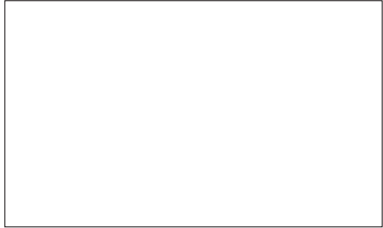


Istruzioni per l'uso
Instruction Manual
Notice d'utilisation
Handbuch
Manual de Instrucciones
Gebruiksaanwijzing



CE 0123

30751/027 - Revisione 7 (06.06.2016)
Fabbriante - Manufactured by
Fabriqué par - Fabricante - Hersteller

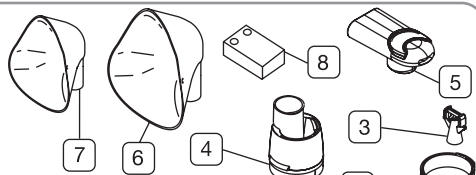
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Italian
Medical
Touch



- 1 - Tubo Aria
- 2 - Corpo Inferiore Ampolla
- 3 - Ugello Nebulizzatore
- 4 - Corpo Superiore Ampolla
- 5 - Boccheruola
- 6 - Maschera Adulto
- 7 - Maschera Pediatrica
- 8 - Forcella Nasale



- 1 - Air Tube
- 2 - Nebulizer Tank
- 3 - Nebulization Nozzle
- 4 - Nebulizer Top
- 5 - Mouthpiece
- 6 - Adult Mask
- 7 - Pediatric Mask
- 8 - Nosepiece

- 1 - Lucht slang
- 2 - Onderste gedeelte van de vernevelaar
- 3 - Sproeistuk
- 4 - Bovenste gedeelte van de vernevelaar
- 5 - Mondstuk
- 6 - Masker voor volwassenen
- 7 - Masker voor kinderen
- 8 - Neusvork

- 1 - Tubo del aire
- 2 - Fondo de la Ampolla
- 3 - Tobera de Nebulización
- 4 - Parte superior de la Ampolla
- 5 - Boquilla
- 6 - Mascarapara Adultos
- 7 - Mascarapara Pediátrica
- 8 - Horquilla nasal

- 1 - Tuyau d'air
- 2 - Base du nébuliseur
- 3 - Busette
- 4 - Couvercle du nébuliseur
- 5 - Embout buccal
- 6 - Masque pour adultes
- 7 - Masque pédiatrique
- 8 - Fourche nasale

- 1 - Luftschauch
- 2 - Zerstäuberunterteil
- 3 - Zerstäuberlüse
- 4 - Zerstäuberoberteil
- 5 - Mundstück
- 6 - Maske für Erwachsene
- 7 - Maske für Kinder
- 8 - Nasensticke

Analisi Granulometrica / Granulometry Analysis
Risultati delle misurazioni effettuate su HI-FLO secondo EN 13544-1
Results of measurement series with HI-FLO nebulizer in compliance with EN 13544-1

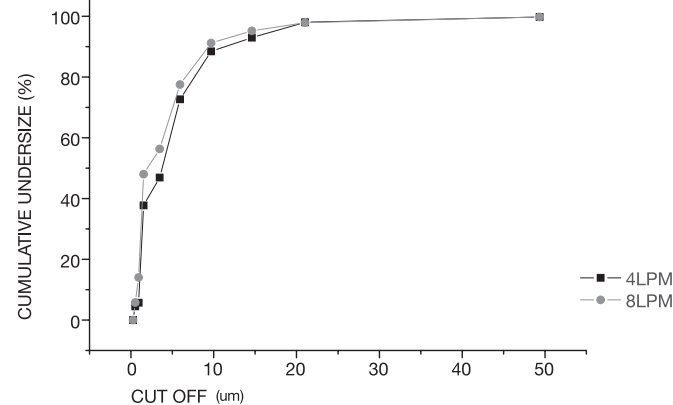
Operating Flow (l/min)	Fill Volume (ml)	MMAD(µm)	GSD
4.0	2.5 ml 2,5% NaF	3.08	2.66
8.0	2.5 ml 2,5% NaF	2.48	2.85

MMAD = Mass Median Aerodynamic Diameter GSD = Geometric Standard Deviation

Caratteristiche di Output / OutPut Specification
Risultati delle misurazioni effettuate su HI FLO secondo EN 13544-1
con Simulatore del Respiro
Results of INHALATION SIMULATOR measurements with HI-FLO nebulizer in compliance with EN 13544-1.

Operating Flow (l/min)	Fill Volume (ml)	Output (µl)	Output Rate (µl/min)
4.0	2 ml 1% NaF	203.6	42.6 (1 min)
8.0	2 ml 1% NaF	303.1	59.6 (1 min)

IN VITRO CUMULATIVE DEPOSITION COMPARATIVE RESULT
- MARPLE CASCADE IMPACTOR



READ INSTRUCTION MANUAL CAREFULLY BEFORE USE DRUG ADMINISTRATION BE UNDER MEDICAL CONTROL.

HI-FLO KIT is an Medical Device (Risk Class IIa - MMD 93/42/EEC and subsequent changes) highly efficient in medical therapies administered by means of aerosol nebulization. This device is designed for the nebulization of for atomising antibiotics and bronchodilator drugs (distribution of drugs with aerosol therapy).

GENERAL WARNINGS

1. Always observe instructions and safety warnings as indicated in the instructions manuals of devices for aerosoltherapy. The device should be used only original accessories shown in this manual.
2. The device has small components which might be removed and easily swallowed. Use by minors and disabled people require presence of an adult with his faculties. Don't leave the device unattended in places easily accessible by minors and disabled people.
3. Dispose of device ads provided by standards in force.
4. This medical device must be destined exclusively for the use for which it has been designed ad described in this manual.
5. Device not suitable for anaesthesia and lung ventilation.
6. In presence of pathologies with microbial contamination and infection hazard a single-patient use of accessories and nebulizer is recommended (always consult your doctor).
7. The device should be used only with compressor for aerosoltherapy that comply with standards in force.
8. Use the "nose piece" accessory only if expressly indicated by your doctor and paying attention **NEVER** to introduce inside the nose the nasal bifurcation, but only bring it as close as possible.
9. The materials used to contain the drugs are made with highly stable thermoplastic polymers that are resistant against chemicals. Such materials were tested with commonly used drugs (Salbutamol, Beclametasone dipropionate, Acetylcysteine, Budesonide, Ambroxol) and no interaction phenomenon was observed. Interactions cannot however be excluded given the variety and the continuous evolution of the drugs that are used. Remember to:
 - To consume the drugs as quickly as possible after opening its package;
 - To avoid keeping the drug in the tray-like container for too long and to clean it immediately after every application;
 - If the tray-like container presents any abnormal situation (such as softening or cracks), do not introduce any solution and do not proceed with the inhalation. Contact the technical service and describe the methods and type of drugs used.

CLEANING AND WASHING OF ACCESSORIES

Before using and/or after cleaning, pay special attention to ensure that all the accessories supplied with the device are intact. Switch off the device before cleaning it and disconnect the mains cable from the electrical socket.

PREPARATION

1. Pull out the air tube from the nebulizer and leave it plugged into the air outlet nozzle of the device.
2. Rotate the upper part of the nebulizer anti-clockwise.
3. Use your fingers to disconnect the internal pisper at the bottom of the nebulizer.

CLEANING

Before and after each use proceed with cleaning all of the components of the nebulizer (with the exception of the air tube) according to one of the two methods described below.

- Method 1:** Thoroughly clean the components for 5 minutes, using warm drinking tap water (about 40° C) and/or mild soap.
Method 2: Clean the components (except for the air tube) by immersing them in a solution with 60% water and 40% white vinegar. When finished, thoroughly rinse with warm drinking water (approx. 40° C).
After cleaning, rinse thoroughly by removing the excess water and allow to air dry in a clean place.



**DO NOT BOIL OR AUTOCLAVE THE AIR TUBE AND MASKS
DO NOT WASH ACCESSORIES IN A DISHWASHER**

WASHING

If there are pathologies with risks of infection and microbial contamination, it is the end user's responsibility to proceed with suitable washing. The washing procedure can only be carried out if the components to be treated have undergone specific cleaning (see chapter on cleaning).

Proceed as follows for the washing procedure:

- Fill a container, of a suitable size to contain all the individual components, with a solution of drinking water and disinfectant (hypochlorite-based solution readily available in a pharmacy) by following the proportions indicated on the packaging of the disinfectant itself.
- The period of time for which is to be immersed in this solution is indicated on the packaging of the hypochlorite solution in accordance with the chosen concentration for preparing the solution.
- Rinse thoroughly with lukewarm drinking water to remove all traces of the solution. Dry and store in a dry, dust-free environment.
- Dispose of the used solution according to the instructions provided by the manufacturer of the disinfectant solution.

For each individual patient it's recommended to use the nebulizer for 6 months or for a maximum of 120 treatments. The nebulizer must be replaced after a long period of inactivity, if it is deformed or broken, or if the nebulizer nozzle is blocked by dry medicine, dust, ecc.

OPERATING TECHNICAL DATA

Operating minimum flow:	4.0 l/min ± 10%
Operating pressure:	68kPa (0.68 Bar) ± 10%
Operating max flow:	8.0 l/min ± 10%
Operating pressure:	110 kPa (1.10 Bar) ± 10%
Min. capacity:	2 ml
Max. capacity:	6 ml
Storage and trasportation temperature:	min -25° C – max 70° C
Storage and trasportation humidity percentage:	min 0% RH - max 93% RH
Working temperature:	min 5° C – max 40° C
Working humidity percentage:	min 10% RH - max 93% RH
Connection air tube:	ø 5x11 (mm)

HOW TO PREPARE AND TO OPERATE THE DEVICE

To pour the medication rotate the nebulizer top (4) counter clockwise and remove it. Pour the quantity of medication prescribed by your doctor into nebulizer tank.



IN CASE YOU DO SO, EMPTY THE NEBULIZER, CLEAN IT THOROUGHLY AND PROCEED WITH NEW FILLING.

When medication has been poured, connect the nebulizer top (4) into the tank (2), rotate clockwise and insert the accessory prescribed by your doctor into the nebulizer top (4). Firmly connect one end of the air tube (1) to the nebulizer and the other end to the air outlet on the compressor nebulizer for aerosoltherapy. Start the compressor to treatment to begin.



**NEVER INHALE IN HORIZONTAL POSITION.
NEVER BEND THE NEBULIZER OVER 60°.**