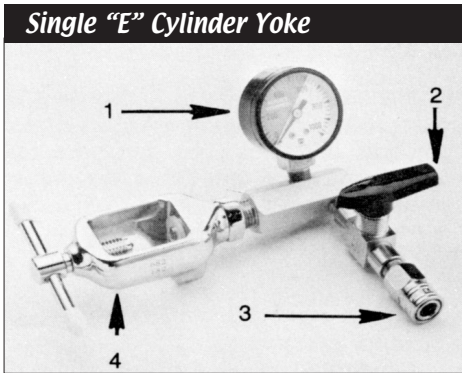


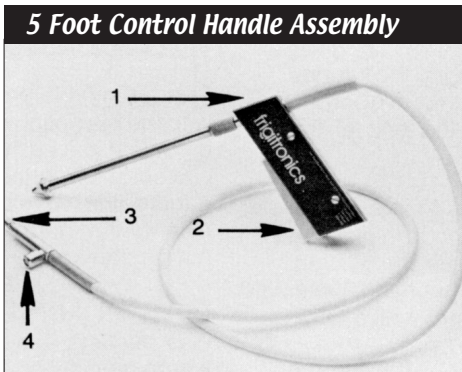
Frigitronics®

CM-73 CRYOSURGICAL SYSTEM

OPERATING & MAINTENANCE MANUAL



- 1 Cylinder Pressure Gauge
- 2 ON/OFF Valve
- 3 Quick Disconnect Safety Lock
- 4 N₂O Pin Index Connector



- 1 Screw-On Probe Connection
- 2 Defrost Trigger Mechanism
- 3 Quick Connect to Yoke
- 4 Gas Exhaust Port

REF # 683

Caution Federal (USA) law restricts this device to sale by or on the order of a physician.

Manufactured by:

CooperSurgical

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Introduction

The Frigitrionics® CM-73 Cryosurgical System uses universally available medical grade nitrous oxide in a completely non-electric instrument to provide temperatures down to -89°C. A selection of interchangeable screw-on probes is available for procedures in gynecology, general surgery and otorhinolaryngology.

When the **ON/OFF** control valve is opened, N₂O gas is supplied to the probe causing rapid cooling via the Joule-Thomson principle. Activating the trigger on the probe handle permits warm gas to be present in the probe for defrosting.

Probes and cylinders of nitrous oxide are quickly and easily changed. The unit features low-pressure operation—except during defrost—for complete safety. A specially designed safety feature prevents the use of high-pressure defrost gas unless the probe is properly secured in the probe handle. The CM-73 Cryosurgical System can be obtained with provisions for single or double cylinder operation. Cylinder yokes are available to accommodate the 6.5 lb. "E" cylinder, the 20 lb. cylinder, and the 60 lb. "G" cylinder (weights are gas content only). Other yokes to fit cylinders manufactured outside the USA are available through our International Department and/or Frigitrionics dealer representatives.

Cryo Probes

The probes are of high-quality stainless steel, welded construction. They are lightweight, slender and easy-to-handle. Available in a variety of configurations, all probes thread securely into the probe handle and feature a knurled finger grip for ease of installation.

Probe Handle Assembly

Consisting of a comfortable handle with a trigger-type defrost, the probe handle assembly is provided with a single coaxial line that both supplies N₂O to the probe and carries away the exhaust gas. A quick-disconnect attaches the probe line for easy installation.

Yoke Assembly

Hand-tightening or a small wrench is all that is required to attach the yoke to a cylinder of nitrous oxide. The key pin index of the "E" cylinder prevents the inadvertent use of any other gas cylinder. Yokes are available for both single and double cylinder operation. A pressure gauge indicates gas pressure in the supply cylinder and a 90-degree **ON/OFF** valve is used to start or stop gas flow to the probe.

Cylinder Valve Handle

A removable handle is provided to open and close the N₂O "E" cylinder(s).

Bottle Carts

Single and double bottle carts are available for securing one or two "E" cylinders of N₂O in a compact mobile carrier. A single bottle cart is also available to accommodate a 20 lb. N₂O cylinder.

Instrument Case

An attractive attache case is compartmentalized to carry all CM-73 components except the cylinders and bottle cart.

Exhaust Gas Venting

The built-in exhaust port is designed for the attachment of tubing to safely vent nitrous oxide exhaust gases out of the treatment area. Silicon tubing, 3/8" inner diameter X 1/16" wall is recommended. All tubing should be routed overhead to minimize the accidental restriction of the exhaust gases.

CAUTION: Use only the exhaust hose provided. Substitutes are not recommended. **DO NOT** restrict or kink the exhaust hose in any way.

System Set-Up

- 1** Place the cylinders of medical grade nitrous oxide in the bottle cart. Orientate the bottles so that the pin index (holes) in the valve face the pins on the yoke with the pressure gauge facing forward.
- 2** Position the "E" cylinder yoke to the cylinder valve. If a double cylinder yoke is being used, set up both cylinders in the same manner. Be sure that the Teflon washer supplied with each "E" yoke is in place. Extra washers are provided in the attache case. Place the yoke over the valve and insert the pins into the valve for the "E" yoke connection.

The 20 lb. cylinder yoke and the "G" cylinder yoke are identical. Attach the yoke assembly to the gas cylinder.

- 3** Tighten the yoke "hand-tight" if using the "E" yoke, and wrench-tight for the 20 lb. or "G" cylinder.
- 4** Place the round cylinder handle on the "E" cylinder valve.

5 **Test Cylinder Pressure**

Test cylinder pressure and yoke assembly by placing the **ON/OFF** valve in the **OFF** position (the handle should be turned 90° to the line) and opening the cylinder valve fully with the handle provided. A reading between 740 and 800 psi should be indicated by the pressure gauge when opening a full cylinder. Pressure is dependent on fullness of cylinder and ambient temperature, but the system should not be used if cylinder pressure is less than 600 psi. At this time, any leaks should be audible. Replace Teflon washer if necessary and tighten yoke.

NOTE: Cylinder should be kept at room temperature (72°F) for a minimum of 2 hours to ensure pressure readings.

Probe Assembly Set-Up

Remove the probe handle assembly from the carrying case. A probe should be on the probe handle at all times to protect the delivery tube from damage.

- 1 To remove a probe** • Unscrew the probe using the knurled finger grip, turning counterclockwise.

CAUTION: The probe must be slid straight forward until it clears the end of the delivery tube.

- 2 To attach a probe** • Select the probe that is desired for the procedure. Check that an undamaged "O" ring is in place at the threaded end. Carefully place the probe over the delivery tube and screw on securely (finger tight).

NOTE: Changing probes should be done with the the **ON/OFF** valve to "**OFF**". To ensure that no gas is flowing through the probe, wait at least 10 seconds before removing tip.

- 3** Attach the probe line to the yoke assembly by placing the probe line male end of the quick-disconnect into the female component on the yoke assembly. Pull the collar back on the female fitting, insert the male fitting to the position such that the collar will slip forward, and the male fitting will lock in place. Pull gently to check that the probe line is secured.

- 4 To check probe operation/Freeze Test** • With the cylinder valve open, turn **ON/OFF** valve "**ON**" (handle parallel with line). The tip of the probe will begin to freeze. Exhaust gas will be audible exiting the exhaust port near the quick-disconnect.

- 5 To check probe operation/Defrost Test** • Firmly depress the trigger on the probe handle. Audible gas flow will stop. The tip of the probe will defrost quickly. In some cases, when using probes with large freezing areas, it may be necessary to momentarily release and then depress the trigger. This supplies additional warm gas for defrost and may be repeated as needed for complete defrost.

Operation

- 1** With the cylinder valve fully opened and the desired probe in position, turn **ON/OFF** valve "**ON**".
- 2** Firmly depress the trigger on the probe handle to warm the end of the probe.
- 3** Apply the end of the probe to the tissue to be treated. Release the trigger to freeze the tissue for the required length of time. An optional timer is available.
- 4** At the end of the freeze time, depress the trigger to warm the probe. Remove the probe from the tissue after the tip has completely defrosted (0°C on the pyrometer). Larger probes, for more extensive freezing, require depressing the trigger two or three times to accelerate the defrost mode.
- 5** Turn **ON/OFF** valve to "**OFF**" and prepare for next procedure.

Shut Down

- 1** With the **ON/OFF** valve to "**OFF**", the probe line can be removed, or the probe can be replaced. The probe line can be disconnected by pushing back the collar on the female part of the quick-disconnect and pulling the probe line connector out.
- 2** At the end of procedure—or the end of the day—shut off supply cylinder by turning the cylinder valve clockwise.

Maintenance

The Frigitronics® CM-73 Cryosurgical System should be handled with the care required of any quality instrument. Avoid dropping or mishandling the unit and periodically inspect the lines, fittings, seals and probes for damage. A probe should always be kept in place over the delivery tube for protection. Do not constrict, kink, clamp, lay objects on, or otherwise damage or restrict the probe line. The line serves as both supply and exhaust for the nitrous oxide.

CAUTION: Do not block the exhaust port located near the quick-disconnect. If the line or exhaust is restricted the outer tube could fill with gas, expand and rupture.

Gas Purifiers

Gas purifiers (optional) are available through CooperSurgical for systems being used in areas where medical grade or dehydrated nitrous oxide is not available. Gas contaminants (water, oil, vapor or solid impurities) may cause blockage and reduce operating efficiency.

Cleaning

Tips, handle and lines can be wiped clean with a mild disinfecting solution or alcohol (70% isopropyl alcohol) presently used in the office or hospital. Cidex cold soaking **MUST NOT** be utilized because it will attack the materials in the probe, and will introduce excessive amounts of liquid.

Sterilization The Removable Probe Tips may be sterilized by:

FLASH AUTOCLAVE

280°F maximum temperature for a minimum of three minutes. Extended exposure time is required with lower temperatures.

EO (ETHYLENE OXIDE) GAS

Temperature125-130°F
50% RH (pre-humidity)60 minutes
.0/+10 minutes
Pre Vacuum24" Hg ± 2" Hg
Gas Pressure 6-8 psig (550-660 mg/L EO)
Exposure Time4 hours minimum
Post Vacuum24" Hg 2X ± 2" Hg
Aeration12-0/+1 hours at 120°F

NOTE: The particular EO cycle should be validated per the equipment manufacturer's requirements. It is recommended that each institution employ procedures which include the use of biological indicators in order to determine the effectiveness of the ethylene oxide process.

The Frigitronics® CM-73 Cryosurgical System probes may be sterilized by autoclaving, flash autoclaving or EO gas, or in accordance with the manufacturer's direction. The probe **MUST NOT BE** immersed more than 6 inches (tip end only). **DO NOT** sterilize handle, line, yoke assembly, etc.

WARNING: Do not immerse or soak the line or handle. Do not let the solution reach probe handle, or enter internally.

Operating Hints

- 1** It is recommended that nitrous oxide cylinders be at room temperature in order to supply gas at the pressures desired. In some cases, cylinders stored outdoors in cold weather will not produce sufficient gas pressure. They must be warmed to room temperature for satisfactory operation.
- 2** Do not attempt to remove yoke assembly without first turning off the supply cylinder.
- 3** Do not unscrew the probe or remove the probe line quick-disconnect without first turning the **ON/OFF** valve to **“OFF”** and releasing the trigger on the probe handle.
- 4** When the trigger valve is depressed and then released during operation, an audible surge of gas will be heard. This is normal.
- 5** Prior to beginning a procedure, the probe should be at room temperature. Depress the trigger to warm the tip before applying to tissue.
- 6** The probe line is supplied with a sintered metal filter located at the male part of the quick-disconnect. Take care to keep the surface of this filter clean.
- 7** In the unlikely event of an uncontrolled freeze, simply turn the **ON/OFF** valve to **“OFF”** and irrigate the probe tip until it defrosts.
- 8** In case of inadequate freeze or premature defrost, check the following:
 - Low cylinder pressure/Replace cylinder.
 - **ON/OFF** valve partially open/Open valve fully.
 - Obstruction in line or delivery tube/Return to CooperSurgical for repair.
 - Contamination in supply cylinder/Clean lines and replace supply cylinder.
 - Leaks in fitting/Check washer and O-ring, tighten fittings.

Replacement Parts

Part	ReOrder Number
• "O"-Ring	20719
• Purifier assembly	P190
• Gas Filters	P191
• "O"-Ring Filter	10924
• Optional Timers	2475
• "E" Cylinder Handles	20364
• "E" Yoke Seals (2)	20371
• 20 lb. "G" Yoke Seals (2)	21837
• 20 foot Scavenger Tubing	32873
• Probe Storage Clip	51200
• Operating & Maintenance Manual	35651

Warranty

CooperSurgical warrants The Frigitronics® CM-73 Cryosurgical System and probes for a period of one year against defects in material and workmanship.

Frigitronics® is a registered trademark of CooperSurgical

Part #35651 • Revised 6/03

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