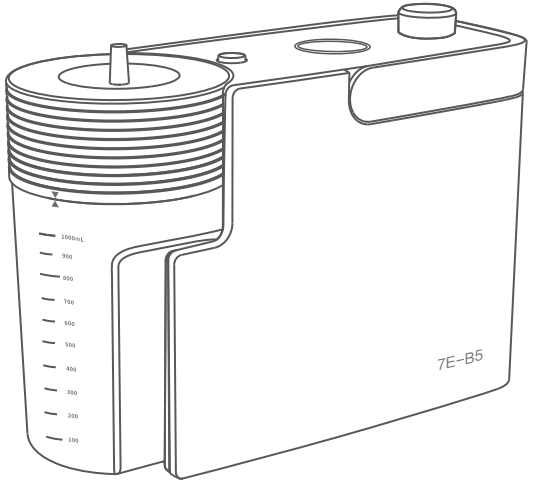
VOROTEK



7E-B5

Portable Phlegm Suction Unit

User's Manual

Please read the user's manual closely before using!

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I. Important Safety Rules

Warning: This product is precision manufactured, finely assembled and wired, so do not disassemble or attempt to repair.All repairs must be carried out by qualified personnel at authorized repair centers.

I. Danger: Reduces the Risk of Electric Shock

1. Cut off the power immediately after each use.
2. Immediately cut off the power When the machine falls into water rather than reach for it.
3. Do not place or store the machine where water or other liquid is easy to drip.
4. Do not touch the machine when it is wet.
5. Do not disassemble the machine. Services shall be performed by qualified service personnel.
6. Regularly check the electrical safety index of the machine.

II. Warning: Reduce the Risk of Burns, Electric Shocks, Fire or Personal Injury

1. When the machine is powered on, it shall not be left unattended.
2. Timely monitor the products when they are used by children or individu-als.
3. This manual only describes the usage of the product. Do not use accessories other than the manufacturer's recommendation. This will reduce the performance of the machine.
4. Please do not use the machine and return it to the service center for inspection and repair when the following situations occur: The power cord or plug is damaged, the machine can't work properly, the machine has been dropped or destroyed, the machine falls into the water and so on.
5. Keep the power cord away from the surface of heating or heating equipment.
6. Do not block the air vent of the product. Avoid soft cloth, nap and other similar things in the vent.
7. Do not drop or insert any substance at the orifice of the machine.
8. It should be noted that excessive negative pressure may cause harm to human body.

II. Product Features

I. Intended Use

- The portable phlegm suction unit is a new generation of oil-free lubricating adsorption device based on similar products at home and abroad. It is suitable for patients who are difficult to remove sputum due to disease, coma and surgery, as well as adsorb blood in clinical practice. It is a commonly used medical equipment in emergency room, operating room and medical room nursing.
- The portable phlegm suction unit is not intended to be used in hazardous areas/in the MRI environment.

II. Structure & Working Principle

- Oil free lubrication pump to keep the environment from being polluted by the oil mist.
- Low noise.
- Round negative pressure meter, and plastic cover.
- No any positive pressure to be generated during running, to ensure reliable and safe operation.
- Negative pressure regulating system can be adjusted steplessly. Small in size, light in weight and portable.
- The operating principle diagram shown as follows:

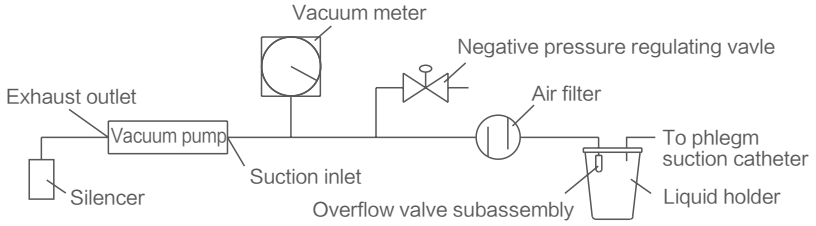


Figure 1：Operating principle diagram

III. Main Technical Performances

1. High negative pressure, High flow
2. Power Supply: □AC230V, 50Hz □AC230V ± 10%, 50Hz
3. Input power: 150VA
4. Limit negative pressure: ⩾80kPa
5. Negative pressure regulating range: 20kPa ~ limit negative pressure
6. Flow rate：⩾20L/min
7. Liquid storage bottle: 1000mL/pc, 1pc
8. Noise: ⩽60dB(A)
9. Weight: 3.9kg
10. Size: 314 × 123 × 233(mm)

⃠ The suction unit is not suitable for use in the place with inflammable & explosive gas.

- Duty cycle : 30 minutes on, 30 minutes off.
- Class Ⅱ device, Type B application part.
- Service life: 5 years(wearing and consumable parts are excluded).

IV. Normal Operating Conditions

Ambient temperature：+5℃~+35℃
Relative humidity：30%~80%
Atmosphere pressure：86kPa~106kPa

⚠ NOTE: When storage temperature is below 5℃, please keep the equipment in normal working condition for at least 4 hours before using.

III. Installing and Commissioning

I. Open Package Inspection

The customer shall carefully inspect if the appearance of product is good, and the varieties & quantities of the attachments are in conformity with those as indicated in the attached list before installing and commissioning. Also, the customer shall timely notify the supplier or manufacturer of damage(s) if any.

II. Connecting (See Figure 2)

(with phlegm suction catheter temporarily not connected)

⚠ NOTE: Apply small amount of distilled water around the part (pressed into the holder mouth) of holder plug during installing, which is good for tightly pressing the holder plug and enhancing its sealing.

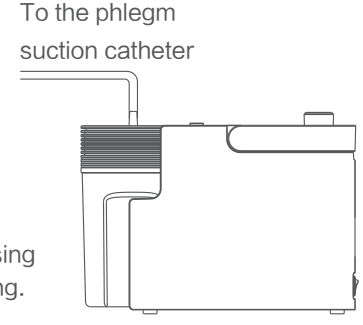


Figure 2：Tube Connecting Diagram

III. Power Line Connection

Connect the plug with the power source. Turn on the power supply, and the power indicator will illuminate.

⚠NOTE: The power plug is used for power shut-off, and the power socket shall be grounded reliably.

IV. Connector Inspection

- Turn tightly the negative pressure regulating valve clockwise, and block the air suction inlet with the finger or the rubber head of dropper, or fold up and hold the suction tube.
- Start the aspirator for running with no strange sound; the pointer of the vacuum meter will quickly reach up to the limit negative pressure. Release the air suction inlet, the pointer will return below 20kPa. If so, the connector can be regarded as being in good connection.
- Attach the phlegm suction catheter. The negative pressure in the negative pressure system shall be less than 70kPa when attaching F8 suction catheter, less than 30kPa when attaching F12 suction catheter. If so, the phlegm aspirator is considered as being in normal condition.

⚠NOTE: Dredge the suction catheter if blocked as per the following method: Bend the suction conductor in "V" form (with no liquid in the holder), and release it to the original status when the negative pressure reaches up to the maximum value. Repeat this procedure several times till the catheter is not blocked.

V. Negative Pressure Regulating

- Block the suction inlet, open the aspirator switch and regulate the negative pressure valve, and the readings on the pressure meter shall be within 20kPa ~ limit negative pressure.
- Control the negative pressure as required for suction by means of the negative pressure valve at the time of clinical practice.
- Increase the negative pressure by turning the valve clockwise.
- Reduce the negative pressure below 20kPa prior to power shut-off.

VI. Inspection & Test on the Overflow Device

- Open the holder plug; clean up the valve mouth, and leveling the rubber valve clack on the float. The valve clack shall not be warped, bent and broken, but well connected with the float. The float shall be able to move freely in its support without any blockage, lift the holder plug with hand to make the float contact the water surface perpendicularly gradually lower the holder cover to let the float rise.
- Tighten the hold plug, attach the suction tube conductor at the inlet, and screw firmly the regulating valve, then, actuate the aspirator.
- Put the suction conductor into one clean water pail or attempt to simulate actual application to suction the liquid into the holder of the overflow device. As a result, the float will rise as the liquid level ascends until the valve is closed and suction stops automatically. The final position of liquid level depends on the suction process adopted.
- Release the regulating valve, set the aspirator switch off, open the holder plug and empty the liquid in the holder. The float shall be at the bottom of the support and the valve is in open status in case of re-screwing firmly the hold plug.
- If so, the overflow device is considered as being in normal condition, which can be used for clinical practice.

⚠NOTE:

1. The liquid level still continuously ascends after the overflow device has been shut off, possibly due to:
   (1) Residual negative pressure still in the holder.
   (2) Valve mouth not fully closed.
- For Item (1), the liquid level in the holder will not ascend when the suction tube conductor is placed again into the liquid as suctioned, and for Item (2), the liquid level still ascends. Thus, it is required to observe carefully, and lift immediately the conductor out of the suctioned liquid when the holder is close to full, then, switch off the aspirator to stop suction, and examine the possible reason of the valve fault.

2. The float is still adhered on the valve mouth as already closed by the float, possibly due to the negative pressure in the line. At this moment, release the regulating valve or shut off the aspirator (to release the negative pressure in the line), the float will descends from the valve mouth under the action of gravity. (It is forbidden to pull the float with hand, in order to avoid the rubber valve clack being separated from the float).

- After shut-off, release the negative pressure, then, open the holder plug.

⃠ Never use the aspirator under the condition of the overflow device & the conductor dismantled.

VII. Stop Running

Turn off the aspirator switch, and pull the power plug out of the socket to shut off the power supply.

VIII. Symbols

Symbols	Description	Symbols	Description
~	Alternating current	⚠	General warning sign
⧈	Class II Equipment		Type B application part
○	OFF (Power)	|	ON (Power)
	KEEP UP		FRAGILE
	KEEP DRY	IPX0	Non-protective
	Manufacturer	CE 0123	CE certification marking
EC REP	Authorized representative in the European Community		

IV. Application and Maintenance

I. Application and Maintenance

- Check the aspirator before using as per the installing and commissioning sequence to ensure its good performances, afterwards, start operation by connecting the suction conductor and the phlegm suction catheter already sterilized.

⚠NOTE: Please refer to the instructions before attempting to use the suction catheter supplied with the aspirator.

- Regulate the negative pressure as required for suction through the regulating valve, open/close the switch based on the situation, and observe frequently the liquid level in the holder in the process of operation. Stop suction if the liquid level in the holder ascends to the rated capacity (still applicable if slanting the aspirator 10 degree), and re-use it after empty and clean-up. Otherwise, the float will rise as the liquid level ascends till the valve is closed and suction stops automatically.

⚠NOTE: Adopt the procedures mentioned in "Inspection & test on the overflow device", if the liquid level still ascends after the overflow device has been shut off.

Emergency measures in the process of application

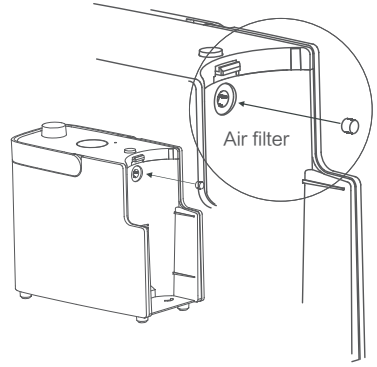
- (1) Quickly loosen the negative pressure regulating knob to release the negative pressure if the suction catheter is blocked by strong phlegm and mucus, and start suction again after changing the suction tube.
- (2) Adopting the above method to loosen the negative pressure regulating knob if it is not easy to take out the suction catheter after completion of suction or the tube is adhered to human body tissue.
- NOTE 1: Bend the tube in "V" form prior to starting suction, insert the suction catheter into the location of existing phlegm on the patient when the negative pressure reaches the desired range after start-up, then, recover the tube to its original status. This will lead to quicker suction effect.
- NOTE 2: The medical personnel shall select the proper suction catheter according to the clinical requirement.
- NOTE 3: The aspirator shall be operated under the medical personnel's instructions strictly according to the scope of application and the operating sequence listed in the instruction manual. Please contact the supplier or manufacturer if there is any question.

II. Changing Air Filter

It is required to change air filter with the one produced by us in case of foam or dusts fully accumulated in the air filter, which leads to gradually darkening of the color of filter diaphragm and obviously reducing or even disappearing of suction force at the inlet of tube while the negative pressure indicated on the vacuum meter climbs up to 40kPa or more.

⚠NOTE 1: The suction force will diminish or disappear, and the negative pressure ascend if the overflow device is closed, and the tube blocked in the process of application. Please refer to "trouble Shooting".

⚠NOTE 2: Necessary to frequently change air filter and destroy it centrally.



III. Maintenance

- It is recommended to have the suction tube suctioned small amount of clean water for cleaning up the inner wall before switching off the aspirator.
- After use, empty the holder, clean up dirt on the holder and plug with soft brush or rag, flush it with water and conduct sterilization. (including the over-flow device, the seal ring and various tubes. Unscrew the overflow device, and separate the float from its support for completely cleaning up, if neces-sary. (Note: The rubber valve clack shall not be separated from the float.)
- Use the physiological saline to clean out the residual strong phlegm and mucus in the tube after used. Replace the suction catheter if not smooth. It is recommended to adopt one-time suction catheter.
- Place the holder, cover and all tubes into the disinfectant compounded with the KONVIDA distinfector tablets (0.5g per tablet) in 1:500 concentration for 1 hour.

⚠NOTE: Keep the holder away from any sharp utensils to avoid drop in the process of cleaning and application.

- Wipe the case outer surface with lightly wet rag already soaked in the disin-fectant, and prevent any liquid seeping into the pump. Never wipe the places marked with letters and patterns.
- Place the machine in dry and clean places, and periodically start running once a time (normally one time every 6 months).

⚠NOTE: Install the overflow device, conductor and other tubes as per the connecting mode before re-use.

IV. Trouble Shooting

Problem	Probable reasons	Solution	Remark
Limit negative pressure< 80kPa	1)Holder mouth leakage 2)Leakage on connecting points 3)Regulating valve loose or released 4)Surrounding atmosphere is not as required.	1)Remove dirt, tighten or change the holder cover, seal ring, and connector 2)Re-tighten each connection point 3)Turn tightly the regulating valve 4)Move the machine to the required atmosphere	Change the broken suction tube
Negative pressure > 40kPa, with distinct reduction or disappearing of suction force at tube outlet	1)Overflow device shut-off 2)Tube blockage 3)Air filter blockage	1)After shut-off, turn the regulating valve loose counterclockwise to release negative pressure in tube, then re-screw 2)Dredge, clean or replace the tube 3)Replace it with air filter produced by us.	1)Empty the holder timely
Normal power voltage, but the indicator doesn't illuminate	1)Loose socket 2)Indicator damaged	1)Repair or change the socket 2)Replace the indicator	By the specialized maintenance worker(Refer to Electric Systematic Diagram)

⚠NOTE: The dismantling & repair on the pump body if fault shall be conducted by the specialized worker. Please contact the manufacturer if required.

V. Precautions

I. Transportation and Storage Environment Conditions

Ambient temperature: -40℃~+55℃
Relative humidity: 10%~93%
Atmospheric pressure: 70kPa~106kPa

⚠NOTE: It is required to store the portable phlegm suction unit in the well-ventilated room without corrosive gas, and avoid any violent shock while handling.

II. Electric Systematic Diagram(See Figure 3)

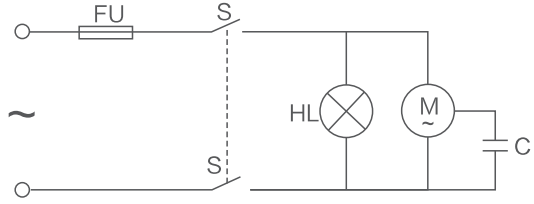


Figure 3: Electric Systematic Diagram

Electric repair to be conducted by the specialized operator.

I. Attachments

1. Suction tube(length 2m，Φ7×Φ12): 1 pc
2. Suction catheter(F8, F12): 1 pc respectively of child & adult
3. Power cord: 1 pc
4. User's manual: 1 pc
5. Air filter: 2 pcs

II. To Dispose the Castoff

The castoff should be disposed in accordance with all applicable government regulations.

VI. EMC Instruction

Instructions for use

1. Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such used is necessary, this equipment and other equipment should be observed to verify that they are operating normally.
2. Use of accessories, transducers and cables other than those specified or provided by the manufacture of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
3. Portable RF communications equipment(including peripherals such as antenna cables and external antennas) should be used no closer than 30cm (12 inches) to any part of the equipment, including cables specified by the manufacture. Otherwise, degradation of the performance of this equipment could result.
4. If the essential performance is lost or degraded due to EM disturbances, the operator can inform customer service staff to overhaul.
5. In order to maintain basic safety and essential performance in regards to EMC, the user should regularly check the equipment lines and components to avoid line aging, component failure, etc.
6. Before using this device, please read the user manual to prevent adverse events to protect patient and operator due to electromagnetic disturbances.

Electric and magnetic environment guidance in use

1. Portable and mobile RF communications equipment may affect the product.
2. You can prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment and the product.

Table1 Guidance and manufacturer's declaration – electromagnetic emissions

<table>
<tr><th colspan="3">Guidance and manufacturer's declaration – electromagnetic emissions</th></tr>
<tr><td colspan="3">The portable phlegm suction unit 7E-B5 is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such environment.</td></tr>
<tr><td>Emissions test</td><td>Compliance</td><td>Electromagnetic environment-guidance</td></tr>
<tr><td>Conducted RF emissions
CISPR 11</td><td>Group 1</td><td>The portable phlegm suction unit 7E-B5 uses RF energy solely for its internal functioning. Therefore, its RF emissions are very low and are not cause interference in proximity of any electronic appliances.</td></tr>
<tr><td>Radiated RF emissions
CISPR 11</td><td>Class B</td><td rowspan="3">The portable phlegm suction unit 7E-B5 is suitable for use in all establishments, including domestic and those directly connected to the public low-voltage power supply network that supplies building used for domestic purposes.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations/ flicker emissions
IEC 61000-3-3</td><td>Complies</td></tr>
</table>

Table 2 Guidance and manufacturer's declaration – electromagnetic immunity

Guidance and manufacturer's declaration – electromagnetic immunity			
The portable phlegm suction unit 7E–B5 is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such environment.			
Immunity test	IEC 60601–1–2 Test level	Compliance level	Electromagnetic environment–guidance
Electrostatic discharges IEC 61000–4–2	± 8 KV contact ± 15 KV air	No degradation of function	Floor should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30% .
Electrostatic fast transient/ burst IEC 61000–4–4	± 2 KV 100 kHz repetition frequency	No degradation of function	Mains power quality should be that of a typical commercial environment or hospital environment.
Surge IEC 61000–4–5	± 1 KV line to line	No degradation of function	Mains power quality should be that of a typical commercial environment or hospital environment.
Voltage dips IEC 61000–4–11	< 5%U_T (> 95% dip U_T)for 0.5 cycle < 5%U_T (> 95% dip U_T)for 1 cycle 70%U_T (30% dip U_T)for 25 cycles	No degradation of function	Mains power quality should be that of a typical commercial environment or hospital environment.. If the user of the portable phlegm suction unit 7E–B5 requires continued operation during power mains interruption, it is recommended that the product be powered from an uninterruptible power supply or battery.
Voltage interruptions IEC 61000–4–11	< 5%U_T (> 95% dip U_T)for 300 cycles	–	
Power–frequency magnetic field IEC 61000–4–8	3 A/m	No degradation of function	Power frequency magnetic fields should be at levels character–istic of a typical location in a typical commercial or hospital environment.

Table 3 Guidance and manufacturer's declaration – electromagnetic immunity

Guidance and manufacturer's declaration – electromagnetic immunity			
The portable phlegm suction unit 7E–B5 is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such environment.			
Immunity test	IEC 60601–1–2 Test level	Compliance level	Electromagnetic environment – guidance
Conducted RF disturbances IEC 61000–4–6	3V rms 150 kHz to 80 MHz	3V rms	The portable and mobile RF communication devices, including cables, must not be used closer to the 7E–B5, than the separation distance calculated by the equation applicable to the transmitter frequency. Recommended separation distance $d=1.2\sqrt{P}$ $d=1.2\sqrt{P}$ 80 MHz to 800 MHz $d=2.3\sqrt{P}$ 800 MHz to 2.7 GHz where P is the maximum nominal output voltage of the transmitter in watts (W) depending on the manufacturer of the transmitter and the recommended separa–tion distance in meters (m). The intensity of the field from the fixed RF transmitters, as determined by an Electromagnetic study of the site[a] , could be lower than the level of conformity of each frequency interval[b]. It is possible to check for interference in proximity to devices identified by the following symbol:
Radiated RF disturbances IEC 61000–4–3	10 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	10 V/m	

NOTE 1: At 80 MHz and 800 MHz, the higher frequency is applied.
NOTE 2: These guidelines may not be applicable in all situations. Electromagnetic propagation is influenced by the absorption and by reflection from buildings, objects and people.

a)The field intensity for fixed transmitters such as the base stations for radiotelephones (mobile and cordless)and terrestrial mobile radio, amateur radio devices, radio AM and FM transmitters and TV transmitters can not be theoretically and accurately foreseen. To establish an electromagnetic environment generated by fixed RF transmitters, an electromagnetic study of the site should be considered. If the field intensity measured in the place where the device will be used surpasses the above mentioned applicable level of conformity, the normal functioning of the device should be monitored. If abnormal performance arises, additional measures such as changing the device's direction or positioning may be necessary.
b)The field intensity on an interval frequency of 150 kHz to 80 MHz should be less than 10 V/m.

Table 4 Recommended separation distance

Recommended separation distance between portable and mobile RF communications equipment and the 7E-B5

The portable phlegm suction unit 7E-B5 is intended to operate in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of 7E-B5 can help prevent electromagnetic interference by keeping a minimum distance between the portable and mobile RF communication devices (transmitters) and 7E-B5 as recommended below, according to the maximum output power of the communications equipment.

Maximum nominal output power of the Transmitter(W)	Separation distance according to frequency of transmitter in meter		
	150 kHz~80 MHz $d=1.2\sqrt{P}$	80 MHz~800 MHz $d=1.2\sqrt{P}$	800 MHz~2.7 GHz $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
NOTE 1: At 80 MHz and 800 MHz, the higher frequency is applied.
NOTE 2: These guidelines may not be applicable in all situations. Electromagnetic propagation is influenced by the absorption and by reflection from buildings, objects and people.