ASPEED PROFESSIONAL

ISTRUZIONI D'USO

INSTRUCTION MANUAL

MANUEL D'INSTRUCTIONS

MONTAGE-UND GEBRAUCHSANWEISUNG

MANUAL DE INSTRUCCIONES

HEALTH CARE

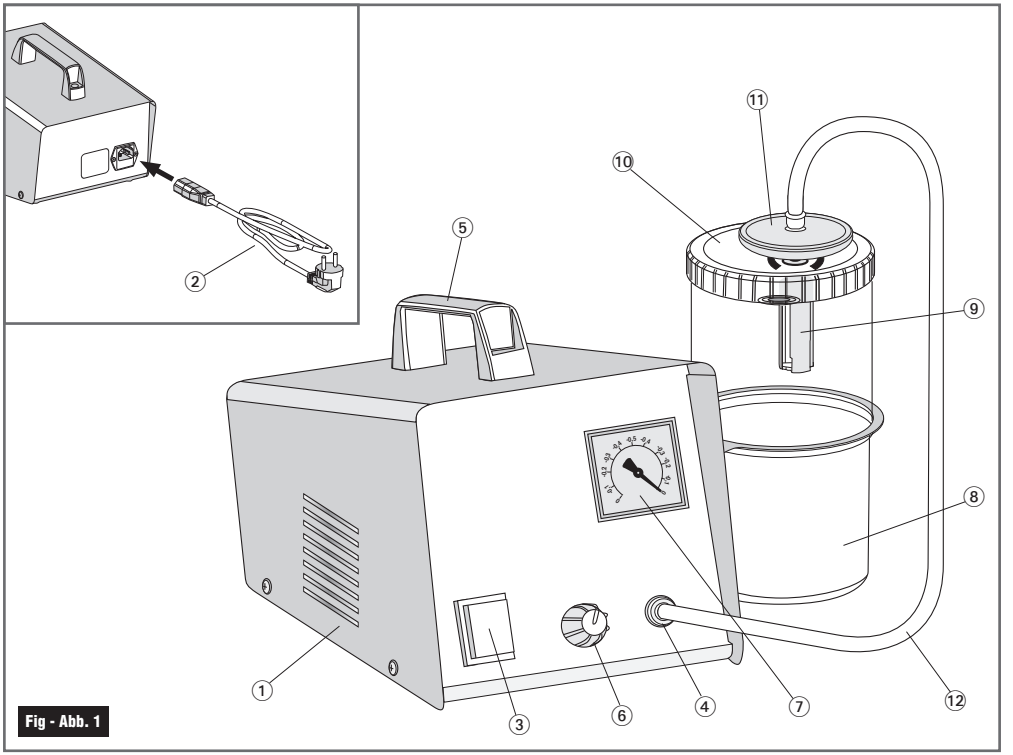

Fig - Abb. 1

IT

1. Aspiratore
2. Cavo alimentazione
3. Interruttore I/O
4. Presa entrata-aria INLET
5. Maniglia di trasporto
6. Regolatore di vuoto
7. Vuotometro
8. Vaso da 1.000 ml
9. Dispositivo di protezione
10. Tappo per vaso
11. Filtro antibatterico
12. Tubo in silicone 50 cm

EN

1. Aspirator
2. Power cord
3. ON/OFF Switch
4. Air inlet connector INLET
5. Trasportation handle
6. Vacuum regulator
7. Vacuum gauge
8. 1.000 ml Vessel
9. Protection device
10. Vessel plug
11. Antibacterial filter
12. 50 cm silicon tube

F

1. Aspirateur
2. Câble d'alimentation
3. Bouton Marche/Arrêt
4. Prise entree air INLET
5. Poignée de transport
6. Régulateur de vide
7. Vacuomètre
8. Vase de 1.000 ml
9. Dispositif de protection
10. Bouchon pour vase
11. Filtre antibactérien
12. Tube en silicone 50 cm

D

1. Aspirator
2. Netzkabel
3. I/O Schalter
4. Anschluss INLET
5. Tragegriff
6. Vakuumregler
7. Vakuummessgerät
8. Gefäß 1.000 ml
9. Schutzvorrichtung
10. Gefäßdeckel
11. Bakterienfilter
12. Silikonschlauch 50 cm

E

1. Aspirador
2. Cable eléctrico
3. Botón ON/OFF
4. Toma entrada-aire INLET
5. Manija de transporte
6. Regulador de vacío
7. Vacuómetro
8. Vaso de 1.000 ml
9. Aparato de protección
10. Tapón para el vaso
11. Filtro antibacteriano
12. Tubo de silicona 50 cm

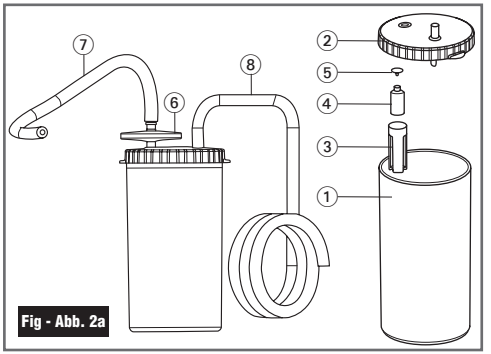

Fig - Abb. 2a

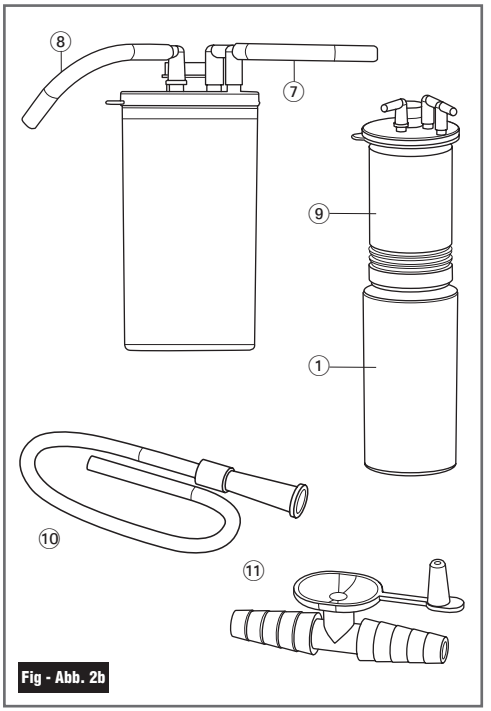

Fig - Abb. 2b

E

1. Frasco de recogida gradado mediane serigrafia 1.000 ml de policarbonato esterilizable
2. Tapón de polipropileno esterilizable
3. Guía del flotador de polipropileno esterilizable
4. Cuerpo del flotador de polipropileno esterilizable
5. Válvula de goma esterilizable
6. Filtro antibacteriano
7. Tubo de silicona esterilizable de Ø 6x12 mm de diámetro - 50 cm
8. Tubo de silicona esterilizable de Ø 6x12 mm de diámetro - 130 cm
9. Bolsa desechable
10. Cánula estéril desechable
11. Regulador manual estéril desechable

IT

1. Vaso di raccolta serigrafato 1.000 ml in policarbonato sterilizzabile
2. Tappo in polipropilene sterilizzabile
3. Guida galleggiante in polipropilene sterilizzabile
4. Corpo galleggiante in polipropilene sterilizzabile
5. Valvola in gomma sterilizzabile
6. Filtro antibatterico Monouso
7. Tubo in silicone sterilizzabile Ø 6x12 mm - Lunghezza 50 cm
8. Tubo in silicone sterilizzabile lungo Ø 6x12 mm - Lunghezza 130 cm
9. Sacca monouso
10. Cannula sterile monouso
11. Regolatore manuale sterile monouso

EN

1. 1.000 ml collection vessel with serigraph, made of sterilisable polycarbonate
2. Sterilisable polypropylene top
3. Sterilisable polypropylene float guide
4. Sterilisable polypropylene float body
5. Sterilisable rubber valve
6. Antibacterial filter
7. Sterilisable silicon tube Ø 6x12 mm - length 50 cm
8. Sterilisable silicon tube Ø 6x12 mm - length 130 cm
9. Disposable bag
10. Disposable sterile cannula
11. Disposable sterile manual regulator

F

1. Pot de collecte sérigraphié 1.000 ml en polycarbonate stérilisable
2. Bouchon en polypropylène stérilisable
3. Guide flottant en polypropylène stérilisable
4. Corps flottant en polypropylène stérilisable
5. Valve en caoutchouc stérilisable
6. Filtre antibactérien
7. Tuyau en silicone stérilisable Ø 6x12 mm 50 cm
8. Tuyau en silicone stérilisable Ø 6x12 mm 130 cm
9. Sac uniservice
10. Canule stérile uniservice
11. Régulateur manuel stérile uniservice

D

1. 1.000 ml Sekretgefäß, mit Siebdruck, aus sterilisierbarem Polykarbonat
2. Sterilisierbarer Propylenstopfen
3. Schwimmführung aus sterilisierbarem Polypropylen
4. Schwimmkörper aus sterilisierbarem Polypropylen
5. Sterilisierbares Gummiventil
6. Antibakterieller Filter
7. Sterilisierbarer Silikonschlauch, Ø 6x12 mm - 50 cm
8. Sterilisierbarer Silikonschlauch, Ø 6x12 mm - 130 cm
9. Steriles Einwegbeutel
10. Steriles Einwegkatheter
11. Steriler Einweghandregler

EN

ASPEED PROFESSIONAL aspirator is a professional unit for outpatient use for secretion aspiration. It is equipped with Vacuum regulator **6**, vacuum gauge **7**, 1.000 ml vessels. 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 PROFESSIONAL** aspirator is supplied with the following accessories: 1.000 ml vessel 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 use** cannula, **sterile and single use** manual regulator, **single use** bag, **single use** antibacterial filter. **N.B.: Only use genuine accessories supplied by 3A Health Care; the accessories supplied with the device by the manufacturer have been tested and proven compliant with the latest current safety standards. WARNING! Correct operation of the device is not guaranteed in the event of use of accessories other than those supplied.**

INTENDED USE

Mains-operated medical /surgical aspirator intended for outpatient use.
Medical purposes: This product is intended for use for the aspiration of body fluids.
Intended users of the product:
• Legally certified medical personnel (doctors, nurses and therapists).
• Users must also be able to understand the operation of the medical device, and the contents of the instruction manual, in general terms.
Intended patients for the product: People who need to remove body fluids (saliva, blood, etc.).
Environment: This product is intended for outpatient use.
Expected duration: Duration may vary based on the operating environment. The lifetime of the device is 5 years and that of the collection vessel and the silicone tubes 1 year or 30 sterilisation cycles. The cannula, manual flow regulator, antibacterial filter and bag are disposable devices and must therefore be replaced after each application. Frequent use of the product may shorten the duration.
Precautions for use: The warnings and cautions described in the instruction manual must be observed.

⚠ 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-capacity and who has read and understood this manual. Ensure that children do not use the device unsupervised some parts are small enough to be swallowed.
- The device must always be used by specifically trained staff who have read this manual.
- This device must only be used for its intended purpose: aspirator for outpatient and domestic use; any other use is considered 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 bottom 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 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.
- Ensure that the connections and vessel closing are performed carefully to prevent suction losses.
- Do not turn over the vessel 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 vessel and replace the antibacterial filter.
- In the event of aspiration without the container and/or antibacterial filter, or if it is suspected that solid and liquid substances have entered the aspiration circuit, it is necessary to send the device to the customer care service.
- In view of their length, the power cord and connection hose could constitute a strangulation hazard.
- The appliance is equipped with two safety fuses, easy to inspect in the event of a fault. They are located in the back of the appliance in the panel socket. **Before performing this operation remove the power supply plug.**
- The pipe and the manual control of the flow are **sterile and single-use** products: they must be replaced after each application. 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.

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 1 (page 2).

2. With the vacuum regulator **6** you can set the depression value (bar). Rotate the knob towards «+» to increase the vacuum and rotate it towards «-» to decrease it, the values can be read on the vacuum gauge **7**.

3. Turn the device on by putting the switch on the «I» position (ON) **3**.

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. Secretion collection vessel - 1.000ml.
The 1.000 ml collection bottle **8** supplied with the aspirator can be used in two ways: as a collection vessel which can be sterilised as shown in figure 2a or as a collection vessel with disposable bag as illustrated in figure 2b.

5.1 Sterilisable secretion collection vessel (figure 2a).

The antibacterial filter **6** must be inserted directly in the vessel's lid **2**. **Never use the aspirator without the antibacterial filter, since it is very dangerous for the patient**. The collection vessel **1** is supplied with overflow valve, lid and vessel in a see through material (polycarbonate).

The antibacterial filter must be placed directly in the lid, only on the hole called VACUUM/VUOTO. The antibacterial filter protects the suction circuit from possible contaminants sucked during use. All the components of the vessel 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 vessel every 30 sterilisation cycles.

Do not turn over the vessel 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 vessel and/or without the antibacterial filter.

5.1.1 Connection: connect one end of the short sterilisable silicon tube **7** to the rubber holder of the antibacterial filter **6** and put the latter in the "VACUUM/VUOTO" input of the blue lid **2**, connect the other end to the "INLET" input of the aspirator.

Connect one end of the sterilisable silicon tube **8** to the "PATIENT/PAZIENTE" input of the blue lid; connect the sterile single-use manual regulator **11** to the other end and connect the single-use sterile cannula **10** to the regulator.

5.2 Secretion collection vessel with single use bag (figure 2b).

The aspirator can be used with the 1.000 cc re-usable transparent secretion collection vessel **1** and with the single use bag **9** supplied. In this case the antibacterial filter is integrated in the single-use bag, therefore the antibacterial filter **6** and the blue lid with the valve **2** 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 operations of the tubes **7**-**8** and vessel **1**, 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 be completely inserted in the vessel in order to prevent any vacuum losses.

N.B.: maximum disposable bag usage vacuum: –0.75 bar (75 kPa).

5.2.1. Connection: connect one end of the short sterilisable silicon tube **7** to the yellow rubber holder (VACUUM) of the bag **9** and the other end to the "INLET" input of the aspirator.

Connect one end of the long sterilisable silicon tube **8** to the red rubber holder (PATIENT) of the bag **9** and connect the sterile single-use manual regulator **11** and the single-use sterile cannula **10** to the other end.

N.B.: only use the single use bags supplied by 3A - Code 3A1687.

CLEANING AND DISINFECTION OPERATIONS

N.B.: If using chemical disinfectants, follow the manufacturer's instructions exactly.

- The cannula and the suction flow manual control are sterile, single use products and must be replaced after every application.
- The antibacterial single use filter must be replaced after every application.
- Never leave the appliance in water or submerged; clean the external casing of the appliance using only a damp cloth with detergent (non abrasive).

PERIODICAL CHECK FOR THE SAFETY OF THE DEVICE

ASPEED PROFESSIONAL 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 approx.
- 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 vessel (figure 2a).
- 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).

PROBLEMS, CAUSES AND SOLUTIONS

PROBLEMS	POSSIBLE CAUSES	SOLUTIONS
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 disconnected and/or badly connected, broken connection tubes. Container not in a vertical position, full, or defective overflow valve. Possible blockage of the hydraulic circuit inside the unit.	- Send to the customer care service. - Check the position of the vacuum regulator. Check the connections and the integrity of the tubes. Position the container in a vertical position, check the overflow valve (blocked) and/or 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 service
The protection fuse is activated any time the device is turned on	Pump damaged or in short circuit	Send to the customer care service
The vacuum gauge does not work	Liquid penetrating the pneumatic circuit.	Send to the customer care service

Note: if you experience faults or malfunctioning problems different to those listed above, always and exclusively contact authorised assistance centres.

TECHNICAL SPECIFICATIONS

Piston electric-compressor, with thermal protection.

	Single pump version	**Double pump version**
	Low flow, high vacuum device	High flow, high vacuum device
Protection against electric shock	Class I	
Fuse	T1, 6A - 250V	
Supply voltage	230V ~ 50Hz 150VA	230V ~ 50/60Hz 100VA
Adjustable vacuum level	0 ÷ -0,85 bar (85 kPa)	
Air flow	approx. 15 l/min.	approx. 22 l/min.
Dimensions	330 x 185 x 210(H) mm	
Weight	3,5 kg approx.	4,2 kg approx.
Noise level	approx. 53 dBA	approx. 63 dBA
Operation cycle	Continuous use	
Class of risk according to the 93/42/EEC directive	IIa	
Operating Temperature/Humidity	+10° C to +40° C/10% to 95% RH	
Storage and Transport Temperature/Humidity	–25° C to +70° C / 10% to 95% RH	
Operating-storage air pressure	min. 690 hPa - max 1060 hPa	

Electromagnetic Compatibility
Compliance levels according to EN 60601-1-2:2015 standard

- ESD immunity: 15 kV air, 8 kV contact (EN 61000-4-2)
- Burst immunity: 2 kV/100 kHz (EN 61000-4-4)
- Surge immunity (EN 61000-4-5): 1 kV common mode /2 kV differential mode
- Magnetic field (EN 61000-4-8): 30 A/m
- Immunity to rf currents in the 150 kHz-80 MHz range (EN 61000-4-6) 3 V modulation 80% 1 kHz
- RF emissions, CISPR 11: Class B
- Harmonics emissions, EN 61000-3-2: Class A

Rf field immunity (EN 61000-4-3):		
Field (V/m)	**Frequency**	**Modulation**
3	80MHz 2700MHz	1kHz AM 80%
27	380MHz 390MHz	18Hz PM 50%
28	430MHz 470MHz	18Hz PM 50%
9	704MHz 787MHz	217Hz PM 50%
28	800MHz 960MHz	18Hz PM 50%
28	1700MHz 1990MHz	217Hz PM 50%
28	2400MHz 2570MHz	217Hz PM 50%
9	5100MHz 5800MHz	217Hz PM 50%

Warnings:
Although compliant with the EN 60601-1-2 standard, the ASPEED PROFESSIONAL medical device may interfere with other devices in the vicinity. The device must not be used in proximity to or stacked on top of other equipment. Install the device well away from other equipment that emits high frequencies (short waves, microwaves, electric scalpels, cell phones).

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are under control. The customer or user can help prevent electromagnetic interference by maintaining a minimum distances between mobile and portable RF communication equipment (transmitters) and the medical device as recommended below, according to the maximum output power of the radio communication equipment.

Rated maximum output power of transmitter (W)	**Separation distance (m) in relation to transmitter frequency**		
	from 150 kHz to 80 MHz d = 1,2 √P	**from 80 MHz to 800 MHz d = 1,2 √P**	**from 800 MHz to 2,5 GHz d = 2,3 √P**
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters with rated maximum output power not listed above, the recommended separation distance d in metres (m) may be determined using the equation adopted for the transmitter frequency, where P is the maximum rated output power of the transmitter in Watts (W) stated by the transmitter manufacturer.

Notes:
(1) At 80 MHz and 800 MHz the highest frequency range applies.
(2) These guidelines might not apply in all situations.
Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

SYMBOLS

Type B device

Ground protection

Safety fuse

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

Keep dry

Single use

STERILE EO Sterilisation by ethyl oxid

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

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.

SIMBOLOGIE

- Aparato de tipo B
- Tierra de protecciòn
- Fusible de protección
- Interruptor apagado
- Interruptor encendido
- Corriente alterna
- No utilice el aparato mientras toma una ducha o un baño
- Es obligatorio leer atentamente las instrucciones antes de usar este dispositivo
- Mantener seco
- Desechable
- STERILE EO — Esterilizado con óxido de etileno

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CE 0051 Conforme con la Norma 93/42/CEE dispositivos médicos

PROCEDIMIENTO DE ELIMINACIÓN (Dir.2012/19/Ue-RAEE) El símbolo colocado en el fondo del aparato indica la recogida separada de los equipos eléctricos y electrónicos. Al término de la vida útil del aparato, no eliminar como residuo municipal sólido mixto sino eliminarlo en un centro de recogida específico colocado en vuestra zona o entregarlo al distribuidor a la hora de comprar un nuevo aparato del mismo tipo y destinado a las mismas funciones. Este procedimiento de recogida separada de los equipos eléctricos y electrónicos se realiza con el propósito de una política del medioambiente comunitaria con objetivos de salvaguardia, defensa y mejoramiento de la calidad del medioambiente y para evitar efectos potenciales en la salud de los seres humanos debido a la presencia de sustancias peligrosas dentro de estos equipos o a un uso inapropiado de los mismos o de algunas de sus partes. **Cuidado!** Una eliminación no correcta de equipos eléctricos y electrónicos podría conllevar sanciones.

CERTIFICATO DI GARANZIA / WARRANTY CERTIFICATE

VALEVOLE 36 MESI dalla data di vendita / VALIDITY 36 MONTHS from date of purchase

Data di vendita
Date of purchase

Rivenditore (timbro e firma)
Dealer (stamp and signature)

La presente garanzia nom è valida se non “unitamente allo scontrino fiscale dell’apparecchio” e all’apparecchio difettoso. Sono esclusi della 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

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