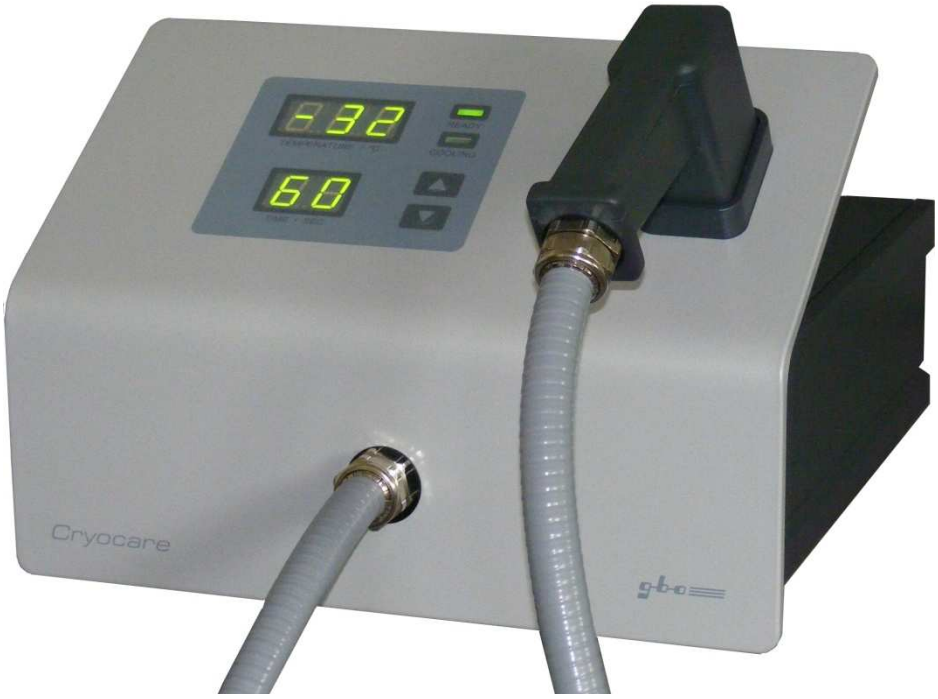
Device for cryotherapy



Cryocare®

Instruction manual

gbo Medizintechnik AG has taken care in preparation of this manual, but makes no expressed or implied warranty of any kind and assume no responsibility for errors or omissions.

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1 Introduction

1.1 Purpose (Intended use)

Cryotherapy for the superficial and local treatment of skin alterations.

1.2 Note concerning the operating personnel

The device is only to be operated by healthcare professionals.

1.3 Description of the unit

Cryotherapy represents a method which has been known for more than a hundred years. Though cryotherapy has proven itself for decades in many dermatological indications, the high operating costs of conventional devices working with cooling medium, and the poorly reproducible results due to inexact dosing of cold have hindered its widespread distribution.

Thanks to the development of new cooling mediums and methods there is now much greater interest in cryotherapy. It is used in dermatology.

Cryocare® generates electronically an almost constant operating temperature of -32°C. This enables the therapist an exactly dosable and localizable application of cold with reproducible therapeutic results. If the device is used and applied in accordance with the instructions for use, there will not occur any unintended frostbite damages.

With ***Cryocare***® it is also possible to eliminate cosmetic disturbances of the human cutaneous system and therefore to realize cryocosmetic treatment.

Warning!
In case of unclear diagnosis, please consult the dermatologist before any cosmetic treatment.

1.4 Product characteristics

- Device for cryotherapy in dermatology and cosmetics for the elimination of aging and pigmentation spots, as well as the elimination of warts, keloids, bulging acne etc.

- The device guarantees an almost constant operating temperature of -32°C and therefore enables a fast, exactly dosable and localizable application of cold with reproducible therapeutic results.

- The cold is generated electronically by a microprocessor-driven high-capacity Peltier element. That means it works without any cooling medium, that means without Fluorcarbon, and without supply of water. The applicator tip of the cryo pistol represents the applied part.
  Once the device has been switched on it is ready for operation within 5 minutes.

- The device is equipped with a timer to adjust the therapy time from 5s to 99s. The timer is released by the Start button located in the cooling dispenser. An acoustic signal will be audible at the beginning and the end of the therapy.

- There are cooling applicators in different forms and sizes available.

- Due to the simple and safe operation it is possible to realize a time-saving application which is also delegable.

2 Start of operation

2.1 Storage, transport and assembly

Cryocare® is a portable unit and assigned for movable connection to an A.C system. ***Cryocare***® is designed for indoor use. It can be used without any impairment of its functionality and safety at room temperatures from +10°C up to +30°C.

The cold in ***Cryocare***® is generated by a high-performance Peltier element. The generated waste heat is dissipated through an internal cooling circuit.

To place the unit, each plane horizontal surface is appropriate. A wall distance to the back of the device of at least 10cm has to be observed. It must not be placed on the floor. The device must not be placed in front of a heater or heat radiator.

Warning!
There are aspiration holes in the bottom of the device. Do not place any paper or other light material below the device which could plug these holes.

The cryo pistol is connected firmly with the device through a supply system and it is not removable. The front side of the device housing is equipped with a fixing device to place the cryo pistol. Whenever no therapy is carried out, the pistol should be placed in the fixing support.

2.2 Connection and switch on

Cryocare® is designed for the connection to a supply voltage of 100 to 240 V. It is not necessary to switch over the voltage – the device adjusts automatically to the right voltage.
Irrespective of the adjusted supply voltage, the device is appropriate for supply frequencies of 50 to 60 Hz.
Connect ***Cryocare***® with the mains cable to a socket with protective ground. The protective earth must work correctly.
Cryocare® is switched on by the main switch on the back of the device.

Warning!
To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth!

2.3 Placing out of operation

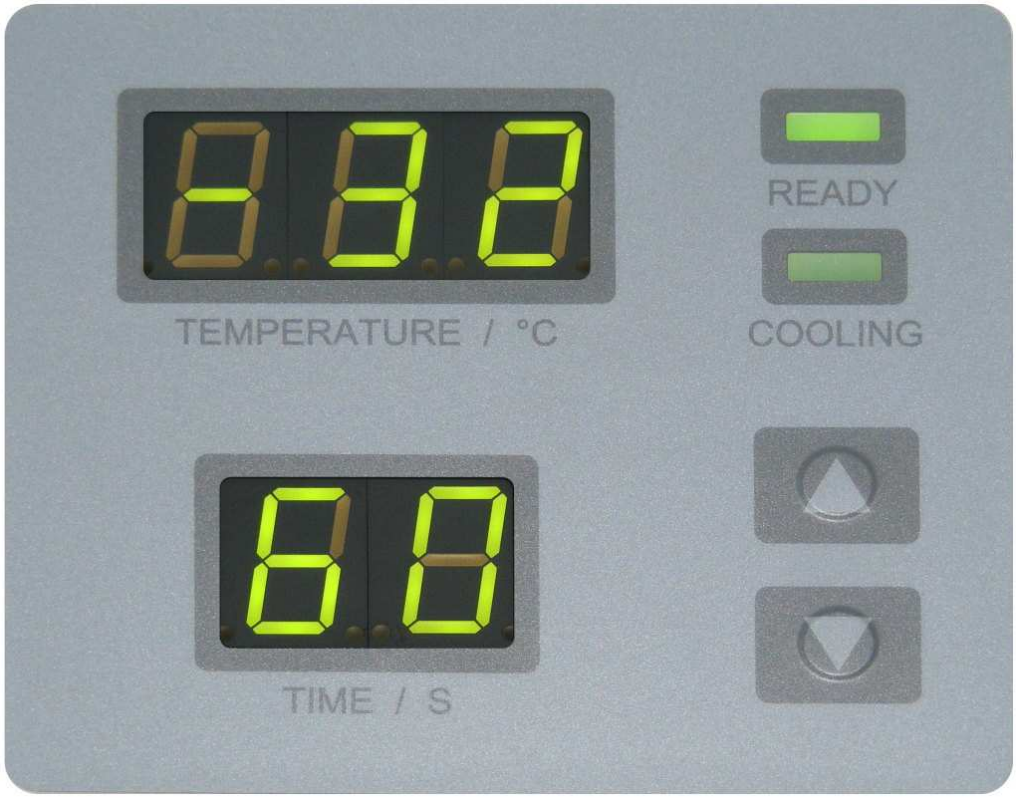
In order to place the device out of operation just disconnect it from the mains power supply. No other measures are to be taken.

3 Description of function

3.1 Operation of the device

3.1.1 Preparations for cryotherapy

Switch on ***Cryocare***® by the mains switch at the back of the device. The device will start now without any other operation to cool down the applicator tip of the cryo pistol to a constant operating temperature of -32°C.



During the cooling down, the **COOLING LED** is lighting continously. The respective temperature of the applicator is displayed in the **TEMPERATURE / °C** window. After a few minutes the temperature indicator reaches -30°C, the green **COOLING** LED stops lighting and the green **READY** LED will light continuously. ***Cryocare***® is ready for operation now.
The applicator will be cooled periodically. The **COOLING LED** will light up for a short moment as indication.

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Note!

The applicator tip of the cryo pistol freezes due to air humidity. Therefore, the cryo pistol should always be placed in the device support – except during the therapy – in order to avoid both unnecessary freezing and unnecessary heat absorption through ambient temperature.

The duration of treatment can be set in seconds with the two keys below the **TIME / s** window. The duration of treatment depends on the indication and also on the kind of skin as well as other medically indicated preconditions.

3.1.2 Treatment procedure

The treatment is started by applying the applicator tip of the cryo pistol onto the respective skin area. Furthermore, the therapy timer has to be set by briefly pressing the key located on the handle of the cryo pistol. The start will be confirmed by a short acoustic signal.

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Note!

- The therapy time will start passing by briefly pressing the key located on the handle of the cryo pistol.
- If a long beep sound (approx. 2s) appears instead of a short one (approx. ½s), the required temperature was not yet reached.

After the expiration of the preselected therapy time the acoustic signal sounds again and indicates the end of treatment to the therapist. Now the cryo pistol should immediately be removed from the skin.

Upon the expiration of the therapy time, the timer reverts to the preselected value, and **CRYOCARE** is ready for the next treatment.

Warning!

Please use the applicator only on dry skin.
The applicator tip may freeze onto the skin if the skin is wet.

3.2 Handling of additional applicators

The tip of the cryo pistol is the most frequently used applicator for many indications. Nevertheless, spread and form of the skin appearance may also require other applicators. The device has been delivered with five applicator types differing in form and size. Individual applicators have been designed for rope-shape, punctiform and rectangular forms of skin appearances.

To use one of the applicator adapters, just place it on the tip of the cryo pistol. As soon as the applicator has frozen on the tip of the cryo pistol and the temperature of -30°C to -32°C has been reached again, ***Cryocare®*** is ready for operation.

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Note!
Before you place the applicator, briefly dip the tip of the cryo pistol into cold water. Herewith, the applicator freezes faster, and furthermore, a better heat transfer between the cryo pistol and the applicator will be produced.

To remove the applicators please dip the tip of the cryo pistol with the applicator briefly into warm water and the applicator will fall off.

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Note!
Please remove the applicators from the cryo pistol before switching off the device!

Warning!
Please do not apply any force or tools to remove the applicators as this could cause damage to the cryo pistol.

3.3 Notes about indications of cryotherapy

With ***Cryocare***® best treatment results have been achieved in:

- pigmentations
- lentigines
- keratosis actinica
- keloids
- lichen ruber papulae
- juvenile warts
- acne nodules
- basaloma
- molluscum contagiosum
- erythematodes chronicus
- prurigo nodularis (among others)

Due to the successful therapy of pigmentations – such as aging spots -, ***Cryocare***® is also used successfully in cryocosmetics.

3.4 Contraindications

Whereas the treatment of open wounds is contraindicated, there are no other contraindications and side effects known, as long as the device is properly used in accordance with the operating instructions.

Warning!
In case of unclear diagnosis, please consult a dermatologist before a cosmetic treatment.

4 Maintenance

Efficacy, reliability and safety characteristics of ***Cryocare®*** are only guaranteed in case of proper use in accordance with the operating instructions. Safety control, maintenance work, repair work and modifications shall be carried out only by the manufacturer or the service agents authorized by him. In case of a failure, parts which influence the safety of the device shall be only replaced by original spare parts of the manufacturer. **There are no user-serviceable parts inside the device**.

4.1 Safety controls

The device is subject to the provisions of the Medical Device Directive. The safety controls have to be carried out on the basis of this directive. Thereby, the operator regulation has to be especially observed.

Irrespective of the legal rules or beyond the scope of the Medical Device Directive, it is recommended to have the device checked at 12-months intervals by the manufacturer or by a service agency authorized by him.

The check shall consist of at least the following:
- Electrical safety check in accordance with the check plan of the manufacturer,
- Check of the device in regard to external integrity,
- Check of all display and operating elements in regard to damage,
- Check of all inscriptions in regard to legibility,
- Check of the power cord
- Functional check

4.2 Disposal of the device and the accessories

According to the WEEE Directive 2002/96/EG (waste electrical and electronic equipment) this device must not be disposed of with the domestic waste. The device must be returned to the manufacturer for disposal. The manufacturer is committed to guarantee the disposal of all devices marketed. This is also indicated by the WEEE sign (crossed out waste container).

4.3 Cleaning, disinfection and care

For cleaning and disinfection of ***Cryocare***® there shall not be used any agents containing higher portions of phenol derivates, alcohol, compounds of chlorine or peracetic acid. It is recommended to use disinfectants on aldehyde basis.

The device is suited neither for heat sterilization nor sterilization with gases.

Warning!

Before cleaning or disinfection unplug the mains plug out of the socket.

Cryocare® is suited for wiping disinfection. It has to be observed that no liquids enter the device. Never shall the plugs or sockets get wet. For cleaning or disinfection the device may not be dizzled.

Warning!

To avoid cross contamination, the applicator should be disinfected between two treatments.

5 Accessories

Part description:	Part number:
Cryocare® incl. mains cable, instructions for use and applicator set	015-0-1000

Accessories for *Cryocare*®

Instructions for use in German for ***Cryocare***®	015-7-1001
Instructions for use in English for ***Cryocare***®	015-7-1002
Applicator set (5 pieces) Consists of: 8 × 8 mm square 10 × 10 mm square 7.5 × 1 mm slit ∅ 9.5 mm mm round ∅ 2.6 mm mm round	015-0-1002
Applicator ∅ 2.6 mm round	015-2-0005
Applicator ∅ 4 mm round	015-2-0007
Applicator ∅ 5.5 mm round	015-2-0008
Applicator ∅ 9.5 mm round	015-2-0010
Applicator ∅ 11.3 mm round	015-2-0012
Applicator 8 x 8 mm square	015-2-0013
Applicator 10 x 10 mm square	015-2-0031
Applicator 7.5 x 1 mm Slit	015-2-0015
Applicator 8 x 2.5 mm Slit	015-2-0016
UNICAR® 2000 device cart	026-0-2000

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Note!

Use gbo original accessories only to guarantee the safe function of the unit.

6 Technical data

Mains voltage and frequency:	100 – 240 V, 50-60 Hz	
Power consumption:	max. 140 VA	
Mains fuse :	T 5A H 250V	
Cryotechnics:	High-performance Peltier element	
Operating temperature:	-32 °C ±15 %	
Mode of operation:	continuous operation	
MDD device class:	IIa	
Protection degree:	I acc. to IEC 601	
Protection class:	B acc. to IEC 601	
Protection against ingress of liquids:	IP X0	
Dimensions:	36cm × 24cm × 35cm (W x H x D) 36cm × 27cm × 35cm (W x H x D) with pistol	
Weight:	10,4 kg	
Color:	aluminium RAL 9006 and dark grey RAL 7016	
Environmental conditions:	operation of the device:	temperature range +10 °C ... +30 °C relative humidity of air 30 ... 75 %
	transport and storage:	temperature range -10°C ... +50 °C relative humidity < 90 %, non condensing

By request of technical personnel gbo Medizintechnik AG can offer spare part lists and circuit diagrams.

The mains connector is used for all-pin disconnection from the mains power supply.

gbo Medizintechnik AG reserves the right to modify design and specifications without prior notice.

7 Explanation of the pictograms

CE 0123 CE conformity sign

Observe the instructions for use!

Type B applied part.

This product complies with WEEE Directive 2002/96/EG (waste electrical and electronic equipment). Separate collection for electrical and electronic equipment.

8 Troubleshooting

8.1 Error messages at the device

E1 Overheating

Switch off the device.

- Check that the air ventilation slots are not covered.
- Check that the device is not placed on a blanket (or similar).
- Protect the cryo pistol from direct sunlight
- Remove all heaters which are located close to the device.
- Observe the device's operating temperature range.

Let the device cool down and switch in on again. Contact the manufacturer if the error message reappears.

E2 System error

Switch the device off and on again. Contact the manufacturer if the error message reappears.

E3 System error

Switch the device off and on again. Contact the manufacturer if the error message reappears.

8.2 Further error situations

1. Even when waiting for a longer periode, the “Ready”-LED does not light up.

- Check that the air ventilation slots are not covered.
- Check that the device is not placed on a blanket (or similar).
- Protect the cryo pistol from direct sunlight
- Remove all heaters which are located close to the device.
- Observe the device’s operating temperature range.

2. A longer beep sound (approx. 2s) is audible when pressing the button at the cryo pistol.

- The required temperature of the cryo pistol was not yet reached.
- Before pressing the button at the cryo pistol, wait until the “Ready”-LED lights up.
- This sound is only intended as advice. The therapy timer will start to elapse anyhow.

9 Appendix

Notes in accordance with the EC directives and Medical Device Directive

Cryocare®is a line-powered device for cryotherapy of safety class **I**.

The device is in accordance with the Medical Device Directive of the EC (93/42/EWG) and therefore carries the CE sign. The according graphical symbol is placed on the back of the device next to the mains switch.

According to the Medical Device directive, ***Cryocare***®is a device of class **IIa**.

The manufacturer is only responsible for the safety, operational reliability and functionality of the device if:

* the device is used in accordance with the instructions for use;
* the electrical installation of the location where the device will be used corresponds to the respective valid requirements of electrical safety;
* the device is not used in hazardous environments and humid locations;
* the mountings, amplifications, readjustments, modifications or repair works are carried out only by personnel authorized by the manufacturer;
* the operator regulation of this EC directive is observed within the scope of the Medical Device Directives.

You may obtain technical support by the manufacturer, dealers or service authorized by the manufacturer. The product's duration of life as scheduled by the manufacturer is 10 years.

Cryocare®is an electronic device. For its disposal the according regulations for electronic devices have to be observed.

On request, the manufacturer will provide you with further technical descriptions for all repairable parts of the device, such as circuit diagrams, spare part lists, and adjustment instructions as far as these are of use for the qualified technical staff of the operator.

Comments on electromagnetic compatibility (EMC)
Medical, electrical devices are subject to special precautions concerning the EMC. They must be installed and operated according to the EMC-advice given in the accompanying documents. In particular medical, electrical devices may be influenced by portable and mobile RF-communication devices.

The manufacturer guarantees the conformity of the unit with the EMC-requirements only when using accessories which are listed in the EC declaration of conformity. The usage of other accessories my cause an increased emission of electromagnetic disturbances or may lead to a reduced electromagnetic immunity.

The unit must not be arranged physically close to other devices or stacked with them. If such an order is necessary nevertheless, the unit must be observed in order to check it for the intentional operation.

You find more EMC-comments in the chapter "Warnings and Safety Precautions" of this manual as well as in the Technical Information on the next two pages.

In accordance with the EMC-regulations for medical products we are obliged by law to provide the following information.

Guidance and manufacturer's declaration — electromagnetic emissions

The equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions, CISPR 11	Group 1	The equipment uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions, CISPR 11	Class B	The equipment is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions, IEC 61000-3-2 (*)	Class A	
Voltage fluctuation/flicker emissions, IEC 61000-3-3 (*)	Complies	
(*) Note: For devices with a power consumption between 75 W and 1000 W only.		

Guidance and manufacturer's declaration — electromagnetic immunity

The equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment.			
Immunity test	**IEC 60601- test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD), IEC61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst, IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge, IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines, IEC 61000-4-11	<5% U_τ for ½ cycle (>95% dip) 40% U_τ for 5 cycles 60% dip) 70% U_τ for 25 cycles 30% dip) <95% U_τ for 5 s (>5% dip)	<5% U_τ for ½ cycle (>95% dip) 40% U_τ for 5 cycles 60% dip) 70% U_τ for 25 cycles 30% dip) <95% U_τ for 5 s (>5% dip)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the equipment requires continued operation during power mains interruptions, it is recommended that the equipment be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field, IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_τ is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration — electromagnetic immunity

The equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment.			
Immunity test	**IEC 60601- test level**	**Compliance level**	**Electromagnetic environment – guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the equipment, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:**
Conducted RF, IEC 61000-4-6	3 V_{rms} 150 kHz to 80 MHz	3 V_{eff}	$d=1,2\sqrt{P}$
Radiated RF, IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3V/m	$d=1,2\sqrt{P}$ for 80 MHz to 800 MHz $d=2,3\sqrt{P}$ for 800 MHz to 2,5 GHz
			Where P is the maximum output power rating of the transmitter in watts according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Interference may occur in the vicinity of equipment marked with the following symbol: 

Recommended separation distances to portable and mobile RF communication equipment

The equipment is intended to be operated in an electromagnetic environment, where radiated RF interference is controlled. The user can help in avoiding interferences by means of meeting minimum separation distances between portable and mobile RF communication equipment (transmitters) according to the maximum output power of the communication equipment.			
Rated power of the transmitter (W)	**Separation distance according to the tranmission frequency (m)**		
	150 kHz to 80 MHz **$d=1,2\sqrt{P}$**	**80 MHz to 800 MHz** **$d=1,2\sqrt{P}$**	**800 MHz to 2,5 GHz** **$d=2,3\sqrt{P}$**
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

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Part No. 015-7-1002