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Технические характеристики на многофункциональные аспираторы модели 330, аксессуары компании ZOLL

Виды товаров: многофункциональные аспираторы, источники питания, шнуры питания, автомобильные кабели, аккумуляторы литий-ионные, держатели канистр, канистры для сбора, стерильные аспирационные трубки, промежуточные трубки в сборе, 24-дюймовые шланги и др.



Chapter 2 Product Overview

This chapter provides an overview of the ZOLL Model 330 Multifunction Aspirator clinical applications and features.

Aspirator Clinical Applications

The aspirator provides medical vacuum for the following clinical applications:

- Surgical procedures
- Upper and lower airway management procedures: nasopharyngeal, oropharyngeal and tracheal
- CASS procedures (Continuous Aspirate of Subglottic Secretions). See Chapter 4 for a description of CASS.
- Gastrointestinal and abdominal cavity drainage with a wide programmable range of intermittent cycles

Note: Also refer to, "ZOLL Model 330 Multifunction Aspirator Indications for Use" in Chapter 1, for further information on aspirator applications.

Aspirator Description

The ZOLL Model 330 Multifunction Aspirator is a small, extremely durable, multifunction suction apparatus. The aspirator is suitable for short or long term use in emergency rooms, mass casualty environments, field hospitals, and during ground or air transport. It is also appropriate for use in a road ambulance, or in fixed and rotary-winged aircraft. The aspirator is for use only by, or on the order of a physician.

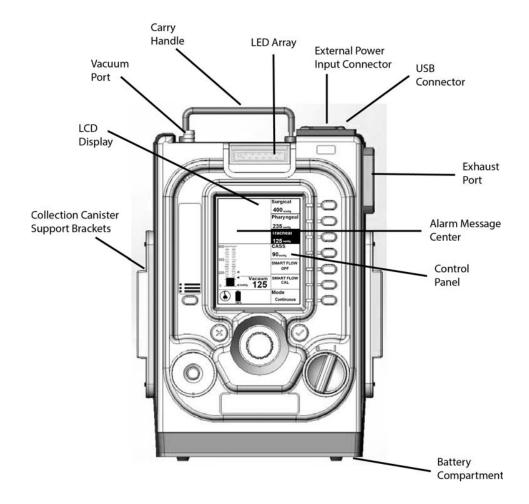
This aspirator provides adjustable vacuum up to 550 mm Hg and is a completely self-contained suction source including vacuum pump and controls. Its small size and light weight facilitates transport, deployment, and storage.

Note: The aspirator is not a sterile device but it can use commercially available, GMP-compliant, disposable/consumable items such as collection canisters, tubing and accessories from appropriate third-party manufacturers which may not be included with the aspirator.

The aspirator is powered from either DC sources provided to the "External Power input" or the internal rechargeable Li-ion battery. General aspirator features include:

- Rugged design
- · Continuous and Intermittent modes
- Intuitive user interface
- Weight: ~9.9 lbs.
- 3 to 8 hours of battery run time
- Rapid charging (90% battery capacity in 2 hours)
- Standby Control
- · Daylight visible display
- Adjustable vacuum range 10 to 550 mm Hg for maximum clinical treatment flexibility depending on operating mode and procedure selected
- ZOLL Smart Help™ which supports the user in managing alarm conditions by providing immediate context-sensitive clinically focused on-screen instructions
- ZOLL Smart Flow™ technology which permits extremely quiet operation during patient care and surgical procedures

This illustration shows the location of ports, connectors, displays, etc. on the aspirator.



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Appendix A Specifications

General

Operation Modes	Continuous/Intermittent
Applied Vacuum	10 mm Hg to 550 mm Hg
	± (2 mm Hg + 8% of setting)
Continuous Vacuum Range:	
Surgical	Adjustable 20 to 550 mm Hg
Pharyngeal	Adjustable 60 to 400 mm Hg
Tracheal	Adjustable 60 to 220 mm Hg
CASS	Adjustable 10 to 40 mm Hg
Intermittent Vacuum Range ON/OFF Times	Vacuum Level: Adjustable 10 to 200 mm Hg ON/OFF Times: 5 to 40 seconds.
FREE AIRFLOW	Continuous: Up to 30 LPM
	Maximum FREE AIRFLOW: Up to 35 LPM*
	*Maximum FREE AIRFLOW rate achieved with the use of Smart Flow.
Collection Canister Capacity	1200 cc
Collection Cannister Material	Polystyrene and durable polyethylene
LED Status/Alarm Indicator	Red, Yellow, and Green

Alarm Volume	~ 80 dBA @ 1 meter	
Noise Level	~ 60 dBA when measured at 1 meter	
Operating Voltages	AC Supply: 100 to 240 VAC (50/60 Hz)	
	Caution Use only the AC/DC power supply that ZOLL provides with the device.	
	DC Supply: Nominal 12.5 to 28.0 VDC (accepts DC voltages between 11.8 to 30 VDC).	
	Caution Use only the DC power supply cable that ZOLL provides with the device.	
Operating Time Internal Battery	3 hours using settings defined in ISO 10079-1:2015 for battery operation testing.	
Aspirator Temperature Ranges	Operating Extreme: - 26 to 55°C (- 15 to 131 °F)	
	Storage Temperature (Battery Removed): - 40 to 70 °C (-40 to 158°F)	
Battery Temperature Ranges	Battery Charge: 0 to 45 °C (32 to 131 °F)	
	Battery Operation: - 26 to 55°C (-15 to 131 °F)	
Size	8.0" Wide x 12.5" High x 4.5" Deep (20.3 cm Wide x 31.8 cm High x 11.4 cm Deep)	
	Dimensions exclude accessories.	
Weight	~9.9 lbs (4.5 kg)	
Warranty	Limited, 1 year	

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Device Classification

The following table describes the ZOLL Aspirator's device classification:

Category	Classification
Type of Protection against Electric Shock	The medical power supply (which contains the system's safety barrier) is labeled as Class I or Class II. Electrical shock protection is not dependent upon earthing since this power supply design includes double insulation.
Degree of Protection against Electric Shock Applied Parts	Aspirator contact is Type B applied part. BF: Type B with floating (F-type) parts.
Degree of Protection against Harmful Ingress of Water and solids	Protection with soft case and rain flap: IP33 Liquid: Spraying water Solid: 2.5mm diameter and greater
Method of Sterilization or Disinfection	Inlet port should be wiped with a damp, soapy cloth and thoroughly dried with a lint- free cloth. The unit's housing should also be cleaned as necessary with a damp, soapy cloth and thoroughly dried with a lint-free cloth. Do not clean with abrasives or chlorinated hydrocarbon cleansers.
Degree of Safety of Application in the presence of a Flammable Anesthetic Mixture with Air or with Oxygen or Nitrous Oxide	Equipment <i>not</i> suitable for use in presence of Flammable Anesthetic Mixture of Air or with Oxygen or Nitrous Oxide.

Emissions and Immunity Compliance

The ZOLL Aspirator 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.

Be prepared to use a manual aspiration technique in event of device interference or failure.

Warning!

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

The device does not have external sensors or transducers that are likely to affect product compliance.

Warning!

Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Warning!

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any party of the aspirator, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

The aspirator should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the ZOLL Aspirator. The device alarms may be issued in event the device is affected by electromagnetic disturbance.

Specifications

Basic Safety and Essential Performance

Instructions for maintaining basic safety and essential performance with regard to electromagnetic disturbances for the expected service life:

- Perform preventive maintenance on the device on an annual basis.
- Follow service procedures as defined in the service manual to ensure EMC performance.
- Be prepared to use a manual aspiration technique if the use location is near (e.g. less than 1.5 km from) AM, FM, or TV broadcast antennas.

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Compliance for each emissions and immunity standard or test specified:

Compliance	Electromagnetic Environment Guidance	
The ZOLL aspirators are intended for use in the electromagnetic environment specified below. The customer or user of the aspirator should ensure that they are used in such an environment.		
Group 1	The ZOLL aspirators use RF energy only for their internal function. Therefore, their RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.	
Class B	The ZOLL aspirators are suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.	
Class B		
Complies		
	re intended for use aspirator should Group 1 Class B Class B	

Immunity Test	Test Level	Compliance Level
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 8 kV contact	+/- 8 kV contact
(EOD) 120 01000-4-2	+/- 15 kV air	+/- 15 kV air
Electrical fast transient/ burst IEC 61000-4-4	+/- 2 kV for power supply lines	+/- 2 kV for power supply lines
54101 120 01000 1 1	+/- 1 kV for input/output lines	+/- 1 kV for input/output lines
Surge	+/- 1 kV line(s) to line(s)	+/- 1 kV line(s) to line(s)
IEC 61000-4-5	+/- 2 kV line(s) to earth	+/- 2 kV line(s) to earth
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	0% Ut, 0.5 cycles at 0, 45, 90, 135, 180, 225, 270, and 315 degrees; 0% Ut, 1 cycle and 70% Ut, 25/30 cycles; single phase at 0 degrees	0% Ut, 0.5 cycles at 0, 45, 90, 135, 180, 225, 270, and 315 degrees; 0% Ut, 1 cycle and 70% Ut, 25/30 cycles; single phase at 0 degrees
Power frequency (50/60 Hz) magnetic field	30 A/m	30 A/m
IEC 61000-4-8		
Conducted RF IEC 61000- 4-6	3 V, 0.15 MHz - 80 MHz; 10 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz; 80% AM at 1 kHz	3 V, 0.15 MHz - 80 MHz; 10 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz; 80% AM at 1 kHz
Radiated RF IEC 61000-4-3	20 V/m, 80 MHz - 2.7 GHz, 80% AM at 1 kHz	20 V/m, 80 MHz - 2.7 GHz, 80% AM at 1 kHz

No deviations from this collateral standard or allowances were used.

Appendix B Accessories

You can use commercially available, GMP-compliant end pieces from appropriate third-party manufacturers with the ZOLL Model 330 Multifunction Aspirator.

Part Number	Part Description	
Power Accessories		
9141-000127	Assembly AC/DC Power Supply, Plug (without output connector)	
708-0042-00	AC Power line cord, 6' (United States Version)	
704-0EMV-06	Automotive Cable	
703-0731-01	Battery Pack, Li-ion	
Aspirator Accessories		
334-0030-00	Collection Canister Holder, chrome plated	
410-0004-12	1200cc Collection Canister, Disposable with lid (case of 12)	
820-0018-00	Sterile Suction Tubing 9/32" I.D. X 6" Long, Sterile R as per manufacturer	
540-0050-00	Intermediate Tubing Assembly, clear PVC, Non-Sterile, 12", 18", and 24" hoses	

Accessories

Part Number	Part Description
Other	
800-0904-01	CCLAW (Critical Care Litter Attachment Widget) Mounting Bracket
800-0903-01	SMEED

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