CooperSurgical

LEEP PRECISION™
Smoke Evacuator, 120 VAC

REF LP-30-120

Operating Manual

Table of Contents

Device Description /Intended Use

The CooperSurgical LEEP PRECISION™ Smoke Evacuator is a stand alone, three-stage air filtration device that is used to capture airborne particulate from smoke plumes produced during electrosurgical procedures.

Cautions

- U.S. Federal law restricts this device to sale by or on the order of a physician.
- This device produces a strong vacuum force and care should be exercised to ensure that the suction and the position of the inlet end of the suction tubing is adjusted properly to prevent injury to the patient or inadvertent damage to surgical materials.
- The materials in the plume removed by this device are potentially hazardous. Handle according to 29 CFR 1910.1030 and OSHA 3127.1992 (Occupational Exposure to Bloodborne Pathogens) guidelines.
- To prevent a fire or explosion hazard, do not use the system in the presence of flammable or potentially flammable materials.
- Do not allow fluid to be pulled into the system.
- To prevent premature failure of the ULPA filter cylinder, do not operate this device without a disposable Pre-Filter in place.
- No modification of this equipment is allowed.
- No Customer serviceable parts.
- Only replacment of power cords or fuses can be done by the user. Only replace with these items with the exact replacement part(s) available from CooperSurgical.

Warning

To avoid risk of Electrical Shock, this equipment must only be connected to a supply mains with protected earth.

Instructions for Use

INITIAL SYSTEM SETUP

The system arrives in one carton that contains the Vacuum Unit. The disposable accessories necessary to conduct procedures may be purchased separately from CooperSurgical.

ULPA FILTER INSTALLATION

Insert the large ULPA Filter cylinder with the Air Flow arrow pointing downward (Photo A).

Photo A

OPERATING INSTRUCTIONS

Prepare the unit for use by inserting a clean, disposable Pre-Filter onto the ULPA Filter cylinder (Photo B). Be sure this device is firmly seated.

Photo B

For procedures requiring close proximity plume removal (i.e., vaginal speculum)

Assemble the ⅜-inch Reducer (Catalog number 6083) onto the port on the disposable Pre-Filter top with a slight twisting motion. Attach one end of an appropriate length of ⅜-inch inner diameter (ID) Evacuation Tubing (Catalog number 6084) to the Reducer Connector and direct the other end to the patient, as well as any appropriate device being used, such as a vaginal speculum equipped with a Smoke Evacuation Adapter (Photo C).

Photo C

For procedures requiring open area plume removal (i.e., external lesions)

1. Assemble the sterile Disposable Evacuation Tubing (Catalog number 6084) directly into the top of the Pre-Filter. Position the opposite end over the site to be treated.
2. Plug the LEEP PRECISION Smoke Evacuator into an appropriate wall outlet (see Specifications).
3. Push the POWER switch to the ON position to start the unit.
4. At the completion of each procedure, activate the system to ensure safe particle containment. Using gloves and a mask, remove the Pre-Filter, the Reducer, and the used section of Suction Tubing and discard into an infectious waste receptacle (see Cautions). The CooperSurgical LEEP PRECISION Smoke Evacuator should be stored with a new Pre-Filter and Reducer in place on the ULPA filter.

NOTE: The expected life of the ULPA filter is 3–6 months depending on usage. It must be discarded into an infectious waste receptacle if plume odor is detected or the suction is diminished.

Maintenance

No maintenance is required during normal operation other than making sure that ample space is maintained around the unit to allow for free air flow and adequate cooling.

Cleaning and Disinfection

After each patient use, follow the combined cleaning/disinfection instructions provided below for the LEEP PRECISION Smoke Evacuator.

CLEANING

1. Prepare an enzymatic, neutral pH cleaner solution according to the Manufacturer's instructions.
2. Immerse a clean, lint-free wipe into cleaning solution and thoroughly wring. Thoroughly wipe the front panel surfaces in a circular motion. Discard the wipe.
3. Using a soft, nylon brush, scrub difficult-to-access areas such as crevices or textured surfaces.
4. Immerse a fresh, clean, lint-free wipe under warm flowing, utility water and thoroughly wring excess water. Thoroughly wipe the front panel surface and crevices for at least 30 seconds. Discard the wipe.
5. Rinse a fresh, clean, lint-free wipe under warm flowing, utility water and thoroughly wring excess water. Thoroughly wipe the front panel surface and crevices for at least 30 seconds. Discard the wipe.
6. Inspect the device for visible soil or debris. If visible soil remains, repeat cleaning steps 2-5 until device is visually clean.

DISINFECTION

7. Use a 70% IPA wipe, or a low-lint wipe, saturated with 70% IPA, to thoroughly wipe the device. Pay particular attention to difficult to reach areas such as device seams and area between buttons.
8. With a fresh wipe saturated with 70% IPA, thoroughly wipe the device. Allow the wiped and wetted device to stand for a minimum of the disinfectant product manufacture's labeled contact time. Re-wet the wipes as necessary to ensure that all surfaces remain wet for the entire time.
9. Allow the device to air dry. Once dry, visually inspect the device for any residual soil. Repeat cleaning/disinfection instructions if visible soil is present.
10. Place the disinfected device in an appropriate dry storage area.

Specifications

Use

Environmental Temperature:	between +10 °C and +40 °C
Relative Humidity:	between 10 % and 90 %
Air Pressure:	between 700 hPa and 1060 hPa

Shipping and Storage

Environmental Temperature:	between +10 °C and +40 °C
Relative Humidity:	between 10 % and 90 %
Air Pressure:	between 700 hPa and 1060 hPa

Fuses:	15A, 250 V, T-Type, slow blow
Safety Class:	I
Power Rating:	1800 VA
Electrical:	120VAC, 60 Hz
Size (W x D x H):	9 inches x 9 inches x 22 inches (22.86 cm x 22.86 cm x 53.24 cm)
Weight:	21 pounds (9.53 Kg)
Air Flow:	35 CFM minimum
Filter:	Pre-Filter, charcoal filter for odor removal, and hydrophobic ULPA filter rated at 99.999 percent efficiency level for 0.014 micron particles (based on Standard CNC Evaluations).

WEEE Directive

In order to preserve, protect and improve the quality of the environment, protect human health and utilize natural resources prudently and rationally - do not dispose of waste electrical or electronic equipment (WEEE) as unsorted municipal waste. Contact local WEEE disposal sites.

Reordering Information

Disposable Pre-Filter:	Catalog (REF) number 52560
ULPA Filter:	Catalog (REF) number 6082
Reducer:	Catalog (REF) number 6083
Disposable Tubing (⅜ inch ID):	Catalog (REF) number 6084

Liability Statement

CooperSurgical guarantees the safety, reliability, and performance of the LEEP PRECISION Smoke Evacuator only if the installation, recalibrations, and repairs are performed by personnel authorized by CooperSurgical and if it is used in compliance with given instructions in an area that meets all applicable IEC requirements.

Warranty Information

CooperSurgical, Inc., warrants that the CooperSurgical LEEP PRECISION Smoke Evacuator (the “Product”) will be free from defects in materials and workmanship for a period of one (1) year from the original date of purchase.

If the Product should become inoperable due to a defect in materials or workmanship during this one (1) year warranty period, CooperSurgical will at its option repair or replace the Product. The limited warranty does not include replacement or service to repair damage resulting from improper installation, external electrical fault, accident, disaster, negligence, modification, or use for any purpose other than that for which it was originally designed or indicated for use in this Operating Manual. This warranty does not cover service or repair by personnel not authorized by CooperSurgical, nor normal wear and tear, and does not apply to disposable or single- or limited-use items or components. The sole and exclusive remedy under this Limited Warranty shall be repair or replacement as provided herein.

The foregoing Limited Warranty states the sole warranty made by CooperSurgical with respect to the Product and all parts thereof, and is in lieu of any other warranty by CooperSurgical with respect to the Product.

COOPERSURGICAL NEITHER MAKES NOR GRANTS ANY OTHER WARRANTY, EITHER EXPRESSED OR IMPLIED, WITH RESPECT TO THE PRODUCT, INCLUDING, WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT WILL COOPERSURGICAL BE LIABLE FOR ANY DAMAGES ARISING OUT OF THE LOSS OF USE OF THE PRODUCT OR ANY OTHER INCIDENTAL OR CONSEQUENTIAL DAMAGES, WHETHER OR NOT COOPERSURGICAL HAS ADVANCE KNOWLEDGE OF THE POSSIBILITY OF SAME.

NOTE: No person, agent, distributor, dealer, or company is authorized to change or modify the terms of this limited warranty.

To Obtain Warranty Service

Contact the Service Department at CooperSurgical to obtain a Return Authorization Number. This Return Authorization Number must appear on all correspondence regarding your warranty claim; CooperSurgical is not required to accept a Product returned without a Return Authorization Number.

The Product must be returned to CooperSurgical together with proof of date of purchase. All products must be properly disinfected prior to returning for service. All shipments to CooperSurgical must be insured and safely and securely packed, preferably in the original shipping carton. Include a letter explaining the problem and a reference to the Return Authorization Number. All return transportation and insurance charges must be prepaid by the customer and the customer will bear all risk of loss.

If CooperSurgical determines that the Product requires repair covered under this Limited Warranty, CooperSurgical will repair or replace the Product as provided above and will return the repaired or replacement Product to the customer, freight prepaid with the risk of loss passing to the customer upon delivery to common carrier.

If CooperSurgical determines that the Product requires a repair that is not covered by this Limited Warranty, CooperSurgical will either return the Product to the customer at the customer's expense or contact the customer for further instructions. If so instructed by the customer, CooperSurgical will repair the Product and return the repaired Product to the customer, freight prepaid with risk of loss passing on the customer upon delivery to the common carrier. CooperSurgical shall be entitled to invoice the customer for the reasonable cost of non-warranty inspection and repair of the Product and the cost of the return freight.

NOTE: There are no user-serviceable parts (excluding intermittent filter changes). Repairs should only be carried out by authorized CooperSurgical service personnel.

EMC Compliance Information

- Medical electrical equipment requires special precautions regarding EMC and must be installed and put into service according to the EMC information provided in the accompanying documents.
- Portable and mobile RF communications equipment can affect medical electrical equipment.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The CooperSurgical LEEP PRECISION Smoke Evacuator is intended for use in the electromagnetic environment specified below. The customer or the end user of the CooperSurgical LEEP PRECISION Smoke Evacuator should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF Emissions CISPR 11	Group 1	CooperSurgical LEEP PRECISION Smoke Evacuators use only RF energy for their internal function. Therefore, RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	CooperSurgical LEEP PRECISION Smoke Evacuators are 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 Fluctuations / Flicker Emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The CooperSurgical LEEP PRECISION Smoke Evacuators are intended for use in the electromagnetic environment specified below. The customer or the end user of the CooperSurgical LEEP PRECISION Smoke Evacuator should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environmental Guidance
Electromagnetic discharge (ESD) IEC 61000-4-2	±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 percent.
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_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the CooperSurgical LEEP PRECISION Smoke Evacuator requires continued operation during power mains interruptions, it is recommended that the CooperSurgical LEEP PRECISION Smoke Evacuator 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_T is the a.c. mains voltage prior to application of the test level; in this case, 230 V.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environmental Guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 V 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the CooperSurgical LEEP PRECiSION Smoke Evacuator, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$ $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 800 MHz to 2.5 GHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcasts, and TV broadcasts cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the CooperSurgical LEEP PRECISION Smoke Evacuators used exceeds the applicable RF compliance level above, the CooperSurgical LEEP PRECISION Smoke Evacuator should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the CooperSurgical LEEP PRECISION Smoke Evacuator.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended Separation Distance

Recommended Separation Distance between portable and mobile RF communications equipment and the CooperSurgical LEEP PRECISION Smoke Evacuator

The CooperSurgical LEEP PRECISION Smoke Evacuators are intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the CooperSurgical LEEP PRECISION Smoke Evacuator can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the CooperSurgical LEEP PRECISION Smoke Evacuator as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter in watts	Separation distance according to frequency of transmitter (Meters) [Notes 1 & 2]		
	150 kHz to 80 MHz $d=\left[\frac{3.5}{V_1}\right]\sqrt{P}$	80 MHz to 800 MHz $d=\left[\frac{3.5}{E_1}\right]\sqrt{P}$	800 MHz to 2.5 GHz $d=\left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	0.1167	0.1167	0.2333
0.1	0.3689	0.3689	0.7379
1	1.1667	1.1667	2.3333
10	3.6894	3.6894	7.3789
100	11.667	11.667	23.333

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output rating of the transmitter in watts (W) according to the transmitter manufacturer.

For the CooperSurgical LEEP PRECISION Smoke Evacuator:

V_1 = 3 Vrms

E_1 = 3 V/m

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Explanation of Symbols

Reorder number

Serial number

Consult instructions for use

Date of Manufacture

Fragile, handle with care

Keep Dry

This side up

High Voltage Symbol

Caution

In order to preserve, protect and improve the quality of the environment, protect human health and utilize natural resources prudently and rationally - do not dispose of waste electrical or electronic equipment (WEEE) as unsorted municipal waste. Contact local WEEE disposal sites.

R_x Only

Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.

Medical equipment with respect to electrical shock, fire and mechanical hazard only in accordance with UL60601-1 and CAN/CSA C22.2 No.601.1

NOTES

CooperSurgical

Made in the USA

95 Corporate Drive
Trumbull, CT 06611 USA
Phone: (800) 243-2974
Fax: (800) 262-0105
International
Phone: +1 (203) 601-9818
Fax: +1 (203) 601-4747
www.coopersurgical.com

37994-B • Rev. A • 11/18