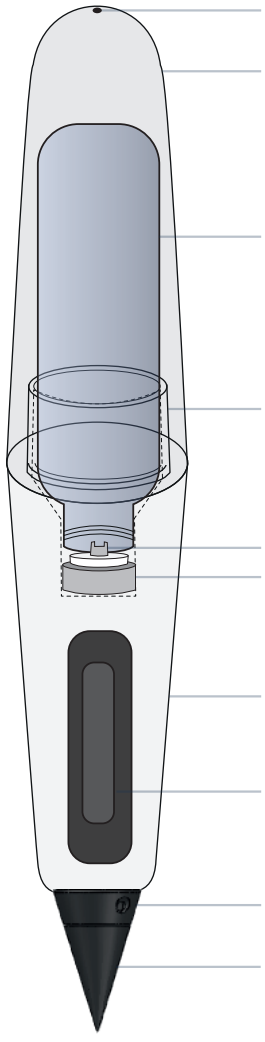


SN

The serial number is engraved in the cavity for all devices except for CryoPen M where the serial number is engraved on the top of the frontend thread.

Please mention your instrument's serial number on all communication with H&O Equipments.

CryoPen M

Other device

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

INSTRUMENTS - *Expected lifetime : minimum 10 years in normal use.*

REF

CryoPen M with blue/red and white/red dot micro-applicators S-HO-CMPE-01
CryoPen O+ with blue/red, white/red, green/red and yellow/red dot micro-applicators S-HO-COPE-02
CryoPen X+ with blue/red, white/red, green/red and yellow/red dot micro-applicators, with blue/red and white/red dot 60mm long micro-applicators S-HO-CXPEP-02

The instrument, the applicators, the tweezer, a support and the user manual come in a hard case for easy transportation.

CARTRIDGES - *Expiring date printed on the cartridges packaging.*

8g N_2O cartridges: 1 carton of 12 boxes each containing 24 cartridges
for use with CryoPen M, CryoPen O+, CryoPen X+ S-HO-NOCX-12-S24

16g N_2O cartridges: 1 carton of 12 boxes each containing 6 cartridges
for use with CryoPen O+, CryoPen X+ S-HO-NOCX-12-S06

APPLICATORS

Blue/red dot applicator for 1-3 mm applications S-HO-CCXO-MA-004
White/red dot applicator for 2-6 mm applications S-HO-CCXO-MA-005
Green/red dot applicator for 4-8 mm applications S-HO-CCXO-MA-006
Yellow/red dot applicator for 7-20 mm applications S-HO-CCXO-MA-007
Blue/red dot long applicator 60 mm for 1-3 mm applications S-HO-CCXO-MA-008
White/red dot long applicator 60 mm for 2-6 mm applications S-HO-CCXO-MA-009
Green/red dot long applicator 120 mm for 4-8 mm applications S-HO-CCXO-MA-026

The above list of products is correct at the time of printing. Some articles may no longer be available when reading this document. Some articles may not be available in certain countries.

CryoPen® is the registered trademark of H&O Equipments nv/sa for Europe, the Middle East, Africa and Asia Pacific.

CryoPen® is manufactured by H&O Equipments nv/sa.

FDA certificate is available and can be obtained upon simple request.

EC Declaration of Conformity and EC certificate are available and can be obtained upon simple request.

Device classification

CryoPen is a non-invasive, non-sterile, reusable medical device.

Intended Use

CryoPen is dedicated for the cryogenic treatment of the following benign skin lesions : Acrochordon, actinic keratosis and cheilitis, capillary haemangioma, cutaneous leishmaniasis, discoid lupus erythematosus, filiform, flat, vulgar, plantar and anogenital warts, rosacea, lichen sclerosus, granuloma annulare, molluscum contagiosum, seborrheic keratosis, viral lesions by dispensing an extremely precise flow of nitrous oxide applied directly on the lesion.

All mentioned products are manufactured in the European Community by,

H&O Equipments nv/sa
Rue des Journaliers 1, 7822 Ghislenghien, Belgium

Telephone: +32 68 26 86 00
Fax: +32 68 55 28 48
E-mail: info@ho-equipments.com
Website: www.ho-equipments.com

This manual's version: Manual_CryoPenM-O+-X+_20230531.

Attention! Reference is made to the liability waiver at the back of this manual.

USED SYMBOLS:

Manufacturer

Caution, consult accompanying documents

Consult the user's guide

-30°C 50°C Do not expose the cartridges to temperatures below -30°C/-22°F and above 50°C/122°F

Keep away from sunlight

REF Catalogue number

SN Serial number

LOT Batch number

MD Medical Device

UDI Unique Device Identification

Use-by date

CE 1639 Notified body nr 1639 SGS BELGIUM

IMPORTANT NOTICE:

- When used correctly, the device does not come into contact with the lesion nor the skin.
- When used normally, there is no need to perform any maintenance, cleaning or disinfection.
- Never clean the thread of frontend and backend. The existing coating should be protected.
- Should the applicator touch the patient in case of misuse, the applicator can be cleaned (autoclaved: 134°C/273°F - 4 min or 121°C/250°F – 20 min) and disinfected (use a non-corrosive disinfecting solution, follow the disinfecting solution manufacturer's recommendations with regards to the concentration and time of application).
- Always gently manipulate all components of CryoPen instruments. Never use more than gentle hand force. Never use pliers or other tools to manipulate the instrument.
- Please ensure to only use the cartridges and filter/openers supplied from H&O Equipments nv/sa. Any other cartridges and filter/openers would damage the instrument.
- Incorrect placement of the filter/opener device into the loading cavity will cause irreversible damage to the instrument.
- Residual foreign matters in the loading cavity while placing a new filter/opener can cause instrument failure.
- When loaded, the instrument is under high pressure. Any change to the construction of the instrument may cause a potential risk.
- Never put your hand on the gas release opening at the end of the backend while removing the cartridge!
- All external parts can be wiped with a cloth soaked in any noncorrosive disinfecting solution. Never immerse the entire instrument in a disinfecting solution.
- The applicators must be kept away from dust and the cartridges must be kept away from extreme temperatures (min -30°C/-22°F and max 50°C/122°F). Leave the applicator cap on when not in use.
- The CryoPen should be handled with care. When storing the instrument with a loaded cartridge in its case, position the CryoPen in such a way that the trigger cannot be pressed when closing the lid of the case. This would cause undesired gas flow.
- CryoPen instruments are intended for professional use only.
- The N_2O cartridges contain both a liquid and a gaseous phase in balance. The proportion of each phase depends on the room temperature which affects the output flow. The best performances are achieved when the cartridge temperature is between 19°C and 22°C (66°F and 72°F). Lower and higher temperatures will give different values of pressure and density of the cryogen. Over 25°C/77°F, the quantity of liquefied N_2O in the CryoPen jet will decrease.
- Empty cartridges should be discarded as metal scrap.

Contraindications:

- Unstable diabetes
- Skin conditions, e.g. skin tumors, esanthema, open wounds, solar hyperkeratosis
- Unexplained, suspicious liver spots and moles
- Cancer tissues and malignant tumors

The contraindications related to temporary conditions:

- Infections accompanied by fever
- Acute chemotherapy or radiotherapy from four weeks before beginning the therapy to four weeks after finishing the therapy
- Pregnancy or breastfeeding
- Cold intolerance
- Vascular insufficiency

Reduce possible side-effects:

Although cryotherapy is a relatively low-risk procedure, some side effects may occur as a result of the treatment.

They include:

- Permanent changes in pigmentation. Both hypopigmentation (lightening of the skin) and hyperpigmentation (darkening of the skin) may occur after cryotherapy. Both generally last a few months, but can be longer lasting. Avoid freezing the basal cell layer where melanocytes (pigment producing cells) are located.
- Sensory impairment. Though rare, damage to nerves is possible, particularly in areas where they lie closer to the surface of the skin, such as the fingers, the wrist, and the area behind the ear. Reports suggest this will disappear within several months.
- Spattering of the cryogen during spraying, when the end nozzle freezes. The innovation of CryoPen is the direct application of nitrous oxide under high pressure (49-53 bar for a cartridge temperature of 66-72°F /19-22°C). This high pressure jet may cause minor shards of frozen humidity in the air blown away in a circle of approximately 30cm of diameter. They will thaw the moment they would eventually touch healthy skin.
- Hair loss. Hair follicles are easily damaged by cryosurgery and permanent hair loss is not uncommon.

Further side-effects:

- Edemas
- Bleeding
- Pain and syncope
- Insufflation of subcutaneous tissue
- Retraction caused by freezing next to orifices
- Cartilage defect during treatment of the nose or the ear
- Infection
- Conjunctival ectopy due to treatments of the eyelid
- Milia
- Depressed or atrophic scars

Interact with your patients

Inform patients that there will be a pain sensation similar to a ballpoint being pushed onto the skin. Generally, little or no discomfort is experienced during the first few seconds when you manage to avoid treatment of healthy tissue. The ice will reach the caudal extent of the lesion after a given amount of time related to the depth of the lesion. From that moment the patient will experience a pain sensation. This may be the moment to stop treatment. You may eventually add a few seconds more depending on the patient's comfort level and upon the clinical evaluation of the operation. There might be a little residual stinging for a few minutes after treatment. Occasionally, a blister might form and persist for a few hours.

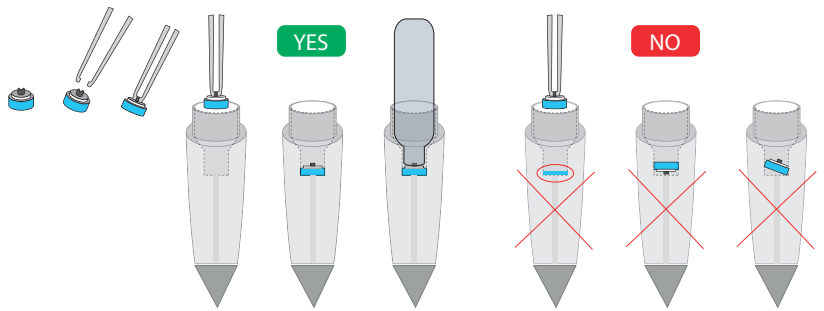
USING THE INSTRUMENT:

Step 1 Load a new cartridge

The cartridges are packed in peel-pack blisters with an assembled filter/opener included. The filters are used for protection of the applicator, the opener for puncturing the cartridge.

CryoPen M can only be used with 8g N_2O cartridges. CryoPen X+ and CryoPen O+ can be used with 16g N_2O cartridges and with 8g N_2O cartridges, thanks to the converter 16/8g. Ensure that the cavity is empty of any remaining parts. Open the peel-pack. Take out the filter/opener with the tweezers. Hold the CryoPen's tip end pointed downward. Place the filter/opener in the instrument and make sure that it is seated flat at the bottom of the loading cavity.

The trocar of the opener should be pointed upward! Take the cartridge and put it into the cavity with the narrow side down, on top of the filter/opener.



Installation of the assembled filter opener

Step 2 Puncture the unused cartridge

Gently screw the CryoPen's backend onto the frontend. Go to the point where you feel that the contact between the assembled filter/opener and the cartridge is established. Now, position your hands so that the last turn will be in an uninterrupted movement. Now, rotate quickly until you feel that the end of the rotation is achieved.
You may eventually hear a short hissing sound.
The shorter the hiss, the better!

Discharge the used cartridge & empty the cavity

Before loading a new cartridge, first release any unused gas from the current cartridge by unscrewing the applicator followed by pressing the trigger. Then unscrew the backend. Discard the used cartridge and filter/opener. Regarding CryoPen X+ and CryoPen O+, be careful not to throw away the converter 16/8g. Ensure that the used filter/opener does not remain inside the cavity. You should have the cavity empty of any remaining parts.

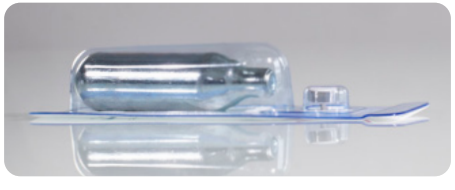
Step 3 Use your CryoPen

Remove the applicator cap. Gently squeeze the trigger to start the flow of N_2O. Release the trigger to close off the flow of cryogenic liquid. 1 or 2 seconds after releasing the trigger, the remaining gas in the applicator is discarded.
A cartridge can be used for several treatments and patients.

Let's see how to load your device. let's see our youtube channel

Converter 16/8g: Adapter to convert the backend for a 8g cartridge

Empty loading cavity



Blistered cartridge and assembled filter/opener

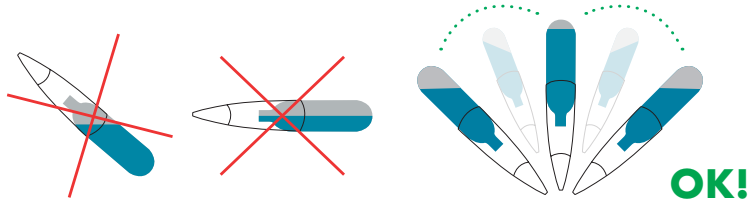
SELECT YOUR APPLICATORS:

Applicators with various flow rates are available depending of the lesion size. Ask your distributor or check on **www.ho-equipments.com.** The table below gives the estimated application with a continuous flow time depending on the applicator and the cartridge size. The measurements were performed between 19°C/66°F and 22°C/72°F.

	8g	16g	Lesion size	Power
Blue/red	135-155s	230-270s	1-3mm	
White/red	80-100s	145-180s	2-6mm	
Green/red	65-80s	110-130s	4-8mm	
Yellow/red		55-65s	7-20mm	
Blue/red 60mm	135-155s	230-270s	1-3mm	
White/red 60mm	80-100s	145-180s	2-6mm	
Green/red 120mm		110-130s	4-8mm	

Position the CryoPen for treatment

The instrument must be held vertically with the tip directed downward.
An angle of less than 45° must be avoided.



Position the CryoPen correctly

Effective application

Before starting treatment take into account age, location, size and number of lesions, skin type, degree of tanning and season.

The applicator tip (from where the liquefied N_2O flows) should be held 0,5 to 3 mm from the lesion. Further than 5 mm from the applicator tip the liquefied N_2O will have expanded into gas phase which is not effective for achieving therapeutic results.

By approaching the lesion with the gas flowing you will observe the focal point of the jet on the tissue. The closer you approach the lesion, the more freezing power you apply to the tissue. It is recommended to keep a greater distance for the smaller and more delicate procedures.

Distance to lesion

The amount of liquid N_2O that you wish to apply can be controlled by moving the applicator quickly towards and away from the tissue. Circular and crossing movements have the same effect.

Condensation of humidity in the air may in some cases create an ice field on top of the lesion. This 'igloo of ice' will hinder the effective working of the liquid phase of the cryogen (at -89°C/-128°F) and should be removed.

The learning curve for utilizing the CryoPen is short. CryoPen provides the possibility to have full control in the application of freezing power. Start practicing on the regular lesions and treat the more delicate ones after having acquired some experience.

Treatments Videos
Let's see our youtube channel

Duration/Depth of the treatment

Hold the tip of the applicator as close as possible to the lesion. In all literature, the rapid drop of temperature (thermal shock) is described as a critical criterion. However, always relate to the part of the body where the operation is applied. In some parts, skin is thinner which requires more caution.

A typical freeze on viral infections may last from 5 to 10 seconds for a small flat wart, and up to 45 seconds for a full thickness plantar wart. For general purposes most lesions take about 2 to 30 seconds.

The duration of the treatment will depend on the surface and the thickness of the tissue being treated. Thickness must be estimated based on clinical experience. After the first freezing cycle the tissue should be allowed to thaw for about 30 seconds followed by a second freeze. Note that the tissue will freeze faster than during the first freezing cycle. This 'freeze-thaw-freeze' technique offers the best opportunity for success.

You will find this procedure in most literature on cryotherapy. A follow-up visit is recommended after 2 to 4 weeks to confirm that all pathological tissue has disappeared and check if a follow-up treatment is necessary.

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. H&O Equipments nv/sa 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 CryoPen, 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 H&O Equipments nv/sa, their affiliates, respective directors, officers, shareholders, employees, agents and contractors, and even if advised of the possibility of such damages. You agree to indemnify H&O Equipments nv/sa, 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.

H&O EQUIPMENTS
Reinventing Cryosurgery

For more information
visit our website: www.ho-equipments.com