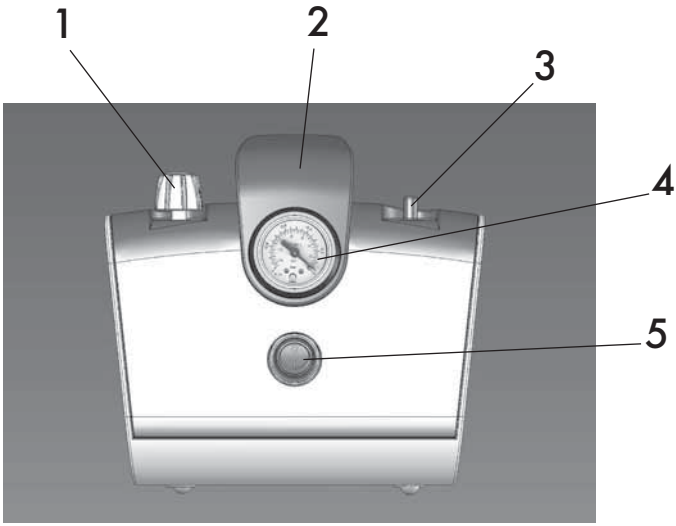
PROFESSIONAL

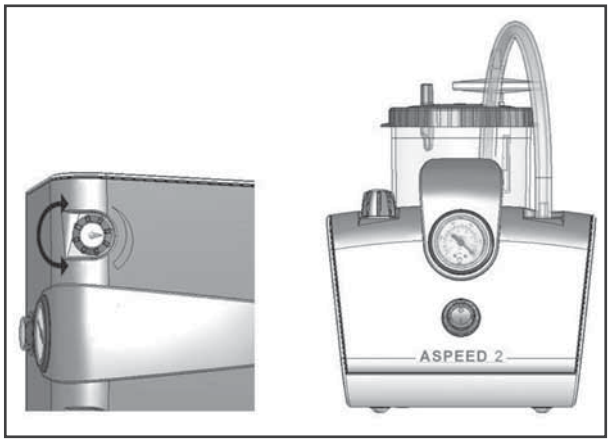
ISTRUZIONI D'USO
INSTRUCTION MANUAL
MONTAGE-UND GEBRAUCHSAWEISUNG
MANUEL D'INSTRUCTIONS
MANUAL DE INSTRUCCIONES

3A
HEALTH CARE

ASPEED 2 ASPIRATOR



1. Vacuum regulator
2. Transportation handle
3. Rubber holder
4. Vacuum gauge
5. Main switch



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USE AND MAINTENANCE MANUAL

CE 0434 dir.93/42/EEC

GB

TECHNICAL SPECIFICATIONS

Piston electric-compressor, with thermal protection
Single puma version: low flow, high vacuum device
Dual pump version: high flow, high vacuum device
Fuse: T1,6A – 250V

Supply voltage, single pump version: **230V ~ 50Hz 150VA**

Supply voltage, dual-pump version: **230V ~ 50Hz 70VA**

Adjustable void level: **0 ÷ -0,85 bar (85 kPa)**

Air supply, single pump version: **15 l/min.**

Air supply, dual-pump version: **22 l/min.**

Size: **196 x 357 x 185(H) mm**

Weight, single pump version: **2,5 kg**

Weight, dual pump version: **3,2 kg**

Noise: **55 dBA**

Class of risk according to the 93/42/EEC directive: **IIa**

Operation conditions: **Temperature min. 0°C max 40°C** – Air humidity: **min. 10% max 95%**

Preservation conditions: **Temperature min. -10°C max 50°C** – Air humidity: **min. 10% max 95%**

Operation/preservation atmospheric pressure: **min. 690 hPa max 1060 hPa**

 BF-Type device

 Read the instructions for use carefully!

 Class II device

I Main switch on

O Main switch off

~ AC

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

 Single use

 Safety fuse

Operation cycle: **Continuous use**

Protection category: **IP20**

CE 0434 Compliant with the 93/42/EEC Directive

Reference standards applied: **EN 10079 -1, EN 60601-1, EN 60601-1-2**

The ASPEED2 aspirator is a professional device suitable for home and outpatient use, specific for secretion-aspiration. It is equipped with Vacuum regulator (1), vacuum gauge (4), 1000 cc pots. with protection device, for the liquid intake on the suction pump, that interrupts the suction flow. It is lubrication-free, handy, easy to use, reliable, sturdy and quiet. The ASPEED 2 aspirator is supplied with the following 3A accessories: 1000 cc. pot with protection device, power supply cable, connection tube in sterilisable silicon Ø 6x12 short, connection tube in sterilisable silicon Ø 6x12 long, sterile and single usepipe, sterile and single use manual regulator, single use bag, Single use antibacterial filter.
Note: Use original 3A accessories ONLY.

⚠ IMPORTANT WARNINGS

This is a medical device and it must be used only upon medical prescription. It must be used as described in this instruction manual. The user must read and understand in full the information regarding the use and maintenance of the unit. For any question, do not hesitate to contact your preferred retailer. MICROBIAL CONTAMINATION: due to pathologies with risk of microbial infection and contamination a personal use of the accessories is recommended (ask your physician). **
The manufacturer does anything possible to provide a product equipped with the highest quality and safety features, although, being it an electric device, some fundamental safety directions must be observed:

- Kids and non self-sufficient people must always use the device under strict supervision of a competent adult in his full-capaci ty and who has read and understood this manual.
- This device must only be used for its intended purpose: aspirator for outpatient and domestic use; any other use is conside red improper and dangerous and the manufacturer cannot be held responsible for any consequence of misuse.
- Never use adapters for voltages different from the voltage indicated on the data label on the back of the device.
- Keep the cable away from hot surfaces.
- This device is not suitable for use in presence of anaesthetic blend inflammable with air, oxygen, or nitrous oxide.
- Never handle the power supply cable plug with wet hands, and never use the device in the bath tub or in the shower. **
- Never leave the device near water, never immerse it in any liquid, never wet it, if it gets wet immediately unplug it from the power supply socket before touching it. Do not use the device if the plug or the power supply cable are worn or wet (immediately send it to your preferred retailer).
- The device is not watertight.
- Always unplug the power supply cable immediately after use.
- Maintenance and/or repair must be carried out only by authorised personnel. Non-authorised repairs void the warranty.
- Do not turn over the pot while it is connected to the device in function, since the liquid would come into contact with the hydro phobic antibacterial filter, immediately blocking suction; in case this happens, empty the pot and replace the antibacterial filter.
- The device is equipped with a safety fuse, mounted inside the device, in case you wish to replace it, unplug the device before proceeding.
- The pipe and the manual control of the flow are sterile and single-use products: they must be replaced after each applica tion. Check the expiration date on the original packaging of the pipe and the suction flow manual control and verify the integrity of the sterile packaging.
- The antibacterial filter is a single-use device and it must be replaced after each application.
- Before each use always perform the cleaning and disinfecting operations as mentioned in the paragraph “Cleaning and disinfecting operations” of this instructions manual.
- Device not protected against splashes.

⚠ INSTRUCTION FOR USE

Before each use, verify that all the accessories are perfectly clean
in accordance with the instructions of the section “CLEANING AND DISINFECTING OPERATIONS”.
1. Connect the device as shown in figure.
2. With the vacuum regulator (1) you can set the depression value (bar). depression - check Rotate the knob towards “+” to increase the vacuum and rotate it towards “-” to decrease it, the values can be read on the vacuum gauge (4).
3. Turn the device on by putting the switch on the “I” position (ON) (5).
4.After the application turn off the device and unplug the cable form the power supply socket and carry out the cleaning and disinfecting operations as described in the “CLEANING AND DISINFECTING OPERATIONS” paragraph.
5. 1000 cc Secretion collection pot.

The 1000 cc collection pot provided with the aspirator can be used in two ways. as sterilisable collection pot, or as collection pot with single use bag.

Sterilisable secretion collection pot
The antibacterial filter must be inserted directly in the pot's lid. Never use the aspirator without the antibacterial filter, since it is very dangerous for the patient. The collection pot is supplied with overflow valve, lid and pot in a see through material (polycarbonate). The antibacterial filter must be placed directly in the lid, only on the hole called VACUUM. The antibacterial filter protects the suction circuit from possible contaminants sucked during use. All the components of the pot can be conventionally sterilised in autoclave at a maximum temperature of 121°C, or by boiling them for 10 minutes. We recommend to replace the whole pot every 30 sterilisation cycles. Do not turn over the pot during use to prevent the backflow valve from being activated; if this happens turn off the aspirator and remove the tube connected to the antibacterial filter. Never use the aspirator without the secretion collection pot and/or without the antibacterial filter.
Connection: connect one end of the short sterilisable silicon tube to the rubber holder of the antibacterial filter and put the latter in the "VACUUM" input of the blue lid, connect the other end to the "INLET" input of the aspirator. Connect one end of the sterilisable silicon tube to the "PATIENT" input of the blue lid; connect the sterile single-use manual regulator to the other end and connect the single-use sterile pipe to the regulator.

Secretion collection pot with single-use bag. The aspirator can be used with the 1000 cc re-usable transparent secretion collection pot and with the single-use bag supplied. In this case the antibacterial filter is integrated in the single-use bag, therefore the antibacterial filter and the blue lid with the valve should not be used. The filter embedded in the bag, also prevents the reflux of the liquids sucked towards the aspirator when it is full, or when it is inadvertently turned over. In this case to restore the device to normal operation, the single-use bag shall be replaced. For the cleaning and disinfecting the vial, sterilise the single parts in autoclave at a maximum temperature of 121°C, or by boiling them for 10 minutes. The bag is single-use and it MUST be replaced after each use. The bag must always fully inserted in the pot to avoid vacuum loss.

Note: Maximum use depression of the single-use bag: -0.75 bar.

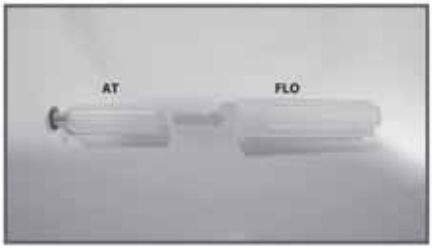
Connection: connect one end of the short sterilisable silicon tube to the yellow rubber holder (VACUUM) of the lid and the other end to the "INLET" input of the aspirator. connect one end of the long sterilisable silicon tube to the red rubber holder (PATIENT) and connect the sterile single-use manual regulator and the single-use sterile pipe to the other end.
Note: only use single-use 1 lt Meditea bag, code: M043002/A.

CLEANING AND DISINFECTING OPERATIONS

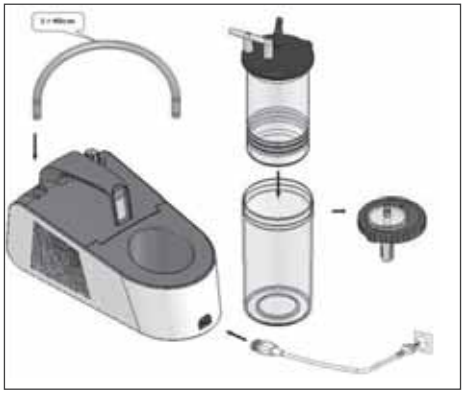
Note: If you are using chemical disinfectants, strictly follow the manufacturer's directions.
- The pipe, the suction flow manual control are sterile single-use products and they must be replaced after each application.
- The antibacterial filter is a sterile single-use product and it must be replaced after each application.
- Never wash the device under the water or immersing it in the water, clean the external cover of the device with a soft cloth dampened with some (non abrasive) detergent.

PERIODICAL CHECK FOR THE SAFETY OF THE DEVICE

ASPEED 2 does not need maintenance and/or lubrication, although it is required to perform some simple checks before each use:
- Check the integrity of the shell and the power supply cable.
- Using a finger, close the suction connector and verify that the vacuum level reaches 0.80÷0.85 bar.
- Verify that there is no disturbing noise that may be the symptom of a malfunction.
- Check that the cage is correctly positioned inside its housing. It must be aligned with the suction hole of the lid, so the valve of the float can obstruct it when the sucked liquid is too much against the maximum quantity that can be assimilated by the pot.
- Check that the float is mounted in the right position and that it is free to slide inside the cage (dirt and deposits can obstruct its movement). The picture below shows how to properly put the float in the cage.



CONNECTION SCHEME FOR THE SINGLE USE BAG VERSION AND THE STERILISABLE POT VERSION



STERILISABLE POT VERSION

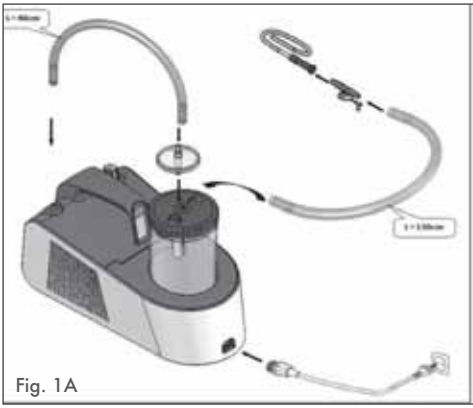


Fig. 1A

SINGLE-USE BAG VERSION

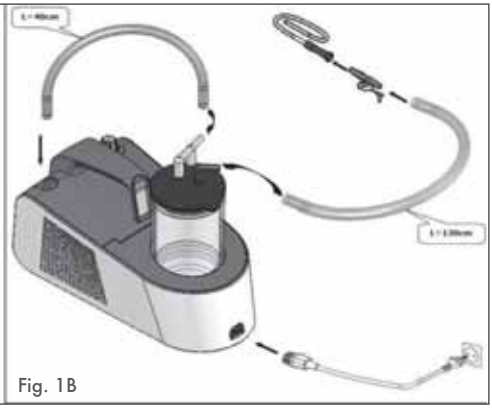


Fig. 1B

Problem, Causes and Troubleshooting

PROBLEMS	POSSIBLE CAUSES	TROUBLESHOOTING
Excessive noise	Damaged pump or obstructions in the internal suction duct	Send to the customer care service
The unit turns on but it does not suck	- Damaged pump - Vacuum regulator fully open. Connection tubes unplugged and/ or not connected properly, damaged connection tubes. Vial in a non-vertical position, full or defective overflow valve; possible obstruction of the internal hydraulic circuit of the unit	- Send to the customer care service - Check the position of the vacuum regulator. Check the integrity of the tubes and their connections. Put the vial in a vertical position, check the overflow valve (blocked) and/or replace the vial. Replace the silicon tubes
The vacuum value cannot be adjusted	Damage to the internal hydraulic circuit or obstruction of the connection tubes to the aspiration unit	Send to the customer care
The protection fuse is activated any time the device is turned on	Pump damaged or in short circuit.	Send to the customer care
The vacuum gauge does not work	Liquids penetrating in the pneumatic circuit	Send to the customer care

Note: In case of anomalies, malfunctions and/or problems different from the ones listed above, always contact only authorised assistance centres.

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.
- 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 S.r.l 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 S.r.l 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.: ASPEED 2

BATCH:_____ SERIAL NUMBER:_____

DEFECT FOUND:_____

_____

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) HIINWEIS 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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