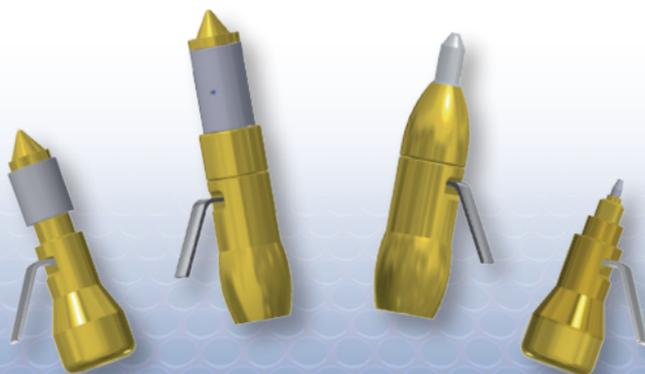




The innovative way of cryosurgery



USER'S GUIDE

DERM, PRO

CE 0537

-89°C / -128°F

English

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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.cryoIQ.com

All mentioned products are manufactured in the European Community by:



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1. Introduction and Warnings

CryolQ® devices are intended for the controlled destruction of unwanted tissue by application of extreme cold using liquidified N₂O (-89°C) or CO₂ (-78°C).



With this device you will operate directly on the patient. Therefore it is mandatory to carefully go through the user guide and to follow the instructions in detail. If there are any doubts please consult your dealer or contact the manufacturer in Sweden.

Only medical professionals or skilled specialists are allowed to use the units. Patients must be informed about eventual risks prior to start the treatment.

2. Legal

CryolQ® is the registered trademark of CryolQ AB.

Other registered trademark are a property of respective owners.

Notified Body Number: 0537

Please note the liability waiver at the back of this user guide.

3. Used symbols



Manufacturer



Warnings



Upper temperature limit 50°C/122°F



Part number



Serial number



Protect from direct sun exposure



Notified body no. 0537

4. Products

This user guide is applicable for the following products and accessories:

Devices

CryolQ DERM - Liquid

CryolQ DERM - Contact 1

CryolQ DERM - Contact 3

CryolQ DERM - Contact 5

CryolQ PRO - Liquid

CryolQ PRO - Contact 1

CryolQ PRO - Contact 3

CryolQ PRO - Contact 5

CryolQ Ref

 C IQ-D-L

 C IQ-D-C1

 C IQ-D-C3

 C IQ-D-C5

 C IQ-P-L

 C IQ-P-C1

 C IQ-P-C3

 C IQ-P-C5

Cartridges with valve*

Cartridge 16 gram N₂O

Cartridge 25 gram N₂O

Cartridge 16 gram CO₂

Cartridge 16 gram N₂O, box of 4 pcs

Cartridge 25 gram N₂O, box of 4 pcs

 C IQ-G-VN16

 C IQ-G-VN25

 C IQ-G-VC16

 C IQ-G-VN16/4

 C IQ-G-VN25/4

Applicators for use with PRO

Long tip, L=130 mm, spray freeze Ø7-18 mm

Dermatology tip, L=22 mm, spray freeze Ø1-6 mm

Dermatology tip, L=22 mm, spray freeze Ø7-18 mm

Dermatology tip, L=22 mm, spray freeze Ø9-22 mm

Contact freezing tip Ø1 mm "gold-plated"

Contact freezing tip Ø3 mm "gold-plated"

Contact freezing tip Ø5 mm "gold-plated"

Angled tip, 45°, L=80 mm, spray freeze Ø7-18 mm

 C IQ-PA-L13

 C IQ-PA-D1

 C IQ-PA-D2

 C IQ-PA-D3

 C IQ-PA-C3

 C IQ-PA-C3

 C IQ-PA-C5

 C IQ-PA-A45

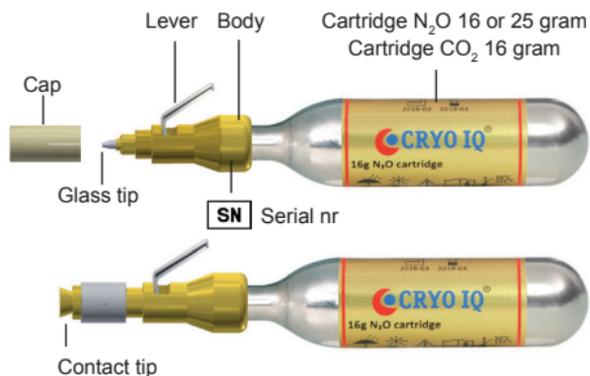
Accessories for use with PRO

LED light, for 16 gram gas cartridge.

 C IQ-A-LED

* Please note the gas cartridges (CA-K-V16 & CA-K-V25) from Cryoalfa® will not work with CryolQ devices even if the products look similar.

5. Models



CryoIQ DERM

Liquid Freezing



CIQ-D-L

Contact Freezing



CIQ-D-C1



CIQ-D-C3



CIQ-D-C5

CryoIQ PRO

Liquid Freezing



CIQ-P-L

Contact Freezing



CIQ-P-C1



CIQ-P-C3



CIQ-P-C5

5.1 Options for Model PRO

Long tips for Liquid "Spray" Freezing

Glass tip, length 130 mm
Treatment area \varnothing 7-18 mm



L13



A45

Angled tip 45° for Liquid "Spray" Freezing

Glass tip, length 80 mm
Treatment area \varnothing 7-18 mm



D1

D2

D3

Tips for Liquid "Spray" Freezing

Glass tip, length 22 mm
D1= Treatment area \varnothing 1-6 mm
D2= Treatment area \varnothing 7-18 mm
D3= Treatment area \varnothing 9-22 mm



C1

C3

C5

Tips for Contact Freezing

Contact surface \varnothing 1, 3, 5 mm



Cartridge 16 /25 gram with valve

Cartridge designed to work with the
CryoIQ® | DERM, PRO

Packed in box with 4 cartridges

6. How to work with your CryoIQ®

- 6.1 **Installation of cartridge N₂O and CO₂:** Unscrew the protection cap of the cartridge and remove the small stopper. Then screw (clockwise) the cartridge into the threads of the CryoIQ® 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 "Spray" 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 N₂O begins.
- 6.3 **Operation "contact freezing":** By pressing the lever with the finger the contact tip starts to cool down. After approx 20 sec the tip has reached -50°C / -58°F (using N₂O) 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 depends on the depth at which the user deems necessary. Please refer to the treatment guidelines (included) for more details.
- 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 package. Once closed, make sure the lever is not being depressed. Otherwise, gas will leak out 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.

- 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 device. 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 replacing 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 Cryo

CryoIQ® Liquid Cryo 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 "spray" 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, diabetics, cancer, HIV, circulation problem, Raynaud's, medicated with anticoagulant medicine, collagen diseases, hemophilia or patient undergoing immunosuppressive treatments, children under 4 year. Consult literature for more absolute contraindications.

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.
- Potential risk for hyperpigmentation when exposing a newly treated area for strong 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 relative 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 too 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 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; instead cover it with plaster or bandage. In extreme cases this might lead to a scar formation or hyperpigmentation.

Follow-up treatment suggestions

- Keep the treated area clean.

9. Suggested freezing times

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

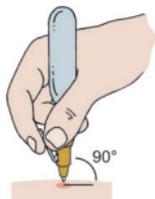
Although not exhaustive, the table below contains suggested freezing times as reported in the literature. These are wide ranges and provide only a guideline for consideration.

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 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. Bassukas ID, Hundeiker M, "Liquid freezing®" A new approach for the cryosurgical treatment of superficial skin lesions
6. Rubinsky B, CryoSurgery, Annual Review Biomedical Engineering, 02:157-187, 2000.
7. 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. When treating warts 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 CryoIQ is penetrating 1 mm in depth of the skin. The freezing times will vary depending on the particular lesion being treated.
6. Freezing starts immediately. 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. CryoIQ AB 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 CryoIQ 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 CryoIQ AB, their affiliates, respective directors, officers, shareholders, employees, agents and contractors, and even if advised of the possibility of such damages. You agree to indemnify CryoIQ AB, 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.