



OPHTHALMIC CRYOUNIT

CR4000

OPERATIONAL

INSTRUCTION

MANUAL

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1.0 INTRODUCTION

This manual should be reviewed with all personnel involved with CR4000 systems to insure proper and safe use.

The MIRA CR4000 and the interchangeable probes were designed to meet the exacting and practical needs of Ophthalmologists who perform Cryosurgery. The system rapidly freezes or defrosts probe tips while the ergonomically designed handles remain warm. It is non-electric, can be used with medical grade CO₂ or N₂O (non-siphon cylinders) and has three pre-selected temperature settings. The unique design of the MIRA Cryo probe isolates the gas expansion chamber at the very tip of the probe, thereby assuring that freezing and defrosting the probe, thereby assuring that freezing and defrosting occurs only at the target area. Tip-only freeze also eliminates the need for an insulating boot, which can obscure the surgeon's view

The MIRA CR4000 has a rapid freeze and defrost cycle available, providing greater control of application time.

Temperature settings for both CO₂ and N₂O allow for pre-selected tip temperatures. The choices of temperatures are -65, -35 and -5 (+/-5deg.C) for CO₂ and -85, -55 and -25 (+/- 5 C) for N₂O

2.0 SYSTEM COMPONENTS

See section 3 for expanded descriptions. Contact your distributor or MIRA, Inc. for more information.

2.1 Base system

The MIRA CR4000 Ophthalmic Cryo System includes the Console, the Footswitch pedal and the following:

CR40xx	-CR4000 instruction video (specify NTSC.,PAL or SECAM)
CR4160	-25ft scavenger hose for system exhaust
CR4260	-60in. high-pressure hose for gas input
CR43xx	-12 gas cylinder connector (section 3.3)
CR4350	-12 Replacement filters and 6 "O" rings

2.2 Accessories

CR40xx	-CR4000 instruction video (specify NTSC, PAL or SECAM)
CR4150	-Dual Cylinder Cryo Carrier with switch-over valve, fittings, hoses and -- -filter assembly
CR4270	-Protective Probe Tip Cap for CR40xx (specify probe type)
CR4360	-30in. pressure hose (3)
CR4400	-Micro-fiber Filter Assembly
CR5400	-Sintered metal filter pack (3 plus 1 washer)

3.0 GENERAL COMPONENT DESCRIPTIONS

3.1 Console

3.1.1. Front Panel (See Fig. 1)

The front panel has an “ON/OFF” switch, a gas supply pressure gauge, a tip temperature selector and a probe receptacle.

Probes are connected to the console when the jack end is completely inserted into the receptacle.

The “ON/OFF” switch controls the flow of the gas supply coming into the console. The pressure gauge indicates supply pressure and **not** pressure to the probe. When the “ON/OFF” switch is in the “OFF” position, the gas pressure gauge will indicate zero. In the “ON” position, the gauge indicator should be in the green zone (680-900psi) in order to achieve maximum efficiency. When cylinder pressure falls into the yellow zone (below 680 psi), the probe tip temperature may vary or be warmer than indicated. This indicates that the cylinder needs to be re-filled or changed. When a cylinder is heated above room temperature it may exceed maximum pressure 900psi (red zone). In this situation allow the cylinder to equilibrate to room temperature (Approx. 70° F) before using*..

The three position temperature selector controls the tip temperature and offers a choice of the following temperatures:

-65°, -35° and -5° (+/- 5° C) for CO₂ -85°, -55° and -25° (+/- 5° C) for N₂O

* **CAUTION:** Do not exceed the following pressures when filling non-siphon gas cylinders.

CO₂: 850psi max @70°F

N₂O: 730psi max. @ 70° F

3.1.2 Rear Panel (See Fig. 1)

The rear panel has a barbed hose fitting for the exhaust system, a threaded fitting for gas input and protected hoses which connect the consoles inner pneumatics for the foot switch actuator mechanisms.

The exhaust system is for removing Nitrous Oxide (N₂O) or Carbon Dioxide (CO₂) from the treatment area. Connect one end of the supplied 25ft. scavenger hose to the barbed fitting and the other end to an aspiration system or operating room scavenger system The gas input is for Nitrous Oxide or Carbon Dioxide coming into the system from the cylinder. It is a 7/16-20 threaded fitting designed for use with the supplied high-pressure hose



Figure 1: Front and Rear panels of the CR4000 Ophthalmic Cryo Console

3.2 60" High Pressure Hose (CR4260)

Both ends of the high pressure hose have 5/8 in. Hex nuts and 7/16-20 female pipe threads. Connect one end to the Cryo Console “gas input” on the rear panel and the other end to the gas cylinder filter connector assembly.

3.3 Gas Cylinder Connectors (CR43xx)

N₂O and CO₂ gas cylinders come in a variety of sizes and with different connector standards. Refer to “Table 1” for the gas cylinder connector that suits your application. If you are unsure or have any questions, contact your distributor or MIRA Inc.

MIRA gas cylinder connectors come in a choice of two configurations:

Without Filter assembly: For use with Dual Cylinder Cryo Carriers that come with factory installed sintered metal filters.

With a Micro-fiber or sintered metal Filter assembly attached: For use with basic CR4000 systems.

IMPORTANT: Micro-fiber or sintered metal filters on the gas line will reduce the introduction of particulates into the system, therefore reducing the chance of malfunction.

3.4 Micro-fiber Filter Assembly/Sintered Metal Filter Assembly

A choice of the above filter systems is supplied with each system either separately; as part of a gas cylinder connector assembly; or factory installed in a Cryo carrier. These filter assemblies are critical elements of the MIRA ophthalmic Cryo CR4000 system. A leading cause of malfunction is the presence of particulates in the system. These particulates originate from the gas supply and must be filtered in order to achieve proper system performance. Replacement Filters; Micro fiber (packs of 12) or Sintered Metal (packs of 3) along with replacement O-Rings are supplied with each system. Replacement filter packs are available from MIRA or your distributor.

Microfiber Filter Assembly (Cont'd)

O-Rings are available from MIRA or your distributor (CR4350). The filter element should be changed every 30 to 45 days depending on use.

3.5 Microfiber Filter Element and O-Ring replacement procedure (CR4350)

1. Turn the gas cylinder valve OFF
 2. Depressurize the CR4000 system. Turn "ON/OFF" switch to an in-between setting. Gas can be heard escaping from the exhaust port.
 3. Unscrew, with a wrench, the bottom cylinder of the Micro-fiber Filter Assembly.
 4. Remove the micro fiber filter element by sliding it off the metal core.
 5. Inspect the O-Ring and replace if needed.
 6. Install a new Micro-fiber Filter element (every 30 to 45 days depending on use).
 7. Screw the bottom cylinder back on hand tight, then tighten no more than 1/4 turn.
- Optional;** Run test procedures as described in section 6.0.

Sintered metal Filter element and O-Ring replacement procedure (CR5350)

Proceed as in items 1, 2 and 3 above

4. Remove the filter element
5. Inspect the sealing ring and replace unless it shows signs of damage.
6. Install a new filter element. With normal use this should last up to twelve months.
7. Screw filter cover back in place and tighten by hand. Use a wrench to tighten a further ¼ turn

Optional; Run test procedures as described in section 6.0

3.6 25ft Scavenger Hose (CR4160)

Connect one end of the 25ft. Scavenger hose to the barbed fitting on the console back panel and the other end to an aspiration system or equivalent. The hose is used to remove exhausted gas from the treatment area.

TABLE 1

Gas Cylinder Connectors.

Model No;	Description
CR4210	Hand-tight N ₂ O connector for "C" 8in. Cylinder (CGA Thread)
CR4310	Hand-tight N ₂ O <u>connector/Filter</u> for "C" 8in cylinder (CGA Thread)
CR4220	Hand-tight CO ₂ connector for "C" 8in cylinder (CGA Thread)
CR4320	Hand-tight N ₂ O <u>connector/filter</u> for "C" 8in cylinder (CGA Thread)
CR4250	Universal T-Yoke connector for "E" 4in cylinder (not available in US)

TABLE 1 (cont'd.)

CR4280	T-Yoke assembly for "E" 4in. Cylinder N ₂ O
CR4380	T-Yoke assembly <u>with Micro filter</u> for "E" 4in. Cylinder N ₂ O
CR4290	T-Yoke assembly for "E" 4in. Cylinder CO ₂
CR4390	T-Yoke assembly <u>with Micro filter</u> for "E" 4in. Cylinder CO ₂

3.7 Cryo Equipment Carrier Single/Dual Cylinder capacity (CR4150)

The CR4150 is specially designed to hold one or two gas cylinder tanks and the CR4000 **Ophthalmic Cryo console at a convenient working height. It is ideal for use in an operating room or office treatment area. Contact your distributor or MIRA for more information.**

Fig 2



3.8 CR4000 Instructional Video (CR40x)

The CR4000 system instruction video is available in several formats: CD, NTSC, SECAM or PAL. A videotape or CD is supplied with each CR4000 system. The format received is customer specified. The video contains an overview of the CR4000 system and is intended to complement this manual. It can also be used as an instructional aid.

3.9 Ophthalmic Probes

All probe shafts and tips are stainless steel. Refer to Table II for a listing of the MIRA Ophthalmic Cryo Probes. The gas expansion chamber is at the very tip of the probes, thereby assuring that freezing and defrosting occurs only at the target area. Warm high-pressure gas insulates the shaft during freezing and defrosting cycles eliminating the need for an insulating boot while reducing the danger of freezing adjacent tissues. The handles present an unobstructed view of the probe shaft and remain comfortable to the hand during use.

TABLE II Probe Model Numbers

Model No;		Description	
		Tip Diameter	Ice Ball Size
CR4010	Curved Retinal	2.8mm	3.5mm
CR4015	Straight Retinal	2.8mm	3.5mm
CR4022	Straight Cataract	2mm	3.0mm
CR4023	Curved Cataract	2mm	3.0mm
CR4025	Mini Curved Cataract	1.5mm	2.0mm
CR4030	Curved Glaucoma	3.5mm	4.0mm
CR4040	Vitreous	1.5mm	2.5mm
CR4045	Mini Straight Vitreous	1.5mm	1.5mm
CR4075	Curved Hammerhead	2.8mm x 6mm long	4.5mm
CR4080	Curved Baby Hammerhead	1.5mm x 4mm long	2.5mm
CR4085	Gaydon ROP	2mm	3.0mm
CR4090	Abramson Retinoblastoma	1.5mm	2.0mm
CR3095	Lashkari Trichiasis	2.8mm	2.5mm

4.0 INITIAL SET-UP PROCEDURE

IMPORTANT: To be performed or double checked each time an element of the CR4000 system is added, changed or disassembled.

Obtain a non-siphon gas cylinder of N₂O or CO₂. The type of cylinder and gas selected will determine the connector needed. See table 1 for a complete selection of gas cylinder connectors.

WARNING; Siphon gas cylinders will vent gas in a liquid state when the valve is opened. Do not use siphon gas cylinders



Be sure that the gas cylinder is properly secured to a rack or the MIRA Equipment Carrier. It is important to prevent the cylinder from tipping over. If the cylinder was not stored critically, set aside for 24 hours. If it is hot or cold due to storage conditions, set it aside for 24hrs to equilibrate to room temperature.

Make sure that the “ON/OFF” valve on the front panel of the console is in the “OFF” position. Connect one end of the high-pressure hose to the “gas input” on the back of the console and the other end to the gas supply through the Micro-Filter Assembly. Tighten both the 5/8 hex nuts by hand then tighten them using an appropriate wrench. Attach cylinder connector to the gas supply cylinder per the appropriate procedure below.

For CGA connector;

- a. Place the adaptor against the mating outlet of the cylinder valve.
- b. Engage the quick-coupling nut and tighten by hand.

For T-Yoke connector;

- a. To ensure a tight seal, use the washer supplied with the cylinder.
- b. Place the T-Yoke connector over the cylinder stub valve.
- c. Tighten the “T” handle by hand.

Connect one end of the 25ft. Scavenger hose to the rear panel fitting labeled “System Exhaust” Connect the other end to an aspiration system or equivalent.

Note; Use of the scavenger hose will result in quieter operation of the CR4000.

Check to be sure that the “ON/OFF” valve on the front panel of the Cryo console is in the “OFF” position. Then, completely open the valve on top of the gas cylinder by turning it counter-clockwise. When the cylinder valve is completely open, turn it back (clockwise) one quarter-turn.

This prevents the cylinder valve freezing and locking in the open position.

Listen and look for leaks at either end of the high-pressure hose. An audible hiss or frost on a fitting identifies a leak. A leak can be corrected by tightening the appropriate 5/8 nut(s) on the high-pressure hose. Any leak in the system will adversely affect the system performance, particularly freezing and defrosting.

5.0 FOOT-SWITCH OPERATION

The foot-switch has approximately 12ft. (3.66metres) of reach in any direction.

A hissing sound is present each time the foot-switch is depressed or released.

Depressing the foot-switch pedal at any compass point will instantly freeze the probe tip. Releasing the foot-switch pedal will instantly defrost the probe tip.

A popping sound may be heard from the relief valve if the foot-switch is depressed within 30 seconds of its last release. This is normal. The purpose is to lower the exhaust pressure so that freezing can take place.

6.0 TEST PROCEDURE - To be performed prior to patient treatment

- 6.1 Select an Ophthalmic Cryo Probe and unscrew the protective cap from the probe jack.
- 6.2 Insert the probe jack all the way into the receptacle on the front panel.
IMPORTANT: When the probe is not in use, the protective cap should be kept on the probe jack to prevent foreign matter and moisture from entering the probe system during handling, cleaning and sterilizing. (See section 8.0).
- 6.3 **PRECONDITION PROBES** - To assure proper probe operation, **gas must be purged from the probes prior to their use.** To properly purge gas from a probe, follow the procedure below,
 - 6.3.1. Set the front panel valve “ON/OFF” switch to “ON”
 - 6.3.2. Verify there is a minimum of 680psi gauge of pressure. Check the pressure gauge Indicator, it should be in the green zone. (680-900psi gauge)
 - 6.3.3. Select the -25° C temperature setting for Nitrous Oxide (N₂O)
Select the -5° C temperature setting for Carbon Dioxide (CO₂)
 - 6.3.4. Depress the foot pedal for 10 seconds and then release.
 - 6.3.5. Wait 60 seconds while the exhaust gas is escaping from the rear scavenger port.
IMPORTANT;
Most of the purging occurs during the last 30 seconds of the purge cycle.
 - 6.3.6. Repeat steps 6.3.4.and 6.3.5.twice. This will remove internal condensation as well as restore ambient temperature to the system.
 - 6.3.7. The system is now ready for use.
Should you wish to perform an “ice ball” test, proceed as follows;
Remove probe tip cap. Submerge the tip into a solution of sterile saline and depress the foot pedal for 10seconds, keeping the tip in the solution. After ten seconds, with the foot pedal depressed, remove the probe tip from the solution. An ice ball of 1.5 to 2.5 mm larger than the diameter of the probe tip should have been formed. Release the foot pedal. In about 4 seconds, the ice ball should be free to move when tipping the probe.
- 6.4. To remove the probe, allow the gas to dissipate for approximately 60 seconds. This relieves the gas pressure in the system. If the probe must be removed quickly, turn the “ON/OFF” valve to “OFF” while depressing the foot-switch. This action depressurizes the system instantly.

7.0 PRESSURE REDUCTION REGULATORS

For optimum performance of the Mini-Vitreous Probe CR4045, a standard pressure reduction regulator should be used to reduce the gas pressure delivered to the CR4000 system. A suitable two-stage pressure reduction regulator is used instead of the cylinder connector. The gas pressure from the cylinder should be adjusted to indicate 625psi on the CR4000 front panel gauge.

A **pressure reduction regulator** is only recommended for the Mini- Vitreous Probe CR4045. For all other probes, the pressure should be set between 680 and 900psi(700psi is preferred), within the green zone of the front panel gauge. Contact your MIRA representative for more information on pressure reduction regulators.

8.0 PROBE CARE

8.1 Use

The Ophthalmic Cryo probes must be handled with care. They are non-electric and are easily inserted or removed from the console's receptacle. Do not use the probe if the tip is scratched or damaged. Return scratched or damaged probes to MIRA for repair.

WARNING; Do not alter the shape of the probe tip. The shape of the probe tip is vital to its proper function. Any change to the probe tip will void the manufacturer's warranty.

8.2. Cleaning

The probes can be cleaned in accordance with the published protocol. **The entire probe should never be submerged in any solution.** The probe jack cap should always be attached during cleaning or sterilization to prevent foreign particles from entering the body.

8.3 Storage

Storing the probes in tight coils is not recommended. Coil loops should be a minimum of 6 inches. The white caps will protect the probe tip and probe jack when being transported or stored.

8.4 Sterilizing

CR4000 probes are made of stainless steel, Teflon and silicone rubber. The probes should be sterilized in accordance with hospital protocol and Mira, Inc. IFU. It is the user's responsibility to select the sterilizing conditions that do not harm these materials. These materials will tolerate steam sterilization.

WARNING; The probe jack cover must be screwed into place before sterilizing regardless of the sterilizing methods used. If moisture from steam or gas enters the probe during sterilization, it will adversely affect the performance of the system.

Please ensure that the probe tip cover is on at all times when the probe is not in use.

9.0 COOLANT INFORMATION

The CR4000 system operates on medical grade Nitrous Oxide (N₂O) or Carbon Dioxide (CO₂). **DO NOT** expose the gas cylinders to direct heat. Compressed gas must be handled with care.

Improper storage temperatures or overfilling cylinders can cause equipment malfunction. Store cylinders at room temperature for 24 hours prior to use.

Cylinder pressure will increase when the cylinder is heated and decrease when it is cooled. The nominal cylinder pressure for N₂O is 730psi and CO₂ is 850psi.

Non-siphon cylinders must be used and should be stored in the upright position.

Gas cylinders used with this system **must be non-siphon**.

WARNING: Liquid N₂O or CO₂ can damage your system

10.0 SAFETY INFORMATION

10.1 Safety Features

Because the CR4000 is completely non-electric, there are no electrical shock hazards.

The micro-fiber filter / Sintered metal filter assemblies prevent foreign particles or oils from entering the CR4000 console and probes. Replaceable Micro-fiber filter / Sintered Metal elements are available from MIRA.

The front panel pressure gauge of the CR4000 console displays gas pressure from the gas supply cylinder reducing the possibility of running out of gas during use. The MIRA Dual Cylinder Cryo Equipment Carrier CR4400 (see section 3.7. and Fig. 2) can hold a spare cylinder. A fresh supply can be made available by using the carriers specially designed switch-over valve.

Adequate pressure regulation (except when using the Mini-Vitreous Probe CR4045, See section 7) is built into the CR4000 Console and calibrated by MIRA to decrease operator intervention and to prevent errors in setting cylinder pressure

The MIRA CR4000 system has a rapid freeze and defrost system available. Gas expansion occurs only at the tips of the MIRA CR4000 probes allowing for greater control of application time and target tissue area.

10.2 General Safety Precautions

Review this manual with all personnel involved with the use of the CR4000.

Always mark the empty gas cylinder so it can be replaced immediately

Liquid N₂O or CO₂ will damage the CR4000 surgical unit. Use only siphon gas cylinders.

If for any reason the Ophthalmic Cryo CR4000 console, probes or accessories has to be returned to MIRA Inc., see section 11.0 for shipping information.

The initial set-up procedure described in section 4.0 should be performed/triple checked each time an element of the CR4000 system is added, changed or disassembled.

The test procedure described in section 6.0 should be performed before patient treatment.

Turn the gas cylinder OFF and depressurize the CR4000 system before changing the Micro-filter/Sintered metal filter or “O” ring

When the probe is not in use, the protective cap should be kept on the probe jack to prevent foreign matter and moisture from entering the probe system during storage, handling, cleaning and sterilization.

Also, please ensure that the probe tip cap is in place whenever the probe is not in use. Do not change the shape of the probe tip as this is vital to the proper functioning of the device.

To assure proper probe operation, gas must be purged from the probes prior to their use.

The probes can be cleaned in accordance with protocols (see addendum A). The entire probe should never be submerged in any solution.

DO NOT expose the gas cylinder to direct heat.

Improper storage temperatures or overfilling cylinders can cause equipment malfunction.

Non-siphon cylinders must be used and should be stored in the upright position.

11.0 Shipping Information

If for any reason the ophthalmic Cryo CR4000 console or any of the probes and accessories has to be returned to MIRA Inc., please do the following:

Before shipping please contact MIRA Customer Service to obtain a Return Goods Authorization (RGA)

Remove the high-pressure hose from the “Gas Input” on the rear of the console.

Remove the scavenger tube from the “Exhaust” fitting on the rear of the console.

Do not remove the foot pedal; It should be packed with the console avoiding sharp bends and kinks of the connecting hoses. Thoroughly clean and sterilize all probes. Place protective caps over probe jacks and tip ends. Do not coil the probe hose into coils less than 6 inches in diameter. Place all probes in plastic bags.

Enter a brief note that includes the following;

- Return Goods Authorization (RGA#)
- Your full address for return of shipment. (Please include specific department)
- Description of the malfunction or reason for return
- Pack equipment securely inside a heavy wall cardboard box using foam and/or bubble pack..
- Ship Carton to: *MIRA INC.* - 414 Quaker Highway - Uxbridge, MA 01569
Tel; 508-278-7877, 1-800-847-MIRA (6472) - Fax;508-278-4555

12.0 Specifications

Console dimension;	-Width 5.5 in (14.0 cm) -Height 6.5 in (16.5 cm) -Depth 11 in (27.9 cm)
Console Weight	- 16lb. (7.3kg)
Power Source (input)	-Pressurized CO ₂ or N ₂ O gas (NON ELECTRICAL)
Temperature settings	N ₂ O: -25, -55, -85 (+/-5° C) CO ₂ : -5, -35, -65 (+/-5° C)
Foot-switch dimensions;	- Approximately 12ft. (3.66 meters)
Gas Input	- 7/16-20 male thread
High Pressure Hose	- 60in, (152.4cm) 5/8" hex nuts
(Gas intake) CR4260 Cylinders	7/16-20 female thread both ends - Non-siphon only
Gauge Pressure	- 680-900psi (Recommended)
Gas Cylinder pressure	- CO ₂ 850psi. max., 70° F - N ₂ O 730psi. max., 70° F Scavenger Hose CR4160 - 25ft. (7.62 meters)

13.0 WARRANTY

MIRA, Inc. warrants material and workmanship of the CR 4000 Cryo Console for a period of one year from the date of shipment. All accessories are warranted for a period of one year. Our obligation under this warranty is limited to replacing any part or parts which shall, upon examination at our factory, be determined to have been defective. The foregoing warranty shall apply only to the original buyer, and is and shall be in lieu of all other warranties, whether expressed or implied, and of all other obligations or liabilities on the part of MIRA Inc., to be liable for any anticipated profits, consequential damages, loss of time or other losses incurred by the buyer with the purchase or operation of the equipment or components thereof. Repair to damaged parts will be made at a minimal charge. The buyer shall pay all shipping charges on the equipment being returned for warranty or charged repairs. Repaired equipment will be returned F.O.B. our plant. For prompter service, fill out and return the warranty card supplied.. **This warranty shall be void if a siphon cylinder is used or if any of the system components are tampered with.**

14.0 CERTIFICATE OF CONFORMANCE



MIRA INC.
414 Quaker Highway
UXBRIDGE MA 01569
Tel; 508-278-7877
Fax: 508-278-2622

Furnished products within this shipment have been manufactured in accordance with the process and the test acceptance criteria requirements of specified drawings and specifications listed in the master device record and safety guidelines of MIRA INC.

Calibration, when applicable has been done with the use of equipment traceable to the National Institute of Standards and Technology (USA)