EN

Instruction for use
Inspiratory muscle trainer

resi IMT

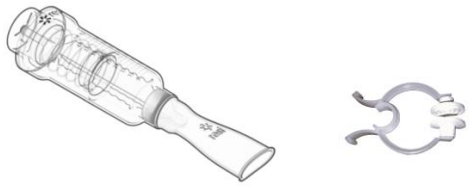
REF IMT1

Dear Patient,

Please read these instructions carefully before using the device. In particular, follow the instructions for cleaning the appliance after each use. If you have any questions about the medical device, please contact your treating specialist.

Content:
- 1 Main body with removable mouthpiece
- 1 Nose clip
- 1 Instruction for use

Figure 1



Scope
resi IMT (Inspiratory Muscle Trainer) is a device for adults (16 years and older) that is intended exclusively for training the respiratory muscles relevant for inhalation. It is used to reduce fatigue and weakness of the respiratory muscles in chronic respiratory diseases such as permanent airway narrowing lung disease like COPD. It is intended to be used several times for 30 consecutive days according to the training regimen prescribed by the practitioner. For each new training cycle (30 days), a new device must be used. The device is not intended for diagnosis, treatment or protection against any disease and is intended for personal use only.

Principle and scheme of action
The training effect of this device is achieved by the fact that a certain amount of force must be applied when inhaling in order to release a valve diaphragm that has been pressed down by a spring. The amount of force required by means of a screw and the adjustment of the spring pressure can be adjusted by the user so that it corresponds to approx. 30% of the maximum inhalation force (PImax) determined by the treating professional.

Contraindications
The device must not be used in the presence of the following diseases and circumstances:

- acute myocardial infarction (3-5 days);
- unstable angina pectoris and acute myocardial ischemia;
- uncontrolled arrhythmias with hemodynamic Impairment;
- acute or active inflammatory heart diseases (endo-, peri-myocarditis);
- decompensated heart failure, especially aortic dissection;
- severe and symptomatic aortic valve stenosis;
- acute pulmonary embolism;
- acute leg/pelvic vein thrombosis;
- severe acute exacerbation of COPD;
- acute extra-cardiopulmonary disease with the risk of deterioration under stress (e.g. infection, renal failure, severe hyperthyroidism);
- psycho-cognitive impairment with inability to Cooperation;
- Spontaneous pneumothorax in the past;
- Traumatic pneumothorax that has not completely healed;
- ruptured or otherwise damaged eardrum;

The use of the device is not recommended in the case of:
- coronary stenosis of the main stem or right coronary artery in the so-called right-side supplier type;
- hemodynamically limiting valvular heart disease;
- uncontrolled arterial hypertension (at rest systolic > 200mmHg, diastolic > 120mmHg);
- hypertrophic obstructive cardiomyopathy;
- tachyarrhythmia or bradyarrhythmia;
- higher-grade atrioventricular conduction disorder;
- advanced or complicated pregnancy;
- electrolyte derailments;
- epilepsy, if there is a risk of convulsion under stress;
- orthopaedic impairment that prevents the performance of a respiratory training under the condition of elevated air flow resistance

Warnings
- the material used for resi IMT is robust, but fragile under high force;
- if the device falls on a hard surface (e.g. tiles), it can be damaged;
- a damaged device must not be reused and must be replaced;
- do not insert anything other than the mouthpiece into the device;
- the device must not be turned beyond the upper or lower pressure settings;
- follow the instructions for cleaning the appliance carefully and do not use any cleaning agents or methods that are not intended for this purpose;
- in particular, heating can lead to deformation of the plastic parts;
- if no pressure is felt when inhaling, check the valve is present and seated flat

Side effects
If resi IMT is used as intended and as directed by the treating professional, there will be no side effects. However, if you become unusually tired, out of breath or feel pain during or after use, you should stop training and consult your healthcare professional.

Serious incidents must be reported directly to the manufacturer and the competent national authority after clarification by the specialist.

Before the first application
We recommend that you thoroughly clean resi IMT according to the instructions and let it dry before using it for the first time**.** Once the two parts are completely dry, the valve resistance can be adjusted to the value recommended by the treating professional by turning the screw (1B) as shown in Fig. 2 using the red mark on the pressure indicator inside the device and the black scale on the outside (1A). The mouthpiece can then be put on (1). Alternatively, the adjustment can also be done with the mouthpiece attached, if this is easier for the user to handle. Make sure there are no foreign objects in the mouthpiece or inside the device.

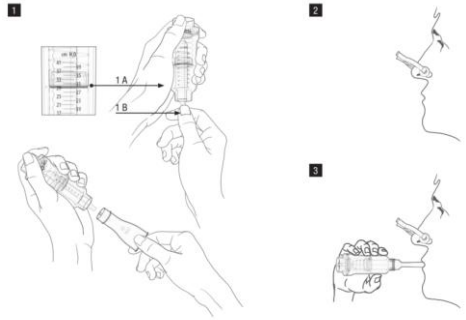
Technical characteristics
The inhalation resistance of the device can be adjusted to a value between 9 and 41 cm H2O using the black scale on the outside and the red marking on the spacer.

Material
The main body of the resi IMT is made of transparent acrylic glass, the mouthpiece and the rotatable spacer inside the device are made of white polypropylene, the spring inside is made of stainless steel and the valve diaphragm is made of silicone.

Storage Instructions
The medical device should not be stored below 0°C and above 50°C (ideally: room temperature) and should be kept safe from children!

Please keep the packaging and instructions for use during the entire period of use.

Application of resi IMT
1. Place the enclosed nose clip so that the nostrils are completely closed and breathing is done exclusively through the mouth (2).
2. Put the mouthpiece in your mouth (3).
3. Inhale and exhale regularly through the mouthpiece. When inhaling, the preset resistance must be overcome. The amount of force required creates the desired training of the respiratory muscles



Frequency of use
Start by exercising for 10-15 minutes a day or as instructed by your specialist. Then gradually increase the training duration to 20-30 minutes per day or 10-15 minutes 2x a day. Try to do it at about the same time and at least every day.
Keep track of the training log. A corresponding training protocol sheet is enclosed with this instruction manual.

Cleaning before use
For hygienic reasons, resi IMT should only be used on a patient-by-patient basis. Before the first use and after each use (so that the device including the mouthpiece remains hygienically clean), both parts should be thoroughly rinsed and cleaned with lukewarm water and Palmolive Original liquid soap after each use. Then rinse the parts with clear cold water, shake off any remaining water and let the device dry in the air and away from direct sunlight. Make sure there are no foreign objects in the mouthpiece or inside the device.
The appliance is not dishwasher safe. Heating during cleaning and drying can cause irreversible damage to the device.

Disposal instructions
resi IMT and the plastic bag can be disposed of in household waste. The instructions for use can be disposed of in paper waste.

Legend of symbols used

	Name and address of the manufacturer	REF	Catalog number	MD	Medical device
	Follow the instructions for use		Protect from sunlight		Temperature limit values
LOT	LOT number / Batch code		Date of manufacture		Use by date / Indicates the date after which the medical device is not to be used
NON STERILE	Non-sterile	1	For reuse on a single patient	CE	CE marking / with the European conformity mark, the manufacturer declares that the product in question meets the requirements of the Medical Device Regulation (EU) 2017/745)
EC REP	Name and address of the Authorised Representative		Name and address of the EU-Importer		

Notification to the authority:

Any serious incident that has occurred in relation to the device must be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

	Anel AG Weyermannstrasse 12, CH-3008 Bern, Switzerland
EC REP	**Basmed GmbH** Hauptstrasse 29 DE-79576 Weil am Rhein, Germany
	Basmed GmbH Hauptstrasse 29 DE-79576 Weil am Rhein, Germany

Training Protocol

			Week	1	2	3	4	5	6	7	8
			setting								
Monday	am	Time of day									
		Duration									
	pm	Time of day									
		Duration									
Thuesday	am	Time of day									
		Duration									
	pm	Time of day									
		Duration									
Wednesday	am	Time of day									
		Duration									
	pm	Time of day									
		Duration									
Thuersday	am	Time of day									
		Duration									
	pm	Time of day									
		Duration									
Fryday	am	Time of day									
		Duration									
	pm	Time of day									
		Duration									
Saturday	am	Time of day									
		Duration									
	pm	Time of day									
		Duration									
Sunday	am	Time of day									
		Duration									
	pm	Time of day									
		Duration									