CA-MI

FLO CLINEB

WITH PISTON COMPRESSOR

USER MANUAL

CE 0123

nebuliser centre

www.nebulisercentre.co.uk

CLINEB is a piston-type compressor nebulizer system working at 230V/50Hz (other voltages available upon request).
High performance with any type of drug, ideal for intensive hospital and clinic use.
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-FLO jet nebulizaer to guarantee quick and accurate drug delivery. 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. If the plug supplied with the appliance is incompatible with the mains electricity socket, contact qualified staff for replacement of the plug with a suitable type. The use of simple or multiple and / or extension adapters is not generally recommended. Whenever their use is indispensable, use those in compliance with safety regulations, however paying attention not to exceed the maximum power supply limits, which are indicated on the adapters and extensions.
4. Never leave the appliance inserted if not necessary disconnect the plug from the mains power supply when it is not being used.
5. Respect the safety regulations indicated for electrical appliances and particularly:
   - Use original components and accessories 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 a way that the air inlets on the back aren't obstructed.
   - 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 device has small components which might be removed and easily swallowed. Use by minors and disabled people require presence of an adult with his faculties. Don't leave the device unattended in places easily accessible by minors and disabled people.
   - 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.
   - Preserve and use the medical device in environments protected from atmospheric factors and at a distance from heat sources.
   - Device not suitable for anesthesia and lung ventilation.
6. 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.
7. **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.
8. Particular precautions must be made concerning electromagnetic compatibility. The medical device must be installed and used according to information supplied with the accompanying documents.
9. Some components of the device are small enough to be swallowed by children: therefore keep the device out of children's reach.
10. 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.
11. 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.

IMPORTANT INFORMATION FOR CORRECT DISPOSAL OF THE PRODUCT IN ACCORDANCE WITH EC DIRECTIVE 2002/96/EC:

In respect of art. 13 Decreto Legislativo 25 Luglio 2005, n.151 "Actuation of European directives 2002/95/EC, 2002/96/EC and 2003/108/EC, for reduction in use of dangerous substances in the electric and electronic device and for garbage disposal".
The symbol as over applied on the device or its packaging means that at the end of its useful life the product must not be disposed of with domestic waste. At the end of device useful, the user will must deliver it to the able collecting centres for electric and electronic garbage, or give back to the retailer in the moment of equivalent new device purchasing, one against one. Disposing of the product separately prevents possible negative consequences for the environment and for health, deriving from inadequate disposal. It also allows the recovery of materials of witch it's made up in order to obtain an important saving of energy and resources and to avoid negative effects to the ambient and health. In case of abusive disposal of device by user, will be applied administrative endorsements in compliance with current standard.

RULES FOR RETURNING AND REPAIRING

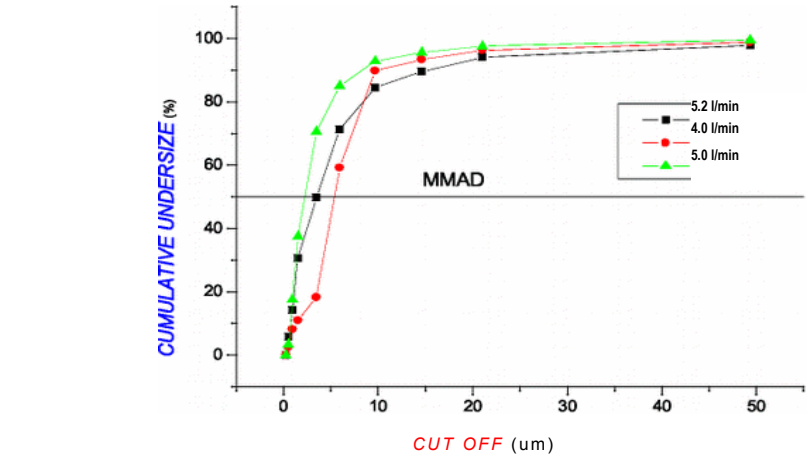
COMPLYING WITH THE NEW EUROPEAN RULES, CA-MI INDICATES THE IMPORTANT POINTS TO PROTECT INSTRUMENT AND OPERATORS HYGIENE. THESE RULES MUST BE RESPECTED IN ORDER TO GUARANTEE HYGIENE AND SAFETY TO ALL THE PEOPLE OPERATING WITH THE INSTRUMENT TO OBTAIN QUALITY AND WELL BEING.

CA-MI warrants it's products for **24 months** after purchasing date.
In front of this warranty, CA-MI will be obliged only to repair or substitute free of charge the products or parts of them that, after verification effected on our factory, or our authorized Service Center, by the Technical Service, results defective.
The product must be accompanied by a description of the defect. The warranty, with exclusion of responsibility for direct and indirect damages, it is thought limited to the solos defects of material or workmanship and it stops having effect when the device results however gotten off, tampered or sheltered out of the Factory or from the Authorized Service center. The commodity always travels to risk and danger of the buyer, without any responsibility of CA-MI for damages caused by the transport or dismay from the vector. 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 a SALE RECEIPT and STAMPED GUARANTEE accompany the same.
CA-MI is not responsible 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.

CA-MI S.R.L. 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 Directive and its normatives.

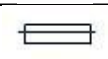
TECHNICAL CHARACTERISTICS

TYPOLOGY (MDD 93/42/EEC)	Class IIa Medical Device
MODEL	**CLINEB**
POWER FEEDING	230V~ / 50Hz
POWER CONSUMPTION	184 VA
FUSE	F 1 x 1.6A 250V
MAX PRESSURE	250 kPa (2.5 Bar)
MAX AIR FLOW	16 l/min
OPERATING PRESSURE	130 kPa (1.30 Bar)
OPERATING AIR FLOW	5.2 l/min a 130 kPa
NEB-RATE (with 4ml of 0.9% NaCl solution)	0.50 ml/min with 4ml of 0.9% NaCl solution
MMAD	3.25 µm
GSD	3.45
WEIGHT	2.20 Kg
SIZE	255 x 190 x 165 (h)
NOISE LEVEL (measured as specifications of EN 13544-1)	Approx. 57dB (A)
DUTY CYCLE (to 40°C and 110% operating voltage)	Not-Stop Operated
ACCURACY OF PRESSURE METER	± 5%
MIN. CAPACITY NEBULIZER	2ml
MAX. CAPACITY NEBULIZER	6ml
WORKING CONDITION	Room temperature: 10 ÷ 40°C Room humidity percentage: 20 ÷ 85% RH Altitude: 0 ÷ 2000m s.l.m.
CONSERVATION CONDITION AND TRASPORT	Room temperature: - 25 ÷ 70°C Room humidity percentage: 10 ÷ 95% RH



MMAD = Mass Median Aerodynamic Diameter
GSD = Geometric Standard Deviation

SYMBOLS

	Class II isolation equipment
CE 0123	CE marking in conformity with EC directive 93/42/EEC and subsequent changes Manufactured by: CA-MI S.r.l. Via Ugo La Malfa nr.31 – 43010 Pilastro (PR) Italy
	Warning, consult the instruction manual
	To Preserve in place coolness and dry land
	Conservation temperature: -25 ÷ 70°C
	Type B equipment
	Fuse
~	Alternate Current
Hz	Mains Frequency
I	ON
O	OFF

CELANING THE ACCESSORIES

Before undertaking and cleaning operation, switch off and unplug the unit.

CLEANING ACCESSORIES

1. Turn the upper part of the nebulizer in an anti-clockwise direction;
2. Disconnect the internal pisper at the base of the nebulizer using the fingers;
3. Wash under running water with mild (non abrasive) washing-up liquid. After each treatment clean thoroughly each component of the nebulizer (except air tube) removing medication residual and possible impurities.
   Clean all parts in warm water. Rinse thoroughly making sure that all deposits are washed away and let dry.

DISINFECTION

1. Use denatured alcohol or a hypochlorite - based solution, easily found at chemist, to clean the accessories;
2. After using the appliance, disassemble the nebulizer and clean all parts in warm water, rinse carefully and remove excess water using a soft cloth and leave to dry in a clean place.

DO NOT BOIL OR PUT IN AUTOCLAVE THE AIR TUBE AND THE MASKS

The device isn't sterile. Before use carry out cleaning and disinfection operations.
The nebulizer HI-FLO, the mouthpiece and the nosepiece must be disinfected by boiling in water (for max. 10 minutes).
We suggest you disinfect the nebulizer HI-FLO, the mouthpiece and the nosepiece using cold disinfecting liquids (solutions with hypochlorite).

Attention: Never use a cleaning brush or put sharp objects into the jet holes as this will damage the nebulizer

Guidance and manufacturer's declaration – Electromagnetic Emissions		
The **CLINEB** aerosol is intended for use in the electromagnetic environment specified below. The customers or the user of the **CLINEB** aerosol should assure that it's used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment - guidance**
Irradiated / Conducted emissions CISPR11	Group 1	The CLINEB aerosol only used RF energy only for its internal functioning. Therefore its RF emissions are very low and are not cause interference in proximity of any Electronic appliances.
Irradiated / Conducted emissions CISPR11	Class [B]	The CLINEB aerosol can be used in all environments, including domestic and those connected directly to the public mains distribution that supplies power to environments used for domestic scopes.
Harmonic emissions IEC/EN 61000-3-2	Class [A]	
Voltage fluctuations / flicker emissions IEC/EN 61000-3-3	Complies	

Guidance and manufacturer's declaration – Electromagnetic Emissions		
The **CLINEB** aerosol is intended for use in the electromagnetic environment specified below. The customers or the user of the **CLINEB** aerosol should assure that it's used in such an environment.		
Immunity Test	**Compliance**	**Electromagnetic environments - guidance**
Electrostatic discharge (ESD) IEC/EN 61000-4-2	± 6kV on contact ± 8kV in air	Floors should be wood, conceret or ceramic tile. If floors are coverei with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient / burst IEC/EN 61000-4-4	± 2kV power supply	Mains power quality should be that of a typical commercial environment or hospital.
Surge IEC/EN 61000-4-5	± 1kV differential mode	Mains power quality should be that of a typical commercial environment or hospital.
Loss of voltage, brief voltage interruptions and variations IEC/EN 61000-4-11	5%U_T for 0.5 cycle 40%U_T for 05 cycle 70%U_T for 25 cycle <5%U_T for 5 sec	Mains power quality should be that of a typical commercial environment or hospital If the user of the CLINEB aerosol request that the appliance operates continuosly, the use of a continuity unit is recommended.
Magnetic field IEC/EN 61000-4-8	3A/m	The power frequency magnetic field should be measured in the intended installation location to assure that it's sufficiently low.
Conducted Immunity IEC/EN 61000-4-6	3Vrms 150kHz to 80MHz (for appliances that aren't life - supporting)	-
Irradiated Conducted IEC/EN 61000-4-3	3V/m 80MHz to 2.5 GHz (for appliances that aren't life - equipment)	-
Note U_T is the value of the power supply voltage		

CLEANING DEVICE

Use a soft dry cloth with not – abrasive and not – solvent detergets.

MAKE SURE THAT INTERNAL PARTS OF THE APPLIANCE DON'T COME INTO CONTACT WITH LIQUIDS AND THE PLUG IS NOT INSERTED

INSTRUCTION FOR USE

- Place the device on a flat, stable and clean surface and plug it in the wall socket. Make sure the power cord id thouroughly unrolled to avoid dangerous overheating. In case the power cord is damaged, contact CA-MI technical assistance for replacement.
- Prepare the HI-FLO nebulizer opening the upper part and pouring the drug prescibed by your doctor into the lower tank. Close the nebulizer.
- Connect the air tube into the air outlet placet above the knob of nebulization.
- Connect the other end of air tube into the bottom of the nebulizer.
- Connect the selected accessory to the nebulizer: child mask, adult mask, mouthpiece or nosepiece.
- Make sure the air filter is placed properly in its seat in the bottom of the device.
  Air Filter replacement: Open the air filter cover, remove the filter and insert the new one. Place back the cover.
- 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.

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

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

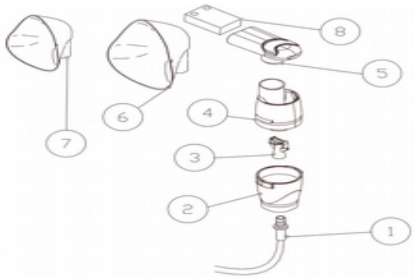
ALWAYS PLACE THE DEVICE IN POSITIONS FOR EASY DISCONNECTION.

STANDARD ACCESSORIES

ACCESSORIES
HI-FLO KIT (Nebulizer HI-FLO, Adult Mask, Pediatric Mask, Air Tube, Mouth-piece and Noisepiece)
Air Filter (+n°3 spare part)

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.
The air filter must be replaced every 25 hours of functioning or when it result particulary worn.
For replacement, lift the filter and replace with a new one. Only use original CA-MI filter.

DON'T USE THE DEVICE WITHOUT AIR FILTER



1- Air Tube
2- Nebulizer Tank
3- Nebulization Nozze
4- Nebulizer Top
5- Mouthpiece
6- Adult Mask
7- Pediatric Mask
8- Nosepiece

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.

MAINTENANCE

The **CLINEB** atomiser does not need maintenance or lubrication.
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 250V**) reachable from exterior and it situated in the plug protects the instrument.
For use replacing, always check the type and the range indicated.

Fault type	Cause	Solution
1. The device doesn't work	a) The plug may be misplaced in the wall socket b) Thermal protector may be on (the device has been working beyond its limits and / or near heat sources)	**a)** Make sure the plug is properly placed in the wall socket. Make sure the ON/OFF switch is in position **I.** **b)** Switch off the device by pressing the switch to position **0** and left the motor cool down for at least 30 minutes.
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 Air tube is bended or squeezed	**a)** 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 **b)** Make sure the air tube is not bended or squeezed.
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 does not nebulizer once the above conditions have been checked, we suggest to contact your dealer or technical service CA-MI.

CA-MI S.R.L. will provide upon request electric diagrams, component list, descriptions, setting instructions and any other information that can help the technical assistance staff for product repair.

BEFORE EVERY CHECKING OPERATION, IN CASE OF ANOMALIES OR BAD FUNCTIONING, PLEASE CONTACT CA-MI TECHNICAL SERVICE
CA-MI DOES NOT GIVE GUARANTEE IF INSTRUMENT, AFTER THE TECHNICL SERVICE CHECKING, APPEARS TO BE TAMPERED