

System INSTRUCTIONS FOR USE

Intended Use

The Flexineb[®] is a portable equine nebuliser system intended to aerosolize veterinarian prescribed liquid solutions into a fine mist for inhalation into the airways of the horse. The end user is liable for the safe operation of the Flexineb[®] and its parts as outlined in the Instructions for Use. Medications must be prescribed by a veterinarian and end users should follow the advice of their veterinarian at all times.

Safety Information

When using the Flexineb[®] for the first time remember it is the first time for the horse too so caution is advised. Softly place the Flexineb[®] over the horses' nose and mouth with the bottom exit valve open so the horse can breathe normally. Push up until the nostrils are covered and a seal is made around the nose and mouth. Once the horse is breathing normally and is getting used to the Flexineb[®], shut the bottom valve by twisting the exit valve and commence treatment. If the horse is resisting the mask be patient and let them look at it and smell it before attempting to fit the mask again. If the horse starts to get scared during treatment, slightly open the exit valve so more air is being inhaled. Close the valve again once the horse is relaxed.

In an emergency situation the exit valve on the bottom of the mask can be pulled out to allow the horse breathe freely. Although the mask material is soft and flexible the front aerosol chamber and battery controller is hard plastic therefore caregivers should be mindful of the risk posed by the horse shaking its head with the Flexineb[®] fitted.

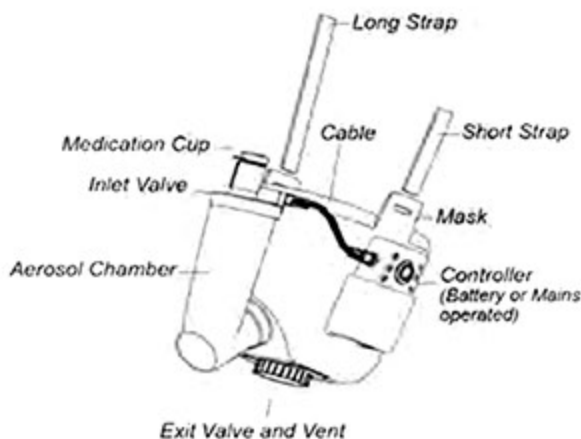


Figure 1: Flexineb Nebuliser

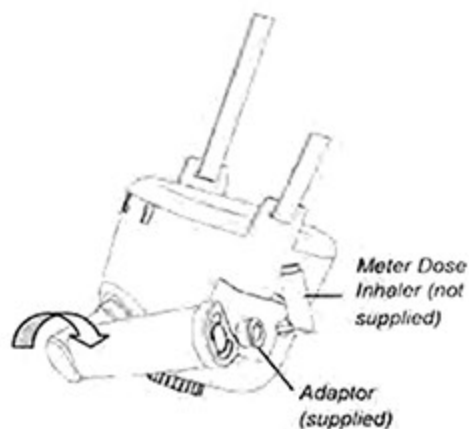


Figure 2: Flexineb MDI Use

Instructions for Use

Flexineb Nebuliser (Fig. 1):

1. Please read the *Intended Use*, *Safety Information* and *Maintenance* sections before using Flexineb
2. Check Inlet and Exit Valves are moving freely before placing the Mask on the horse
3. Rotate and open the Vent at bottom of Mask to allow the horse become familiar with the device
4. Fill the Medication Cup strictly following advice of your veterinarian
5. Close the vent in the bottom of the Mask when the horse is familiar with the Mask
6. Switch on the Controller and nebulisation will begin after a few seconds
7. You will see the Aerosol Chamber fill with aerosol and empty when the horse inhales
8. The Controller will time out after approximately 35 minutes or it can be switched off manually
9. To re-charge the battery only use the Flexineb supplied charger

Flexineb MDI Use (Fig. 2):

1. Remove the Controller, Cable and Medication Cup
2. Plug the supplied Adaptor into the Inlet Valve on top of the Aerosol Chamber
3. Rotate the Aerosol Chamber to the horizontal position
4. Insert the MDI and administer medication following the advice of your veterinarian

Controller Functions

Operation LEDs:

Power Levels 1-2-3:

There are three user selectable Power Levels 1,2,3. The default power level is 1. To change power levels press the button again during the start-up fast blink LED period to select the desired level for the liquid nebulised. Once the selected power level LED changes to CONSTANT ON then the power level is set and nebulisation begins. Pressing the button again will power the unit OFF.

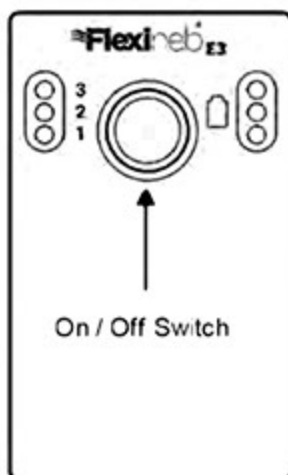
End of Dose Detection:

When the Med Cup runs dry the selected power level LED will eventually begin to blink slowly indicating the dose is complete and power to the Med Cup has switched off. To re-start turn OFF and ON again for the next run. Alternatively the unit will auto power off after 35 minutes.

Warning Indicator:

The bottom LED will turn RED and the unit will power off if there is a break in the circuit or an internal electronic problem.

Contact your customer service for assistance.



Battery Indicator LEDs:

During use you will see the Battery GREEN LED drop down through the levels. When the battery is low the bottom LED will eventually change from GREEN to RED to indicate charging is required. If the low battery RED LED is ignored then the bottom LED will eventually flash RED and power off the controller until charging is completed.

Charging:

With the 9V charger plugged in the LEDs will roll to indicate the battery is charging. The top LED will stay ON CONSTANT when charging is complete.

Warning:

Charger Input Voltage is LOW (<8V) → ALL Battery LEDs will flash RED with ON/OFF ratio 1:3. If Charger Input Voltage is HIGH (>10V) → ALL Battery LEDs will flash RED with ON/OFF ratio 3:1.

Technical Information

Flow Rate:

Typically ≥ 1.0 ml/min with 0.9% NaCl solution. The flow rate is very dependent on the drug used.

Aerosol Droplet Size:

Flexineb generates aerosol droplets in the respirable range for delivery to the airways of the horse.

The aerosol droplet size is dependent on the drug used.

Medication Cup Volume:

The medication cup will hold 10ml of liquid but is expandable to 30ml using the plug in extension cup supplied.

The controller has a timer function therefore, if the extension cup is used the controller will need to be re-started to complete the dose.

Battery Power:

Battery Type: 7.4V Li-ion rechargeable battery. Use the Flexineb supplied battery only. Use of another type of battery may present a risk of fire or explosion.

Operating Time: ~ 6 hours from fully charged.

Battery Charging:

Use the Flexineb supplied charger only. Use of an alternative charger may present a risk of fire or explosion. A fully discharged battery can take 4 to 5 hours to reach full charge.

Mains Power Supply: (Input: 100 to 240v AC / 50 to 60 Hz)

The Flexineb can also be operated using the Power Supply provided with the system. The same Power Supply charges the battery. Use the Flexineb Power Supply only.

Use of an alternative Power Supply may present a risk of fire or explosion and void warranty.

Environmental Conditions:

Operating: 5°C to 45°C and up to 95% RH

Storage and Transportation: -20°C to +45°C and 15% to 95% RH

Troubleshooting

Refer to www.flexineb.com website for detailed information on troubleshooting Flexineb problems.

Maintenance / Cleaning

Medication Cup:

Do Not use 'Well Water' & Do Not Place in Dishwasher.

Cleaning: It is very important to wash out the Med Cup after each use to avoid contamination or damage of the metallic vibrating mesh. Protect the electrical connector from getting wet when cleaning by using the protective cap provided. To clean out the Med Cup open up the soft blue Cap and place 2-3 drops of mild dish-washing liquid (**do not use dishwasher detergent**) into the Cup and fill with distilled water. Close the soft blue Cap and shake the Cup vigorously for about 15 seconds and squeeze the soft Cap to push water through the mesh whilst shaking. Open the Cap and rinse out from both sides with distilled water. Shake off excess water and let air dry before re-use.

Disinfection: To disinfect the outside surfaces of the Med Cup use anti-bacterial wipes.

CAUTION:

Do not immerse the Med Cup in water or cleaning chemical solutions!

Do not nebulize or put chemical cleaning solutions inside the Cup as they may permanently damage the metallic mesh or reduce its life!

Do not use sharp instruments to clean the metallic mesh in the Med Cup!

For continuity of treatment it is highly recommended to carry spare Med Cups!

Mask:

Cleaning: The Mask can be washed using clean warm tap water with some dish washing up liquid.

Rinse off with warm clean tap water and dry off before re-use.

Disinfection: First disassemble all parts of the Mask and wash them thoroughly with clean warm tap water and dish washing up liquid. Rinse the parts off and let them air dry on a clean dry surface.

Disinfect each part by wiping down thoroughly with anti-bacterial wipes before re-assembly.

Alternatively the Mask parts can be soaked in Nortev approved disinfectant chemicals.

Refer to separate information sheet or www.flexineb.com for details on recommended disinfectants.

Check www.flexineb.com for updates and video instructions on Cleaning & Disinfecting Flexineb.

Controller: To maintain the function of the electronic controller it must be used and stored in dry conditions. To maintain the battery function it must be charged when the Battery LED turns Red.

CAUTION:

Do not immerse the controller in water or any liquid as this will permanently damage the electronics!

Warranty

Mask Assembly (excluding valves), Controller (excluding battery) and Cable, Power Supply (charger): 24 months. Battery: 6 months. The Medication Cup is a wearing part and its life is very dependent on drugs nebulised and how well it is maintained therefore it is not covered by warranty.

Damage caused by improper handling or misuse is not covered by warranty.

Use of an alternative Power Supply may present a risk of fire or explosion and void warranty.

Compliance

Flexineb complies with the essential requirements of all relevant European Directives and Harmonized Standards.



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