Geratherm® Respiratory

Ambistik

Serial numbers: xx|4500|004|yyy



Instructions for Use

Version: 7
Revision: 1
Release date: 27th February 2024

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. Ambistik is a 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 Ambistik fulfills the regulatory requirements for medical devices (class I).

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 Ambistik, 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 Ambistik 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 Ambistik. 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 Ambistik 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 Ambistik.

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!**
	**Electronic instructions for use** To indicate on product or product packaging that relevant information for use of the product is available in electronic form rather than, or in addition to, printed paper form.
	**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.
	**Serial number** This symbol identifies the serial number given by the manufacturer.

Symbol	Explanation
	**Catalog number** This symbol identifies the catalog number given by the manufacturer.
	**Medical Device**
	**Unique Device Identifier (UDI)** Unique identifier of the product.
	**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).
	**Caution, non-ionizing electromagnetic radiation** Precautions must be taken to avoid an unexpected effect of non-ionizing radiation.
	**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.

Symbol	Explanation
	**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.
	**Package** The symbol indicates the identifier of the package and the total number of packages.

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 Ambistik which is not described in this IFU is deemed improper use. The responsible organisation of Ambistik 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

The medical device Ambistik is a PC-based measuring device which is used to determine the environmental conditions.
As an accessory to our products in the field of spirometry and spiroergometry, the Ambistik is intended to enable automatic recording of ambient conditions.
When breathing, air is inhaled at room conditions.
As such, the volumes of air inhaled increase due to an increase in body temperature, as well as an increase in air humidity up to the point of saturation. In order to balance out this effect, the volumes inhaled are multiplied within the software with the BTPS factor (Body Temperature Pressure Saturated).
This factor is calculated by using the ambient conditions for temperature, air pressure and air humidity.
As such, the software has to detect the actual ambient conditions during the measurement process.
So the user is saved from having to input values manually, and in order to minimise any potential errors resulting from information being input incorrectly, Ambistik automatically transfers these parameters to the software via the USB interface.
The Ambistik consists of a case with integrated electronics, as well as sensors for temperature, air humidity and pressure.
The Ambistik is always supplied with other Geratherm® Respiratory lung function devices, as well as the BLUE CHERRY® software.



You can find more information in:

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

2.1.1 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 Ambistik. They are responsible for instructing the users 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 Ambistik is used by their employees (users / operators).

User
is a medically trained specialist who is familiar with lung function examinations, who uses Ambistik after verifiable instruction by the responsible organisation and / or is responsible for rectifying faults to the Ambistik.

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 Ambistik.
Trainee medical specialists must also be supervised in addition to receiving training in how to use Ambistik.

Operator
is a person who has received instruction on cleaning Ambistik 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.

2.2 Intended Use

Ambistik 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. 4.1.2 “System Construction and Electrical Safety”)

In all cases, the Ambistik 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 Ambistik 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. 2.1.1 “Definition of the Groups of People”) operates Ambistik. Personnel must demonstrably have been given training in the function of Ambistik. 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 Ambistik may only be used for the duration of its service life if the specifications are observed.
Any changes to Ambistik, in particular unauthorised modifications, are prohibited.

Any other than the described use is deemed improper use.
The responsible organisation of Ambistik 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 60601-1-2:2006-10; VDE 0750-1-2:2006-10; IEC 60601-1-2:2001 + A1:2004. See chap. **Fehler! Verweisquelle konnte nicht gefunden werden.** “Electromagnetic Compatibility / EMC Guidelines”. Ambistik 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 Ambistik.

The installation or use of other products can, under certain circumstances, negatively change constructive prescribed properties of Ambistik 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.
(see also chap. 15.2 “Warranty Exemption“)

⚠ 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 materials 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. 4.1.2 of this IFU
- Further information on Ambistik in the separate Ambistik IFU

Component	Description / name	Supply scope in units	REF
	**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®.	01	884000 [old:40.300]
	**USB Docking Station** ➢ For USB based devices (1.5 m)	01	652725 [old:40.300-01]

2.2.2 Auxiliary Materials

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
Disinfectant	**For wipe disinfection**, alcoholic quick-acting ➢ Bacillol Tissues (BODE Chemie GmbH) ➢ Sprayln (Dr. Deppe GmbH)	depending on provider

3 Safety in Handling

Ambistik 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 operators / users, patients and third parties as well as damage to Ambistik 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 Ambistik or the complete 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 manual carefully and in its entirety before using the Ambistik. 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 complete 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 Ambistik 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. Triggering Ambistik malfunctions. Unqualified personnel can discover sources of fault too late or even cause them.** Therefore:

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

3.2 Storage Conditions stipulated by the Manufacturer

⚠ CAUTION	**Possible physical injury.** Reason: **Device damage as well as impurities / contamination due to improper handling of components.** Therefore: • Observe the storage conditions stipulated by the manufacturer! Reason: **Measurement error due to leakage caused by incorrect assembly of components.** Therefore: • Carefully observe the assembly instructions!

3.3 The Technical State of Ambistik and System Construction

⚠ WARNING	**Possible danger to life.** Reason: **Electric shock. Cross-contamination. Misdiagnosis caused by measurement error.** Therefore: • Do not overstress Ambistik! Use with care! • Do not modify or use product Ambistik or complete system contrary to the respective manufacturer's specification! • Only use the USB connection cable / docking station supplied by manufacturer within the scope of delivery and available as a spare part, which is always part of the medical device! • Under no circumstances use or connect any devices, systems, equipment and other products that are not part of the complete system! This also includes only components approved by the manufacturer such as Bluetooth dongle, (rechargeable) batteries, battery chargers, (connection) cables and computers that are not permitted by the manufacturer. See chap. 12 "Technical Specifications"!

- Do not connect any additional USB (except mouse, keyboard, printer and other devices which have not been approved by the manufacturer!
- Do not install any other software!
- Ask your authorised specialist retail partner which devices are approved by the manufactuer!
- 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!

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 complete system! Request maintenance work from your authorised specialist retail partner!

For this**: Only use Ambistik within its performance limits!** Therefore**:**

- 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 perfect condition!

3.4 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 Ambistik if there are flammable or explosive gases in the room!
- Do not operate Ambistik near the magnetic field of an MRI system!

WARNING

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

- Prevent improper assembly / installation!
- Ambistik should only be assembled and installed by officially trained personnel authorised by the manufacturer!
- Ensure that the used components are undamaged and that you are working in a careful way!
- Prior to each use, visually inspect the complete 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: **Misdiagnosis caused by measurement error due to incorrect components or improper use.**
Therefore:

- Always follow instructions (see chap. 8 "Servicing / Maintenance" and chap. 9 "Cleaning and Disinfection")!


Attention

Ambistik could be damaged.
Reason: **Penetrating liquid. Uncleanliness. External exposure. Condensation** Therefore:

- Do not use any liquids near Ambistik!
- Do not expose Ambistik or the entire system to dust or other contamination!
- Do not drop any objects on Ambistik!
- Do not lay any objects on it!
- Never push foreign objects into the housing!
- Do not expose the Ambistik to excessive temperature fluctuations during operation!

Reason**: Careless operation.** Therefore**:**

- Assure that all cables and tubes are connected carefully!
- Generally, do not expose cables, tubes and their connections to mechanical stress such as tension, pressure, bending or similar!

Malfunctions possible.
Reason: **Components and e. g. plug connections can be damaged.** Therefore:

- Ensure that all connections are made carefully and without excessive force!

3.5 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 Ambistik, 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**: Misdiagnosis caused by uncontrollable electromagnetic fields. Triggering malfunctions. Device damage due to improper handling of components.** Therefore**:** • 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 Ambistik!

Attention	**Ambistik 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!

3.6 Cleaning and Disinfection

WARNING	**Possible danger to life.** Reason: **Cross-contamination.** For this: **Observe the general medical principles!** Therefore: • Clean and disinfect the Ambistik and its reusable components as instructed by the manufacturer at regular intervals as specified!
Attention	**Ambistik could be damaged.** Reason**: Improperly treated components**. Therefore: • For cleaning and disinfection only use those active substances that are approved by the manufacturer (see chap. 9 “Cleaning and Disinfection“)! • Follow the instructions on the concentration and dwell time stated by the cleanser and disinfectant manufacturer! • Do not place Ambistik in the cleaning and disinfection solution! The device contains electrical components that will be damaged by doing this! Reason**: Ambistik sensors are precise and high-resolution components.** For this: **Ensure the respective functions are preserved!** Therefore**:** • Exactly follow the instructions for cleaning, disinfection, and calibration!

4 Structure and General Function of Ambistik

4.1 Hardware

4.1.1 Overview



[1] Ambistik
[2] Docking station with data connection port and power connection port (see also chap. 4.1.2)
[3] USB cable
[4] Type label (see also chap. 14)

4.1.2 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 Ambistik.
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:



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

- Do not modify or use the Ambistik or complete 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 complete system! This also includes only components approved by the manufacturer such as Bluetooth dongle, (rechargeable) batteries, battery chargers, (connection) cables and computers that are not permitted by the manufacturer!
  See chap. 12 "Technical Specifications".

- 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 Ambistik 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!

Reason: **Misdiagnosis due to incorrect measurement results.** Therefore:

- Do not install any other software!

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 complete system! Request maintenance work from your authorised specialist retail partner!

Reason: **Ignorance of safety instructions.** Therefore:

- The manufacturer of a system must provide the user / operator with all separate IFU applicable for the complete system!


Attention

Ambistik 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!

4.1.2.1 Bluetooth / Computer / Printer Data Connection



The Ambistik only communicates with the diagnostic software platform for pulmonary function BLUE CHERRY®.
For further information see:

- Chap. 7.2 “Initial Operating”
- The separate IFU BLUE CHERRY®

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.

4.2 Technical Protection Measures

Ambistik 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 of the Ambistik 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 see:

- The separate IFU of BLUE CHERRY® – information on the configuration and use of the software BLUE CHERRY®

5 Transport, Storage and Assembly

5.1 Transport to the Location of Use

Ambistik is secured against damage during transport in a carton.



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. 0 “
-
- Warranty and Service“

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

5.2 Storage

The Ambistik is a mobile, portable device.
Requirements regarding space requirements, media connections and operating conditions can be found in chap. 12 "Technical Specifications".
The responsible organisation of the Ambistik 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! • Ambistik should only be assembled and installed by officially trained personnel authorised by the manufacturer!



For further information see
- Chap. 4.1.2 “System Construction and Electrical Safety”

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

6 Operation

The initial operation of Ambistik, as well as any return to operation after service work in accordance with the duties of the responsible organisation (see chap. 8 “Servicing / Maintenance”), 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 complete 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 System Overview

Ambistik automatically measures and transfers the ambient conditions temperature, pressure and humidity to the diagnostic platform BLUE CHERRY®.
BLUE CHERRY® allows the user to check the data and uses the ambient conditions for BTPS compensation during spirometry, PFT and CPET tests.



1. **Ambistik is plugged directly into the docking station.**
   (Data connection port **[1]**) using its USB connector).
2. **The power connection port [2] of the docking station is not used.**
3. **The docking station is connected to the PC via the USB cable [3].**

In order to capture the ambient conditions as accurately as possible, the docking station with the Ambistik is placed in a well-ventilated area near the patient.
It must be ensured that there is no heat source in the immediate proximity that may distort the measurement data of the Ambistik.

6.2 Recommissioning

The operator is responsible for recommissioning after maintenance / cleaning work for which the user is authorised.

For the steps for recommissioning correspond to the initial commissioning, see chap. 7.2 “Initial Operating".

7 Operating Instructions


Attention

Ambistik could be damaged.
Reason: **Penetrating liquid. Uncleanliness. External exposure.**
Therefore:

- Do not use any liquids near the Ambistik!
- Do not expose Ambistik or the entire system to dust or other contamination!
- Do not drop any objects on Ambistik!
- Do not lay any objects on it!
- Never push foreign objects into the housing!

7.1 Checking for Worn Parts



The Ambistik should be checked for defective wearing parts each day before beginning treatments. You can get a description in:

- Chap. 8 “Servicing / Maintenance”

And:

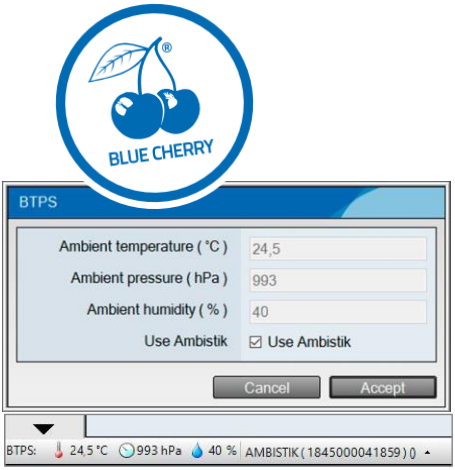


Possible danger to life.
Reason: **Misdiagnosis caused by measurement error due to incorrect components or improper use.**
Therefore:

- Always follow instructions!
  (see chap. 8 "Servicing / Maintenance" and chap. 9 "Cleaning and Disinfection")

7.2 Initial Operating

The measurements of the Ambistik are processed by the diagnostic platform BLUE CHERRY®.



1. Startup the PC and press the “BLUE CHERRY®” icon on the desktop to start the software.
2. Press the “BTPS” button to get access to the ambient conditions. If you want to enter the ambient conditions manually, deactivate the “Use Ambistik” check box.
3. The ambient conditions are also shown at the left of the screen (figure right above, with sample data).

8 Servicing / Maintenance

8.1 Duties of the responsible Operator

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 Ambistik 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 complete system! Request maintenance work from your authorised specialist retail partner!

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 Ambistik functional and clean. The following intervals apply:

Component	Interval	Method
All touchable parts	Weekly	Wipe disinfection with a soft cloth and a weak soap solution.

9.1 Disinfection

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

Ambistik could be damaged
Reason: **Improperly treated components.** Therefore:

- For cleaning and disinfection only use those active substances that are approved by the manufacturer (see chap. 2.2.2 “Auxiliary Materials”)!
- Follow the instructions on the concentration and dwell time stated by the cleanser and disinfectant manufacturer!
- Do not place Ambistik in the cleaning and disinfection solutions! The device contains electrical components that will be damaged by doing so!
- Wipe off any remaining moisture with a dry cloth!
- Observe the maximum permissible temperature of 75 °C for cleaning and disinfection!
- Do not dry with heat!



When selecting a suitable disinfectant, please observe

- chap. 2.2.2 “Auxiliary Materials”

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 Ambistik 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 Ambistik!

Error	Rectification
Ambistik is not detected.	Check the USB connection. Choose a different USB port. Check the USB connector.
Ambistik transmits no measurement data.	
Measurement data are not plausible.	Check installation location – install the device as close as possible to the patient. Do not install the device near a heat outlet of the computer (for example fan) or other devices (for example air-condition). Send device to authorised specialist retail partner for repair / replace the device.
Error message “Internal communication error”	Disconnect / connect the device. Send device to authorised specialist retail partner for repair / replace the device.
Error message “Measured **values outside the** measuring range”	Send device to authorised specialist retail partner for repair / replace the device.
Error message “Error reading pressure”	Send device to authorised specialist retail partner for repair / replace the device.
Error message “Error **reading temperature /** humidity”	Send device to authorised specialist retail partner for repair / replace the device.

11 Decommissioning / Disposal

11.1 Expected Service Life

The expected service life of Ambistik 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 Disposal

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

11.2.1 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.

11.2.2 Ambistik

Ambistik 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 Ambistik 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 Ambistik and / or the accessories.

12 Technical Specifications

12.1 Technical Data

Medical device:	Class I (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 type:	IP20 IEC 529
PC interface:	USB 2.0
Power supply:	via USB port
Power consumption:	5 VDC / < 2.5 VA
EMC:	Group 1 / Class B

Temperature measurement:	
Measurement range:	0 °C to +50 °C
Resolution:	0.01 °C
Scan rate:	0.25 Hz
Accuracy:	±1 °C

Humidity measurement:	
Measurement range:	10 – 90 %
Resolution:	0.1 %
Scan rate:	0.25 Hz
Accuracy:	±5 % at 50 %

Pressure measurement:	
Measurement range:	700 – 1100 hPa
Resolution:	1 hPa
Scan rate:	0.25 Hz

Accuracy:	±10 hPa at 1000 hPa

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

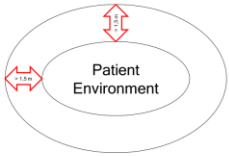
The following conditions supplement chap. 2.2 "Intended Use" and must be observed to maintain the properties of the Ambistik guaranteed by the manufacturer and for the safety of the patient and operator.

Storage / Transport:	**min.**	**max.**	
Temperature:	-10 °C	+50 °C	
Relative air humidity:	10 %	95 %	non-condensing
Operation:	**min.**	**max.**	
Environmental temperature:	+10 °C	+35 °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**		
Environment / room:	not an explosive or flammable environment!		
	not near an MRI!		
Operating Mode:	**Continuous operation**		

12.3 Electrical Safety Concept

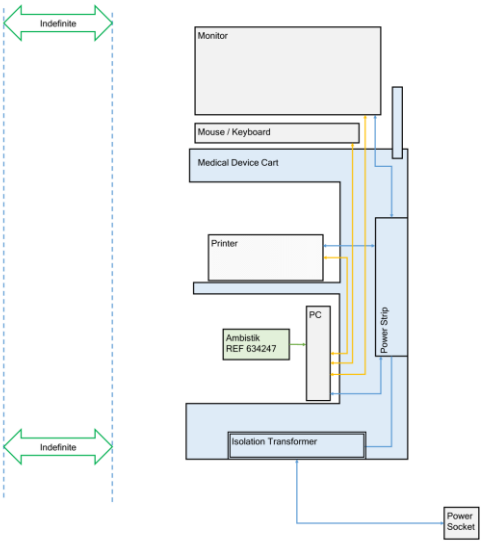
12.3.1 Ambistik with Medical Device Cart and Isolation Transformer

- Ambistik Power Supply and Communication via USB Interface
- With Isolation Transformer via Medical Device Cart



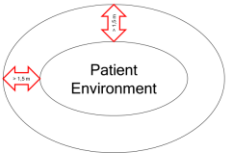
Green Blocks = Geratherm Respiratory Medical Devices
Blue Blocks = 3rd Party Medical Devices
Grey Blocks = Non-Medical Devices
Hatched Blocks = Optional Devices respectively Medical Devices
Blue Lines = Mains Power 100-240 VAC N/L/PE
Green Lines = USB Connectivity
Yellow Lines = Unknown, External Data Connections
Double Framework = Galvanic Isolation from Electrical Connections
Arrows = Plug Connections





12.3.2 Ambistik without Medical Device Cart and without Isolation Transformer

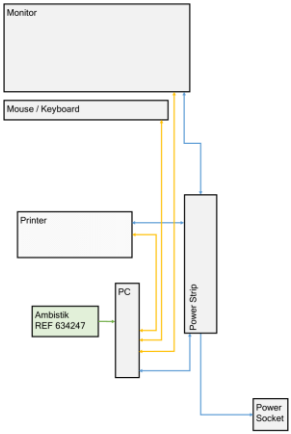
- Ambistik Power Supply and Communication via USB Interface
- Without Medical Device Cart, without Isolation Transformer



Green Blocks = Geratherm Respiratory Medical Devices
Grey Blocks = Non-Medical Devices
Hatched Blocks = Optional Devices respectively Medical Devices
Blue Lines = Mains Power 100-240 VAC N/L/PE
Green Lines = USB Connectivity
Yellow Lines = Unknown, External Data Connections
Double Framework = Galvanic Isolation from Electrical Connections
Arrows = Plug Connections







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 **Ambistik** is determined for operation in an electromagnetic environment as specified below. The user / operator of the **Ambistik** should ensure that it is operated in this environment.		
Measurement of electromagnetic emissions	Compliance	Electromagnetic environment – Guideline
RF emissions CISPR 11	Group 1	The **Ambistik** 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	
Emissions of harmonic oscillations according to IEC 61000-3-2	Not applicable	Power supply via USB
Emissions of voltage fluctuations / flicker according to IEC 61000-3-3	Not applicable	Power supply via USB
		The **Ambistik** 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.

12.4.2 Interference Resistance for all ME Systems Guideline and Manufacturer Declaration

Guidelines and manufacturer's declaration – **electromagnetic interference immunity**			
The **Ambistik** is determined for operation in an electromagnetic environment as specified below. The user / operator of the **Ambistik** 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	±6 kV contact ±8 kV air	±6 kV contact ±8 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 supply frequency current frequency (50/60 Hz) according to IEC 61000-4-8	3 A/m	3 A/m	Magnetic fields at the mains frequency should correspond to the typical values found in business and hospital environments.

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

<table>
<tr><th colspan="4">Guidelines and manufacturer's declaration – electromagnetic interference immunity</th></tr>
<tr><td colspan="4">The Ambistik is determined for operation in an electromagnetic environment as specified below. The user / operator of the Ambistik should ensure that it is operated in this environment.</td></tr>
<tr><td>Measurement of interference immunity</td><td>IEC 60601 – test level</td><td>Compliance level</td><td>Electromagnetic environment - Guidelines</td></tr>
<tr><td colspan="3"></td><td>Portable and mobile RF communication devices should not be used at a shorter distance from the Ambistik as the recommended safety distance calculated according to the equation applicable to the transmission frequency.</td></tr>
<tr><td colspan="3"></td><td>Recommended safety distance</td></tr>
<tr><td>Radiated RF
IEC 61000-4-3</td><td>3 V/m
80 MHz to 2.5 GHz</td><td>E_1=3 V/m</td><td>$d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$
from 80 MHz up to 800 MHz</td></tr>
<tr><td colspan="3"></td><td>$d = \left[\frac{7}{E_1}\right]\sqrt{P}$
from 800 MHz up to 2.5 GHz</td></tr>
<tr><td colspan="3"></td><td>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:
</td></tr>
<tr><td colspan="4">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.</td></tr>
</table>

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 **Ambistik** is used exceeds the abovementioned compliance levels, the **Ambistik** 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 **Ambistik**.

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 Ambistik

The **Ambistik** is determined for operation in an electromagnetic environment in which the RF disturbances are controlled. The user / operator of the **Ambistik** may help to avoid electromagnetic interference by keeping the minimum distance between portable and mobile RF telecommunication devices (transmitters) and the **Ambistik,** 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	80 MHz to 800 MHz	800 MHz to 2.5 GHz
	$d = \left[\frac{3.5}{U_1}\right]\sqrt{P}$	$d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$	$d = \left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	0.12	0.04	0.07
0.1	0.37	0.11	0.22
1	1.17	0.35	0.70
10	3.70	1.11	2.21
100	11.70	3.50	7.00

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 according to MDR 2017 / 745 EU as well as according to the safety standards according to DIN EN 60601-1. The product Ambistik will be marketed transitionally until May 21, 2025 still originally approved according to MDD 93 / 42 EEC.

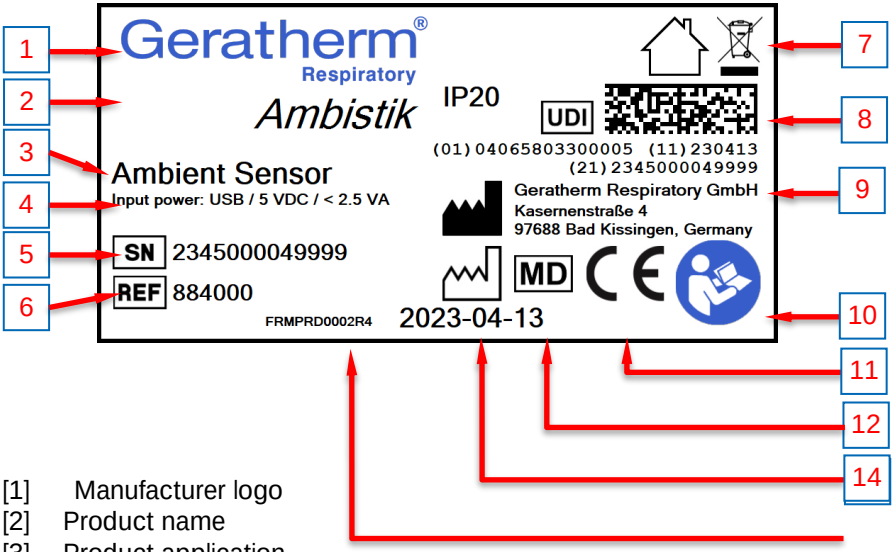
All materials which are used are carefully selected and correspond to the biocompatibility requirements (in accordance with ISO 10993-1 ff) and those of the RoHS directive 2011 / 65 / EU (RoHS II). All materials in contact with the patient were evaluated and tested according to DIN EN ISO 10993-1:2017-04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

Ambistik is a class I 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 back of the Ambistik.

- See chap. 1.3 “Symbols”.



[1] Manufacturer logo
[2] Product name
[3] Product application
[4] Input power
[5] Serial number
[6] Catalog number
[7] For symbol descriptions see chap 1.3 “Symbols”
[8] Unique Device Identifier (UDI)
[9] Manufacturer details
[10] Follow the IFU
[11] Conformity mark in accordance with the Medical Device Regulation 2017/745 (MDR)
[12] Medical Device
[13] Date of manufacture
[14] Type label revision indication

Safety symbols have been applied to the Ambistik 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/

Attachment – Declaration of Conformity

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