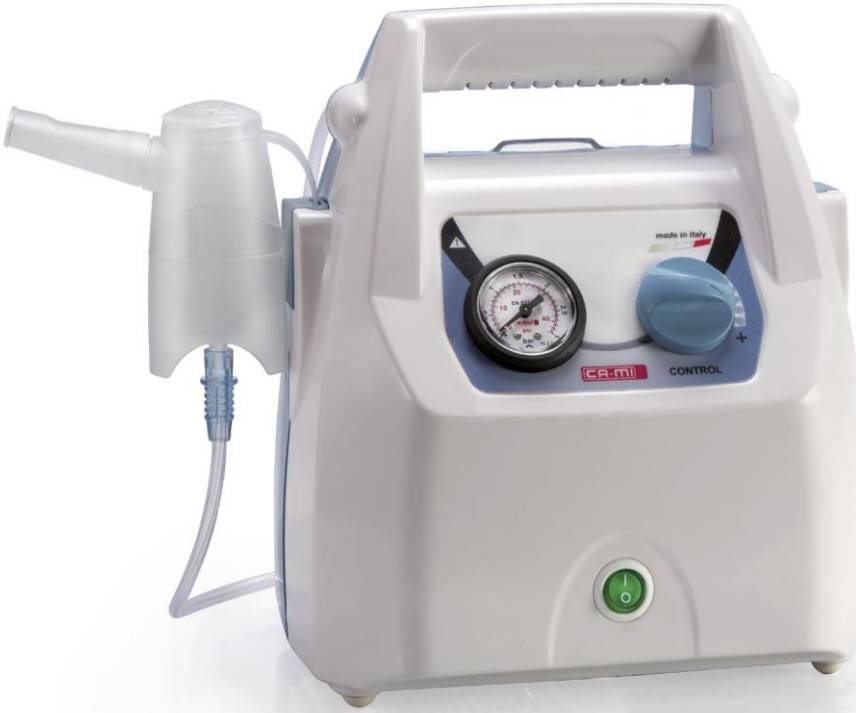
CLINEB PRO

Italian Medical Touch



IT Manuale d'uso

EN Instruction Manual

FR Mode d'emploi

ES Manual de istrucciones

DE Handbuch

PT Manuale de instruções

CE 0123

CLINEB PRO is a piston-type compressor nebulizer system working at 230V/50Hz, ideal for intensive hospital and clinic use. High performance with any type of drug, Manufactured with high termal and electric insulation plastic chassis in compliance with the latest European Safety regulations. The oil-free piston compressor has long durability and is equipped with the highly efficient HI-4 nebuliser (featuring 4 different useful positions to adjust the nebulisation speed) to provide fast and accurate treatments. The device is designed for easy tranport and halding and is recommended for atomising antobiotics and bronchodilator drugs. The medical device is designed for continuous use.

GENERAL WARNING

READ INSTRUCTION MANUAL CAREFULLY BEFORE USE

DRUG ADMINISTRATION MUST BE UNDER MEDICAL CONTROL

THE INSTRUMENT MUST NOT BE DISASSEMBLED. FOR A TECHNICAL SERVICE ALWAYS CONTACT CA-MI

IMPORTANT SAFETY RULES

1. On opening the packaging, check the integrity of the appliance, paying particular attention to the presence of damage to the plastic parts, which may make access possible to internal live parts and also to breakage and / or peeling of the power supply cable. **In these cases don't connect the plug to the electric socket. Carry out these controls before each use;**
2. before connecting the appliance always check that the electric data indicated on the data label and the type of plug used, correspond to those of the mains electricity to witch it's to be connected;
3. Never leave the appliance inserted if not necessary disconnect the plug from the mains power supply when it is not being used;
4. Respect the safety regulations indicated for electrical appliances and particularly:
   - Only use original accessories and components provided by the manufacturer CA-MI to guarantee the highest efficiency and safety of the device;
   - Never immerge the appliance into water;
   - Position the appliance on flat stable surfaces;
   - Position the device in order not to block the cooling vents on the back of the device;
   - Never use the device in environments which have anaesthetic mixtures inflammable with air, oxygen or nitric oxide;
   - Don't touch the device with wet hands and always prevent the appliance coming into contact with liquids;
   - The use of this device by children and / or incompetent person always requires the careful surveillance of an adult in possession of their full mental faculties;
   - The medical device, and most of all the nebulae, must be kept out of children's reach as it contains small parts hat could be swallowed;
   - Don't leave the appliance connected to the power supply socket when not in use;
   - Don't pull the power supply cable to disconnect the plug remove the plug from the mains socket correctly;
   - Store and use the device in places protected against the weather and far from any sources of heat. After each use, it is recommended to store the device in its own box away from dust and sunlight.
   - In general, it is inadvisable to use single or multiple adapters and/or extensions. Should their use be necessary, you must use ones that are in compliance with safety regulations, however, taking care not to exceed the maximum power supply tolerated, which is indicated on the adapters and extensions.
5. For repairs, exclusively contact CA-MI technical service and request the use of original spare parts. Failure to comply with the above can jeopardise the safety of the device;
6. **This medical device must be destined exclusively for the use for witch it has been designed ad described in this manual. It must therefore be used as an aerosol therapy system.** Any different use must be considered incorrect and therefore dangerous; the manufacturer cannot be considered liable for damage caused by improper, incorrect and / or unreasonable use or if the appliance is used in electrical plants that are not in compliance with the regulations in force;
7. The medical device requires special precautions regarding electromagnetic compatibility and must be installed and used in accordance with the information provided with the accompanying documents: the CLINEB PRO device must be installed and used away from mobile and portable RF communication devices (mobile phones, transceivers, etc.) that may interference with the said device.
8. Store the accessories out of reach of children. Children and people with learning difficulties must only use the medical device under the strict supervision of an adult with full mental faculties. Keep the ampoule out of reach of children under 36 months as it contains small parts that may be swallowed accidentally. **Never leave the device unattended in places accessible to minors and / or the disabled.**
9. **WARNINIG:** None of electric or mechanical parts have been designed to be repaired by customers or end-users. Don't open the device, do not mishandle the electric / mechanical parts. Always contact CA-MI technical assistance.
10. The medical device may come into contatct with the patient via the nubuliser / masks / mouthpiece and / or nosepiece, components compliant with the requirements of regulation ISO 10993-1: therefore, no allergic reaction and skin irritation may occur.
11. The product and its parts are biocompatible in accordance with the requirements of regulation EN 60601-1.
12. Operation of the device is very simple and therefore no further explanations are required other than those indicated in the following user manual.

13. Using the device in environmental conditions different than those indicated in this manual may harm seriously the safety and the technical characteristics of the same;
14. 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.
15. Remember to:
    - Only use this device with medicines prescribed by your doctor;
    - Carry out the treatment only using the accessory indicated by the doctor according to the pathology.

TECHNICAL CHARACTERISTICS

Model	**CLINEB PRO**			
Typology (MDD 93/42/EEC)	Class IIa Medical device			
Power Feeding	230V ~ / 50 Hz			
Power Consumption	170VA			
Fuse	F 1 x 1.6A L 250V			
Max Pressure	300 kPa (3.0 Bar)			
Max Air Flow	16 l/min			
Operating Pressure	95 kPa (0.95 Bar)			
Operating Air Flow	8.0 l/min a 95kPa			
NEBULIZZAZIONE (**)	Pos. A (closed)	Pos. B	Pos. C	Pos. D
	0,40 ml	0,60 ml	0,70 ml	0,80 ml
MMAD (µm) * Mass Median Aerodynamic Diameter	Pos. A (closed)	Pos. B	Pos. C	Pos. D
	3.32	4.07	4.23	4.18
GSD (*) Geometric Standard Deviation	Pos. A (closed)	Pos. B	Pos. C	Pos. D
	4.12	2.64	2.74	2.49
Output Rate (ml/min) *	Pos. A (chiuso)	Pos. B	Pos. C	Pos. D
	0.077	0.105	0.124	0.138
Output (ml) *	Pos. A (closed)	Pos. B	Pos. C	Pos. D
	0.189	0.237	0.247	0.260
Weight	2.20 Kg			
Size	230 x 250 (H) x 190mm			
Noise Level (measured as specifications of EN 13544-1)	Approx. 60dB (A)			
Duty Cycle	Non-Stop Operated			
Min Capacity Nebulizer	2ml			
Max Capacity Nebulizer	8ml			
Working Condition	Room temperature: 5 ÷ 40 °C Room humidity percentage: 10 ÷ 93 % RH Atmospheric pressure: 700 ÷ 1060 hPa			
Conservation condition and Transport	Room temperature: - 25 ÷70 °C Room humidity percentage: 0 ÷ 93% RH Atmospheric pressure: 500 ÷ 1060 hPa			

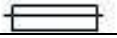
(*) Data determined with Cascade Impactor 290 series, compliant with EN 13544-1, by spraying 2 ml of NaF 1.0%.
(**) Data from free nebulisation of 2 ml of NaCl 0.9% (average nebulisation value per minute).

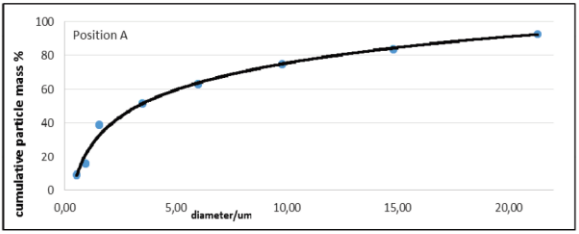
IMPORTANT INFORMATION FOR CORRECT DISPOSAL OF THE PRODUCT IN ACCORDANCE WITH EC DIRECTIVE 2012/19/UE-WEEE:
The symbol on the device indicates the separated collection of electric and electronic equipment. At the end of life of the device, don't dispose it as mixed solid municipal waste, but dispose it referring to a specific collection centre located in your area or returning it to the distributor, when buying a new device of the sample 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.

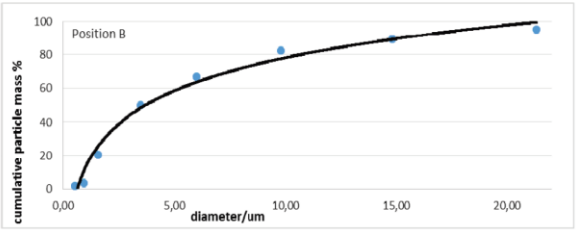
CLEANING DEVICE

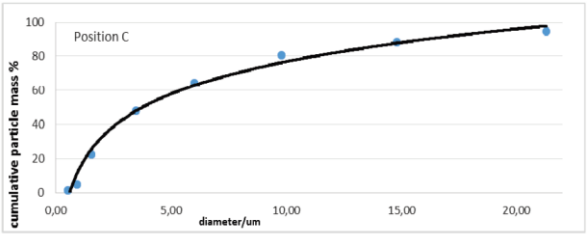
Use a soft dry cloth with not – abrasive and not – solvent detergents. The device's plug must be removed from the wall socket before proceeding with any cleaning procedures.

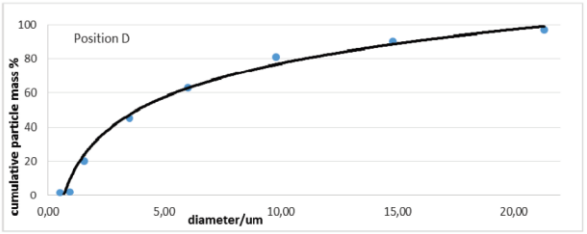
SIMBOLOGY

	Class II isolation equipment
	CE marking in conformity with EC directive 93/42/EEC and subsequent changes
	General warnings and/or specifications
	Consult the instruction manual
	Manufacrurer: CA-MI S.r.l., Via Ugo La Malfa nr.13 – Frazione Pilastro 43013 Langhirano (PR) Italia
	Applied part type B (Nebulizer, mouthpiece, nosepiece, pediatric masck and Adult mask)
	Operating limit temperature / Transport and storage limit temperature
	Keep in a cool, dry place
	Fuse
~	Alternate Current
Hz	Mains Frequency
I	ON
0	OFF
LOT	Lot Number
SN	Serial Number
REF	Identification device









NB: The measures and curves are not valid for the high viscosity suspension drug.

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 nebuliser.

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.

STANDARD ACCESSORIES

ACCESSORIES
HI-4 KIT – REF RE 300350 (Nebulizer HI-4, Adult Mask, Pediatric Mask, Air Tube and Mouth-piece, Nosepiece)
Power Cable (SP.0021)

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.. **Only use the original nebulizer supplied by CA-MI with the device**
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.
In the presence of infection or microbial contamination prone pathologies, we recommend using your personal accessories and nebulizer (always consult your doctor).

The mask and tube must be replaced as soon as the materials they are made of show signs of deterioration.

RULES FOR RETURNING AND REPAIRING

COMPLYING WITH THE NEW EUROPEAN RULES, CA-MI INDICATES THE IMPORTANT POINTS TO PROTECT INSTRUMENT AND OPERATORS HYGIENE. THESE RULES MUST BE RESPECTED IN ORDER TO GUARANTEE HYGIENE AND SAFETY TO ALL THE PEOPLE OPERATING WITH THE INSTRUMENT TO OBTAIN QUALITY AND WELL BEING.

This device is guaranteed against any material or manufacturing defect for **2 years** from the date of purchase.
Every returned instrument will be hygienically checked before repairing. If CA-MI finds instrument not suitable for repairing due to clear signs of internal or external contamination, the same will be returned to customer with specification of NOT REPAIRED INSTRUMENT, accompanied by an explanation letter.
CA-MI will decide if contamination is due to bad functioning or misuse. If contamination is due to bad functioning, CA-MI will substitute the instrument, only if SALE RECEIPT and STAMPED GUARANTEE accompany the same.
CA-MI is not responsable for contaminated accessories, they will be substitute at customer's expenses.
For this reason it is **COMPULSORY** to carefully disinfect the external part of the instrument and accessories with a cloth soaked in methylated spirits or hypochlorite-based solutions. Put the instrument and accessories in a bag with indication of disinfecting. We also request to specify the kind of fault, in order to speed up repairing procedures.
To this end, please read the instructions carefully in order to avoid damaging the equipment through improper use.
Always specify the fault encountered so that CA-MI can establish whether it falls into the category of the faults covered by the guarantee.

MAINTENANCE

The **CLINEB PRO** atomiser does not need maintenance or lubrication.
With regard to training, given the information contained in the user manual and since it is easy to understand the said device, it doesn't appear to be necessary.
Before use always check correct functioning and safety of the device. Carry out disinfection as described in the "CLEANING ACCESSORIES" section. Unpack the instrument and **always check** integrity of plastic parts and feeding cable, they might have been damaged during previous use. Connect cable to electrical network and turn switch on.
Close the air outlet with one finger to make sure that noise produced is regular and there is no malfunctioning.
With the air outlet always closed check the correct functioning of the nebulization regulator by turning the knob form MIN to MAX. Make sure the indicator of the pressure meter is working correctly. Verify that the atomiser is not damaged by previous use (it was badly put away or badly knocked). A protection fuse (**F 1x1.6A L 250V**) reachable from exterior and it situated in the plug protects the instrument. For use replacing, always check the type and the range indicated.

CA-MI S.r.l will provide upon request electric diagrams, components list, description, setting instructions and any other information that can help the technical assistance staff for product repair.

Fault type	Cause	Solution
1. The device doesn't work	a) The plug may be misplaced in the wall socket b) Internal wires disconnected c) Blocked Motor	a) Make sure the plug is properly placed in the wall socket. Make sure the ON/OFF switch is in position **I.** b) Contact your dealer or the CA-MI service centre c) Contact your dealer or the CA-MI service centre
2. Low Nebulization	Clogged Nebulizer Tank	Clean and disinfect the nebulizer tank as explained in the instruction manual
3. Low Nebulization	Clogged Nebulizer Tank	If cleaning was not succesful change cruet
4. Absence of Nebulization	Clogged Nebulizer Tank	Check that the nebulizer contains medication; Make sure that the nebulizer is not clogged; Check the connection between the compressor air outlet port and the accessories
5. Slow Nebulization	Highly dense drug	Dilute drug in physiological liquid
6. Noisy Device	Extended use	Call retainer or manufacturer CA-MI
Fault 1 - 2 - 3 - 4 - 5 - 6	**No solution with previous items**	**Call retainer or manufacturer CA-MI**

If the unit doesn't nebulizer once the above conditions have been checked, we suggest to contact your dealer or technical service CA-MI.

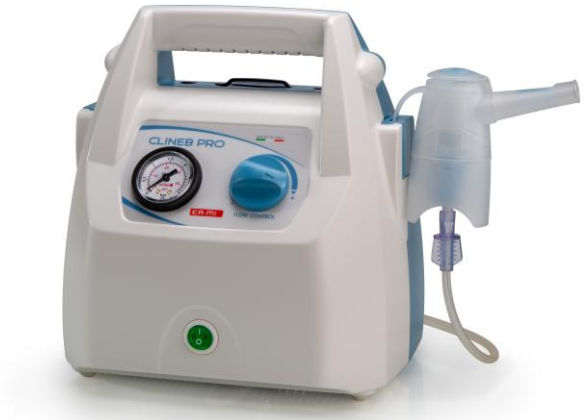
⚠ **The manufactured cannot be held liable for accidental or indirect damages should the device be modified, repaired without authorization or should any of its component be damaged due to accident or misuse. Any minimal modification / repair on the device voids the warranty and does not guarantee the compliance with the technical requirements provided by the MDD 93/42/EEC (and subsequent changes) and its normatives.**

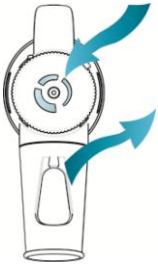
INSTRUCTION FOR USE

- The device must be checked before each use in order to detect malfunctions and / or damage caused by transport and / or storage.
- During the inhalation must sit in an upright and relaxed position at a table and not in an armchair, to avoid compressing the airways and therefore compromising the effectiveness of the treatment.

WARNING: Put the device on a flat and stable surface in order not to block the cooling vents on the sides of the device.

- Extract the power supply cable and insert the plug into the mains socket.
  It is recommended to unwind the entire length of the power supply cable to prevent dangerous overheating. If the power supply cable is damage and must be replaced contact the CA-MI technical service;
- Using your fingers, press the two side tabs of the nebuliser cup that hold the top of the nebuliser cup against the bottom of the same component;
- Pour the medicine prescribed by the doctor into the nebulizer;
- Re-close the nebulizer, re-screwing the lid;
- Connect the air tube to the air outlet nozzle of the device positioned inside the accessory compartment, making sure to keep the cover lifted during operation;
- Connect the desired accessory to the nebulizer: child mask or adult mask, mouth-piece or nosepiece;
- Ensure that the supplied air filter is present;
- Press the ON/OFF switch to position **I** to start nebulization.
- To interrupt or stop the treatment press again the ON/OFF switch.
- Adjust the nebulization speedy by turning the know towards MIN for longer treatments, or towards MAX for quicker treatments.
- After treatment has been completed press the ON/OFF switch to position **0** and pull out the plug from the wall socket.
- Wash the nebulizers and the accessories as explained in the Cleaning section.
- Place back power cord and accessories into the compartments.





Inhalation Valve:
Three vents on top are mechanically opened by patient inhalation force, entraining ambient air. The airflow generated by the compressor along with the airstream entrained by patient enhance the nebulisation activity inside the chamber, thus increasing the volume of aerosol delivered to the patient.

Exhalation Valve:
While remaining closed during inhalation to prevent aerosol to be wasted in the air, the exhalation valve opens when patient starts exhaling, directing the exhaled air in the ambient and preventing mixing with medication in the chamber.

Speed Selector:
By rotating and stopping the speed selector on one of the 4 available positions (I-II-III-IV), speed of nebulization can be doubled while maintaining a stable and optimal particle size.

Always use the nebulizer facing upwards so that substances and / or medicines cannot escape from the nebulizer during the normal use.

WARNING: The power supply cable plug is the element of separation from the electrical mains system: even if the units equipped with a special on / off switch button, the power supply plug must be kept accessible once the device is in use so as to allow a further method of disconnection from the mains supply system.

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

MAKE SURE THAT CHILDREN AND/OR MENTALLY ILL PEOPLE DO NOT USE THE DEVICE WITHOUT ADULT SURVEILLANCE

RISK OF ELECTROMAGNETIC INTERFERENCE AND POSSIBLE REMEDIES

This section contains information regarding the conformity of the compliance with the EN 60601-1-2 (2015) Standard. CLINEB PRO is a medical device particularly suitable for home applications. CISPR group and category classification: group 1, category B. CLINEB PRO is an electromedical device that requires special precautions regarding electromagnetic compatibility and needs to be installed and commissioned according to the information specified in the accompanying documents.

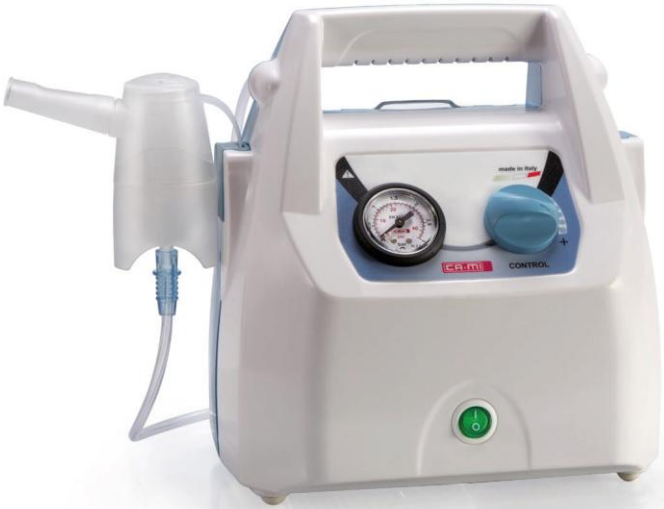
The device should not be used adjacent to or stacked with other equipment, as this could result in improper operation. If such use is necessary and unavoidable, special precautions should be taken so that the electro-medical device functions properly in its intended operating configuration (for example, constantly and visually checking for the absence of anomalies or malfunctions).

The use of accessories, transducers and cables other than those provided by the manufacturer of the device may result in an increase in electromagnetic emissions and/or a decrease in the electromagnetic immunity of this device, causing it to malfunction.

Portable and mobile radio communication devices (mobile phones, transceivers, including peripherals such as antenna cables and external antennas, etc.) may interfere with the medical device and should not be used in close proximity with (at a distance of more than 30 cm from any part of the device, including cables), adjacent to or on top of the medical device. If such use is necessary and unavoidable, special precautions should be taken so that the electro-medical device functions properly in its intended operating configuration (for example, constantly and visually checking for the absence of anomalies or malfunctions).

CLINEB PRO

Dispositivo medico di Classe IIa (93/42/CEE e s.m.i.)
Class IIa medical device (MDD 93/42/EEC and subsequent changes)
Dispositif médical Classe IIa (Directive 93/42/EEC et modifications ultérieures)
Dispositivo médico classe IIa (93/42/EEC y siguientes cambios)
Geräteklasse IIa (93/42/EWG und nachfolgende Änderungen)
Dispositivo médico de classe IIa (93/42/ EEC e sucessivas alterações)



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