User Manual

FRIGO™ 05 REF **141049**

FRIGO™ 03 REF **141048**

Manufacturer

Nomard Oy
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www.nomard.fi

CE
0598

The product complies with the EC Medical Device Directive 93/42/EEC

SALES AND SERVICE

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Warning!

Read the instructions before use!

When filling, cold-resistant insulating protective gloves/face protection/eye protection must be used.

Liquid nitrogen gasifies in cylinders and produces an operating pressure.

When filled, it contains liquid nitrogen; may cause the risk of freezing.

May only be used for the administration of liquid nitrogen.

”**ONLY FOR THE USE OF A TRAINED PHYSICIAN**”

Storage

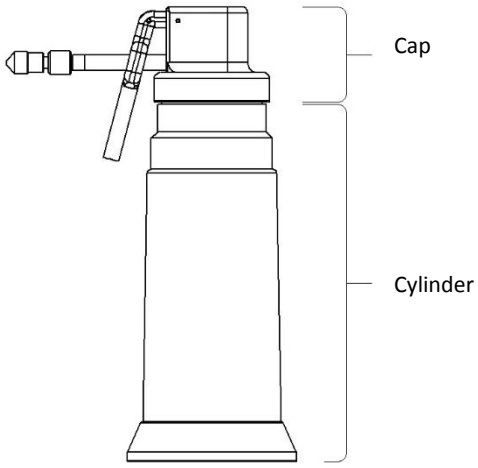
Store in a dry place.

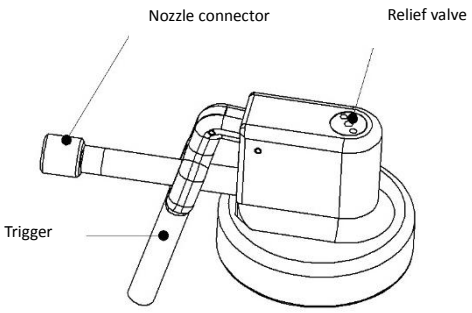
Packaging and labelling

Contains	1 cryogenic treatment device (cap and cylinder)
	4 nozzles
	1 instructions

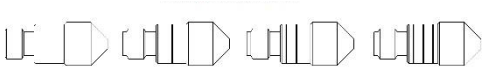
Product description

The product consists of two primary components, a cap and a cylinder. The cap includes a nozzle connector, relief valve and a trigger.





Nozzles



0.5mm 0.7mm 0.9mm 1.2mm

Dimensions

	FRIGO™ 05	FRIGO™ 03
Volume	**0.5l**	**0.3l**
Width	**85mm**	**85mm**
length	**130mm**	**130mm**
height	**278mm**	**220mm**
weight (empty)	**500g**	**435g**

Operational conditions

The product is intended to be stored and used indoors under normal conditions.

Intended use

Frigo™ 05 and Frigo™ 03 devices are designed for the cryogenic treatment of skin lesions. Attached is a treatment table of the most common lesions to be treated by means of cryogenic treatment.
The use for anything other than cryogenic treatment is forbidden!

Liquid nitrogen

Liquid nitrogen is extremely cold (boiling point -196°C) and when handling, extreme care must be taken. Liquid nitrogen (N_2) can only be stored in its intended containers. If necessary, request a safety data sheet from the supplier of liquid nitrogen.

Instructions for filling

The cap of the device is screwed open and the liquid nitrogen is carefully poured in the cylinder. If you have a separate filling device in use, follow the filling device's instructions. For the device to operate correctly, the filling level should be 30%-75%. It is recommended that a filling level of approx. 40% is used.

After filling, screw back the cap properly. If the device is warm when filling, wait 30-60 seconds before closing the cap, until the liquid nitrogen stops boiling. Do not tighten while holding the trigger. DO NOT SCREW THE CAP TOO TIGHTLY.

WARNING: If the device has been used, the pressure of the cylinder must be reduced before removing the cap. Screw the cap open ½ a turn and wait until taped. After this, the cap can be removed.

User instructions

This cryogenic treatment device has been designed to be compatible with both Frigo™ nozzles and other manufacturers' nozzles that use the same connection type. In case of other manufacturers' nozzles, the relevant manufacturer's instructions must be followed. The device is supplied with a range of cryogenic treatment nozzles. Choosing the cryogenic treatment nozzle depends on the size and quality of the lesion. To ensure the proper operation, the nozzles must be securely tightened.

The following happens on the table standing device:

1) Water condensates to the top of the device, and the device may steam up slightly.
2) An operating pressure will form within the device. Due to this: the cap must be dry before using it again. If the device is used before that, the condensed water will freeze and the device may not work properly. If the device is lifted quickly, after it standing for some time, the liquid nitrogen inside will boil and the increasing pressure within the cylinder will be released through the relief valve. The rustling sound does not mean that the device is leaking.

At the end of the day, the cap of the device is left closed regardless of whether there is nitrogen in the cylinder.

WARNING: Avoid excessive tilting. If the device is tilted horizontally or completely upside down, nitrogen may leak through the relief valve.

Maintenance

The device does not need any maintenance. The device can be wiped with ethyl alcohol (more than 70%vol.) and a lint-free cloth.

Troubleshooting

Do not use a faulty device!

If the described common problems do not provide a solution, please contact the reseller or manufacturer of the device without delay.

In the event of a fault in the Frigo™ device, it must be delivered to the reseller for repair. The device must be packaged appropriately. A general description of the fault must be included in the package. The fault notice should also be submitted at www.nomard.fi

Problem-if the spray of nitrogen is intermittent or non-existent.
Cause-The nozzle is blocked.
Solution-Remove the nozzle and open with a suitable needle. Try the device without a nozzle. If the fault is still present, please contact your authorised dealer for service.

Problem-if the trigger jams in the open position.
Cause-The valve mechanism is dirty.
Solution-Remove pressure from the cylinder immediately by unscrewing the cap ½ a turn. Check the movement of the trigger before connecting to the cylinder. If the fault is still present, please contact your authorised dealer for service.

Problem-The outside of the device steams up and the relief valve makes a lot of noise.
Cause-The insulating vacuum of the cylinder is worn or diminished due to the age or damage of the device.
Solution-Take the device to your authorised dealer to have the cylinder replaced.

Problem-Not enough pressure is formed in the device.
Cause-The sealing of the device has weakened (it is, however, normal during use that the pressure drops. To increase pressure, the device must be slightly shaken so that the nitrogen splashes inside the cylinder.)
Solution-please contact your authorised dealer for service.

Warranty and service

The device has a 3-year warranty for manufacturing and material faults from the date of purchase. If the device requires more extensive service or repair, deliver the product to your authorised dealer for service. Unprofessionally completed repair work shall release the manufacturer of all liability for damages. More information from the manufacturer or authorised reseller.

Continuous development is important to us. We kindly request feedback on our product. Providing feedback is easy, either write the following address in your browser or scan the following QR code with a mobile device. We appreciate your feedback!

www.nomard.fi/yhteys/

Annex 1. Treatment table

Freezing times of most common cryogenically treated lesions.

Freeze with a 1 mm margin outside the lesion.

The lesion can be frozen several times.

ICD code	Lesion	Freezing time	
B07.8	Flat wart	5	secs
L81	Melasma	7	secs
L72	Sebaceous cyst	5-10	secs
L82	Seborrheic keratosis	10	secs
B07.9	Wart	15-20	secs
L28.1	Prurigo nodularis	30	secs
L91.0	Keloid	30	secs
D18.0	Hemangioma	60 +	secs
L85.9	Keratoacanthoma	30	secs
D21	Dermatofibroma	60 +	secs
L92.2	Granuloma faciale	30	secs
L92.0	Granuloma annulare	20	secs
H61.0	Chondrodermatitis	30	secs
L40.0	Plaque psoriasis	15-30	secs
I78.1	Senile nevus	10	secs
D22	Nevus	10	secs
K13.2	Leukokeratosis	15	secs
K11.6	Mucocele	30	secs
B08.1	Molluscum contagiosum (MC)	5-10	secs

Note!
The recommended treatment times above are for reference only. The times depend on the size of the lesions to be treated and how deep they extend.