FLAEM®
Medical Devices

AirFeel IMT

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DE > BEDIENUNGSANLEITUNG
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ΕΛ > ΕΓΧΕΙΡΙΔΙΟ ΟΔΗΓΙΩΝ ΧΡΗΣΗΣ
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SV > BRUKSANVISNING
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HR > PRIRUČNIK S UPUTAMA ZA UPO RABU
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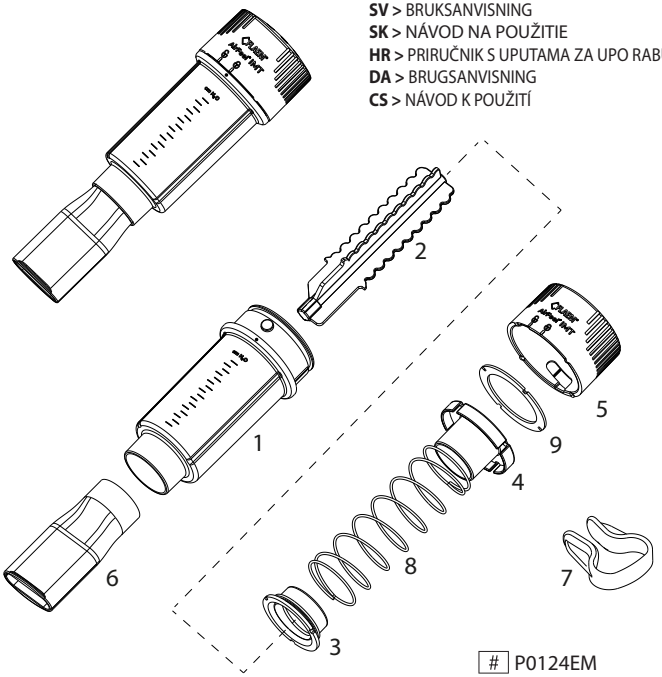
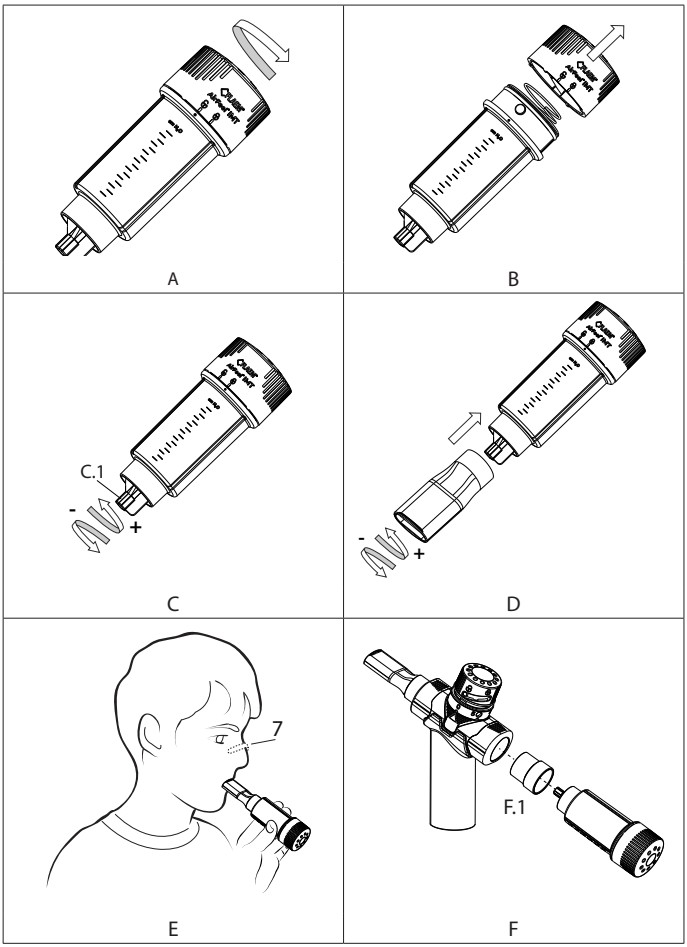
CS > NÁVOD K POUŽITÍ



P0124EM

Schema di collegamento - Connection diagram - Anschlussplan - Schéma de branchement - Verbindingsschema - Διάγραμμα σύνδεσης - Schemat połączeń - Esquema de conexión -Monteringsschema -Schéma pripojenia - Dijagram povezivanja - Tilslutningsdiagram - Schéma připojení -


A
B
C.1
-
+
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F

Medical device for respiratory gymnastics

These user instructions are provided for the device model P0124EM.

INTENDED PURPOSE. Medical device for inspiratory muscle training. Use must be prescribed by professional medical personnel.

USER INSTRUCTIONS. This device is intended to alleviate symptoms in major debilitating diseases such as COPD, asthma, cardiac disorders, dyspnoea or other medical indications. Before use, setting and any changes to the device settings must be carried out by medical personnel or by the patient as prescribed by their doctor/physiotherapist.
Notes for medical personnel: The workload for respiratory exercise should be based on the patient's respiratory muscle strength, determined by measuring the maximum inspiratory pressure (MIP) with a manometer. The MIP is the maximum negative pressure that a patient can generate during the inhalation phase.

⚠ **CONTRAINDICATIONS. Do not use the device with:**
- Patients who have recently undergone abdominal surgery and patients with abdominal hernia.
- Asthma patients who have a very low perception of symptoms and suffer from frequent, severe exacerbations or have an abnormally low perception of dyspnea.
- Patients suffering from a ruptured eardrum or any other ear disease.
- Patients with significantly elevated left ventricular end-diastolic volume and pressure.
- Patients with worsening signs and symptoms of heart failure after MRI/IMT.

The following conditions are also highlighted in order to seek medical advice before using the device:
- People suffering from severe pneumothorax or coughing up large amounts of blood (massive haemoptysis).
- Pulmonary hypertension.
- Large blebs on chest X-rays.
- Severe degree of osteoporosis with a history of rib fractures.
- Desaturation during or after IMT (<94%).

It is not recommended to use the device immediately after lung surgery and in individuals with a history of pneumothorax who need to have their blood pressure monitored. If during treatment severe tiredness, shortness of breath or a noticeable increase in heart rate is experienced, stop treatment and seek for medical advice. Inform your doctor or therapist if you notice any side effects not listed in these instructions for use.

INTENDED USERS. The devices are intended to be used by professional medical personnel. The device can be used directly by the patient.

⚠ **TARGET PATIENT GROUP.** The device may be used:
- Adults.
- Individuals under 16 years of age, only when under the supervision of an adult.

The device may not be used with infants.
The frequency and duration of use are determined by professional medical personnel based on the patient's individual needs. Before using the device, the user manual must be read carefully and an adult responsible for safety must be present if the device is used by children or people with limited abilities (e.g., physical, mental or sensory). It is up to the medical personnel to assess a patient's condition and capabilities in order to determine whether they can operate the device independently or are unable to use it safely on their own, and, therefore, whether the usage practices should be carried out by a responsible person. Please refer to professional medical personnel for the evaluation of the use of the device on particular types of patients, such as pregnant women, lactating women, incapacitated persons or individuals with limited physical capabilities.

OPERATING ENVIRONMENT. This device can be used in healthcare facilities, such as hospitals, outpatient clinics, etc., or even at home.

WARNINGS.
- This product is not intended for the diagnosis, treatment, cure or prevention of any disease.
- The following side effects may occur: Dizziness.
- Only use the device as intended. This medical device is not intended as a life-saving device. Any other use is considered misuse and there may be hazards. The manufacturer shall not be held liable for any improper use.
- This product must only be used as described in these instructions for use.
- The time required to switch from storage to operating conditions is about 2 hours.
- Keep this manual carefully for further reference.
- When the device is used in combination with another medical device, the instructions for use of said second device must also be complied with.
- The materials used in the device are biocompatible materials and comply with statutory regulations, however possible allergic reactions cannot be completely ruled out.
- The device does not administer drugs and/or substances.
- At the end of every use, once the device has been cleaned as per section HYGIENIC PREPARATION, store it in a dry and dust-free place.
- It is not recommended to use the device when suffering from a cold, sinusitis or respiratory tract infection. If in doubt, seek for medical advice.
- In case of a cold, some users may experience a slight discomfort in the ears during treatment that is caused by inadequate pressure equalisation between the mouth and ears. If symptoms persist, seek for medical advice.
- During use of the device, resistance to inhalation must be felt, but this should not be painful. If you experience any pain while using the device, stop training immediately and seek for medical advice

Risk of suffocation: Some components of the device are small enough to be swallowed by children, therefore, keep the device out of the reach of children.

Risk of ineffectiveness of the device:
- Use the device in the correct position (see relevant user instructions section).
- Only use original Flaem spare parts; no liability shall be accepted if non-original parts or accessories are used.

Risk of infection: Carry out hygienic preparation before and after each use. Ensure that the device is not stored in the vicinity of other accessories or devices for different therapies (e.g. infusions).

TROUBLESHOOTING

Problem	Cause	Remedy
Breathing effort is too heavy or too light	Incorrect setting of the respiratory load	Check the indicator for correct position as per the prescription. If correct, seek your doctor's/ physiotherapist's advice
The indicator is crooked	Incorrect assembly of the indicator on the inner screw	Disassemble the device and assemble it properly.
During inhalation, no effort is felt	Inspiration valve or seal missing	Check for their presence and, if necessary, re-assemble the device with the missing parts

If, after checking the conditions described above, the apparatus still is not working properly, we recommend that you contact your trusted dealer or an authorised FLAEM service centre nearest to you. You can find a list of all Service Centres at http://www.flaemnuova.it/it/info/assistenza

DISPOSAL. All product components can be disposed of with household waste unless prohibited by the disposal regulations in force in the respective member countries.

Packaging

Product box

Product packaging bag

REPORTING SERIOUS EVENTS. Serious events occurring in connection with this product must be reported immediately to the manufacturer or the competent authority. An event is considered serious if it causes or may cause, directly or indirectly, death or an unforeseen serious deterioration in a person's state of health.

SYMBOLS ON DEVICE OR PACKAGING

MD Medical device	See instructions for use	Manufacturer
# Model number	Production date	LOT Batch code
CE marking ref. EU regulation 2017/745 as amended	UDI Unique device identifier	PHTHALATES & BPA FREE Phthalate- and bisphenol-free
Moisture limits	Temperature limits	Attention
Atmospheric pressure limits		

TECHNICAL FEATURES. Model: P0124EM

Weight: 0.05 kg approx. Range accuracy: 7-67 cm H_2O

MEDICAL DEVICES THAT CAN BE USED IN COMBINATION WITH THE DEVICE.

The device can be used in combination with the following medical device: AirFeel respiratory exercise device, model P0920EM, P0920EM-1 (not included) for IMT therapy and PEP / O-PEP therapy simultaneously.
Combination therapy must be prescribed by medical personnel.
The devices can be connected by using the appropriate fitting F.1 as shown in fig.F.
It can be used with tracheostomy attachments via catheter mounts with 22M connection, according to the instructions of the treating physician.

ENVIRONMENTAL CONDITIONS

Operating conditions:	**Storage and transport conditions:**
Ambient temperature: Between +10°C and +40°C	Ambient temperature: Between -25°C and +70°C
Relative air humidity: Between 10% and 95%	Relative air humidity: Between 10% and 95%
Atmospheric pressure: Between 69 KPa and 106 KPa	Atmospheric pressure: Between 69 KPa and 106 KPa

DURATION. Model: P0124EM

Average service life is 5 years.

APPLIANCE AND MATERIAL INFORMATION Please refer to the picture on page 1 of this instruction manual.	
The equipment includes:	**Information on materials**
1 - Main body 2 - Central screw 3 - Spring tensioner 4 - Valve holder 5 - Cap	
6 - Polypropylene mouthpiece	
7 - Nose plug F.1 - Airfeel fitting (optional) 8 - Spring 9 - Valve holder sealing ring	

OPERATING INSTRUCTIONS

Before and after each application, the product components must be thoroughly cleaned according to the instructions in the HYGIENIC PREPARATION section.

Load intensity adjustment: To adjust the inspiratory load, act on peg C.1 (fig. C): turning the peg clockwise brings the signalling ring closer to the mouthpiece, thus reducing the load; conversely, turning the peg counterclockwise moves the signalling ring away from the mouthpiece, thus increasing the load. The inspiratory load can also be adjusted after assembling the mouthpiece, again by turning it clockwise or counterclockwise in its seat as described for peg C.1.

Preparation for the session: Insert the mouthpiece (6) inside the main body (1) as shown in fig. D. It is advisable to wear the nose plug (7) over the nostrils to make the most of therapy by inhaling and exhaling through the mouth only.

Make sure you are sitting or standing and feel relaxed.

Holding the device in your hand, close the mouthpiece tightly between your lips, as shown in fig. E.

Breathe in deeply so that the internal valve opens: when it trips, you can easily feel a flow of air passing through the device.

Continue therapy by inhaling and exhaling through the device, without removing it from your mouth.

Notes for therapy: It is advisable to start with short training sessions, applying the inspiratory pressure load as recommended by your doctor or physiotherapist. Do not change this parameter without first consulting your doctor.

By training consistently, the exercise time can be increased.

HYGIENIC PREPARATION

To open the device, turn the cap (5) anti-clockwise (fig.A) and remove it from the main body (1) as shown in fig.B. Disassemble the device into its individual parts as shown in the connection diagram.

Please note: Do not remove the valve and the snap ring mounted on the valve holder (4). Do not remove the snap ring mounted on the main body (1).

These instructions also apply to optional fitting F.1.

Sanitisation

Sanitise the components by choosing one of the methods provided in the table and described below.

method A: Sanitise the accessories under warm drinking water (approx. 40°C) with mild dishwashing detergent (non-abrasive).

method B: Sanitise the accessories in the dishwasher with the hot cycle (70°C).

method C: Sanitise the accessories by soaking in a solution of 50% water and 50% white vinegar, then rinse thoroughly with warm drinking water (approx. 40°C).

Disinfection

After sanitising the components, disinfect them by choosing one of the methods provided in the table and described below. Each method can be performed for a limited number of times (see figure in table).

method A: Obtain a disinfectant of the electrolytic chloride type (active ingredient: sodium hypochlorite), specifically for disinfection, available in all pharmacies.

Execution:

- Fill a container of a suitable size to hold all the individual components to be disinfected with a solution of drinking water and disinfectant, observing the proportions indicated on the packaging of the disinfectant.
- Completely immerse each individual component in the solution, taking care to avoid the formation of air bubbles in contact with the components. Leave the components immersed for the period of time indicated on the disinfectant packaging, and associated with the concentration chosen for the preparation of the solution.
- Recover the disinfected components and rinse them thoroughly with lukewarm drinking water.
- Dispose of the solution according to the disinfectant manufacturer's instructions.

method B: Disinfect the components by boiling them in water for 10 minutes; use demineralised or distilled water to prevent hard water deposits.

method C: Disinfect the components in a hot bottle steamer (not microwave). Carry out the process strictly according to the hot bottle steamer's instructions. For disinfection to be effective, choose a steriliser with an operating cycle of at least 6 minutes.

If you also want to carry out sterilisation, skip to the Sterilisation section.

After disinfecting the accessories, shake them vigorously and place them on a paper towel, or alternatively dry them with a hot air jet (e.g. hair dryer).

Sterilisation

Equipment: Steam steriliser with fractionated vacuum and overpressure compliant with EN 13060.

Execution: Package each individual component to be treated in sterile barrier system or packaging in accordance with EN 11607. Place the packaged components in the steam steriliser. Perform the sterilisation cycle in accordance with the instructions for use of the equipment by selecting a temperature of 134°C and a time of 4 minutes first.

Storage: Store sterilised components according to the instructions for use of the system or sterile barrier packaging chosen.
The sterilisation procedure was validated in accordance with ISO 17665-1.

At the end of each use, store the device complete with its accessories in a dry and dust-free place.

Table of planned methods / patient accessories										
Method	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**F1**
HYGIENIC PREPARATION AT HOME										
Sanitisation										
method A	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
method B	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
method C	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Disinfection										
method A	300	300	300	300	300	300	300	\	300	300
method B	300	300	300	300	300	300	300	300	300	300
method C	300	300	300	300	300	300	300	300	300	300
HYGIENIC PREPARATION IN THE CLINIC OR HOSPITAL										
Disinfection										
method A	300	300	300	300	300	300	300	\	300	300
method B	300	300	300	300	300	300	300	300	300	300
Sterilisation										
	300	300	300	300	300	300	300	300	300	300
✓: planned \: not planned 300: ✓ MAX 300 TIMES										