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Introduction

Thank you for purchasing the Welch Allyn, Inc. Cryosurgery System for use in your clinic or private practice.

Each system is meticulously handcrafted and thoroughly tested prior to shipment. Proper care and maintenance ensures a long and useful life. This Operating Manual is intended to acquaint you with your new Cryosurgery System, its directions for use, cleaning and storage, and the necessary safety precautions.

![Precautions]

Do not store gas cylinders above normal room temperatures.

Use only Medical Grade Nitrous Oxide (N₂O)/Carbon Dioxide (CO₂) gas.

Do not crimp or tightly bend the gas hose. Coil the hose no tighter than an 8-inch circle. If a hose is damaged, replace it.

Verify the O-ring is in place at the end of the cryogun prior to installing a cryotip. Inspect O-ring and replace if cracked or damaged.

Hand tighten all connections. Tools are not necessary.

Turn the gas cylinder valve off before disconnecting the console from the gas cylinder.

Verify the gas is off at the console before changing tips.

If a cryotip is dropped, inspect for damage and replace as necessary.

This manual is not meant to teach the proper technique or any of the medical considerations regarding the use of this equipment. Welch Allyn recommends that prospective users obtain appropriate training before using this equipment as improper use is potentially hazardous to the patient and the user. DO NOT use this device without proper training.
CAUTION: FEDERAL LAW RESTRICTS THE SALE OF THIS DEVICE TO OR ON THE ORDER OF A LICENSED MEDICAL PRACTITIONER OR DESIGNATED AGENT.

WARNING: EXPOSURE TO NITROUS OXIDE (N₂O) MAY RESULT IN IMPAIEMENT OF PERFORMANCE, COGNITION, OR DEXTERITY. VENTILATE WELL.

IT IS THE USER’S RESPONSIBILITY TO FIT THE EXHAUST HOSE BETWEEN THE CRYOSURGERY UNIT EXHAUST AND DISPOSAL POINT TO MINIMIZE NITROUS OXIDE (N₂O)/CARBON DIOXIDE (CO₂) EXPOSURE.

The Cryosurgery System

READ THIS ENTIRE MANUAL BEFORE OPERATING YOUR NEW CRYOSURGERY INSTRUMENT.

The Cryosurgery System is designed for easy assembly and operation. No tools are necessary.

The system is delivered in an attaché carrying case along with cleaning plugs, a gas scavenging hose, and a package of replacement “O” rings. On the end of the cryogun barrel is a tip protector, which is removed when the cryotip is used and replaced when the cryogun is not in use.

A 20# N₂O (Nitrous Oxide) or CO₂ (Carbon Dioxide) gas cylinder is available for the Cryosurgery Unit. Nitrous Oxide/Carbon Dioxide is used as the refrigerant for the cryogenic process. Use the N₂O/CO₂ only in a well-ventilated area. A 20-ft. scavenging hose is provided to divert used gas away from the operator. Use the mobile hand cart for cylinder movement. Do not drag, slide, or roll the cylinder. Store the cylinders upright and firmly secured to prevent falling or accidentally
getting knocked over. Refill the compressed gas cylinders only by qualified producers of compressed gases. Do not allow the storage cylinder temperature to exceed normal room temperatures.

<table>
<thead>
<tr>
<th>No.</th>
<th>Description</th>
<th>No.</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>1</td>
<td>20# Cylinder</td>
<td>5</td>
<td>Cleaning Plugs and “O” Rings</td>
</tr>
<tr>
<td>2</td>
<td>20# Mobile Cart</td>
<td>6</td>
<td>Console</td>
</tr>
<tr>
<td>3</td>
<td>Carrying Case</td>
<td>7</td>
<td>Cyrogun</td>
</tr>
<tr>
<td>4</td>
<td>Quick Connect</td>
<td>8</td>
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</table>
General Instructions

Check the gas cylinder to verify that it contains adequate gas. The pressure gauge should read between 600 and 800 PSI for proper freeze to occur. A pressure below 600 PSI may not provide enough pressure for sufficient freeze or defrost.

Securely seat the gas cylinder onto the mobile cart and hold it into place with the safety chain provided.

Examine the tubing leading from the console to the gun by running the line between the thumb and forefinger, checking for any kinks or abrupt bends. A kink in the line can cause a weakness which can erupt under pressure.

Inspect the “O” ring seal located between the tip and the gun barrel prior to each use.

Scavenging Hose

A 20’ scavenging hose is provided with the unit to divert the N₂O/CO₂ gas away from the operator and patient to a remote, well-ventilated or uninhabited area. Push one end of the scavenging hose over the exhaust muffler on the console (a small amount of mild soapy water on the inside diameter of the hose will ease this operation) of the cryo unit and lead the other end to a remote, well-ventilated or uninhabited area.
Directions for Use

1. A 20# CO2 tank requires an adapter (supplied). Verify the plastic gasket (1) is in place (as shown) prior to fastening the adapter to the tank valve.

2. Tighten the quick-connect to medical grade N₂O/CO₂ gas supply as shown (or to the adapter). (A)

3. Connect the gas scavenging hose to the exhaust muffler on console. Vent to remote location. (B)
4. Select the proper tip for the cryo procedure and unscrew the protective shield (C) from the end of the cryogun. Hand tighten the cryo tip (D) onto the gun.

**NOTE:** Verify the O-ring is in place at the end of the cryogun prior to installing a cryotip. Inspect O-ring and replace if cracked or damaged.

(C) (D)

5. Open the gas supply valve on cylinder.

6. Turn the arrow valve to ON position. Verify pressure is in the working range.

**NOTE:** this manual is not meant to teach the proper technique or any of the medical considerations regarding the use of this equipment. Welch Allyn recommends that prospective users obtain appropriate
training before using this equipment as improper use is potentially hazardous to the patient and the user. DO NOT use this device without proper training.

7. Apply probe to surgical site and squeeze the trigger to freeze (normal time is approx. 3 minutes).

8. Release trigger and remove the tip from the site and allow to stand for approximately 3 minutes. Repeat steps 6 and 7 one time.

9. When the procedure is complete, turn the arrow valve to the OFF position.

10. Close the gas supply valve on the cylinder.
Care and Storage

Upon completion of the surgical procedure, shut off the system at both the console and the tank. A squeeze of the trigger releases any residual gas in the console. Remove the cryo tip from the gun for cleaning and place the tip protector onto the end of the gun. Wipe down the gun barrel. The console can remain connected to the gas cylinder and the gun can hang on the mobile cart hook. Or, disconnect the system and return to the carrying case for storage.

Cleaning

WARNING: DO NOT USE BLEACH OR ANY PRODUCT CONTAINING CHLORINE IN THE CLEANING OF THIS PRODUCT.

CAUTION: DO NOT Rinse OR Soak Tips Without First Installing CLEANING PLUGS. VERIFY THE CLEANING PLUGS HAVE RUBBER O-RINGS IN PLACE TO PREVENT LIQUID FROM ENTERING THE TIPS.

NOTE: NOT USING CLEANING PLUGS WILL CONTRIBUTE TO UNIT MALFUNCTION.

Clean the cryogun and tips by wiping down with alcohol. Clean the tips in a mild soap and water solution with cleaning plugs installed and O-rings in place. After cleaning, remove the cleaning plugs and return to the storage pouch. For storage, cleaning tips also fit on the metal studs located on the console.

Disinfection

To disinfect the tips, soak in a cold disinfectant with cleaning plugs installed and O-rings in place. Clean tips before disinfecting. Follow the disinfectant manufacturer’s guidelines for disinfection.
Sterilization

WARNING: DO NOT AUTOCLAVE THIS INSTRUMENT

NOTE: DO ALL CLEANING AND STERILIZATION WITH CLEANING PLUGS AND O-RINGS IN PLACE ON TIPS.

COLD STERILIZATION: Sterilize the tips by soaking in a cold sterilant with cleaning plugs installed and O-rings in place. Follow the sterilant manufacturer’s guidelines for sterilization.

ETO STERILIZATION: Thoroughly clean and dry cryotips prior to ETO Sterilization. Do not exceed 130° F or 100 PSI when sterilizing the tips.

Service

Customers with instruments requiring service should contact the Welch Allyn Technical Service Department at (800) 535-6663, 315-685-4100, or FAX: 315-685-4653.

Accessories

Contact Welch Allyn Customer Service for additional information on the following accessories:

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<tr>
<th>Part Number</th>
<th>Description</th>
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<tbody>
<tr>
<td>88374</td>
<td>General Purpose Cryotip- Round End</td>
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<tr>
<td>88376</td>
<td>General Purpose Cryotip- Flat End</td>
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<tr>
<td>88378</td>
<td>Exocervical Cryotip</td>
</tr>
<tr>
<td>88380</td>
<td>Exo/Endocervical Cryotip - Short Top</td>
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<td>88382</td>
<td>Exo/Endocervical Cryotip - Long Top</td>
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<tr>
<td>88388</td>
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<td>Curved Anorectal Cryotip</td>
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<td>Derm Bevel Cryotip</td>
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<td>Berm Bevel Large Cryotip</td>
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<td>88398</td>
<td>Maxiderm Cryotip</td>
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<td>Microderm Cryotip</td>
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<td>88402</td>
<td>Soll Lash Epillating Cryotip</td>
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<tr>
<td>88404</td>
<td>“E” Cylinder Tank Adapter, CO₂</td>
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<tr>
<td>88406</td>
<td>“E” Cylinder Tank Adapter, N₂O</td>
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<tr>
<td>88408</td>
<td>20 Lbs Cylinder N₂O</td>
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<tr>
<td>88410</td>
<td>20 Lbs Cylinder CO₂</td>
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<td>88412</td>
<td>20 Lbs Cylinder Cart</td>
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<td>88414</td>
<td>7 Lbs E-Cylinder N₂O</td>
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<tr>
<td>88416</td>
<td>7 Lbs E-Cylinder CO₂</td>
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<td>88420</td>
<td>Carrying Case</td>
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<tr>
<td>88422</td>
<td>O-Rings (package of 10)</td>
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<tr>
<td>88424</td>
<td>Cleaning Plugs (package of 4)</td>
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Warranty

One Year Limited Warranty On New Instruments

Instrumentation purchased new from Welch Allyn, Inc. (Welch Allyn) is warranted to be free from original defects in the material and workmanship under normal use and service for a period of one year from the date of first shipment from Welch Allyn. This warranty shall be fulfilled by Welch Allyn or its authorized representative repairing or replacing at Welch Allyn’s discretion, any such defect, free of charge for parts and labor.

Welch Allyn should be notified via telephone of any defective product and the item should be immediately returned, securely packaged and postage prepaid to Welch Allyn. Loss or damage in shipment shall be at purchaser’s risk.

Welch Allyn will not be responsible for loss associated with the use of any Welch Allyn product that (1) has had the serial number defaced, (2) has been repaired by anyone other than an authorized Welch Allyn Service Representative, (3) has been altered, or (4) has been used in a manner other than in accordance with instructions.

THIS WARRANTY IS EXCLUSIVE AND IN LIEU OF ANY IMPLIED WARRANTY OF MERCHANTABILITY, FITNESS FOR PARTICULAR PURPOSE, OR OTHER WARRANTY OF QUALITY, WHETHER EXPRESSED OR IMPLIED. WELCH ALLYN WILL NOT BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL DAMAGES.

If you have questions regarding any Welch Allyn products, please call Customer Service at (800) 535-6663, 315-685-4560, or FAX:315-685-3361.