



Instructions for Use

US Patents 6,620,171 ; 6,872,212 ; 6,901,345
Other Patents Pending

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 **M E D E V C O**
The Medical Device Company

Instructions for Use

VacuLink

VacuLink is a disposable monitoring system that interfaces with the vacuum devices configured with Luer fittings and the maternal/fetal monitor. It provides a real time record of the vacuum events that occur during a vacuum assisted delivery (such as vacuum, number and duration of pulls and number of pop-offs). Note: VacuLink is compatible with Philips (HP), GE (Corometrics) and Spacelabs monitors.

VacuLink electronically displays and prints the vacuum events of delivery on the maternal/fetal monitor. The data is permanently archived by the central monitoring system.

The VacuLink is intended for obstetric use in the measurement and recording of data related to vacuum-assisted delivery (such as vacuum, number and duration of pulls and number of pop-offs) on the strip chart.

Contraindications

This device is contraindicated for use when labor monitoring requires continuous display of uterine activity. VacuLink requires connection to uterine activity channel of maternal/fetal monitor, thus removing uterine activity from continuous display.

If operator believes uterine activity tracing is of higher importance than electronically monitoring vacuum delivery, do not use VacuLink.

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VacuLink

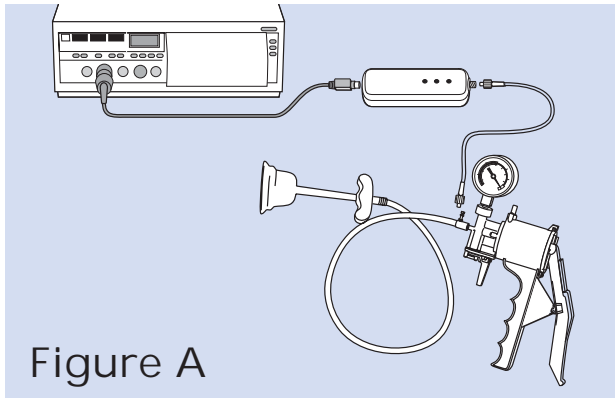


Figure A

VacuLink Connected to Maternal/Fetal Monitor and Mityvac® Vacuum Device

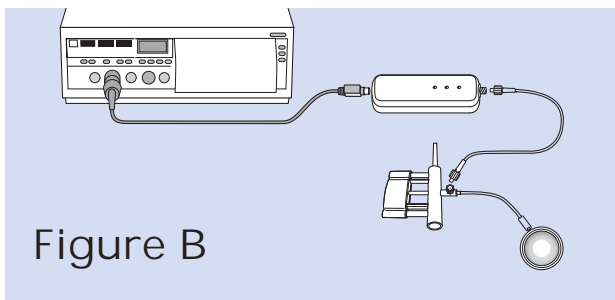
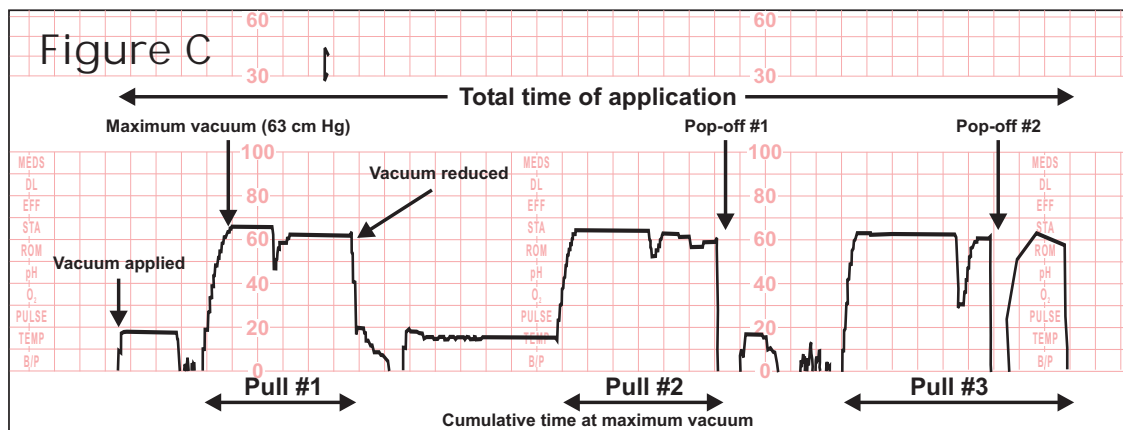


Figure B

VacuLink Connected to Maternal/Fetal Monitor and Kiwi® Vacuum Device



Sample VacuLink Tracing

Definitions

Total Time of Application: Amount of time from initial application of vacuum cup until delivery.

Vacuum Applied: Precise time when vacuum is applied to fetal head.

Maximum Vacuum: The highest recorded vacuum value.

Pull: "Pull" refers to pulling efforts which coincide with a contraction; there are generally three distinct pulling episodes per contraction.

Vacuum Reduced: Common US practice is to release vacuum between contractions in order to maintain cup application to fetal head at lower than maximum vacuum amount.

Pop-off: "Pop-off" or involuntary release of vacuum, is noted by immediate drop in vacuum tracing to zero cm Hg.

Preparation

Step 1 Gather necessary equipment and supplies:

- VacuLink package (device, sterile tubing)
- "T" Adaptor (Mityvac®)
- Reusable Blue VacuLink cable
- Maternal/fetal monitor
- Vacuum delivery device

Step 2 Plug reusable VacuLink cable into uterine activity channel of maternal/fetal monitor channel designated UA or Toco (see Figure D).

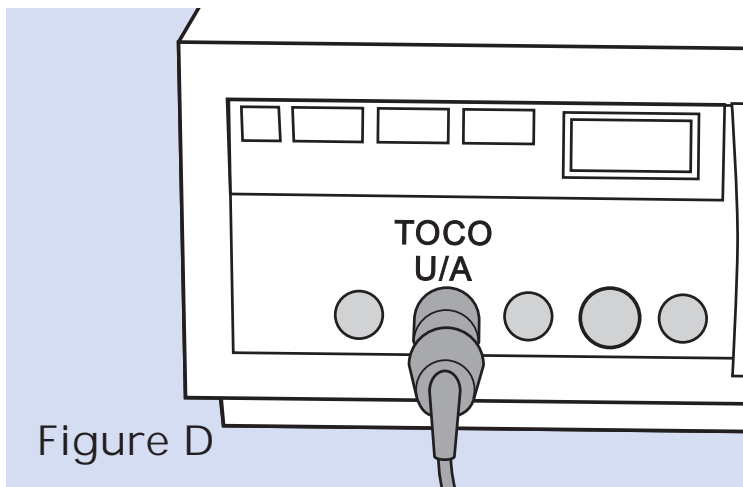


Figure D
VacuLink Cable Connected to Maternal/Fetal Monitor

Note: VacuLink is compatible with Philips (HP), GE (Corometrics) and Spacelabs monitors.

Step 3 Open VacuLink package and remove VacuLink and sterile tubing.

Step 4 With Kiwi products, place sterile tubing on the delivery table using aseptic technique. Deliveries using Mityvac® do not require that the tubing remain sterile.

Connection

Step 5

Connect VacuLink mini-DIN connector to blue VacuLink cable (see Figure E).

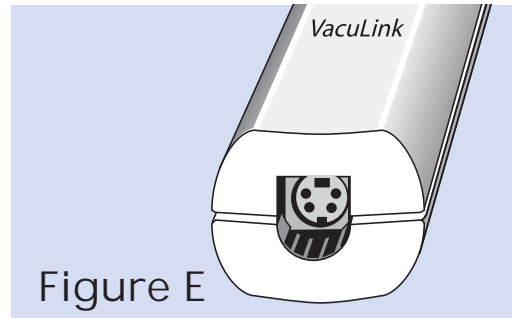






Figure E
VacuLink mini-DIN Connector

Step 6

Power On Self Test occurs after connection. Watch for LEDs to illuminate as follows (see Figure F):

-  Red illuminates for 1-2 seconds
-  Yellow illuminates for 1-2 seconds
-  Green flashes for 10 seconds
-  Green becomes solid

Solid green indicates VacuLink is ready for operation
Note: If solid green does not illuminate see Troubleshooting (Page 5)

Warning: The VacuLink system does not contribute any information to the assessment of maternal or fetal well-being

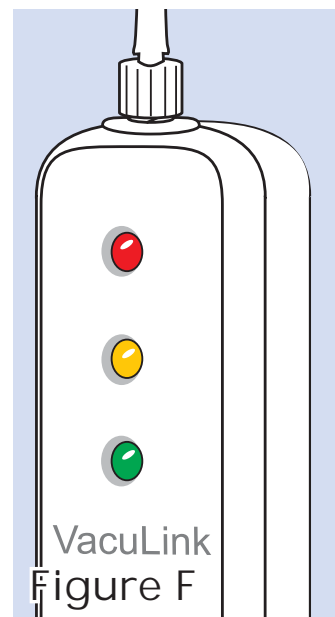


Figure F
Power On Self Test LEDs

Step 7

Zero to atmosphere according to monitor manufacturer's instructions.
Note: Procedure is same as with IUPCs.

Do not zero system until Power On Self Test is complete

Step 8

Connect VacuLink tubing to Luer fitting. (see Figure G).

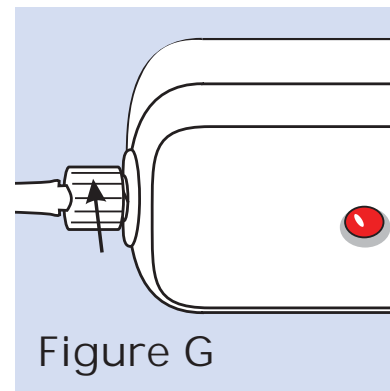


Figure G
VacuLink Luer Fitting

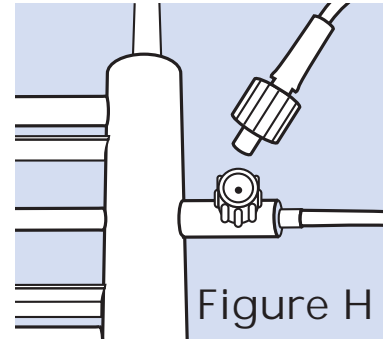
Connection (con't)

Step 9

Connect sterile tubing to vacuum device Luer fitting.

For Kiwi, remove Luer cap and attach tubing to pump (see Figure H).

For Mityvac[®], ensure that "T" adaptor is attached to vacuum port on pump, then attach tubing to Luer fitting on "T" adaptor (see Figure I).

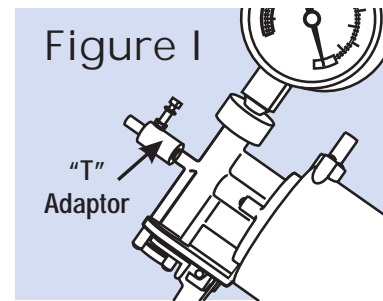


Kiwi Luer Fitting

Step 10

Per manufacturer's recommended guidelines, test vacuum system and verify vacuum values are being displayed on maternal/fetal monitor.

Note: If vacuum values are not displayed, see Troubleshooting section (Page 5).



"T" Adaptor Luer Fitting on Mityvac[®] Pump

Procedure

Step 11 Perform vacuum procedure according to standard hospital protocol.

Use vacuum cup in accordance with manufacturer's guidelines for use

Clean Up

Step 12

Disconnect VacuLink from blue cable and discard disposable parts according to hospital protocol as follows:

For Kiwi, discard VacuLink, tubing and Kiwi as connected.

For Mityvac[®], discard VacuLink, Mityvac[®] cup and all tubing. Save "T" adaptor from Mityvac[®] pump (see Figure I).

Do not discard reusable blue VacuLink cable

Troubleshooting

No solid green during Power On Self Test

If VacuLink LEDs do not transition to solid green during Power On Self Test (see Page 3, Step 6), check the following:

- If red LED illuminates continuously, VacuLink has been previously used and will not function. Discard and use new VacuLink.
- If yellow LED illuminates but does not transition to green, battery is low. Use new VacuLink and contact Medevco for replacement.

LEDs Fail to Illuminate

If LEDs fail to illuminate after cable is connected, do the following:

- Check cable attachments to both maternal/fetal monitor and VacuLink.
- If cable is correctly attached and lights still do not illuminate for Power On Self Test, exchange VacuLink cable.

Unable to Maintain Vacuum

If the vacuum cup is properly applied to fetal head and vacuum is leaking, check following:

- Ensure that VacuLink tubing is tightly connected to Luer fittings on vacuum pump and VacuLink.
- For Mityvac[®] deliveries, ensure "T" adaptor is properly fitted to Mityvac[®] pump and vacuum cup tubing is properly connected to adaptor.

Miscellaneous

If electronic monitoring equipment (including VacuLink or the maternal/fetal monitor) appears to malfunction during the delivery, do not initiate troubleshooting activities until the fetus is safely delivered. After delivery the following procedure may resolve possible problems with electronic interference.

The computer within the VacuLink may create a radio frequency energy that could affect the operation of other electrical equipment in the immediate area. If such interference is suspected, turn the VacuLink 90 degrees from its original position or move the VacuLink farther away from the malfunctioning equipment. If interference persists, seek other sources of radio frequency energy and follow corrective actions recommended by the manufacturers of those devices.

Pop-Off Versus Manual Release

To create a tracing and record commensurate with vacuum events, be mindful of the following:

1. When the vacuum pump is manually released too rapidly, the record of the event on the maternal-fetal monitor tracing may appear to be identical to that of a pop-off. In that case, such an interpretation after the delivery would be erroneous. To prevent such an interpretation, it is recommended that the pump operator reduce the vacuum gradually after each contraction so that the record will indicate that vacuum was intentionally released.
2. Also, some manufacturers recommend the option of reducing vacuum to a lower level between contractions. In following this recommendation, the tracing will reflect the time periods where maximum vacuum was maintained; which should correlate with the mother's contractions and the physician's pulling attempts. If your practice is to lower vacuum between contractions, reduce the vacuum slowly at the completion of each contraction, but at a level sufficient to keep the cup attached to the fetal head.

Equivalent Vacuum Values

cmHg	mmHg	kPa	Kg/cm ²	Inches Hg	cm H ₂ O	lb/in ²	bar
10	100	13	0.13	3.9	134	1.9	0.13
20	200	27	0.27	7.9	268	3.9	0.26
30	300	40	0.41	11.8	402	5.8	0.39
40	400	53	0.54	15.7	536	7.7	0.53
50	500	67	0.68	19.7	670	9.7	0.66
60	600	80	0.82	23.6	804	11.6	0.79
70	700	93	0.95	27.0	938	13.5	0.92
76	760	101	1.03	29.9	1018	14.7	1.00

From: Vacca A. Handbook of Vacuum Extraction.

Specifications

Performance

Dynamic Range: 0 to 70 cm Hg Vacuum
Sensitivity: 5 μ V/cm Hg, +/- 2.285 cm Hg
Linearity: Within 1% of operating range

Isolation

Live Parts to Earth: Leakage less than 0.2 μ amps
Enclosure to Earth: Leakage less than 0.1 μ amps

High Voltage Breakdown (Before and after humidity changes)

Enclosure: No leakage to external foil at 4000 volts
Input Pins: No leakage to external foil at 1500 volts
Tubing: No leakage to external foil at 4000 volts or 1500 volts

Electrical Properties

Output Impedance: 400 ohms nominal
Input Impedance: 2000 ohms nominal
DC Excitation: 10 volts or less
AC Excitation: 10 volts peak or less
Frequency: from dc to 10,000 Hz

Environmental (Sensor temperature compensated for continued accuracy)

Operating Temperature: from 15 °C to 40 °C
Storage Temperature: from 10 °C to 75 °C
Shock Resistance: Designed to survive drop from 30 inches

Physical

Dimensions: 3.25 in X 1.25 in X 1 in
Materials: Sealed ABS plastic with internal electronic parts
Weight: 59 grams
Tubing Length: 48 inches

Medevco is dedicated to improving the quality of healthcare through the synergy of technology and education.



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