REF A-9250

STERILE EO

Rx ONLY

PLEUR-EVAC® *Plus*

CONTINUOUS REINFUSION AUTOTRANSFUSION SYSTEM

INTRODUCTION

Autotransfusion is the harvest, storage, and reinfusion of blood products into the same patient. This therapy can be administered on a continual basis by simultaneously reinfusing blood as it is collected (continuous reinfusion), or it can be collected in a collection bag and reinfused once sufficient volume has been collected (bag reinfusion).

PRODUCT DESCRIPTION

The A-9250 PLEUR-EVAC® Plus Autotransfusion System is a three-chamber, collection/reinfusion system. This device is provided as a sterile, non-pyrogenic unit intended for single patient use. The A-9250 PLEUR-EVAC Plus is used for the collection and continuous reinfusion of autologous blood. By attaching the PLEUR-EVAC A-1500 Autotransfusion Bag, or by attaching a blood transfer bag, the A-9250 PLEUR-EVAC Plus serves as a bag reinfusion system. The PLEUR-EVAC A-1500 Austotransfusion Bag and a blood transfer bag are available as accessory items. When autotransfusion is completed, the A-9250 PLEUR-

INDICATIONS FOR USE

- For the collection of autologous blood from the patient's pleural cavity or mediastinal area for reinfusion purposes in trauma and post operative situations
- To evacuate air and/or fluid from the chest cavity or mediastinum
- To help prevent air and/or fluid from reaccumulating in the chest cavity or mediastinum
- To help re-establish and maintain normal intrathoracic pressure gradients
- To facilitate complete lung re-expansion to restore normal breathing dynamics.

CONTRAINDICATIONS FOR AUTOTRANSFUSION

- Pericardial, mediastinal, or systemic infections
- Pulmonary and respiratory infection or infestation
- Presence of malignant neoplasms
- Coagulopathies
- Suspected thoraco-abdominal injuries with possible enteric contamination
- Impaired renal function
- Intraoperative thoracic or mediastinal cavity use of topical thrombin, microfibrillar hemostatic agents or providine-iodine antiseptic gels or solutions and non I.V. compatible antibiotics

WARNINGS:

1. **Do not initiate continuous reinfusion unless a minimum of 50cc of blood remains in the collection chamber after the reinfusion system, including microaggregate filter, have been primed with blood or sterile saline.**
2. **A microaggregate filter must be used during reinfusion.**
3. **If all air is not removed from the system prior to reinfusion, air embolism may result.**
4. **When using the A-1500 Autotransfusion Bag for reinfusion, carefully monitor the patient line when pressure reinfusing to prevent the infusion of air. Clamp the line when the drip chamber empties.**
5. **Negativity during autotransfusion should not exceed - 60cm H_2O.**
6. **Stripping of the thoracic tubing in addition to the on-going mechanical action of the infusion pump can cause excessive negativity.**
7. **Chest tubes should not be clamped except when changing PLEUR-EVAC systems. In the event of an air leak, clamping chest tubes could lead to a tension pneumothorax.**
8. **Stripping of the thoracic tubing must be done with the thoracic tubing clamps open. Stripping with the clamps closed can result in the build-up of excessive positive pressure.**

CAUTIONS:

1. **Collected autologous shed blood should be**

DISPOSAL:

This device should be handled and disposed of in accordance with all applicable regulations including, without limitation, those pertaining to human health and safety and the environment.

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Assembled in Mexico with U.S. and Foreign Components.

EVAC Plus can serve as a water seal/dry suction chest drainage collection unit. These instructions will address the set-up and operation of the A-9250 PLEUR-EVAC Plus Autotransfusion System.

Please refer to manufacturer's directions for use, warnings, and cautions for microaggregate filters, I.V. blood administration sets, and blood compatible infusion pumps prior to use with this autotransfusion system.

ADVERSE REACTIONS FOR AUTOTRANSFUSION

The following complications have been known to occur during autotransfusion:

- Blood trauma
- Coagulopathies
- Particulate or air embolism

Caution should be used when the possibility exists for exposure to blood or body fluids. Follow hospital policy regarding the use of protective wear.

reinfused within six hours from the initiation of collection.

2. **Keep the PLEUR-EVAC below the patient's chest level at all times.**
3. **Avoid loops in the patient tubing.**
4. **Be sure the clamp on the exit port tubing is in the closed position and the tethered cap in place after discontinuation of continuous reinfusion.**
5. **Monitor the PLEUR-EVAC collection chamber. To avoid overflow, replace the unit before exceeding the fill capacity of 2100ml indicated by the volume graduation printed on the collection chamber.**

US Patent Numbers 4,443,220; 4,698,060; 4,784,642; 4,756,501; 4,105,031; 4,889,531; 4,955,873; 4,955,874 and 5,300,050.

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A-9250 PLEUR-EVAC® PLUS SET-UP INSTRUCTIONS

A. Open Package

GRASP BOTTOM EDGE OF FLAP AND PULL UP TOWARD STERILE OPENING (Fig. 1).

Fig. 1

PULL FLAP BACK PUSHING WRAPPED UNIT OUT OF BAG.

OR...COMPLETELY REMOVE I.E. DUPONT TYVEK® STRIP. PUSH WRAPPED UNIT OUT OF BAG USING ASEPTIC TECHNIQUE (Fig. 2).

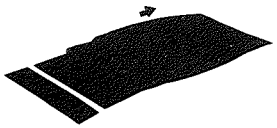
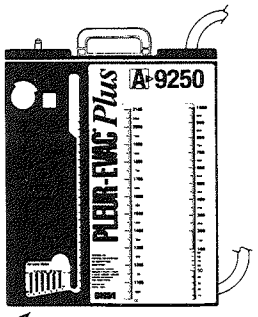


Fig. 2

B. Fill Water Seal Chamber with STERILE WATER or SALINE

- A sterile water bottle to be used on Pleur-Evac Chest Drainage units only is provided to facilitate filling. To open, twist and break the bottle seal.
- Attach the exposed tip into the suction port.
- Squeeze the bottle. The bottle contains enough water to fill the Water Seal chamber (Fig. 3). Fill to the "fill line." Avoid overfilling.
- Once filled, the water will turn blue



Water Seal Chamber

Fig. 3

C. Connect to Patient Chest Tube

CONNECT the long tube from the collection chamber to the patient's thoracic catheter (Fig. 4).

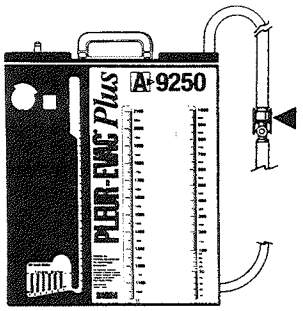


Fig. 4

D. Connect to Suction Source

CONNECT the suction source to the suction port (Fig. 5).

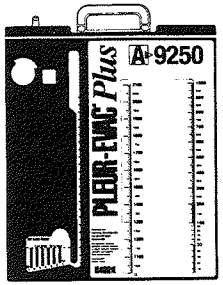


Fig. 5

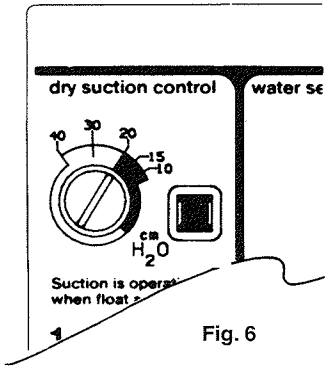


Fig. 6

Suction control dial at -40 setting (Fig. 7).

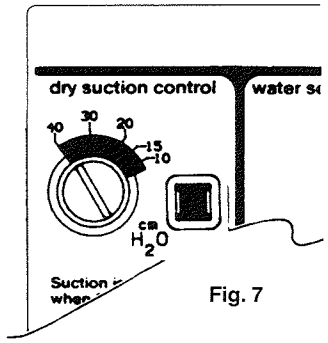


Fig. 7

E. Suction Control

A dial to set the suction control setting is located on the upper left side of the unit.

No water is needed in the suction control chamber.

To set the suction control setting, turn the dial until the red stripe appears in the semi-circular window at the prescribed suction level line. Suction can be set at -10, -15, -20, -30 and -40cm H_2O.

Suction control dial at -20 setting (Fig. 6).

F. Turn on the Suction Source

Increase suction source until the orange float appears in the suction control indicator window. The setting of the suction control dial determines the approximate amount of suction imposed regardless of the amount of source suction – as long as the orange float appears in the indicator window.

NOTE: Source suction must be capable of delivering a minimum of 20 liters per minute (LPM) air flow.

A-9250 PLEUR-EVAC® PLUS OPERATIONAL FEATURES

A. Suction Control Chamber

S-1 SUCTION CONTROL INDICATOR – the suction level is determined by the position of the red stripe in the suction control window. When suction is applied and the orange float appears in the suction indicator window, the approximate suction imposed is determined by the dial setting (red stripe). As long as the float appears in the window, the unit is operating at the suction setting that appears in the suction control window.

NOTE: In the presence of a large air leak, air flow through the PLEUR-EVAC may be increased by increasing source suction, WITHOUT increasing imposed negativity. It is not necessary to change the suction setting on the PLEUR-EVAC unit.

Check the unit periodically to ensure that adequate suction is being applied to the unit and that the orange float remains in the suction indicator window.

NOTE: If suction setting is changed from a HIGHER level to a LOWER level, the patient negativity may remain at the higher level unless the negativity is relieved. Use high negativity relief valve to reduce negativity to desired level (See W-5).

S-2 SUCTION PORT for connection to suction source, if suction is prescribed. If suction is not required, the suction port should remain OPEN, and free of OBSTRUCTIONS, to allow air to exit and minimize the possibility of a tension pneumothorax.

B. Water Seal Chamber

The water seal chamber serves three purposes:
- It acts as a one-way valve to allow air to exit from the pleural space.
- It serves as a manometer – measuring the amount of negativity in the patient's chest cavity.
- It allows for observation of the degree of air leak.

W-1 WATER SEAL PRESSURE SCALE (to determine negativity in patient's chest cavity): WITHOUT SUCTION, the pressure in the chest cavity is read directly by the fluid level in the calibrated water seal pressure scale. WITH SUCTION, add the reading from the suction dial setting to the reading of the water seal pressure scale. (Example: -20 suction plus -10 water seal= -30cm H_2O patient negativity.) The orange float must appear in the suction indicator window, indicating suction is operative, in order to determine the negative pressure in the chest cavity. PATENCY of the patient's thoracic catheter can be observed as oscillation in the water seal chamber. The water level rises and falls as the patient breathes. Oscillations may not be present when suction is operative, the lung is fully expanded, or the tubing is blocked or kinked.

W-2 PATIENT AIR LEAK METER indicates the approximate degree of air leak from the chest cavity. Observe bubbling in the columns of the patient air leak meter. The meter is labeled from LOW (1) to HIGH (7). The higher the numbered column in which bubbling appears, the greater the degree of air leak.

W-3 POSITIVE PRESSURE RELIEF VALVE opens with increases in positive pressure, preventing pressure accumulation.
WARNING: Do not obstruct the positive pressure relief valve.

W-4 HIGH NEGATIVITY FLOAT VALVE preserves the water seal in the presence of high negativity. Water floats the valve up into the closed position when excessive negativity occurs; valve opens upon decrease in negativity. The high negativity relief valve may be used to reduce negativity. When bubbling persists in water seal chamber:
1. Check for air leak in connections, tubing and apparatus.
2. If there is no external air leak, air is coming from the pleural space.

W-5 FILTERED HIGH NEGATIVITY RELIEF VALVE is provided to vent excessive negativity. Depress button to relieve negativity. Filtered air will enter the unit and water level in water seal will drop. Release button when desired level of negativity, as indicated by water level in water seal pressure scale, has been attained. Stripping or milking of the thoracic tubing can cause excessive negativity. Use the high negativity relief valve to restore negativity to prescribed levels.
CAUTION: If suction is not operative while depressing this valve, negative pressure may be reduced to zero (atmosphere).

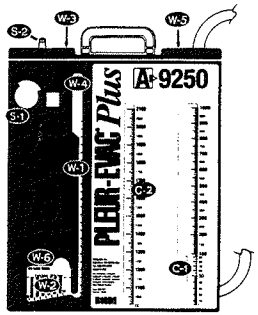


FIG. 8

W-6 SELF-SEALING DIAPHRAGM is provided in the front of the unit to adjust the fluid level in water seal chamber. Sterile saline may need to be added due to evaporation. Fluid may need to be withdrawn if chamber is overfilled. To adjust water seal level, a syringe with a 1½", 18 or higher gauge needle angled downward, may be used.

C. Collection Chamber

C-1 THE ATS COLLECTION CHAMBER is calibrated in 2ml increments up to 50ml, 5ml increments up to 200cc, and 10cc increments to 2100ml (±10%).
C-2 In the event fluid collected in the ATS compartment is greater than 1000ml, then the fluid will spill over into the 2nd collection compartment. **Blood is not recoverable from the second compartment.** When drainage reaches 2100ml, the unit is filled to capacity. Replace the unit. When changing the unit maximum speed can be achieved by making ready a new unit and following the set-up and operating instructions.
A carrying handle is provided for ease of patient ambulation of transport of the unit.

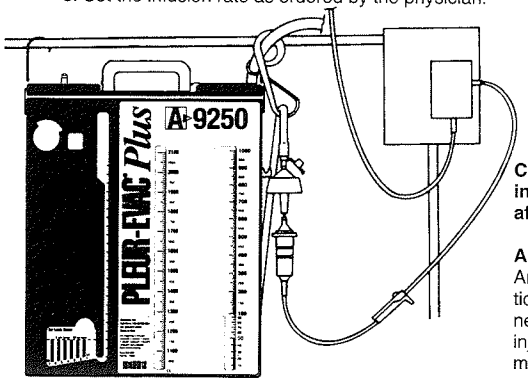
Marking surfaces are for making notations. Use pen or pencil.

Two wire hangers are provided to hang the PLEUR-EVAC from bed, O.R. stand, stretcher, etc. Autotransfusion Connectors (red and blue) are provided in the patient tube. A needleless sampling site is provided in the connector for taking samples of patient drainage. Use a standard luer lock syringe for withdrawing samples. The connector and syringe can be inverted to facilitate sample collection.
CAUTION: Use only a standard luer lock syringe to withdraw samples from the Autotransfusion Connector. NO NEEDLE IS REQUIRED.
Monitor the PLEUR-EVAC collection chamber. To avoid overflow, replace the unit before exceeding the fill capacity of 2100ml indicated by the volume graduation printed on the collection chamber.

A-9250 PLEUR-EVAC® PLUS CONTINUOUS REINFUSION SET-UP

A. Collection and Continuous Reinfusion (Fig. 9).

1. Set up a blood compatible I.V. pump.
2. Obtain a microaggregate filter and administration set for use with that pump.
3. If the infusion pump being used requires prepriming with sterile saline:
   a. Prime the microaggregate filter and administration set with sterile normal saline.
   b. Assure the clamp on the exit port tube is open.
   c. Holding the tubing below the bottom of the PLEUR-EVAC unit, gently milk the tubing until it is primed with blood and free of air.
   d. Close the clamp on the exit port tube.
   e. Remove the tethered cap from the exit port tube, and spike the tube with the saline primed microaggregate filter and
4. If the infusion pump being used does not require pre-priming with saline:
   a. Assure the clamp on the exit port tube is open.
   b. Holding the tubing below the bottom of the PLEUR-EVAC unit, gently milk tubing until it is primed with blood and free of air.
   c. Close the clamp on the exit port tube.
   d. Remove the tethered cap from the exit port tube and spike the tubing with microaggregate filter and administration set.
   e. Position the microaggregate filter and the administration set in a spike up orientation for priming.
   f. Open the clamp.
   g. Use the I.V. pump or a 60cc syringe and stopcock to prime the microaggregate filter and administration set with blood.
5. Using the tubing placement strap provided, position the reinfusion line with the spike port in the down position.
6. If needed, depress the high negativity relief valve on the top of the collection unit to relieve excessive
7. Make sure the infusion line is filled with blood and contains no air. Attach the infusion line to the patient's I.V. catheter. Check to assure all connections are secure.
8. Set the infusion rate as ordered by the physician.



B. Discontinuing Continuous Reinfusion

At the conclusion of continuous reinfusion therapy, a decision must be made either to:
1. Begin autotransfusion bag collection for reinfusion. (Refer to Autotransfusion Bag Set-up Instructions).
2. Discontinue reinfusion and use the A-9250 as a simple chest drainage collection unit. Keep the exit port tubing in the upward position using the grey placement strap.

CAUTION: Be sure the clamp on the exit port tube is in the closed position and the tethered cap is in place after discontinuing continuous reinfusion.

ANTICOAGULATION
Anticoagulants are recommended for use at the discretion of the physician. Add anticoagulant using a standard needleless luer lock syringe through the self-sealing injection site in the ATS connector. Either CPD or heparin may be used.

A-9250 PLEUR-EVAC® PLUS AUTOTRANSFUSION BAG SET-UP

A. Connecting the A-1500 Autotransfusion Bag to the A-9250 Unit

1. Obtain and unwrap an A-1500 Replacement Bag (Fig. 10).
2. Close the two clamps on the top of the A-1500 Replacement Bag.
3. Close the clamp on the PLEUR-EVAC patient tubing and drain blood from the tubing into the PLEUR-EVAC.
4. Disconnect the red and blue connectors.
5. Remove the red protective cap from the collection tubing on A-1500 Replacement Bag and connect to the red connector on the patient chest drainage tubing.
6. Remove the blue protective cap from the tubing on the A-1500 Replacement Bag and connect to the blue connector on the 6' PLEUR-EVAC tubing.
7. OPEN ALL CLAMPS. Secure all connections.
8. The autotransfusion system is now operational.
9. Attach the A-1500 Replacement Bag to the PLEUR-EVAC using the foot hook and ATS hanger on the side of the unit (Fig. 10).
10. If prescribed, anticoagulants may be added, as directed by the physician (see ANTICOAGULATION).

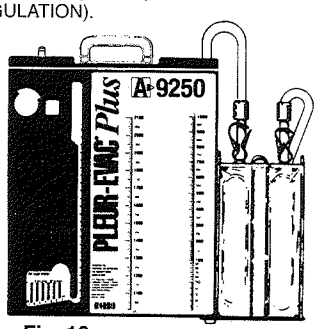


Fig. 10

B. Discontinuing Blood Collection for Reinfusion

At the conclusion of autotransfusion, a decision is made to:

1. Discontinue collection and complete chest drainage with the PLEUR-EVAC.
2. Add another autotransfusion bag and continue collection.
3. Use the A-9250 as a continuous reinfusion unit as previously described in Continuous Reinfustion Set Up Instructions section.

C. Removing the A-1500 Autotransfusion Bag from the A-9250 Plus Unit

1. Use the high negativity relief valve to reduce excessive negativity to the prescribed level.
2. Close the clamps on the patient tubing and on top of the autotransfusion bag.
3. Disconnect all red and blue connectors.
4. Attach red and blue connectors on top of the autotransfusion bag.
5. Securely attach red and blue connectors, joining the patient tube (red) to the 6' PLEUR-EVAC tube (blue).
6. Open the clamp on the patient tube.
7. Patient drainage will now be collected in the PLEUR-EVAC.
8. Remove the autotransfusion bag from PLEUR-EVAC by removing the ATS bag frame from the hanger on the side of the unit. Disconnect the foot hook from the PLEUR-EVAC unit.
9. Prepare the autotransfusion bag for reinfusion (see E).

D. Changing the A-1500 Autotransfusion Bag

1. Use the high negativity relief valve to reduce excessive negativity to the prescribed level.
2. Open a new A-1500 Replacement Bag.
3. Close the two clamps on the top of the new bag.
4. Close the clamps on the patient tubing and on top of the original autotransfusion bag.
5. Disconnect all connectors (red and blue) between the original autotransfusion bag, patient tube, and PLEUR-EVAC 6' tubing.
6. Remove the red protective cap from the collection tubing on replacement bag and connect that tube to the patient tube using red connectors.
7. Remove the blue protective cap from the tubing on the replacement bag and connect to the 6' PLEUR-EVAC tubing using the blue connectors.
8. OPEN ALL CLAMPS (two on replacement autotransfusion bag and one on patient tube). Check to assure all connections are secure.
9. The autotransfusion system is again operational.
10. Attach the red and blue connectors on top of the original autotransfusion bag.
11. Remove the original autotransfusion bag from the PLEUR-EVAC by removing the ATS bag frame from hanger on side of unit. Disconnect the foot hook from the PLEUR-EVAC unit. Prepare for reinfusion. (see E).
12. Attach the replacement bag to the PLEUR-EVAC using the foot hook and ATS hanger on side of unit.
13. If prescribed, anticoagulants may be added as directed by the physician.

E. Preparing for Reinfusion

1. Slide the autotransfusion bag off the wire support frame.
2. Invert the bag so the spike port points upward, and remove the protective cap.
3. Insert a microaggregate filter into the spike port using a constant twisting motion. Attach the infusion set.

NOTE: For each autotransfusion bag used, a new microaggregate filter is recommended.

4. Evacuate residual air from bag. Open the infusion set clamp, keeping the unit inverted, and carefully squeeze all air from the bag through the filter and drip chamber assembly. If not ready to prime, close the infusion set clamp.
5. With infusion set clamps open and keeping the unit inverted, gently squeeze the autotransfusion bag, allowing blood to slowly prime the reinfusion filter. Continue squeezing until the filter is saturated with blood and the drip chamber is half full. Close the clamp on the infusion line.
6. Invert the autotransfusion bag and suspend it from the I.V. pole using the plastic strap.
7. Open the infusion set and carefully flush the administration line to remove the air.

F. Reinfusion

1. Attach the distal end of the infusion set assembly to the appropriate patient line.
2. Infuse the blood according to approved hospital procedure, using gravity or pressure cuff reinfusion. Pressure cuff infusion should not exceed 150mmHg.

ANTICOAGULATION

Anticoagulants are recommended for use at the discretion of the physician. Add anticoagulant using a standard needleless luer lock syringe through the self-sealing injection site in the ATS connector. Either CPD or heparin may be used.

A-9250 PLEUR-EVAC® PLUS TRANSFER BAG SET-UP

A. Transferring Blood To A Transfer Bag

1. Remove the tethered cap from the end of the exit port tube on the A-9250.
2. Remove the cover from the spike on the Transfer Bag and spike the port on the end of the exit port tube.
3. Suspend the Transfer Bag as far below the exit port of the A-9250 as possible and depress the High Negativity Relief Valve on the A-9250 to speed the rate of blood transfer to the Transfer Bag.
4. When the desired amount of blood has been transferred evacuate any air in the Transfer Bag by squeezing the bag and forcing the air back into the A-9250 collection chamber.
5. Close the clamp on the exit port tube. Close the clamp on the transfer line of the Transfer Bag.
6. Disconnect the Transfer Bag. Replace the tethered cap on the end of the exit port tube.

B. Preparing for Reinfusion

1. Prime a 40 micron microaggregate filter and I.V. administration set with sterile, normal saline.
2. Open the protective cover on the spike port on the Transfer Bag and spike the port with the primed 40 micron filter and I.V. administration set.
3. Reinfuse blood by gravity reinfusion or by using a pressure cuff, if needed.

CAUTION: Be sure to observe the manufacturer's recommendations for reinfusion and for use of a pressure cuff.

C. Continuing With Chest Drainage Operation

1. Ensure the PLEUR-EVAC A-9250 is positioned and configured properly to continue chest drainage operation.
2. Keep the exit port tube in the upward position using the gray placement strap.

CAUTION: Be sure the clamp on the exit port tube is in the closed position and the tethered cap is in place after disconnecting the Transfer Bag.