



ZOLL Model 330 Multifunction Aspirator Operator's Guide



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Chapter 1

General Information

This chapter provides general information about the ZOLL® Model 330 Multifunction Aspirator product and the ZOLL Model 330 Multifunction Aspirator Operator's Guide, which ZOLL provides with the product. Specifically, this chapter provides:

- A brief description of the aspirator.
- Information about this guide (ZOLL Model 330 Multifunction Aspirator Operator's Guide).
- Information about unpacking and assembly.
- A table that describes the symbols that appear on the aspirator and in this guide.
- A table that describes the symbols and icons that appear on the aspirator's display.
- Indications for Use.
- Warnings and Cautions regarding aspirator use.
- A description of guide conventions.
- An abbreviation and acronym list.
- Information regarding FDA tracking requirements, warranty and software license.
- How to contact ZOLL Medical Corporation for service to this product.

Product Description

The Model 330 Multifunction Aspirator is a small, extremely durable, multifunction digital aspirator designed to operate in hospitals and severe or under-resourced environments. It can be used in prehospital, field hospital and hospital settings.

How to Use this Guide

The ZOLL Model 330 Multifunction Aspirator Guide provides information that operators need for the safe and effective use and care of the aspirator. It is important that all persons using this device read and understand all the information contained within. Please thoroughly read the warnings section beginning on page 1-7. Refer to Chapter 7, "Maintenance" for aspirator care procedures.

Operator's Guide Updates

An issue or revision date for this guide is shown inside its front cover. If more than 3 years have elapsed since this date, contact ZOLL Medical Corporation to determine if additional product information updates are available.

All users should carefully review each update to understand its significance and then file it in its appropriate section within this guide for subsequent reference.

Product documentation is available through the ZOLL website at www.zoll.com. From the **Products** menu, choose **Product Manuals**.

Unpacking

Carefully inspect each shipping container for damage. If the shipping container or cushion material is damaged, keep it until the contents have been checked for completeness and the device has been checked for mechanical and electrical integrity. If the contents are incomplete, there is mechanical damage, or the aspirator does not pass its self test procedure, U.S.A. customers should call ZOLL Medical Corporation (1-978-421-9655). Customers outside of the U.S.A. should contact the nearest ZOLL authorized representative. If the shipping container is damaged, also notify the carrier. If there is no apparent sign of mechanical damage, read instructions contained within this guide before attempting operation.

Assembly

The aspirator, collection canister and tubes are supplied clean and are ready for use with a patient. The suction tube is provided in a sterile package. Follow sterile procedures when handling this accessory. The aspirator requires attachment of its canister and tubes to begin use. Detailed assembly and set up instructions appear in, Chapter 3 “Setting up the Aspirator”.

Symbols on the Aspirator

The following symbols appear on the aspirator, its display, or in this guide.

Symbol	Description
	Device Off
	Device On
	Mute/Cancel: Identifies the button that mutes the active alarms or cancels the parameter selection.
	Confirm: Identifies the button that accepts (confirms) a parameter selection.

Symbol	Description
	Identifies the Rotary Encoder Dial that allows the selection of parameter values.
	ESD: Warns that connector pins should not be touched.
	Menu icon. This icon identifies the button that, when pressed, displays a menu of options that you can select to configure the aspirator.
	Do Not Re-Use: This item should not be re-used.
	Do Not Discard: Follow all governing regulations regarding the disposal of any part of this medical device.
SN	Serial Number: Numbers following "SN" indicate the serial number.
	BF Symbol: Protection against electric shock, Type B with floating (F-type) parts.
	Direct Current: Identifies the location to connect external DC Power.
	Power Input Orientation: Locates the DC input identifying its point of insertion.
	Manufacturer: This symbol shall be adjacent to the name and address of the manufacturer.
	Manufacturer Date: Manufacturer Date Symbol identifies the device's date of manufacture.
	Consult Instruction: Consult the instructions for use or operation manual.

Symbol	Description
	Refer to instruction manual.
	Indicates the entity importing the medical device into the locale.

Symbols on the Aspirator's Graphical User Interface (GUI)

The following symbols appear on the aspirator's Graphical User Interface (GUI) during operation.

Symbol	Description
	Alarm Bell Outline: Identifies alarm limit settings; Identifies the on-screen alarms.
	Alarm Bell: Identifies the number of off-screen alarms.
	Attention: High Priority Alarm Active.
	Caution: Medium Priority Alarm Active.
	Warning: Low Priority Alarm Active.
	Mute: Active Alarm Audible Signal Muted.
	Speaker: Active Alarm Audible Signal.
	Plot: Identifies active off-screen plot available.

Symbol	Description
	Plot: Identifies active off-screen plot has been selected.
	External Power: Indicates the device is operating using an external power source.
	No External Power: Indicates the device is operating without an external power source.
	Internal Battery: Provides indication of battery capacity and charging. The number below the icon displays the percent (%) of charge for the battery.
EXT BATT	Indicates that an external battery is powering the aspirator.
	No Internal Battery: Indicates when internal battery is not an available power source.
off	Feature off -- feature or alarm is not operational.
on	Feature on -- feature or alarm is operational.

Conventions

This guide uses the following conventions:

Within text, the names and labels for physical buttons and softkeys appear in **boldface** type (for example, “Press the **Confirm** button”).

This guide uses uppercase italics for text messages displayed on the screen (for example, *Self Check Fault*).

Warning!	Warning statements alert you to conditions or actions that can result in personal injury or death.
-----------------	---

Caution	Caution statements alert you to conditions or actions that can result in damage to the device.
----------------	--

Abbreviations and Acronyms

ACLS - Advanced Cardiac Life Support	LCD - Liquid Crystal Display
ALS - Advanced Life Support	LED - Light Emitting Diode
ATLS - Advanced Trauma Life Support	LPM - Liters Per Minute
AMC - Alarm Message Center	ml - Milliliters
APOD - Advanced Probe Off Detection	mm - Millimeter
ATPD - Atmospheric Temperature and Pressure Dry	mm Hg -- Millimeters of Mercury
B/V - Bacterial/Viral Filter	O₂ - oxygen
CASS - Continuous Aspiration of Subglottic Secretions	PMC - Periodic Maintenance Check
CPR - Cardiopulmonary Resuscitation	psig - Pounds per Square Inch Gage
CPU - Central Processor Unit	RF - Radio Frequency
dBA - Decibel	RGA # - Returned-Goods-Authorization number
DISS - Diameter Index Safety System	RTC - Real time clock
EMC - Electromagnetic Compatibility	SAM - Smart Aspirator Module
ESD - Electrostatic Discharge	USP - United States Pharmacopeia
GMP - Good Manufacturing Practices	UTC - Coordinated Universal Time
HME - Heat and Moisture Exchanger	VAC - Volts AC
HMEF - Heat and Moisture Exchanger/Bacterial Viral filter combined	VDC - Volts DC
Hz – Hertz (as in frequency, cycles per second)	
ID - Internal Diameter	
L - Liters	

ZOLL Model 330 Multifunction Aspirator Indications for Use

Aspirator

The ZOLL Model 330 Multifunction Aspirator is a self-contained suction device designed for removing debris from a patient's airway or respiratory system, secretions, blood, vomitus, surgical fluids, tissue (including bone), bodily fluids and infectious materials during surgery. Programmable intermittent gastrointestinal and abdominal wound drainage can also be performed with the device. It is suitable for use in prehospital, hospital, mass casualty and transport environments, including aeromedical. The aspirator is only for use by or on the order of a physician.

Features

- Portable (You can use the aspirator in hospital settings, aeromedical and ground transport, mass casualty situations, and extreme environments).
- Continuous and Intermittent modes.
- Intuitive user interface.
- Lightweight -- less than 9.9 lbs (4.5 k) without accessories.
- Rechargeable battery provides over 3.5 hours of operation.
- Adjustable vacuum - range 10 to 550 mm Hg for maximum clinical treatment flexibility depending on operating mode selected.
- Standby Mode (control) that minimizes power consumption between uses.
- Smart Flow™ - allows the user to select OFF, or ON operation for reduced noise.
- Smart Help™ - provides user instructions when an alarm is activated to guide the operator through on-screen commands when responding to alarms.
- Operating temperature range for extreme conditions: -26 °C to 55 °C (-14.8 to 131° F).

Warnings

General

- The aspirator is intended for use by qualified personnel only. You should read this guide before using the aspirator.
- Before using the aspirator with a patient, you must test the device in its normal configuration to ensure proper operation.
- Do not modify this equipment without authorization of the manufacturer.
- This operator's guide is not meant to supersede any controlling operating procedure regarding the safe use of the aspirator.
- Follow all governing regulations regarding the disposal of any part of this medical device, the handling of materials contaminated by body fluids, and shipment of the Li-ion batteries.

Aspirator

- The aspirator can operate from its internal battery or from an external power source. When using an external power source, position the power supply cables to avoid accidental disconnect.
- The use of accessories and cables other than those sold by ZOLL may result in increased emissions or decreased immunity of this device.
- Portable and mobile RF communication equipment may affect the performance of this device. We describe the EMC performance for this device in the Specifications section of this operator's guide.
- The aspirator may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating of the device or shielding the location.

- Do not connect to an electrical outlet controlled by a wall switch or dimmer.
- Position the mains plug so it is easy to disconnect the device from mains.
- Grounding:
 - Do not remove the grounding conductor from the power plug.
 - Do not use extension cords or adapters of any type. The power cord and plug must be intact and undamaged.
- As with all medical equipment, carefully route the aspirator accessories, patient cabling, and external power cables to reduce the possibility of patient entanglement or strangulation.
- Failure to make proper connections could cause harm to the patient or operator.
- Do not use the aspirator during magnetic resonance imaging (MRI) scanning.
- Do not operate the aspirator with a patient when the USB port is connected to any other device (the USB port is used only for servicing the aspirator).

Batteries and Power Supply

- If you witness a battery or the battery compartment starting to balloon, swell up, smoke, or feel excessively hot, turn off the device, disconnect external power, observe it in a safe place for approximately 15 minutes, do not attempt to remove the battery from the device, and send the device for service. Never puncture or disassemble the battery packs or cells.
- Only use the power supply provided with the device. Use of any other power supply could cause damage or create a fire and/or destroy the battery and device.

Operator Safety

- The collection canister and patient suction tubing and/or catheters should be considered potentially hazardous. Use proper Personal Protection Equipment and handle accordingly.
- Electric shock hazard: Do not remove equipment covers. You may only perform maintenance procedures specifically described in this guide. Refer all servicing to ZOLL or a ZOLL-authorized service center.
- Possible explosion hazard if used in the presence of flammable anesthetics or other flammable substances in combination with air, oxygen-enriched environments, or nitrous oxide.
- This device is not intended for use in explosive atmospheres.
- Pins of connectors identified with the ESD warning symbol should not be touched. Always use precautionary procedures with ESD-sensitive connections.

Patient Safety

- Do not place the device or external power supply in any position that might cause it to fall on the patient.
- Do not lift collection canister by its lid. The weight of the contents might cause the lid to separate from the canister.
- Never attempt to carry the aspirator by the hoses, cords, canister holder, or the collection canister. This can result in damage to the device and possible injury to the user or patient.
- **Never** service the aspirator while in use with a patient.

Cautions

- Do not omit the canister from the suction path for any patient procedure.
- Use only the AC/DC power supply that ZOLL provides with the device.
- During any cleaning or decontamination procedure, ensure that there is no external power to the aspirator and that the device is turned off.
- Only qualified biomedical equipment technicians should service the device.
- Internal components are susceptible to damage from static discharge. Do not remove device covers.



- Possession or purchase of this device does not convey any expressed or implied license to use the device with unauthorized sensors or cables, which would, alone, or in combination with this device fall within the scope of one or more of the patients related to this device. ZOLL cannot ensure the proper functioning of this device if it is used with unauthorized sensors, cables, or patient circuits.
- Do not leave the device in the bed or cot with the patient to avoid possible heat build-up.

FDA Tracking Requirements

U.S. Federal Law (21 CFR 821) requires the tracking of aspirators. Under this law, owners of this aspirator must notify ZOLL Medical Corporation if this product is:

- Received
- Lost, stolen, or destroyed
- Donated, resold, or otherwise distributed to a different organization

If any such event occurs, contact ZOLL Medical Corporation in writing with the following:

1. Originator's organization – Company name, address, contact name, and contact phone number.
2. Model number, and serial number of the aspirator.
3. Disposition of the aspirator (for example, received, lost, stolen, destroyed, distributed to another organization), new location and/or organization (if known and different from originator's organization) – company name, address, contact name, and contact phone number.
4. Date when the change took effect.

Please address the information to:

ZOLL Medical Corporation

Attn: Tracking Coordinator

269 Mill Road

Chelmsford, MA 01824-04105

Fax: (978) 421-0007 Telephone: (978) 421-9655

Notification of Adverse Events

As a health care provider, you may have responsibilities under the Safe Medical Devices Act (SMDA), for reporting to ZOLL Medical Corporation, and possibly to the FDA, the occurrence of certain events.

These events, described in 21 CFR Part 803, include device-related death and serious injury or illness. In addition, as part of our Quality Assurance Program, ZOLL Medical Corporation requests to be notified of device failures or malfunctions. This information is required to ensure that ZOLL Medical Corporation provides only the highest quality products.

Software License

Note: Read this Operator's Guide and License agreement carefully before operating any of the ZOLL products.

Software incorporated into the system is protected by copyright laws and international copyright treaties as well as other intellectual property laws and treaties. This software is licensed, not sold. By taking delivery of and using this system, the Purchaser signifies agreement to and acceptance of the following terms and conditions:

1. **Grant of License:** In consideration of payment of the software license fee which is part of the price paid for this product, ZOLL Medical Corporation grants the Purchaser a nonexclusive license, without right to sublicense, to use the system software in object-code form only.
2. **Ownership of Software/Firmware:** Title to, ownership of, and all rights and interests in the system software and all copies thereof remain at all times vested in the manufacturer, and Licensors to ZOLL Medical Corporation and they do not pass to purchaser.
3. **Assignment:** Purchaser agrees not to assign, sublicense, or otherwise transfer or share its rights under the license without the express written permission of ZOLL Medical Corporation.
4. **Use Restrictions:** As the purchaser, you may physically transfer the products from one location to another provided that the software/firmware is not copied. You may not disclose, publish, translate, release, or distribute copies of the software/firmware to others. You may not modify, adapt, translate, reverse engineer, decompile, crosscompile, disassemble, or create derivative works based on the software/firmware.

NO IMPLIED LICENSE

Possession or purchase of this device does not convey any express or implied license to use the device with replacement parts, which would, alone, or in combination with this device, fall within the scope of one or more of the patents relating to this device.

Limited Warranty

During the warranty period, ZOLL will repair or replace the device or any part which upon examination is shown to be defective. At its sole discretion, ZOLL may choose to supply a new or equivalent replacement product or refund the amount of the purchase price (on the date sold by ZOLL). To qualify for such repair, replacement, or refund, the defective device must be returned to the ZOLL Service Center within thirty (30) days from the date that the defect is discovered. This warranty does not apply if the device has been repaired or modified without the authorization of ZOLL or if the damage was caused by incorrect (off-label) use, negligence, or an accident.

Batteries, which by their nature are consumable and subjected to environmental extremes, will be warranted only for a period of ninety (90) days. Accessories, also consumable in usage, such as suction tubing and collection canisters, are not warranted.

DISCLAIMER OF IMPLIED & OTHER WARRANTIES:

THE PRECEDING WARRANTY IS THE EXCLUSIVE WARRANTY AND ZOLL MAKES NO OTHER WARRANTY OR REPRESENTATION OF ANY KIND WHATSOEVER, EXPRESS OR IMPLIED, WITH RESPECT TO MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR ANY OTHER MATTER. THE REMEDIES STATED IN THIS DOCUMENT WILL BE THE EXCLUSIVE REMEDIES AVAILABLE TO THE CUSTOMER FOR ANY DEFECTS OR FOR DAMAGES RESULTING FROM ANY CAUSE WHATSOEVER AND WITHOUT LIMITATION.

ZOLL WILL NOT IN ANY EVENT BE LIABLE TO THE CUSTOMER FOR CONSEQUENTIAL OR INCIDENTAL DAMAGES OF ANY KIND, WHETHER FOR DEFECTIVE OR NONCONFORMING PRODUCTS, BREACH OR REPUDIATION OF ANY TERM OR CONDITION OF THIS DOCUMENT, NEGLIGENCE, OR ANY OTHER REASON.

Service

If a device requires service, contact the ZOLL Technical Service Department.

For customers In the U.S.A.		For customers outside the U.S.A.
Telephone:	1-800-348-9011 1-978-421-9655	Call the nearest authorized ZOLL Medical Corporation representative. To locate an authorized service center, contact: ZOLL Medical Corporation 269 Mill Road Chelmsford, MA 01824 Telephone: 1-978-421-9655

When requesting service, please provide the following information to the service representative:

- Device serial number
- Description of the problem
- Department using the equipment and name of the person to contact
- Purchase order to allow tracking of loan equipment
- Purchase order for a device with an expired warranty

Returning a Device for Service

Before sending a device to the ZOLL Technical Service Department for repair, obtain a service request (SR) number from the service representative.

The Li-ion battery should remain inside the device. Follow directions provided on the return authorization form. Pack the device with its cables in the original shipping containers (if available) or equivalent packaging. Be sure the assigned service request number appears on each package.

For customers	Return the device to
In the U.S.A.	ZOLL Medical Corporation 269 Mill Road Chelmsford, MA 01824 Attention: Technical Service Department (<i>SR number</i>) Telephone: 1-978-421-9655

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.

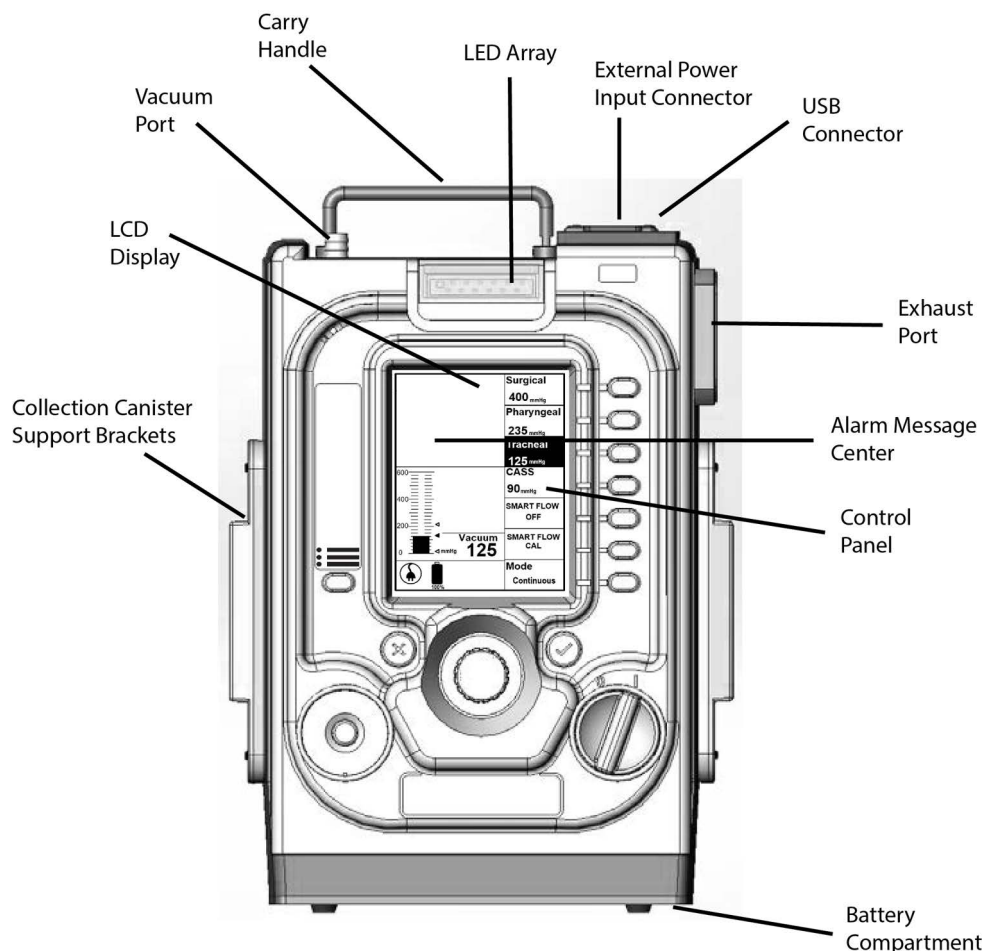
This aspirator provides adjustable vacuum up to 550 mm Hg and is a completely self-contained suction source including vacuum pump and controls. Its small size and light weight facilitates transport, deployment, and storage.

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

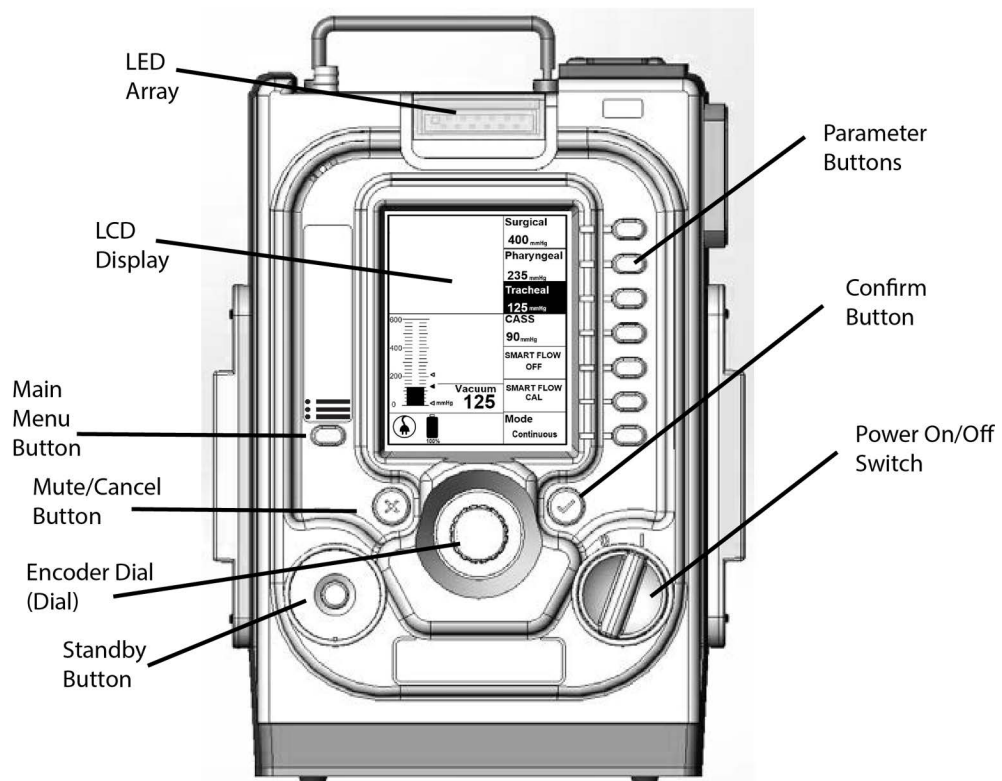
This illustration shows the location of ports, connectors, displays, etc. on the aspirator.



Item	Location on Aspirator	Description
Vacuum Port	Top	Connects the device to the collection canister
Status Indicator LED Array	Top	Lights up to indicate status of the device, connected to alarms
External Power Input Connector	Top	Connects the device to an external power source
USB Connector	Top	Connects the device to service and maintenance equipment
Carry Handle	Top	Chassis mounted for strength during transport
LCD Display	Front	Displays the device settings, measured vacuum, and alarm information
Alarm Message Center (AMC)	Front	Displays active alarm(s) and mitigation information
Control Panel	Front	Access to device settings
Battery Compartment	Bottom	Contains the device's rechargeable Li-ion battery
Exhaust Port	Side	Vacuum pump exhaust
Collection Canister Support Brackets	Side	Secures wire holder and collection canisters in place

Controls and Indicators

The aspirator has controls and indicators that facilitate ease of use and visibility in all operating environments. Indicators include: an LCD display screen, LED array, and the controls that you use to set up, manage, and monitor the aspirator. The following illustration shows the location of controls and indicators on the aspirator.

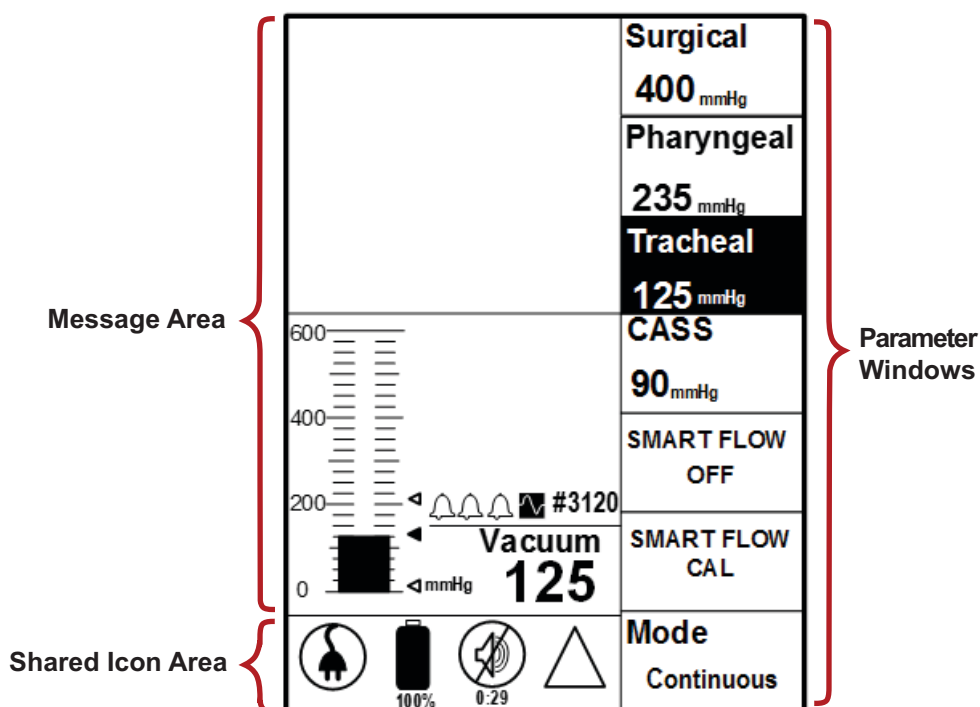


Controls consist of the following (refer to the figure above for control location).

Figure Call-Out	Control or Indicator	Function
1	Power On/Off switch	Turns the device on and off
2	Parameter buttons	Provides parameter selection and control
3	Main Menu button	Displays the main menu
4	Encoder Dial (Dial)	Changes the value of the highlighted parameter
5	Mute/Cancel button	Mutes audible alarm indicators, cancels parameter entries, and exists menus
6	Confirm button	Confirms (accepts) parameter value entries, pop up conditions, or menu selections
7	Standby button	Enable or disable Standby Mode
8	LCD display	Displays menus and messages
9	LED array	Indicates device status and alarm conditions lighting red, yellow, or green LEDs

Display Screen

The aspirator's display screen appears as follows:



Message Area

The display screen's message area can display the following:

Message Type	Description
Menus	Displays the Main Menu after you press the Menu button on the control panel.
Alarms	When an alarm occurs, the Message Area displays Smart Help messages that identify the alarms, possible causes, and actions to take in response. Alarms can obscure the Vacuum Gage but the numerical value of measured vacuum is always visible.
Pop up windows	Display information that assists you when adjusting parameter values.
Vacuum gauge	Under normal operation (as in the example above), the message area displays the vacuum gauge and the measured vacuum range.

Parameter Windows

These windows provide control of parameters depending on the mode you select.

When you select Continuous mode, you also specify the following parameter options:

Continuous Mode	Range (mm Hg)	(kPa)
Surgical	20 to 550 mm Hg	3 to 73
Pharyngeal	60 to 400 mm Hg	8 to 53
Tracheal	60 to 220 mm Hg	8 to 28
CASS	10 to 40 mm Hg	1.3 to 5.3
Note: Smart Flow (On or Off) is also a selectable option when in Continuous Mode.		

When you select Intermittent mode, you also specify the following parameters options:

Intermittent Mode	Range	kPa
Vacuum Level	10 to 200 mm Hg	1 to 27 kPa
Time On/Off	5 to 40 seconds	Not Applicable

Shared Icon Area

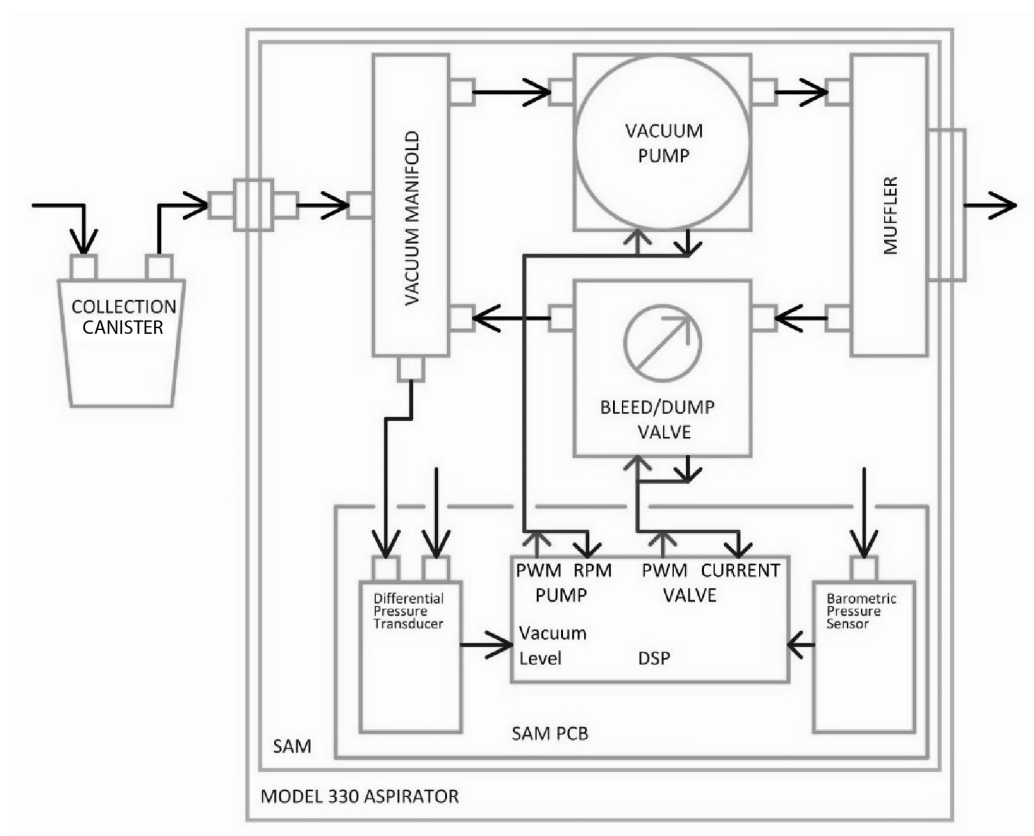
Directly below the message area, the device displays icons that indicate:

- Power source (external power or internal battery)
- Battery Charge Status
- Alarm Muted/Audible
- Alarm Priority

Pneumatic Design

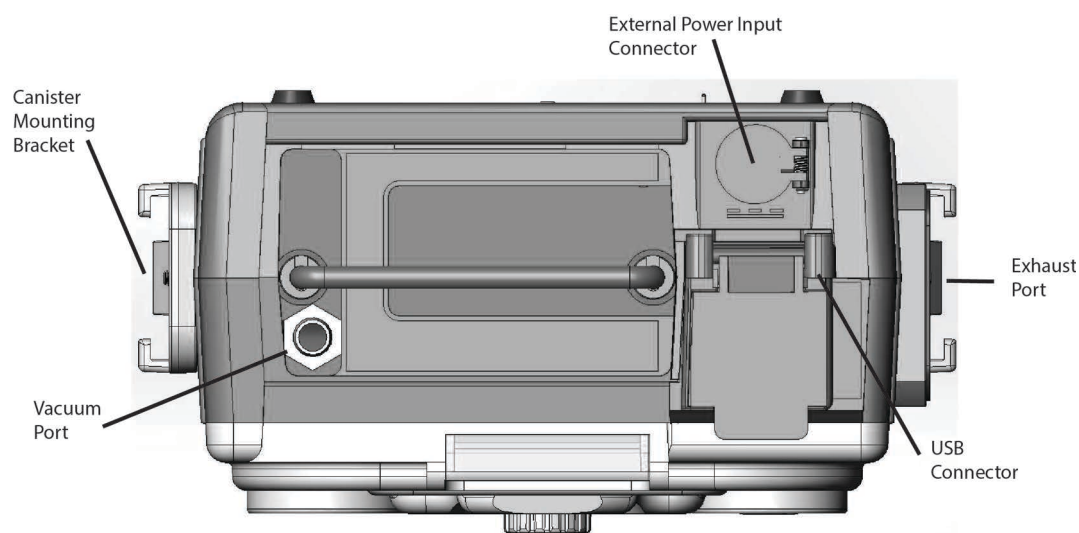
The aspirator uses a microprocessor to regulate a vacuum pump and bleed valve to control the vacuum level (see figure below). Transducers continuously monitor the vacuum level and barometric pressure to ensure the vacuum level is as set by the user.

The collection canister is part of the pneumatic system. It collects fluids and prevents patient waste from entering the aspirator. The Vacuum Port is a 3/8-inch barbed port on the top of the aspirator. Gas from the tubing and collection canister passes through the vacuum manifold and vacuum pump, then it is ejected through the 22 mm Exhaust Port on the side of the device. Tubing connects the Vacuum Port to the collection canister. The canister also provides overflow protection in the event the user attempts to aspirate more fluid than the collection canister can hold.



Top Panel

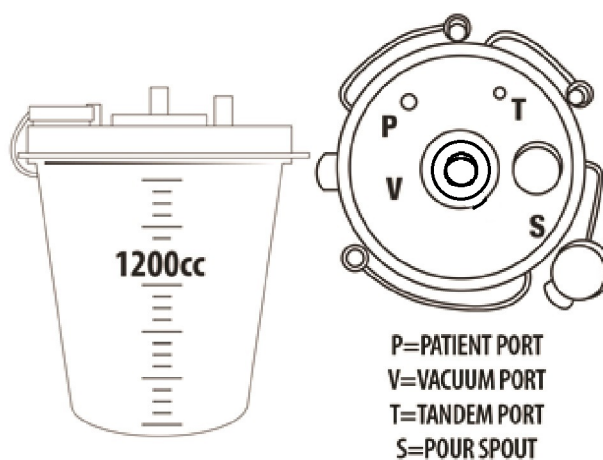
The aspirator's top panel appears in the figure below.



Collection Canister

Typical use of the aspirator is with a single collection canister and lid as shown.

Warning! Only use collection canisters that have both a filter and overflow protection.



Canister and Lid

Power Sources

The aspirator can operate using external power or it can operate powered by its internal Li-ion battery.

The external AC/DC power supply provided with the device is a universal supply that can operate with an input of 100 to 240 VAC 50/60 Hz and with a 400 Hz 110 VAC input. The power supply provides both Class I and Class II electrical protection. The voltage delivered to the device is 24 VDC at 4 A. When connected to external power, the aspirator automatically charges its internal battery while operating.

Operating Using External DC Power

Direct Current (DC) power can also be used to operate the device using the ZOLL-provided 12 VDC automotive cable. The device will both operate and charge using DC power sources between 11.8 to 30.0 VDC.

Caution Always physically disconnect the aspirator from vehicle power when jump starting the vehicle. Failure to do so could damage the device.

Operating Using Battery Power

When the aspirator is disconnected from external power, the device automatically switches to its internal battery for operating power and triggers the External Power Low/Fail alarm; there is no interruption in operation or loss of any alarms. When external power returns, operating power automatically switches to the external power source.

In the event you need to shutdown, turn the Power Switch to the OFF ("O") position. If this fails to work or puts the patient or operator at possible risk, disconnect the device from the external power source.

The Li-ion battery pack used in the device exhibits excellent charge retention characteristics. (See Chapter 6 regarding battery care). It rapidly recharges to 90% of its capacity in approximately 2 hours when the battery is completely depleted. It can take another 2 hours of trickle-charging to reach 100% capacity, depending on use and environmental conditions.

The aspirator will always use the external power source to preserve the internal battery charge. This ensures power is available for transport use or emergency back-up. If the External Power Low/Fail alarm occurs, the device will automatically revert to its internal battery for operating power.

Caution Continuous battery charging reduces the life of the battery. When the device is not in regular use, charge it for 4 hours or overnight every 4 to 6 months.

The table below provides estimates of the battery run time in various modes of use.;

Mode	Run-Time	Vacuum Level (mm Hg)	Typical Use
Surgical	4 Hours	350 mm Hg	15 sec on, 15 sec free flow
Pharyngeal	6 Hours	200 mm Hg	
Tracheal	8 Hours	120 mm Hg	
Intermittent	8.5 Hours	120 mm Hg	10 sec on, 20 sec off

Power Indicator Icons

The aspirator uses icons (displayed in the shared icon area) to indicate the power and battery status.

Icon	Description
	External power connected. Aspirator is operating from external power.
	External power NOT connected. Aspirator is operating from internal battery power.
	Estimated remaining internal battery capacity. Dark area indicates level of battery charge and the number below the icon displays the percent (%) of charge in the battery.

When the battery is charging, horizontal lines scroll vertically through the icon, from the bottom row to the top. The scroll rate faster when the battery is rapid charging and it slows when trickle charging.

When the device is “OFF” and connected to power, the screen provides a battery indicator. When charging, the indicator scrolls as described above: when fully charged the indicator is static and percent (%) charge is 100%.

Device Mounting Options

Mounting options for the device include the CCLAW and SMEED (see Accessories Section for part number information). These mounts allow the collection canister to be mounted in either side of the aspirator.

Noise, Power, and Use Features

The noise, power and use features include:

- Smart Flow
- Standby
- Pause

Smart Flow

The Smart Flow feature automatically detects when the user applies suction and quickly increases the pump speed to achieve the set vacuum level. This feature has the most benefit when used in surgery where it reduces the noise generated by the pump and reduces power consumption. To accommodate various suction catheters the device can determine the resistance if the catheter tubing and collection cannister so that Smart Flow triggers the device when needed. See Chapter 4 “Smart Flow Calibration.

Standby

To conserve power, reduce noise and allow for immediate use of the aspirator, the aspirator has a “Standby” feature.

To start and stop Standby, press the Standby button. When Standby is active:

- *Standby* displays in the Alarm Message Center (AMC)
- The vacuum pump is de-energized, not flowing (zero RPM)
- The LCD is dimmed
- The LED array alternates Green/Yellow to indicate the device status

When standby is stopped, by pressing the **Standby** button, the aspirator immediately begins operation with the last settings.

Pause

To minimize risk to the patient, the device enters a Pause state where the device waits for input from the user.

- *Pause* displays in the Alarm Message Center (AMC)
- The vacuum pump is de-energized, not flowing (zero RPM)
- The bleed valve relieves pressure
- The LED array alternates Green/Yellow to indicate the device status

Pause occurs whenever the device switches between modes (Continuous and Intermittent) to prevent patient exposure to an unintended vacuum level. The Pause state ends as soon as the user enters a vacuum level.

Chapter 3

Setting up the Aspirator

This chapter describes how to set up the ZOLL Model 330 Multifunction Aspirator to an external power source and attach its collection canister, and tubing. Additionally, this chapter describes the procedure to test the aspirator to determine if it is set up properly.

To set up the aspirator, you must perform the following tasks:

1. Connect the aspirator to an external power source, if available
2. Attach collection canister and tubing.
3. Turn ON the aspirator.
4. Perform an operational test.

We describe how to perform these tasks in the following sections of this chapter.

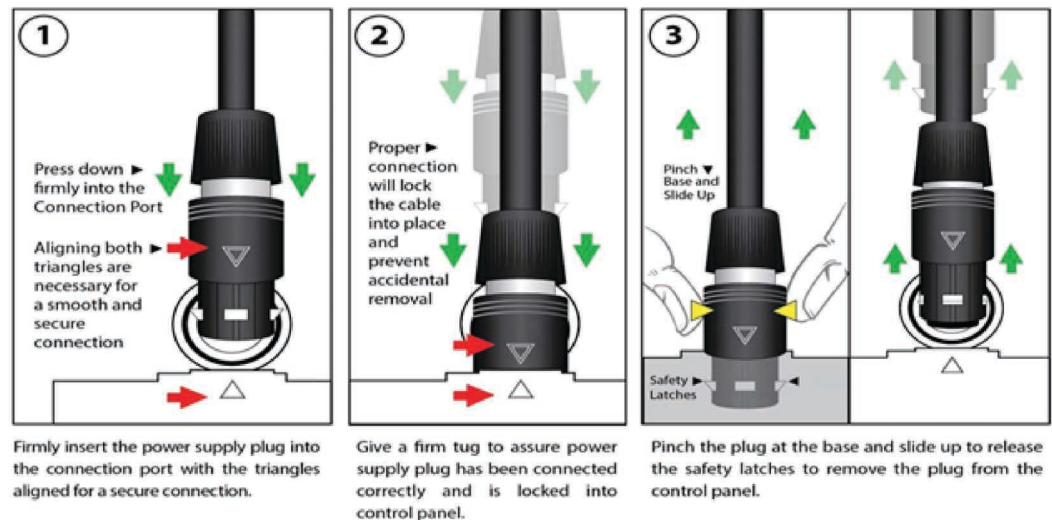
Before You Begin

You need the following items to use the aspirator:

- Power supply or 12 VDC automotive cable if external power is available.(
- Collection canister
- Aspirator to collection canister tubing
- Patient tubing (aspirator circuit)
- Suction catheter or surgical suction accessory as needed to perform the intended suction procedure
- Other accessories as required (Refer to Appendix B, “Accessories”, for a list of available accessories)

Connect to an External Power Source

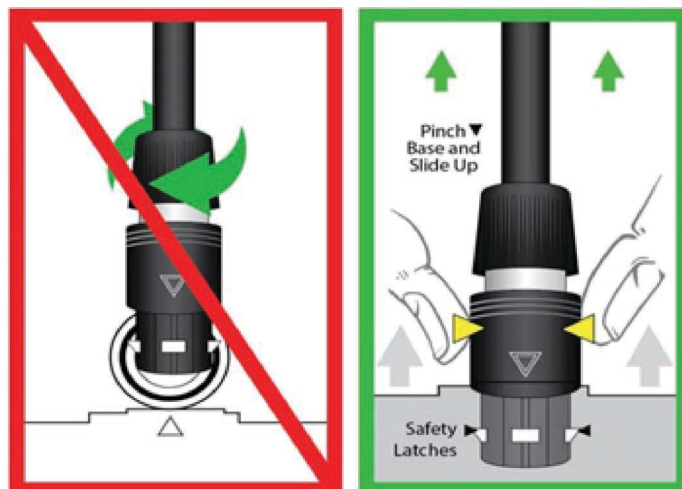
Connect the external power cable to the aspirator as follows:



Connecting and Disconnecting the Power Supply

Caution Do not twist the power cable connection plug. Pinch the plug and slide up to release the safety latches. Failure to do so may damage the power connection plug and prevent it from functioning.

Warning! If there is damage to the power supply, power cable, or power connection plugs or they become damaged during use, immediately disconnect the power cable from external power, disconnect the power cable from the device and label the failed part(s) to prevent further use. Failure to do so could cause the power supply to overheat and/or create an electrical short condition.



Warning! Always position the aspirator to enable the quick and effective disconnection of the aspirator's external power connection. Failure to do so could create a trip or entanglement hazard.

Attach the Collection Canister and Tubing

Attach the collection canister and tubing as follows:

1. Secure the lid on the collection canister by pressing the lid firmly around the entire perimeter until it is completely sealed.
2. Secure the pour spout cap firmly on the pour spout on the lid.
3. Place the collection canister basket into bracket on side of device.
4. Place collection canister inside the basket and secure it with the Velcro strap as shown.
5. Firmly attach the connection hose (PVC, 0.375 inch internal diameter) between the aspirator's vacuum port and the vacuum port on the collection canister.
6. Attach patient tubing to patient port.

Note: If the sterile packaging for the patient tubing is damaged, discard that tubing and use the tubing from an intact package.

An overflow protection float prevents aspiration of more fluid than the capacity of the collection canister. In the event of overflow, the float blocks the suction path preventing fluid from reaching the aspiratory. When this occurs, enable Standby on the device to reduce the applied vacuum. Replace the collection canister. Make all connections to the device before resuming operation.

When overflow protection is triggered, turn the aspirator OFF (or place into Standby), disconnect the collection canister, and dispose of the filled canister following local hazardous material procedures.

Warning! Always use a collection canister that provides both overflow protection and a filter. Failure to do so can result in aspirator contamination and require extended service to clean the internal components of the device.

If liquid or other material is drawn into the aspirator, remove the aspirator from use immediately. Place the contaminated aspirator into a biohazardous waste bag, and send it for service. Contact ZOLL Medical Corporation for additional instructions.

Using the Aspirator

To start the aspirator, turn the POWER switch to “I”.

Once turned ON the device performs a self-check of the internal system that includes: preexisting alarm conditions, pneumatic system function, internal communication, and the power system.

Operational Test

Before using the device with a patient, the user must perform a check to ensure proper device performance.

1. Ensure that the collection canister, suction tubing, and fittings are properly connected.
2. Turn the device ON using the power switch. Following the internal check procedure the Start Menu appears.
3. Select Surgical suction by pressing its parameter button and then the **Confirm** button.

Note: When using an initial start option (Adult or Pediatric) the interface presents the Continuous Mode following the self-check procedure.

4. Verify operating power from the external power sources, the External Power icon should be present, If the aspirator does not detect external power, the External Power icon appears with a slash through it. Check all power connections and ensure the power source is active. If operating from an internal battery, note the percent (%) of charge and monitor the battery status while the device operates.

Test the vacuum level by pinching or occluding the suction tubing. When this is done, the Vacuum Gauge should rise to the Surgical vacuum level, $\pm (2 \text{ mm Hg} + 8\%)$. If the vacuum level is higher or lower than this value, ensure the suction tubing is occluded and that the tubing and collection canister are assembled securely.

Refer to Chapter 4, “Understanding the User Interface”, for detailed instructions for using the aspirator.

Next Steps

Before using the aspirator with a patient, read the remainder of this manual and ensure that you are familiar with the operation and specifications of the device including alarms. Before using the device in transport or deployed environments read Chapter 6 which provides specific instructions for operating the aspirator in harsh and hazardous environments.

Chapter 4

Using the Aspirator User Interface

This chapter describes the ZOLL Model 330 Multifunction Aspirator user interface and provides descriptions of controls, buttons, and power switch. The user interface has two primary functional elements: suction controls and device controls. Suction controls allow you to configure the device to perform a suction procedure. Device controls let you manage the start up behavior of the device, LCD performance, and access critical information about the device. Device controls are supported by alarms and pop up messages to guide operation during normal use and when there is a fault or failure that affects device performance or safety.

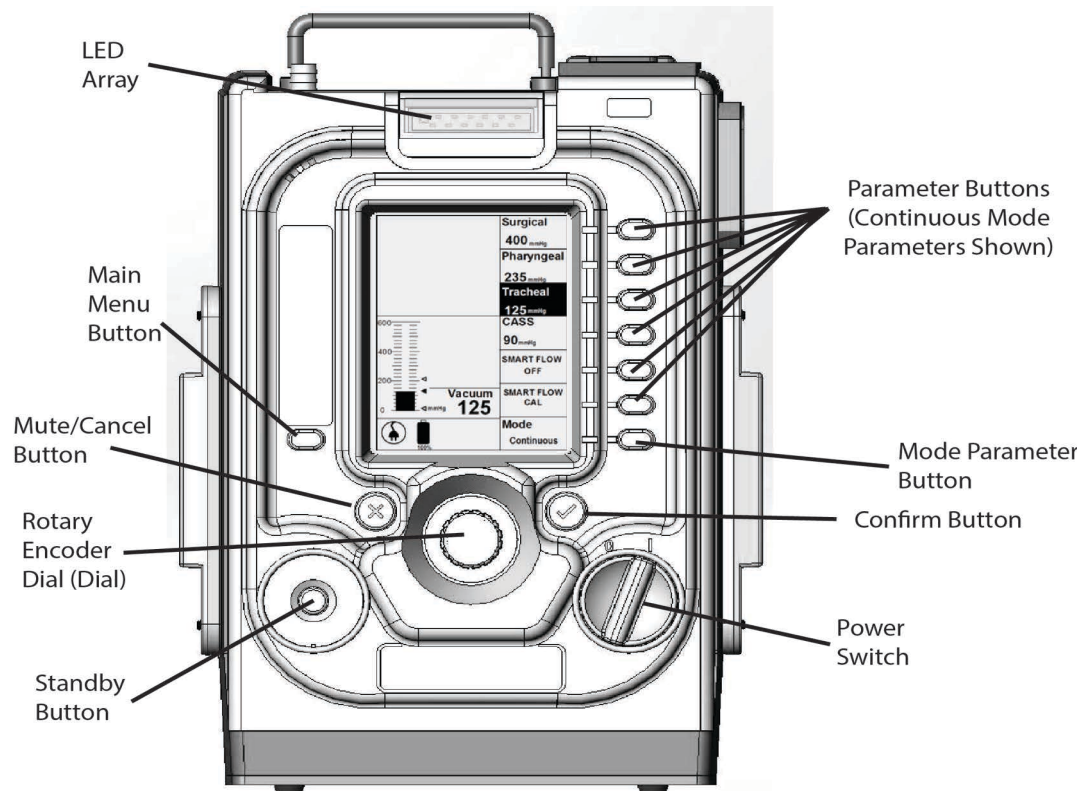
Interface Overview

The user interface, allows the user to configure two groups of settings.

1. Suction controls and monitoring include the following:
 - Suction mode
 - Suction procedure
 - Vacuum Level (mm Hg value)
 - Pop up messages
 - Alarms
2. Device controls and information include the following:
 - Alarm configuration: disable certain alarms
 - Power-up settings: chose how the device starts
 - LCD Contrast: adjust the contrast based in ambient light conditions
 - LCD Brightness: adjust the LCD backlight based on the ambient light conditions
 - UTC Offset: adjust the internal clock based on local time
 - Unit Info: device information such as serial numbers, software information, and date of next preventative maintenance)

Device Buttons and Controls

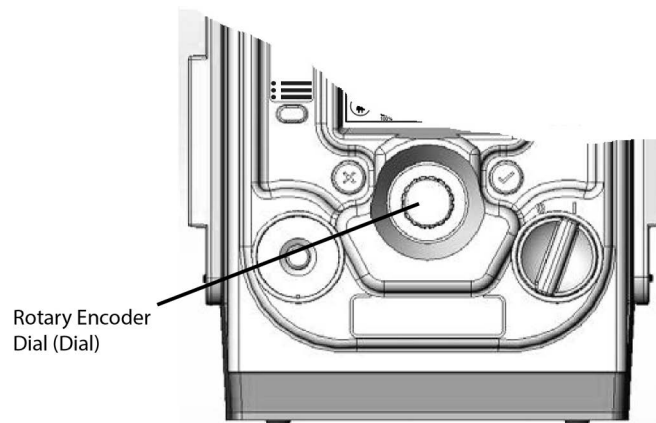
The location of all buttons and other controls are as shown in the figure below.



Rotary Encoder Dial

Turning the Rotary Encoder Dial (Dial) clockwise and counterclockwise allows you to do the following:

- Scroll through menu choices
- Adjust the vacuum levels

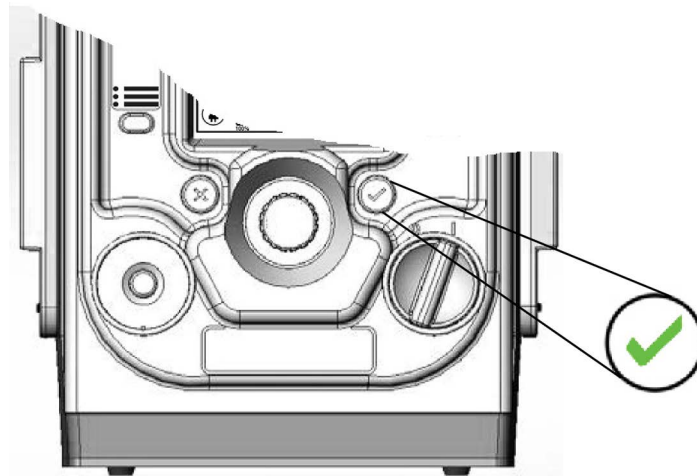


Confirm Button

Pressing the **Confirm** button confirms the setting you have chosen. It is also used to acknowledge pop up messages.

Note: Failure to press the **Confirm** button cancels your chosen setting in approximately 5 minutes.

The button is labeled with the following symbol:

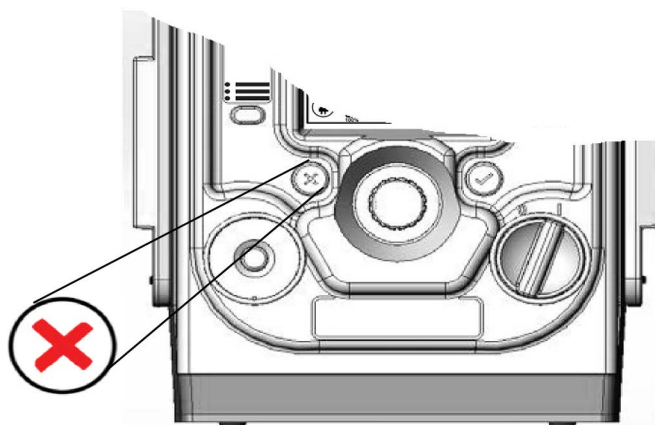


Mute/Cancel Button

Pressing the **Mute/Cancel** button silences the audible alarm when an alarm is detected (the alarm message displays as long as the alarm is active). Pressing the **Mute/Cancel** button acknowledges the alarm condition and allows the user 30 seconds to adjust settings. The **Mute/Cancel** button can also be used to cancel a parameter change or step back from a menu sequence. Pressing the **Mute/Cancel** button when alarms are not active suppresses the audible alarm for 30 seconds to minimize nuisance noise.

Note: Pressing the **Mute/Cancel** button has no affect when a high priority alarm is active. Both the audible and visual alarms continue until the alarm is resolved or the device is turned OFF.

The button is labeled with the following symbol:

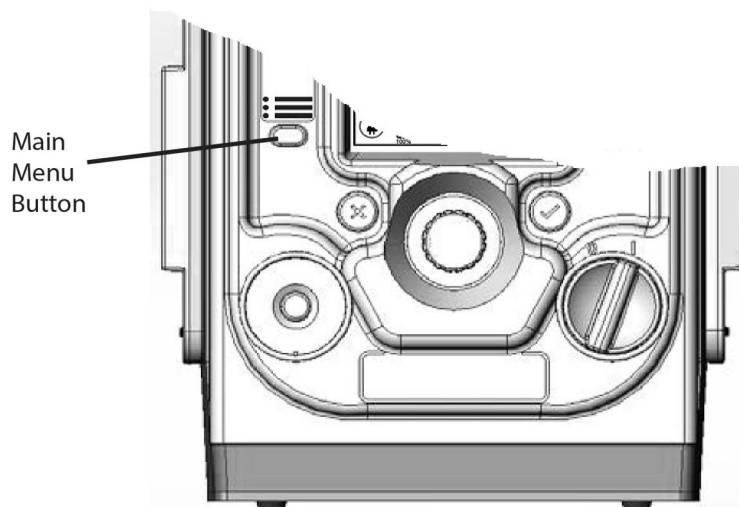


Main Menu Button

Pressing the **Main Menu** button provides access to the device menu. Main Menu controls are accessed by turning the **Dial** to highlight the control, and then pressing the **Confirm** button. to access the range of values for the control.

To cancel a setting selection, press the **Main Menu** button. To exit the Main Menu or setting, press the **Mute/Cancel** button again.

The **Main Menu** button is labeled with the following symbol just above the button.



Note: Pressing the **Main Menu** button displays the following settings. Initially, the **Power Up** setting is always selected when the Main Menu opens.

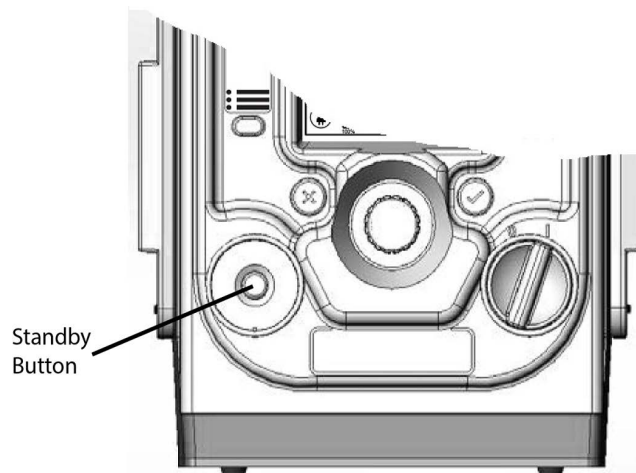
The following settings can be accessed and set through the Main Menu.

- Alarm Configuration
- Power Up settings
- LCD Contrast
- LCD Brightness
- UTC Offset

Standby Button

The aspirator can be placed in a Standby state that minimizes power usage by turning OFF the vacuum pump and decreasing the light intensity of for both the LCD backlight and LED array. When placed in Standby state, the LED array alternates between green and yellow to indicate its status and remind the user that input is required to begin suctioning.

To put the aspirator in Standby, press the **Standby** button (see Figure below)



While in Standby state, all device alarms remain active. Should a fault or failure condition occur, the appropriate alarm is triggered and is annunciated. When lower priority alarms are resolved the user acknowledges the alarm by pressing the **Mute/Cancel** button, the device returns to the Standby state which appears in the user interface.

To exit Standby state and resume aspiration at the time the **Standby** button was pressed, press the **Standby** button again.

Note: The device can only be placed in Standby state when operating in Continuous mode. Pressing the **Standby** button when in Intermittent mode has no effect. This is done to prevent inadvertent discontinuation of suction.

Parameter Buttons

A set of seven parameter buttons are positioned on the right side of the device (see Figure below). The function of these buttons is dependent upon which suction mode is enabled on the aspirator (Continuous or Intermittent) and is indicated on the aspirator screen immediately to the left of each parameter button.

When in **Continuous** mode, the displays to the left of the parameter buttons indicate:

- The suction mode (Continuous)
- The procedure set (Surgical, Pharyngeal, Tracheal, or CASS)
- The vacuum level for the procedure
- The status of Smart Flow (ON or OFF).

Additionally a parameter button is assigned for Smart Flow calibration.

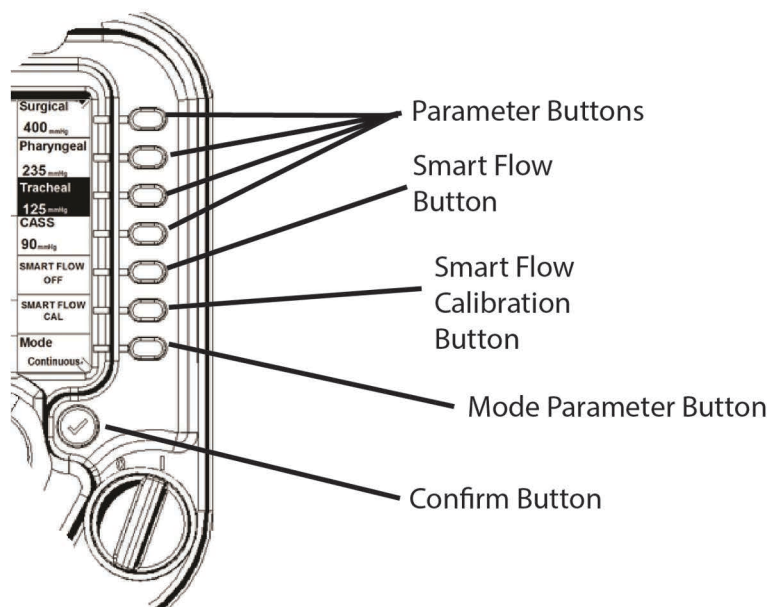
When in **Intermittent** mode, the displays to the left of the buttons indicate:

- The suction mode (Intermittent)
- The vacuum level
- The set ON Time value
- The set OFF Time value

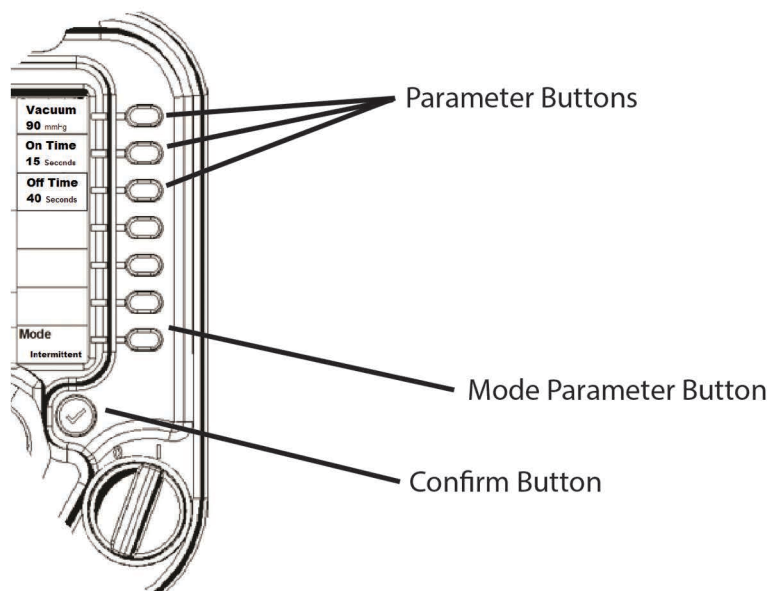
To prevent setting of a vacuum level outside the typical clinical range, the aspirator has fixed ranges for each procedure. See tables on pages 4-9 and 4-10 for more information.

Note: When in Continuous mode, the Surgical procedure provides the maximum vacuum level.

Continuous Mode
Button Arrangement



Intermittent Mode
Button Arrangement



Initial Use and Operation

When started, the aspirator displays the following:

- The startup configuration while performing its self-check procedure.
- The LED alternately blinks yellow and green. The alternating yellow/green pattern indicates that the device is ready to operate and that user input is required to begin operation.
- When the self-check procedure completes, the aspirator is operational.

If you want to operate the aspirator in Continuous mode with the initial Adult settings and Smart Flow enabled, follow these steps.

1. Press the parameter button that corresponds to the procedure you wish to perform.
 - Surgical
 - Pharyngeal
 - Tracheal
 - CASS
2. Adjust the vacuum level for your use, use the **Dial** to adjust it, then press the **Confirm** button.
3. Test the aspirator to verify the vacuum level.
4. If needed, calibrate Smart Flow. See, “Smart Flow Calibration”, in this chapter.

Note: When Smart Flow is ON, the pump is operating at a low speed. Occlude the suction tubing to ensure that the collection system is intact and that the set vacuum level is reached.

Refer to, “Continuous Mode Settings”, in this chapter for descriptions of these procedures.

Note: Failure to adjust a highlighted parameter or press the **Confirm** button within 5 seconds automatically cancels the action. This system ensures inadvertent button presses do not result in an unintended change

Note: Upon initial start, Smart Flow is ON (enabled). For information about the Smart Flow feature, see, “About Smart Flow”, later in this chapter.

Refer to section, “Suction Settings” in this chapter for additional information and instructions to change modes, choose procedures, and set vacuum levels.

Suction Settings

Aspirator settings include:

- Suction Mode
 - Continuous
 - Intermittent

Continuous Mode parameters include:

- Suction Procedure (Surgical, Pharyngeal, Tracheal, CASS)
- Vacuum level
- Smart Flow
- Smart Flow calibration

Intermittent Mode parameters include:

- Vacuum level
- ON Time
- OFF Time

The sections that follow describe these settings and provide instructions for choosing a value.

Setting the Suction Mode

The aspirator allows you to choose one of two suction modes:

- Continuous
- Intermittent

Refer to the, “Continuous Mode Operation” or, “Intermittent Mode Operation”, sections that follow for additional information and instructions.

To set a suction mode, follow these steps:

1. Press the **Mode** parameter button.
2. Turn the **Dial** to **Continuous** or **Intermittent**.
3. Press the **Confirm** button.

After choosing a mode, the additional settings for that mode display.

Note: When operating the aspirator, if you decide to change the suction mode by pressing the **Mode** parameter button, the aspirator enters **Pause**, allowing you to choose the new mode and additional settings for it.

The aspirator enters **Pause** to prevent exposing the patient to excessive or inappropriate vacuum. During **Pause**, the light intensity of the LCD backlight and the LED array remains at the operational level. This differs from Standby state where the light intensity is decreased for both to save power.

To set parameters for Continuous Mode, see, “Continuous Mode Operation”, in this chapter.

To set parameters for Intermittent Mode, see, “Intermittent Mode Operation”, in this chapter.

Continuous Mode Operation

Continuous mode provides four suction procedures. The procedures, and their initial vacuum level, provide the user with a quick method for controlling the device and the suction pressure. Using the correct vacuum level can reduce the risk of tissue damage that can result when too much pressure is used.

Procedure	Description
Surgical	The surgical procedure provides adjustable levels across the full range of the device. The device provides a portable solution with a range of suction typically used in medical facilities. When addressing the patient airway management the device provides additional procedure selections in the Continuous Mode. These selections use the same pneumatic design with specified limitations to the adjustable level.
Pharyngeal	The pharyngeal procedure provides the appropriate range to remove secretions of the upper airway.
Tracheal	The tracheal procedure provides the appropriate range for the use of the device clear the pulmonary passage.

Procedure	Description
CASS	The Continuous Aspiration of Subglottic Secretions (CASS) procedure uses low level of vacuum applied either with a special endotracheal tube (ETT) or with an adjunct to a standard endotracheal tube to provide suction during mechanical ventilation. The vacuum removes the secretions that collect above the cuff of the ETT that are known to increase the risk of ventilator associated pneumonia (VAP).

:

Procedure	Vacuum Range	Adult Initial Vacuum Level	Pediatric Initial Vacuum Level
Surgical	20 to 550 mm Hg	500 mm Hg	500 mm Hg
Pharyngeal	60 to 400 mm Hg	300 mm Hg	300 mm Hg
Tracheal	60 to 220 mm Hg	100 mm Hg	80 mm Hg
CASS	10 to 40 mm Hg	30 mm Hg	10 mm Hg

Choosing a Procedure, Vacuum Level, and Use of Smart Flow

To choose a procedure and set the vacuum level for it, follow these steps:

1. Press the parameter button associated with the procedure (Surgical, Pharyngeal, Tracheal, or CASS).
2. Press the **Confirm** button to use the initial vacuum level for the procedure, or change it by turning the **Dial** clockwise (to increase the vacuum level) or counterclockwise (to decrease the vacuum level), then press the **Confirm** button.
3. Turn Smart Flow ON or OFF, by pressing the **Smart Flow** parameter button, then turn the **Dial** clockwise (Smart Flow ON) or counterclockwise (Smart Flow OFF). See the “Smart Flow” and “Smart Flow Calibration” sections, in this chapter, for more information.

Intermittent Mode Operation

Intermittent Mode allows you to control the following parameters.

- Vacuum level.
- ON Time
- OFF Time

The Intermittent Mode vacuum range, adult and pediatric initial vacuum level settings are:

Control	Vacuum Range	Adult Initial Vacuum Level	Pediatric Initial Vacuum Level
Vacuum	10 to 200 mm Hg	90 mm Hg	80 mm Hg
ON Time	5 to 40 seconds	15 seconds	15 seconds
OFF Time	5 to 40 seconds	40 seconds	40 seconds

Setting Intermittent Mode Vacuum Level and ON/OFF Time

To set the vacuum level, ON Time, and OFF Time, follow these steps:

1. To active Intermittent mode, press the **Mode** parameter button; then the **Confirm** button.
2. Turn the **Dial** to select **Intermittent**, then press the **Confirm** button to confirm.
3. Adjust the vacuum level. Use the **Dial** to set the required level and then press the **Confirm** button to confirm the new level.
4. Press the **ON Time** button, then turn the **Dial** clockwise (to increase the time) or counterclockwise (to decrease the time), and then press the **Confirm** button to confirm the new ON Time value.
5. Press the **OFF Time** button, then turn the **Dial** clockwise (to increase the time) or counterclockwise (to decrease the time), and then press the **Confirm** button to confirm the new OFF Time value.

About Smart Flow

The aspirator is equipped with Smart Flow that reduces the noise and power usage when the device is not actively aspirating fluid or debris. The optional feature is available only when the aspirator is operating in Continuous mode.

Smart Flow works by using a constant low flow to detect when the user applies suction. It does this by measuring the vacuum level (pressure) change that results when the resistance at the end of the suction catheter changes. When the vacuum level drops below the threshold, the vacuum pump increases its speed (RPM) to reach the intended vacuum level target. When suctioning is removed, the vacuum level drops below the threshold and the vacuum pump continues operation for a few more seconds to clear the suction catheter and tubing. Since the resistance of suction setup and catheters can vary, Smart Flow may require calibration so that it performs as intended with different accessories, see “About Smart Flow Calibration”, below.

Users can turn Smart Flow ON or OFF in Continuous mode when surgical, pharyngeal or tracheal procedures are active. During CASS or when the set vacuum level is less than 50 mm Hg in Continuous mode Smart Flow is not displayed

When Smart Flow is ON, it can take 1 to 3 seconds for the system to detect use and ramp up the vacuum pump. If immediate vacuum is required do not use Smart Flow. In instances where suction may be needed, turning OFF Smart Flow and placing the aspirator in Standby state will minimize noise and reduce power while still maintaining the ability to quickly provide suction.

About Smart Flow Calibration

To ensure that the Smart Flow feature works properly for your application and accessory package, Smart Flow may need calibration. During calibration the aspirator should be in the Continuous mode operational state.

Warning!	Do not calibrate Smart Flow when the aspirator is in-use with a patient.
-----------------	---

To perform calibration, follow these steps.

1. Connect ALL accessories that will be used during aspiration. Ensure that the vacuum accessories are not occluded and open to the air.

2. Press the **Smart Flow Cal** parameter button, a pop up message will display with instructions on how to perform the calibration.
3. When ready, press the **Confirm** button. The aspirator runs through an automated calibration procedure. A pop up message confirms that the calibration is in process. During calibration, do not disturb or obstruct the vacuum path.

When the calibration is complete, the pop up message clears from the display. The aspirator is now calibrated and ready for use.

Note: You can cancel the calibration process by pressing the **Mute/Cancel** button prior to confirming the pop up.

Device Settings — Main Menu

Device settings are aspirator settings that affect how the aspirator generally operates and include:

Main Menu Choice	Description
Alarm Configuration	Allows the user the ability to silence two alarms: RTC Battery Low and PM Due to minimize nuisance alarms during operation.
Power Up settings	Allows the user control the configuration of the suction parameters when the device starts.
LCD Contrast	Allows the user to control the contrast of the LCD display.
LCD Brightness	Allows the user to control the brightness of the LCD display.
UTC Offset	Allows the user to set the time offset from Coordinated Universal Time (UTC) based on the time zone in which the user is operating.
Unit Info	Allows the user to view information about the aspirator including: software revisions, serial number, etc.

When the Main Menu appears, use the **Dial** to scroll between the Main Menu options. Press the **Confirm** button to edit the option and use the **Dial** to adjust the variable; then press the **Confirm** button to confirm the change. While in the Main Menu, pressing the **Standby** button has no effect.

The sections that follow describe Main Menu choices in greater detail

Alarm Configuration

Selecting the Alarm Configuration allows the operator to disable the audible and visible alarm alerts associated with specific alarms in order to prevent nuisance alarms. While the menu shows all of the alarms that can be disabled, the system does not allow for an alarm to be disabled until detected. The device provides the user the ability to silence only two alarms: RTC Battery Low and PM Due.

To disable an alarm, follow these steps.

Note: During Steps 1 through 4, you can press the **Mute/Cancel** button to cancel your last action.

1. Press the **Main Menu** button to display the menu.

2. Turn the **Dial** to highlight **Alarm Config**, and then press the **Confirm** button.
3. Immediately, PM Due is highlighted. To turn the alarm OFF, press the **Confirm** button, use the **Dial** to select OFF, then press the **Confirm** button. The alarm is now OFF for this use.
4. To turn OFF the RTC Battery Low alarm, use the **Dial** to select RTC Battery Low, then press the **Confirm** button, use the **Dial** to select OFF, then press the **Confirm** button. The alarm is now OFF for this use.

Power Up Settings

The initial starting configuration is described in, “Initial Power ON and Operation” found previously in this chapter. However, you can configure how the aspirator starts (powers up) based on your use or patient population. The aspirator **Power Up** setting options include:

Power Up Option	Aspirator State on Power Up
Adult	Continuous mode with Adult initial settings for procedures (Surgical Pharyngeal, Tracheal, CASS), and Smart Flow ON.
Pediatric	Continuous mode with Pediatric initial settings for Procedures (Surgical Pharyngeal, Tracheal, CASS), and Smart Flow ON.
Custom	Allows the user to customize Continuous and Intermittent mode parameter settings, including initial settings, and which mode is active when the device starts.
Start Menu	Aspirator starts with the Start Menu displayed allowing the user to choose between Adult, Pediatric, Custom setting, or the Last Settings

In addition to controlling how the device starts, the **Power Up** settings sub-menu also allows the user to save the current device configuration for use as the Custom starting configuration and which language will be used when the device starts.

To configure new power-up settings, follow these steps;

1. Press the **Main Menu** button to display the menu.
2. Turn the **Dial** to highlight **Power Up** settings, then press the **Confirm** button.
3. If needed, turn the **Dial** to highlight the **Power Up** choice, then press the **Confirm** button which then presents the sub-menu where **Power Up** is highlighted.
4. Press the **Confirm** button, then turn the **Dial** to the desired starting configuration.
 - Adult
 - Pediatric
 - Custom
 - Start Menu
5. Press the **Confirm** button to confirm the new starting configuration.

Specifying Custom Settings

To save the current configuration for use at start up, follow these steps:

1. Press the **Main Menu** button, then turn the **Dial** to **Power Up** settings, then press the **Confirm** button.
2. Turn the **Dial** to highlight the Custom Setting choice, and then press the **Confirm** button which confirms the selection and returns the highlight to the **Power Up** setting sub-menu.

3. Turn the **Dial** to select Customer settings, then press the **Confirm** button. Press the **Confirm** button again to save the current parameter configuration for the Custom start initial settings. The current parameter settings will present the next time the aspirator is started.

LCD Contrast

The LCD Contrast choice allows the user to adjust the contrast of the aspirator display screen to optimize visibility in the current lighting environment. Given the use environment, the device automatically compensates for the temperature changes that can effect LCD performance. However, in temperatures outside its performance specification, -26 to 49 °C (-14 to 120 °F), or when the device temperature is rapidly changing (warm storage into a very cold environment) the contrast can fade making viewing difficult. The initial contrast value is 0 and ranges from -42 to 42 °C (-43 to 108 °F).

To adjust the LCD screen contrast, follow these steps:

1. Press the **Main Menu** button to display the menu.
2. Turn the **Dial** to highlight **LCD Contrast**, and then press the **Confirm** button.
3. Turn the **Dial** while watching the LCD to determine the best contrast value based on visibility and press **Confirm** to confirm the new contrast value. Turning the **Dial** clockwise decreases the contrast while turning the **Dial** counterclockwise increases the contrast.
4. Press the **Main Menu** button to leave the menu and have the aspirator enter **Pause**.

Note: The contrast value is saved between uses. This may require that the contrast value be readjusted when the temperature is within the device operating range or with the next use.

Note: In the event the LCD is not viewable due to extreme temperature conditions there is a short cut to the contrast control. Press and hold the **Main Menu** button for 2 to 3 seconds. Doing this, jumps the menu highlight directly to the contrast control where the contrast can be adjusted as described above.

LCD Brightness

The LCD Brightness control allows the user to adjust the brightness of the LCD display screen to optimize visibility in the current lighting environment.

The initial numerical value is 25. The brightness ranges from 0 to 31.

To adjust the LCD screen brightness, follow these steps:

1. Press the **Main Menu** button to display the menu.
2. Turn the **Dial** to highlight **LCD Brightness**, and then press the **Confirm** button.
3. Turn the **Dial** while watching the LCD to determine the best brightness value based on visibility and press **Confirm** to confirm the new brightness value. Turning the **Dial** clockwise increases the brightness while turning the **Dial** counterclockwise decreases the brightness.)
4. Press the **Main Menu** button to leave the menu and have the aspirator enter **Pause**.

UTC Offset

The UTC Offset control allows the user to offset the aspirator clock to match the local time zone relative to Coordinated Universal Time (UTC) when logging alarms.

Currently, the device does not use this feature.

Unit Info

The Unit Info choice allows the user to view the following information about the aspirator as follows:

Item	Description
SAM SW Rev	The Smart Aspirator Module (SAM) software revision that is in use with the device
SAM SN	The serial number of the SAM
SW Rev	The aspirator user interface software revision that is in use with the device
Device SN	The aspirator serial number
Device Model	The model version of aspirator
Date	The current date (day/month/year)
PMC Date	The date of the last Periodic Maintenance Check (PMC)

Chapter 5

Alarms

This chapter provides a detailed description and comprehensive reference for the ZOLL Model 330 Multifunction Aspirator alarms and pop up messages. This chapter:

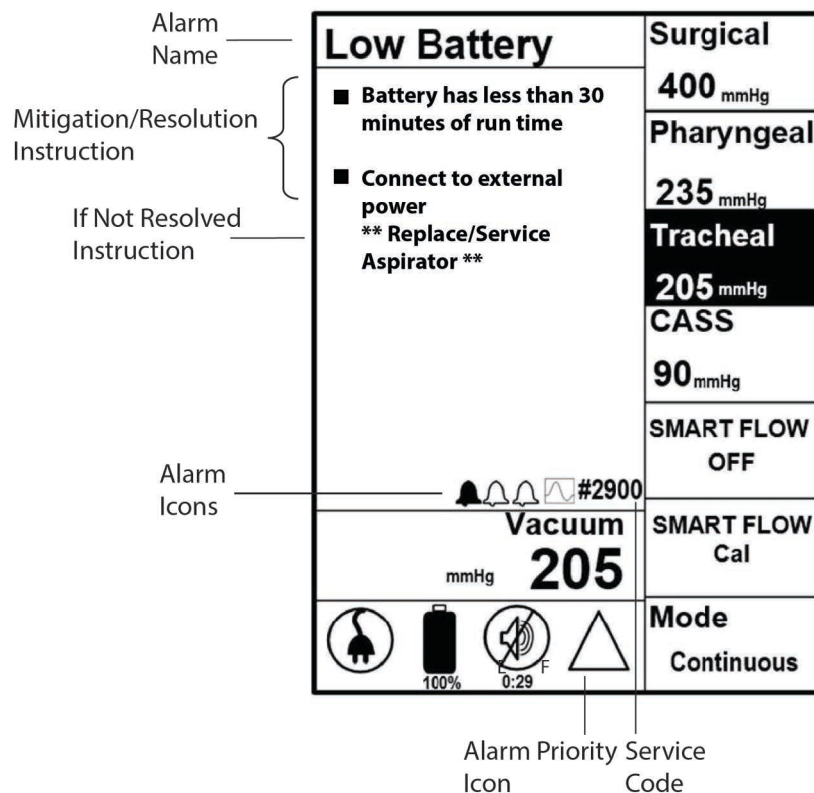
- Describes the display format and use of ZOLL's Smart Help messages in detail.
- Describes alarm types and priorities.
- Provides a comprehensive list of alarms and pop up messages.

Alarm Overview

To safeguard the patient, the aspirator continuously monitors the applied vacuum, environment and its performance to ensure that all of the systems are functioning as intended. When the device detects a problem, it triggers an alarm and displays a Smart Help message to the user.

The Smart Help message provides a multi-line alert that appears in the upper left-hand corner of the display screen called the Alarm Message Center (AMC). The AMC displays the alarm name, additional information about the cause or nature of the alarm, and a series of instructions to help you resolve the alarm. Alarms are prioritized based on the risk to the patient and always present the alarm with the greatest risk to the patient first when multiple alarms are active.

The Alarm Message Center (AMC) contains the information and instructions for all active alarms, as in the following example:



Item	Description
Alarm Name	Provides the name of the alarm
Mitigation/Resolution Instructions	Additional information about the fault or failure and prioritized instructions that describe how to resolve the alarm state.
If Not Resolved Instructions	Provides instruction on what to do if the alarm is not resolved. The instruction is always shown in the following format: **Message...**.
Alarm Icons	For each active alarm, an alarm bell appears. When multiple alarms are active, the number of bells corresponds to the number of alarms. The solid alarm bell indicates the displayed alarm and its priority. To view each active alarm, turn the Dial to scroll through all active alarms. The plot icon is also in the list which allows the user to see the vacuum level plot to better assess the nature of the failure. A maximum of five alarms can be displayed when the vacuum plot icon is omitted (done automatically).
Alarm Priority Icon	Identifies the severity of the alarm: Low, Medium, or High priority. See the Symbols table in Chapter 1 for the appearance of the warning triangle for each of these three alarms.

Item	Description
Service Code	Each alarm has a 4 digit number associated with it, which helps the operator identify the specific alarm when communicating with technical support. The service codes appear in the following format: 1###High Priority Alarm 2###Medium Priority Alarm 3###Low Priority Alarm

Alarm Priorities

Alarm priorities define the operational status of the device and its ability to provide suction. The alarm priorities are as follows:

High Priority

Ability to provide vacuum is no longer possible. This alarm priority requires immediate intervention. This includes system failure alarms where the CPU has failed and a backup has taken over to sound the audible and visual alarms. These alarms also include when the device is turned on and there is no internal or external power source.

When triggered, these alarms present an audible tone and the LED array is red. Pressing the **Mute/Cancel** button has no effect on a high priority alarm. Silencing the alarm is only accomplished by turning the aspirator off.

Medium Priority

Operation is possible (maybe for a finite period of time) but, there is a failure or fault with the ability to provide vacuum, pneumatic subsystem, power, or environmental condition. This alarm priority requires your immediate intervention.

When triggered, these alarms present an audible tone and the LED array is red. It is distinguished from the high priority alarm by a slower pulse tones and LED flash rate. Pressing the **Mute/Cancel** button mutes medium priority alarms for 30 seconds. If the alarm trigger still exists after 30 seconds, the audible alarm sounds again.

Low Priority (Advisory)

The device is operating but there is a fault that you must be aware of to ensure safe management of the patient or device.

Low priority alarms sound an audible tone and display yellow LED alarm signal alerting you to the condition. Pressing the **Mute/Cancel** button cancels the audible signal. If the alarm is not resolved, the yellow LED remains illuminated to remind you of the fault or failure.

Note: Some low priority alarms are canceled and the Alarm LED turns green when you push the **Mute/Cancel** button. For others, the audible alarm is canceled but the Alarm LED stay yellow to remind you that the device is operating in a state that needs careful monitoring.

Preemptive Mute

Preemptive mute is means to prevent excessive noise in the patient care environment patient. When there is no active alarm, pressing the **Mute/Cancel** button preemptively mutes medium priority alarms for 30 seconds. This enables you to prevent the audible alarm. When the alarm is triggered the AMC displays the alarm and the LED is read, but there is no audible alarm.

Muting in High Noise Environments

In high noise environments, you may be inclined not to mute the alarm while addressing the problem. Not pressing the **Mute/Cancel** button may limit the your ability to resolve the alarm because the alarm may be retriggered and any parameter changes you are attempting are canceled as the alarm retriggers.

Note: During the muting of an audible alarm, the LED alarm light and alarm message are still present.

Alarm Types

The aspirator uses a series of alarm types to provide a framework for you to see the scope and range of the alarms that the device uses. The alarm types are:

Environment - Environment Alarms address the device inputs: external power, battery, ambient and battery temperature, barometric pressure (Altitude)

Self Check -- Self Check Alarms address the performance of the device systems and include

- **Internal Communication (Comm):** faults and failures of internal communication, cyclic redundancy checking, or processor-related issues
- **Pneumatic Sensor:** faults and failures of the pressure transducers.
- **Pneumatic System:** faults and failures of the vacuum pump or bleed valve.
- **Power System:** faults and failures of the power system could affect the ability to operate from external power or charge/operate from the internal rechargeable battery.
- **Preventive Maintenance:** alarms that occur when device is due for preventive maintenance.

Alarm Groups

The following table displays the ZOLL Aspirator's Alarm Groups:

Alarm Groups	
Environment	Self-Check
Battery - Battery Drained - Battery Nearly Drained - Battery Low - Discharge Fault - Too Hot/Cold	Ambient Pressure - Low - Sensor Failure
External Power Current High DC Power Reversed High Low/Disconnect	Firmware Mismatch
	Internal Comm Fault/Failures
	Pneumatic Sensors Transducers
	Pneumatic System - Pump - Valve
	Power Cycle Needed
	Preventive Maintenance
	Temperature - High/Low - Sensor Failure - Internal

High Priority Alarms

Service Code	Alarm Name/Mitigation/Resolution
1001	Self Check Failure Alarm triggers when the vacuum pump fails to operate or fails to provide the flow required to deliver a vacuum. <i>Mitigation/Info: Pneumatic System: Vacuum, Manually Aspirate Patient, **Contact Service Center*</i>
1010	Self Check Failure Alarm triggers when the bleed valve fails to reduce the applied vacuum <i>Mitigation/Info: Manually Aspirate Patient, **Contact Service Center*</i>
1140	Ambient Temperature Fault Alarm occurs when the internal device temperature exceeds 80 °C (176 °F) <i>Mitigation/Info: **Monitor Patient and Aspirator**</i>
1052	Self Check Failure Communication between the pressure sensor and SAM is lost. When this happens, replace the aspirator and contact the service center for additional information. <i>Mitigation/Info: Pneumatic Sensor: Vacuum Pressure, Manually Aspirate Patient, **Contact Service Center**</i>
1172	Self Check Failure Alarm occurs when the 5 volt power bus fails to provide the required voltage. If this failure occurs, replace the aspirator and contact the service center for additional information. <i>Mitigation/Info: Power System, Manually Aspirate Patient, **Contact Service Center**</i>
1173	Self Check Failure Alarm occurs when communication fails between one of the subcomponents and the host processor. If this failure occurs, restart the aspirator, replace the aspirator and contact the service center for additional information. <i>Mitigation/Info: Internal COMM, Manually Aspirate Patient, Backup Aspirator **Contact Service Center**</i>
1175	Self Check Failure Alarm triggers when the internal communication bus and the host are not able to communicate with the sub-assemblies. If this failure occurs, restart the aspirator, replace the aspirator and contact the service center for additional information. <i>Mitigation/Info: Internal COMM, Manually Aspirate Patient, **Contact Service Center**</i>

Service Code	Alarm Name/Mitigation/Resolution
1176	Self Check Failure Alarm triggers when the calibration file fails its integrity check. You should replace the aspirator and contact the service center for additional information. <i>Mitigation/Info: Internal COMM, Manually Aspirate Patient, **Contact Service Center**</i>
1420	Self Check: Complete Power Failure Alarm triggers when power is lost from both the internal battery and an external source during operation. When this failure occurs, the LCD blanks (no power for operation), the audible alarm pulses rapidly, and the visual alarm flashes rapidly. This alarm lasts approximately two minutes. If the device can be recharged after the failure and there are no other issues, it can be returned to service. If there are any questions, contact the service center for additional information. <i>Mitigation/Info: None – No LCD Display.</i>
1430	Drained Battery Alarm triggers when the internal battery power drops below the amount required to provide vacuum and external power is not connected. When this condition occurs, there is enough power to operate the user interface and provide information to you. You should manually suction the patient while an external source of power is sought. To cancel the alarm and begin operation with external power, the device must be turned off and then back on. <i>Mitigation/Info: Manually Aspirate Patient, Connect External Power, **Contact Service Center**</i>
1471	Self Check Failure Alarm triggers when the device is no longer able to communicate with the User Interface Module (UIM) and the interface controls. When this failure occurs, aspiration continues at the current settings and the high priority alarm sounds. You should replace the aspirator and contact the service center for additional information. <i>Mitigation/Info: Internal COMM, Manually Aspirate Patient, Backup Aspirator **Contact Service Center**</i>
1472	Self Check Failure Alarm triggers when the device is no longer able to communicate with the Smart Aspirator Module (SAM). When this failure occurs, vacuum continues at the current settings and the high priority alarm sounds. You should replace the aspirator and contact the service center for additional information. <i>Mitigation/Info: Internal COMM, Manually Aspirate Patient, Backup Aspirator, **Contact Service Center**</i>
1474	Self Check Failure Alarm triggers when cyclic redundancy checking between the device and SAM fails. When this failure occurs, vacuum continues at the current setting and the high priority alarm sounds. You should replace the aspirator and contact the service center for additional information. <i>Mitigation/Info: Internal COMM, Manually Aspirate Patient, Backup Aspirator, **Contact Service Center**</i>

Service Code	Alarm Name/Mitigation/Resolution
1475	Self Check Failure Alarm triggers when the device has lost communication with the contrast control and in most instances the content of the LCD is not visible. When this failure occurs, vacuum continues at the current settings and the high priority alarm sounds. You should replace the aspirator and contact the service center for additional information. Mitigation/Info: Internal COMM, Manually Aspirate Patient, Backup Aspirator, **Contact Service Center**
1480	Self Check Failure Alarm triggers when the device and SAM software loads are not compatible. This alarm is typically associated with an SAM change where the technician failed to update the device and SAM to the current software revision. You should replace the aspirator and contact the service center for additional information. Mitigation/Info: Firmware Mismatch, Manually Aspirate Patient, Software Compatibility Failure, **Contact Service Center**

Medium Priority Alarms

Service Code	Alarm/Mitigation/Resolution
2111	Self Check Failure Alarm occurs when the device detects a potential valve fault, the vacuum level is not reduced during the intermittent mode of operation. Mitigation/Info: "Manually Aspirate Patient", **Contact Service Center**
2140	Ambient Temperature Fault Alarm occurs when the internal device temperature exceeds 74 °C (165 °F) Mitigation/Info: **Monitor Patient and Aspirator**
2421	Self Check Fault Alarm triggers when there is a failure of the input protection circuit and the device is able to operate. The alarm continues until the device is turned off. You can mute the alarm for 30 seconds by pushing the Mute/Cancel button. You should replace the aspirator and contact the service center for additional information. Mitigation/Info: Power System, Power System Needs Repair, Internal Battery Operation, Monitor Battery % Charge, **Contact Service Center**
2423	Self Check Fault Alarm triggers when the internal power circuit has failed and external power is connected but cannot be used. The fault cannot be repaired by you. You can mute the alarm for 30 seconds by pushing the Mute/Cancel button. Replace the aspirator and contact the service center for additional information. Mitigation/Info: Power System, Power System Needs Repair, Internal Battery Operation, Monitor Battery % Charge, **Contact Service Center**

Service Code	Alarm/Mitigation/Resolution
2430	Nearly Drained Battery Alarm triggers when the device detects that there is 5 minutes of battery operation remaining and external power is not connected. You should immediately seek a source of external power. Attaching external power clears the alarm immediately though a low priority alarm remains until the internal battery has recharged so that the device can provide 30 minutes of operating time. This takes approximately 5 to 10 minutes. If recharging the battery does not resolve the issue, contact the service center for additional information. <i>Mitigation/Info: < 5 Minutes Operation, Connect External Power, Ensure ability to manually aspirate patient **Contact Service Center**</i>
2450	Battery Discharge Fault Alarm triggers when the battery temperature reaches 70 °C (158 °F) which is 5 °C (41 °F) from its maximum operating temperature using the internal battery and external power is not connected. When the battery temperature reaches 75 °C (167 °F) the battery shuts down to prevent failure and the device sounds a high priority alarm and shutdown. If possible, you should provide a source of external power which allows operation to continue at the current and higher temperatures. Shading the patient and aspirator from direct sunlight may also help reduce the battery temperature. <i>Mitigation/Info: Temperature Within 5°C (41 °F) of High Limit, Ensure External Power Available, Ensure ability to manually aspirate patient **Move To Cooler Location**</i>
2455	Battery Fault Alarm triggers when the device is not able to communicate with the internal battery. When this fault occurs, the device does not know the current charge of the battery and operation could stop at any time. To continue operation, you should connect external power. When external power is connected the alarm priority decreases to Low Priority, replace the aspirator and contact the service center. <i>Mitigation/Info: Battery Communication, Connect External Power, Ensure ability to manually aspirate patient **Contact Service Center**</i>

Low Priority Alarms

Service Code	Alarm/Mitigation/Resolution
3110	RTC Battery Low Alarm triggers when the real-time clock (RTC) battery is <~ 2.5 volts. The alarm condition is checked at start up and if this alarm occurs the device is safe to operate but you should replace the device when appropriate and consult the service center for additional information. You cannot change the RTC battery. The RTC battery provides power for the clock that tracks the local time. The RTC battery is replaced every 4 years during preventive maintenance. <i>Mitigation/Info: Aspirator Fully Functional, **Contact Service Center**</i>

Service Code	Alarm/Mitigation/Resolution
3120	PM Due Alarm triggers at start up when the preselected number of days has elapsed since the last calibration. When appropriate the device should be replaced and sent for preventive maintenance. The low priority message serves as a reminder. Calibration is due every 365 days. You should schedule the device for service as soon as possible. You can suspend the yellow alarm notification for the current use by turning the alarm off using the Alarm Configuration submenu in the Main Menu. <i>Mitigation/Info: Preventive Maintenance Due, Aspirator Functioning with No Faults, **When Appropriate, Contact Service Center**</i>
3130	Self Check Fault Alarm triggers when the ambient pressure transducer fails. When this fault occurs, the device is no longer able to properly detect the ambient pressure. When this alarm is active during aeromedical transport you should be cautious of pressure readings if the aspirator cannot be replaced. You should also monitor flow to ensure adequate aspiration. <i>Mitigation/Info: Sensor Failure: Barometric Pressure, **Contact Service Center**</i>
3132	Low Altitude Alarm triggers when the ambient pressure transducer detects an altitude <- 2,500 feet below sea level (610 meters, 15.8 psig or 103 kPa). This can be caused by use in subterranean rescue operation or mistaken use in a hyperbaric chamber. Beyond this pressure level performance could be compromised. NOTE: The device is not intended for use in hyperbaric chambers or at hyperbaric pressures. <i>Mitigation/Info: High Barometric Pressure Detected, Monitor Patient and Aspirator, **Reduce Ambient Pressure**</i>
3140	Ambient Temperature Fault Alarm triggers when the ambient temperature exceeds the normal operating range, > 55 °C (131 °F) for the aspirator. The device allows operation at these temperatures but alerts you to the condition. Operating above the specified range can affect the longevity of the internal battery and the duration of operating time. <i>Mitigation/Info: High Temperature Detected, **Monitor Patient and Aspirator**</i>
3141	Ambient Temperature Fault Alarm triggers when the ambient temperature falls below the normal operating range < - 10 °C (14 °F) for the aspirator. The device allows operation at these temperatures but alerts you to the condition. Operating below the specified range can affect the longevity of the internal battery and the duration of operating time. Extremely cold temperatures can significantly reduce operating time. <i>Mitigation/Info: Low Temperature Detected, **Monitor Patient and Aspirator**</i>

Service Code	Alarm/Mitigation/Resolution
3143	Self Check Fault - Environmental Sensor Alarm triggers when there is failure of the internal temperature sensors. When this fault occurs, the device is no longer able to detect if it is operating outside of the allowable temperature range. If operating inside of the temperature range -26 to 55 °C (-13 to 120 °F) there is no effect on operation. If operating outside this range, you should monitor the device continuously. When appropriate, you should replace the aspirator and contact the service center for additional information. <i>Mitigation/Info: Environmental Sensor: Temperature, Aspirator Operating, Service Required, ** Contact Service Center**</i>
3421	External Power Low / Disconnect Alarm triggers when the external power (either AC or DC) drops below minimum level (~11 VDC as supplied by either the AC/DC Power Supply or a direct DC source) or power is intentionally disconnected. Since the device operates with either external power or using its internal battery this is a low priority alarm that clears when you press the Mute/Cancel button. Pressing the Mute/Cancel button is the your acknowledgment that the device is operating on internal battery. If this alarm occurs and you believe that the device is still connected to external power, you should investigate the external power source and contact the service center for additional information. <i>Mitigation/Info: Internal Battery Operation, Check Power Connection/Supply, Monitor Battery Status, ** Contact Service Center**</i>
3422	Battery Fault Alarm triggers when the internal battery has been removed or communication between the battery and CPU has failed. When external power is applied the device is capable of operation however, loss of external power results in loss of suction and a high priority alarm. Operating in this state should only be done when no other alternatives are available. <i>Mitigation/Info: Battery Power Not Available, DO NOT Remove External Power!, Ensure ability to manually aspirate patient **Contact Service Center**</i>
3423	Battery Charging Fault Alarm triggers when the battery charging circuit fails. When this alarm is active, the battery cannot be charged. The device can only run with external power. If power is lost, aspirator stops and a high priority alarm triggers. Operating in this state should only be done when no other alternatives are available. Contact the service center for additional information. <i>Mitigation/Info: Aspirator Operating, Power System Needs Repair, Battery Cannot Charge, Maintain External Power, **Contact Service Center**</i>
3430	Low Battery Alarm triggers when the device detects that there is < 30 minutes of battery operation remaining and no external power is connected. You should seek a source of external power. Attaching external power the alarm clears immediately however, alarm #3431 will occur in its place. See description of Alarm 3431 below. <i>Mitigation/Info: < 30 Minutes Operation, Connect External Power, Ensure ability to manually aspirate patient **Contact Service Center**</i>

Service Code	Alarm/Mitigation/Resolution
3431	Low Battery This triggers when external power is connected to a device that has an internal battery that has drained to a low battery status. The device is warning you that in the event of an external power failure the device has < 30 minutes of backup. This alarm resolves when the internal battery charge has > 30 minutes of operation. You must maintain monitoring of the device and the patient constantly during this period. <i>Mitigation/Info: < 30 Minutes Operation, Operating With External Power, Continue Charging With External Power, Ensure ability to manually aspirate patient **Contact Service Center**</i>
3441	External Power Fault Alarm triggers when the supplied DC power is > 33 VDC. When this fault occurs, the device automatically switches to operation using the internal battery. If the supplied voltage drops to < 30 VDC the device automatically returns to operation using external power. If the external power source is known to be good then the AC/DC Power Supply may be faulty and need replacement. Contact the service center for additional information. <i>Mitigation/Info: External Voltage Too High, Internal Battery Operation, Check/Replace Power Supply, **Contact Service Center**</i>
3442	External Power Fault Alarm triggers when the external power supply has insufficient current. When this fault occurs, the device automatically switches to operation using the internal battery. If the external power source is known to be good then the AC/DC Power Supply may be faulty and need replacement. Contact the service center for additional information. <i>Mitigation/Info: External Power Insufficient Current, Internal Battery Operation, Check/Replace Power Supply, **Remove DC Connection**</i>
3444	External Power Fault Alarm triggers when the voltage polarity is reversed when the device is attached to an external DC source. When this fault occurs, the device automatically switches to operation using the internal battery. This condition is most likely caused by a faulty DC source. You should seek an alternate power source. <i>Mitigation/Info: DC Voltage Reversed, Internal Battery Operation, Disconnect Power Source **Replace Power Source**</i>
3450	Battery Discharge Fault Alarm triggers when the battery temperature reaches 70 °C (158 °F) which is 5 °C (41°F) from its maximum operating temperature and external power is connected. When the battery temperature reaches 75 °C (167 °F) the battery shuts down to prevent failure. When this fault occurs, the device will continue operation using external power only. Shading the patient and aspirator from direct sunlight may also help reduce the battery temperature. <i>Mitigation/Info: Battery Within 5 °C (41°F) of High Limit, DO NOT remove External Power!, Ensure ability to manually aspirate patient, Shade Patient and Aspirator, **Move To Cooler Location**</i>

Service Code	Alarm/Mitigation/Resolution
3451	Battery Discharge Fault Alarm triggers when the battery temperature reaches 75 °C (167 °F) and external power is connected. Discharging the battery beyond this temperature could destroy the battery and damage the device. During the alarm condition, the device continues operation using external power. Shading the patient and aspirator from direct sunlight might also help reduce the battery temperature. <i>Mitigation/Info: Battery Too Hot to Discharge, Do NOT Remove External Power!, Ensure ability to manually aspirate patient, **Move To Cooler Location**</i>
3452	Battery Charging Fault Alarm triggers when the battery temperature is > 45 °C (122 °F). Charging the battery above this temperature could destroy the battery and damage the device. During the alarm condition the device continues to operate using external power and if external power is lost, the device operates using internal battery power. Shading the patient and aspirator from direct sunlight might also help reduce the battery temperature. <i>Mitigation/Info: High Battery Temperature, Battery Does Not Charge When It is Too Hot, Ensure External Power Available, Shade Patient and Aspirator, **Move To Cooler Location**</i>
3453	Battery Charging Fault Alarm triggers when the battery temperature is 0 °C (32 °F). Charging the battery below this temperature could destroy the battery and damage the device. During the alarm condition the device continues to operate using external power and if external power is lost the device operates using internal battery power. <i>Mitigation/Info: Battery Too Cold To Charge, Ensure External Power Available, **Move to Warmer Location**</i>
3455	Battery Fault Alarm triggers when the device is not able to communicate with the internal battery and external power is connected. To continue operation, the device must remain connected external power. Use in this state should only be done if there are no other alternatives. Contact the service center for additional information. <i>Mitigation/Info: Battery Communication, Do Not Remove External Power, **Contact Service Center**</i>
3470	Self Check Fault Alarm triggers when the device is no longer able to communicate with the Power Interface Module (PIM). When this fault occurs, you should monitor operation continuously, replace the aspirator when possible. Contact the service center for additional information. <i>Mitigation/Info: Power System, Power Management Fault, Monitor Power Source, **Replace/Service Aspirator**</i>
3480	Self Check Failure Alarm occurs when the device detects a change in hardware (mismatched serial numbers). <i>Mitigation/Info: Hardware Compatibility Failure, **Replace/Service Aspirator**</i>

Pop Up Messages

Pop Up Name	Information	Message
Silent/Dark Mode Enabled	Pop up triggers when you attempt to begin operation using Silent/Dark mode. In order to proceed, you must press the Confirm button to begin operation. Note: Not all devices are provided with the capability to operate with Silent/Dark mode, please check with your organization.	Press Accept Key to Enter Silent/Dark Mode Now
Smart Flow Cal Enabled	Pop up triggers when you attempt to begin a calibration of the Smart Flow feature. The pop up instructs you to ensure that all accessories are connected to the device but not attached to a patient. In order to proceed, you must press the Confirm button to begin the calibration procedure.	Attach accessories to aspirator before starting Smart Flow calibration. Press the Accept key to begin calibration.
Smart Flow in Progress	Pop up triggers after you press the Smart Flow Cal: button and the Smart Flow calibration process begins. The pop up tells you that the calibration is in progress and to wait for the completion of the calibration. The pop up clears automatically when the calibration process completes.	Please wait until calibration is complete. This pop up clears and the previous operation procedure resumes when calibration is complete.

Notifications

Notification	Information	Message
Altitude Conflict/Limit	Notification occurs when the vacuum setting is within 76% of environmental (barometric) pressure.	Target too high for ambient pressure.

Chapter 6

Operating in Harsh Environments

This chapter describes how to operate the ZOLL Model 330 Multifunction Aspirator in harsh environments.

Using the Aspirator in Harsh Environments

The aspirator operates in harsh pre-hospital environments and during air and ground transport. In order to safely manage the patient, you must understand the operating characteristics of the aspirator and monitor the patient and device in these environments. The unit continuously monitors environmental conditions (temperature and ambient pressure) and when it detects extreme environments, the unit alerts you with a Low Priority alarm which defines the operating condition and prompts your actions. Low Priority alarms are advisory and you should remember that the device is operating as designed.

Airborne Particulates

Under normal operating conditions, the filtration system in the canister protects the gas flow path from particulates entrained through vacuum intake. However, when operating in areas where fine dust or dirt is airborne due to wind or vehicle movement, you can use a disposable off-the-shelf in-line filter. You can also use a bacterial/viral filter can also be used on the gas outlet if there is concern for airborne pathogens. Visually inspect any filters used for dust/dirt build up for extended operation in harsh environments; you should change the filters as they become dirty.

Extreme Temperature Environments

Traditional transport aspirators typically operate from 0 to 40°C (32 to 104°F). The aspirator can operate over the range of -26 to 55 °C (-14.8 to 131 °F) during emergencies.

Aspirator Operation at High Temperatures

You might observe alarm conditions associated with Li-ion battery performance when operating the aspirator at high temperatures.

Alarm Condition	Description
Charging	If operating using external power, the device may issue an alarm when the battery reaches its high charge temperature limit of 45 (113 °F).
Discharging	If operating using external power, the device may issue an alarm when the battery reaches its high discharge temperature limit of 49 °C (120 °F).

Aspirator Operation at Low Temperatures

You might observe alarm conditions associated with Li-ion battery performance when operating the aspirator at low temperatures.

Alarm Condition	Description
Charging	If operating using external power, the unit may issue an alarm when the battery reaches its low charge temperature limit of 0 °C (32 °F).
Discharging	If operating using external power, the unit may issue an alarm when the battery reaches its low discharge temperature limit of -25 °C (-13 °F).

Altitude

The aspirator operates from -2,250 to 25,000 feet (-685 to 7620 meters). The aspirator's pressure sensors monitor ambient pressure and the device uses this information to continuously assess the suction that it provides. You should monitor the barometric pressure and vacuum level setting when changing altitudes. The aspirator will continue to provide suction up to the user-selected vacuum limit as long as the ambient pressure makes operation at the maximum vacuum setting possible.

Maximum vacuum limit decreases with altitude. When the operating altitude makes it impossible for the aspirator to achieve the user-selected vacuum level, the device displays a notification to indicate this and provides suction at the maximum limit that it can achieve. The following table displays, for a range of altitudes, the aspirator's corresponding approximate vacuum limit:

Altitude	Aspirator Vacuum Limit (Approximate)
Sea Level (0 ft)	550 mm Hg
6,000 ft	470 mHg

Altitude	Aspirator Vacuum Limit (Approximate)
10,000 ft	400 mHg
15,000 ft	330 mHg
20,000 ft	270 mHg
25,000 ft	220 mHg

Warning! **The unit is not intended for hyperbaric operation. Using the aspirator in a hyperbaric chamber can result in harm to the patient and/or damage to the device.**

Rain and Snow

You should prevent exposing the aspirator to rain or snow. In driving rain, where water could enter the vacuum pump, care should be taken to limit the exposure of the device. The aspirator is capable of operating in these conditions if you keep the device in its soft case and use the rain flap provided with the case. The soft case and rain flap prevent water from puddling on the aspirator's surfaces.

To best protect the aspirator from rain and snow, do the following:

1. Place the aspirator in its soft case.
2. Position the aspirator in its operational upright position.
3. Secure the aspirator in the soft case using the zippers, finishing at the bottom of the device.
4. Apply the rain flap over the aspirator using the Velcro strap to secure it.

In cases of driving rain, where water could possibly enter the device's vacuum pump, you can use an in-line filter to protect the pump inlet.

Chapter 7

Maintenance

This chapter describes how to maintain the ZOLL Model 330 Multifunction Aspirator to ensure its optimum working condition and readiness for immediate use. Specifically, this chapter describes how to:

- Inspect the device
- Clean the device
- Replace intake filters, as necessary
- Store the device
- Troubleshoot operational problems

In addition to the activities that we describe in this chapter, it is also important to perform preventative maintenance and replace worn or defective components as necessary. Mechanical components are subject to wear and fatigue over time and deteriorate more quickly when used continuously. To insure compliance with operating specifications, it is your responsibility to insure that periodic preventative maintenance is performed. Only ZOLL-trained and certified personnel should perform maintenance using the ZOLL Remote Calibration System (RCS).

Inspecting the Aspirator

You should perform the following physical inspections of the aspirator on a regular basis:

Ensure that the aspirator is clean and free of visible damage.

- Inspect all accessories and connectors for signs of damage or excessive wear. Replace worn or defective items.
- Replace crimped, cracked or worn suction tubing and hoses as required.
- If there is any sign of physical degradation or the device is indicating problems, you should replace the collection canister.
- Examine the muffler foam and replace it if it is dirty or clogged.
- Inspect the external AC /DC adapter, line cords, and DC power cables for wear or damage. Replace if worn or damaged.

Configuration and firmware information appears on the display screen after powering on the device. Additional device information is available through the Main Menu (select Unit Info), including the unit's calibration date. The aspirator operates on an annual preventative maintenance cycle, and the device issues a low priority alarm to remind you when calibration is due.

Cleaning

Keep the aspirator and its accessories clean at all times. Never allow grease or oil to enter the system or coat its components.

Clean the unit at regular intervals and maintain up-to-date records of inspections, cleaning, and maintenance.

Take care to prevent liquids from entering the aspirator. Never submerge the aspirator and avoid using excessive amounts of water that might enter the unit. Dry all exposed parts following usage in wet environments.

Clean the unit's housing and vacuum port with a damp, soapy cloth.

For general decontamination and cleaning, apply a 10% bleach solution with a damp cloth. Do not use hydrocarbon cleansers, which damage the housing and interface lens.

After cleaning, thoroughly dry the unit with a lint-free cloth. Make sure that all exposed surfaces are cleaned and dried.

Caution	Never clean the aspirator using abrasives or chlorinated hydrocarbon based cleansers as they damage the plastic.
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Post-Contaminated Environment Cleaning

If you have used the aspirator in an environment where it may have been exposed to contamination from a hazardous materials accident, mass epidemic, or weapon of mass destruction, we recommend that you follow these guidelines:

1. Always follow the decontamination procedures specified by the local Incident Command Safety Officer.
2. You should clean and decontaminate the equipment as soon as possible after use. Personnel should always wear the appropriate Personal Protective Equipment while decontaminating equipment.
3. Review the cleaning instructions that we provide in the previous section.
4. Since the potential amount of contaminants that the aspirator might be exposed to is so large, it is difficult to provide an appropriate cleaning method for each type of exposure. An effective cleaning agent for one type of exposure may not be effective with another. Cleaning and sterilizing practices may vary between institutions. Consult your facility's procedures for the cleaning and disinfection of medical equipment for further guidance.

Suction Canister and Tubing



Single patient use accessories, such as the collection canister, canister lid, and associated suction tubing, should not be cleaned or sterilized for reuse. Dispose of the canister, lid and associated suction tubing according to hospital policy or local protocols for the disposal of medical waste.

Battery Maintenance

The aspirator uses a rechargeable Li-ion battery, which offers a wide temperature operating range, and a long operating time. Avoid exposing the battery to direct sunlight or heat sources.

Following the guidelines that we describe in this chapter prevents premature depletion of the battery's charge and reduction of the battery's life.

Observe the warnings and cautions that follow for safe use of the battery:

Warning! **If you witness a battery or the battery compartment starting to balloon, swell up, smoke, or feel excessively hot, turn off the unit, disconnect external power, and observe it in a safe place for approximately 15 minutes and send the unit for service. Never puncture or disassemble the battery packs or cells.**

Only use the Power Supply provided with the device . Use of any other power supply could damage the aspirator or cause a fire and destroy the device.

Caution Never attempt to completely discharge the battery by shorting it or some other method and never ship the battery in a completely discharged state.

Caution During continuous, uninterrupted use (>100 hours), you should disconnect the aspirator from AC power for 30 seconds to allow the battery to run diagnostics while the battery is discharging.

Note: The aspirator continuously monitors the available power sources; occasionally a false Low Priority power alarm can be triggered for approximately 1 second. These false alarms immediately clear themselves.

While the unit is operating on battery power, you can best determine the relative amount of charge in the internal battery by looking at the BATTERY Icon. The BATTERY icon appears in outline form and is filled with horizontal rows of lines indicating its current capacity. Each line represents approximately 5% of battery capacity.

The aspirator monitors temperature and controls the charging and discharging of the battery under the following conditions:

- Best operating conditions are between 15 to 40°C (59 to 104 °F).
- -20 to 60 °C (-4 to 140 °F) for discharging
- 0 to 45 °C (32 to 113 °F) for charging

Best operating conditions are between 15 to 40°C (59 to 104 °F). The battery rapidly recharges to 90% of its capacity in approximately 2 hours. It takes approximately another 2 hours of trickle-charging to top off the battery to 100% of its capacity. Continuous charging is permissible with the AC/DC power supply and 12 VDC automotive cable that ZOLL provides.

Note: When connected to power for an extended period of time (> 30 days), the device indication may drop below 100% stored charge which allows the battery to perform diagnostics. To reset, power cycle by removing and reconnecting the connection to external power. Once this is done, the battery will recharge back to 100% in a few minutes. Note: If when operating on battery power the device shuts down due to loss of power, connect external power and power cycle the device to restore function.

Note: If when operating on battery power the device shuts down due to loss of power, connect external power and power cycle the device to restore function.

Battery Storage

Li-ion batteries discharge during storage. Higher temperatures (above 20° C (68 ° F) reduce the battery storage life.

Follow these rules to ensure the best storage life of the aspirator batteries:

1. Always store the aspirator with the battery fully charged. DO NOT store the aspirator with the batteries discharged.
2. For long-term storage, the optimum storage temperature range is -15 to 21°C (5 to 71°F). Avoid exposing the battery to direct sunlight or heat sources. It is not recommended to store batteries at high temperatures (above 40 °C (104 °F)).
3. If long-term storage is common, recharge the unit every six months; this ensures that the battery charge is maintained at 80% capacity or better.
4. When batteries are in extended storage, you should charge them at recommended intervals when not continuously connected to an external power source. See the table below.

STORAGE AMBIENT	RECHARGE INTERVAL
20 °C (68°F)	12 Months
20 to 30 °C (68 to 86 °F)	6 Months
30 to 40°C (86 to 104 °F)	3 Months

Aspirator Storage

For optimal prolonged storage, you should store the device indoors and follow the storage recommendations described in this chapter.

The environment should be clean and out of direct sunlight. Storage in non-controlled environments should only be done if batteries are removed. Follow the battery storage recommendations that we describe in this chapter.

Following 6 months (or longer) of continuous storage, inspect the device, perform an Operational Test, and recharge the unit's batteries before attempting to use it with a patient.

If the device has been stored in non-controlled environments (such as a vehicle), allow the unit sufficient time to stabilize to a temperature within its specified operating range.

Battery Replacement and Shipping Regulations

Only trained technicians at a authorized ZOLL Service Center can replace the aspirator's battery. Contact your local service center for return instructions and please note the following:

- Shipping of the aspirator's battery should always use proper State of Charge (SOC), which must never exceed 30%. The aspirator's Rechargeable Li-ion battery follows these and other important regulations, which IATA/DOT UN 38.3 mandates. The aspirator's battery is less than 100Wh, and thus is Classified as Class 9 Exempt and does not require Class 9 labeling or marking.
- Always check all applicable local, national, and international regulations before transporting a Li-ion battery.
- Transporting an end-of-life, damaged, or recalled battery may, in certain cases, be specifically limited or prohibited.

Functional Checks

The aspirator continuously performs a self check to monitor the pneumatic system.

You should always check the aspirator's vacuum level as part of the annual service procedure. Check the aspirator:

- Every 12 months.
- Whenever significant usage warrants a shorter period between preventative maintenance inspections.
- Whenever you suspect the unit is not functioning properly.
- Following mass deployment before the device is returned to storage.

You should maintain a record of functional checks for devices not returned to ZOLL for maintenance. If the unit fails the functional check, return it to ZOLL or an authorized Service Center.

To perform a functional check, you must use the ZOLL RCS system; only ZOLL-trained and certified personnel can use the ZOLL RCS system.

Troubleshooting

You can quickly address common problems by following the alarm mitigation instructions. Should this device fail to operate properly, verify the integrity of all accessories, suction tubing, and fitting connections. Check all control panel settings and follow the alarm mitigation instructions provided by the aspirator's Smart Help messages.

Verify that the vacuum port is not clogged or dirty. Check for operating power with internal batteries and external power sources.

If the tests above do not resolve an operating problem, service is required. Contact the closest authorized ZOLL Service Center or the ZOLL Customer Service Department.

The aspirator contains no user-serviceable parts. However, before contacting ZOLL or an authorized ZOLL Service Center, please check for the following possible causes of a failure.

Condition	Actions to Take
The device does not turn on.	1. Check that there is an appropriate connection to an external power source. 2. Verify that the power source is live by plugging in another device to check that it functions.
The pump is running, but there is no vacuum.	1. Check that all suction tubing is connected properly. 2. Check suction tubing connections for leaks or damage. 3. Check if the is full. If so, remove and replace according to section 3.2. 4. Check to make sure all of the ports on the collection canister are sealed appropriately.

Condition	Actions to Take
Pump runs but the device does not reach a high vacuum level.	1. Use Parameter Buttons and Rotary Encoder to increase vacuum level by turning clockwise. 2. Check for leaks.
The device does not run when operating on battery.	1. Plug device into an appropriate outlet for charging. Verify that the External Power Icon is displayed. 2. Verify that the power source is live. 3. Charge the battery ~2 hours before attempting to run on battery to maximize run time.

Disposal

Batteries



Li-ion batteries must be disposed of according to local policies and protocols.

Collection Canister



Single patient use accessories, such as the collection canister, canister lid, and associated suction tubing, should not be cleaned or sterilized for re-use. Dispose of the canister, lid and associated suction tubing according to hospital policy or local protocols for the disposal of medical waste.



To prepare the collection canister, lid with built-in filter, and suction tubing for disposal:

1. Turn off the aspirator and disconnect all suction tubing from the collection canister.
2. Seal vacuum and patient ports on the collection canister lid with the attached port caps.
3. Remove canister from the canister holder and transport to disposal area along with the suction tubing.
4. Place the collection canister and suction tubing in a biohazard bag and then seal it.

Device



At the end of its useful life the aspirator must be disposed of according to hospital policy or local protocol.

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 Pharyngeal Tracheal CASS	Adjustable 20 to 550 mm Hg Adjustable 60 to 400 mm Hg Adjustable 60 to 220 mm Hg 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

Specifications

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

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.
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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.
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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 part of the aspirator, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
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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.

Compliance for each emissions and immunity standard or test specified:

Emissions Test	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.		
RF emissions CISPR 11	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.
RF emissions CISPR 11	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.
Harmonic emissions IEF 61000-3-2	Class B	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Immunity Test	Test Level	Compliance Level
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 8 kV contact +/- 15 kV air	+/- 8 kV contact +/- 15 kV air
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
Surge IEC 61000-4-5	+/- 1 kV line(s) to line(s) +/- 2 kV line(s) to earth	+/- 1 kV line(s) to line(s) +/- 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 IEC 61000-4-8	30 A/m	30 A/m
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.

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.

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

Appendix C

Silent/Dark Mode Operation

Silent/Dark Mode is a feature available with the ZOLL Model 330 Multifunction Aspirator.

Under normal conditions, the aspirator's audible and visual alarms alert the operator to potential problems with the patient or ventilator. There are, however, situations where the audible and visual alarms could present a hazard to both the patient and operator by alerting others to their presence. In Silent/Dark mode, the aspirator:

- Suppresses the audible alarm.
- Suppresses the back lights for the LCD display and the **Confirm** and **Mute/Cancel** buttons.
- Emits only infrared light for the alarm LED indicator.

When operating in this mode, the LCD remains viewable by transreflecting visible light or with night vision goggles (NVG) equipment under dark conditions. The NVG equipment used in this mode of operation must be capable of detecting infrared light in order to enable the operator to detect alarm conditions.

Warning!	Never use Silent/Dark mode without the appropriate NVG equipment and always ensure that the NVG equipment is capable of detecting the infrared light prior to commencing operation
-----------------	---

Silent/Dark Mode Operating Procedure

Follow these steps.

1. Press both the **Main Menu** and **Standby** buttons while turning the device on. This configures the device to start with no visible light and no audible alarms. The device will display *SILENT/DARK MODE ENABLED. PRESS ACCEPT KEY TO ENTER SILENT/DARK MODE NOW*. Starting the device in this way enables Silent/Dark mode for the duration of the power cycle (turning off the device cancels Silent/Dark mode; it must be enabled again the next time the device is powered on).
 - a. Pressing **Confirm** while the message is displayed continues operation in Silent/Dark mode.
 - b. Pressing **Mute/Cancel** enables the audible and visual alarms and the LCD back light. In addition, Silent/Dark mode is added to the **Menu**, so that the operator can enter Silent/Dark mode at a later time for the duration of the current power cycle.
2. When aspirating in Silent/Dark mode, the operator should be extremely diligent in monitoring the patient and device.
3. To end Silent/Dark mode operation, press the **Main Menu** button, select *SILENT/DARK MODE*, then select *OFF*, followed by **Confirm**.
 - a. Silent/Dark mode can be reentered, provided the device has not been turned off.
4. When a High Priority alarm is detected, the infrared LED blinks at 2 Hz.
 - a. Pressing the **Mute/Cancel** button does not affect the infrared LED blink rate.
5. When the device detects a Low or Medium priority alarm, the infrared LED blinks at 1 Hz.
 - a. The infrared LED continues to blink while Medium Priority alarms are active. Pressing **Mute/Cancel** results in the infrared LED being lit continuously for 30 seconds.
 - b. The infrared LED blinks when the device detects a Low Priority alarm. Pressing the **Mute/Cancel** button stops the blinking, leaving only the persistent message.

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