

CE 0494



User Manual CRYOALFA®

Super, Lux

CRYOALFA ORIGINAL®
Made in Germany

English

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1. Introductions and warnings

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



With this unit you will operate directly on the patient. Therefore it is mandatory to go carefully 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 skilled 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

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

3. Used symbols



Manufacturer



Warnings!!



Upper temperature limit 50°C



Part number



Serial number



Protect from direct sun exposure



Steam sterilization

CE 0494

Notified body nr 0494

4. Products

This user manual is applicable for the following products and accessories.

Instrument

Instrument	REF
Cryoalfa® Super - Liquid Freezing	CA-S
Cryoalfa® Super - Contact Freezing	CA-S-C
Cryoalfa® LUX - Liquid Freezing	CA-L
Cryoalfa® LUX - Contact Freezing	CA-L-C
Cryoalfa® Premium - Liquid Freezing	CA-P
Cryoalfa® Premium - Contact Freezing	CA-P-C

Gas Cartridges with valve

Gas Cartridge 16 gram N ₂ O	CA-K-V16
Gas Cartridge 25 gram N ₂ O	CA-K-V25

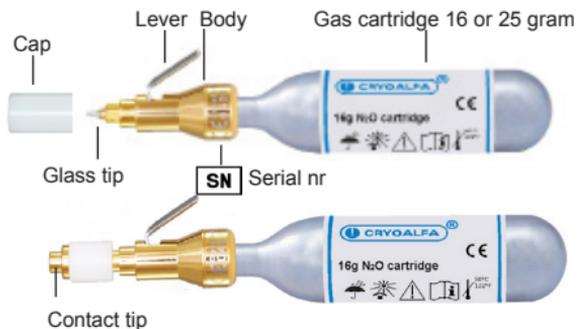
Applicators for use with LUX, PREMIUM

Cervix applicator length 50 mm, Ø4 mm	CA-M-G5
Cervix applicator length 90 mm, Ø4 mm	CA-M-G9
Cervix applicator length 130 mm, Ø4 mm	CA-M-G13
Dermatology, applicator, length 22 mm, Ø1 mm	CA-M-D1
Dermatology, applicator, length 22 mm, Ø2 mm	CA-M-D2
Dermatology, applicator, length 22 mm, Ø3 mm	CA-M-D3
Dermatology, applicator, length 22 mm, Ø4 mm	CA-M-D4
Contact-surface applicator 3 mm "gold-plated"	CA-M-C3
Contact-surface applicator 5 mm "gold-plated"	CA-M-C5
Contact-surface applicator 7 mm "gold-plated"	CA-M-C7
Dental applicator, 45° length 8 cm, Ø4 mm.	CA-M-De

Accessories for use with LUX, PREMIUM

CAP for Cryoalfa® Super	CA-Z-SKa
CAP for Cryoalfa® LUX, Premium	CA-L-SKb
LED Ligth	CA-Z-L

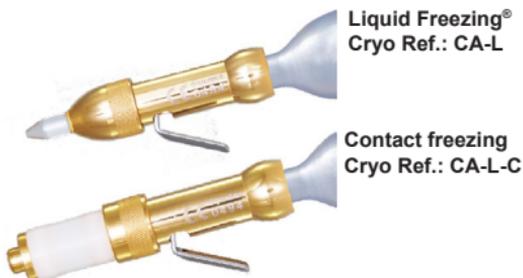
5. Models



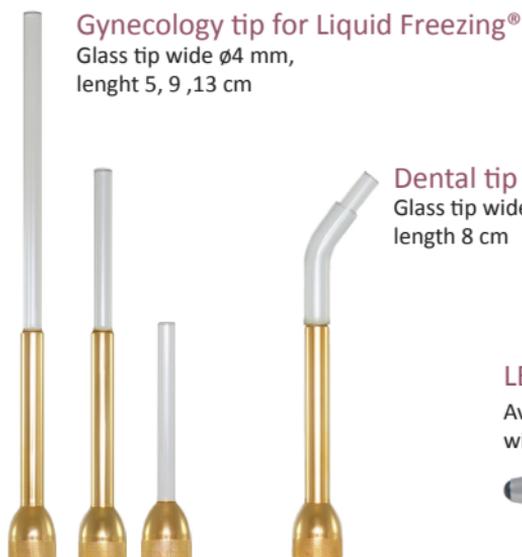
Cryoalfa® SUPER



Cryoalfa® LUX



5.1 Options for Model **Cryoalfa® LUX**



Gynecology tip for Liquid Freezing®

Glass tip wide \varnothing 4 mm,
length 5, 9, 13 cm

Dental tip 45°

Glass tip wide \varnothing 4 mm,
length 8 cm

LED Light

Available for all models
with 16 gram Cartridge



Tip for Liquid Freezing®

Glass tip wide \varnothing 1, 2, 3, 4 mm,
length 22 mm



Tip for contact freezing

Contact surface \varnothing 3, 5, 7 mm



Gas cartridge 16 /25 gram with valve

Gas cartridge design to work with the
Cryoalfa® | SUPER, LUX

Packed in box with 10 gas cartridges

6. How to work with your Cryoalfa®

6.1 Installation of gas cartridge:

Do not use other than original Cryoalfa® cartridges to operate the device! Unscrew the protection cap of the gas cartridge and remove the small stopper. Then screw (clockwise) the gas cartridge into the threads of the Cryoalfa® body, continue to turn until feeling a light stop position. **DO NOT USE FORCE!**

The gas cartridge has a built-in filter and valve and can be screwed or unscrewed without any gas loss. When the gas 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 therapy position. The device has to point in the direction of the therapeutically area. By pressing the lever with the finger the liquid flow starts.

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: For all typical indications occurring in medical practice, like treatment of all types of warts, haemangioma, papilloma, keratosis, condyloma, lentigo and more.

6.5 Treatment time: Treatment time lasts only for a few seconds depending on type and size of a lesion and is set at the discretion of the user. See time table.

6.6 Cleaning: The glass-/contact tip can be cleaned and disinfected with a disinfectant or alcohol. In touch with blood, mucous or any infected area it is mandatory to steam sterilize it.



Screw off the gas cartridge from the body and sterilize the body and glass-/contact tip. Use 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 in a way that the lever is not pressed by the cover, otherwise gas escapes and empties the gas cartridge unintentionally.



Protect the gas cartridge from heat and direct sun exposure; Never expose the gas cartridge for a temperature above $+50^{\circ}\text{C}$ / $+122^{\circ}\text{F}$.



Storage in 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 has to be done in a professional way and according to the country specific laws. Empty gas cartridge may be disposed of as scrap metal.
- 6.9 **Safety instructions and risk:** Only use the device as described in the user's guide and 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.



Observe the storage instruction since the gas cartridge is under pressure of 50 bar.



Never use a damaged unit. Any device that has been dropped should be checked by us, 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:** There is a 2 years warranty against technical defects. The warranty is strictly limited to the exchange of defective parts. Dropped device 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 high freezing speed, which is a condition to obtain 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 lesion without wasting gas. With a temperature of -89°C / -128°F the liquid gas is evaporating on the lesion. This removes heat from the surrounding tissue and affects a freezing of the treated area. This low temperature is converted to therapeutic energy with minimal loss.

As a result of this process the tissue cells are destroyed permanently 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

Absolute contraindications

Cryosurgery is contraindicated in patients with cryoglobulinemia. Please consult literature for more information.

Relative contraindications

- Insecurity when making diagnosis of kind of lesions (biopsy by skin carcinoma).
- Depigmentation as a side effect on dark skin can be cosmetically disturbing. On light skin depigmentation can hardly be seen and the skin tends to recover after exposure to the sun.
- Freezing too deep, especially peripherally on fingers, toes, wrist or the area behind the ear can theoretically give tissue damage.
- It is recommended by multiple lesions that freezing is done only on one side of the finger or toe.
- Lesions which in principal could be cryosurgically treated but also are infected should initially be medically treated for infection.
- In case of freezing nerves, continued pains are possible. Nerves or vessels can usually be protected by lifting, folding or moving the lesional skin.
- Treatment of areas on the head can provoke short headaches.
- Please consult literature for more information other potential contraindications.

Not getting expected result?

- A. No result - Treatment probably did not last long enough or the glass tip did not have contact with the skin. Snow and the ice crystals do not effect the result only the liquid placed directly on the skin. Cryosurgery can normally 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, cover it with plaster or bandage. In extrem case this might lead to a scar formation or hyperpigmentation.

Follow-up treatment suggestions

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

9. Suggested freezing times

The medical literature has many reports of varying cryogen freezing times, also the thickness, location and hydration of the target tissue can affect outcomes. Medical professionals should be familiar with cryosurgical techniques when using Cryoalfa®.

Although not exhaustive, the table below contains suggested freezing times as reported in the literature. These are wide ranges and provide only a guideline for consideration.

Type of lesion	Literature freeze Time range in seconds
Acne	4 - 6
Actinic Keratosis	4 - 8
Basiloma	8 - 9
Cavernous Angioma	4 - 6
Condyloma	5 - 12
Granuloma Anulare	5 - 6
Keloids	4 - 6
Lentigo	2 - 5
Molluscum Contagiosum	3 - 10
Seborrheic Keratosis	5 - 10
Skin Tags	5 - 10
Verucca Plana	5 - 15
Verucca Plantaris	10 - 20

References for Liquid Freezing®

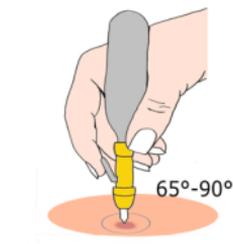
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2. Hundeiker M, Sebastian G, Bassukas ID, Cyrotherapy guidelines for dermatology
3. Bassukas ID, Hundeiker M, "Liquid freezing®" A new approach for the cryosurgical treatment of superficial skin lesions
4. Hundeiker M, "Simplified cryotherapy" Daily practice 42:311-314, 2001.
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References for cryosurgery in general

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3. Andrews M, CryoSurgery for Common Skin Conditions, American Family Physician, 69:10, 2365-2372, 2004.
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10. Sample



1. Draw a circle round 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 patient journal.
2. Debride the wart to pinpoint bleeding. If the wart is bleeding we recommend you to use homeostatic solution to stop the bleeding (this point only valid for footwarts).
3. Put the patient in such a way that you easily can treat the lesion. The lesion to be treated should point up against the sealing.
4. 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 on distance has absolutely no effect.**
5. The freezing effect is approx 3 mm deep and 8-10 mm diameter on 12 seconds. The freezing result will vary depending on thickness of the skin, type of lesion and freezing time.
6. Freezing starts immediately, this can be seen by a whitening of the skin. From this moment the patient could feel a shooting feeling or sometimes a slight pain if there are many nerve endings turned downwards in the treated area. Even a small part of healthy skin shall be treated during this process. Approx. 5 minutes after the treatment is completed a skin blush will replace the part which was white coloured by the freezing treatment.
7. If treatment has been done on a part where the patient is walking on we recommend a plaster on the area to relieve the treated area.
9. Reserve a time for next visit within 2 weeks. Sometimes 2 to 3 treatments are necessary before the wart / lesion is removed. By each treatment occasion the prescribed procedure should be taken.

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.