

WELLS JOHNSON

WHISPERATOR ASPIRATOR

REF: 20-5026-00 Model 115 VAC

REF: 20-5028-00 Model 230 VAC

INSTRUCTIONS FOR USE



CAUTION: *Federal law restricts this device to sale by or on the order of a physician.*

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Device Description

The Whisperator Aspirator is a high-powered vacuum system intended for use during liposuction and adipose tissue harvesting procedures. The system generates negative pressure to facilitate the aspiration of adipose tissue through a compatible cannula and tubing set into a collection system.

The Whisperator Aspirator is equipped with two oilless piston vacuum pumps operating in parallel to provide the vacuum required for aspiration. When connected to compatible Wells Johnson tubing, cannula, and collection system, the aspirator creates negative pressure that aspirates adipose tissue and fluids through the cannula and tubing into the collection system.

CAUTION: *Carefully read these instructions before using the Wells Johnson Whisperator Aspirator. Keep these instructions in a safe place for future reference.*

Device Diagram



Intended Use

The Whisperator Aspirator is intended to provide controlled negative pressure for the aspiration of

adipose tissue during liposuction procedures.

Intended Users

The Whisperator Aspirator is intended to be used by qualified and trained healthcare professionals, such as licensed surgeons and operating room personnel.

Use Environment

The Whisperator Aspirator is intended for use in healthcare settings, including operating rooms and other clinical environments where liposuction procedures are performed.

Contraindications

No known contraindications.

Setup and Operation

1. Carefully remove the Whisperator Aspirator from the shipping container. Retain the shipping container and packing materials for use if the unit needs to be returned for service.
2. Place the Whisperator Aspirator on a level floor surface at the intended operating location. The Whisperator Aspirator is equipped with four casters. Engage the two front caster locks before operating the device. Ensure that the unit is positioned so that the ventilation openings are not obstructed and the power cord and tubing can be connected without creating a tripping hazard.
3. Open the accessory cardboard container and locate the following accessories:
 - Power cord
 - Footswitch
 - Vacuum gauge
 - Overflow trap assembly
 - Bacterial filters (2)
 - Sterile single-use tubing (set of 10)
 - Reusable collection canister(s)
 - Non-sterile single-use canister liner (set of 10)
 - IFU
4. Connect the footswitch to the designated connector on the Whisperator Aspirator.
5. Connect the power cord to the Whisperator Aspirator and then to an appropriate electrical outlet.
6. Locate the vacuum gauge and connect it to the quick-connect fitting on the top of the Whisperator Aspirator.
7. Locate the toggle switches for power and footswitch on the top panel of the Aspirator.

8. Turn the power switch ON.
9. Turn the footswitch ON.
10. To verify operation, place a finger over the main suction hose coming out of the top of the Whisperator Aspirator. Observe the vacuum gauge reading. Vacuum performance may vary with elevation. After verifying operation, turn the Whisperator Aspirator OFF.
11. Place the overflow trap between the four metal mounting pegs on the top panel of the Whisperator Aspirator. Position the overflow trap so that the arrow on the top points toward the vacuum gauge.
12. Connect the in-line bacterial filter to one end of the overflow trap using the 6-inch silicone tubing. Connect the other end of the bacterial filter to the main suction hose.

CAUTION: *Replace the in-line bacterial filter between patients.*

12. Set up the selected collection system according to the applicable instructions provided in this IFU. The Whisperator Aspirator is compatible with the following collection systems:
 - Baxter 1500 mL
 - Sorenson 2000 mL
 - Quick-Fit 3000 mL

Baxter Canister 1500 mL System Setup and Operation

1. Place the reusable canister in the canister holder on the top panel of the Whisperator Aspirator.
2. Snap the lid firmly to the liner, making sure that all locking tabs are engaged. Insert the assembled liner into the reusable canister. Press down firmly on the lid to ensure a proper seal.
3. Connect the red hose from the canister to the port on the top of the liner lid labeled **VACUUM**.
4. Connect the 9-inch silicone tubing from the overflow trap to the red port on the side of the canister.
5. Connect the sterile aspiration tubing to the port labeled **PATIENT**.

WARNING: *The Baxter Liner and liner lid are non-sterile and for single use only. Do not reuse. The hard-shell canister is reusable.*

CAUTION: *Do not use the Baxter Liner after the expiration date.*

WARNING: *Aspiration tubing is sterile and for single use only. Do not reuse. Reuse may result in cross-contamination.*

CAUTION: *Prevent aspirated material from entering the overflow trap.*

If the overflow trap becomes full or contains aspirated material, stop operation and refer to the “Overflow Condition” subsection under “Overflow Trap” for instructions.



Sorenson Canister 2000 mL System Setup and Operation

1. Place the reusable canister in the canister holder on the top panel of the Whisperator Aspirator.
2. Insert the Sorenson Liner into the canister. Make sure the liner lid properly seals the canister, and the canister Tee connector is securely tightened.
3. Connect the tubing attached to the liner lid to one end of the canister Tee connector.
4. Connect the 12-inch silicone tubing from the overflow trap to the other Tee connector.
5. Connect the sterile aspiration tubing to the port on the liner lid labeled **PATIENT**.

WARNING: *The Sorenson Liner and lid are non-sterile and for single use only. Do not reuse. Reuse may result in cross-contamination. The hard-shell canister is reusable.*

CAUTION: *Do not fill the canister beyond 1900 mL.*

WARNING: *Aspiration tubing is sterile and for single use only. Do not reuse. Reuse may result in cross-contamination.*

CAUTION: *Prevent aspirated material from entering the overflow trap.*

If the overflow trap becomes full or contains aspirated material, stop operation and refer to the “Overflow Condition” subsection under “Overflow Trap” for instructions.



Quick-Fit Canister 3000 mL System Setup and Operation

1. Place the reusable canister in the canister holder on the top panel of the Whisperator Aspirator.
2. Ensure that the stopcock is in the open position.
3. Insert the Quick-Fit Liner into the canister. Press the lid firmly around the perimeter to ensure a proper seal.
4. Connect the white vacuum hose to the **VACUUM** port of Quick-Fit Liner.
5. Connect the 12-inch silicone tubing from the overflow trap to the canister stopcock hose barb underneath the stopcock.
6. Connect the sterile aspiration tubing to the port on the liner lid labeled **PATIENT**. Cap all other unused ports.

WARNING: *Quick-Fit Liner is non-sterile and for single use only. Do not reuse. The hard-shell outer canister is reusable.*

WARNING: *Aspiration tubing is sterile and for single use only. Do not reuse. Reuse may result in cross-contamination.*

CAUTION: *Do not allow aspirated material to enter the overflow trap.*

If the overflow trap becomes full or contains aspirated material, stop operation and refer to the “Overflow Condition” subsection under “Overflow Trap” for instructions.



Device Specifications

Specification	Description
Weight	80 lb
Dimensions	18.5 in × 18 in × 15 in
Voltage/Frequency: Model 20-5026-00	110–120 VAC, 50 Hz 115–120 VAC, 60 Hz
Voltage/Frequency: Model 20-5028-00	220–240 VAC, 50 Hz 230–240 VAC, 60 Hz
Configuration	Mobile
Maximum Vacuum	26.5 inHg (at elevation 2389 ft)
Maximum Air Flow Rate	4.0 ft ³ /min
Vacuum Gauge Units	inHg / kPa
Overflow Protection	Automatic cutoff
Microbial Filtration	In-line bacterial filter
Sound Level	50 ± 3 dB at 6 ft
Pump Type	Two-cylinder piston
Number of pumps	2
Motor Power	2/3 hp

NOTE: The number of canisters supplied depends on the collection system ordered.

Collection System	Number of Canisters
Baxter Canister 1500 mL	1
Sorenson Canister 2000 mL	2

Collection System	Number of Canisters
Quick-Fit Canister 3000 mL	1

Component Description

1. Vacuum Pumps

The Whisperator Aspirator uses:

- Two 1/3 hp, two-cylinder piston pumps operating in parallel
- Oil-less, non-lubricated pistons and cylinders
- Permanently lubricated ball bearings
- Stainless steel valves
- Lightweight aluminum components
- Long-life, high-performance piston seals
- Twin-fan cooling system
- UL-recognized motors
- Thermal protection
- Balanced for low vibration operation
- Capacitor

2. Circuit Breaker

The circuit breaker is designed to protect the equipment from electrical overload and reduce the risk of electric shock. A resettable circuit breaker is located on the right side of the Whisperator near the power cord connection.

If an electrical overload or motor overheating condition occurs, the circuit breaker may trip.

To reset the circuit breaker:

1. Turn the Whisperator OFF.
2. Allow the unit to cool if overheating has occurred.
3. Push the circuit breaker button inward to reset it.
4. Turn the Whisperator ON.

If the unit does not restart after resetting the circuit breaker and allowing the unit to cool, discontinue use and contact Wells Johnson Customer Service for assistance.

WARNING: *Do not bypass, disable, or defeat the circuit breaker. Only qualified technicians may service or troubleshoot the electrical system.*

Thermal Protection: The motors are equipped with thermal protection. If a motor overheats, it will automatically stop and restart after it has cooled to a safe operating temperature. Ensure the aspirator is positioned and operated in a manner that prevents unintended movement or contact during automatic restart.



3. Vacuum Control

The Vacuum Control adjusts the vacuum level generated by the Whisperator Aspirator. Turn the control toward **HIGH** to increase vacuum or toward **LOW** to decrease vacuum. The vacuum gauge indicates the vacuum level.

NOTE: *Vacuum performance may vary with elevation above or at sea level. The vacuum gauge indicates the vacuum level at the device.*

4. Volume Control

Volume Control adjusts the airflow through the aspiration system. Turn the control toward **HIGH** to increase airflow or toward **LOW** to decrease airflow.

NOTE: *Do not position both the Vacuum Control and Volume Control in the **LOW** position at the same time, as this may result in little or no noticeable suction.*

5. Footswitch

The Whisperator Aspirator can be operated with or without a footswitch.

A. Operation With Footswitch:

1. Connect the footswitch cord to the designated connector on the Whisperator Aspirator.
2. Turn Power switch and footswitch toggle to **ON**.
3. Press the footswitch pedal to start the Whisperator Aspirator.
4. Press the pedal again to stop the operation.

B. Operation Without Footswitch:

Turn the Power switch to **ON** and leave the footswitch toggle in the **OFF** position.

NOTE: *The power switch must be in the **ON** position for the Whisperator Aspirator to operate.*

6. Overflow Trap

The overflow trap is designed to help prevent aspirated material from entering the Whisperator Aspirator vacuum pump if material bypasses or overflows from the collection system.

If aspirated material enters the overflow trap, the liquid level causes the float inside the trap to rise and interrupt the vacuum pathway.

WARNING: *The overflow trap is a protective component intended to help prevent aspirated material from entering the vacuum pump. Do not rely on the overflow trap as the only protective measure to prevent aspirated material from entering the vacuum pump.*

WARNING: *If tissue enters the pumps, the pumps may become contaminated with potentially infectious biological material and may pose a biological hazard to personnel. Immediately*

discontinue use of the unit. Do not attempt to open, clean, or service the pumps. The unit must be removed from service and replaced.

Overflow Condition: If aspirated material enters the overflow trap, perform the following steps:

1. Turn the Whisperator Aspirator **OFF** immediately.
2. Check liner positioning.
3. Check all tubing connections.
4. Check tubing for kinks or obstruction.
5. Check all tubing and accessory connections to ensure the system is correctly assembled.
6. Inspect the canister for cracks or other damage.
7. Confirm the vacuum pathway is correctly assembled.
8. Restart only after the cause has been corrected.

Verify that the vacuum and volume controls are set to the **HIGH** position.

NOTE: *A collapsing liner or aspirated material entering the overflow trap does not necessarily indicate a problem with the Whisperator Aspirator. These conditions may result from an interruption or obstruction of the vacuum pathway. Check the liner, tubing, and all connections to ensure the vacuum pathway is correctly assembled and unobstructed. If the overflow condition cannot be corrected, discontinue use and contact Wells Johnson Customer Service or Technical Support.*

Cleaning and Disinfection

Clean and disinfect the exterior surfaces of the Whisperator Aspirator between patients and whenever contamination occurs.

1. Turn the Whisperator Aspirator OFF and disconnect the power cord from the electrical outlet before cleaning.
2. Remove and dispose of all single-use tubing, liners, and other single-use components according to facility protocols. Replace the bacterial filter between patients.
3. If the reusable collection canister is used, remove, clean, and disinfect the canister.
4. Wipe the exterior surfaces of the Whisperator Aspirator with a soft, lint-free cloth moistened with an appropriate hospital-grade disinfectant. Follow the disinfectant manufacturer's instructions for application and contact time.
5. Allow the surfaces to dry completely before reconnecting the device to the power supply or using the device on another patient.

CAUTION: *Do not immerse the Whisperator Aspirator in water or other liquids. Do not allow liquid to enter the device, electrical connectors, switches, or other openings.*

CAUTION: *Do not spray cleaning or disinfecting solutions directly onto the Whisperator*

Aspirator.

Cleaning the Reusable Canister:

Clean and disinfect the reusable outer canister (Baxter, Sorenson, and Quick-Fit) after each use.

Recommended cleaning agents include warm water with soap, ethanol, isopropanol, or bleach. Follow the cleaning agent manufacturer's instructions for use, including recommended concentration, contact time, and rinsing requirements.

CAUTION: *Do not use strong alkaline, acetone-based, or phenol-based cleaners, as they may cause chemical degradation of the material and result in product failure.*

Maintenance

The Whisperator Aspirator does not require routine lubrication. The pumps contain oilless, sealed components that are lubricated during manufacture and do not require additional lubrication.

- Do not lubricate the pumps.
- Do not allow liquid or aspirated material to enter the pumping system.
- Inspect the Whisperator Aspirator before each use for visible damage or other conditions that could affect operation. Do not operate the device if damage is observed.
- Verify proper vacuum operation before use.
- Replace the in-line bacterial filter between patients.
- Replace the mufflers after approximately 80 hours of operation.
- No other routine preventive maintenance is required. If service or repair is needed, contact Wells Johnson Customer Service or Technical Support.

WARNING: *Do not modify or alter the Whisperator Aspirator. Servicing or modifications must be performed only by authorized personnel.*

Part List

ITEM	PART NUMBER
Power Cord for 20-5026-00 Model 115 VAC	20-5100-00
Power Cord for 20-5028-00 Model 230 VAC	20-5101-00
Power Cord Type G for 20-5028-00 Model 230 VAC	20-5101-13
Internal Tubing Kit	17-5003-00
Muffler	16-5075-00
Footswitch (Single)	20-5102-00
Footswitch (Dual)	20-5103-00

ITEM	PART NUMBER
Vacuum Gauge	16-5030-00
In-line Bacterial Filter (case of 10)	20-5201-00
Overflow Trap Assembly	17-5100-00
Baxter Canister Holder	20-5159-01
Baxter Canister Outer Reusable 1500 mL	20-5153-00
Baxter Liner Single-Use, Non-Sterile 1500 mL (case of 10)	20-5154-00
Standard Ultra-Limp Aspiration Tubing, 9 ft, Sterile, Single-Use (case of 10)	24-5103-00
Sorenson Holder	20-5159-00
Sorenson Reusable Canister 2000 mL	20-5157-00
Sorenson Non-sterile, Single-Use Liner 2000 mL (case of 10)	20-5158-00
MB Ultra-Limp Aspiration Tubing, 9 ft, Sterile, Single-Use (case of 10)	24-5104-00
Quick-Fit Canister Holder	20-5159-03
Quick-Fit Reusable Canister 3000 mL	20-5156-00
Quick-Fit Non-sterile, Single-Use Liners 3000 mL (case of 10)	20-5155-00

Troubleshooting

SYSTEM WILL NOT POWER ON

- Ensure the supplied power cord is fully seated in the receptacle on the side of the machine and connected to the appropriate wall outlet. If the unit still does not power on, contact Wells Johnson Company Customer Service.
- The circuit breaker may have tripped due to a voltage surge or overheating of the motors during previous use. If the circuit breaker has tripped, reset it by pushing it in. If the unit still does not power on, contact Wells Johnson Customer Service.

LITTLE TO NO SUCTION

- Ensure the “Volume Control” knob on the top of the Whisperator is in the “High” position and the “Vacuum Control” knob is adjusted as needed. If both controls are in a low position, there may be little or no noticeable suction.
- Verify that all tubing is free of kinks and securely attached to the barbs of the bacterial filter, overflow trap, canister and cannula.
- Ensure the canister, liner and lid are properly connected.
- Check that the overflow trap and bacterial filter are securely connected and free of clogs or occlusions.
- If the liner is collapsing, replace the canister. A collapsing liner may indicate a cracked canister.
- Ensure the aspiration tubing is the correct tubing specified by Wells Johnson Company.
- Inspect all suction lines to ensure they are free of tissue, kinks and clogs. If tissue enters the pumps, immediately discontinue use of the unit.

WARNING: If tissue enters the pumps, the pumps may become contaminated with potentially infectious biological material and may pose a biological hazard to personnel. Immediately

discontinue use of the unit. Do not attempt to open, clean, or service the pumps. The unit must be removed from service and replaced.

FOOTSWITCH NOT WORKING

- Ensure the toggle switch labeled “Footswitch” on the top of the Whisperator is in the “ON” position.
- Check that the footswitch is fully inserted into the receptacle and twisted to secure the connection.

NOTE: *Before starting an aspiration procedure, allow the Whisperator to reach full vacuum after switching it on. If the Whisperator is temporarily turned off during operation, allow the vacuum gauge indicator to return to “0” before restarting the machine. Allow all air to clear from the vacuum lines before resuming operation. Failure to follow this procedure may result in loss of vacuum.*

Symbols Used

Symbol	Title	Description	Standard
	Manufacturer	Indicates the medical device manufacturer	ISO 15223-1:2021, 5.1.1
	Catalog number	Indicates the manufacturer’s catalog number so that the medical device can be identified	ISO 15223-1:2021, 5.1.6
	Serial number	Indicates the manufacturer’s serial number so that a specific medical device can be identified	ISO 15223-1:2021, 5.1.7
	Consult instructions for use or consult electronic instructions for use	Indicates the need for the user to consult the instructions for use	ISO 15223-1:2021, 5.4.3
	Medical device	Indicates the item is a medical device	ISO 15223-1:2021, 5.7.7
	Prescription Only	Federal law restricts this device to sale by or on the order of a physician	FDA-recognized prescription-device designation under 21 CFR 801.109
	Unique Device Identifier	Indicates a carrier that contains unique device identifier information	ISO 15223-1:2021, 5.7.10

Symbol	Title	Description	Standard
	Quantity	Indicates the quantity of product contained in the labeled container.	None

WARRANTY

- The Whisperator Aspirator is warranted for five (5) years for parts and labor from the date of shipment.
- Unauthorized handling, modification, or servicing of the Whisperator Aspirator may void the warranty.
- Ingestion of aspirated material into the pumping system will void the warranty.
- Retain the custom-made shipping container and foam packaging for use if the unit needs to be returned for service.
- All returns require prior authorization from Wells Johnson Customer Service.

Customer Service and Technical Support

Report any product malfunction, adverse event, or complaint to Wells Johnson Customer Service or Technical Support:

Phone: +1 520-298-6069 or 800-528-1597

Email: customerservice@wellsgrp.com



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