

-89°C / -128°F

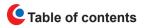


Innovative Veterinary Cryosurgery エス B



Veterinary line User's Guide Super, LUX, Premium

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The most recent version of this user manual and other language versions can be downloaded from the manufacturer's website www.cryoalfa.com

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1. Introduction and Warnings

Cryoalfa veterinary devices are intended for the controlled destruction of unwanted tissue by application of extreme cold using liquidfied N₂O.



With this unit you will operate directly on the animal. Therefore it is mandatory to carefully go through the manual and to follow the instructions in detail. If there are any doubts please consult your dealer or contact the manufacturer in Germany.

Only licensed specialists are allowed to use the units. Patients must be informed about eventual risks prior to start the treatment.

2. Legal

Cryoalfa[®] is the registered trademark of Cryoalfa Europe LTD. Liquid Freezing[®] is the registered trademark of Cryoalfa Europe LTD.

Notified Body Number: 0494

Patented technology in:

USA, Canada, China, Hong Kong, Japan and also other international patents pending.

Please also note the liability waiver at the back of this manual.

3. Used symbols

***	Manufacturer
\wedge	Warnings
50°C	Upper temperature limit 50°C
REF	Part number
SN	Serial number
*	Protect from direct sun exposure
STERILE	Steam sterilization
C€₀₄94	Notified body nr 0494 SGS DE



4. Products

This user manual is applicable for the following veterinary products and accessories:

Veterinary	instrument
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Cryoalfa Super Vet - Liquid Freezing Cryoalfa Super Vet - Contact Freezing Cryoalfa LUX Vet - Liquid freezing Cryoalfa LUX Vet - Contact Freezing Cryoalfa Premium Vet - Liquid Freezeing Cryoalfa Premium Vet - contact freezing

Cartridges with valve for veterinary use only

Cartridge 16 gram N_2O , box of 4 pcs Cartridge 25 gram N_2O , box of 4 pcs

Cryoalfa Ref

REF CA-S-VET REF CA-S-CX-VET REF CA-L-VET REF CA-L-CX-VET REF CA-P-VET REF CA-P-CX-VET

REF CA-K-V16/4-VET
REF CA-K-V25/4-VET

Veterinary applicators for use with LUX Vet, PREMIUM Vet

Long applicator, length 50 mm, Ø4 mm Long applicator, length 90 mm, Ø4 mm Long applicator, length 130 mm, Ø4 mm

Dermatology, applicator, length 22 mm, Ø1 mm Dermatology, applicator, length 22 mm, Ø2 mm Dermatology, applicator, length 22 mm, Ø3 mm Dermatology, applicator, length 22 mm, Ø4 mm

Contact-surface applicator Ø3 mm "gold-plated" Contact-surface applicator Ø5 mm "gold-plated" Contact-surface applicator Ø7 mm "gold-plated"

Dentistry applicator, 45°, length 80 mm, Ø4 mm.

Accesories for use with LUX, PREMIUM

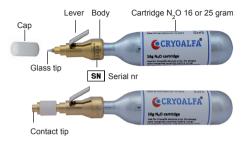
CAP for Cryoalfa Super Vet CAP for Cryoalfa LUX Vet, Premium Vet LED Light

REF CA-M-G5 REF CA-M-G9 REF CA-M-G13 REF CA-M-D1 REF CA-M-D2 REF CA-M-D3 REF CA-M-D4 REF CA-M-C3 REF CA-M-C5 REF CA-M-C7 REF CA-M-De

REF CA-Z-SKa REF CA-M-SKb REF CA-Z-L



5. Veterinary Instruments







Liquid Freezing® Cryo Ref.: CA-S-VET



Contact freezing Cryo Ref.: CA-S-C-VET

Cryoalfa LUX Vet



Liquid Freezing® Cryo Ref.: CA-L-VET



Contact freezing Cryo Ref.: CA-L-C-VET

Cryoalfa PREMIUM Vet



Liquid Freezing® Cryo Ref.: CA-P-VET



Contact freezing Cryo Ref.: CA-P-C-VET



5.1 Options for Model LUX Vet & PREMIUM Vet



Cartridge N₂O desgined to work with the Cryoalfa[®] | SUPER Vet, LUX Vet and PREMIUM Vet

Packed in box with 4 gas cartridges

6. How to work with your Cryoalfa® Vet

6.1 Installation of cartridge: Unscrew the protection cap of the cartridge and remove the small stopper. Then screw (clockwise) the cartridge into the threads of the Cryoalfa[®] body, continue to turn until feeling a light stop position. DO NOT USE FORCE!

The cartridge has a built-in filter and valve and can be screwed or unscrewed without any gas loss. When the cartridge is empty replace it with a new one.

- 6.2 Operation "Liquid Freezing": Remove the protecting cap from the glass tip. Bring the device into towards the lesion. By pressing the lever with the finger the flow of Nitrous Oxide begins.
- 6.3 Operation "contact freezing": By pressing the lever with the finger the contact tip starts to cool down. After approx 18 sec the tip has reached -80°C / -112°F and you are ready to start the treatment.
- 6.4 Application range: All skin lesions, in and out of mouth are approved to be treated with the Cryoalfa.
- 6.5 Treatment time: Treatment time depends on the depth at which the user deems necessary. Please refer to the treatment guidelines (included) for more details.
- 6.6 Cleaning: Cleaning: The glass-/contact tip can be cleaned and disinfected with a disinfectant or alcohol. If the device comes into contact with blood, mucous, or any other infected area it is mandatory to steam sterilize.

STERILE

Screw off the gas cartridge from the body and sterilize the body and glass-/contact tip. Use a steam sterilizer at 134°C / 273°F, according to EN norms 13060 and 285. All other sterilization methods are excluded.



A hot air sterilization may damage the glass tip and must be avoided under all circumstances.

6.7 Storage: After use, put the device back in the original packing. Once closed, make sure the lever is not being depressed. Otherwise, gas will escape unintentionally.



Protect the gas cartridge from heat and direct sun expo-Never expose the gas cartridge to a temperature above $+50^{\circ}$ C / $+122^{\circ}$ F.

Store at room temperature 21°C / 70°F. Make sure that the tip is always protected by the cap.



Keep the device out of the reach of children and unauthorized users.

- 6.8 Disposal: Disposal must be conducted in accordance with local requirements. Empty gas cartridge may be disposed of as scrap metal.
- 69 Safety instructions and risk: Only use the device as described in the user's quide for the purpose specified therein. Do not try to modify the device. Any manipulations of the device will result in an exclusion of warranty and liability



Cartridges are under extreme pressure. Follow all suggested safety instructions.



Never use a damaged unit. The manufacturer should check any device that has been dropped before it is used again.

Do not apply pressure when connecting the components. Put on the feeder's thread perfectly straight when changing the cartridge.

6.10 Warranty: The warranty is strictly limited to the exchange of defective parts. Dropped devices or broken tips are not under warranty. Other claims for damages such as loss of working hours, incorrect treatment and their consequences, non executed after treatment and their consequences as well as the non- observance of the safety instructions are excluded from all warranty and liability.

7. Liquid Freezing

Cryoalfa® Liquid Freezing® provides a highly concentrated freezing for a successful treatment. Our cryosurgical devices are equipped with a specific liquid gas dosing applicator. The operator is able to control the release of sufficient liquid N2O to treat lesions without wasting gas. With a temperature of -89°C / -128°F the liquid gas is evaporating on the lesion. A freeze thaw freeze method is recommended to achieve maximum results

This process causes the cells of the tissue to be destroyed due to the cell membrane rupturing as a consequence of ice crystal formation within the cell.

Please note: According to clinical studies, the freezing method Liquid Freezing[®] with N₂O is as efficient as liquid nitrogen (N₂) in most cryodermatologic indications

8. Medical considerations

Not getting expected result?

- A. No result Treatment probably did not last long enough or the glass tip was to far away from the lesion. Snow and the ice crystals do not effect the result only the liquid placed directly on the skin. Cryosurgery can normaly be repeated. A "second freezing" can be applied after about one minute.
- B. A blister, sometimes filled with blood, may develop after the treatment. Do not puncture the blister; instead cover it with plaster or bandage.

Follow-up treatment suggestions

- · Showering and swimming are permitted.
- · Keep the treated area clean.
- The animal should not pick or scratch the treated area.



9. Suggested freezing times

The veterinary literature has many reports of varying cryogenic freezing times. Also the thickness, location and hydration of the target tissue can affect outcomes. Veterinary professionals should be familiar with cryosurgical techniques when using Cryoalfa[®].



10. Simple treatment for success



- Draw a circle around the lesion to be treated. Measure the size of the lesion to be able to see the treatment result by the next visit, document in a animal journal.
- Put the animal in such a way that you can easily treat the lesion. If possible, the Cryoalfa unit should be perpendicular to the lesion being treated.
- Place your device with a soft pressure against the lesion which is going to be treated. Activate your device by pressing the lever on the side. The angle against the treatment area should be 65-90° to get the best result. Spraying at a distance has absolutely no effect, max distance <1 mm.
- For every 3 seconds of freeze, the Cryoalfa is penetrating 1mm in depth of the skin. The freezing times will vary depending on the particular lesion being treated.
- 5. Freezing begins immediately. The animal may feel a little discomfort due to the extreme cold. However, a treatment will never exceed 20 seconds limiting any severe discomfort. Approximately 5 minutes after treatment, a skin blush will appear over the treatment area.



Liability waiver

Improper use, including excess freezing levels beyond those, which are recommended or for an excessive duration, may result in bodily injury to clients/patients or to operator. Cryoalfa Europe LTD and their affiliates. respective directors, officers, shareholders, employees, agents and contractors are not liable or responsible, regardless of whether such liability or responsibility is based on breach of contract, tort, strict liability. breach of warranties, failure of essential purpose, fundamental breach or otherwise, for any death or injury, whether physical or mental, or for any incidental, consequential, indirect, special or punitive damages, arising out of the Cryoalfa products, its design, specifications, possession and use, and treatment procedures, and whether or not any such death, injury, loss, damage(s) result from the negligence, default or error in judgment by Cryoalfa Europe LTD, their affiliates, respective directors, officers, shareholders, employees, agents and contractors, and even if advised of the possibility of such damages. You agree to indemnify Cryoalfa Europe LTD. their affiliates, respective directors, officers, shareholders, employees, agents and contractors, from and against any and all liability, damages, losses, costs, judgments, fines, penalties and expenses (including legal expenses) of any kind or nature, including, without limitation, incidental, consequential, indirect, special or punitive damages, arising out of claims, demands, actions, causes of action, proceeding or suits. whether in law or in equity, due to any death, injury, loss, damage or damages as hereinbefore referred to