MYNEB

INSTRUCTION MANUAL

3A HEALTH CARE

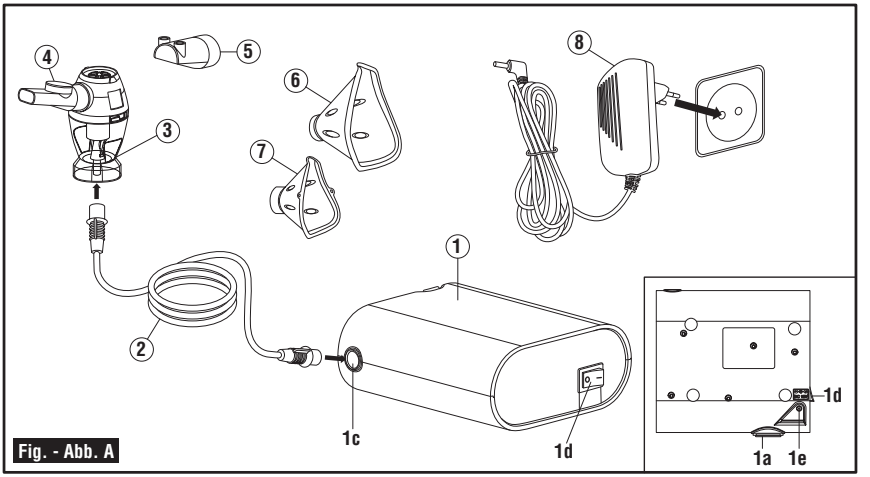

Fig. - Abb. A

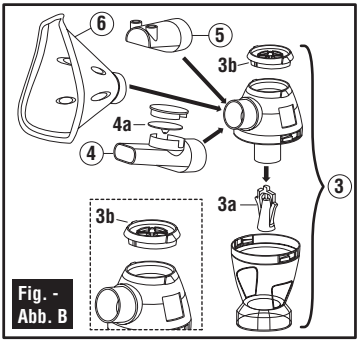

Fig. - Abb. B

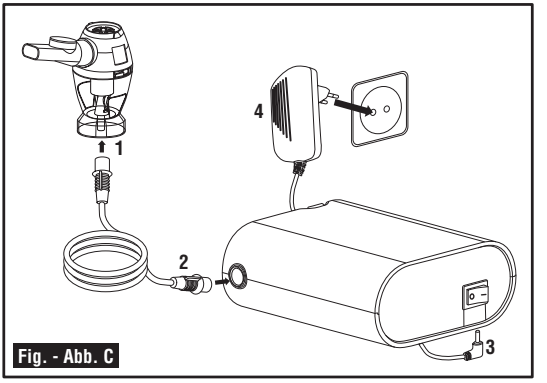

Fig. - Abb. C

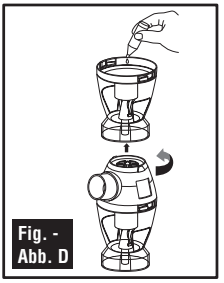
Fig. - Abb. D

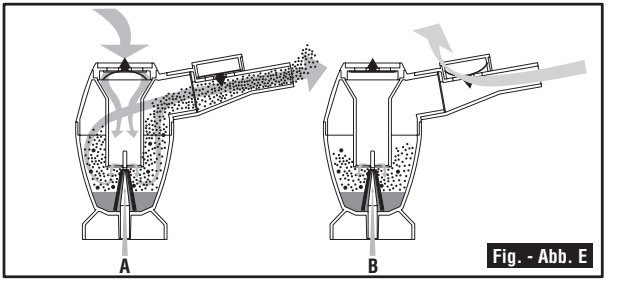

Fig. - Abb. E

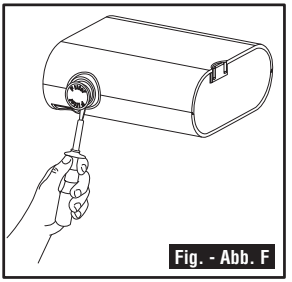
Fig. - Abb. F

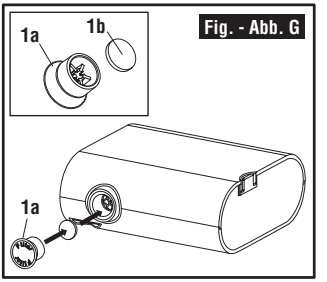

Fig. - Abb. G

3A HEALTH CARE

EN

PISTON MICRO-COMPRESSOR NEBULIZER

1 Piston compressor
1a Air filter compartment
1b Air filter
1c Air hose connector
1d ON/OFF Switch
1e AC adapter socket
2 Air hose
3 Nebuliser Fasterjet
3a Vaporiser head
3b Inspiratory valve
4 Mouthpiece with valve
4a Expiratory valve
5 Nose piece
6 Adult face mask
7 Child face mask
8 AC adapter
Fig. B Assembling nebuliser kit
Fig. C Assembling the device
Fig. D Filling the nebuliser
Fig. E Breath-enhanced nebulisation
Fig. F Opening the air filter compartment
Fig. G Replacing air filter

Dear Customer,
this nebuliser is a high quality device for inhalation therapy for asthma, chronic bronchitis, and other respiratory illnesses. This medical device generates aerosols with variable characteristics to adapt to the patient's respiratory pathology and generating a medicinal mist of particles that are small enough to reach even the deepest regions of your lungs and be of maximal benefit. The operation and usage of the device is very straightforward. All common liquid medication can be used for inhalation therapy. Please read through these instructions carefully so that you understand all functions and safety information. We want you to be happy with your **MYNEB** product. For any further questions you may have, please ask your chemist or usual retailer.

⚠ IMPORTANT WARNINGS

- This device may only be used for the purposes described in these instructions. The manufacturer cannot be held liable for damage caused by incorrect application.
- This device is not suitable for anaesthesia and lung ventilation.
- This device should only be used with original accessories as shown in these instructions.
- Do not use this device and the AC adapter if you think they are damaged or notice anything unusual. Never open this device and the AC adapter.
- This device comprises sensitive components and must be treated with caution. Observe the storage and operating conditions described in the «Technical Specifications» section.
- Protect it from: water and moisture, extreme temperatures, impact and dropping, contamination and dust, direct sunlight, heat and cold.
- Only use the medication prescribed for you by your doctor and follow your doctor's instructions with regard to dosage, duration and frequency of the therapy. All accessories should only be used by one person.
- Never bend the nebuliser over 60°.
- The unit should not be used in the presence of anesthetic mixture inflammable with air, oxigen or nitrous oxide.
- Only use the AC adapter model SJ-1220-E (cod. 3A3309). Do not use this device with other AC adapters. Keep the cord away from hot surfaces.
- Never plug in or unplug the AC adapter with wet hands. Never use this device (with the AC adapter inserted) close to water, do not get the device wet or immerse it in any liquids. If by accident it falls into water, pull the plug out of the wall socket immediately before recovering it.

Ensure that children do not use this device unsupervised; some parts are small enough to be swallowed. Be aware of the risk of strangulation in case this device is supplied with cables or tubes.

⚠ Use of this device is not intended as a substitute for a consultation with your doctor.

PREPARATION AND USAGE OF THIS DEVICE

Prior to using the device for the first time, we recommend cleaning it as described in the section «Cleaning and Disinfecting».

1. Assemble the nebuliser kit **(Fig. B)**. Ensure that all parts are complete.

2. Fill the nebuliser with the inhalation solution as per your doctor's instructions **(Fig. D)**. Ensure that you do not exceed the maximum level.

3. Connect the nebuliser **(3)** with the air hose **(2)** to the air hose connector **(1c)** of the compressor **(1)**, as shown in figure C. Connect the AC adapter **(8)** to the AC adapter socket **(1e)** of the device and plug the power plug of AC adapter into the wall socket.

4. Switch the ON/OFF switch **(1d)** to position «I» to turn on the device and place the mouthpiece **(4)** in the mouth or fit one of the face masks over mouth and nose.
- The mouthpiece gives you a better drug delivery o the lungs.
- Choose between adult **(6)** or child face mask **(7)** and make sure that it encloses the mouth and nose area completely.
- Use all accessories including the nose piece **(5)** as prescribed by your doctor.

5. Breathe in and out calmly during the therapy. Sit in a relaxed position with the upper body upright. **Do not lie down while inhaling**. Stop inhalation if you feel unwell.

6. After completing the inhalation period recommended by your doctor, switch the ON/OFF switch **(1d)** to position «O» to turn off the device. Disconnect the AC adapter **(8)** from the wall socket and from the device.

7. Disconnect the air hose **(2)** from the nebuliser **(3)** and from the air hose connector **(1c)** of the device.

8. Empty the remaining medication from the nebuliser and clean the device as described in the section «Cleaning and Disinfecting».

This device was designed for intermittent use of 30 min. On / 30 min. Off.

Switch off the device after 30 min. use and wait for another 30 min. before you resume treatment.

FASTERJET NEBULIZER (fig. E)

This compressed air system for aerosoltherapy is equipped with the innovative Fasterjet nebuliser with a breath-enhanced valve system. This enables the correct quantity of medication to be featured to the respiratory capacity of each patient. The valve controls the flow of medication during inhalation, thus reducing medication loss during exhalation. Fasterjet increases the quantity of inhaled medication. Fasterjet is capable of nebulising efficiently all medications for inhalation therapy. A synchronized functioning of the nebuliser is possible only by using the mouthpiece with expiratory valve. In order to increase nebulising speed, it is recommended to remove the inhalation valve (blue support) **(3b)** when using a mask or a nose piece.

CLEANING AND DISINFECTING

Thoroughly clean all components to remove medication residuals and possible impurities after each treatment. The compressor **(1)** and the air hose **(2)** should be cleaned with a clean, moist cloth.

• Always wash your hands well before cleaning and disinfecting the accessories.

• Do not expose the compressor to water or heat.

• Replace the air hose for each treatment with a new patient or in case of impurities.

⚠ **Always unplug** the AC adapter from the power supply before cleaning.

Cleaning with water

Wash all nebuliser components (except air hose) **under warm tap water (max 60 °C) for about 5 minutes** adding if necessary a small quantity of detergent following dosage and use limitations as provided by detergent manufacturer. Rinse thoroughly making sure that all deposits are washed away and leave to dry.

Disinfecting

All nebuliser components (except air hose) can be disinfected with chemical disinfectants following dosage and use limitations as provided by disinfectant manufacturer. Disinfectants are usually available at pharmacies.

Sterilizing with steam

All nebuliser components (except air hose and masks) can be heat steam sterilized up to 121 °C (20 min.) or 134 °C (7 min.). EN554/ISO11134.The sterilization packaging must conform to EN868/ISO11607 and be suitable for steam sterilization. After sterilization always let all components cool down to ambient temperature before further use.
Do not repeat sterilization cycle when components are still warm.

MAINTENANCE, CARE, AND SERVICE

Order all spare parts from your dealer or pharmacist.

- It is advisable replace nebulizer after some 100 to 120 treatments on single patient or after about 20 sterilization cycles. Check the filter continually for cleanliness and replace it if dirty, or after a maximum of 3 months use. Spare filters are provided with the device.
- To replace the air filter **(1b)**, extract the air filter compartment **(1a)** from the device using a screwdriver **(Fig. F)**. Exchange the used air filter with a new filter. Gently place the new filter into the inner part of the compartment **(Fig. G)** and make sure that it is correctly fixed.

MALFUNCTIONS AND ACTIONS TO TAKE

• The device cannot be switched on

Ensure the AC adapter **(8)** is correctly plugged to the AC adapter socket **(1e)** of the device and the power plug into the wall socket. Ensure the ON/OFF switch **(1d)** is in the position «I». **(Fig. C)**

• The nebuliser functions poorly or not at all

Ensure the air hose **(2)** is correctly connected at both ends.
Ensure the air hose is not squashed, bent, dirty or blocked. If necessary, replace with a new one.
Ensure the nebuliser **(3)** is fully assembled and the vaporiser head **(3a)** is placed correctly. **(Fig. B)**.
Ensure the required medication has been added. **(Fig. D)**

GUARANTEE

This device is covered by a **3 year** guarantee from the date of purchase. The guarantee is valid only on presentation of the guarantee card completed by the dealer (see back) conforming date of purchase or the receipt. The guarantee covers only the compressor. The replaceable components like nebuliser, masks, mouthpiece, air hose, and filters are not included. Opening or altering the device invalidates the guarantee. The guarantee does not cover damage caused by improper handling, accidents or noncompliance with the operating instructions.

IMPORTANT INFORMATION REGARDING ELECTRO MAGNETIC COMPATIBILITY (EMC)

Electronic devices (PC's, mobile phones, televisions, etc) that generate electromagnetic interference can affect the correct functioning of medical devices. This situation can lead to incorrect functioning creating unsafe conditions.
In order to show compliance with the Directives on Electromagnetic Compatibility (EMC), all the tests introduced by the standard EN60601-1-2:2007 have been implemented. This standard defines the levels of immunity to electromagnetic interference as well as maximum levels of electromagnetic emissions for medical devices: **3A HEALTH CARE** products comply with the levels specified in the standard.
However, when the device is in use, it is best practise not to use mobile phones or other electronic devices which generate strong electromagnetic fields near the medical device. This may create dangerous conditions that put the successful outcome of treatment at risk. On the basis of experience and tests conducted, it is recommended that a minimum distance of 7 m be kept: if the distance is less, the correct functioning of the device should be verified.
Documentation regarding the standard EN60601-1-2:2007 is available from **3A HEALTH CARE** (see the address in the instruction manual) and on the website **www.3-a.it**.

TECHNICAL SPECIFICATIONS

Nebulisation rate:	0.45 ml/min. (NaCl 0.9%)
Particle size:	75% < 5 µm NaCl 0.9%
	3.11 µm (MMD with 0.9% NaCl using Cascade Impactor)
Compressor air flow:	12 l/min.
Acoustic noise level:	51 dB
Power source:	12V DC 2A
AC adapter:	Input: 100-240VAC 50/60Hz 0.6A
	Output: 12V DC 2A
Nebuliser capacity:	min. 2 ml; max. 16 ml
Operating limits:	30 min. On / 30 min. Off
MDD 93/42/EEC	
Class of risk:	IIa
Weight:	approx. 450 g
Dimensions:	132(L) x 140(W) x 60(H) mm
Expected service life:	5 years

Technical alterations reserved.

Operating Temperature/Humidity: +10° C to +40° C / 10% to 95% RH
Storage and Transport Temperature/Humidity/Air Pressure: –25° C to +70° C / 10% to 95% RH / 690 - 1060hPa

SYMBOLS

Type BF device

Class II

Switch “OFF”

Switch “ON”

Alternating current

Do not use the unit when taking a bath or a shower

It is compulsory to carefully read the instructions before using this device

IP21 The device’s casing is protected against solid particles having diameter of 12.5 mm or above, vertically falling water drops and access to hazardous parts with a finger.

CE 0051 Conforms to Directive 93/42/EEC for medical devices

3A HEALTH CARE S.r.l.
Via Marziale Cerutti, 90F/G
25017 Lonato del Garda (BS) - ITALY

DISPOSAL PROCEDURE (Dir. 2012/19/Ue-WEEE) The symbol on the bottom of the device indicates the separated collection of electric and electronic equipment. At the end of life of the device, do not dispose it as mixed solid municipal waste, but dispose it referring to a specific collection centre located in your area or returning it to the distributor, when buying a new device of the same type to be used with the same functions. This procedure of separated collection of electric and electronic devices is carried out forecasting a European environmental policy aiming at safeguarding, protecting and improving environment quality, as well as avoiding potential effects on human health due to the presence of hazardous substances in such equipment or to an improper use of the same or of parts of the same. **Caution!** The wrong disposal of electric and electronic equipment may involve sanctions.

CERTIFICATO DI GARANZIA

Valevole 36 mesi dalla data di vendita

WARRANTY CERTIFICATE

Validity 36 months from date of purchase

Data di vendita _____ Rivenditore (timbro e firma) _____

Date of purchase _____ Dealer (Stamp and signature) _____

La presente garanzia non è valida se non “unitamente allo scontrino fiscale dell’apparecchio” e all’apparecchio difettoso. Sono esclusi dalla garanzia danni causati da usi impropri, incidenti o mancanza di cure opportune.
This warranty certificate is valid only if returned to your dealer along with Receipt and Faulty Unit. Warranty does not cover damages caused by misuse, crashes or lack of attention.

DESCRIZIONE GUASTO / FAULT DESCRIPTION

3A HEALTH CARE S.r.l.
Via Marziale Cerutti, 90F/G
25017 Lonato del Garda (BS) - ITALY

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