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Air Liquide
HEALTH CARE

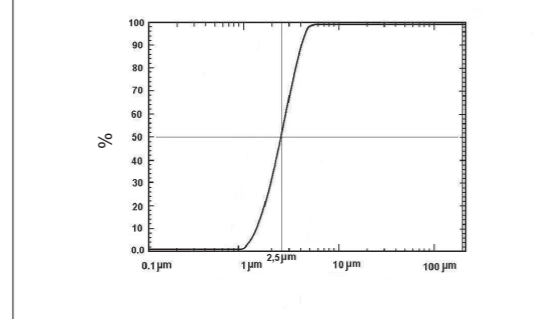
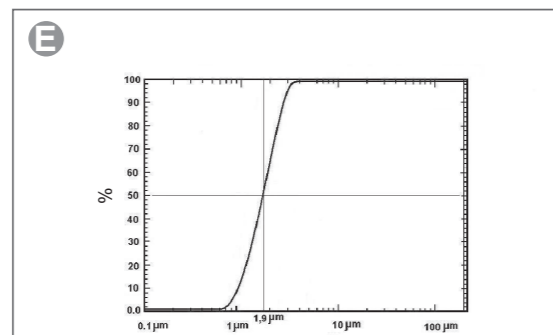
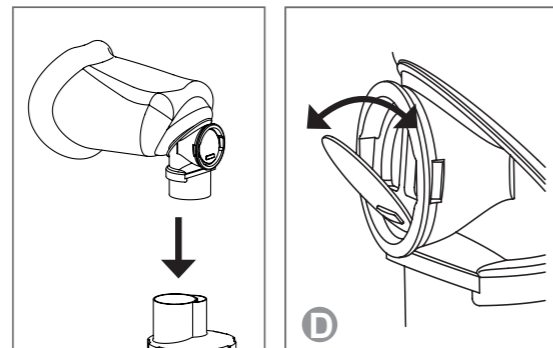
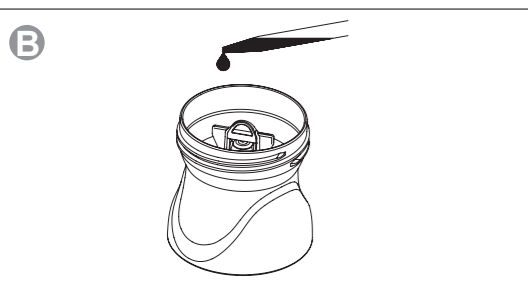
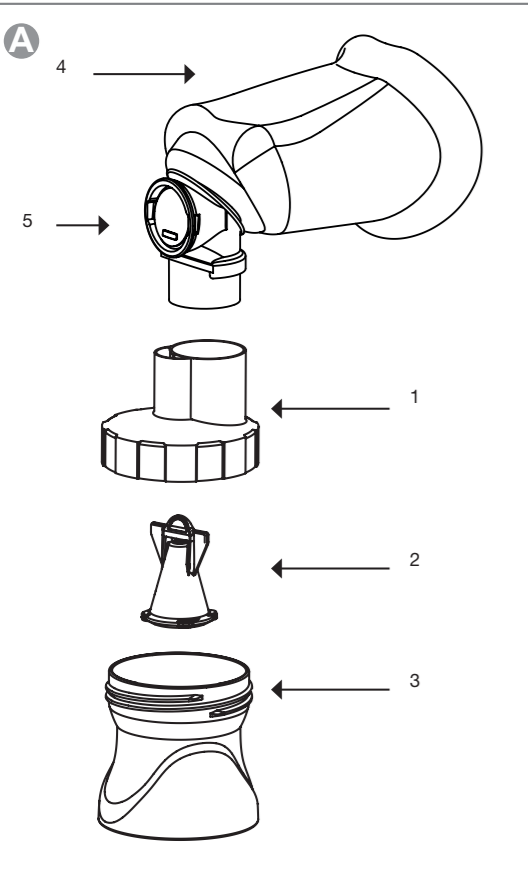


The apparatus described herein was designed and built by:
Le dispositif décrit dans cet ouvrage a été conçu et fabriqué par:
Das in der vorliegenden Veröffentlichung beschriebene Gerät ist ein Produkt der Firma:



Cod. 822178 Rev. 11/2019

Kit nebula spacer



ENGLISH

Please read the instructions and the important notes (1.3) carefully before using the apparatus.

1 - IMPORTANT INDICATIONS

1.1 - APPLICATION

Kit Nebula Spacer (nebuliser + spacer mouth mask) can be used to treat bronchial asthma, chronic bronchitis, pulmonary emphysema, cystic fibrosis and other respiratory disorders by administering drugs in aerosol form.

The administration of drugs requires a medical prescription specifying the type of drug, the dosage and the length of treatment.

Kit Nebula Spacer is designed and made in Italy in accordance with EU Directive 93/42/EC regarding medical devices (and subsequent updates) and bears the CE mark.

1.2 - SYMBOLS USED

Important - read the instructions carefully

Keep the device dry

Does not contain phthalates No traces of natural latex

1.3 - IMPORTANT NOTES

- Read the instructions carefully and keep them in a safe place for future reference.
- This device must only be used for treating the lower airways. It must not be used for any other purpose.
- Air Liquide Medical Systems S.r.l. disclaims all liability for the device with which Kit Nebula Spacer is used if it is of any other make. The device must comply with EU Directive 93/42/EC on Medical Devices (and subsequent updates) and must bear the CE mark.
- Some components are small enough to swallow and may lead to suffocation.
- Read the list of components in the table in section 7 to see if there are any components that have caused an allergic reaction in the past.
- Consult the manufacturer's instructions of the device with which Kit Nebula Spacer is used, to make sure they are compatible (see 6 - TECHNICAL DATA).
- Follow the important notes provided for the device used with Kit Nebula Spacer.
- Children must only be allowed to use the device under the supervision of an adult who has read and understands the instructions.
- The administration of drugs in aerosol form requires a medical prescription, specifying the type of drug, the dosage and the length of treatment.
- Do not use essential oil solutions (e.g. with menthol or eucalyptus) as they are not compatible with the material of which the nebuliser is made.
- Do not use Kit Nebula Spacer in the bath or shower.

1.4 - PATIENT GROUPS

Kit Nebula Spacer provides highly effective inhalation therapy for patients of any age, from young children to the elderly.

1.5 - CONTENTS

The package contains the following parts (Fig. A):

- a nebuliser comprising the following:
 - upper section (1)
 - atomiser (2)
 - lower section (3)
- a spacer mouth mask comprising the following:
 - mask body (4)
 - fitting with a discharge valve (5)

The spacer mask fitting (5) is inserted in the upper section (1) of the nebuliser. The lower section (3) has a terminal to which the air pipe is connected.

2 - PREPARING AND USING KIT NEBULA SPACER

Kit Nebula Spacer must be connected to a source of air, which can be compressed air from an aerosol device, medical air from a centralised system or from a cylinder via a pressure reducer. In all cases, it is important to make sure that the source of air is compatible with the nebuliser (see 6 - TECHNICAL DATA).

Please read section 3 before using the device.

- Proceed as follows to use the Kit Nebula Spacer:
 - Make sure the atomiser (2) is correctly inserted in the central sleeve in the lower section (3) of the nebuliser.
 - The lower section has a graduated scale that shows the approximate amount of liquid inside. The purpose is merely to give an approximate indication of the contents. Use a graduated syringe to get an accurate dose. Pour the liquid into the tank (Fig. B), keeping to the dosage specified by your doctor.

Readings must be taken on the graduated scale with the atomiser mounted on the lower section.

- Screw the upper section (1) of the nebuliser onto the lower section (3)
- Connect the fitting of the spacer mouth mask (5) to the upper section (1) of the nebuliser (Fig. C).

- Connect the lower end of the tube to the nebuliser and the other end to the air intake of the aerosol device.
- Start up the device.
- During treatment, hold the nebuliser upright in your hand to enable it to work efficiently.
- If the above operations have been performed correctly, a spray will come out of the mask.

The spacer mouth mask (4) must be placed gently over the mouth – the top of the mask rests underneath the nose. For the treatment to be effective, you should breathe slowly and deeply, in through the mouth and out through the nose. If the user breathes out through the mouth, the valve on the fitting releases the exhaled air (Fig. D).

Do not obstruct the valve on the fitting during use (Fig. D).

When you have used up all the drug or interrupt treatment, switch off the aerosol device or turn off the air supply. A small amount of liquid may remain in the nebuliser at the end of the session but this has no importance.

3 - CLEANING, DISINFECTING AND STERILIZING

Before proceeding, unplug the apparatus and disconnect Kit Nebula Spacer and tube.

If it is necessary to clean, disinfect or sterilize this medical device, using a method other than that given in this section, contact the manufacturer first.

To prevent the risk of microbial contamination, Kit Nebula Spacer must be cleaned and disinfected, and if necessary sterilized, after each treatment and before use, following the instructions carefully. Before, cleaning, disinfecting or sterilizing any of the components, disassemble them as follows:

- Remove the tube.
- Remove the spacer mouth mask (4, 5) from the nebuliser (1, 2, 3).
- Detach the fitting (5) from the mask (4).
- Unscrew the upper section (1).
- Remove the atomiser (2).

3.1 - CLEANING

The disassembled nebuliser (1, 2 and 3) and the disassembled spacer mouth mask (4 and 5) can be washed in water at an approximate temperature of 40 °C with the addition of detergent (refer to the manufacturer's instructions), then rinsed in running water.

When all the parts have been cleaned, dry them with a soft cloth and place in the storage compartment.

3.2 - DISINFECTING

After washing, all the components of the nebuliser (1, 2 and 3) and spacer mouth mask (4, 5) can be immersed in a cold disinfectant solution (e.g. a solution containing up to 2% sodium hypochlorite). Follow the manufacturer's instructions.

The components of Kit Nebula Spacer can be disinfected by boiling in a saucepan of water for a maximum of 10 minutes. Make sure the components are not in direct contact with the bottom of the saucepan.

Boiling may alter the colour or appearance of the components, but this will not affect operation of the device.

3.3 - STERILIZING

The components of the nebuliser (1, 2 and 3) and spacer mouth mask (4, 5) can be sterilized in an autoclave at 121 °C for at least 15 minutes (but no more than 30 minutes), for up to 20 times.

Sterilization is recommended when the apparatus is used in a hospital environment or by more than one patient.

4 - MAINTENANCE

When cleaning, disinfecting or sterilizing Kit Nebula Spacer components, you can check them visually and determine when they need to be replaced. Repeated sterilization may affect the materials of which the nebuliser and mask are made, so the components should be inspected regularly. Kit Nebula Spacer must be replaced when there are clear signs of deterioration.

5 - PROBLEMS, POSSIBLE CAUSES AND SOLUTIONS

PROBLEMS	POSSIBLE CAUSES	SOLUTIONS
The nebuliser does not generate a spray.	- The device is switched off. - There is no liquid in the nebuliser. - Too much liquid has been poured into the nebuliser. - The nebuliser has not been assembled correctly.	- Switch on the device. - Pour liquid into the nebuliser. - Reduce the quantity of liquid in the nebuliser to below the maximum level. - Check that the atomiser (2) is properly inserted in the base of the nebuliser (3). - Screw the upper section (1) onto the base and check that air comes out of the little hole at the top of the base. - Unblock the hole.
	- The air outlet in the base (3) is blocked. - The air tube is not connected correctly	- Connect the air tube properly

PROBLEMS	POSSIBLE CAUSES	SOLUTIONS
The nebuliser does not perform as stated.	- The air source does not provide the required pressure and rate of flow	- Check the characteristics of the air source
The nebulised liquid does not reach the mask or there is difficulty exhaling	- The spacer mask (4, 5) has not been assembled correctly. - The valve (Fig. D) has jammed.	- Assemble the spacer mask (4, 5) correctly. - Release the valve.

6 - TECHNICAL DATA

Minimum supply pressure	1.5 bar (150 kPa)
Maximum supply pressure	3 bar (300 kPa)
Air flow at minimum pressure	7 l/min
Air flow at maximum pressure	15 l/min
Nebuliser capacity	8 ml
Drug delivery at minimum pressure(*)	0.20 ml/min
Drug delivery at maximum pressure (*)	0.45 ml/min
MMAD at minimum pressure(**)	2.5 µm
MMAD at maximum pressure(**)	1.9 µm

(*) The values shown refer to the use of physiological solution (0,9% NaCl) and may vary with the drug used. The values given do not apply to drugs in suspension or high-viscosity drugs. The manufacturer of the drug can provide the necessary details.

(**) 50% by volume of the particles atomised by the nebuliser are less than the MMAD (Median Mass Aerodynamic Diameter). This value is indicative of the nebuliser's ability to produce small particles. Clinical studies have shown that the effectiveness of the nebuliser is measured by its ability to atomise the drug in particles with a diameter of 1-5 micron to allow maximum deposition in the lungs, thereby increasing the effectiveness of the treatment.

The MMAD values shown are measured using a MACH 2 API AEROSIZER.

The y-axis of the graphs (Fig. E) represents the percentage of volume of atomised solution with sizes lower than the corresponding dimensional value expressed in µm on the x-axis.

7 - DISPOSING OF KIT NEBULA SPACER

All the components must be disposed of in accordance with current regulations in bins for plastic materials. The table below shows the kind of plastic of which each component is made. None of the materials used contains phthalates or traces of natural Latex.

COMPONENT	MATERIAL
Upper section (1)	Polycarbonate
Atomiser (2)	Nylon
Lower section (3)	Polycarbonate
Mask body (4)	Silicone
Fitting with discharge valve (5)	Polycarbonate and Silicone

8 - OPERATING CONDITIONS

- Temperature range +5 °C to +40 °C
- Relative humidity 15% to 93%
- Atmospheric pressure 700 hPa - 1060 hPa

9 - STORAGE CONDITIONS

- Temperature range -25 °C to +50 °C
- Relative humidity less than 93%
- Atmospheric pressure 700 hPa - 1060h Pa

10 - WARRANTY

The manufacturer is liable for the safety, reliability and performance of the apparatus, provided that it is used in accordance with the instructions and for the intended purpose only, and any repairs are carried out by the manufacturer or an approved service centre. The manufacturer declines all liability and the warranty will be invalidated if the user fails to follow the instructions and the important notes contained herein.

11 - TECHNICAL UPDATES

Air Liquide Medical Systems S.r.l. periodically reviews and modifies all its medical devices in order to improve their performance, safety and reliability. The instruction booklets are updated accordingly to include any new or changed features. If the booklet accompanying the apparatus gets damaged or mislaid, a replacement copy can be obtained from the manufacturer by quoting the data shown on the rating plate.

12 - COPYRIGHT

The information contained in this booklet must not be used for any purpose other than the reason for which it is provided. This booklet is the property of Air Liquide Medical Systems S.r.l. and no part of it may be reproduced without the manufacturer's written permission. All rights reserved.

FRANÇAIS

Lire attentivement cette notice d'instructions et les mises en garde (section 1.3) avant d'utiliser l'appareil.

1 - INDICATIONS IMPORTANTES

1.1 - DESTINATION D'EMPLOI

Le Kit Nebula Spacer (chambre de nébulisation avec masque buccal volumétrique) est indiqué dans le traitement de l'asthme bronchique, des bronchites chroniques, de l'emphysème pulmonaire, de la fibrose kystique et autres pathologies respiratoires à travers l'administration de médicaments sous forme d'aérosol.

L'administration de médicaments doit être prescrite par le médecin qui définit le type de médicament, la dose à administrer et la durée du traitement.

Le Kit Nebula Spacer a été conçu et fabriqué en Italie en conformité avec les dispositions de la directive 93/42 CEE relative aux dispositifs médicaux (et mises à jour postérieures) et porte le marquage CE.

1.2 - DESCRIPTION DES SYMBOLES EMPLOYÉS

Attention, lire les instructions d'utilisation

Maintenir sec

Ne contient pas de phtalates Sans latex naturel

1.3 - MISES EN GARDE

- Lire attentivement les instructions d'utilisation et les garder en lieu sûr.
- Le dispositif ne doit être utilisé que dans les traitements des voies aériennes inférieures. Toute autre utilisation est formellement interdite.
- Air Liquide Medical Systems S.r.l. décline toute responsabilité sur l'appareil (non de sa propre production) avec lequel le Kit Nebula Spacer est utilisé. Utiliser des appareils construits conformément avec la Directive 93/42 CEE en matière de dispositifs médicaux (et ses mises à jour successives) et portant la marque CE.
- Certains composants, du fait de leur taille réduite, risquent d'être avalés et de provoquer l'étouffement.
- Il est conseillé de vérifier dans le tableau (section 7) si l'appareil contient des matériaux ayant provoqué, par le passé, une réaction allergique quelle qu'elle soit.
- Lire attentivement le mode d'emploi de l'appareil avec lequel le Kit Nebula Spacer est utilisé afin de vérifier la compatibilité avant de l'utiliser (voir 6 - DONNÉES TECHNIQUES).
- Respecter les avertissements du fabricant de l'appareil utilisé avec le Kit Nebula Spacer.
- L'utilisation de l'appareil par un enfant doit toujours se faire sous la surveillance d'un adulte connaissant les présentes instructions.
- L'administration de médicaments sous forme d'aérosol doit obligatoirement être prescrite par le médecin, qui définit le type de médicament, la dose à administrer et la durée du traitement.
- Ne pas employer de solutions d'huiles essentielles (par exemple menthol, eucalyptus, etc.) car elles sont incompatibles avec le matériau de la chambre de nébulisation.
- Ne pas utiliser le Kit Nebula Spacer dans le bain ou sous la douche.

1.4 - GROUPES DE PATIENTS

Le Kit Nebula Spacer assure une thérapie d'inhalation de grande efficacité pour les patients de tous âges, des tout petits enfants jusqu'aux adultes.

1.5 - CONTENU DE L'EMBALLAGE

L'emballage contient les éléments suivants (Fig. A).

- Une chambre de nébulisation comprenant les parties suivantes :
 - corps supérieur (1)
 - atomiseur (2)
 - corps inférieur (3)
- Un masque buccal volumétrique comprenant les parties suivantes :
 - corps du masque (4)
 - raccord avec valve d'évacuation (5)

Le raccord du masque volumétrique (5) s'enclenche sur le corps supérieur de la chambre de nébulisation (1) alors que le corps inférieur (3) présente un embout pour le raccordement du tube d'aménée d'air.

2 - PRÉPARATION ET UTILISATION DU KIT NEBULA SPACER

Le Kit Nebula Spacer a besoin d'être raccordé à une source d'air - qui peut être l'air comprimé produit par un appareil d'aérosol ou de l'air médical issu d'une installation centralisée ou d'un réducteur de pression branché à une bouteille. Dans tous les cas, il est nécessaire d'assurer la cohérence des prestations de la source d'air avec les données de fonctionnement de la chambre de nébulisation (voir section 6 - DONNÉES TECHNIQUES).

