CE 0494

-89°C / -128°F

English

CRYOALFA®

LIQUID FREEZING®

The innovative way of cryosurgery

User's Guide

PERFECT

Table of contents

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

All mentioned products are manufactured in the European Community by;

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1. Introduction and Warnings

Cryoalfa devices are intended for the controlled destruction of unwanted tissue by application of extreme cold using liquidfied N_2O.

With this unit you will operate directly on the patient. 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 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

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

4. Products

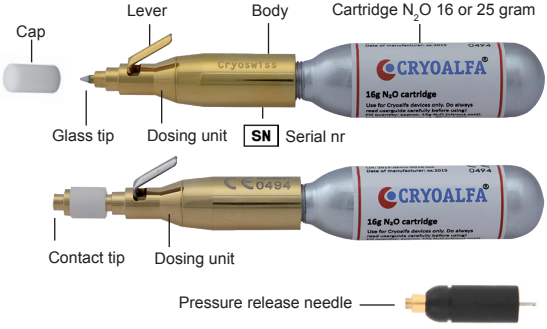
This user manual is applicable for the following products and accessories.

Instrument	Cryoalfa Ref
Cryoalfa Perfect - Liquid Freezing	REF CA-Pr
Cryoalfa Perfect - Contact Freezing	REF CA-Pr-C
Cartridges without valve	
Cartridge 16 gram N_2O, box of 4 pcs	REF CA-K-G16/4
Cartridge 25 gram N_2O, box of 4 pcs	REF CA-K-G25/4
Accesories for use with Perfect	
CAP for Cryoalfa Perfect	REF CA-Pr-SKa
Pin for tighting gas cartridge ”Perfect”	REF CA-Z-P
O-ring for ”Perfect”	REF CA-Pr-Or

Liquid Freezing®
Cryo Ref.: CA-Pr

Contact freezing
Cryo Ref.: CA-Pr-C

5. Models



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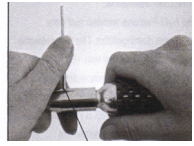
6. How to work with your Cryoalfa®

6.1 Attaching the Cartridge: Take the device in your hand and put the metal pin in the intended hole in the unit body. This helps to grip the body without damaging the lever. Screw the cartridge in a clockwise direction quickly and fully into the body of the unit. Take care to align the cartridge straight and never to force the thread. No noise of escaping gas should be heard whilst attaching the cartridge. Thereafter the unit is ready for use.

Replacing the Cartridge:
For technical reasons a residual amount of gas remains in the cartridge. To exchange the cartridge the following procedure must be followed. Only change the gas cartridge if you are sure that it is not under pressure.

1. Protect your hands from contact with gas/liquid by using gloves when changing the cartridge. Use also goggles to protect your eyes.
2. Have the pressure release needle ready.
3. Hold the device tightly in your hand, you may use the anti-slip cloth.
4. Unscrew the ”dosing unit” (see the picture in section 5) slowly counterclockwise and carefully put it aside.
5. Now screw the pressure release needle slowly (insert hollow pin into the adapter). Do not lean over the device doing this and keep the pressure release needle pointing away from you. The gas escapes through the pressure release needle now. The leaking noise will decrease in volume until there is no more pressure in the cartridge. The cartridge can now be safely unscrewed.



6. Unscrew the pressure release needle from the adapter and reattach the dosing unit again (tighten it slightly by hand)

Warning:

If you can not unscrew the gas cartridge with a light hand, it must be assumed that the gas cartridge is still under pressure!

6.2 Operation "Liquid Freezing": Remove the protective 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 approximately 18 sec the tip has reached -80°C / -112°F and you are ready to start the treatment.

6.4 Application range: 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 the time table in section 9.

6.6 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.

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 exposure. Never expose the gas cartridge to a temperature above +50°C / +122°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.

6.9 Safety instructions and risk: Only use the device as described in the user's guide 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.

AThis 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 N_2O is as efficient as liquid nitrogen (N_2) 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 or was to far away from the skin. 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. In extreme cases 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 cryogenic 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	Molluscum Contagiosum	3 - 10
Actinic Keratosis	4 - 8	Seborrheic Keratosis	5 - 10
Basiloma	8 - 9	Skin Tags	5 - 10
Cavernous Angioma	4 - 6	Verruca Juvenile	3 - 4
Condyloma	5 - 12	Verucca Plana	5 - 15
Granuloma Anulare	5 - 6	Verucca Plantaris	10 - 20
Keloids	4 - 6	Verruca Vulgaris	10 - 20
Lentigo	2 - 5		

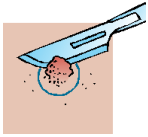
References for Liquid Freezing®

1. Hundeiker M, "Liquid freezing®" in esthetical dermatology Dt.Dermat, 51:55-56, 2003
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.
5. Hundeiker M, Bassukas ID, "Cryosurgery in Office Dermatology" An Update, 2005.

References for cryosurgery in general

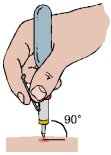
1. Dockery G, Treating A Child With Multiple, Mildly Pruritic Papules, Podiatry Today, 20:4, 2007.
2. Strumia R, La Crioterapia in Dermatologia, Published by Business Enterprise SRL, 2006.
3. Dawber R, Colver G, Jackson A, Cutaneous Cryosurgery - Principles and Clinical Practice, Martin Dunitz Publisher, 3:d Edition, 2005.
4. Andrews M, CryoSurgery for Common Skin Conditions, American Family Physician, 69:10, 2365-2372, 2004.
5. Rubinsky B, CryoSurgery, Annual Review Biomedical Engineering, 02:157-187, 2000.
6. Gage A, What Temperature is Lethal for Cells? J Dermatol Surg Oncol, 5-6, 1979.

10. Simple treatment for success



1. 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 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 ceiling.

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 at a distance has absolutely no effect.**

5. 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.

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 coloured white by the freezing treatment.

7. If treatment has been done on the footpad we recommend a plaster on the area to relieve the treated area.

8. 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.