 Conditions of Use

Any other use of Spirostik which is not described in this IFU is deemed improper use. The responsible organisation of Spirostik alone is liable for any direct or indirect damage resulting from not adhering to these conditions. They are then solely responsible for the fulfillment of the basic requirements of the medical device and assumes complete product liability for the whole system.

2.1 Intended Purpose

Spirostik is an electric medical device. It is a PC-connected spirometer, intended to identify the static and dynamic lung volume in pulmonary function testing in a clinical setting and by established physicians.

Spirostik is designed for use in the mouth, nose, upper throat area, trachea and lungs of the patient (definition see chap. 2.1.3 "Definition of the Groups of People").

The standard version of the accompanying software permits measurements for spirometry, flow / volume and MVV as well as pre / post examinations and trend analysis.

Using Spirostik, you can also carry out the examination stated below.

Examination	Required option
Bronchoprovocation	Provocation (Bronchial Provocation Software REF 403680)



You can find more information in:

- Spirometry IFU
  for carrying out the examination
- BLUE CHERRY® IFU
  for the general operation of the software and carrying out the examination

2.1.1 Indication

With Spirostik, pulmonary function examinations can be carried out for diagnosing, monitoring of process, screening and assessing the severity of pulmonary diseases. In particular, this includes:

Obstructive diseases

- Complaints such as dyspnea (shortness of breath) or coughing when at rest as well as under stress
- Bronchial asthma
- Chronic obstructive pulmonary disease (COPD)
- Pulmonary emphysema

Restrictive diseases

- Interstitial lung diseases
- Pulmonary fibrosis
- Impairments of the chest
- Neuromuscular diseases

Allergy diagnosis

2.1.2 Contraindication and Side Effect

2.1.2.1 Contraindications

The following contraindications apply for spirometric examinations:

Contraindications	Absolute	Relative
Patients with a new (< 1 month old) myocardial infarction	X	X
Aneurysm of the ascending aorta	X	X
Pulmonary embolism	X	X
Tension pneumothorax		X
Acute internal bleeding		X
Recent eye operations		X
Recent thorax / abdominal operations		X
Hemoptysis		X
Acute diarrhea		X
Angina		X
Severe hypertension (SBP > 200 mmHg, DBP > 120 mmHg)		X
Confusion / dementia		X
Infectious diseases		X

As the transitions between absolute and relative contraindication can be fluid in the assessment, the assertion of a physician should be regarded as binding.
(Source: Miller MR, Crapo R. Hankinson J et al. 2005. General considerations for lung function testing. Eur Respir J. 26:153–161.)

2.1.2.2 Side Effects

If there are no contraindications and the examination is carried out in accordance with the descriptions in this IFU, side effects rarely occur in pulmonary function examinations. These can be described as follows:

Side effect / Frequency	Rules of conduct
Side Effect / Frequency Dizziness, syncope / on a case-by-case basis.	Examinations should preferably be performed in a sitting position and the patient should be permanently observed during the examination.
Spontaneous pneumomediastinum, pneumopericardium and subcutaneous emphysema in spirometry / in extremely rare cases.	Investigate any persistent dyspnea that occurs after the examination.

2.1.3 Definition of the Groups of People

Groups of people named in this IFU are defined as follows:

Manufacturer
specifies all measures to ensure the safe and proper handling and application of Spirostik. They are responsible for instructing the operator in relation to this via the corresponding specialist retail partner.

Responsible Organisation
is any natural or legal person who is responsible for the operation of the health institution where Spirostik is used by their employees (users).

User
is a medically trained specialist who is familiar with spirometry examinations, who uses Spirostik on the patient after verifiable instruction by the responsible organisation and / or is responsible for rectifying faults to the Spirostik, as well as its calibration.

Users must be aware of the clinical meaning and, for example, be a physician, physician's assistant, assistant or trained maintenance personnel with basic electrical or mechanical training. The user is able to identify, assess and, in the best case, to avoid possible hazards when using Spirostik.
Trainee medical specialists must also be supervised in addition to receiving training in how to use Spirostik.

Operator
is a person who has received instruction on cleaning Spirostik by a medically trained specialist.

Patient
is a person undergoing medical treatment (check-up, initial diagnosis as well as progress / treatment monitoring) to assess their pulmonary function. The persons can be adults without an age limitation as well as children form 4 years of age.
A requirement for carrying out the examination is the ability to follow the instructions of the user.

2.2 Intended Use

Spirostik can be operated independently as a non-stationary device or in combination with all other Geratherm® Respiratory GmbH products via the universal software BLUE CHERRY®. (see chap. 4.1.3 “System Construction and Electrical Safety”)

In all cases, the Spirostik is only intended for use in closed, pleasantly temperature-controlled (19 °C - 25 °C) rooms in a clinical area.

In the respective room, there must be neither flammable or explosive gases, nor magnetic fields (e.g. MRI).

The following applies in general: The installation of Spirostik is only deemed safe and in line with intended use when this is carried out in accordance with the details in chap. 12.2 “Installation and Operating Conditions”.

The responsible organisation must ensure that only medically trained specialist personnel (see chap. 2.1.3 “Definition of the Groups of People”) operates Spirostik. Personnel must demonstrably have been given training in the function of Spirostik. This also includes a complete study of this IFU.

The manufacturer has determined the expected service life (see chap. 11.1 "Expected Service Life") and the maintenance work required for this (see chap. 8 "Servicing / Maintenance").
The Spirostik may only be used for the duration of its service life if the specifications are observed.
Any changes to Spirostik, in particular unauthorised modifications, are prohibited.

The Spirostik is not intended for the control of vital physiological parameters where the nature of the change could lead to immediate danger to the patient, e.g. changes in heart function, respiration or central nervous system activity.

Any other than the described use is deemed improper use.
The responsible organisation of Spirostik alone is liable for any damage resulting from not adhering to these conditions.

Intended use also includes complying with all further information and instructions in this IFU, without exception.

Attention	Electromagnetic compatibility (EMC) in accordance with DIN EN 60601-1-2:2016-05; VDE 0750-1-2:2016-05; IEC 60601-1-2:2014. See chap. 12.4 “Electromagnetic Compatibility / EMC Guidelines”. Spirostik is suitable for use in all institutions including those in residential areas and those which are directly connected to the public supply network which also supplies buildings used for residential purposes.

2.2.1 Original Spare Parts / Accessories / Optional Expansions

Intended use also includes using prescribed original spare parts, accessories and expansions in constructing the system.

Only the components stated in the following are deemed tested and approved, as products by the manufacturer of Spirostik.

The installation or use of other products can, under certain circumstances, negatively change constructive prescribed properties of Spirostik and, in the worst case, impair the safety of the patient, user / operator and / or third parties.

The manufacturer assumes no liability for such consequences. All warranty claims shall expire.

⚠ WARNING	**Possible danger to life.** Reason: **Cross contamination.** Therefore: • Do not use consumable articles with a limited life span after their use-by date has expired!
⚠ CAUTION	**Possible physical injury.** Reason: **Device damage as well as impurities / contamination due to improper handling of components.** Therefore: • Protect separately stored components, accessories and consumable items from unauthorised access! • Observe the storage conditions stipulated by the manufacturer!

2.2.1.1 Original Spare Parts / Accessories

The following components can be purchased via specialist retail partners.

You will find:

- A list of specialist retail partners as an insert in this IFU or in your medical device book, as well as the most updated version at www.geratherm-respiratory.com/login/
- Instructions on safe system construction in chap. 4.1.3 of this IFU
- Further information on Ambistik in the separate Ambistik IFU

Component	Description / name	Supply scope in units	REF
	**Spirostik, Case** ➢ For safe and secure transport of Spirostik. ➢ For organised and structured storage of components and accessories.	01	177882

Component	Description / name	Supply scope in units	REF
	**Spirostik** ➢ USB 2.0 Spirometer with simple to use snap-in-handle for disposable, low deadspace Spiraflow flow sensor. ➢ Easy installation without additional drivers. ➢ Comes together with intuitive Windows based diagnostic software platform BLUE CHERRY®.	01	361333 [old:40.001]
	**BLUE CHERRY® Media Pack** ➢ Modular and intuitive Windows based diagnostic software platform for pulmonary function.	01	598197 [old:10.500]
	**Spiraflow & Softclip Set** ➢ Single use disposable flow sensor with low deadspace and Softclip noseclip for use with the Spirostik and Spirostik Complete. ➢ Sensor codes validated during production ensure measurement quality and avoid frequent calibration.	03	340968 [old:10.401]

Component	Description / name	Supply scope in units	REF
	**Silicon Adapter, Large** ➢ Silicon adapter size large used for Spiraflow to connect to calibration syringe.	01	158822 [old:10.805]
	**USB-Extension Cable, 30 cm** ➢ 30 cm extension cable to connect USB based devices to PC.	01	583407 [old:10.837]
	**Quick Start Guide, Spirostik** ➢ Short instruction manual for quick start of Spirostik.	01	531666 [old:40.001-02]

2.2.1.2 Optional Expansions

The following add-ons can be purchased via specialist retail partners.

You will find:

- A list of specialist retail partners as an insert in this IFU or in your medical device book, as well as the most updated version at www.geratherm-respiratory.com/login/
- Instructions on safe system construction in chap. 4.1.3 of this IFU
- Further information on Ambistik in the separate Ambistik IFU

Component	Description / name	REF
	**Calibration Syringe** ➢ Precision calibration instrument for calibration of flow or volume based systems. ➢ 3 liter volume (nonadjustable). ➢ Comes together with adapter for Spiraflow, Ergoflow and Blueflow.	608220 [old:10.801]
	**Ambistik** ➢ USB 2.0 ambient conditions module for accurate online BTPS conditions. ➢ Continuous measurement of ambient temperature, pressure and humidity. ➢ Runs on modular and intuitive Windows based diagnostic software platform for pulmonary function BLUE CHERRY®.	634247 [old:40.300]

Component	Description / name	REF
	**Provocation** ➢ For performing bronchial provocation tests with BLUE CHERRY® diagnostic platform. ➢ Offers pre-defined and user configurable protocols with timers for testing and dosage administration. ➢ Automatic calculation of threshold parameters.	403680 [old:10.507]

2.2.2 Consumable Items / Auxiliary Materials

The following items were tested by the manufacturer for Spirostik. The use of other consumable items as well as auxiliary materials with different properties is deemed improper use.

You will find a list of specialist retail partners as an insert in this IFU or in your medical device book, as well as the most updated version at www.geratherm-respiratory.com/login/

Component	Description / name	REF
	**Spiraflow & Softclip Set** ➢ Single use disposable flow sensor with low deadspace and Softclip noseclip for use with the Spirostik and Spirostik Complete. ➢ Sensor codes validated during production ensure measurement quality and avoid frequent calibration.	340968 [old:10.401]
	**Softclip** ➢ Disposable noseclip for lung function tests ➢ Made of soft, skin-friendly foam for best wearing comfort ➢ One size	787158 [old:10.200]
	**Spirostik Handle** ➢ Simple to use snap-in handle for connection of Spiraflow disposable flow sensor with Spirostik.	395992 [old:40.003]

Component	Description / name	REF
Disinfectant	**For wipe disinfection**, alcoholic quick-acting ➢ Bacillol Tissues (BODE Chemie GmbH) ➢ Sprayln (Dr. Deppe GmbH) **For disinfection bath** with low chloride concentration ➢ Korsolex plus (BODE Chemie GmbH) ➢ Korsolex extra (BODE Chemie GmbH) ➢ InstruPlus (Dr. Deppe GmbH) ➢ Sekusept active (Ecolab GmbH) ➢ Sterilization tablets and -solvents	depend-ing on provider

3 Safety in Handling

Spirostik has been designed and built in accordance with the state of technology and its recognised safety and technical regulations.

In spite of this, dangers of injury to users / operators, patients and third parties as well as damage to Spirostik or other materials may occur if this is:

- Not used in accordance with the conditions of intended use.
- Not operated in a technically flawless state.
- Operated by untrained or uninstructed personnel
- Maintained or serviced improperly.

⚠ DANGER

In order for Spirostik or the total system to be operated in accordance with its intended use, the safety information and procedures in this IFU must be understood. **Ensure that these are followed! Otherwise, in the worst case, death or severe injuries are the consequence resulting from the risks described in more detail in the respective chapters!** Therefore:

- **Read this IFU carefully and in its entirety before using the Spirostik. Keep it in close proximity to the medical device for later reference and make it accessible to the user / operator at all times!**
- Also observe the safety information of all other accompanying documents of the total system!
- If you have any questions, ask your authorised specialist retail partner!

3.1 General Safety at Work and Personnel Qualification

⚠ WARNING

Possible danger to life.
Reason: **Not complying with health and safety regulations. Ignoring essential preventive measures.**
Therefore:

- Always comply with general national regulations on accident prevention! Instruct users / operators accordingly!
- Safety and warning information on Spirostik may not be altered or removed! Have missing or not readable information replaced immediately!
- When working with auxiliary materials, always observe the safety information from the respective manufacturer! Wear suitable protective clothing!

Reason: **Electric shock. False diagnosis. Ignoring contraindications. Triggering malfunctions of Spirostik. Unqualified user / operator can detect sources of failures too late or even cause them.** Therefore:

- Only use officially trained users!
- Users must be familiar with the test methods and their clinical significance!
- All maintenance and servicing work may only be performed by specialised personnel who have been authorised by the manufacturer!

3.2 The Technical State of Spirostik and System Construction

⚠ WARNING

Possible danger to life.
Reason: **Electric shock. Cross-contamination. Misdiagnosis caused by measurement error.**
Therefore:

- Do not overstress Spirostik! Use with care!
- Do not modify or use Spirostik or total system contrary to the respective manufacturer's specification!
- Only use Spirostik within its expected service life, determined by the manufacturer!
- Under no circumstances use or connect any devices, systems, equipment and other products that are not part of the total system! This also includes only components approved by the manufacturer such as (connection) cables and computers that are not permitted by the manufacturer. See chap. 12 "Technical Specifications"!
- Do not connect any other Bluetooth devices which have not been approved by the manufacturer!
- Do not install any other software!
- Ensure that in the patient environment – a distance of 1.5 meters to the patient – there are no accessible electrical parts (interfaces, plugs, etc.) that are not isolated from the mains with an isolation voltage of 4 kV!
- Ensure that the users or third party persons do not touch the patient and any conductive connections or parts of the device that are located outside the patient environment at the same time!

- Ensure that Spirostik cannot fall down! Otherwise, the functionality must be checked properly before putting into operation!

Reason: **Electric shock and / or misdiagnosis due to loss of electrical safety caused by exceeding the recommended maintenance schedule.**
Therefore:

- Regularly check the specified maintenance schedule!
- If a maintenance schedule is exceeded, do not continue to use the total system! Request maintenance work from your authorised specialist retail partner!
- Only use accessories, components and consumable materials which have been approved by the manufacturer, as well as approved spare parts, optional add-ons and auxiliary materials. Check that the components are in a functional and safe condition!

3.3 Operation / Servicing and Maintenance

DANGER

Danger to life.
Reason: **Electric shock. Explosion. Device damage. Unpredictable movement of metal parts.** For this: **Comply with the required installation and operating conditions!** Therefore:

- In principle, observe chap. 12 “Technical Specifications”!
- Do not operate Spirostik if there are flammable or explosive gases in the room!
- Do not operate Spirostik near the magnetic field of an MRT system!

WARNING

Possible danger to life.
Reason: **Electric shock. Cross-contamination. Misdiagnosis caused by measurement error. Device damage.** Therefore:

- Ensure that the used components are undamaged and that you are working in a careful way!
- Do not use consumable items with a limited expected service life after their use-by date has been reached!
- Prior to each use, visually inspect the total system (housing, connectors, etc.) for any damages!
- If there are any damages, do not operate the system. The damaged parts must be replaced or repaired properly!
- Calibrate Spirostik at the intervals stated!

Reason: **Ignoring a contraindication. Misdiagnosis caused by measurement error. Cross-contamination.**
For this: **Observe the general medical principles!**
Therefore:

- Inform yourself and observe the respective contraindications before each test!
- When carrying out tests, observe the content of the applicable guidelines and recommendations (e.g. ATS / ERS Guidelines)!
- Do not use single use products more than once!

3.4 Electromagnetic Compatibility (EMC)

⚠ WARNING

Possible danger to life.
Reason: **Misdiagnosis due to measurement error caused by a system failure due to uncontrollable electromagnetic fields of inadmissible transmitting devices.** Therefore:

- While using Spirostik, do not use any transmitting devices (e.g. mobile phones, portable phones, power lines …) within close proximity (< 30 cm) that exceed the immunity levels as specified in the EMC guidelines!
- Ask your authorised specialist retail partner about this!
- No stacking of devices on top of each other and no close arrangement. Observe the installation and operating conditions from the manufacturer!
- Check the correct function of the Spirostik!

3.5 Cleaning and Disinfection

⚠ WARNING

Possible danger to life.
Reason: **Cross-contamination.** For this: **Observe the general medical principles!** Therefore:

- Clean and disinfect the Spirostik and its reusable components as instructed by the manufacturer at regular intervals as specified!

Possible severe physical injury.
Reason: **Contamination with transferable germs during improper disposal.** Therefore:

- Dispose single use items (disposable flow sensors, mouthpieces and noseclips) after each use. For this observe the applicable regulatory requirements for biologically hazardous materials!
- Observe regulations on wearing personal protective equipment (PPE)!

4 Structure and General Function of Spirostik

4.1 Hardware

4.1.1 Overview



[1] Easy to use snap-in handle
[2] Spirostik (see also chap. 7.6)
[3] Spiraflow flow sensor (see also chap. 4.1.2.1)
[4] Type label / (on the bottom of the device) (see also chap. 14)
[5] USB-extension cable, 30 cm (see also chap. 4.1.3.1)

4.1.2 Connectors / Interfaces of the Spirostik

4.1.2.1 Flow Sensor



Spirostik could be damaged.
Reason: **Flow Sensors of Spirostik are precise and high-resolution components.** For this: **Ensure the respective functions are preserved!** Therefore:

- Exactly follow instructions for cleaning, disinfection and calibration!

The heart of the Spirostik is the Spiraflow flow sensor.
The Spiraflow is a disposable sensor and the measuring accuracy is constantly checked during production.

As the flow sensor ensures the precise flow measurements, the cleaning and calibration requirements must absolutely be adhered to.



For further information see:

- Chap. 9 “Cleaning and Disinfection”
- The separate manual Calibration flow sensor

4.1.3 System Construction and Electrical Safety

The following instructions are intended for safe handling of the entire system, taking into account the electrical safety concept of the Spirostik.

The Spirostik connects directly with the PC and forms a medical electrical system (ME system) with the computer where the application software is installed. The following instructions are intended to safely form such a system, considering the electrical safety concept of the Spirostik (see chap. 12.3 "Electrical Safety Concept").

Preferably, the system should be constructed by a specialist retail partner but may also be carried out by the responsible organisation of Spirostik themselves.

It is essential to note: Anyone who combines additional devices or medical devices or unauthorised or non-original components / spare parts / consumables with existing medical, electrical equipment or systems, and this combination is used by third parties or this combination is placed on the market, will legally become a producer of a system or a procedure pack. In any case the assembler of a system is therefore responsible for compliance with the requirements placed on the system by the relevant, harmonised standards and the additional national and international standards and guidelines in the currently valid versions!



You will find a detailed description of the correct system formation in:

- The technical manual "Formation of Systems".

Independent of this, the following should also be observed:

⚠ WARNING

Possible danger to life.
Reason: **Electric shock. Misdiagnosis.** Therefore:

- Do not modify or use Spirostik or total system contrary to the respective manufacturer's specification!
- Under no circumstances use or connect any devices, systems, equipment and other products that are not part of the total system! This also includes only components approved by the manufacturer such as (connection) cables and computers that are not permitted by the manufacturer!
  See chap. 12 "Technical Specifications".

Reason: **Electric shock. Misdiagnosis.** Therefore:

- Ensure that in the patient environment – a distance of 1.5 meters to the patient – there are no accessible electrical parts (interfaces, plugs, etc.) that are not isolated from the mains with an isolation voltage of 4 kV!
- When connecting Spirostik to other devices, make sure that all connections and cables are secured and cannot come loose by themselves!
- Do not connect any portable multiple sockets or extension cables to the system!
- Do not connect any additional USB devices (except mouse, keyboard and printer)!
- Do not install any further software!
  Ask your authorised specialist retail partner which Devices are approved by the manufacturer!

Reason: **Electrical shock and / or misdiagnosis due to loss of electrical safety caused by exceeding the recommended maintenance schedule.** Therefore:

- Regularly check the specified maintenance schedules!
- If a maintenance schedule is exceeded, do not continue to use the total system! Request maintenance work from your authorised specialist retail partner!

Attention

Spirostik could be damaged.
Reason: **Electrostatic discharges.** Therefore:

- Preferably no floor made of synthetic material!
- Otherwise a relative air humidity of at least 30 % is required!

4.1.3.1 Bluetooth / Computer / Printer Data Connection

The data connection between measuring electronics and computer is already integrated in the Spirostik.

All measurement results and graphical data can be displayed on the screen as well as printed out via the Windows printer interface. Any printer compatible with Windows can be used for this.

4.1.3.2 Power Supply

The Spirostik is powered directly via the 5 V of the USB interface.

4.2 Technical Protection Measures

Spirostik has been designed and built in accordance with the recognised state of technology and the requirements of the applicable, safety-relevant regulations.

The technical safety condition is checked by the authorised specialist retail partner of the manufacturers within the framework of technical monitoring
(see also chap. 8 “Servicing / Maintenance”).

4.3 Software

The measurement device (Spirostik) is supplied with BLUE CHERRY® software. This serves to manage patient and examination data as well as carry out, depict, process and record measurements with the devices of the manufacturer.

The communication between the BLUE CHERRY® software and a practice computer system or hospital information system is supported by standardised software interfaces (e.g. HL7, GDT). Paid software options are necessary for this, if applicable.

A modular and flexible hardware and software concept makes it possible to combine this with additional measurement options and consequently allows the overall system to be configured separately for individual customers.

For the identification of the current firmware version, this can be read by the BLUE CHERRY® device management system.



For further information to the configuration and use of the software BLUE CHERRY® see:

- The separate IFU of BLUE CHERRY®

5 Transport, Storage and Assembly

5.1 Transport to the Location of Use

Spirostik is secured against damage during transport in a case.



The packaging must be kept by the user / operator in case the device must be returned to the authorised specialist retail partner or manufacturer.

For further information see:

- Chap. 11.3.1 “Transport Packaging”
- Chap. 15.3 “Packaging and Shipping“

The specialist retail partner authorised by the manufacturer is responsible for supplying Spirostik to the responsible organisation.
Unpacking and transport to the actual place of use are the responsibility of the responsible organisation.

5.2 Storage

The Spirostik is a mobile, portable device that can be transported safely and securely in its case and stored and kept in an organised manner.

Requirements regarding space requirements, media connections and operating conditions can be found in chap. 12 "Technical Specifications".

The responsible organisation of the Spirostik is solely in charge of compliance with these requirements.

For storage and transport conditions see chap. 12 "Technical Specifications".

5.3 Assembly

⚠ WARNING	**Possible danger to life.** Reason: **Electric shock. Misdiagnosis caused by measurement error.** Therefore: • Prevent improper assembly / installation! • Spirostik should only be assembled and installed by officially trained personnel!

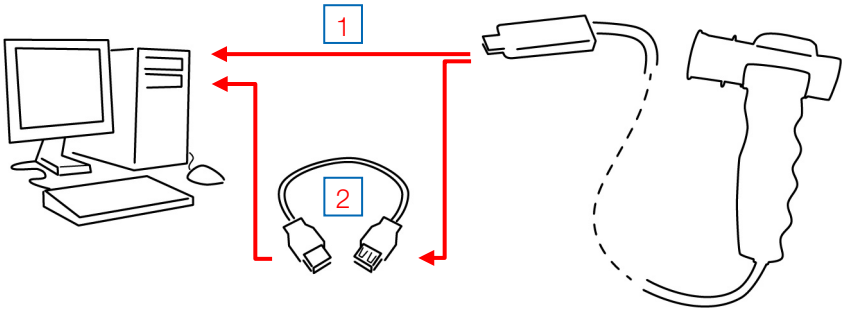
For further information see:

- Chap. 4.1.3 “System Construction and Electrical Safety” – safe installation

Assembly work is not required for the initial operation of Spirostik, as this is supplied in a ready-for-operation state.

As a consumable, the flow sensor must be replaced constantly, which is therefore not considered assembly.

The Spirostik is connected directly to the PC via the USB interface **[1]**. Alternatively, the USB extension cable **[2]** can be placed between the PC and the Spirostik, increasing the range of the Spirostik by a further 30 cm.



6 Operation

The initial operation of Spirostik, as well as any return to operation after service work in accordance with the duties of the responsible organisation (see chap. 8.2 “Servicing / Maintenance by the User / Operator”), may be carried out by the responsible organisation's own authorised specialist personnel. This can also be the operator / user themselves.

⚠ WARNING

Possible danger to life.
Reason: **Electric shock.** Therefore:

- After assembly or modification of a system, a test of the electrical safety of the total system as well as all tests required by the respective manufacturer of the individual devices must be carried out before putting into operation!

6.1 Initial Operating

6.1.1 Calibrate Spirostik / Set up funtional Operations

Spirostik is only completely ready to function after calibration and once the initial operation is complete.

For details on conducting the calibration, please consult:

- The separate IFU Calibration flow sensor

For further information see:

- Chap. 7.5 “Calibrating Spirostik” – the calibration requirements while operating the Spirostik

6.2 Returning to Operation after Servicing / Cleaning Work

The responsible organisation is responsible for returning the device to operation after servicing / cleaning work for which the operator / user is authorised.

Servicing work here also includes the necessary checks which are necessary if Spirostik should fall down.

Before the Spirostik can be used for measurements again, all components must be properly connected / mounted and calibrated. Calibration also fulfils the regulatory requirement of MPBetreibV §7 for functional testing after maintenance work.

Please proceed as described in the respective chapters.



You can get precise instructions on assembly etc. in:

- Chap. 7.4 “Inserting the Flow Sensor”
- Chap. 7.5 “Calibrating Spirostik”

⚠ WARNING

Possible physical injury.
Reason: **Measurement error due to leakage caused by the incorrect assembly of components.** Therefore:

- Carefully observe the assembly instructions! (See chap. 8.2.1 “Checking for Damage”)

7 Operating Instructions

 Attention	Spirostik could be damaged. Reason: **Penetrating liquid. Uncleanliness. External exposure.** Therefore: • Do not use any liquids near the Spirostik! • Do not expose Spirostik or the entire system to dust or other contamination! • Do not drop any objects on Spirostik! Do not lay any objects on it! Never push foreign objects into the housing!

7.1 Checking for Worn Parts



The Spirostik should be checked for defective wearing parts each day before beginning treatments.

- You can get a description in chap. 8 “Servicing / Maintenance”

And:

⚠ WARNING	Possible danger to life. Reason: **Misdiagnosis caused by measurement error due to incorrect components or improper use.** Therefore: • Replace the flow sensor and the mouthpiece in case of a functional error! • Always follow instructions (see chap. 8 "Servicing / Maintenance" and chap. 9 "Cleaning and Disinfection")!

7.2 Preparing the Device for Operation



To activate ready-for-operation state, please read:

- Chap. 6.1.1ff “Calibrate Spirostik / Set up funtional Operations”

7.3 Switching Spirostik On / Off

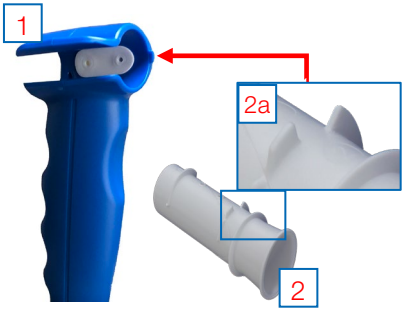
As soon as the Spirostik is connected to the PC by the USB interface, the device is automatically detected and started. It is ready for operation.



If the calibration, as in chap. 6.1.1 "Calibrate Spirostik / Set up funtional Operations", has not been carried out, it must be carried out subsequently, otherwise no functional readiness is possible.

7.4 Inserting the Flow Sensor

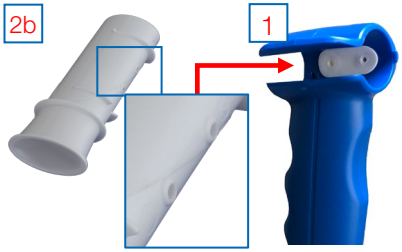




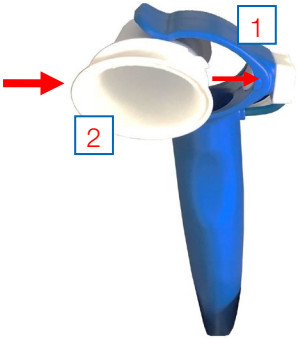
1. **Insert Spiraflow [2] into the handle [1]**
   For this:

   Align the Spiraflow so that the interrupted guide rib **[2a]** and the nose on the handle are on the same side

   and



   the pressure tapping holes **[2b]** show in the direction of the handle.



2. **Snap the Spiraflow [2] into the handle [1]!**
   For this:
   Apply light pressure

   Spiraflow not only must be fixed, but also locked in place!
   For this:
   Check the correct position in the handle on the basis of the interrupted guide rib and the nose and correct it if necessary.

7.5 Calibrating Spirostik

There are various processes to be carried out for Spirostik in order to calibrate or validate the volume measurement.

Insert the flow sensor as described in chap. 7.4 "Inserting the Flow Sensor". Connect the calibration pump to the flow sensor (on the mouthpiece).

The required frequency is shown in the tables below.



For details on individual calibrations, please read:

- The separate IFU Calibration Flow Sensor

Interval	Calibration
Once per day	Volume calibration
After beginning a new flow sensor carton	
Once per week	Fluss linearity test
After maintenance / cleaning	Volume calibration

7.6 Using Spirostik / Carrying Out Measurements



For further information see:

- The separate IFU Spirometry
- The separate IFU BLUE CHERRY®

⚠ WARNING

Possible danger to life.
Reason: **Disregard a contraindication.**
Misdiagnosis caused by measurement error. For this: **Observe the general medical principles!** Therefore:

- Inform yourself and observe the respective contraindications before each test!
- When carrying out tests, observe the content of the applicable guidelines and recommendations (e.g. ATS / ERS Guidelines)!
- Replace the Flow Sensor immediately in case of saliva or moisture inside the Flow Sensor!

Reason: **Misdiagnosis due to measurement error caused by a system failure due to uncontrollable electromagnetic fields of inadmissible transmitting devices.** Therefore:

- While using Spirostik, do not use any transmitting devices (e.g. mobile phones, portable phones, power lines …) within close proximity (< 30 cm) that exceed the immunity levels as specified in the EMC guidelines!
- Ask your authorised specialist retail partner about this!

Reason: **Electric shock.** Therefore:

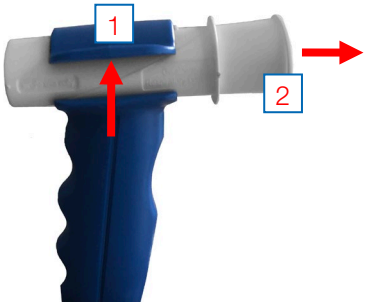
- Ensure that the users or third party persons do not touch the patient and any conductive connections or parts of the device that are located outside the patient environment at the same time!

7.7 Removing the Flow Sensor

⚠ WARNING	**Possible danger to life.** Reason: **Cross-contamination. Contamination with transferable germs during improper disposal.** For this: **Observe the general medical principles!** Therefore: • Do not use single use products more than once! • Clean and disinfect Spirostik and its reusable components as instructed by the manufacturer at regular intervals as specified! **Possible severe physical injury.** Reason: **Contamination with transferable germs during improper disposal.** Therefore: • Dispose single use items (disposable flow sensors, and noseclips) after each use. For this observe the applicable regulatory requirements for biologically hazardous materials!

The combination of single use flow sensors and noseclips offers the highest degree of patient safety from cross contamination only if all contaminated parts are replaced and disposed of after the examination.

Proceed as follows for removal:



1. **Unlock the handle**
   For this:

   Slightly bend up the locking device **[1]** by pressure from below.

2. **Remove the flow sensor [2] from the handle**
   (towards mouthpiece side)

3. **Dispose the flow sensor**

4. **Insert a new flow sensor if necessary (see chap. 7.4)**

For further information see:

- Chap. 11.3.3 “Infectious / Contaminated Single Use Items” – disposal of single use products

8 Servicing / Maintenance

8.1 Duties of the Responsible Organisation

Responsible organisations of medical devices are obligated, in accordance with the corresponding, applicable regulations, to preserve the properties of this medical device assured by the manufacturer over its whole service life. This also includes carrying out regular and proper servicing as well as safety checks at intervals recommended by the manufacturer carried out by specialist personnel who have been authorised by the manufacturer for the respective tasks.

The expected service life of Spirostik is 8 years.

In its development, a great deal of value was placed on making the servicing of all device components as simple as possible. Only a little work is necessary to guarantee a fault-free operation of the device.

However, to maintain a high quality of measurement results and the safe operation, the manufacturer recommends having the device safety and measurement precision checked by an authorised specialist retail partner every 24 months.

These checks include:

- Visual check
- Electrical measurement
- Functional Check

⚠ WARNING	**Possible danger to life.** Reason: **Electric shock and / or misdiagnosis due to loss of electrical safety caused by exceeding the recommended maintenance schedule.** Therefore: • Regularly check the specified maintenance schedule! • If a maintenance schedule is exceeded, do not continue to use the total system! Request maintenance work from your authorised specialist retail partner!

Attention	Independent of this, the user / operator must carry out regular checks during day-to-day operation, see also the following chap. 8.2 “Servicing / Maintenance by the User / Operator”!

8.2 Servicing / Maintenance by the User / Operator

In order to ensure a flawless operation of Spirostik over its whole service life, regular servicing and repairs, if applicable, are required.

Interval	Servicing work
Once per day	Visual checks of the device and its components for damage and replacing them if necessary (see chap. 8.2.1 “Checking for Damage”)
Once per day	Checking the sealing rubber of the head for tears / wear and replacing the head if necessary (see chap. 8.2.1.2 “Checking / Replacing the Handle”)
Once per year	Replacing the head (see chap. 8.2.1.2 “Checking / Replacing the Handle”)

⚠ WARNING	**Possible danger to life.** Reason: **Electric shock. Misdiagnosis caused by measurement error.** For this: **Ensure that the used components are undamaged and that you are working in a careful way!** Therefore: • Prior to each use, visually inspect the total system (housing, connectors, etc.) for any damages! • If there are any damages, do not operate the system. The damaged parts must be replaced or repaired properly!

Reason: **Electric shock. Triggering malfunctions of Spirostik. Unqualified user / operator can detect sources of failures too late or even cause them.**
Therefore:

- All maintenance and servicing work may only be performed by specialised personnel who have been authorised by the manufacturer!

8.2.1 Checking for Damage

8.2.1.1 General

All parts of Spirostik should be checked for visible mechanical damage (cracks, tears) each day. If damage is ascertained, the corresponding component must be replaced.



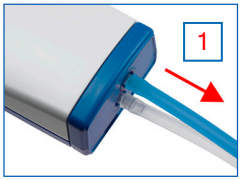
For replacing components see:

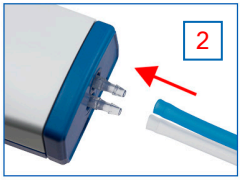
- Chap. 4.1.3 “System Construction and Electrical Safety”
- Chap. 6.2 “Returning to Operation after Servicing / Cleaning Work”

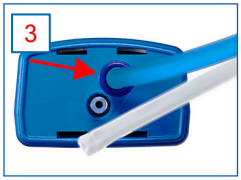
8.2.1.2 Checking / Replacing the Handle

When inspecting the sealing rubber on the Spirostik handle each day, you must take into account mechanical damage or signs of wear. If necessary, the handle must be replaced completely. In general, this should be replaced once per year.
To do this, proceed as follows:









1. **Remove the used handle [1].**
   For this:

   Carefully remove both tubes (blue, white) off the Spirostik connector **[1]**.

2. **Mount a new handle [2].**
   For this:

   Push the two tubes of the new handle (blue, white) onto the connecting pieces of the Spirostik as far as possible **[2]**, taking care to.

3. **Slide the blue tube onto the connection piece with the marking (blue, slightly highlighted ring [3]).**

When sliding the blue tube onto the Spirostik, make sure that the connection is correct!

9 Cleaning and Disinfection

The devices of the manufacturer were designed in such a way that minimal effort is required for cleaning and disinfection. This is why just a few tasks are necessary to keep Spirostik functional and clean. The following intervals apply:

Component	Interval	Method
Single use flow sensor	After each patient	Dispose of!
Noseclip	After each patient	Dispose of!
All other touchable parts	Weekly	Surface / Wipe disinfection

9.1 Single Use



For instructions on handling single use flow sensors and noseclips, read:

- Chap. 7.7 “Removing the Flow Sensor”

9.2 Disinfection

All parts of the Spirostik can be cleaned of dirt with a soft cloth using a cleaning solution / weak soapy water.

All parts of Spirostik which come into contact, or could come into contact, with the patient must be treated with a surface disinfection. Otherwise, these can be wiped with a soft cloth using a weak soap solution.

When using a disinfectant that has not been tested and approved by the manufacturer, the following steps must be observed:

- Preferably use agents that correspond in composition to the approved agents. The composition is available on data sheets, which we can provide on request.
- Check bactericidal and virucidal effect suitable for the intended use.
- Use only disinfectants listed in public databases (e.g. RKI)
- Check data sheet for material compatibility with plastics (especially polyoxymethylene, polystyrene, acrylonitrile butadiene styrene, Makrolon®) as well as metal
- First test the disinfectant for material compatibility in an inconspicuous place.
- During the regular visual inspection for damage, also pay attention to material changes (discoloration, cracks, embrittlement...)
- Observe long-term trend of calibrations for changes in measuring function

The manufacturer accepts no liability for any resulting equipment damage or any consequential damage caused by the use of disinfectants that have not been tested and approved by the manufacturer.



Attention

Spirostik could be damaged.
Reason: **Improper treated components.** Therefore:

- For cleaning and disinfection only use those active substances that are approved by the manufacturer! (see chap. 2.2.2 “Consumable Items / Auxiliary Materials”!
- Follow the instructions on the concentration and dwell time stated by the cleanser and disinfectant manufacturer!
- Do not place Spirostik in the cleaning and disinfection solutions! The device contains electrical components that will be damaged by doing so!

Reason: **Avoid penetration of liquid into electrical components**. Therefore:

- Remove the (rechargeable) batteries from Spirostik before cleaning and disinfection work!
- Wipe off any remaining moisture with a dry cloth!

Reason: **Higher temperatures can lead to deformation and damage** Therefore:

- Observe the maximum permissible temperature of 75 °C for cleaning and disinfection!
- Do not dry with heat!

Possible impairment of the measuring function.
Reason: **Moisture in the connection port.** Therefore:

- Ensure that there is no moisture in the tubes before recommissioning!



When selecting a suitable disinfectant, please observe:

- Chap. 2.2.2 “Consumable Items / Auxiliary Materials”

For selection of suitable disinfectants for surface / wipe disinfection also note:

- The separate IFU Cleaning and Disinfection

Information on the application and dosing of the disinfectant can be found in the separate manual of the respective manufacturer. The safety instructions contained must be observed.

10 Fault Indication and Repair

Simple errors which occur when using Spirostik can be recognised quickly and rectified using the following table. If you cannot find the error in the table or the problem cannot be rectified using the method described, please contact your specialist retail partner.



You will reach your authorised specialist retail partner via contact form on the manufacturer's website www.geratherm-respiratory.com/login/

DANGER

Danger to life.
Reason: **Unauthorised work carried out by the user to troubleshoot and rectify an error.** Therefore:

- Users may only carry out work which is described and permitted by the manufacturer!

In case of not complying with this restriction, the responsible operator alone is liable for any resulting injuries to persons and / or damages to Spirostik!

Error	Rectification
Software error message: „Flow out of range"	Perform zero adjustment. Check the tube connection between handle and Spirostik. Disconnect Spirostik from PC and reconnect to USB port.
Software error message: "Internal communication error"	Disconnect Spirostik from PC and reconnect to USB port.
obvious measuring error	Check last calibration date and recalibrate if necessary (see chap. 7.5)

11 Decommissioning / Disposal

11.1 Expected Service Life

The expected service life of Spirostik has been stated by the manufacturer as 8 years.

This applies provided the operating conditions, the prescribed servicing intervals, taking into account and complying with all safety information such as is described in this IFU as well as other technical standard regulations are adhered to.

11.2 Removing from Operation

To decommission the Spirostik, remove any contaminated material from it.

11.3 Disposal

In general, the applicable national laws and regulations stipulated by the local authority should be complied with for disposal.

11.3.1 Transport Packaging

The transport packaging should be reused or sent for material recycling. Before doing so, you should check whether it is possible to reuse the packaging.

11.3.2 Spirostik

Spirostik is an active medical device and is thus subject to the WEEE directive 2012 / 19 / EU and the German law on electrical and electronic devices (ElektroG) for the disposal for old electrical items. Neither Spirostik itself, nor any of its components may be disposed of via household or practice waste.



In order to ensure environmentally friendly disposal, please contact the authorised specialist retail partner where you purchased Spirostik and / or the accessories.

11.3.3 Infectious / Contaminated Single Use Items

All contaminated items such as single use flow sensors, filters, mouthpieces and noseclips must be disposed of via hospital or medical practice waste.

⚠ WARNING	**Possible severe physical injuries.** Reason: **Contamination with transferable germs during improper disposal.** Therefore: • Dispose single use items (disposable flow sensors, mouthpieces and noseclips) after each use. For this observe the applicable regulatory requirements for biologically hazardous materials! • Observe regulations on wearing protective equipment (PPE)!

12 Technical Specifications

12.1 Technical Data

Medical device:	Class IIa (in accordance with MDD 93 / 42 Council Directive of 14.6.1993 annex IX)
Dimensions:	(L) 76.5 mm x (W) 30 mm x (H) 18.5 mm
Weight:	20 g

Electrical data:	
Protection class:	1 or 2 (depending on the PC system)
Protection type:	IP20
Application component:	BF (corresponding DIN EN 60601-1)
PC interface:	USB 2.0
Power supply:	5 V via USB
Power consumption:	Max. 2.5 VA

EMC:	Group 1 / Class B
Noise emission:	Typically < 40 dB(A)

Flow measurement:	
Flow Sensor:	Spiraflow
Measuring principle:	Differential pressure
Measuring range:	±16 l/s
Ventilation measuring range:	0 – 300 l/min
Flow resistance:	< 0.15 kPa/(l/s) < 14 l/s
Dead space:	< 26 ml (effective)
Flow resolution:	15 Bit
Sample rate:	125 Hz
Accuracy:	±3 % oder 50 ml/s

Volume:

Measuring range:	0 – 20 l
Accuracy:	±3 % oder 50 ml

Minimum PC system requirements:

Standard:	at least EN 62368-1 / EN 60950 recommended EN 60601
Processor:	X86 / amd64 compatible, 1 GHz or higher
RAM storage:	1 GB or higher
Hard drive storage:	5 GB or higher
Monitor:	XGA (1024 x 768) or higher
PC interface:	USB 2.0 recommended
Operating system:	Windows 8.1 or higher

12.2 Installation and Operating Conditions

The following conditions supplement chap. 2.2 "Intended Use" and must be observed to maintain the properties of the Spirostik guaranteed by the manufacturer and for the safety of the patient and operator.

Storage / Transport:	min.	max.	
Temperature:	-10 °C	+60 °C	
Relative air humidity:	0 %	95 %	non-condensing
Atmospheric pressure:	700 hPa	1100 hPa	

Operation:	min.	max.	
Environmental temperature:	+0 °C	+40 °C	Avoid extreme fluctuations in temperature!
Relative air humidity:	20 %	95 %	non-condensing
	(min. 30 % for synthetic flooring)		
Atmospheric pressure:	800 hPa	1080 hPa	

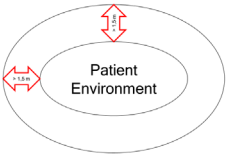
Setup:	mobile
Space requirement:	(L) 76.5 mm x (W) 30 mm x (H) 18.5 mm
Environment / room:	Closed, clinical area air-conditioned not an explosive or flammable environment! not near an MRI! well ventilated

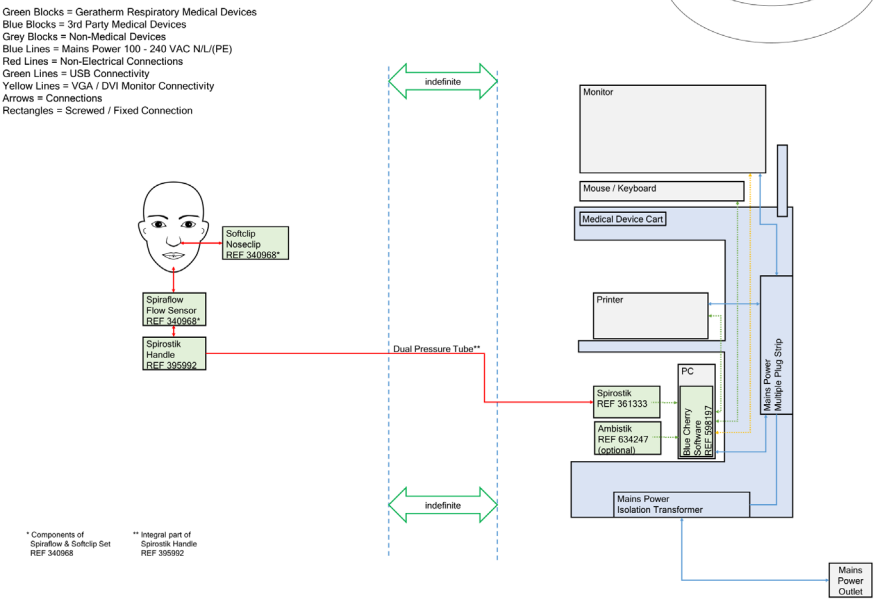
Operating Mode:	Continuous operation

12.3 Electrical Safety Concept

12.3.1 Spirostik with Medical Device Cart and Isolation Transformer

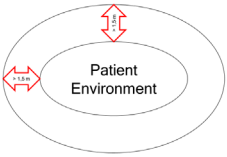
- Spirostik Power Supply and Communication via USB Interface
- With Isolation Transformer via Medical Device Cart
- Protection Class of Spirostik depending on the Protection Class of the PC

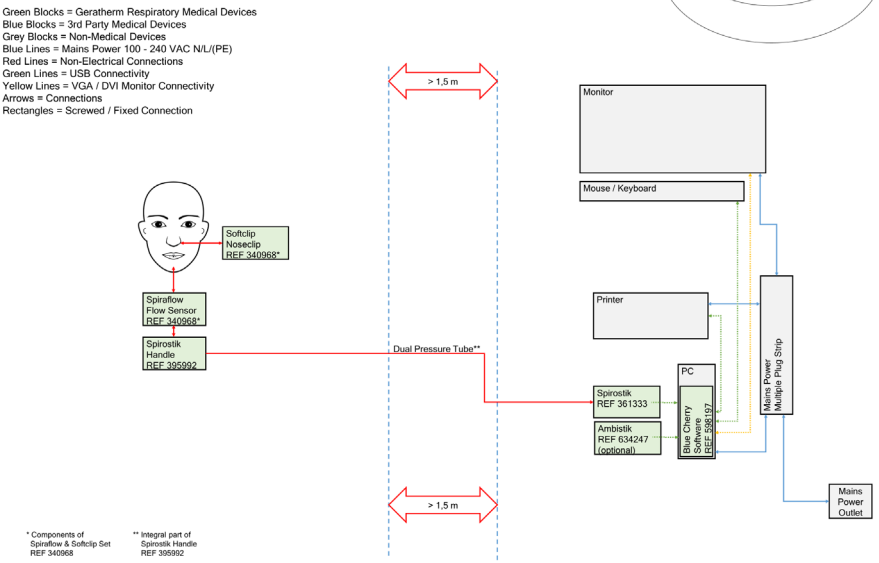




12.3.2 Spirostik without Medical Device Cart and without Isolation Transformer

- Spirostik Power Supply and Communication via USB Interface
- Without Medical Device Cart and without Isolation Transformer
- Protection Class of Spirostik depending on the Protection Class of the PC





12.4 Electromagnetic Compatibility / EMC Guidelines

The manufacturer tests his products for emitted interference and interference resistance. Compliance with the relevant standards and directives is certified in the Declaration of Conformity that accompanies this device. The results of the EMC test can be found in the following chapter.

12.4.1 Emitted Interference Guideline and Manufacturer Declaration

Guidelines and manufacturer's declaration – electromagnetic emissions		
The **Spirostik** is determined for operation in an electromagnetic environment as specified below. The user / operator of the **Spirostik** should ensure that it is operated in this environment.		
Measurement of electromagnetic emissions	Compliance	Electromagnetic environment – Guideline
RF emissions CISPR 11	Group 1	The **Spirostik** uses RF energy exclusively for its internal function. Therefore, its RF emission is very low and is improbable to interfere with adjacent electronic equipment.
RF emissions CISPR 11	Class B	The **Spirostik** is suitable for use in all establishments, including living areas and those directly connected to the public supply network, which also supplies buildings used for residential purposes.
Emissions of harmonic oscillations according to IEC 61000-3-2	Not applicable	
Emissions of voltage fluctuations / flicker according to IEC 61000-3-3	Not applicable	

12.4.2 Interference Resistance for all ME Systems Guideline and Manufacturer Declaration

Guidelines and manufacturer's declaration – electromagnetic interference immunity			
The **Spirostik** is determined for operation in an electromagnetic environment as specified below. The user / operator of the **Spirostik** should ensure that it is operated in this environment.			
Measurement of interference immunity	IEC 60601 – test level	Compliance level	Electromagnetic environment – Guideline
Electrostatic discharge (ESD) according to IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be made of wood, concrete or ceramic tiles. If the floor is covered with synthetic material, the relative humidity must be at least 30 %.
Magnetic field at the supply frequency (50/60 Hz) to IEC 61000-4-8	30 A/m	30 A/m	Magnetic fields at the mains frequency should correspond to the typical values as found in the business and hospital environment.

12.4.3 Interference Resistance for Non-Life-Supporting ME Systems Guideline and Manufacturer Declaration

Guidelines and manufacturer's declaration – electromagnetic interference immunity			
The **Spirostik** is determined for operation in an electromagnetic environment as specified below. The user / operator of the **Spirostik** should ensure that it is operated in this environment.			
Measurement of interference immunity	IEC 60601 -level	Compliance level	Electromagnetic enviroment - Guidline
			Portable and mobile RF communication devices should not be used at a shorter distance from the **Spirostik** as the recommended safety distance calculated according to the equation applicable to the transmission frequency.
			Recommended safety distance:
Radiated HF-distrubance according to IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	E_1= 10 V/m	$d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ from 80 MHz up to 800 MHz
			$d = \left[\frac{7}{E_1}\right]\sqrt{P}$ from 800 MHz up to 2.7 GHz
	27 V/m, PM 18 Hz, 385 MHz	E_2= 27 V/m PM 18 Hz	$d = \left[\frac{6}{E_2}\right]\sqrt{P}$
	28 V/m FM± 5 kHz Hub 1 kHz Sinus, 450 MHz	E_3= 28 V/m FM± 5 kHz Hub 1 kHz Sinus	$d = \left[\frac{6}{E_3}\right]\sqrt{P}$
	9 V/m PM 217 Hz, 710 MHz, 745 MHz, 780 MHz	E_4= 9 V/m PM 217 Hz	$d = \left[\frac{6}{E_4}\right]\sqrt{P}$
	28 V/m PM 18 Hz, 810 MHz, 870 MHz, 930 MHz	E_3= 28 V/m PM 18 Hz	$d = \left[\frac{6}{E_3}\right]\sqrt{P}$
	28 V/m PM 217 Hz, 1720 MHz, 1845 MHz,	E_3= 28 V/m PM 217 Hz	$d = \left[\frac{6}{E_3}\right]\sqrt{P}$

	1970 MHz, 2450 MHz		
	9 V/m PM 217 Hz, 5240 MHz, 5500 MHz, 5785 MHz	E_4= 9 V/m PM 217 Hz	$d = \left[\frac{6}{E_4}\right]\sqrt{P}$
			P is the maximum rated power of the transmitter in watts (W) according to the manufacturer's specifications and *d* is the recommended safety distance in meters (m) Field strengths from fixed RF transmitters should be less than the compliance level at all frequencies according to on-site investigations. Interference may occur in the environment of equipment marked with the following symbol: 

Note 1: The higher frequency range shall be used at 80 MHz and 800 MHz.
Note 2: These guidelines may not be applicable in all cases. The propagation of electromagnetic parameters is influenced by absorptions and reflections from buildings, objects and people.

a) The field strengths of stationary transmitters, such as base stations and mobile land-based radios, amateur radio stations, AM and FM radio and television transmitters, can theoretically not be predicted exactly. In order to determine the electromagnetic environment with regard to the stationary transmitters, a study of the electromagnetic phenomena of the site should be considered. If the measured field strength at the site where the **Spirostik** is used exceeds the abovementioned compliance levels, the **Spirostik** should be observed to demonstrate its intended function. If unusual performance characteristics are observed, additional measures may be required, such as a change in orientation or in location of the **Spirostik**.
b) Over the frequency range from 150 kHz to 80 MHz, the field strengths should be less than 3 V/m.

12.4.4 Recommended Safety Distances for Non-Life-Supporting ME Systems

Recommended safety distance between portable and mobile RF communication devices and the Spirostik

The **Spirostik** is determined for operation in an electromagnetic environment in which the RF disturbances are controlled. The user / operator of the **Spirostik** may help to avoid electromagnetic interference by keeping the minimum distance between portable and mobile RF telecommunication devices (transmitters) and the **Spirostik**, depending on the emitted power of the communication device as indicated below:

Power rating of the transmitter [W]	Safety distance, depending on the transmitter frequency [m]		
	150 kHz to 80 MHz $d = 1.17\sqrt{P}$	80 MHz to 800 MHz $d = 1.17\sqrt{P}$	800 MHz to 2.7 GHz $d = 2.33\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	12	12	23

For transmitters whose maximum power rating is not given in the table above, the recommended safety distance *d* in meters (m) can be determined using the equations given with each column, where *P* is the maximum power rating of the transmitter in watts (W) as specified by the manufacturer.

Note 1: The higher frequency range shall be used at 80 MHz and 800 MHz.
Note 2: These guidelines may not be applicable in all cases. The propagation of electromagnetic parameters is influenced by absorptions and reflections from buildings, objects and people.

13 Safety of Product and Material

The manufacturer develops, produces and tests its products according to the essential requirements of MDD 93 / 42 EEC and the safety standards of DIN EN 60601-1.

All materials which are used are carefully selected and correspond to the biocompatibility requirements (in accordance with ISO 10993-1 ff) and those of the RoHS directive 2011 / 65 / EU (RoHS II). All materials in contact with the patient were evaluated and tested according to DIN EN ISO 10993-1:2017-04 "Biological evaluation of medical devices" (biocompatibility).

Spirostik is a class IIa active medical device. Conformity with the underlying standards and directives is certified in the declaration of conformity which is included in the documentation accompanying the device.

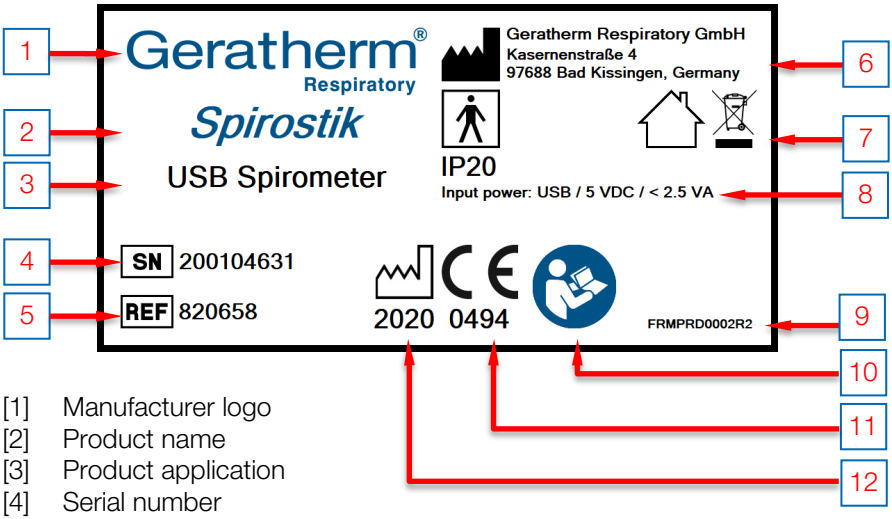
14 Product Labeling / Type Label

The type label can be found on the bottom of the housing on the Spirostik.

- See chap. 4.1.1 “Overview” point [4].

For more information about the symbols, please read:

- Chap. 1.3 “Symbols”.



[1] Manufacturer logo
[2] Product name
[3] Product application
[4] Serial number
[5] Catalog number
[6] Manufacturer details
[7] Do not dispose of the device along with general household waste!
[8] Input power
[9] Type label revision indication
[10] Follow the IFU
[11] Conformity mark in accordance with the Medical Device Directive 93 / 42 / EEC with identification of the involved notified body
[12] Date of manufacture

Safety symbols have been applied to the Spirostik type label. It may not be changed or removed. If information should become unreadable, the type label should be replaced immediately. Contact the manufacturer to do this.

15 Warranty and Service

15.1 General Conditions

The manufacturer guarantees that the products you have purchased fulfill the listed technical data and that the medical devices are free from technical material and production defects. This limited warranty is valid for 12 months from the date of purchase. During this time, the manufacturer declares that it will replace or repair defective products. The date of purchase corresponds to the delivery date if the product was purchased directly from us, or the date of installation if you purchased the device via a specialist retail partner.

All repairs to products which are covered by the warranty must be carried out by the manufacturer or by a specialist retail partner. All warranty claims expire if the repairs were unauthorised.

15.2 Warranty Exemption

The warranty does not cover damage which was caused by the following:

- Not complying with the storage or transportation conditions
- Improper use, servicing or repair
- Use of spare parts other than the original spare parts or spare parts approved by the manufacturer
- Any technical changes to the device
- Overvoltage or undervoltage
- Installing and operating third-party software which has not been approved by the manufacturer
- Connecting third-party devices which has not been approved by the manufacturer
- Operating the device outside of the valid environmental conditions

15.3 Packaging and Shipping

To avoid damage during transport, devices must be sent along with the warranty claim in the original packaging. This also applies for defective devices being repaired.
Transport damage arising from improper packing is the responsibility of the customer. In addition, insurance during transport is recommended. Claims due to loss or damage must be made by the shipper.

16 Authorised Specialist Retail Partner

You can reach your responsible specialist retail partner via a contact form of the manufacturer
www.geratherm-respiratory.com/login/

See depositors

Attachment – Declaration of Conformity

The Spirostik declaration of conformity is enclosed with each device by the manufacturer.