

cabot medical

Operations Manual

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CABOT MEDICAL CORPORATION
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 **BERKELEY**TM
**VACUUM
CURETTAGE
SYSTEMS**

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Berkeley™ Vacuum Curettage Systems
 Operations Manual
 Cabot Medical Corporation
 2021 Cabot Boulevard West
 Langhorne, Pennsylvania 19047 U.S.A.

LIMITED WARRANTY

This LIMITED WARRANTY AND LIMITATION OF BUYER'S REMEDIES (the "LIMITATIONS") applies to the goods now being purchased by the Buyer. It is expressly understood that these LIMITATIONS constitute a material part of the Purchase Agreement, and that Cabot Medical Corporation ("Cabot") would not enter into this sale without Buyer's agreement to these LIMITATIONS.

BUYER ACKNOWLEDGES THAT IT IS A MERCHANT AND IS EXPERIENCED IN THE USE OF the items being purchased.

I. LIMITATION ON AND EXCLUSION OF EXPRESS WARRANTIES

A. Cabot makes no warranty, express or implied, with respect to the goods being purchased except as set forth in this paragraph (#I.A). Cabot warrants, for a period of one (1) year from the date of shipment to the buyer (other than buyer for resale) that the goods shall be free from defects in material and workmanship when properly installed, maintained, handled and/or used for the intended purpose. The warranty applies only to the buyer (other than buyer for resale). The buyer (other than buyer for resale) must inspect this equipment within fourteen (14) days following receipt by the buyer and no claim for any defect then existing and discovered upon inspection shall be allowed unless made in writing to Cabot within a fourteen (14) day period. Any misuse, mishandling or modification of the equipment shall render this warranty null and void.

II. LIMITATION ON AND EXCLUSION OF IMPLIED WARRANTIES

The parties expressly agree that Cabot makes no IMPLIED WARRANTIES relating to the goods that Cabot expressly DISCLAIMS AND EXCLUDES all implied warranties, including but not limited to the IMPLIED WARRANTY OF MERCHANTABILITY and the IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE.

III. REPAIR OR REPLACEMENT

The Buyer's sole remedy, if the goods are found to be defective per paragraph (#I.A) above, shall be to have Cabot repair or, at Cabot's option, replace the defective parts without charge. Cabot reserves the right to make an examination and make the necessary repair/replacement in its own factory, at any authorized repair station, or at the Buyer's place of business. Any shipping charges incurred shall be prepaid by the Buyer. Any goods returned by Buyer for repair or replacement must be adequately protected for shipment by the Buyer and Cabot DISCLAIMS all responsibility to repair, replace or otherwise remedy goods injured during shipment. Cabot shall not, in any event, be liable for incidental or consequential damages, including but not limited to loss of income, loss of time, loss of sales, injury to personal property, liability of customer with respect to any other person, or for any other type or form of incidental or consequential damage or economic loss. This EXCLUSIVE REMEDY shall not be deemed to have failed of its essential purpose so long as Cabot is willing and able to repair or replace defective parts in the prescribed manner.

IV. BUYER'S ACKNOWLEDGEMENT

Buyer hereby agrees that neither Cabot nor its representatives have made any warranties through writings, oral statements, conduct, samples, models, descriptions, promises, affirmations of fact or otherwise, and that there are no warranties, except as provided explicitly in paragraph (#I.A) above.

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Berkeley™ Vacuum Curettage Systems have been designed to safely and rapidly evacuate the products of the first trimester of pregnancy. These systems enable a significant reduction in blood loss, myometrial damage and anesthesia requirement.

All Berkeley™ Vacuum Curettage Systems are equipped with a dual collection bottle system and a safety trap with automatic vacuum restriction. A high capacity, double diaphragm pump and vacuum system reaches optimum operating vacuum in about 5 seconds. The pump and motor are designed to require only minimal maintenance. Each VC system comes complete and ready to operate.

VC-2

The Berkeley™ VC-2 high performance model meets hospital operating room safety requirements and is designed for the ultimate in reliable service in a volume usage environment. The construction is rugged with stainless steel top, baked enamel sides and a protective rubber bumper. Rubber wheels are included for mobility and a storage compartment for convenience. A cord-wrap is provided on the back panel.

VC-5

The Berkeley™ VC-5 is a compact model designed for minimal space requirements and easy transport between facilities. The unit is equipped with carrying handles, mounted on rubber wheels, and easily rolls under tables or counters for storage. The stainless steel top and baked enamel sides are durable and easy to clean. A cord-wrap is provided on the back panel.

VC-7

The Berkeley™ VC-7 is designed to complement any clinical environment. Modern cabinet design features recessed collection bottles, a molded instrument tray on top and a storage compartment for supplies and accessories. Rubber wheels are included for mobility. The VC-7 is an extremely quiet operating model. A cord-wrap is provided on the back panel.

All references to Berkeley™ Bio-Engineering are likewise a reference to Cabot Medical Corporation in the context of this publication.

PREOPERATIVE ASSEMBLY

1. Open the shipping carton and remove the contents carefully, as some of the components are fragile. Collection bottles, hoses, and other accessories may be shipped in the unit's storage compartment or in a separate carton.
2. Verify that the line voltage rating shown on the back panel corresponds to the available power, either 115V AC 60 Hz, or 230V AC 50 Hz, and that the power receptacle to be used is grounded.
3. The VC-2 and VC-5 bottle holders must be attached to the top panel (VC-7 bottle holders are built-in).

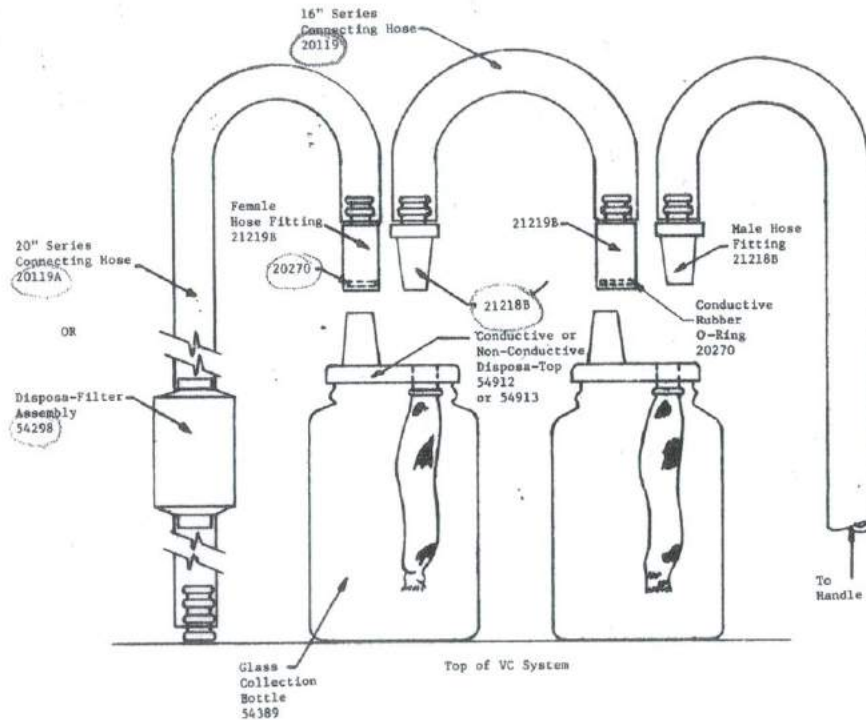
Insert the mounting screw — welded to the bottom of each bottle holder — into the top panel. Be sure that the secondary stabilizing post is inserted into the second hole on the top panel. Secure the mounting screws beneath the top panel using the lockwashers and wingnuts provided.

4. Place the collection bottles into the bottle holders and connect the tubing as shown in Collection System Hookup Diagram.
5. Select the appropriate Vacurette® and connect it to the collection tubing handle assembly.

The VC System is now ready to operate.

“Vacurette”® is a registered trademark of Cabot Medical Corporation.

PRELIMINARY INSTRUCTIONS



COLLECTION SYSTEM
HOOKUP DIAGRAM
FIG — 2.10

- * Disposa-Filter is NON-CONDUCTIVE and should NOT be used on systems-operated in an explosive atmosphere. Disposa-Filter should be replaced whenever the filter becomes soiled or clogged. Operating the system with a clogged filter can lead to vacuum deficiency and possible overheating and permanent motor damage.
- ** The white Disposa-Top, P/N 54912, is NON-CONDUCTIVE and should NOT be used on systems operating in an explosive atmosphere. Use the black, conductive Disposa-Top, P/N 54913, when operating in an explosive atmosphere.

VACUUM OPERATION

The maximum attainable vacuum, with the vacuum adjust valve completely closed (fully clockwise), at sea level, is approximately 73 cm Hg. There is a reduction of vacuum by 2.6 cm Hg per 1,000 feet (8.5 mm Hg per 100 meters) of elevation above sea level.

The vacuum adjust knob is pre-set at the factory in the fully *clockwise* (closed) position for maximum vacuum. If a reduction in vacuum is desired, turn the knob *counterclockwise*. To determine the maximum vacuum level available at any particular setting, turn the unit on and observe the vacuum reading on the gauge while completely occluding the intake opening of the collection bottle.

Vacuum-tight connections are assured when the collection system tapered fittings are properly connected and maintained. Proper sealing will maintain a consistent vacuum level throughout the system.

Important: If, when the system is "off", the vacuum gauge indicates the collection system has residual vacuum, bleed off the vacuum by turning the vacuum adjust knob *counterclockwise* before turning the power "on" or the pump motor will not start.

Vacuum Check

Continuous vacuum is supplied to the Vacurette® tip while the pump and motor are in operation, unless otherwise controlled by the slip ring on the rotating handle of the collection tubing assembly. This slip ring is used to open and close the orifice on the handle. The orifice is left open when the operator does not want vacuum at the Vacurette® tip.

To determine the vacuum that is being generated, place a finger over the inlet at the end of the hose and handle system of the collection bottle. Continue to occlude the opening and observe the vacuum gauge until it stabilizes. The level shown on the gauge is the maximum vacuum level at the particular setting of the vacuum adjust knob. Turn the vacuum adjust knob *counterclockwise* to decrease vacuum, or *clockwise* to increase vacuum. Verify that the vacuum gauge has stabilized after each knob adjustment before applying the system in a procedure.

TROUBLESHOOTING**Overloads**

Unless operating under conditions of very high ambient temperature and little or no ventilation, the motor should not overheat before one hour of continuous operation. Prolonged operation such as this is highly unlikely; nevertheless, the electric motor contains an internal thermal overload mechanism to protect against motor damage by shutting down the motor and pump if the motor begins to overheat. In the Model VC-2, the thermal overload protection is in the explosion proof switch.

When an overload occurs, the operator should turn the system power switch "Off", open the motor compartment door, and allow sufficient time for the motor to cool. The motor will start up again when its temperature has been reduced sufficiently. The motor is still too hot if it does not start up when the power switch is "On".

No Motor Function

If the motor does not function when the power is turned on and the motor is not potentially overheated, check the electrical connection at the wall socket. Examine the plug and cord for wear. Worn parts should be repaired or replaced. If no problem is apparent, open the motor compartment and check the connection between the power supply and the motor. Contact Cabot Medical Corporation Service Department for further assistance.

Insufficient Vacuum

If the motor functions, but the vacuum gauge indicates insufficient vacuum (vacuum level is below the green zone on the gauge), or if the vacuum gauge reads appropriately (in the green zone) but little or no vacuum is present at the Vacurette® tip, then there is either a leak or blockage within the collection system. The following troubleshooting procedure is recommended.

Step 1. Verify that the lack of vacuum is not caused by improper vacuum adjust knob setting. Turn the vacuum adjust knob clockwise until it stops. Read the vacuum gauge and fingercheck* suction at the Vacurette® tip. If the vacuum level is not adequate, go on to Step 2.

* Momentarily occluding the vacuum line or fitting with a finger to estimate the level of vacuum available at that particular point.

TROUBLESHOOTING

Step 2. Examine the slip ring on the Vacurette® handle. If the ring is worn or marred, the handle should be replaced or repaired. Read the vacuum gauge and fingercheck suction at the Vacurette® tip. If the vacuum level is not adequate, go on to Step 3.

Step 3. The connection between the Vacurette® handle and the hose should be checked for cracks and leaks. If no problem seems to exist, disconnect the Vacurette® hose assembly at the inlet to the first collection bottle. Examine the O-Ring fitting and examine the Disposa-Top for wear. If either of these are worn, replace them. Read the vacuum gauge and fingercheck* suction at the bottle opening. If the vacuum level is not adequate, go on to Step 4.

Step 4. Repeat Step 3 to check out second collection bottle. If the vacuum level is still not adequate, go on to Step 5.

Step 5. Disconnect collection hose (or Disposa-Filter) at the inlet fitting on the top panel of the unit. Fingercheck this fitting and read the vacuum gauge. If the gauge reads maximum, the Disposa-Filter or hose should be replaced. If the vacuum is *not* at maximum level, proceed to Step 6.

Step 6. Open the upper and lower compartments of the unit. Check the continuity of the vacuum line between the second collection bottle and the pump. Inspect for kinks, leaks, and obstruction along the tubing, and at each fitting. Examine carefully the safety trap and its float ball. Liquid will collect in the trap if the collection bottles overflow. The float ball will rise to the roof of the jar and reduce the vacuum. Any fluid in the trap must be removed. The trap should be disassembled by unscrewing the trap jar. Discard contents. Clean jar and float ball thoroughly. Check trap body for blockage of port openings. If no cause for blockage is found, leakage may be suspected. Check jar for cracks and leaks, the gasket for wear, and the jar fitting for looseness. Replace any worn parts. The jar with float ball should be reassembled into the trap body. Check for firm jar seat against the trap body gasket to avoid leakage. Fingercheck the top panel inlet fitting again, reading the vacuum gauge, and if the vacuum level is still not satisfactory, go on to Step 7.

TROUBLESHOOTING

Step 7. Disconnect the tubing at the inlet fitting to pump head #1. Attach a vacuum gauge known to be in good working condition to the pump head. If vacuum is appropriate according to this external gauge, then the pump is functioning well and the problem appears to be a faulty vacuum gauge in the top panel. The gauge should be replaced, the tubing reconnected at the inlet fitting to the pump head, and the vacuum level checked. If the external vacuum gauge did *not* indicate the appropriate vacuum level, then the pump requires service. If so, the entire unit may have to be returned to the factory for pump repair or replacement. Contact Cabot Medical Corporation Service Department for further information.

The VC-2 contains one further checkpoint in the troubleshooting sequence:

If the motor seems to be functioning, yet vacuum is still insufficient or non-existent, check the coupling between the motor and pump for cracks or breaks. If the coupling is not secure, it should be replaced. Contact Cabot Medical Service Department for assistance.

WARNING: Whenever operational difficulties are encountered and resolved, A THOROUGH TEST OF THE ENTIRE UNIT MUST BE MADE PRIOR TO BEGINNING ANOTHER SURGICAL PROCEDURE. Attach a Vacurette® and aspirate 100 to 200cc of water into the first collection bottle to verify the operating integrity of the VC System.

MAINTENANCE

- Check the float ball mechanism within the safety trap periodically. Whenever any liquid is present, the trap should be cleaned thoroughly with soap and water. Be sure the safety trap is dry before reinstalling it.
- Clean any soiled areas on the cabinet with a small amount of soap and water and a soft cloth or sponge.
- Replace Disposa-Filter when it becomes soiled or clogged.

NOTE: The pump and motor do not require lubrication. All moving parts are self-lubricating.

CONDUCTIVE HOSE STERILIZATION PROCEDURE

STEAM STERILIZATION

1. Immerse the hose in a medical grade detergent and water solution for ten (10) minutes.
2. Flush the hose thoroughly, first with cold tap water, then with distilled water.
3. Coil the hose loosely with the conductive stripe to the inside, and wrap the coil in a surgical wrap. Do *NOT* coil the tubing tightly, or allow it to kink; otherwise the hose may develop stress cracks and lose conductivity.
4. Autoclave at 250°F (121°C) for ten (10) minutes. Follow the autoclave manufacturer's instructions.

The hose will normally turn cloudy during the sterilization process. This cloudiness will disappear as the wrapped hose returns to room temperature.

CHEMICAL DISINFECTION

1. Immerse the hose in a medical grade detergent and water solution for ten (10) minutes.
2. Flush the hose thoroughly, first with cold tap water, then with distilled water.
3. Immerse the hose in cold sterilizing solution for at least thirty (30) minutes.
4. Flush the hose with sterile saline solution.

GAS STERILIZATION

1. Immerse the hose in a medical grade detergent and water solution for ten (10) minutes.
2. Flush the hose thoroughly, first with cold tap water, then with distilled water. Thoroughly wipe or air dry the hose prior to sterilization.
3. Coil the hose loosely with the conductive stripe to the inside, and wrap the hose using standard wrapping procedure.
4. Follow the sterilizer manufacturer's operating instructions, allowing a minimum of three (3) hours exposure time. A minimum of seven (7) days aeration time should be provided following sterilization to reduce ethylene oxide residues to acceptable limits.

A catalog containing complete descriptions and ordering information for Berkeley™ VC Systems accessories and supplies is available from Cooper Medical Corp. Some supplies are presented here.

VACURETTE®

Semi-rigid vacuum aspiration curette with rounded tip, insertion depth marker, and tapered to fit Swivel Handle and Disposable Collection Set. (10 per package)

Order No.	Size
21655	8mm Straight
21413	9mm Straight
21414	10mm Straight
21415	11mm Straight
21416	12mm Straight
20317	8mm Curved
21552	9mm Curved
21553	10mm Curved
21554	11mm Curved
21555	12mm Curved

VACURETTE® F TIP

Flexible (Karmann cannula type) vacuum aspiration curette with rounded tip, dual ports, insertion depth marker, and tapered to fit Swivel Handle and Disposable Collection Set. (10 per package)

Order No.	Size
21663	4mm
21664	5mm
21665	6mm
21744	7mm
21745	8mm

VACURETTE® F SET

Flexible (Karmann cannula type) vacuum aspiration curette (identical to F Tip) complete with six feet (1.8 m) of vacuum tubing and tapered fitting.

Order No.	Size
23138	5mm
23135	6mm
23157	7mm
23158	8mm

PERMEABLE GAUZE SACKS

Gauze collection sack readily attaches to the collection bottle for simple and efficient separation of tissue from aspirated fluid. (10 per package)

Order No. 21163

DISPOSABLE COLLECTION SET

Rotating vacuum flow-control handle with a slip ring for fingertip control, six feet (1.8 m) of vacuum tubing, and tapered fitting.

(10 per package)

Order No. 23116

DISPOSA-FILTER ASSEMBLY

Disposable Filter system designed to prevent aspiration material from reaching the pump and motor of the VC system. (10 per package)

Order No. 54298

DISPOSA-TOPS

Disposable or reusable plastic bottle tops for use with the Glass Collection Bottle (Order No. 54389). This Disposa-Top system is clean, comes ready to use with the Permeable Gauze Sack attached, and is simple to install and remove. Disposa-Tops are available in two styles: Non-Conductive (white) or Conductive (black) for specific use in explosive atmosphere. (10 per package)

Order No.

54912	Non Conductive Disposa-Top
54913	Conductive Disposa-Top

GLASS COLLECTION BOTTLE

Glass collection bottle (1/2 gallon with graduations to 1400 cc) with a wide mouth for ease in cleaning and a translucent band to reduce the visibility of the aspirated material from the patient. Conductive or Non-Conductive Disposa-Tops must be used with this bottle.

Order No. 54389

CONDUCTIVE HOSE, HANDLE, AND MALE FITTING ASSEMBLY

Metal swivel handle (Order No. 23127), nine foot (2.7 m) conductive hose (Order No. 21387), and male fitting (Order No. 21218B). Designed for use with 8 to 12 mm Vacuorettes and 4 to 8 mm Vacurette F Tips. Entire assembly is reusable.

Order No. 23039B

CONDUCTIVE HOSE

Reusable conductive hose, nine feet (2.7 m) long and 1/8 inch (9.5 mm) inner diameter.

Order No. 21387

METAL SWIVEL HANDLE ASSEMBLY

Metal swivel handle with slip ring for finger tip vacuum control. Designed for use with 8 to 12 mm Vacuorettes and 4 to 8 mm Vacurette F Tips.

Order No. 23127

SERIES CONNECTING HOSES

Between collection bottles: 16 inch (40 cm) conductive hose.

Order No. 20119

Between second collection bottle and VC System: 20 inch (50 cm) conductive hose.

Order No. 20119A

LAMICEL™ OSMOTIC CERVICAL DILATOR

A sterile disposable tent made of polyvinyl alcohol surgical sponge, impregnated with magnesium sulfate (<400 mg). The tent is shaped to assume easy, safe insertion and passage into the endocervical canal to just beyond the internal os. (20 per box)

Order No.	Size
002202-501	3mm
002203-501	5mm