

HO CryoPen & CryoProbe Series User Guide

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Instruments

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

Instruments	CryoPen ref.		CryoProbe ref.
CryoPenlc/CryoProbelc with white/white dot applicator	S-HO-CCPE-XX- 201	REF	S-HO-CCPR-XX-8 01
CryoPenlm/CryoProbelm with white/red, blue/red, and gree n/red dot applicators	S-HO-CMPE-XX-30	REF	S-HO-CMPR-XX-9 01
CryoPenlx/CryoProbelx with white/red, blue/red, green/red and yellow/red dot applicators	S-HO-CXPE-XX-20	REF	S-HO-CXPR-XX-80
CryoPenlx plus/CryoProbelx plus with white/red, blue/red, g reen/red, yellow/red applicators, with blue/red and white/re d 60 mm long applicators and with white/red 120 mm long applicator	S-HO-CXPEP-00	REF	S-HO-CXPRP-00

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

Cartridges

8g N20 cartridges: 1 carton of 12 boxes each containing 24 cartridges for use with CryoPenIc/CryoProbelc, CryoPenIm/CryoProbelm and CryoPenix/CryoProbelx	S-HO-NOCX-12-S2 4	REF	S-HO-NOCX-12-S 24-PR
16g N20 cartridges: 1 carton of 12 boxes each containing 6 cartridges for use with CryoPenlx/CryoProbelx	S-HO-NOCX-12-S0 6	REF	S-HO-NOCX-PR-1 2-S06

Applicators for use with CryoPenIc/CryoProbeic

White/white dot applicator for 2-5 mm applications	S-CCX0-MA-002	REF	S-HO-NOCX-MA-0 02-PR
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 $\label{lem:condition} \mbox{Applicators for use with CryoPenlm/CryoProbelm, CryoPenlx/CryoProbelx, and CryoProbelx plus / CryoProbelx plus} \mbox{\cite{CryoPenlm/CryoProbelx}} \mbox{\cite{CryoPenlm/CryoProbelx}} \mbox{\cite{CryoPenlm/CryoProbelx}} \mbox{\cite{CryoPenlm/CryoProbelx}} \mbox{\cite{CryoPenlm/CryoProbelx}} \mbox{\cite{CryoPenlm/CryoPenlm/CryoProbelx}} \mbox{\cite{CryoPenlm/CryoPenlm/CryoProbelx}} \mbox{\cite{CryoPenlm/CryoPenlm/CryoProbelx}} \mbox{\cite{CryoPenlm/Cryo$

Blue/red dot applicator for 1-3 mm applications	S-HO-CCX0-MA-00	REF	S-HO-CCX0-MA-0 04-PR
White/red dot applicator for 2-5 mm applications	S-HO-CCX0-MA-00 5	REF	S-HO-CCX0-MA-0 05-PR
Green/red dot applicator for 4-8 mm applications	S-HO-CCX0-MA-00	REF	S-HO-CCX0-MA-0 06-PR
Yellow/red dot applicator for 7-15 mm applications	S-HO-CCX0-MA-00 7	REF	S-HO-CCX0-MA-0 07-PR
Blue/red dot long applicator 60 mm for 1-3 mm applications	S-HO-CCX0-MA-00 8	REF	S-HO-CCX0-MA-0 08-PR
White/red dot long applicator 60 mm for 2-5 mm application s	S-HO-CCX0-MA-00 9	REF	S-HO-CCX0-MA-0 09-PR
White/red dot long applicator 120 mm for 2-5 mm applications	S-HO-CCX0-MA-01	REF	S-HO-CCX0-MA-0 10-PR
Long applicator set	S-HO-CCX0-MA-L	REF	S-HO-CCX0-MA-L- PR

Accessories

Tweezers for filter/opener placement	S-HO-AXXX-FO-00	REF	S-HO-AXXX-FO- 001
Locking cap for CryoPenic/CryoProbelc, CryoPenlm/CryoProbelm, and CryoPenlx/CryoProbelx applicators	S-HO-APPL-CAP	REF	S-HO-APPL-CAP

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 the Asia Pacific.

EC or the Canadian Declaration of Conformity is available and can be obtained upon simple request.

CryoProbe™ is the registered trademark of H&O Equipments NV/SA and is distributed under that name in the US and Canada.

CryoPen® and CryoProbe™ are the same instruments and are both manufactured by H&O Equipments nv/sa.

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

CryoPen and CryoProbe instruments are intended for the controlled destruction of unwanted tissue by application of extreme cold using liquefied N20. Pathological indications are benign skin lesions such as angiofibroma, granuloma, condyloma, dermatofibroma, molluscum contagiosum, porokeratosis, seborrheic keratosis, actinic keratosis, solar lentigo, warts on the feet, warts on the hands. This list is not complete.

All mentioned products are manufactured in the European Community by,

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This manual's version: 120415CPEPR



Notified Body Number: 0120 Canadian License Number: 89787

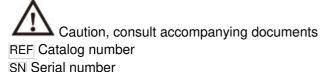
The most recent version of this user manual and other language versions can be downloaded from the

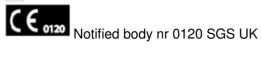
manufacturer's website under 'Press & Manuals': www.ho-quipments.com Attention! Reference is made to the liability waiver at the back of this manual.

Used symbols



Manufacturer





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Step 1 Empty the loading cavity



Empty loading cavity

Before loading a new cartridge, release any unused gas from the used cartridge by pressing the button or unscrewing the applicator cap (CryoPen1c/CryoProbelc). Discard the used cartridge. Please ensure that the used filter does not remain inside the cavity.



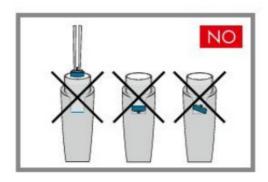
Blistered cartridge and assembled filter/opener device

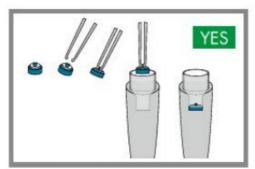
The cartridges are packed in peel-pack blisters with an assembled filter and cartridge opener included. The filters are used for the protection of the applicator. The opener punctures the cartridge.

CryoPen1c/CryoProbelc and CryoPenlm/ CryoProbelm can be used with 8g cartridges only. CryoPenlx/CryoProbelx can also be used with 16g cartridges. The CryoPenlx/CryoProbelx backend is for use with 8g cartridges. The CryoPenlx1/ CryoProbelx1 backend is for use with 16g cartridges. 8g and 16g indications are clearly applied on the cartridge's packaging.

Ensure that the loading cavity is empty of all residue. Open the peel-pack. Take out the filter/opener with the tweezers. Hold the CryoPen/CryoProbe's tip end pointed downward. Place the filter 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 device.

Step 3 Puncture the unused cartridge





Installation of the assembled filter/opener device

Gently screw the CryoPen/CryoProbe's backend onto the front end. Go to the point where you feel that the contact between the assembled filter/opener device 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!

Step 4 Use your CryoPen/CryoProbe

Remove the applicator cap. On CryoPenlc/ CryoProbelc, this will initiate the flow of cryogenic liquid. To stop, just

put the cap back on. On CryoPenlm/CryoProbelm and CryoPenlx/CryoProbeix, gently squeeze the trigger switch to start the working. Releasing the trigger will close off the flow of cryogenic liquid. You may observe that during 1 or 2 seconds after releasing the trigger, the remaining gas in the applicator is discarded.



Blue dot applicator for applications of 1-3 mm



Applicators with various flow rates are available. Ask your distributor or check on www.ho-equipments.com.



Green dot applicator for applications of 4-8 mm



Yellow dot applicator for applications of 7-15 mm



- Always gently manipulate all components of CryoPen/CryoProbe instruments. Never use more than gentle hand force. Never use pliers or other tools to manipulate 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 an instrument fa lure.

- When loaded, the instrument is under high pressure. Any change to the construction of the instrument may cause a potential risk.
- Never block the gas release opening at the end of CryoPen/ CryoProbe's backend!
- All external parts can be wiped with a cloth soaked in any noncorrosive disinfecting solution. Never immerse
 the entire instrument in a disinfecting solution. Only the applicators can be autoclaved.
- The applicators and the cartridges must be kept away from dust and high temperatures. Leave the cap on when not in use.
- The CryoPen/CryoProbe should be handled with care. When storing the instrument with a loaded cart judge in its case, position the CryoPen/CryoProbe in such a way that the trigger switch cannot be depressed when closing the lid of the case. This would cause undesired gas flow.
- CryoPen/CryoProbe instruments are intended for professional use only.
- Best results are obtained with instruments and cartridges at room temperature (21°C/77°F). Lower temperatures will give less pressure in gas flow with a longer flow time. Higher temperatures will cause higher gas pressure and shorter flow time.
- Empty cartridges should be discarded as metal scrap.

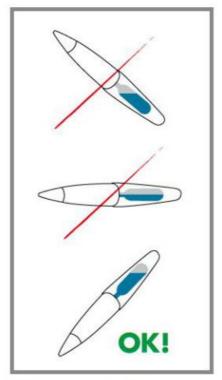
Position the CryoPen/CryoProbe for treatment.

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

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 N20 flows) should be held 0,5 to 4 mm from the lesion. Further than 5 mm from the applicator tip the liquefied N20 will have expanded into the gas phase which is not effective for achieving therapeutic results.



Position the CryoPen/ CryoProbe correctly

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.

The amount of liquid N20 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. Do not hold the CryoPen/CryoProbe applicator still above the lesion. It may flood the area and damage healthy tissue surrounding the lesion. This can cause blisters and pair to patients.

Condensation of humidity in the air on the frozen field of the lesion during operation may in some cases create an ice field on the top of the lesion. This 'iglo of ice (at ca 0°C)' will hinder the effective working of the liquid phase of the cryogen (at -89°C/-128 °F) and should be removed with the applicator tip.

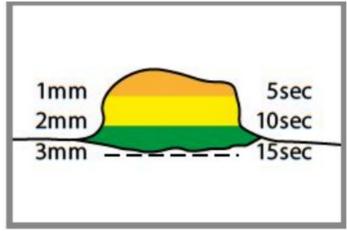
After thawing, the tissue turns reddish and has the aspect of a zone of inflammation due to interstitial bleeding. The learning curve for utilizing the CryoPen/CryoProbe is short. CryoPen/CryoProbe provides the possibility to have full control in the application of freezing power. Start practicing on the regular lesions and treat the more delicate ones after having acquired some experience.



Distance to lesion

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. The penetration rate of freezing with the CryoPen/CryoProbe is approximately 1 mm per 5 seconds with a maximum freezing depth of 3 to 6 mm depending on the used applicator. The duration of the treatment time will depend on the surface area 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 or that follow-up treatment is necessary.



Penetration is 1 mm per 5 seconds. Consequently, treatment of a 3 mm deep lesion will take 15 seconds. A pain signal from the patient will help you to control treatment time.

Interact with your patients.

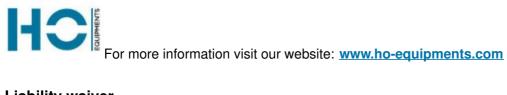
Inform patients that there will be a pain sensation similar to a ballpoint being pushed onto the s<in. Generally, little or no discomfort is experienced during the first few seconds when you manage to avoid treatment of healthy tissue. At a penetration rate of 1 mm per 5 seconds, the ice will reach the 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.

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:

- Pigmentary changes. 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. Repeated short freezing cycles of 3 to 6 seconds at two-week intervals should be used in cases with darker skin types. This will reduce or avoid inflammation in the area with melanocytes.
- Nerve damage. 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.
- Shards of frozen humidity. The innovation of CryoPen/CryoProbe is the direct application of nitrous oxide under high pressure (55 bar). This high-pressure jet may cause minor shards of frozen humidity in the air blown away in a circle of approximately 30cm. They will thaw the moment they would eventually touch healthy skin. The learning curve for utilizing the CryoPen/CryoProbe is short. Upon the clinical evaluation of the thickness of the lesion, the operator will choose an application time from 1 to 30 seconds. With pinpoint accuracy collateral damage resulting in pain is easy to avoid.
- · Lesions on sites with coarse terminal hair. Hair follicles are easily damaged by cryosurgery and permanent alopecia is not uncommon.

The learning curve for utilizing the CryoPen/CryoProbe is short. Upon the clinical evaluation of the thickness of the lesion, the operator will choose an application time from 1 to 30 seconds. With pinpoint accuracy collateral damage resulting in pain is easy to avoid.



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 the 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, a 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/CryoProbe, 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.

Documents / Resources



HO CryoPen & CryoProbe Series [pdf] User Guide HO, CryoPen, CryoProbe Series

Manuals+, home privacy