Geratherm®
Respiratory

Diffustik

(incl. system variant PFTstik)

Serial numbers: xx|8|401|yyy and 2401xxxxx

Instructions for Use

Version: 14

Release date: 21 July 2022

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. Diffustik and the variant PFTstik are 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 Diffustik and the variant PFTstik 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 Diffustik resp. the variant PFTstik, 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 Diffustik resp. the variant PFTstik 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 Diffustik resp. the variant PFTstik. 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 instructions for use 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 Diffustik resp. the variant PFTstik 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 Diffustik resp. the variant PFTstik.

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.
IP40	Protection type (safe environmental conditions) IP4x: Protection against penetration of foreign bodies with a diameter of > 1.0 mm IPx0: No protection of enclosure against harmful ingress of water.

Symbol	Explanation
	**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.
	**For single use only!** This symbol does not refer to the Diffustik resp. the variant PFTstik 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.

Symbol	Explanation
CE 0494	**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.
	**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

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 Diffustik resp. the variant PFTstik which is not described in this IFU is deemed improper use. The responsible organisation of Diffustik resp. the variant PFTstik 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

For the Diffustik variant, the separate IFU
Add-on CO Diffusion is additionally intended for the following purposes.

The Diffustik resp. the variant PFTstik is a medical electrical device. As a PC-linked PFT system, it is mainly intended to determine lung volumes and airway resistances (Rint) in lung function diagnostics in the clinical sector and by general practitioners.

Diffustik resp. the variant PFTstik 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 Diffustik resp. the variant PFTstik and the Flow sensor may only come into contact with intact skin and mucous membrane.

The standard version of the associated software enables the Measurement of Spirometry, Flow / Volume, Airway Resistance (Rint) as well as Pre / Post Examinations and Trend Analysis.

Using Diffustik resp. the variant PFTstik, you can also carry out the examination stated below.

For a detailed description of the option ”CO Diffusion“, please refer to the separate IFU:

- Add-on CO Diffusion

Examination	Required option
CO Diffusion	Variant Diffustik: Included Variant PFTstik: Add-on CO Diffusion (REF 259149)
MIP / MEP	MIP / MEP (REF 250798)
P0.1	MIP / MEP (REF 250798)
Breathing Pattern Analysis	MIP / MEP (REF 250798)

You can find more information in:

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

2.1.1 Indication

With Diffustik resp. the variant PFTstik, 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 to lung function examinations:

Contraindications
Due to increases in myocardial demand or changes in blood pressure • Acute myocardial infarction within 1 week • Systemic hypotension or severe hypertension • Significant atrial / ventricular arrhythmia • Noncompensated heart failure • Uncontrolled pulmonary hypertension • Acute cor pulmonale • Clinically unstable pulmonary embolism • History of syncope related to forced expiration / cough
Due to increases in intracranial / intraocular pressure • Cerebral aneurysm • Brain surgery within 4 weeks • Recent concussion with continuing symptoms • Eye surgery within 1 week
Due to increases in sinus and middle ear pressures • Sinus surgery or middle ear surgery or infection within 1 week
Due to increases in intrathoracic and intraabdominal pressure • Presence of pneumothorax • Thoracic surgery within 4 weeks • Abdominal surgery within 4 weeks • Late-term pregnancy
Infection control issues • Active or suspected transmissible respiratory or systemic infection, including tuberculosis • Physical conditions predisposing to transmission of infections, such as hemoptysis, • significant secretions, or oral lesions or oral bleeding

Spirometry should be discontinued if the patient experiences pain during the maneuver. Relative contraindications do not preclude spirometry but should be considered when ordering spirometry. The decision to conduct spirometry is determined by the ordering healthcare professional on the basis of their evaluation of the risks and benefits of spirometry for the particular patient. Potential contraindications should be included in the request form for spirometry.
(Source: Graham, B. L. et al. 2019. Standardization of Spirometry 2019 Update. Am J Respir Crit Care Med Vol 200, Iss 8, pp e70–e88.)

2.1.2.2 Side Effects

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

Side effect / Frequency	Rules of conduct
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 Diffustik resp. the variant PFTstik. They are responsible for instructing the user 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 Diffustik resp. the variant PFTstik is used by their employees (users / operators).

User
is a medically trained specialist who is familiar with spirometry examinations, who uses Diffustik resp. the variant PFTstik on the patient after verifiable instruction by the responsible organisation and / or is responsible for rectifying faults to the Diffustik resp. the variant PFTstik, 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 Diffustik resp. the variant PFTstik.
Trainee medical specialists must also be supervised in addition to receiving training in how to use Diffustik resp. the variant PFTstik.

Operator
is a person who has received instruction on cleaning Diffustik resp. the variant PFTstik 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

Diffustik resp. the variant PFTstik 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. 4.1.4 “System Construction and Electrical Safety”)

 Attention	The Diffustik resp. the variant PFTstik must be operated exclusively with the equipment cart approved by Geratherm® Respiratory (REF 10.905). The equipment cart provides electrical isolation from the power supply network. All necessary peripheral devices such as computer, printer and monitor may only be connected to the power supply network via the equipment cart. See also. chap. 4.1.4 "System Construction and Electrical Safety". If you have any questions, please contact your local specialist dealer.

In all cases, the Diffustik resp. the variant PFTstik 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).
With the Diffustik variant or the PFTstik variant in combination with the Add-on CO Diffusion extension, the room must always be well ventilated, to protect users and third parties from continuous exposure to harmful carbon monoxide (CO).
The following applies in general: The installation of Diffustik resp. the variant PFTstik 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 Diffustik resp. the variant PFTstik. Personnel must demonstrably have been given training in the function of Diffustik resp. the variant PFTstik. This also includes a complete study of this IFU.
The manufacturer has determined the expected service life (see Chapter 11.1 "Expected Service Life") and the maintenance work required for this (see chap. 8 "Servicing / Maintenance").
The Diffustik resp. the variant PFTstik may only be used for the duration of its service life if the specifications are observed.
Any changes to Diffustik resp. the variant PFTstik, in particular unauthorised modifications, are prohibited.
The Diffustik resp. the variant PFTstik 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 Diffustik resp. the variant PFTstik 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”. Diffustik resp. the variant PFTstik 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 Diffustik resp. the variant PFTstik.

The installation or use of other products can, under certain circumstances, negatively change constructive prescribed properties of Diffustik resp. the variant PFTstik 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”.

⚠ 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!

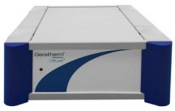
2.2.1.1 Original Spare Parts / Accessories

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. 4.1.4 of this IFU

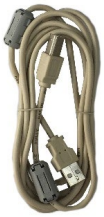
The list of original spare parts and the scope of supply described in the separate IFU Add-on CO Diffusion also applies to the Diffustik variant.

Component	Description / name	Supply scope in units	REF
	**Diffustik Device** ➢ Pulmonary function testing device for measurement of SVC, FVC, MVV and Rint. ➢ Includes USB 2.0 based desktop device, height adjustable arm, flow unit, shutter system and Ambistik for measurement of ambient conditions and continuous BTPS-compensation. ➢ Comes together with intuitive Windows based diagnostic software platform BLUE CHERRY®.	01	131710 [old:40.040]

Component	Description / name	Supply scope in units	REF
	**Height-Adjustable Arm** ➢ Height adjustable	01	281404 [old:40.702-06]
	**Adapter Stand Clamp** ➢ Adapter Stand Clamp to mount arm of PFTstik or Diffustik to a PFT cart.	01	421998
	**Table Clamp, Arm** ➢ Table Clamp to mount arm of PFTstik or Diffustik to a suitable table.	-* *Can be ordered instead of Adapter Stand Clamp*	420241 [old:10.906]
	**BLUE CHERRY® Media Pack** ➢ Modular and intuitive Windows based diagnostic software platform for pulmonary function	01	598197 [old:10.500]
	**Ambistik** ➢ USB 2.0 Ambient conditions module for accurate online BTPS conditions. ➢ Continuous measurement of ambient temperature, pressure and humidity. ➢ Runs on Windows based diagnostic software platform BLUE CHERRY®. For more information see separate IFU "Ambistik")	01	634247 [old: 40.300]

Component	Description / name	Supply scope in units	REF
	**USB-Docking Station** ➢ Docking station (1.5 m) for USB based devices.	01	652725 [old:40.300-01]
	**Ergoflow** ➢ Re-useable lightweight flow sensor for use with Ergostik, PFTstik, Bodystik and Diffustik device.	01	139094 [old:10.600]
	**Flow Unit** ➢ Flow unit for PFTstik, Bodystik and Diffustik. Including flow electronic and rubber seal plates.	01	40.630
	**Shutter Drive** ➢ Electromagnetic shutter drive for shutter system.	01	122919 [old:40.610]
	**Shutter Block** ➢ Shutter block for shutter system for fast occlusion of breathing path. ➢ For connection of shutter system with flow unit (see also shutter plug) or demand valve with flow unit. *Replaces shutter head (40.612) or shutter head CO (40.613) and shutter cage (40.611). Can be retrofitted for all systems.*	1* *from 11 / 2018*	198961 [old:40.620]

Component	Description / name	Supply scope in units	REF
	**Shutter Plug** ➢ Plug to close opening for demand valve in shutter block ➢ Diffusion (Demand-Ventil) Can be retrofitted for all systems	1* *from 11 / 2018*	347975 [old:40.622]
	**Shutter-Cage** ➢ For fast occlusion of breathing path. *Replaced by shutter block (40.620).*	1* *until 11 / 2018*	40.611
	**Shutter Head** ➢ For connection of shutter system with flow unit without Add-on CO Diffusion (demand valve) *Replaced by shutter block (40.620).*	01* *until 11 / 2018 without Add-on CO Diffusion*	40.612
	**Shutter Head CO** ➢ For connection of shutter system with flow unit with Add-on CO Diffusion (demand valve) *Replaced by shutter block (40.620).*	01* *until 11 / 2018 with Add-on CO Diffusion*	40.613
	**Mounting Plate** ➢ Mounting plate to fix the shutter system on the height adjustable arm.	01	700178 [old:40.702-07]

Component	Description / name	Supply scope in units	REF
	**Softclip** ➢ Disposable noseclip for lung function tests ➢ Made of soft, skin-friendly foam for best wearing comfort ➢ One size	03	787158 [old:10.200]
	**Neumofilt** ➢ Single use disposable bacterial and viral filter for use in pulmonary function testing.	03	199479 [old:10.003]
	**Power Cord, CEE 7 / 7, C13 (IEC 60320, EU)** ➢ Power cord with European plug with protective earth.	01	719626 [old:10.838-01]
	**USB-Connection Cable** ➢ USB connection cable (male A and male B) for connecting USB-based devices to the PC. ➢ Length: 1.8 m	01	362803 [old:10.820]
	**Silicon Adapter, Small** ➢ Silicon adapter size small used for Ergoflow to connect to calibration syringe.	01	919774 [old:10.831]
	**O-Ring Set, Shutter Head** ➢ 2 x 23 x 2 mm for shutter head (outside)	01* *from 11 / 2018*	40.623
	**O-Ring, Demand Valve** ➢ O-Ring 1 x26 x 3 mm for demand valve.	01* *from 11 / 2018*	457033 [old:40.617]

Component	Description / name	Supply scope in units	REF
	**O-Ring Set, Shutter Head** ➢ O-Ring Set 2 x 23.52 x 1.78 mm and 2 x 30 x 2 mm for shutter head and shutter head CO.	01* *until 11 / 2018*	952017 [old:40.616]
	**Rubber Seal, Flow Unit** ➢ 2 Rubber seal plates for flow unit.	01	885146 [old:40.630-05]
	**Retaining Ring, Ø 10 mm** ➢ Retaining ring to fix the mounting plate on the height adjustable arm.	01	292655 [old:40.702-08]
	**Pressure Regulator GM, Diffusion Gas** ➢ For bottle with connector DIN 477-1, 1990 Nr. 14 (External thread, Left-hand thread, M 19 x 1.5)	normally not included but recommended!	392281 [old: 659623]
	**Pressure Regulator GM, Diffusion Gas** ➢ For bottle with connector DIN477-1, 1990 No. 1 (External thread, Left-hand thread, W 21.80 x 1/14")	normally not included but recommended!	224718 [old: 781429]

Component	Description / name	Supply scope in units	REF
	**PFT Cart** **Consisting of** ➢ Cart for PFT systems consisting of base frame, ➢ Drawer block, ➢ 1 storage shelf, ➢ 1 monitor holder, ➢ 10-liter gas bottle holder and 1 universal bottom storage shelf. ➢ Includes safety transformer and multiple sockets. **Mandatory** (See also chap. 4.1.4 "System Construction and Electrical Safety" 4.1.4.1 "Equipment Cart with Isolating Transformer")	---	509409 [old:10.905]

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. 4.1.4 of this IFU

Component	Description / name	REF
	**Add-on CO Diffusion** ➢ Single breath CO Diffusion option adds DLco measurement to Bodystik or Diffustik / Variant PFTstik. ➢ Includes: o Fast NDIR CO / CH_4 Analyzer (CO: 0 – 3000 ppm, o CH_4: 0 – 3000 ppm), o Demand Valve and Connection Tubes / Cable. **The Add-on CO Diffusion is already included as an integral part of the Diffustik variant.**	259149 [old:40.702]
	**Pressure Regulator GM, Diffusion Gas** ➢ For bottle with connector DIN 477-1, 1990 Nr. 14 (External thread, Left-hand thread, M 19 x 1.5)	392281 [old: 659623]

Component	Description / name	REF
	**Pressure Regulator GM, Diffusion Gas** ➢ For bottle with connector DIN477-1, 1990 No. 1 (External thread, Left-hand thread, W 21.80 x 1/14")	224718 [old: 781429]
	**Pressure Regulator, Diffusion** No longer available ➢ Pressure Regulator for CO Diffusion measurement gas mixture (Providing a fixed pressure of 5 bar, connector DIN 477-1:1990 No. 14.) ➢ According to ISO 10524-1	659623 [old:10.822]
	**Calibration Syringe** ➢ Precision calibration instrument for calibration of flow or volume-based systems. 3 liter volume (nonadjustable). ➢ Comes together with adapter for Spiraflow and Ergoflow	608220 [old:10.801]
	**MIP / MEP** ➢ Software option for BLUE CHERRY® to add measurement of o Maximum inspiratory pressure (MIP), o Maximum expiratory pressure (MEP) o P0.1.	250798 [old:10.525]

2.2.2 Consumable Items / Auxilary Materials

The following items were tested by the manufacturer for Diffustik resp. the variant PFTstik. 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
	**Softclip** ➢ Single use disposable noseclip for use in pulmonary function testing. ➢ Made of soft foam for best wearing comfort. ➢ One size fit all.	787158 [old:10.200]
	**Neumofilt** ➢ Single use disposable bacterial and viral filter for use in pulmonary function testing.	199479 [old:10.003]
Disinfectant	**For wipe disinfection**, alcoholic quick-acting ➢ Bacillol Tissues (BODE Chemie GmbH) ➢ Sprayln (Dr. Deppe GmbH)	depend-ing on provider
	For disinfection bath with low chloride concentration ➢ InstruPlus (Dr. Deppe GmbH) ➢ Bomix Plus (BODE Chemie GmbH) ➢ Desinfektion N (ANTISEPTICA Dr. Hans-Joachim Molitor GmbH) ➢ Gigasept Pearls (Schülke & Mayr GmbH) ➢ Milton liquid disinfectant (Milton Pharmaceutical UK Limited)	

3 Safety in Handling

Diffustik resp. the variant PFTstik have 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 Diffustik resp. the variant PFTstik 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.

For the Diffustik variant resp. when the "CO Diffusion" option is added to the PFTstik variant, the safety instructions in the separate IFU Add-on CO Diffusion also apply:

DANGER

In order for Diffustik resp. the variant PFTstik 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 Diffustik resp. the variant PFTstik. 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 Diffustik resp. the variant PFTstik 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 Diffustik resp. the variant PFTstik. 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 Diffustik / Variant PFTstik and System Construction

⚠ WARNING

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

- Do not overstress Diffustik resp. the variant PFTstik! Use with care!
- Do not modify or use product Diffustik resp. the variant PFTstik or total system contrary to the respective manufacturer's specification!
- Only use Diffustik resp. the variant PFTstik 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!
- Never obstruct the access to the mains plug or On / Off Switch of the equipment cart! Disconnection of the power supply must be easily accessible!
- Only use accessories and consumables which are authorised by the manufacturer as well as authorised replacement components, add-ons and auxiliary materials.
  Ensure that the components are in faultless condition!
- 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 total system! Request maintenance work from your authorised specialist retail partner!
- The device may only be operated in conjunction with the equipment cart (ergoline ergocar PC) offered by manufacturer!

Reason: **Electrical shock**. Therefore:

- Only connect the Diffustik resp. the variant PFTstik to a supply system with a protective earth conductor!

3.3 Operation / Servicing and Maintenance

DANGER

Danger to life.
Reason: Electric shock. Carbon monoxide (CO) intoxication. 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"!
- When using the optional diffusion measurement, note the separate IFU Add-on CO Diffusion!
- Do not operate Diffustik resp. the variant PFTstik if there are flammable or explosive gases in the room!
- Do not operate Diffustik resp. the variant PFTstik near the magnetic field of an MRT system!

WARNING

Possible danger to life.
Reason: Electrical shock. Cross-contamination or measurement error. For this: Ensure that the used components are undamaged and that you are working in a careful way! Therefore:

- Do not use consumable articles with a limited life span after their use-by date has expired!
- Prior to each use, visually inspect the total system (housing, cables, connectors, tubings, pneumatic connections, 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. Misdiagnosis due to measurement errors. Equipment damage.** For this: **Ensure that the components used / applied are undamaged and that the device is operated carefully!** Therefore:

- Calibrate the Diffustik resp. the variant PFTstik at the specified intervals!
- Do not let any objects fall on the Diffustik resp. the variant PFTstik!
- Do not put any objects on the Diffustik resp. the variant PFTstik!
- Never push foreign objects into the housing!

Reason: **Disregard of 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!

⚠ **CAUTION**

Possible physical injury.
Reason: **Height-adjustable arm, Diffustik resp. the variant PFTstik and / or complete equipment cart falls over.** Therefore:

- Never change the pre-assembled height-adjustable arm!
- Do not attach any other components to the device!

- Do not lean on the height-adjustable arm or hold on to it!

Reason: **Skin burn caused by short-circuit inside the device.** Therefore:

- Do not touch shutter drive in case of excessive heat!

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 Diffustik resp. the variant PFTstik, 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!
- 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 Diffustik resp. the variant PFTstik!

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 Diffustik resp. the variant PFTstik 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)!

⚠ CAUTION

Possible physical injury.
Reason: **misinterpretation of obvious measuring errors (drift) caused by liquid in the tubes.** Therefore:

- Clean tubes only externally!
- Replace dirty tubes!

Attention

Diffustik resp. the variant PFTstik could be damaged.
Reason**: Penetrating liquids into electronic components**.
Therefore**:**

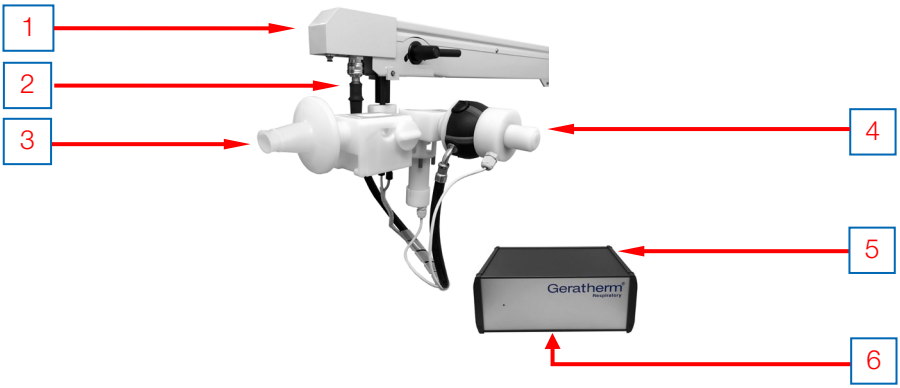
- Disconnect the Diffustik resp. the variant PFTstik from the power supply before cleaning and disinfecting! (When switching off via the On / Off switch of the equipment cart), shut down the PC completely before doing so!
- Wipe off remaining moisture with a dry cloth!

4 Structure and General Function of Diffustik resp. the Variant PFTstik

4.1 Hardware

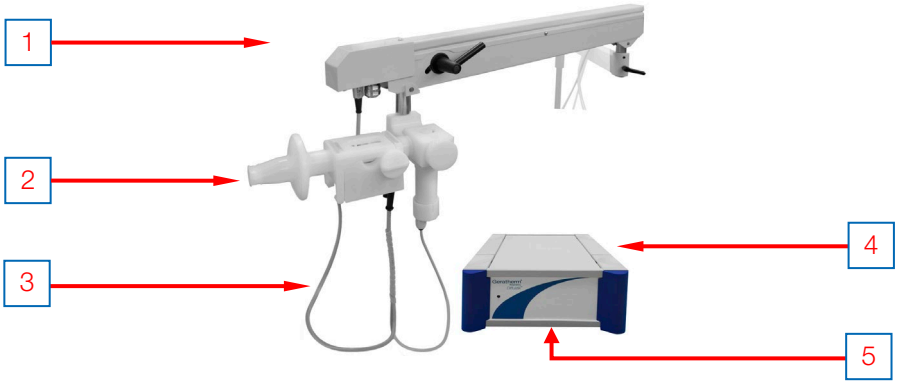
For the Diffustik variant, or when the "CO Diffusion" option is added to the PFTstik variant, the complete system also includes the components described in the separate IFU Add-on CO Diffusion.

4.1.1 Overview of the Complete System of the Diffustik Variant



[1] Movable arm for connection of **[3]**
[2] Connections for gas sample and gas supply CO Diffusion (see also chap. 4.1.3.3)
[3] Flow-measuring and shutter system (see also chap. 6.2.1 und 6.2.2)
[4] Demand valve
[5] CO / CH_4 Analyzer
[6] Type label on the back of the housing (see also chap. 14)

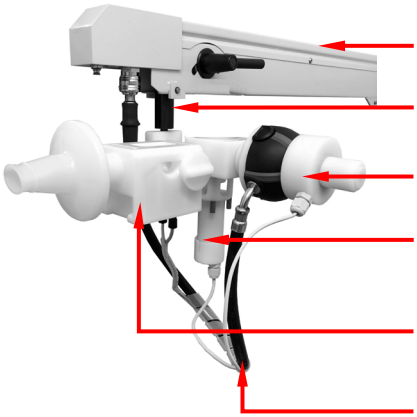
4.1.2 Overview of the Complete System of the PFTstik Variant



[1] Movable arm for connection of **[2]**
[2] Flow-measuring and shutter system (see also chap. 6.2.1 und 6.2.2)
[3] Connections for gas sample and gas supply CO Diffusion (see also chap. 4.1.3.3
[4] Diffustik / Variant PFTstik (see also chap. 4.1.2)
[5] Type label on the bottom of the case (see also chap. 14)

4.1.3 Diffustik / Variant PFTstik

4.1.3.1 Height-Adjustable Arm with Flow Measurement / Shutter System Variant Diffustik



Height- adjustable arm

Connection sockets
(see photo below)

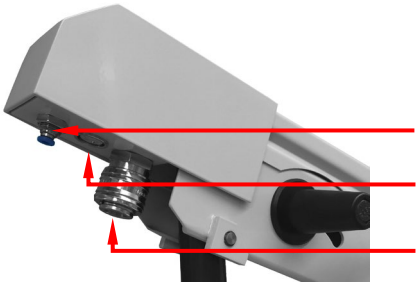
Demand valve
(see also chap. 6.2.3)

Shutter drive with shutter cage
(see also chap. 6.2.2)

Flow unit
(see also chap. 6.2.1)

Connection cable
(see also chap. 6.2.3)

Connection Height- Adjustable Arm PFTstik



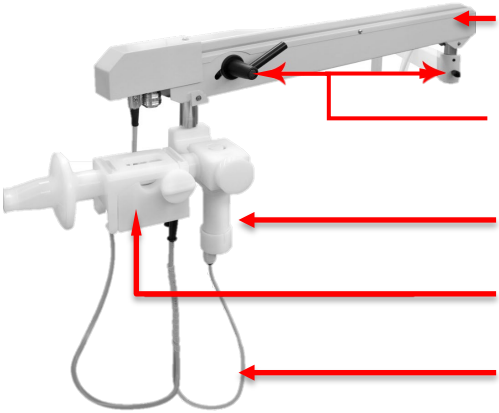
Gas sample
(Connection CO Diffusion)

Flow unit

Gas supply CO Diffusion

4.1.3.2 Height-Adjustable Arm with Flow Measurement / Shutter System Variant PFTstik

From Prod. 11 / 2018



Height-adjustable arm

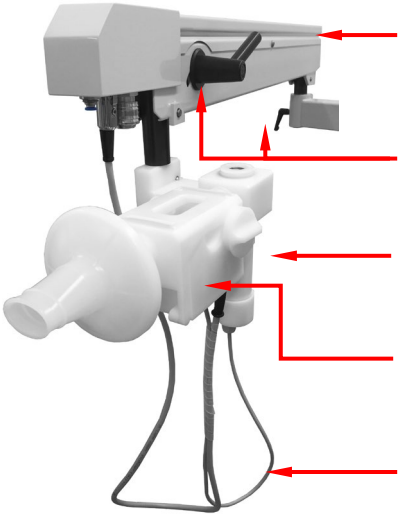
Lever for height regulation and for moving
(see also chap. 7.4)

Shutter drive with shutter block and shutter plug
(see alo chap. 6.2.2)

Flow unit
(see also chap. 6.2.3)

Connecting cable
(see also chap. 4.1.3.4)

To Prod. 11 / 2018



Height-adjustable arm

Lever for height regulation and for moving
(see also chap. 7.4)

Shutter drive with shutter cage
(see also chap. 6.2.2)

Flow unit
(see also chap. 6.2.3)

Connecting cable
(see also chap. 4.1.3.4)

For the Diffustik variant resp. when the "CO Diffusion" option is added to the PFTstik variant, the connection of the relevant components is described in the separate IFU Add-on CO Diffusion.

4.1.3.3 Diffustik Device / Connections

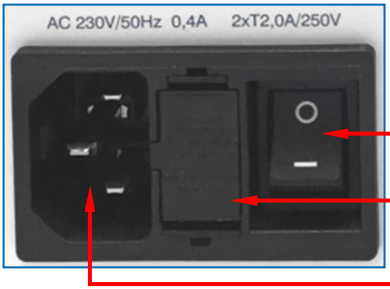
Device front view

LED
to show the power supply

Connections at the rear of the device

USB-Connection

Bus-Connection
for flow electronics



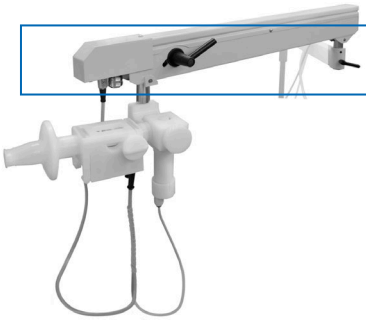
On / Off switch

Fuse

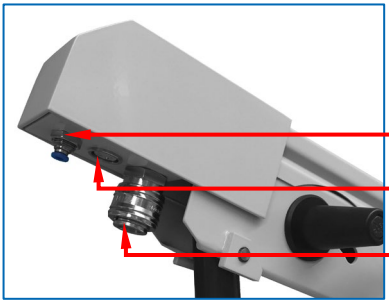
Input AC 230 V

For the Diffustik variant resp. when the "CO Diffusion" option is added to the PFTstik variant, the connection of the relevant components is described in the separate IFU Add-on CO Diffusion.

4.1.3.4 Connection on the Height-Adjustable Arm



Connection sockets on the height-adjustable arm



Gassample
(Connection CO Diffusion)

Flow unit

Gas supply CO Diffusion

For the Diffustik variant resp. when the "CO Diffusion" option is added to the PFTstik variant, the connection of the relevant components is described in the separate IFU Add-on CO Diffusion.

4.1.3.5 Sensors


Attention

Diffustik resp. the variant PFTstik could be damaged
Reason: **Diffustik resp. the variant PFTstik flow sensors are precise and high-resolution components.**
For this**: Ensure the respective functions are preserved!**
Therefore:

- Exactly follow instructions for cleaning, disinfection and calibration!

You will find a detailed description in:

- Chap. 9 "Cleaning and Disinfection".
- The separate IFU Volume Calibration.

Flow Sensor
The heart of the Diffustik resp. the variant PFTstik for precise flow measurement is the Ergoflow flow sensor. It must be calibrated after every cleaning and before the first examination of a day.

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

Mouth Pressure Sensor
A precise and long-term stabile pressure sensor for measuring the mouth pressure is integrated in the flow unit. This can be calibrated with the help of an external manometer.

4.1.3.6 Pressure Reducer (optional with Extension „Diffusion Measurement“)

The CO Diffusion measurement is possible with the Diffustik variant resp. by extending the PFTstik variant with the Add-on CO Diffusion. A suitable pressure reducer for the Diffusion gas bottle is required for safe application.
If you are planning the extension with Diffusion measurement, please note:

DANGER

Danger to life.
Reason: **Poisoning by carbon monoxide (CO) during prolonged exposure.** Therefore:

- Arrange the pressure reducer so that it is easily accessible to enable the gas supply to be quickly interrupted in the event of leakage!

Reason: **damage to the CO Analyzer because of excessive working pressure on the demand valve.** Therefore:

- Only use a pressure reducer that complies with the specifications defined by the manufacturer and provides a fixed outlet pressure of 5 bar!

A suitable pressure reducer has been approved by the manufacturer and is recommended for use. You can receive this from your authorised specialist retail partner.

- See also chap. 2.2.1 "Original Spare Parts / Accessories / Optional Expansions"

Depending on the regulations in the country of use, similar pressure reducers may be considered. The inspection and maintenance intervals specified in the operating instructions of the pressure reducer used must be observed.

For a complete explanation of the diffusion measurement with the Diffustik variant resp. when the "CO Diffusion" option is added to the PFTstik variant, please refer to the separate IFU Add-on CO Diffusion.

4.1.4 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 Diffustik resp. the variant PFTstik.
The system may be set up only by an authorised specialist retail partner.
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".

For the Diffustik variant resp. when the "CO Diffusion" option is added to the PFTstik variant, the connection of the relevant components is described in the separate IFU
Add-on CO Diffusion.

⚠ WARNING

Possible danger to life.
Reason: **Electric shock due to lack of galvanic separation with composition of non-approved components.** Therefore:

- Only use the USB connection cable supplied by the manufacturer as spare parts, which are always part of the medical device!
- The device may only be operated in conjunction with the equipment cart (ergoline ergocar PC) offered by 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 schedule!
- If a maintenance schedule is exceeded, do not continue to use the total system! Request maintenance work from your authorised specialist retail partner!

Reason: **Misdiagnosis caused by measurement error.**
Therefore:

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

Attention

Diffustik resp. the variant PFTstik 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!

4.1.4.1 Equipment Cart with Isolating Transformer

The cart, approved by the manufacturer, meets the requirements of the IEC 60601 series of standards and is mandatory to use.
You will find more detailed information in:

- Chap. 2.2.1 "Original Spare Parts / Accessories / Optional Expansions"
- Respectively consult with your authorised specialist retail partner.

4.1.4.2 Data Connection

The hardware connection between the device and computer is established via an integrated USB interface and USB cable. This is considered to be a spare part approved by the manufacturer and can be obtained from an authorised specialist retail partner (see also chap. 2.2.1.1 "Original Spare Parts / Accessories").

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

Diffustik resp. the variant PFTstik have 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. 3.3 “Operation / Servicing and Maintenance”).

For a detailed description of the option "CO Diffusion“, please refer to the separate IFU:

- Add-on CO Diffusion

4.3 Software

The measurement device (Diffustik resp. the variant PFTstik) 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 about the configuration and use of the software BLUE CHERRY® see:

- The separate IFU BLUE CHERRY®

5 Transport Storage and Assembly

5.1 Transport to the Location of Use

The Diffustik resp. the variant PFTstik is transported secured against damages, in a carton.

The packaging must be kept by the user / operator in case the device must be returned to the authorised distributor or manufacturer.
For further information see:

- Chap. 11 “Decommissioning / Disposal”
- Chap. 15 “Warranty and Service“

The specialist retail partner authorised by the manufacturer is responsible for supplying Diffustik resp. the variant PFTstik to the responsible organisation.

5.2 Storage

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

The responsible organisation of the Diffustik resp. the variant PFTstik is solely in charge of compliance with these requirements.

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

5.3 Assembly

Installation or assembly for the first commissioning of the Diffustik resp. the variant PFTstik may only carried out by qualified personnel of the manufacturer's specialist retail partners.

⚠ WARNING

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

- Prevent improper assembly / installation!
- Diffustik resp. the variant PFTstik should only be assembled and installed by officially trained personnel authorised by the manufacturer!

For further information see:

- Chap. 4.1.4 “System Construction and Electrical Safety” – safe installation

Information on assembly work in connection with the Recommissioning in

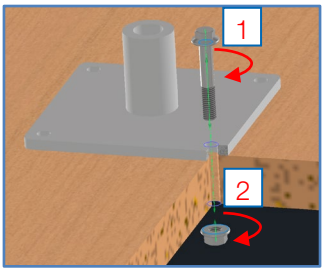
- Chap. 6.2 "Recommissioning after Servicing / Cleaning Work".

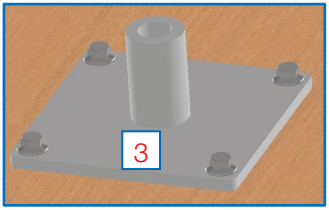
5.3.1 Assembly of the table holding plate

⚠ WARNING

Possible severe physical injury.
Reason: **System can tilt over.** Therefore:

- Ensure sufficient load-bearing capacity of the mounting surface!
- If the static properties of the bearing surface are unclear, it is essential to consult a specialist!
- Use suitable fasteners!
- Check system for tilt resistance after assembly!





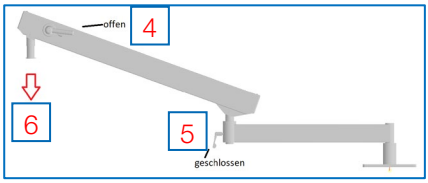
1. **Prepare the sub-construction.**
   For this:

   Drill holes in the statically suitable sub-construction in accordance to the specified holes on the table holding plate.

2. **Mount the table holding plate.**
   For this:

   Fix the table holding plate to the sub-construction **[3]** with four M10 flanged hexagonal bolts of grade 8.8 **[1]** and four M10 flanged hexagonal nuts **[2]**.

No fixing materials are enclosed with the article. The above-mentioned fixing materials are a recommendation.



3. **Perform the tilting test.**
For this:

Mount the height-adjustable arm on the table holding plate and bring it to the maximum deflection. The clamping lever for height adjustment must be open **[4]**. The clamping lever for horizontal adjustment must be closed **[5]**.

Attach a load to the front end of the height-adjustable arm **[6]**. This load must be increased slowly up to max. 18 kg.

6 Operation

For the Diffustik variant resp. when the "CO Diffusion" option is added to the PFTstik variant, the safety instructions in the separate IFU Add-on CO Diffusion also apply:

6.1 Initial Operating

The first commissioning of the Diffustik resp. the variant PFTstik and its recommissioning after maintenance work in accordance with the responsible organisation's obligations (see chap. 8 "Servicing / Maintenance"), which is carried out by qualified personnel of the specialist retail partner, is also only carried out by these qualified personnel.

Diffustik resp. the variant PFTstik is only completely ready to function after calibration and once the initial operation is complete.

6.2 Recommissioning after Servicing / Cleaning Work

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

Servicing work here also includes the necessary checks which are necessary if Diffustik resp. the variant PFTstik should fall down.

Attention

Diffustik resp. the variant PFTstik could be damaged.
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!

⚠ WARNING	Possible danger to life Reason: **Electric shock.** Therefore: • Never obstruct the access to the mains plug or On / Off switch of the equipment cart! Disconnection of the power supply must be easily accessible!

Before the Diffustik resp. the variant PFTstik can be used to perform measurements again, all components must be properly reconnected, the USB connection to the computer must be established, and the Diffustik resp. the variant PFTstik must be connected to the power supply and calibrated. Calibration also fulfils the regulatory requirements for functional testing after maintenance work.

Please proceed as described in the respective chapters.

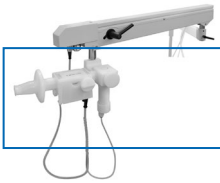
6.2.1 Assembly Flow Measuring System

⚠ CAUTION	Possible physical injury. Reason: **Measurement error due to leakage caused by incorrect assembly of components.** Therefore: • Carefully observe the assembly instructions! Reason: **Height-adjustable arm, device, or complete cart falls over.** Therefore: • Never change pre-assembled height-adjustable arm! • Do not attach any other components to the device! • Do not lean on the height-adjustable arm or hold on to it!

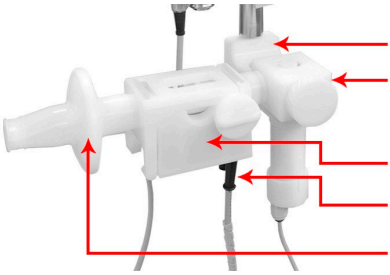
Attention

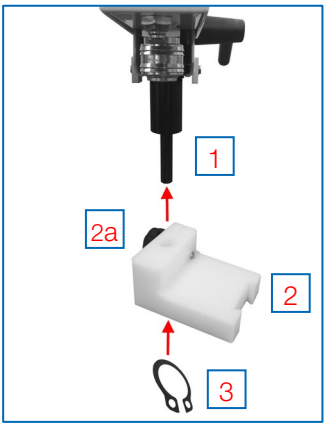
Functional disorders possible.
Reason: **Components and e.g. plug connections can be damaged.** Therefore:

- All connections must be made carefully and without too much force!



Flow measuring system and shutter system on the height-adjustable arm



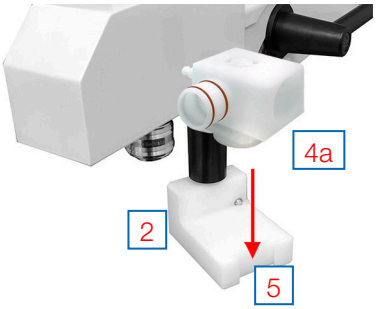


1. **Attach the stand mounting plate [2] to the height-adjustable arm**
   For this:

   Put the mounting plate on the bolts [1] on the height-adjustable arm.

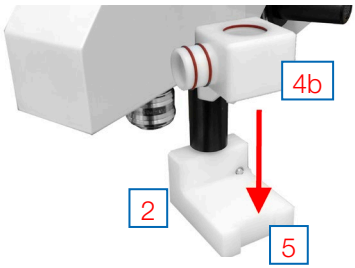
   By turning the rotary knob **[2a]** until the mounting plate remains movable.

   Attach snap ring **[3]** to bolt **[1]**



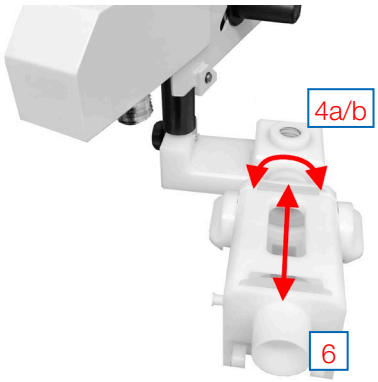
2. a) Connect the shutter block [4a] to the mounting plate from prod. 11/2018
By

pressing in the dovetail of the shutter block into the appropriate groove **[5]** of the mounting plate **[2]**.



b) Connect the shutter block [4a] to the mounting plate until prod. 11 / 2018
By

pressing in the dovetail of the shutter block into the appropriate groove **[5]** of the mounting plate **[2]**.

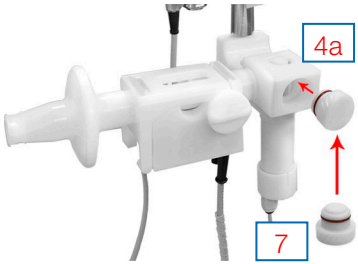


3. Connect the flow unit [6] to the connection socket of the shutter block or shutter head [4a / b]
For this:

Push the flow unit with the fixed side slightly to the stop and simultaneously turn it back and forth.

Turning in both directions has no functional task, but serves only to protect the O-Rings.

4. Connect the connector cable at the bottom of the height-adjustable arm
(see chap. 4.1.3.4 "Connection on the Height-Adjustable Arm")

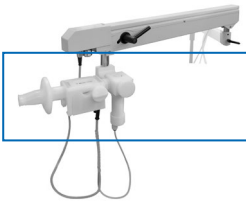


5. **For installation of the PFTstik variant from 11 / 2018:**
   Connect shutter plug **[7]** to shutter block **[4a]**

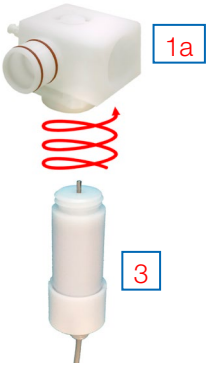
For the Diffustik variant resp. when the "CO Diffusion" option is added to the PFTstik variant, the connection of the relevant components is described in the separate IFU

- Add-on CO Diffusion.

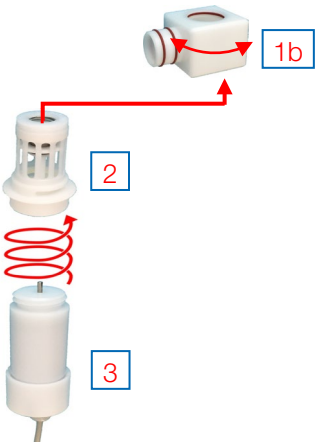
6.2.2 Assembly Shutter System



Shutter system on the height-adjustable arm



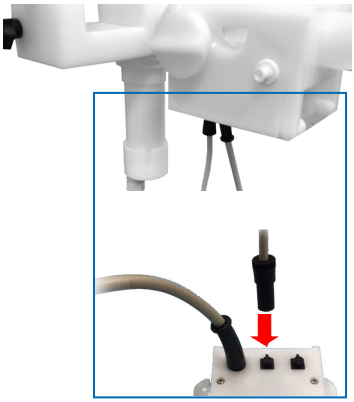
1. **a) from prod. 11 / 2018:**
   Screw shutter drive **[3]** to shutter block **[1a]** until stop



b) until prod. 11 / 2018:
Screw shutter drive **[3]** on the shutter cage **[2]** until stop

Slide the shutter cage into the shutter head [1b]
By

slight rotation (to protect the O-Rings) until stop



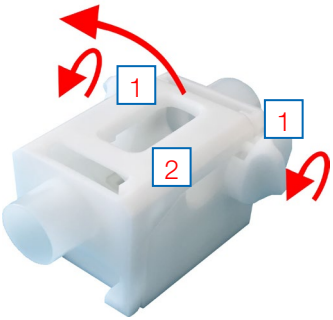
2. **Connect the connector cable of the shutter drive [3]**
with
three-pole socket on the flow unit - central

If possible, observe the sequence of the work steps, because otherwise it is more difficult to assemble!

For the Diffustik variant resp. when the "CO Diffusion" option is added to the PFTstik variant, the connection of the relevant components is described in the separate IFU

- Add-on CO Diffusion.

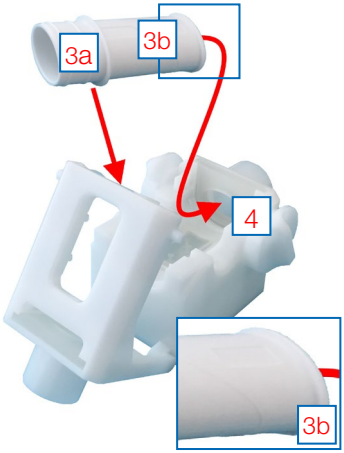
6.2.3 Inserting the Flow Sensor



1. **Open the closing clap [2] on the flow unit**
   For this:

   Turn the closure panel **[1]** on the left and right side
   and

   Open the closure cap **[2]** upwards.



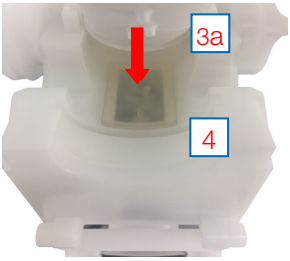
2. **Insert flow sensor [3]**
   For this:

   Carefully press the patient-far side with connection piece **[3b]** into the holder with silicone seal **[4].**

   Press the patient-close side **[3a]** into the receptacle.

3. **Close and lock the closure panel**
   For this:

   Proceed in reverse order as described in point 1.



Attention

Measurement function could be impaired.
Therefore:
Make sure that the sensor pins **[3a]** inserted in the silicone seal **[4]**!

6.2.4 Power Supply and Computer Connection

⚠ WARNING	**Possible danger to life.** Reason: **Electric shock due to lack of galvanic separation with composition of non-approved components.** Therefore: • Only use the USB-Connection Cable supplied by the Manufacturer as spare parts, which are always part of the medical device! • The device may only be operated in conjunction with the equipment cart (ergoline ergocar PC) offered by manufacturer!

To make the Diffustik resp. the variant PFTstik ready for operation, connect it:

1. **USB-connection cable**
   to USB socket of the Diffustik device
   to free USB port of the computer

2. **Power supply cable**
   at socket Input AC 230 V and with power cord to a socket

In addition for Diffustik resp. the variant PFTstik with equipment cart

3. Insert the power cord of the cart into the socket
4. Switch on the cart with On / Off switch
   → **Display “Power Supply“ of the cart lights up**

The Diffustik resp. the variant PFTstik is only ready for operation again after a new calibration. See also:

- Chap. 7.3 ”Calibrating Diffustik / Variant PFTstik“
- Separate IFU Volume Calibration

For the Diffustik variant resp. when the "CO Diffusion" option is added to the PFTstik variant, the connection of the relevant components is described in the separate IFU

- Add-on CO Diffusion.

7 Operating Instructions

For the Diffustik variant resp. when the "CO Diffusion" option is added to the PFTstik variant, the work steps in the separate IFU Add-on CO Diffusion also apply:

7.1 Checking for Worn Parts

The Diffustik resp. the variant PFTstik 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!
- Replace the flow sensor immediately in case of saliva or moisture inside the flow sensor!
- Always follow instructions!
  (see chap. 8 "Servicing / Maintenance" and chap. 9 "Cleaning and Disinfection").

7.2 Switching Diffustik / Variant PFTstik On / Off

Switching off the Diffustik resp. the variant PFTstik can be done by disconnecting the power supply. If an equipment cart is used, it can be switched on / off via the on / off switch of the equipment cart or via the on / off switch of the Diffustik resp. the variant PFTstik. Disconnection from the mains can only be effected by removing the power cable connector of the power supply unit from the socket.
The Diffustik resp. the variant PFTstik is intended for continuous operation and therefore doesn't need be switched on and off daily.

For descriptions of "Recommissioning after Servicing and Cleaning Work" see:

- Chap. 6.2 "Recommissioning after Servicing / Cleaning Work"

7.3 Calibrating Diffustik / Variant PFTstik

There are various processes to be carried out for Diffustik resp. the variant PFTstik in order to calibrate or validate the volume measurement.

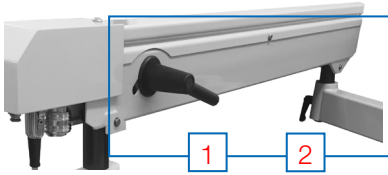
The required intervals can be found in the tables below.

Interval	Calibration
Once per day, and after changing the flow sensor	Volume calibration
Once per week	Flow linearity test
Once per year	Mouth Pressure Calibration

For details on individual calibrations, please read:

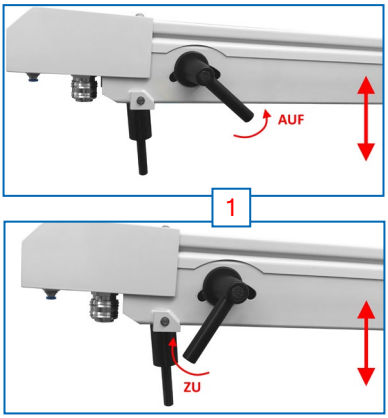
- The separate IFU Calibration

7.4 Setting the Height-Adjustable Arm



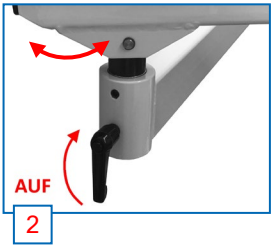
Lever
[1] for height regulation and
[2] to swivel to the side
(horizontal)

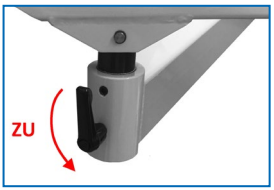
7.4.1 Height Adjustment



1. **Hold the height-adjustable arm**
2. **Move the lever [1] counterclockwise**
   ➢ Locking of the height-adjustable arm is released
3. **Adjust the desired height**
   (continuously variable)
4. **Move the lever [1] clockwise**
   ➢ Height-adjustable arm is locked again
5. **Check secure locking**

7.4.2 Horizontal Adjustment





1. **Move the lever [2] clockwise**
   - ➢ Locking of the height-adjustable arm is released
2. **Swivel the height-adjustable arm into the desired position** (infinitely variable)
3. **Move the lever [2] counterclockwise**
   - ➢ Height-adjustable arm is locked again
4. **Check secure locking**

7.5 Using Diffustik / Variant PFTstik / Performing measurements

Descriptions of the individual examinations can be found in the separate IFUs:

- Spirometry
- Rint
- Respiratory Drive
- CO Diffusion

And for general use of the software:

- BLUE CHERRY®

⚠ WARNING

Possible danger to life.
Reason: **Disregard of a contraindication. Misdiagnosis due to measurement errors.** For this: **Observe 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)!

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

- While using Diffustik resp. the variant PFTstik, 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!

Reason: **Electric shock. Device Damage.** Therefore:

- Do not let any objects fall on the Diffustik resp. the variant PFTstik!
- Do not put any objects on the Diffustik resp. the variant PFTstik!
- Never push foreign objects into the housing!

⚠ WARNING	**Possible danger to life.** Reason: **Electrical 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!
⚠ CAUTION	**Possible physical injury.** Reason: **Height-adjustable arm, Diffustik resp. the variant PFTstik and / or complete equipment cart falls over.** Therefore: • Never change pre-assembled height-adjustable arm! • Do not attach any other components to the device! • Do not lean on the height-adjustable arm or hold on to it! Reason: **Skin burn caused by short-circuit inside the device.** Therefore: • Do not touch shutter drive in case of excessive heat!

Attention	**Diffustik resp. the variant PFTstik could be damaged** Reason: **Penetrating liquid. Uncleanliness.** Therefore: • Do not use any liquids near the Diffustik resp. the variant PFTstik! • Do not expose the Diffustik resp. the variant PFTstik or the entire system to dust or other contamination! Reason: **Condensation.** Therefore: • Do not expose Diffustik resp. the variant PFTstik to excessive temperature fluctuations during operation!

7.6 Exchange of Disposable Products / Disinfection

7.6.1 Bacteria- and Virus Filter / Noseclip

⚠ WARNING

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

- Do not use single use products more than once!
- Dispose of bacteria / virus filter and noseclip after each use!

The bacteria and virus filters provided by the manufacturer are optimally adapted to the measuring systems and, due to the very high filtration rate, offer maximum patient safety while protecting against cross-contamination.
The filters must also be disposed after each examination or patient. The same applies to the noseclip.

For further weekly cleaning and disinfection tasks, please refer to:

- Chap. 9 ”Cleaning and Disinfection”

Information on the disposal of disposable products can be found in:

- Chap. 11.3 "Disposal" / 11.3.3

8 Servicing / Maintenance

For the Diffustik variant resp. when the "CO Diffusion" option is added to the PFTstik variant, the work steps in the separate IFU Add-on CO Diffusion also apply.

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 Diffustik resp. the variant PFTstik 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 Diffustik resp. the variant PFTstik 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).
Once per day	Checking the sealing rubber of the head for tears / wear and replacing the head if necessary (see chap. 8.2.2).
Once per year	Replacing O-rings and sealing rubbers (see chap. 8.2.2).

⚠ 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, cables, connectors, tubings, pneumatic connections, 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 Diffustik resp. the variant PFTstik. 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 / Exchange of Tubes and Cables

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

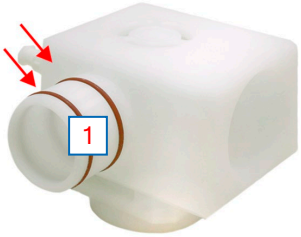
For replacing components see:

- Chap. 4.1.3.3 “Diffustik Device / Connections”
- Chap. 4.1.4 “System Construction and Electrical Safety”
- Chap. 6.2 “Recommissioning after Servicing / Cleaning Work”

8.2.2 Checking / Replacing O-Rings and Sealing Rubbers

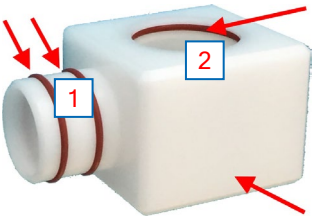
During the daily inspection of the O-rings and sealing rubbers, attention must be paid to mechanical damage or signs of abrasion. If necessary, any affected parts must be replaced. Once a year it must generally be replaced. Proceed as described below:

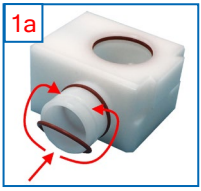
O-Rings Shutter Block

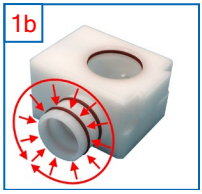


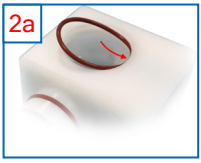
[1a] Insert with a slight rotation
[1b] Press firmly
Identical steps **[1a und 1b]**, see below.

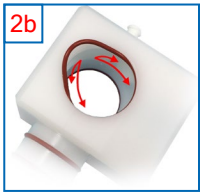
O-Rings Shutter Head

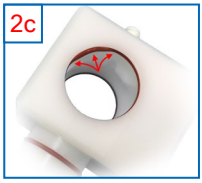


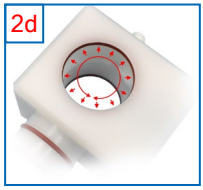










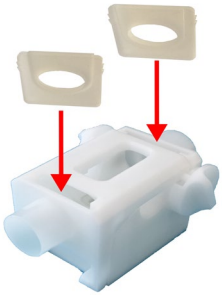


[1a] Insert with a slight rotation
[1b] Press firmly
[2a] Insert one side into the groove
[2b] Slightly screw in
[2c] Press the second side into the groove
[2d] Press all around

To remove the rings, proceed in reverse order.

Attention	**The unit may be damaged.** Therefore: Do not use any pointed / sharp objects for removal!

Sealing Rubber Flow Unit



When ordering new O-Rings and sealing rubbers, please note:

- Chap. 4.1.4 “System Construction and Electrical Safety"
- Chap. 6.2 "Recommissioning after Servicing / Cleaning Work"

9 Cleaning and Disinfection

For the Diffustik variant resp. when the "CO Diffusion" option is added to the PFTstik variant, the work steps in the separate IFU

- Add-on CO Diffusion also apply.

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 Diffustik resp. the variant PFTstik functional and clean.
Cleaning and disinfection may cause discolouration of the components, but without impairing their function.
The following intervals apply:

Component	Interval	Method
Bacteria and virus filter	After each patient	Dispose of!
Noseclip	After each patient	Dispose of!
Flow unit (chap. 9.2.2)	Weekly	Wipe disinfection
Ergoflow (chap. 9.2.3)	Weekly	Cleaning and disinfection bath
Shutter block (chap. 9.2.4.1)	Weekly	Cleaning and disinfection bath
Shutter plug (chap. 9.2.4.1)	Weekly	Cleaning and disinfection bath
Shutter-cage (chap. 9.2.4.1)	Weekly	Cleaning and disinfection bath
Shutter head (chap. 9.2.4)	Weekly	Cleaning and disinfection bath
Shutter-drive (chap. 9.2.4.2)	Weekly	Surface / Wipe disinfection
All other touchable parts	Weekly	Surface / Wipe disinfection

⚠ CAUTION	**Possible physical injury.** Reason: **misinterpretation of obvious measuring errors (drift) caused by liquid in the tubes.** Therefore: • Clean tubes only externally! • Replace dirty tubes!

Attention	**Diffustik resp. the variant PFTstik could be damaged or fail.** Reason: **Penetrating liquid into electrical components.** Therefore: • Disconnect the Diffustik device before cleaning and disinfecting! • (When switching off via the On / Off switch of the equipment cart, shut down the PC completely!) shut down the PC completely before doing so! • Wipe off remaining moisture with a dry cloth! Reason: **Damaged connections**. Therefore: • To disconnect electrical connections, always pull the plug and never the cable!

9.1 Single Use

For instructions on handling bacteria and viruses filter and noseclips, read:

- Chap. 7.6 “Exchange of Disposable Products / Disinfection”

9.2 Disinfection

In spite of the high filtration rate and single use of the bacteria and virus filters, it is necessary to clean and disinfect at least once a week all components which come into contact with the patient respiratory flow. This applies to the flow unit, Ergoflow, shutter cage and shutter head or shutter block.
All parts of the Diffustik resp. the variant PFTstik can be cleaned from dirt with a soft cloth using a cleaning solution / weak soapy water.

All parts of Diffustik resp. variant PFTstik 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

Diffustik resp. the variant PFTstik could be damage.
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 / Auxilary Materials")!
- Follow the instructions on the concentration and dwell time stated by the cleanser and disinfectant manufacturer!
- Do not put the flow unit and the shutter drive in cleaning or disinfection fluid!
  (Both are containing electronic components)
- Do not disassemble the demand valve or put it into disinfection fluid! Only surface disinfection!

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!

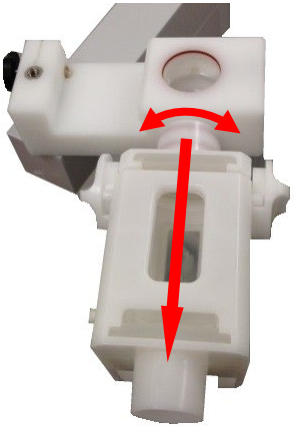
Possible impairment of the measuring function.
Reason**: Moisture in the connection port.** Therefore**:**

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

9.2.1 Height-Adjustable Arm

All parts of the height adjustable arm which come or could come into contact with the patient must be treated with surface disinfection.

9.2.2 Flow Unit



1. **Remove the Ergoflow**
   For this:

   Proceed in reverse order as described in chap. 6.2.1 "Assembly Flow Measuring System".

2. **Perform a wipe disinfection**
   For this:

   Wipe all accessible surfaces with a wet disinfecting cloth.

9.2.3 Ergoflow / Flow Sensor

Attention

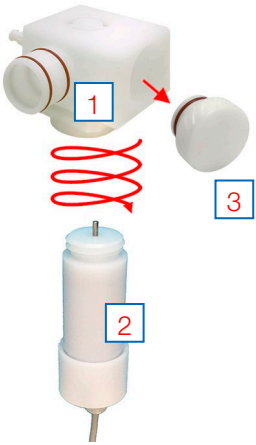
Diffustik resp. the variant PFTstik could be damaged.
Reason: **destruction of the orifice.** Therefore:

- Do not clean the interior of the sensor, mechanical or with hard water jet!
- Do not use any disinfectants which contain high chloride concentrations!

1. **Remove the flow sensor**
   (in reverse order as in chap. 6.2.3. "Inserting the Flow Sensor" described)
2. **Visible contamination wipe off with a soft cloth**
3. **Put the sensor in disinfectant fluid**
4. **Wash the sensor in distilled water thoroughly**
   so that no residual dirt and disinfectants remain
5. **Sensor air-dry until no moisture is visible**

9.2.4 Shutter System

9.2.4.1 Shutter-Cage or Shutter Block



1. **Disassemble the shutter system**
   For this:

   Procced in reverse order as described in chap. 6.2.2 ”Assembly Shutter System“

2. **a) Until product. 11 / 2018: disconnect the shutter block [1] from the shutter drive [2] by turning it counterclockwise.**
   Also separate the shutter block **[1]** from the shutter plug **[3]** by screwing and pulling it out.
   b) Until product. 11 / 2018: disconnect the shutter cage [4] from the shutter drive [2]
   by turning it counterclockwise.

3. **Remove visible dirt with a soft cloth**

4. **Put the components [1] + [3] or [4] + [5] in disinfectant fluid.**

5. **Wash the components [1] + [3] or [4] + [5] thoroughly in distilled water** so that no residues of contamination and disinfectants remain.

6. **Components [1] + [3] or [4] + [5] air dry until no more moisture is visible**

9.2.4.2 Shutter-Drive

Perform a wipe disinfection
For this:

Wipe the surface with a wet disinfecting cloth.

10 Fault Indication and Repair

For the Diffustik variant resp. when the "CO Diffusion" option is added to the PFTstik variant, the notes in the separate IFU

- Add-on CO Diffusion also apply.

Simple errors which occur when using Diffustik resp. the variant PFTstik 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 organisation alone is liable for any resulting injuries to persons and / or damages to Diffustik resp. the variant PFTstik!

Error	Rectification
The Device is not recognised by the PC	Checking the power supply - cable OK and connected?
	Checking the USB connection - cable OK and connected?
Error message: "Flow: No flow-electronics detected"	Checking the connection between flow unit and height-adjustable arm (see chap. 4.1.3.3)
Error message: "Pm: No mouth-pressure-sensor detected".	Checking the connection between flow unit and height-adjustable arm (see chap. 4.1.3.3)
Error message: "Flow out of the valid range" or "PM out of the valid range".	Checking the position of the Ergoflow in the flow unit (see chap. 6.2.1)
	Checking the connection of the flow unit and the height-adjustable arm (see chap. 4.1.3.3)
	System restart – Computer and Diffustik resp. the variant PFTstik (see chap. 6.2)
Obvious measuring error	Checking the last calibration date and recalibrate if necessary (see chap. 7.3)

11 Decommissioning / Disposal

11.1 Expected Service Life

The expected service life of Diffustik resp. the variant PFTstik 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 Decommissioning

To decommission the Diffustik resp. the variant PFTstik, 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 Diffustik / Variant PFTstik

Diffustik resp. the variant PFTstik 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 the Diffustik device 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 Diffustik resp. the variant PFTstik 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 trough the 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 personal protective equipment (PPE)!

12 Technical Specifications

12.1 Technical Data

For the Diffustik variant resp. when the "CO Diffusion" option is added to the PFTstik variant, the technical specifications described in the separate IFU

- Add-on CO Diffusion also apply.

Medical device:	Class IIa (in accordance with MDD 93 / 42 Council Directive of 14 / 6 / 1993 annex IX)
Dimensions:	(L) 210 mm x (W) 175 mm x (H) 75 mm
Weight:	1120 g
Electrical data:	
Protection class Diffustik device:	II
Protection type:	
Diffustik device:	IP40 (IEC 529)
Height-Adjustable Arm:	IP20
Flow Unit:	IP20
Shutter-System:	IP20
Applied part:	BF (according to DIN EN 60601-1)
PC interface:	USB 2.0
Power supply:	100 – 240 V/50 – 60 Hz
Power consumption:	approx 25 VA
Required protection:	2 x T2.0A / 250V
EMC:	Group 1 / Class B
Noise emission:	< 80 dB(A)
Surface temperature:	
Normal operation:	< 48 °C
First error:	< 65 °C

Flow measurement:

Flow sensor:	Ergoflow
Measuring principle:	Differential pressure
Measuring range:	±16 l/s
Ventilation measuring range:	0 – 300 l/min
Flow resistance:	< 0.12 kPa / (l/s) < 14 l/s
Dead space:	< 32 ml
Flow resolution:	15 Bit
Sample rate:	125 Hz
Accuracy:	±3 % or 50 ml/s

Volume:

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

Mouth pressure:

Measuring principle:	Semiconductor
Measuring range:	±25 kPa
Accuracy:	±0.25 % FSS
Flow resolution:	15 Bit

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 Diffustik resp. the variant PFTstik guaranteed by the manufacturer and for the safety of the patient and user / operator.

Storage / Transport:	min.	max.	
Temperature:	-10 °C	+50 °C	
Relative air humidity:	10 %	95 %	non-condensing
Atmospheric pressure:	700 hPa	1100 hPa	

Operation:	min.	max.	
Environmental temperature:	+10 °C	+35 °C	Avoid extreme fluctuations in temperature!
Relative air humidity:	20 %	95 %	non-condensing
	(at least. 30 % for synthetic flooring)		
Atmospheric pressure:	700 hPa	1100 hPa	

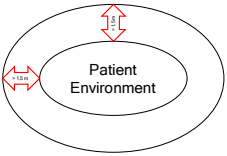
Setup:	mobile
Space requirement: (complete with medical cart)	(L) 900 mm x (W) 900 mm x (H) 1900 mm
Required floor load capacity:	150 kg/m^2
Flooring:	stable; even; conductive
Environment / room:	Closed, clinical area
	air-conditioned
	not an explosive or flammable environment!
	not near an MRI!
	well ventilated

Operating Mode:	Continuous operation

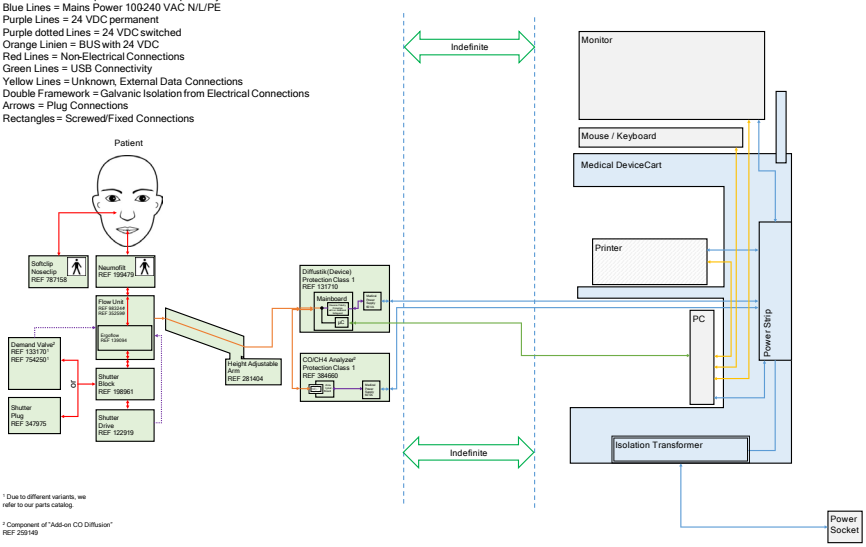
12.3 Electrical Safety Concept

12.3.1 Variant Diffustik with Medical Device Cart and Isolation Transformer

- Internal Medical Power Supply in Diffustik (Device) (Protection Class 1)
- Internal Medical Power Supply in Analysator (Protection Class 1)
- Communication with PC 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 Devicesrespectively Medical Devices
Blue Lines = Mains Power 100240 VAC N/L/PE
Purple Lines = 24 VDC permanent
Purple dotted Lines = 24 VDC switched
Orange Linien = BUS with 24 VDC
Red Lines = Non-Electrical Connections
Green Lines = USB Connectivity
Yellow Lines = Unknown, External Data Connections
Double Framework = Galvanic Isolation from Electrical Connections
Arrows = Plug Connections
Rectangles = Screwed/Fixed Connections

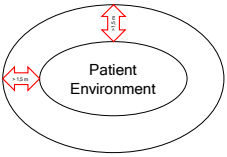


¹ Due to different variants, we refer to our parts catalog.

² Component of "Add-on CO Diffusion" REF 259149

12.3.2 Variant PFTstik with Medical Device Cart and Isolation Transformer

- Internal Medical Power Supply in PFTstik (Protection Class 1)
- Internal Medical Power Supply in Analysator (Protection Class 1)
- Communication with PC via USB Interface
- With Isolation Transformer via Medical Device Cart



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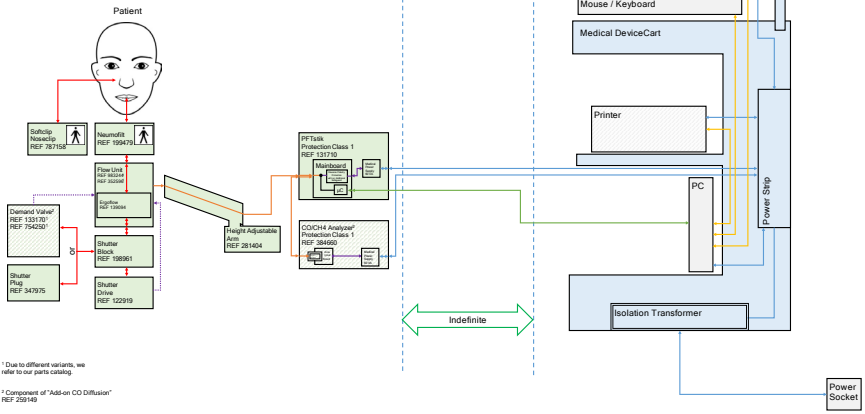


¹ Due to different variants, we refer to our parts catalog.

² Component of "Add-on CO Diffusion" REF 259149

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 **Diffustik** is determined for operation in an electromagnetic environment as specified below. The user / operator of the **Diffustik** should ensure that it is operated in this environment.		
Measurement of electromagnetic emissions	Compliance	Electromagnetic environment – Guideline
RF emissions CISPR 11	Group 1	The **Diffustik** 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 **Diffustik** 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	Class A	
Emissions of voltage fluctuations / flicker according to IEC 61000-3-3	Compliance	

12.4.2 Interference Resistance for all ME Systems Guideline and Manufacturer Declaration

Guidelines and manufacturer's declaration – electromagnetic interference immunity			
The **Diffustik** is determined for operation in an electromagnetic environment as specified below. The user / operator of the **Diffustik** 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 %.
Fast transient electrical disturbances, bursts according to IEC 61000-4-4	±2 kV for power cables ±1 kV for input and output lines	±2 kV for power cables ±1 kV for input and output lines	The quality of the supply voltage should be appropriate for a typical business- or hospital environment
Surges according to IEC 61000-4-5	±1 kV Voltage outer conductor - outer conductor ±2 kV Voltage outer conductor end	±1 kV Voltage outer conductor - outer conductor ±2 kV Voltage outer conductor end	The quality of the supply voltage should be appropriate for a typical business or hospital environment
Voltage dips, short interruptions and supply voltage fluctuations according to IEC 61000-4-11	0% U_T, ½ Period at 0, 45, 90, 135, 180, 225, 270, 315 Degree	0% U_T, ½ Period at 0, 45, 90, 135, 180, 225, 270, 315 Degree	The quality of the supply voltage should be appropriate for a typical business or hospital environment. If the user of the **Diffustik** requires continued operation even during power interruptions, it is recommended that the **Diffustik** be powered from an uninterruptible power supply or a battery.
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 **Diffustik** is determined for operation in an electromagnetic environment as specified below. The user / operator of the **Diffustik** 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 **Diffustik** as the recommended safety distance calculated according to the equation applicable to the transmission frequency.
			Recommended safety distance:
Conducted HF-distrubance variable IEC 61000-4-6	3 V Effective value 150 kHz to 80 MHz	U_1= 3 V	$d = \left[\frac{3.5}{U_1}\right]\sqrt{P}$
	6 V Effective value **ISM-frequency bands:** 6.765 MHz to 6.795 MHz 13.553 MHz to 13.567 MHz 26.957 MHz to 27.283 MHz 40.66 MHz to 40.70 MHz **Amateur Radio frequency bands:** 1.8 MHz to 2.0 MHz 3.5 MHz to 4.0 MHz 5.3 MHz to 5.4 MHz	U_2= 6 V	$d = \left[\frac{6}{U_2}\right]\sqrt{P}$

	7 MHz to 3 MHz 10.1 MHz to 10.15 MHz 14 MHz to 14.2 MHz 18.07 MHz to 18.17 MHz 21.0 MHz to 21.4 MHz 24.89 MHz to 24.99 MHz 28.0 MHz to 29.7 MHz 50 MHz to 54.0 MHz		
Radiated HF-distrubance according to IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	E_1= 3 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 **Diffustik** is used exceeds the abovementioned compliance levels, the **Diffustik** 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 **Diffustik**.
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 Diffustik

The **Diffustik** is determined for operation in an electromagnetic environment in which the RF disturbances are controlled. The user / operator of the **Diffustik** may help to avoid electromagnetic interference by keeping the minimum distance between portable and mobile RF telecommunication devices (transmitters) and the **Diffustik**, 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 2.7 GHz
	$d = 1.17\sqrt{P}$	$d = 1.17\sqrt{P}$	$d = 2.33\sqrt{P}$
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).

Diffustik resp. the variant PFTstik 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.

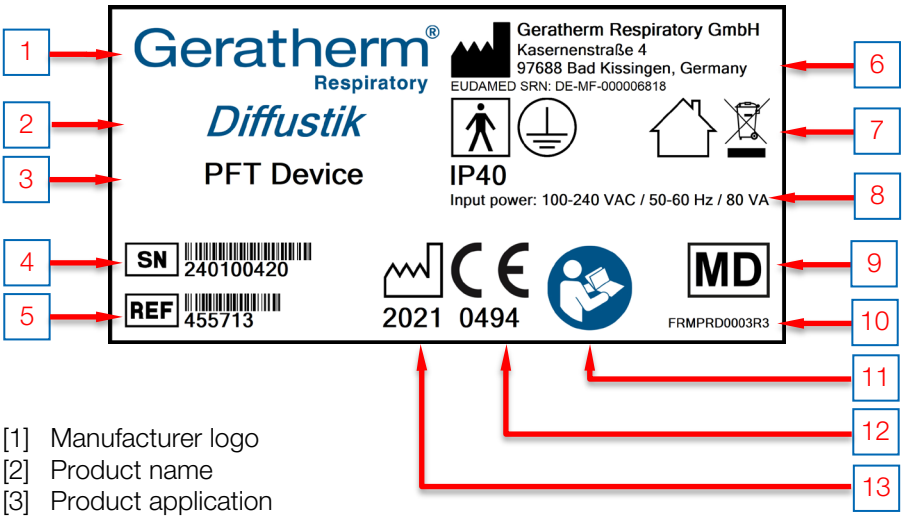
14 Product Labeling / Type Label

The Type Label can be found on the bottom of the Diffustik device housing. See:

- Chap. 4.1.1 “Overview” point **[6]**.

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] For symbol descriptions see chap 1.3 "Symbols".
[8] Power input
[9] Medical Device
[10] Type label revision indication
[11] Follow the IFU
[12] Conformity mark in accordance with the Medical Device Directive 93 / 42 / EEC with identification of the involved notified body
[13] Date of manufacture

Safety symbols have been applied to the Diffustik device 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 Diffustik resp. the variant PFTstik declaration of conformity is enclosed with each device by the manufacturer.