ENG

Instructions for use

Patients

RESPIFIT S

Inspiratory Muscle Training Device

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Sales

eumedics

Manufacturer

BIEGLER MEDIZINELEKTRONIK

IMPORTANT

These instructions for use are essential for operating the device. They must be kept in a suitable place near the device, and should be kept with the device. If the device is transferred to another user, the instructions for use must be supplied with it.

For proper and safe operation and use of this device, it is essential that the instructions for use, including safety instructions and warnings, are read and complied with prior to commissioning. It is the user's responsibility to fully familiarise themselves with how to operate the device correctly.

Target group:

These instructions for use are aimed at patients who use the RESPIFIT S.

More information on the settings and functions is available for clinical users such as physiotherapists, care staff and doctors in the RESPIFIT S (clinic) instructions for use.

Table of Contents

1 DESCRIPTION

1.1 General Description

The RESPIFIT S is a portable device for inspiratory muscle training.

The device is designed for the following indications: Patients with chronic obstructive pulmonary disease and lung emphysema; for pre- and post-operative respiratory therapy in association with pulmonary rehabilitation and for patients with neuromuscular diseases involving the respiratory muscles at an early stage of the disease.

The RESPIFIT S can be used to set up training programmes to increase both strength and endurance of the respiratory muscles. Integrated functions can also determine the capacity of the inspiratory muscles, i.e. the strength and endurance of this muscle group.

An essential component of the device is the graphical representation of the exercise sequence, which shows the patient whether he/she is actually complying with the required training intensity

The patient’s individual exercise and configuration data is stored on the removable datakey.

The interchangeable handheld patient module offers the ultimate in hygiene and safety.

1.2 Intended Use

The RESPIFIT S is designed for personal training to increase the strength and endurance of the inspiratory respiratory muscles in patients from the age of 10 years.

1.3 Indication

Chronic obstructive pulmonary diseases (COPD)

- For COPD stage GOLD II – IV as a measure that is ancillary to established medicinal therapy and rehabilitation procedures.

Neuromuscular diseases

- Slowly progressive course
- Inspiratory vital capacity > 25% of the reference value
- $paCO_2$ (Carbon dioxide partial pressure in the blood) < 45 mmHg

Other disease patterns involving respiratory muscle weakness, such as

- Cystic fibrosis
- Kyphoscoliosis or diaphragm dysfunction
- Pre- and post-operatively in thoracic procedures
- Chronic heart failure

1.4 Contraindications

- Any acute disease
- Any acute change in condition, also as part of a chronic underlying condition
- Any chronic underlying condition that is not sufficiently controlled with treatment, e.g. arterial hypertension or diabetes

1.5 Scope of delivery

Number	Description	Catalogue number
1	RESPIFIT S device	LR1003004 from SN: 402005
1	RESPIFIT S instructions for use clinic and patient	FK1003008 FK1003009
1	Handheld patient module	IB1002001
1	Datakey	AG6110050
1	Power supply unit Mean Well Type GEM06I05	CJ1003004

1.6 Accessories

Description	Catalogue number
Handheld patient module	IB1002001
Datakey	AG6110050
Power supply unit Mean Well Type GEM06I05	CJ1003004

2 GENERAL SAFETY INSTRUCTIONS

- RESPIFIT S may only be used under the direction of the treating physician / therapist.
- RESPIFIT S (mouthpiece of the handheld patient module) may only be used if the mucous membrane is intact.
- If the patient feels dizzy or unwell during the training session, the exercise must be stopped and a doctor / therapist must be consulted.
- Unplugging the mains plug is the only safe way to disconnect from the mains power supply. Only plug the power supply unit into sockets that are easily accessible, so they can be disconnected quickly if necessary.
- The power supply unit must not be brought into contact with any liquids.
- It is prohibited to use the RESPIFIT S in extension cable connectors.
- The power supply unit must not be covered while in operation and must not be operated in immediate proximity to any heater or in direct sunlight.
- The device must not be used in dusty environments. Fluff and dust may impair the function of the device.
- The device must be kept away from pests and pets.
- Keep Respifit S out of the reach of children.
- Caution: Risk of strangulation when handling the tube!
- RESPIFIT S must not be used in rooms with potential explosion hazard.

- RESPIFIT S may only be used in areas in which the electrical installations comply with the standards and regulations in force.
- This device is subject to specific preventive measures with regard to electromagnetic compatibility (EMC) and must therefore be set up and commissioned in accordance with the EMC instructions contained in Section 12 of these instructions for use. Portable and mobile HF communications equipment can affect medical electrical devices. As specified in Table 6 of IEC 60601-1-2 for medical electrical equipment, a typical mobile phone with a maximum output of 2 W results in a distance d = 3.3 m for an immunity level of 3 V/m.
- The device may be impaired by other devices set up in the vicinity, or may impair these devices.
- All extraneous influences such as radiation or high temperatures must be kept to a minimum
- Only persons and service centres authorised by Biegler may carry out repairs and modifications to the RESPIFIT S.
- RESPIFIT S and its accessories must not be sterilised with steam or by thermochemical methods and must not be immersed in liquid. The handheld patient module may be immersed in liquid when being cleaned as described in Section 5.
- It is absolutely essential that the periodic technical safety inspections (see Section 6.2) are carried out and that the relevant inspection date is documented.
- Only use original Biegler consumables in conjunction with the RESPIFIT S.
- Only use original Biegler accessories in conjunction with the RESPIFIT S. Power supply unit MEAN WELL Type GEM06I05, handheld patient module, datakey.
- The connector and the patient must not be touched simultaneously.
- The handheld patient module must only be used **repeatedly** by a **single** patient.
- If, as a result of repeated cleaning processes, the handheld patient module shows signs of functional defects or if the finite operating life for "single patient use" is exceeded, then the module must no longer be used and must be replaced with a new handheld patient module.
- If the datakey is pulled out during operation, this may result in device (menu) or datakey defects.

- If the device is plugged in without the datakey inserted, the display indicates “DATAKEY ⊗ “
- Measurements using RESPIFIT S serve only as a basis for training settings and do not constitute a complete determination of pulmonary function. For diagnosis and monitoring, measurements must be carried out by the treating physician / therapist, independently of the RESPIFIT S.
- If the device is dropped, damaged due to force, or functions in a way other than described in the instructions for use, stop using the device immediately and return it to the service centre.

3 INITIAL OPERATION AND USE

Consult the instructions for use! Users must thoroughly familiarise themselves with the contents of these instructions before putting the system in operation.

RESPIFIT S may only be used under the direction of the treating physician / therapist.

Remove the device from the packaging and wait until the device has reached room temperature.

If the temperature is in the lower or upper range of the storage temperature, this process takes no more than 15 minutes.

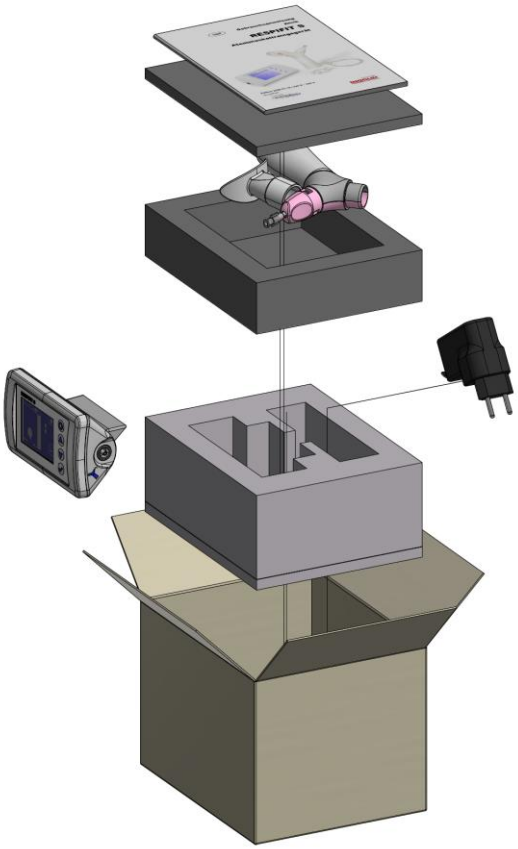

Figure 1: RESPIFIT S in packaging

3.1 Handheld patient module

The handheld patient module must only be used **repeatedly** by a **single** patient (refer to cleaning instructions in Section 6).

Important: The maximum service life of the handheld patient module is three months. The handheld patient module therefore has to be disposed of after no more than three months and a new patient module used.

To calculate the resistance RES, three different aperture diameters are available to the treating physician / therapist: A, B or C.

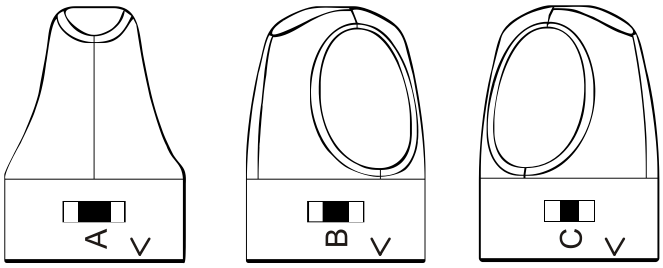

Figure 2: Resistance RES in the aperture diameters A, B or C

Once the appropriate aperture has been selected, the adjustment mechanism is pushed down and locked and is therefore inaccessible to the patient. Thereafter the adjustment mechanism can no longer be released.

When purchasing a new handheld patient module, please ensure that the treating physician / therapist makes the patient-specific adjustments once again and subsequently locks the adjustment mechanism.

Moreover, for each aperture you can select strength exercise or endurance exercise by rotating.

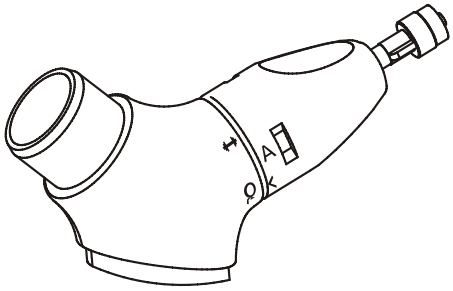

Figure 3: Strength / endurance exercise setting

Assembling the handheld patient module

The handheld patient module must be assembled before starting therapy. The mouthpiece and tube must be attached in accordance with the figure below.

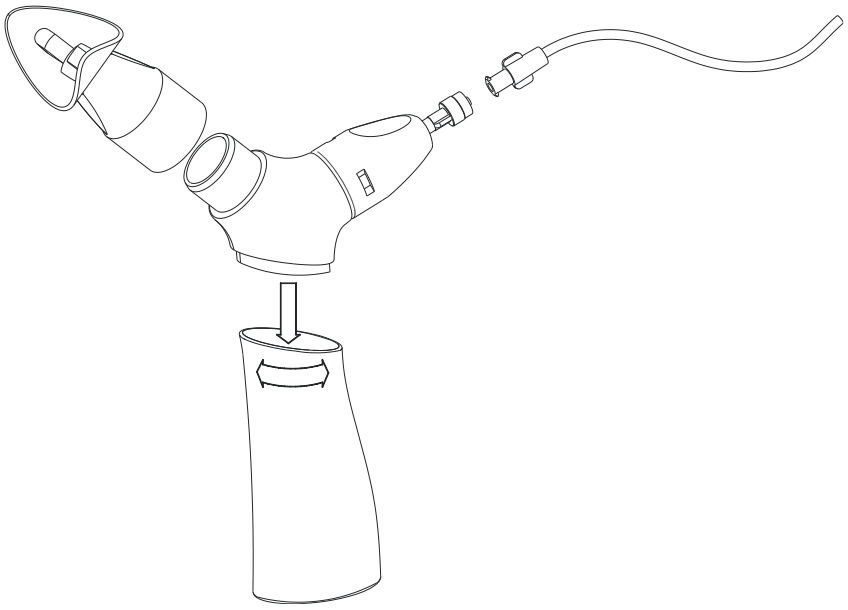

Figure 4: Connecting the handheld patient module

3.2 Datakey

Before the patient starts therapy with the RESPIFIT S, the patient-specific settings must be determined under the direction of the treating physician / therapist and stored on the datakey.

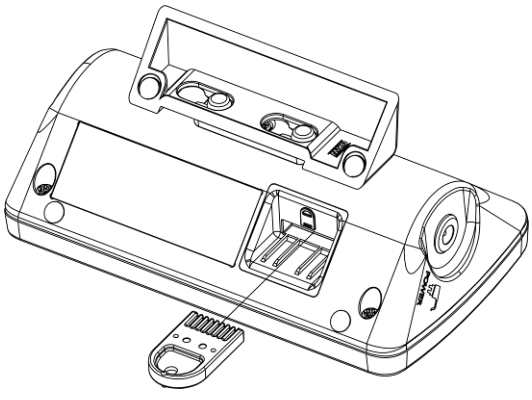

Figure 5: Insert the datakey into the back of the device

Insert the datakey into the device at the position indicated.

If the device is plugged in without the datakey inserted, “DATAKEY ⊗ “ appears on the screen.

3.3 Connecting the device and accessories

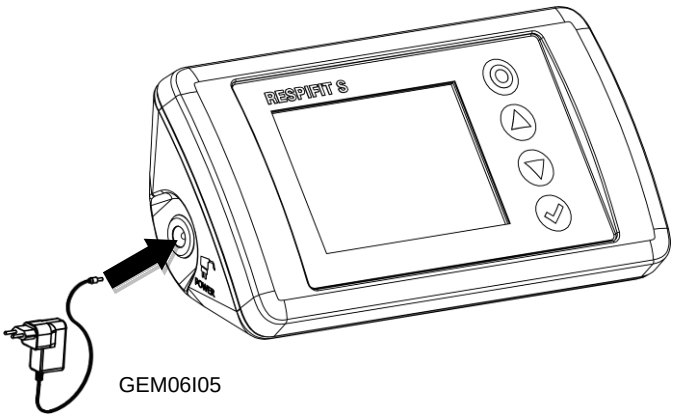

Figure 6: Connecting the power supply unit to the device

Insert the connector plug of the connection cable into the labelled socket of the device and connect the power supply unit to the mains power.

Connect the connection tube to the handheld patient module and the device with Luer connectors.

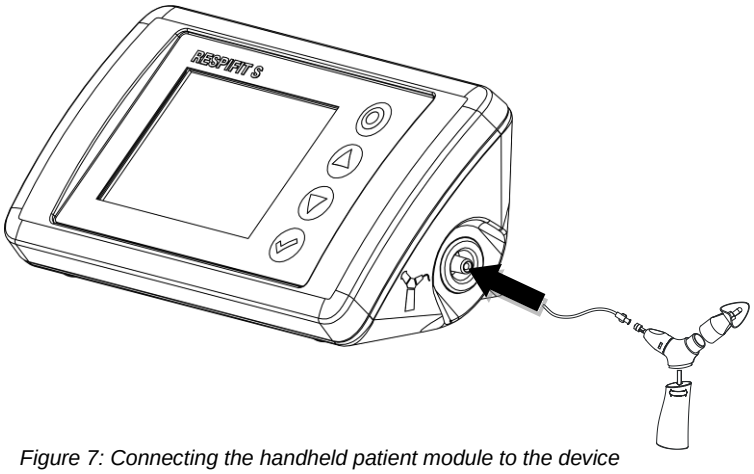

Figure 7: Connecting the handheld patient module to the device

Figure 8: Patient module in use

3.4 Setting up before training

Before training, the treating physician / therapist adjusts the device one single time to the needs of the patient.

As training advances, the treating physician / therapist can make ongoing adjustments.

4 TRAINING WITH THE RESPIFIT S

IMPORTANT

RESPIFIT S may only be used under the direction of the treating physician / therapist.

Prior to training, commission the device and accessories as described in Section 3.

Figure 9: Welcome screen

After switching on the device (plugging in the mains plug) with the datakey inserted, a **welcome screen** appears. The name of the patient stored on the datakey is displayed.

Briefly press the ▼ button to access the **training mode**.

4.1 The strength exercise

Important: A nose clip must be used for carrying out the exercises set out below. Breathe freely without the handheld patient module between individual exercises to ensure sufficient tidal breathing.

Each individual strength exercise consists of an inspiratory manoeuvre against near-maximum resistance. The respiratory muscles, in particular the diaphragm, are under maximum strain. In the strength exercise, the cross-section of the air duct is reduced to such an extent that only a minimum volume of air can be aspirated.

Each inspiratory manoeuvre will start from a state of maximum exhalation (residual volume). During inhalation, the dumbbell, the icon for the strength exercise, is raised in accordance with the negative pressure achieved. In order for an exercise to be successfully completed, the dumbbell must be held above the preset minimum strength value for one second.

One strength training (exercise block) consists of up to 20 individual exercises. The doctor / therapist determines how many individual exercises should be included in an exercise block. Once all individual exercises have been successfully completed, the exercise block is closed and stored on the datakey as a successful training session.

For each exercise block, a defined number of failed attempts may be permitted. It is deemed to be a failed attempt if the preset minimum

strength value is not achieved at all or not achieved in one breath (coughing, etc). It is also deemed to be a failed attempt if the dumbbell is not held above the preset minimum strength value for one full second. If there are more defective breaths than are permitted, the exercise block is closed and stored on the datakey as a failed training session.

There must be a pause between the individual exercises, for recovery. A minimum pause time of between 1 and 30 seconds is stipulated. The device is subsequently ready for the next individual exercise.

For the strength exercise, the following parameters must be set in advance by the treating physician / therapist:

- Minimum strength value
- Number of strength exercises (per exercise block)
- Number of failed attempts (per exercise block)
- Pause time (between the individual exercises)

Before starting the exercises, the arrow on the handheld patient module must point towards the dumbbell icon (as shown on the screen).

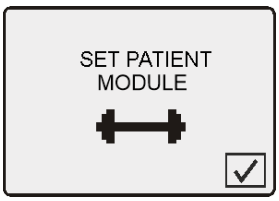

Figure 10: Strength training screen display

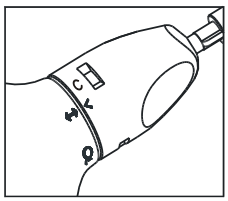

Figure 11: The arrow on the handheld patient module points towards the dumbbell

Press the ✔ button to access the training screen for the strength exercise.

The **training screen for the strength exercise** is structured as follows:

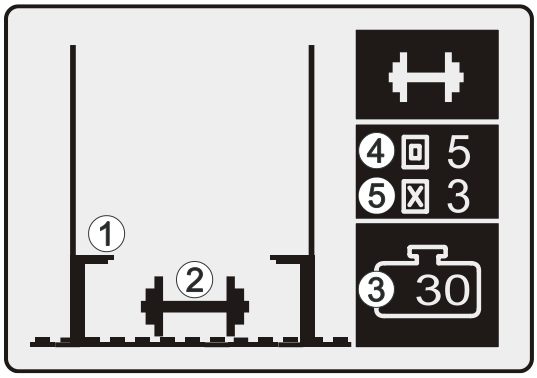

Figure 12: Strength exercise training screen

① The strength bar shows how high the dumbbell must be lifted for each exercise. The dumbbell must be held above the preset minimum strength value for one second.

② The dumbbell is raised when inhaling, in accordance with the pressure reached.

③ The set minimum strength value, which must be attained for each exercise, is displayed as a numerical value within the weight. During inhalation, the current actual pressure attained is displayed.

④ The number of individual exercises is displayed next to the "exercise" icon. This number goes down with each successfully completed individual exercise.

⑤ The number of failed attempts that are permitted for each exercise block is displayed next to the "failed attempt" icon. This number goes down with each failed attempt.

After each individual exercise, a separate screen indicates whether the exercise has been carried out correctly or not. A smiling face is displayed if the exercise was successful and a sad face is displayed after a failed attempt. An hourglass shows how long the patient should pause between two exercises.

Figure 13: Exercise successful

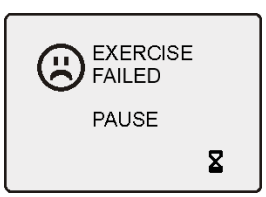

Figure 14: Exercise failed

The strength training is concluded either once the required number of individual exercises has been completed or the number of permitted failed attempts has been exceeded.

A separate screen indicates whether the training (exercise block) has been successfully completed or not.

Figure 15: Training successful

Figure 16: Training failed

Unplug the power supply unit to shut down the device.

If both strength training and endurance training have been set up by the treating physician / therapist, press the ✔ button to access the endurance training.

4.2 The endurance exercise

Important: A nose clip must be used for carrying out the exercises set out below. Breathe freely without the handheld patient module between individual exercises to ensure sufficient tidal breathing.

For the endurance exercise, inhalation is carried out against a pre-established resistance. The cross-section of the air duct is reduced by the set aperture (A, B or C).

Inhaling and exhaling through the handheld patient module at normal breathing rate (tidal breathing frequency) moves the balloon up and down on the screen. The balloon moves up with each inhalation and drops back during exhalation. The exercise is deemed to have been successfully completed if the balloon does not touch either the floor or the sky during the one-minute exercise duration. The exercise starts as soon as the first breath is taken.

One endurance training session (exercise block) consists of up to 20 individual exercises. A defined number of failed attempts may be permitted per exercise block.

There must be a pause between the individual exercises, for recovery. A minimum pause time of between 1 and 20 seconds is stipulated. The device is subsequently ready for the next individual exercise.

For the endurance exercise, the following parameters must be set in advance by the treating physician / therapist:

- Number of endurance exercises (per exercise block)
- Number of failed attempts (per exercise block)
- Pause time (between the individual exercises)
- Minute volume
- Handheld patient module settings

Before starting the exercises, the arrow on the handheld patient module must point towards the balloon icon (as shown on the screen).

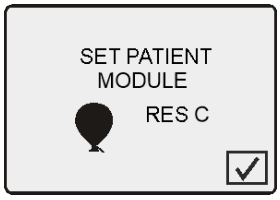

Figure 17: Endurance training screen display

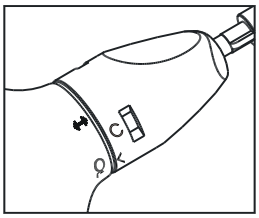

Figure 18: The arrow on the handheld patient module points towards the balloon

Press the ✔ button to access the training screen for the endurance exercise.

The **training screen for the endurance exercise** is structured as follows:

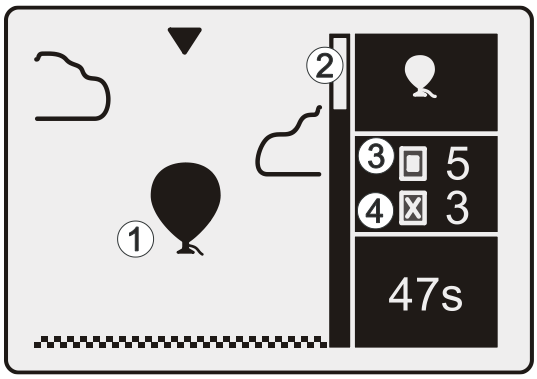

Figure 19: Endurance exercise training screen

① The balloon rises and falls while breathing. The patient's task is now to move the balloon up and down by inhaling and exhaling at tidal breathing frequency, making use of the full screen height. The sky

and the ground, depicted symbolically on the screen, represent the boundaries within which the balloon must be moved.

② During the exercise, the seconds indicator continuously counts down from 60 seconds and the time bar diminishes accordingly.

③ The number of individual exercises is displayed next to the "exercise" icon. This number goes down with each successfully completed individual exercise.

④ The number of failed attempts that are permitted for each exercise block is displayed next to the "failed attempt" icon. This number goes down with each failed attempt.

After each individual exercise, a separate screen indicates whether the exercise has been carried out correctly or not. A smiling face is displayed if the exercise was successful and a sad face is displayed after a failed attempt. An hourglass shows how long the patient should pause between two exercises.

Figure 20: Exercise successful

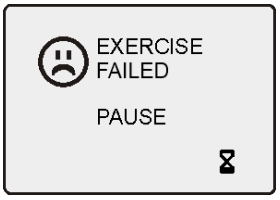

Figure 21: Exercise failed

The endurance training is concluded either once the required number of individual exercises has been completed or the number of permitted failed attempts has been exceeded.

A separate screen indicates whether the training (exercise block) has been successfully completed or not.

Figure 22: Training successful

Figure 23: Training failed

Press the ✔ button to go back to the **welcome screen**.

4.3 Results display

The results of the exercises can be displayed by pressing ○ on the start screen.

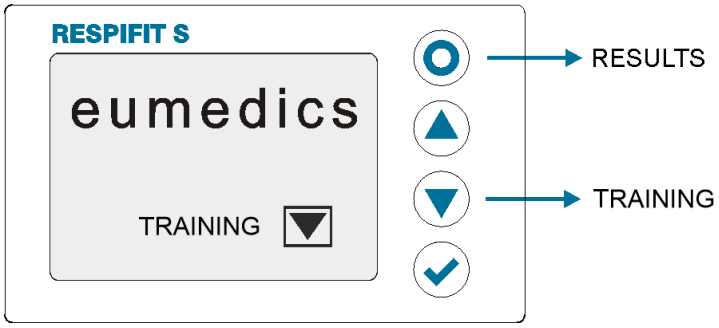

Figure 24: Results selection on the device

The results of the exercises performed are displayed along with any stops during the training session.

The settings made by the treating physician / therapist are also shown in the display, under “INFO”.

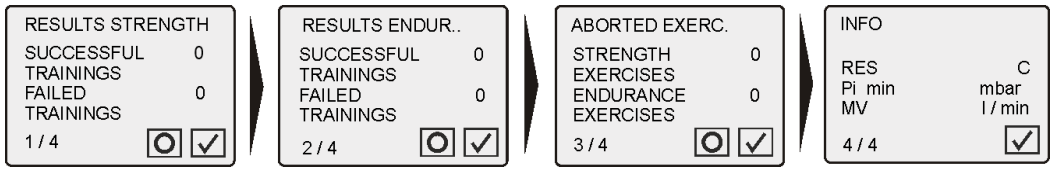

Figure 25: Display order of results

The next display is opened by pressing the ✔ button.

4.4 Decommissioning

Unplug the power supply unit to shut down the device.

5 CLEANING

IMPORTANT

Before cleaning, the device must always be disconnected from the mains power supply.

The device may only be cleaned using a soft cloth with water-soluble, non-abrasive cleaning agents or special cleaning agents for plastics.

In all instances of cleaning, never allow any liquid to get into the device or into the transparent measuring lead (tube) of the handheld module. Prior to beginning the cleaning process, disconnect the measuring lead from the system.

The handheld patient module must only be used **repeatedly** by a **single** patient.

The handheld patient module must be cleaned after each application and must be replaced after 3 months of use or in the event of any operational defects.

The treating physician / therapist decides whether the handheld patient module is to be cleaned with or without subsequent disinfection.

The handheld patient module must be cleaned without the connecting tube, since any moisture remaining in the tube can damage the pressure sensor in the device.

Cleaning

The handheld patient module must be disassembled and completely immersed in warm water with a little washing up liquid added to it. It should then be carefully rinsed off with water and left to dry.

Cleaning and disinfection

The handheld patient module must be disassembled and completely immersed in warm water with a little washing up liquid added to it. It should then be carefully rinsed off with water. The disinfection agent Cidex OPA (0.55% ortho-phthalaldehyde) from Johnson & Johnson, Gigasept FF from Schülke or Korsolex extra from Bode should be used to disinfect the handheld patient module. When using the disinfection solution, the instructions for use supplied by the manufacturer of the

disinfection agent must be followed exclusively. After the disinfection procedure, let the handheld patient module dry.

Use of the disinfection agent may cause slight discolouration of the plastic. However, the function of the handheld patient module will not be affected by this.

To allow any liquids to run off, turn the individual parts so that their openings face downwards or to the side while drying. Turn the current aperture setting (A, B, C) on the handheld module to the ● position to ensure that any liquid will run out through the opening. Disassemble and reassemble as depicted in this diagram.

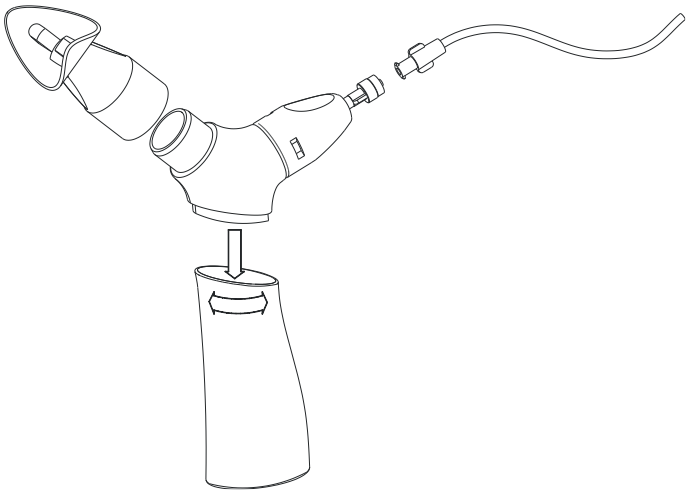

Figure 26: Connecting the handheld patient module

Ensure that the membrane on the valve seat of the Y-piece is handled with the utmost care during cleaning.

Important: Do not remove the membrane under any circumstances.

The device will not work correctly if the membrane is damaged or lost.

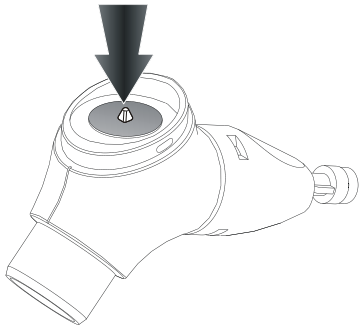

Figure 27: Membrane on valve seat

6 MAINTENANCE

The inspiratory muscle training device RESPIFIT S is designed as a low-maintenance device.

For long-term maintenance of quality and functional safety, please observe the following points:

The handheld patient module must only be used repeatedly by a single patient for reasons of hygiene. The cleaning directions, as set out in the instructions for use, must be meticulously observed in order to achieve repeated use of the handheld patient module (for cleaning instructions see Section 5).

Avoid exerting force on the training device or its accessories.

If the device is dropped, damaged due to force, or functions in a way other than described in the instructions for use, stop using the system and return it to the service centre.

6.1 Troubleshooting

Errors	Possible cause	Solution
Display is blank.	No power supply	Insert the mains plug. If the error persists, send the device for servicing.
“DATAKEY ⊗“	Datakey is not inserted or datakey is inserted incorrectly or datakey is defective.	Insert datakey. If the error persists, the datakey may be incorrectly inserted or faulty. If the datakey is faulty, request a new one from the doctor / therapist.

6.2 Periodic Inspections

The periodic technical safety inspections (according to EN 62353, for example) must be carried out on the therapy device at least every 24 months. Contact the treating physician / therapist, the clinic or the retailer to arrange this. The periodic inspection must be carried out by trained and knowledgeable persons who have practical experience and are qualified to carry out such technical safety inspections.

- The safety labels on the device and its accessories must be easily legible.

- The mechanical status of all components must permit additional and safe use.
- The therapy device or its accessories must not show any signs of dirt that could be detrimental to safety.
- The power supply unit and cables must be visually inspected (only Biegler original parts are permitted, see section 1.6).
- Housing and patient leakage currents must be checked.

The results of the periodic inspection must be documented, along with the date, the inspecting agency and the device number.

Important: If a malfunction is discovered during the periodic inspection, suitable warning signs should be attached to the device to ensure that it is not used before the required service and repair work has been carried out. It must be returned for repair to the manufacturer or service centres expressly authorised by the manufacturer.

7 RETURNING DEVICES OR ACCESSORIES

Devices or accessories must be carefully cleaned before being returned in the original packaging.

If the original packaging is no longer available, the product must be suitably packaged for shipment.

8 DISPOSAL

Dispose of the device and its accessories in accordance with the applicable local regulations.

Do not dispose of this product as unsorted municipal waste

9 MANUFACTURER LIABILITY

The manufacturer and the supplier of the device / accessory reject any liability if

- the device is not used in accordance with the instructions for use.
- the patient or doctor / therapist is not sufficiently informed about the way the device functions as per the instructions for use and the safety instructions.
- repairs are not performed exclusively by the manufacturer or by persons and service centres expressly authorised by the manufacturer.
- the device is used in places in which the electrical installations do not comply with the applicable national standards, or if the power supply during the period of use of the device is not guaranteed.

10 WARRANTY CONDITIONS

Please check the package contents after opening. Unfortunately, complaints submitted later cannot be accepted.

The warranty period is 24 months. The manufacturer guarantees that all material and manufacturing defects which arise within 24 months of the date of purchase will be repaired free of charge.

Claims are only accepted under the following terms:

- The manufacturer and/or supplier is informed immediately of the fault for which the warranty claim is being made.
- The instructions of the manufacturer and/or supplier regarding storage or return of the device are complied with.
- Presentation of a legible copy of the invoice for the device concerned, showing the date of purchase.
- An exact description of the defects or malfunctions identified by the customer.

The manufacturer’s warranty will be void if it is established that the maintenance, cleaning and inspection instructions have not been followed according to the instructions for use; the device has been damaged by force or operating error; or has been used in any way contrary to the operating instructions and safety instructions.

The warranty will also be void if original Biegler materials were not used as replacement parts, or measures for repair were undertaken by persons not authorized by the manufacturer or supplier.

If the manufacturer is required to meet a warranty claim in accordance with these terms, the customer shall bear the costs and risks of transport of the device from and to the place of use.

The manufacturer and/or supplier shall under no circumstances assume liability for slight negligence. Compensation for lost earnings and profits is likewise excluded.

11 ELECTROMAGNETIC COMPLIANCE

11.1 Emissions

Test	Limits
Conducted emissions	CISPR 11, Group 1, Class B
Radiated emissions	CISPR 11, Group 1, Class B
Harmonic current emissions (IEC 61000-3-2)	IEC 61000-3-2, Class A
Voltage changes and flicker (IEC 61000-3-3)	IEC 61000-3-3, complies with requirements

11.2 Immunity test level

Test	Test level
Electrostatic discharge (ESD) (IEC 61000-4-2)	Contact discharge: ± 8 kV Air discharge: ±2 kV, ±4 kV, ±8 kV, ±15 kV
HF radiated disturbances (IEC 61000-4-3)	80–2700 MHz; 1kHz AM 80%; 3 V/m
Proximity fields from HF wireless communications equipment (IEC 61000-4-3)	385 MHz; Pulse modulation: 18 Hz; 27 V/m 450 MHz, Pulse modulation: 18 Hz: 1 kHz Sinus; 28 V/m 710, 745, 780 MHz; Pulse modulation: 217 Hz; 9 V/m 810, 870, 930 MHz; Pulse modulation: 18 Hz; 28 V/m 1720, 1845, 1970 MHz; Pulse modulation: 217 Hz; 28 V/m 2450 MHz; Pulse modulation: 217 Hz; 28 V/m; 5240, 5500, 5785 MHz; Pulse modulation: 217 Hz; 9 V/m

Electrical fast transients/bursts (IEC 61000-4-4)	Power cables: 2 kV; 100 kHz repetition frequency Signal lines: 1 kV; 100 kHz repetition frequency
Surges (IEC 61000-4-5)	L-PE and N- PE: 2kV L-N: 1kV
HF conducted disturbances (IEC 61000-4-6)	0.15–80 MHz; 1kHz AM 80%; 3 Vrms, 6 Vrms in ISM Band
Power frequency magnetic fields (IEC 61000-4-8)	30 A/m, 50 Hz and 60 Hz
Power supply voltage dips, short interruptions and voltage variations (IEC 61000-4-11)	0% U_T for 0.5 cycles at 8 phase angles 0% U_T for 1 cycles at 0° 70% U_T for 25/30 cycles at 0° 0% U_T for 250/300 cycles at 0°

12 SYMBOLS

CE 0123 Certifies compliance with the Directive 93/42/EEC

MD Medical device

SN Serial number

Consult instructions for use

Follow the instructions for use

Manufacturer

Manufacturing date

"ESC" button for exiting the relevant menu

Button for confirming a selection

Button for selecting and for increasing a value

Button for selecting and for reducing a value

Cursor on the display

Relevant place for inserting the datakey

POWER Power supply socket on the device

Measuring lead from patient module


The device and its accessories must be disposed of in accordance with the local regulations.


Protection class II


Degree of protection Type BF

DC (direct current)

IP21 Protection type


Permissible relative humidity for transport and storage


Temperature limit for transport and storage

Language version German

Unique Device Identification

Additional symbols for the handheld patient module

Must only be used **repeatedly** by a **single** patient (refer to cleaning instructions)

Batch number

Catalogue number

13 OPERATING AND STORAGE CONDITIONS

The RESPIFIT S is intended for use in the following facilities:

- Medical establishments, incl. on-site examination rooms, general practices and therapy rooms.
- Home use

Permissible environmental conditions for the device and accessories:

	Transport and storage	Operation
Temperature	-25 to 70 °C	10 to 40 °C
Relative humidity	15 – 93% non-condensing	30–75%
Ambient pressure	700–1060 hPa	700–1060 hPa


Important: Values higher or lower than the ranges specified above may cause damage to the device or its accessories.

14 TECHNICAL DATA

Device:	Inspiratory Muscle Training Device
Type designation:	RESPIFIT S
Voltage:	5V DC voltage
Power supply unit GEM06I05:	100 - 240 V / 50 - 60 Hz
Power consumption:	0.18A - 0.09A
Protection class:	II
Type:	BF
Applied part:	Mouthpiece
Protection type: (Does not apply to the power supply unit)	IP21 - Protected from touch by fingers and from vertically dripping water
Device weight:	240 g
Handheld module weight:	61 g
Classification:	IIa according to Rule 9
Device dimensions:	W x D x H 141 x 81 x 65 mm
Dimensions of handheld module:	W x D x H 60 x 140 x 162 mm
Pressure measurement	
Measuring range:	-180 mbar
Resolution:	1 mbar
Precision:	+/- 4 %
RESPIFIT S product life:	5 years
Product life of the handheld patient module:	3 months

15 MANUFACTURER AND SALES

Manufacturer:

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3001 Mauerbach
AUSTRIA

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Fax. +43 1 979 21 05 16

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www.eumedics.at

16 MANUFACTURER'S DECLARATION

The inspiratory muscle training device RESPIFIT S is a medical device as defined by Directive 93/42/EEC.

This is documented through the CE mark.

Notified Body: TÜV SÜD Product Service GmbH, Approval number

CE 0123

NOTES