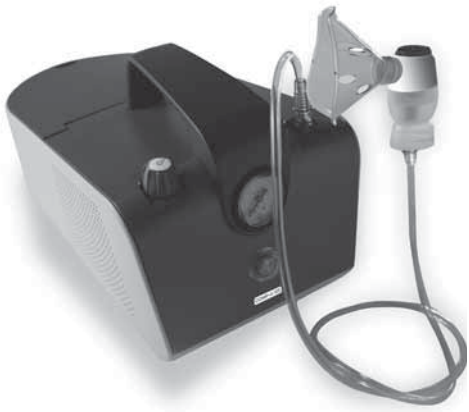
COMP-A-NEB

GUARANTEED 3 YEARS

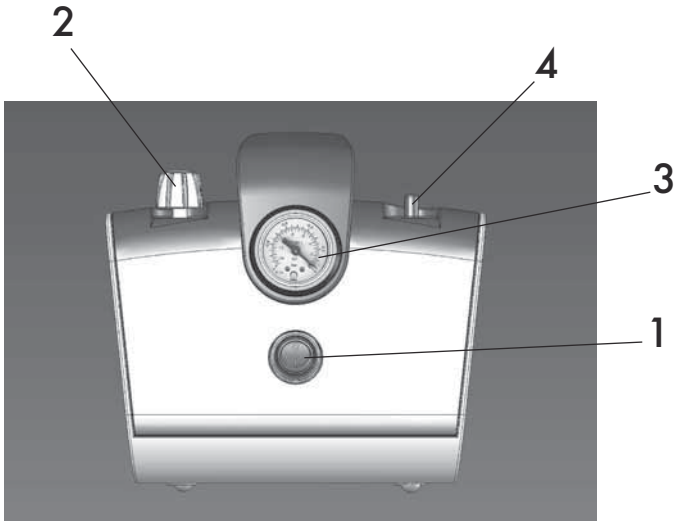
PROFESSIONAL

ISTRUZIONI D'USO
INSTRUCTION MANUAL
MONTAGE-UND GEBRAUCHSAWEISUNG
MANUEL D'INSTRUCTIONS
MANUAL DE INSTRUCCIONES



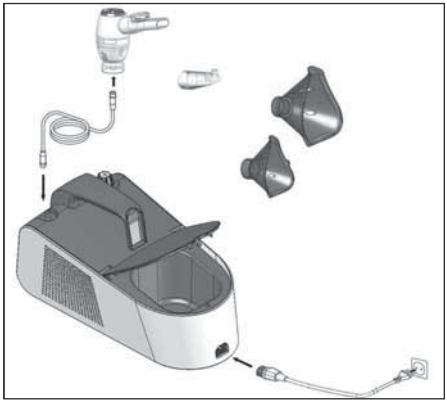
3A HEALTH CARE

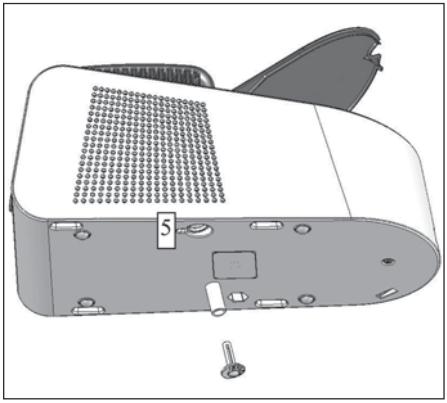
COMP - A NEB



1. I/O Switch
2. Vial pressure regulator
3. Vial pressure display gauge
4. Air connector
5. Intake air filter

SUPPLIED ACCESSORIES:
FASTERJET Nebuliser Kit
(Nebuliser – Paediatric and adult masks – Mouth piece - Nasal tube) *
SEE ACCESSORIES MANUAL
Porex filter replacement





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USE AND MAINTENANCE MANUAL

CE 0434 dir.93/42/EEC

GB

Medical Device (Class II – MDD 93/42/EEC)
Read the instructions carefully before use

COMP-A NEB is a professional device for the administration of drugs to treat and ease the respiratory organs and tracts, administered via aerosol therapy upon personal physician's recommendation. ** Ideal for both, domestic and outpatient use.
COMP-A NEB is equipped with a piston compressor and a built-in replaceable air filter (which shall be replaced every 70 applications).
Rugged and reliable and lubrication-free, it is manufactured in accordance with the current European Regulations for the safety of electromedical devices **(EN 60601–1; EN13544-1)** and it is tested in accordance with the EMC Regulations **(EN60601-1-2);**
COMP-A NEB is supplied with 3A production accessories (see accessories manual), laboratory tested and inspected according to the latest scientific criteria regarding biological safety and efficacy (the biocompatibility of the accessories is certified by specialised Laboratories).

WARNING

- This is a medical device for for personal/professional use and it must be used only upon medical prescription. It must be used as described in this manual. E' importante che il paziente legga e comprenda le informazioni per l'uso e la manutenzione dell'unità. Contattate il Vostro rivenditore di fiducia per qualsiasi domanda.
- Do not use this device for anything other than its intended use, which is aerosol therapy. The manufacturer is not responsible for misuse.
- This device is not suitable for anesthesia and pulmonary ventilation.
- This device is not suitable for use in presence of anaesthetic blend inflammable with air, oxygen, or nitrous oxide.
- The device is not watertight. **
- This device must be used exclusively with the original accessories described in the instruction manual.
- Always use the device and its accessories following the recommendations and instructions of your physician. Use exclusively the proprietary medicinal products prescribed by your physician, administering them as recommended by your physician.
- Never use extension cables or adapters, always fully unwind the power supply cable, in order to avoid overheating, which is dangerous. Keep the device and the cable away from hot surfaces. Always unplug the cable after use.
- Never immerse the product into water; if this happens, unplug the cable from the socket immediately. Never pull out or touch the device immersed in water before having unplugged the cable form the socket. Do not use the device after it has been pulled out from water (send it immediately to your preferred retailer).
- Never open and/or alter the device. If the device is not functioning correctly, turn it off and check the instructions. For any type of repair, contact your preferred retailer.
- The device contains small parts that can easily be removed and ingested. ** Minors and disabled people must always be assisted by an adult in full mental capacity. Never leave the device unattended in places that easily accessible by minors and disabled people.
- Keep it in a dry and clean place, away from light, heat sources and wather. **
- Dispose the device according to the existing regulations.

INSTRUCTION FOR THE OPERATION OF THE DEVICE

1. Plug the device to a power supply socket with the same voltage ad the one specified for the device.
2. * Unscrew the vial to split it in two parts (fig. A).
3. * Fill the lower part of the vial with the drug prescribed by the physician (fig.B). Warning: the level marks on the vial are only indicative.
4. * Reassemble the two parts of the vial (fig.C).
5. * Insert the tube coming from the OUTLET compressor (fig.C).
6. * Apply, with the apposite joint, the desired treatment accessory: mask, mouthpiece or nasal tube.
7. After the application turn off the device and unplug the cable.

*** Also check the accessories instructions manual.**

CLEANING AND DISINFECTING

Clean your hands thoroughly before cleaning and the disinfecting of the accessories.

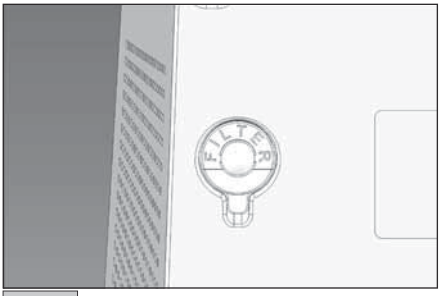


Fig.1a

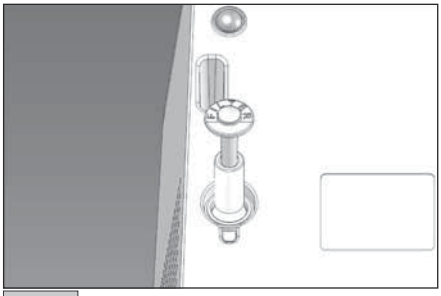


Fig.2b

Replacing the filter:
Lift the filter lid on the bottom of the device, applying leverage with a flathead screwdriver as shown in figure 1A; remove the filter you wish to replace and put the new one as shown in figure 1b. Then place the filter lid in its housing, making sure it adheres to the surface.

Cleaning the compressor:
Never wash the device under the water or immersing it in the water, if you wish to clean it use soft cloth dampened with some (non abrasive) detergent.

Cleaning the accessories:
See the accessories instructions manual

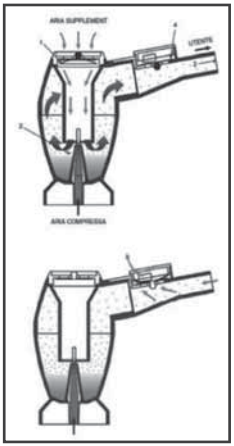
Note In case the device does not work correctly after the inspections, contact your preferred retailer.

TECHNICAL CHARACTERISTICS OF THE DEVICE

Rotation piston compressor, lubrication-free. The device is thermally protected. In case high temperatures are reached, the thermal protector intervenes and it interrupts the operation of the device. In this case let the device cool off for at least 60 minutes before turning it on again.

- Supply voltage: see data label
- Safety fuse: see data label
- Operation pressure (nebuliser): from 0 to 110 kPa approx. (suggested range: from 70 to 110 kPa)
- MAX pressure: 280 kPa approx.
- Air supply to compressor: 15 l/min. approx.
- Air supply to vial: from 0 to 6.8 l/min
- Size: 196 x 357 x 185 (H) mm
- Weight: 2.5 Kg
- Noise emission (from 1 Mt.): 55 dBA (according to EN13544-1)
- Continuous use
- Nebuliser 0.60 ml/min (tap closed)
- Professional aspiration filter: 50/70 micron
- Operation conditions: Temperature: min. 10°C; max. 40°C
- Air humidity: min. 10%; max. 95%
- Preservation conditions: Temperature: min. – 25°C; max. 70°C
- Air humidity: min. 10%; max. 95%
- Performance of the nebuliser (EN13544-1): See accessories user manual
- Nebulisation setting parameters with vial filling volume of 4ml of NaCl 0.9%

The Fasterjet vial is equipped with a valve system that decreases the dispersion of the drug:



Inhalation phase (active)
Valve (1) opens due to the pressure applied by the user during the inhalation phase. The additional air flow, is drawn by Venturi effect by the depression in the spray generation area (2). This flow increases considerably the external convey of the spray , towards the user (3). The exhaust valve (4) remains closed and no nebulisation dispersion occurs.

Exhalation phase (passive)
The user terminates the inhalation phase and the valve (1) goes back to the idle position, closing the convey of additional air. The external convey of the spray generated by the nebuliser is therefore inhibited and is available for the next inhalation phase. Druing the exhalation phase, the user generates a pressure increase that opens the exhaust valve (4) that lets out the exhaled air.

NEBULISATION: 3 USEFUL TIPS

The drug is drawn by the user during the inhaling phase. It reaches the respiratory tracts, without being dispersed in the environment.
When exhaling, the drug convey is inhibited, so it will be available for the following inhalation.

Synchronised operation with valve system is possible when using the mouthpiece as an accessory. In case you are using the nasal tube or the masks, we recommend to remove the inhaling valve (1) to increase the nebulisation speed

B-Type device

Caution!! Check the instructions!

Class II device

Switch on

Switch off

AC

Do not use this device in the bathtub or in the shower

Safety fuse

CE 0434 Compliant with the 93/42/CEE Directive

Problem, Causes and Troubleshooting

THE DEVICE DOES NOT TURN ON
Make sure that it is properly plugged in to a power supply socket. Make sure that the switch is positioned on (I), ON position.
THE DEVICE IS ON BUT IT DOES NOT NEBULISE
Make sure that the nebulisation nozzle (pisper) in inserted in the vial. Make sure that the air connection tube is not twisted or pressed. Make sure that the air intake filter is not occluded or dirty. In this case, replace it. Make sure that the drug is inside the vial.
THE DEVICE DOES NOT WORK
Thermoprotection intervened for the following reasons: the device was working near heat sources or in environments with temperature higher than 40°C. Let the device cool off for at least 60 minutes, then turn it on again.

WARRANTY

Valid for 36 months since the date of purchase

WARRANTY CONDITIONS

- The device is guaranteed for 36 months from the date of purchase against any manufacturing or material flaws, as long as it has not been altered by the client or non-authorised personnel.
The warranty covers the replacement or the repair of the construction components.
- For sanitary reasons the replacement of the device is strictly forbidden, since it is a strictly personal medical device.
- This warranty does not cover those parts subject to normal wear, the damage caused by misuse, falling, transport, lack of maintenance, or any other cause that cannot be imputed to the manufacturer.
- 3A Health Care declines any responsibility for direct or indirect damage due to misuse.
- In case of failure, the device, properly cleaned and packaged, must be immediately sent to your preferred retailer, attaching this warranty certificate, filled-in as required, along with the receipt or the purchase invoice; otherwise the warranty will be considered void and the repair will be charged.
- The shipping costs must be borne by the customer.
- 3A Health Care is not responsible for further warranty extensions provided by third parties.

ATTENTION: THE WARRANTY IS VALID ONLY IF IT HAS BEEN COMPLETELY FILLED IN AND IF IT IS COMPLETE WITH RECEIPT/PURCHASE INVOICE.

MOD.: COMP-A NEB

SERIAL NUMBER:_____

DEFECT FOUND:_____

_____

Attach the receipt or purchase invoice	Retailer (stamp and signature)

AVVERTENZE PER IL CORRETTO SMALTIMENTO DEL PRODOTTO AI SENSI DELLA DIRETTIVA EUROPEA 2002/95CE - 2002/96CE - 2003/108CE. Il simbolo del cassonetto barrato riportato sull'apparecchiatura indica che il prodotto alla fine della propria vita utile deve essere raccolto separatamente dagli altri rifiuti. L'utente dovrà, pertanto, conferire l'apparecchiatura giunta a fine vita agli idonei centri di raccolta differenziata dei rifiuti elettronici ed elettrotecnici, oppure riconsegnarla al rivenditore al momento dell'acquisto di una nuova apparecchiatura di tipo equivalente, in ragione di uno a uno. L'adeguata raccolta differenziata per l'avvio successivo dell'apparecchiatura dismessa al riciclaggio, al trattamento e allo smaltimento ambientalmente compatibile contribuisce ad evitare possibili effetti negativi sull'ambiente e sulla salute e favorisce il riciclo dei materiali di cui è composta l'apparecchiatura. Lo smaltimento abusivo del prodotto da parte dell'utente comporta l'applicazione delle sanzioni amministrative di cui al dlgs. n. 22/1997" (art. 50 e seguenti del dlgs. n. 22/1997). WARNING REGARDING DISPOSAL OF THIS APPLIANCE IN COMPLIANCE WITH THE PROVISIONS OF 2002/95CE – 2002/96CE – 2003/108CE EUROPEAN DIRECTIVESThe crossed-out wheeled bin symbol on this equipment means that this product must be collected separately from normal wastes at the end of its useful lifespan.At the end of the appliance useful lifespan, users must therefore take it to an authorised disposal centre for the recycling of electronic and electro-technical waste or they should take it back to the retailer upon purchase of a new, similar appliance, on a one-to-one basis.An adequate separate waste collection system for later recycling, treatment and environmentally-friendly disposal of the appliance avoids a negative impact on the environment and health, as well as it facilitates the recycling of the product's different components.Users who dispose of products in an unauthorised manner shall be liable for administrative penalties in compliance with Article 50 of the Legislative Decree No. 22/1997 and the following articles. AVERTISSEMENT CONCERNANT L'ÉLIMINATION CORRECTE DU PRODUIT AUX TERMES DE LA DIRECTIVE EUROPÉENNE 2002/95CE - 2002/96CE - 2003/108CELe symbole d'une poubelle barrée présent sur l'appareil indique que, à la fin de sa vie utile, il doit être traité séparément des autres déchets.L'utilisateur devra donc remettre l'appareil usé aux centres de collecte et tri des déchets électroniques et électrotechniques correspondants, ou le rendre au revendeur au moment d'acquérir un nouvel appareil du même type, à raison d'un par un.La collecte et le tri appropriés de l'appareil rejeté - destiné par la suite au recyclage, au traitement et à l'élimination compatibles du point de vue écologique - contribue à éviter de possibles effets négatifs sur l'environnement et sur la santé, et favorise le recyclage des matériaux composant l'appareil.L'élimination abusive du produit de la part de l'utilisateur entraîne l'application des sanctions administratives conformément au décret législatif n° 22/1997 (art. 50 et successifs) HINWEIS FÜR DIE ENTSORGUNG DES PRODUKTES GEMÄSS DER EUROPÄISCHEN RICHTLINIEN 2002/95 EG – 2002/96 EG – 2003/108 EGDas auf der Anlage angebrachte durchgestrichene Containersymbol weist darauf hin, dass das Produkt am Ende seiner Lebensdauer gesondert entsorgt werden muss.Das heißt, der Benutzer muss die Anlage am Ende ihrer Nutzungsdauer an einen für elektrische und elektrotechnische Abfälle befugten Entsorger übergeben, oder sie bei der Anschaffung einer neuen bzw. ähnlichen Anlage bei dem Händler abgeben.Die für das spätere Recycling, Behandlung und umweltfreundliche Entsorgung angemessene selektive Abfallsammlung der Anlage trägt dazu bei, mögliche negative Auswirkungen auf die Umwelt und für die Gesundheit zu vermeiden und das Recycling der Materialien der Anlage zu fördern.Die unbefugte Produktentsorgung seitens des Benutzers führt zur Verhängung der in der Gesetzverordnung N.22/1997 (Paragraph 50ff der Gesetzverordnung N. 22/1997) aufgeführten Verwaltungsstrafen. ADVERTENCIAS PARA LA ELIMINACIÓN DEL PRODUCTO CONFORME A LA DIRECTIVA EUROPEA 2002/95CE – 2002/96CE – 2003/108CEEl símbolo del contenedor tachado presente en el equipo indica que el producto, cuando finaliza su vida útil, se debe recoger en forma separada del resto de los residuos.Por lo tanto, cuando finaliza la vida útil del equipo, el usuario debe entregarlo a los centros de recogida selectiva de residuos electrónicos y electrotécnicos idóneos, o bien, entregarlo al revendedor cuando se adquiere un nuevo equipo similar, en razón de uno a uno.La recogida selectiva apropiada para el posterior reciclado, tratamiento y eliminación ambiental compatible del equipo, contribuye a evitar posibles efectos negativos en el ambiente y en la salud, y favorece el reciclado de los materiales que conforman el equipo.La eliminación no autorizada del producto por parte del usuario implica la aplicación de las sanciones administrativas descritas en el Decreto Legislativo n. 22/1997 (Art. 50 y sucesivos del Decreto Legislativo n. 22/1997).

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