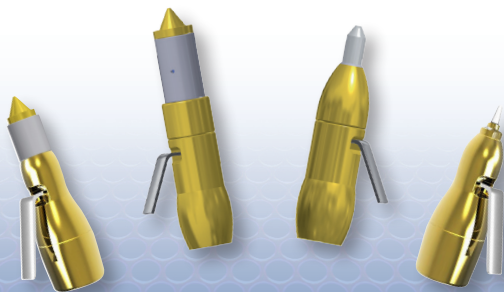




The innovative way of cryosurgery



USER'S GUIDE

DERM PLUS, 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/-128°F) or CO₂ (-78°C / -108,4°F).



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 Skafte Medlab.
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 plus - Liquid
CryolQ DERM plus- Contact 1
CryolQ DERM plus- Contact 3
CryolQ DERM plus- Contact 5

CryolQ PRO - Liquid
CryolQ PRO - Contact 1
CryolQ PRO - Contact 3
CryolQ PRO - Contact 5
CryolQ PRO - Contact 7

CryolQ Ref

REF CIQ-DP-L
REF CIQ-DP-C1
REF CIQ-DP-C3
REF CIQ-DP-C5

REF CIQ-P-L
REF CIQ-P-C1
REF CIQ-P-C3
REF CIQ-P-C5
REF CIQ-P-C7

Cartridges with valve*

Cartridge 16 gram N₂O
Cartridge 25 gram N₂O
Cartridge 16 gram CO₂
Cartridge 16 gram N₂O, box of 4 pcs

REF CIQ-G-VN16
REF CIQ-G-VN25
REF CIQ-G-VC16
REF CIQ-G-VN16x4

Applicators for use with PRO

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"
Contact freezing tip Ø7 mm "gold-plated"

REF CIQ-PA-D1
REF CIQ-PA-D2
REF CIQ-PA-D3

REF CIQ-PA-C3
REF CIQ-PA-C3
REF CIQ-PA-C5
REF CIQ-PA-C7

Long tip, L=130 mm, spray freeze Ø7-18 mm
Angled tip, 45°, L=80 mm, spray freeze Ø7-18 mm

REF CIQ-PA-L13
REF CIQ-PA-A45

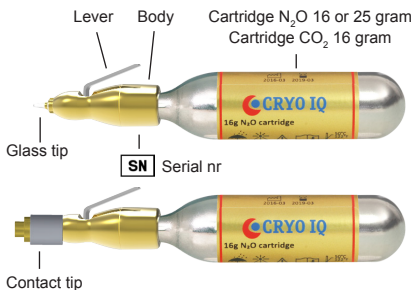
Accessories for use with PRO

LED light, for 16 gram gas cartridge.

REF CIQ-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-DP-L

Contact
Freezing



CIQ-DP-C1



CIQ-DP-C3



CIQ-DP-C5

CryoIQ PRO

Liquid
Freezing



CIQ-P-L

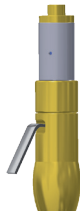
Contact
Freezing



CIQ-P-C1



CIQ-P-C3



CIQ-P-C5



CIQ-P-C7

5.1 Options for Model PRO

Long tip 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



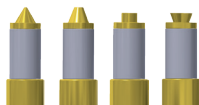
D1

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

C7

Tips for Contact Freezing

Contact surface \varnothing 1, 3, 5, 7 mm



Cartridge 16 /25 gram with valve

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

Packed in box with 1 cartridge
Packed in box with 4 cartridges

6. How to work with your CryoIQ®

- 6.1 **Installation of cartridge N₂O:** Unscrew the cap of the cartridge and remove the small white plastic stopper. Then screw (clockwise) the cartridge into the threads of the CryoIQ® body, continue to turn until you feel a light stop position (resistance). **DO NOT USE FORCE!**

The cartridge has a built-in filter and valve and can be screwed or unscrewed without any gas loss. The cartridge is empty when no white stream of nitrous oxide is being expelled anymore through the applicator when pressing the lever. There is only air coming out at that point. Replace the empty cartridge with a new one in the next treatment.

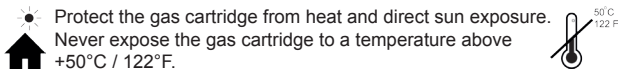
- 6.2 **Operation Liquid "Spray" Freezing:** Remove the cap from the glass tip and bring the device in an angle towards the lesion. By pressing the lever the flow of Nitrous oxide starts. You have to stay in the first 4mm distance of the skin as Otherwise only air will be expelled onto the skin instead of liquid nitrous oxide and there will be no freezing effect. Always, move the applicator around in small circles or in a diagonal line from the border of the lesion towards the center or from the center to the border. For smaller lesions (1-2 mm) a tipping movement can be practiced toward the lesion. Movement is needed to avoid ice crystals building up on top of the lesion. The closer the tip is on the lesion, the larger of a surface will be treated and more freezing power is brought onto the lesion.
- 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 and you are ready to start the treatment.
- 6.4 **Application range:** All typical skin indications occurring in a medical practice, such as treatments of all types of warts, hemangioma, 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 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.

Unscrew the gas cartridge from the body and sterilize the body and glass tip. Use a steam sterilizer at 134°C / 273°F, according to EN norms 13060 and 285. All other sterilization methods are excluded. **NEVER STERILIZE A CARTRIDGE!**




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


- 6.7 **Storage:** After use, place the device back in the storage case. Once closed, make sure the lever is not being pressed down by the lid of the storage box. Otherwise, the gas will leak out unintentionally.



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

- 6.8 **Disposal:** The disposal of a cartridge must be conducted in accordance with local requirements. An 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 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. Place the cartridge straight in the threads of the unit's body 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

CryolQ® 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 N_2O 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 N_2O is as efficient as liquid nitrogen (N_2) in most cryodermatology indications.

8. Medical considerations

Absolute contraindications

Cryosurgery is contraindicated in patients with cryoglobulinemia, diabetics, cancer, HIV, circulation problems, Raynaud's, collagen diseases, hemophilia, patients undergoing immunosuppressive treatments, patients being medicated with anticoagulant medicine, and children under 4 years. Consult literature for more absolute contraindications.

Relative contraindications

- Insecurity when making a diagnosis of the skin lesion (biopsy by skin carcinoma).
- Depigmentation as a side effect on dark skin can be cosmetically disturbing. On light skin depigmentation this can hardly be seen and the skin tends to recover after exposure to the sun.
- Potential risk for hyperpigmentation when a newly treated area is exposed to a lot of sun.
- Freezing too long, especially peripherally on fingers, toes, wrist or the area behind the ear can theoretically give tissue damage.
- It is recommended that a treatment of multiple lesions on a toe or finger is done on one side at a time.
- Lesions which in principal could be cryosurgical treated but also are infected should initially be medically treated for the infection.
- In case of freezing nerves, a short period of pain is possible. Nerves or vessels can usually be protected by lifting, folding or moving the skin with the lesion.
- Treatment of areas on the head can cause brief headaches.
- Please consult literature for more relative contraindications.

Not getting expected result?

- A. No result – The treatment time was probably not long enough, the glass tip wasn't within the 1-4 mm range from the skin or a freeze-thaw-freeze cycle wasn't performed. Ice crystals will affect the result when they are build-up onto the lesion into an pyramid form as the cryogen will be expelled only to the sides..
- B. A blister, sometimes filled with blood, may develop after the treatment. Do not puncture the blister; instead cover it with a band aid. In rare, 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 various cryogenic freezing technics. The thickness, location and hydration of the target tissue can affect outcomes. Medical professionals should be familiar with cryosurgical techniques when using CryoIQ®.

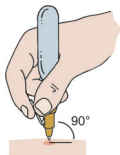
Although not exhaustive, the table below contains suggested freezing times as reported in the literature. These are wide ranges and provide only a guideline for consideration.

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	Verruca Plana 5 - 15
Granuloma Anulare	5 - 6	Verruca 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 the findings in a patient journal.
2. When treating warts debride the wart to pinpoint bleeding. If the wart is bleeding we recommend you to use hemostatic solution to stop the bleeding (this point only valid for warts on the foot).
3. Place the patient in such a way that you easily can treat the lesion. The lesion to be treated should point towards the ceiling.
4. Place your device within the 1-4 mm range from the target lesion. 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 from a further 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 on the patient could feel a stinging sensation or sometimes a slight pain if there are many nerve endings turned downwards in the treated area. Even a small part of healthy skin may be treated during this process. 7. If the treatment has been done on the sole of the foot we recommend to cover the area with a band aid the area in order to relieve the treated area.
7. If treatment has been done on the footpad we recommend a plaster on the area to relieve the treated area.
8. A follow up visit should be scheduled within 2-3 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.