ATP Manual

Standard operating procedure for Air Transportable Perfusion kit

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Alcor Life Extension Foundation
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Purpose:

The ATP is intended for remote locations such as a mortuary, and should be used as soon as possible after legal death has been pronounced. It consists of a pump, heat exchanger, filter, reservoir, sterile tubing, and ancillary equipment to wash out the patient's blood and replace it with a solution that cools the patient rapidly and minimizes cellular damage during subsequent transport of the patient to Alcor.

Components

You will need all of these components:

1. Main ATP Kit. Large black plastic case labeled "ATP" contains the primary hardware.

2. Perfusate. Smaller black plastic case labeled "MHP" contains 20 liters of MHP-2 solution.

3. ATP Support Kit. Large black plastic case labeled "MISC" contains additional items.

4. Enough cubed ice to fill two or more large ice chests. Each chest should be at least 1 foot x 1 foot x 2 feet in size, preferably with wheels. The ice and the ice chests will be purchased where the standby takes place. You will need half the patient's weight in ice, plus 200 lbs repacked in Ziploc bags for shipment via commercial airline.

5. Two buckets, each 5 gallons or larger. These can be bought or borrowed locally. Wastebaskets will do. One will hold ice, the other will collect waste water if a drain is not available nearby.

Summary of Procedure

A. Unpack and set up the ATP.

B. Attach neuro accessory kit if required.

C. Prime the circuit: Fill the tubing with perfusate.

D. Purge the circuit: Eliminate bubbles.

E. Cannulate and perfuse the patient with 20 liters of washout solution.

F. Clean and repack the ATP.

Basic Principles

The ATP does two things. First, it washes out the patient's blood with an organ preservation solution that will protect the patient during transport. Second, it cools the patient before transport.

The flow diagrams on the next two pages show how plastic tubes connect the patient with the ATP hardware.

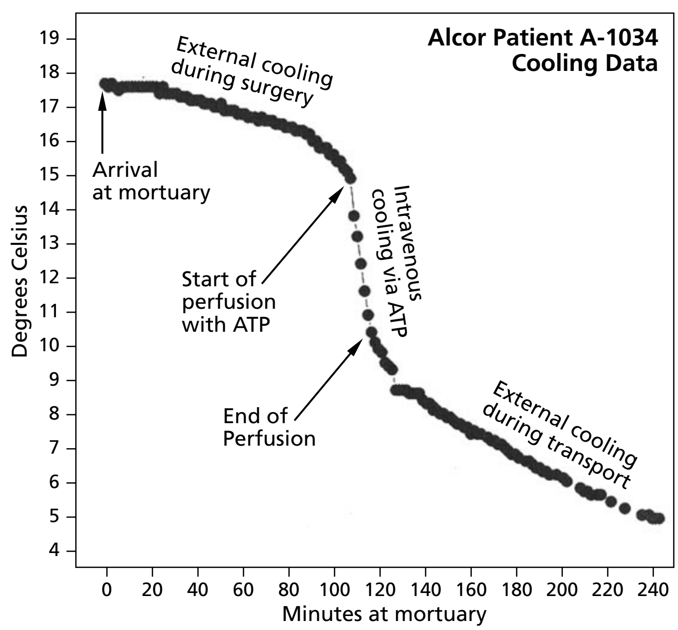
Initially you must draw perfusate in from the supply (at bottom-left in the diagram) and force air out of the tubing circuit. This is called priming the circuit. You clamp the tube at position A1, so that the pump is cut off from the reservoir and has to take perfusate from the supply. Follow the white dotted line and you will see that the pump pushes the perfusate through a heat exchanger (which cools the perfusate) and then through a filter, up toward the patient. If the bypass is unclamped, the perfusate takes a short- cut through it and down the venous line. Put a clamp at B2, and the perfusate goes back to the reservoir, a plastic bag in the lid of the ATP case. Open the stopcock at the top of the reservoir to vent air through the bleed line, into the waste bladder.

When the circuit is full of perfusate and contains no air, it can be attached to the patient to begin blood washout. Close the the bypass, so that perfusate is forced into the patient's femoral artery. Move the clamp from B2 to B1, so that the venous return goes into the waste bladder. Perfusate is now being pumped from the supply, through the heat exchanger and the filter, and through the patient, into the waste bladder. This is called open-circuit perfusion.

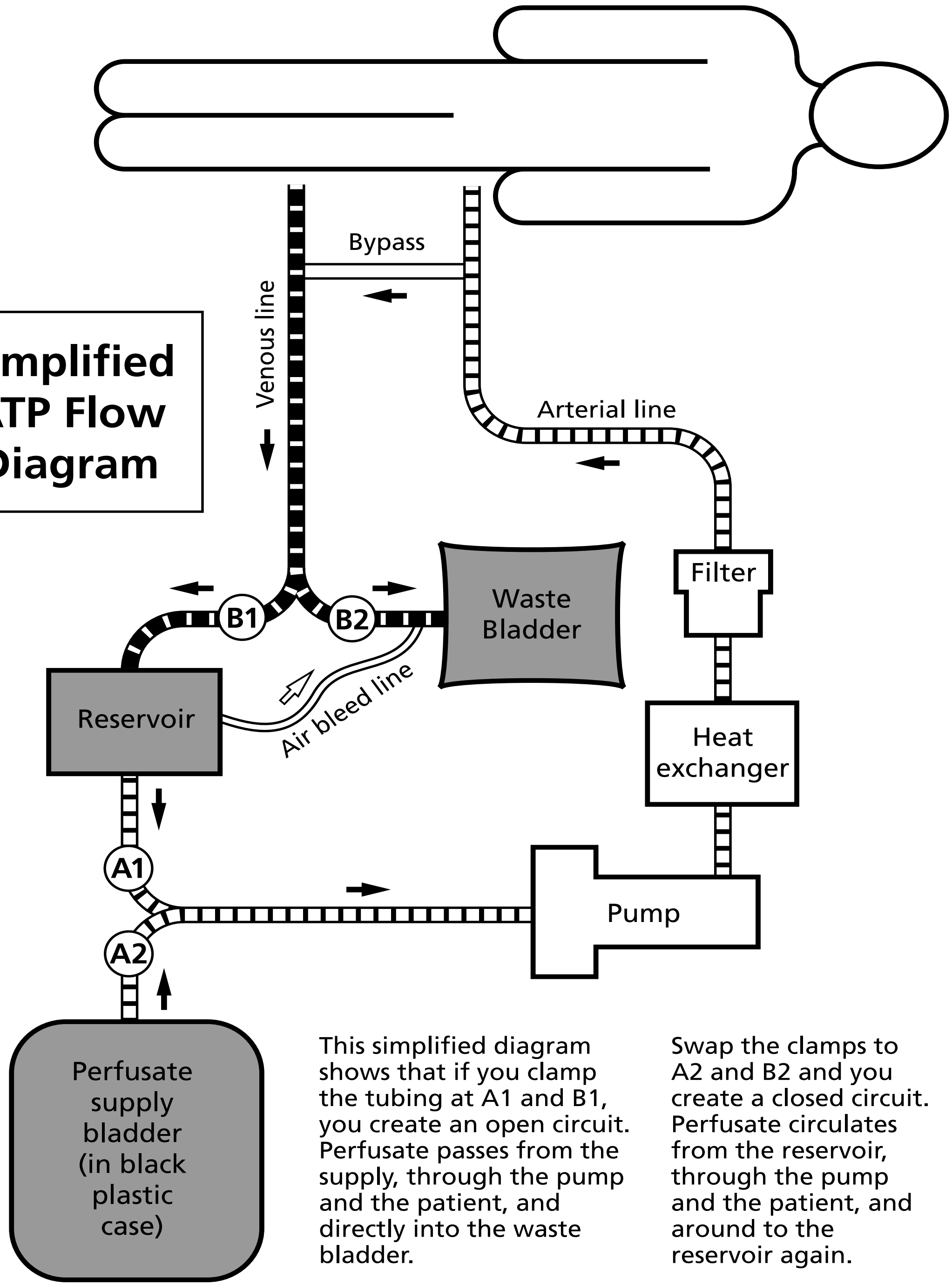
You will use up half your perfusate within a couple of minutes. Now you must switch from doing blood washout to cooling the patient. Move the clamp from B1 to B2, so that the venous return doesn't go into the waste bladder anymore. Instead, the perfusate circulates back to the reservoir.

Move the other clamp from A1 to A2, and the pump takes perfusate from the reservoir instead of from the perfusate supply. The perfusate circulates until thepatient is cool enough for transport.

Intravenous cooling is very effective. The graph at right is compiled from actual cooling data. It shows that a patient packed in ice cooled at only about 1 degree Celsius per hour until the ATP was applied. The sooner you use the ATP, the better your patient's chances will be.

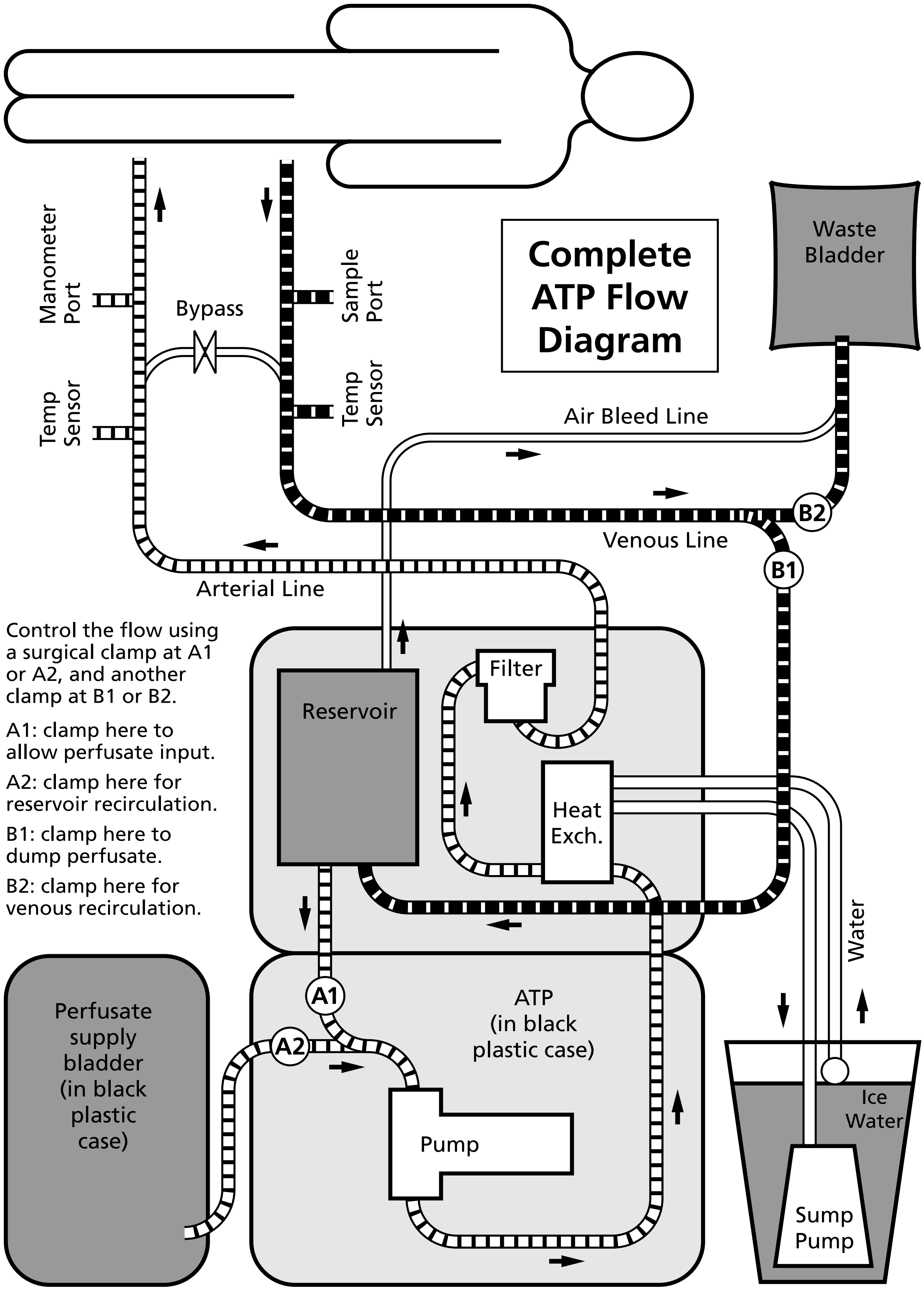


Simplified ATP Flow Diagram



This simplified diagram shows that if you clamp the tubing at A1 and B1, you create an open circuit. Perfusate passes from the supply, through the pump and the patient, and directly into the waste bladder.

Swap the clamps to A2 and B2 and you create a closed circuit. Perfusate circulates from the reservoir, through the pump and the patient, and around to the reservoir again.


Complete ATP Flow Diagram
Waste Bladder
Manometer Port
Bypass
Sample Port
Temp Sensor
Temp Sensor
Air Bleed Line
Venous Line
B2
B1
Arterial Line
Control the flow using a surgical clamp at A1 or A2, and another clamp at B1 or B2.
A1: clamp here to allow perfusate input.
A2: clamp here for reservoir recirculation.
B1: clamp here to dump perfusate.
B2: clamp here for venous recirculation.
Reservoir
Filter
Heat Exch.
Water
A1
A2
ATP (in black plastic case)
Perfusate supply bladder (in black plastic case)
Pump
Ice Water
Sump Pump

A. Setup

1. Verify that the location where you will use the ATP is suitable.

Is there easy access to the prep room? (Wide hallways, no stairs.) Is there an electric outlet nearby? Is there sufficient space for the ATP on the floor beside the perfusate, an icewater bucket, and the waste bladder? If the patient hasn't arrived yet, leave room for the portable ice bath containing the patient to reach the operating table.

2. Note the need for any precautions against infectious disease.

3. Position the ATP.

Place the ATP case on the floor, ideally so that it will be on the patient's left side, with the back of the open lid facing the patient. Leave space for the perfusate case left of the ATP (the perfusate should be refrigerated until you are ready to begin work).

> *The ATP must be below or beneath the patient to minimize the risk of air being sucked into the perfusate. If the ATP is raised above the patient, the circuit may fill with air.*

4. Open the ATP case.

Turn the two metal catches under the lid to release the sterile-wrapped tubing and metal plate (see photo 1). Carefully peel off the large sterile wrapping, but do not

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remove the smaller sterile wrapping from the arterial-venous tubing loop (see photo 12). Remount the metal plate in the lid by rotating the metal catches downward, as in photo 2.

5. Remove loose components from case.

Spread the sterile wrappings on a nearby surface, and place the components on the wrappings.

6. First check that all outlets on the power strip are off. Then plug it in.

7. Deploy the controller.

The controller is a gray box with a power cord and an additional wire that connects with the pump. You will use the controller to adjust the pump speed. Plug in the controller, turn on the switch beside the outlet on the power strip, and turn the switch on the right-hand side of the controller. Reset the controller for the appropriate tubing size if necessary (otherwise, the flow rate indicated by the controller will be incorrect). Press the stop/start button on the controller and listen for the pump. Press the stop/ start switch again to stop the pump.

8. Safeguard the arterial-venous loop.

Place it out of the way, with its sterile wrapping still protecting it. Do not get it wet.

9. Remove the embolus-filter rubber cover cap, if present.

10. Mount the pump shoe in the pump head.

The pump shoe is a length of softer, less transparent, slightly yellowish tubing about 18 inches long, located about 18 inches below the Y connector from the perfusate supply. Be careful to use this tubing and not the very transparent, stiffer tubing, which is insufficiently flexible to work in the pump. Push the lever on the pump head away from you (see photos 3, 4, and 5 on the next page) to open the pump head. Thread the tubing into the open gap, so that the pump will draw perfusate from the rear toward the front. Look deep into the pump head to make sure the tubing is aligned. Close the pump head gently while holding the tubing in place.

11. Attach the reservoir bag.

If the reservoir bag is loose at any point, press the holes in the edge of the bag over the round-headed nuts on the six bolts at the left side of the lid.

12. Deploy the waste bladder.

Place the waste bladder on the floor outside of the ATP case in a location where no one will trip over it or step on it. (See photo 12 for an overview of the recommended equipment layout.) Attach the waste line from the bladder to the Y connector in the venous return line, if the waste line is not already connected. Follow the thin air-bleed tube from the waste bladder back to the reservoir in the lid of the case, and make sure the stopcock on the reservoir is OPEN to the waste bladder. If the stopcock has the word OFF marked on its lever, this should point away from the tube when the stopcock is open. Remove manufacturer's tape from stopcock if necessary.

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13. Connect the sump pump.

Note that the sterile tubing which will contain perfusate is completely separate from the tubing that will carry water to and from the sump pump. The water and the perfusate never mix.

You should have two sump pumps: One for use with the ATP, the other for use in the portable ice bath.

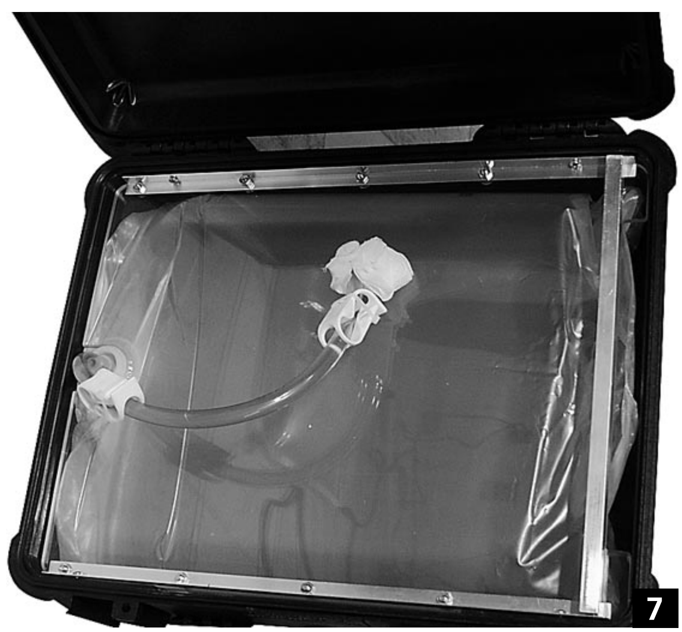
Connect a sump pump to the INLET of the heat exchanger (the upper nozzle on the right-hand side). See photo 12. Connect the OUTLET of the heat exchanger (the lower nozzle on the right-hand side) to the tube that ends in a diffuser (metal ball with holes in it). Place a clean bucket on the floor to the right of the ATP case. Put the pump in the bottom of the bucket, as in photo 6, above. Fill the bucket with ice. Add sufficient water to submerge the pump. Rest the diffuser on top of the ice. Plug in the pump and switch it on to test it.

Switch off the pump. If the pump will not be used immediately, take it out of the bucket to prevent its bearings from freezing. Place it somewhere higher than the heat exchanger to prevent it from siphoning water out of the bucket.

Whenever the pump is idle for more than a minute, remove it from the ice bucket to protect its bearings. If the bearings freeze, warm the pump by placing it in hot water.

14. Open the perfusate case.

Remove the perfusate case from the refrigerator and place it flat on the floor beside the ATP case. Open the perfusate case as in photo 7, taking care that its tubing does not fall on the floor or any nonsterile surface. Do not lift the case into a vertical position yet.



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15. Flush the circuit with carbon dioxide, if available.

Soon you will be filling the circuit with perfusate. After that, you will have to remove air bubbles. You can minimize air bubbles by using a source of compressed CO2 to force air out of the circuit before you introduce perfusate. Acceptable sources of CO2 include small cylinders that charge soda siphons, and spray cans for blowing dust off camera lenses. Make sure that your source contains only carbon dioxide. Clamp the circuit at position A1 on the ATP Circuit Diagram, introduce the gas at the inlet tube through A2, and vent air to the waste bladder through the stopcock at the top of the reservoir.

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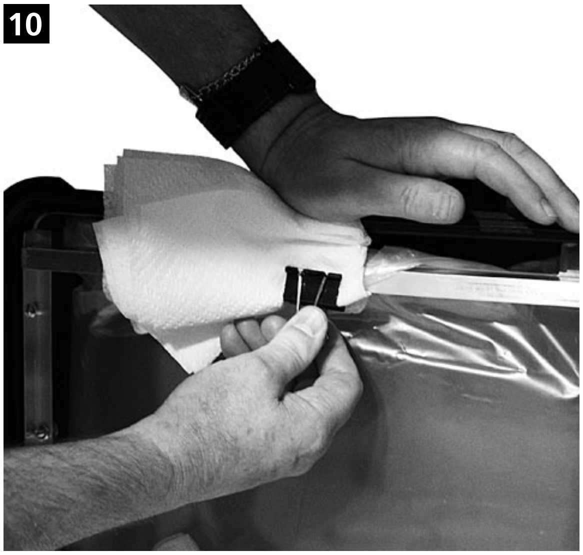
16. Create a sterile end on the perfusate tubing.

Tubing from the perfusate supply has been fitted with two plastic clamps. You will cut the tubing between the clamps. Use an alcohol prep to sterilize the tubing where the cut will be made. Sterilize the blades of the scissors from the ATP Support Kit.

Cut the tubing at a slight angle as shown in photo 8, and throw away the severed end of the tube, along with its plastic clamp.

17. Attach perfusate supply to reservoir.

Apply a surgical clamp to the outlet tube from the reservoir. Remove the cover from the tubing connector on



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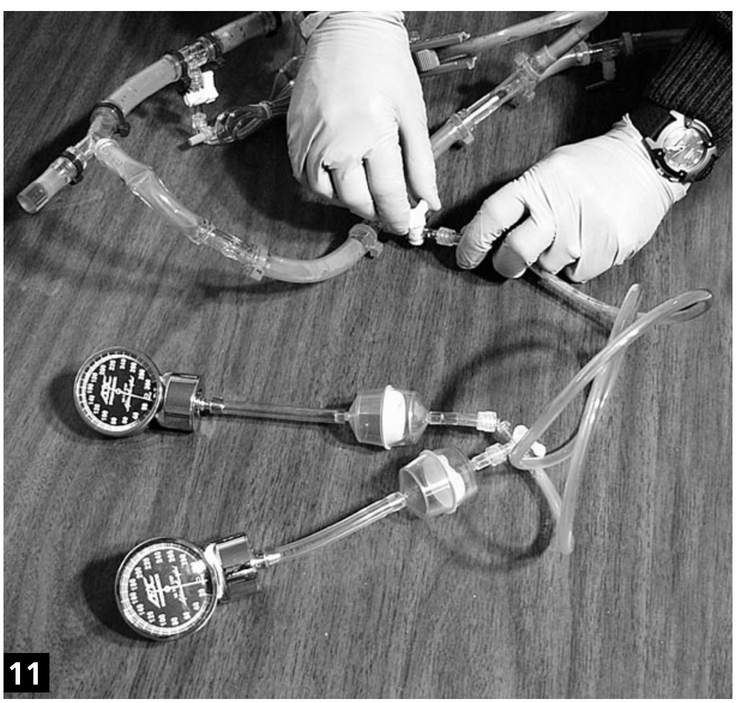
the perfusion feed tube (a one-foot length of tubing attached to the Y connector on the inlet tube to the reservoir). Join the tubing connector to the outlet tube from the perfusate supply bladder. Use the banding gun from the ATP Support Kit to put a plastic band around the connection. Remove the surgical clamp and set it aside, to avoid using it accidentally in the future.

Cut the band from around the plastic clamp on the outlet tube from the perfusate supply bladder. Open the clamp, move it up the tubing, and massage the tubing to remove any dent left by the clamp.

18. Lift the perfusate case.

Lift the perfusate case into a vertical position. Gently pull up the perfusate bladder, fold it around the aluminum bar at the top end of the case, and clip the bladder to the aluminum bar as in photo 10, using a paper towel under the clip to prevent it from damaging the bladder.

You have now deployed all the main elements of the ATP. The setup should look like photo 12 on the next page. Take a moment to compare your circuit with the photograph.



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19. Remove sterile wrap from arterial-venous loop.

See photo 13 for an itemization of all the components in the loop, and their functions. The loop should be placed in a sterile area.

20. Attach manometers (pressure gauges).

Attach the manometers to the portal on the arterial line. DIsplay them both at the same height, to achieve consistent readings. A convenient way to do this is by stretching a bungee cord just underneath the top

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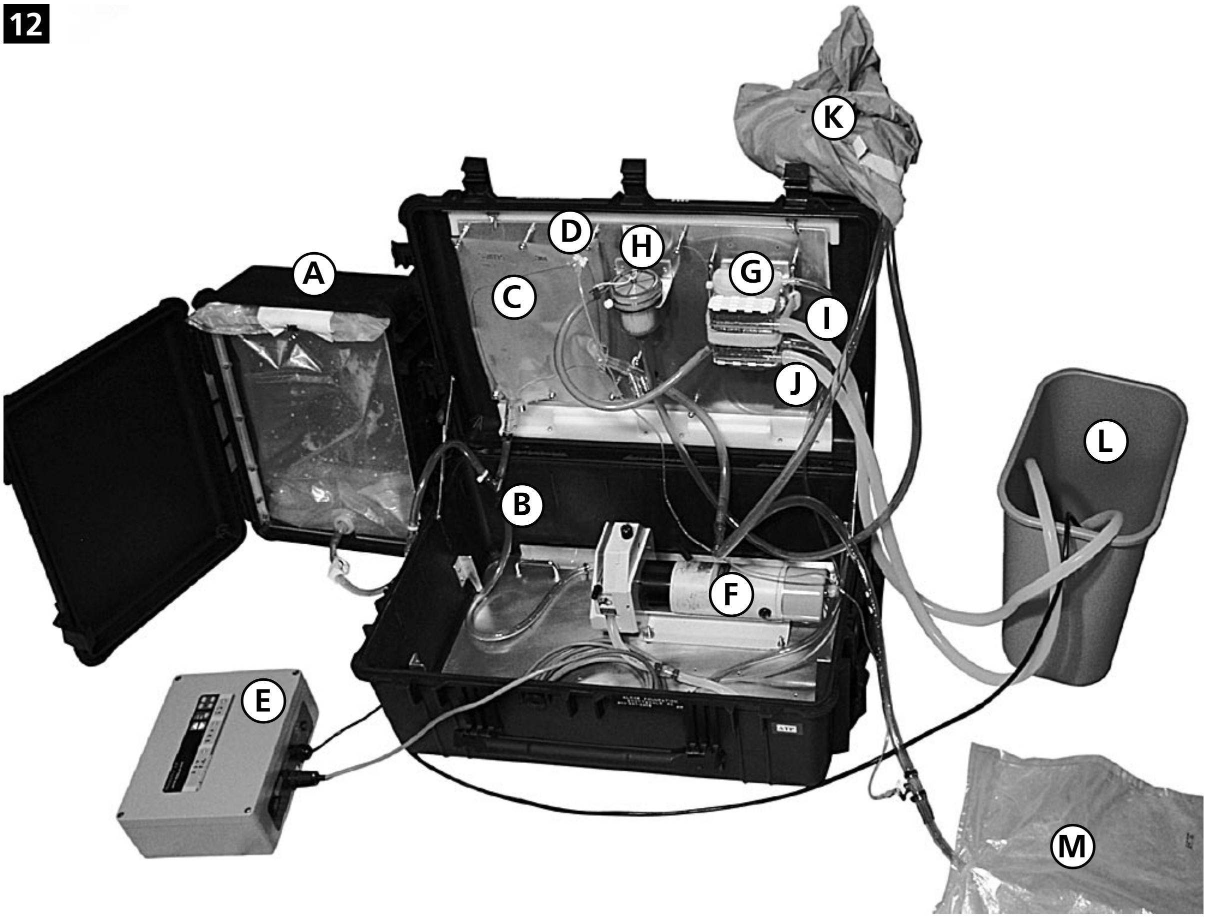


Photo 12: All components of the ATP deployed, except for the arterial-venous loop..

A: *The perfusate supply bladder in its protective case.*

B: *Y connector. Position a clamp here to select perfusate supply or reservoir bag.*

C: *Reservoir bag. Allows some fluctuation of volume in the circuit. Should never be more than two-thirds full.*

D: *Stopcock. When opened, it allows air to be squeezed out through bleed line.*

E: *Pump controller. Sets tubing size and pump speed, and switches pump on and off.*

F: *Pump.*

G: *Heat exchanger (also contains an oxygenator, which is not generally used).*

H: *Filter. Helps to remove some air from circuit, and blood clots during washout.*

I and J: *Inlet and outlet for icewater, in the heat exchanger.*

K: *Venous-arterial loop, sterile-wrapped. See Photo 13 on next page.*

L: *Sump pump in bucket or waste basket. Pumps ice-water through the heat exchanger, to cool the perfusate.*

M: *Waste bladder. Accumulates washout solution and air from circuit.*

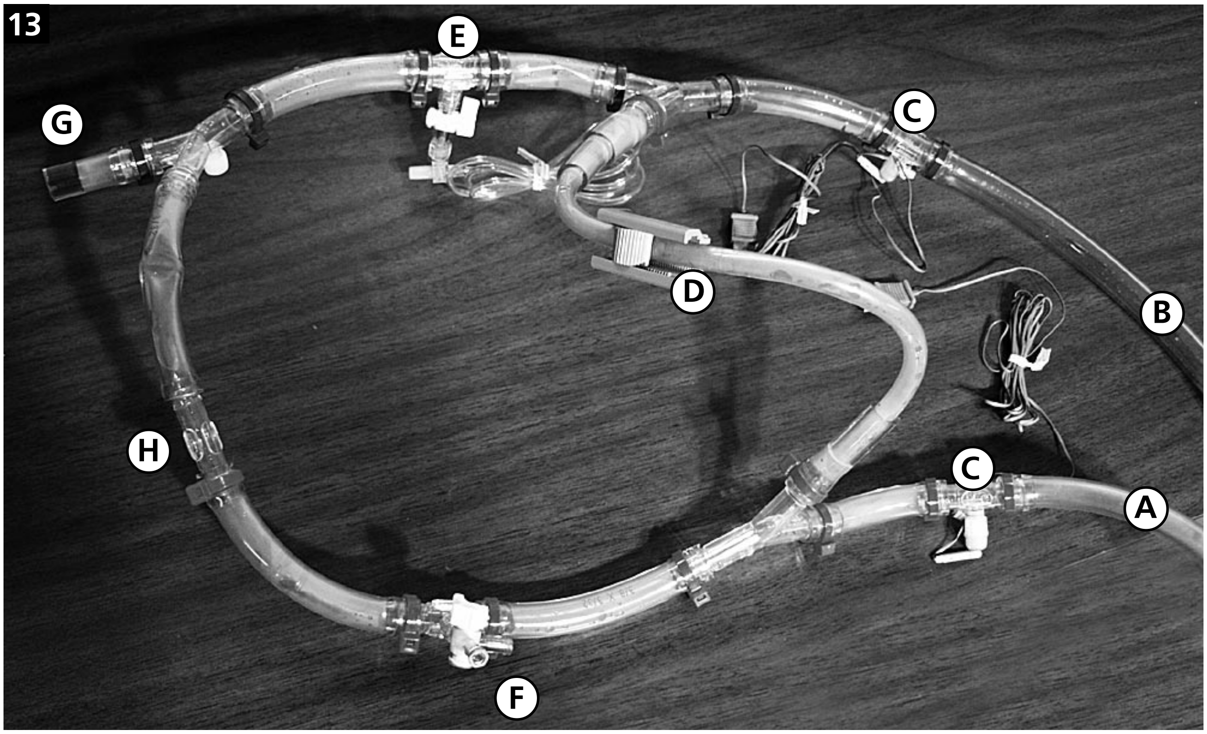


Photo 13: The arterial-venous loop, unwrapped.

A: *Arterial branch, with red bands at tubing joints.*

B: *Venous branch, with blue bands at tubing joints.*

C: *Ports for temperature-sensing thermocouples. The wires terminate in plugs that are inserted in a DuaLogR data recorder.*

D: *Bypass. The roller functions as a clamp which opens and closes the bypass.*

E: *Sample port. The thin tube can be attached to a sample container.*

F: *Manometer port. Twin manometers (pressure gauges) are attached here. See photo 11 for details.*

G: *Venous branch. If the surgeon cannulates both femoral veins, the cannula from the second vein can be attached here. If not, this branch remains capped.*

H: *Manifold. This small section of tubing is removed when the venous-arterial loop is attached to the patient's femoral artery and femoral vein(s).*

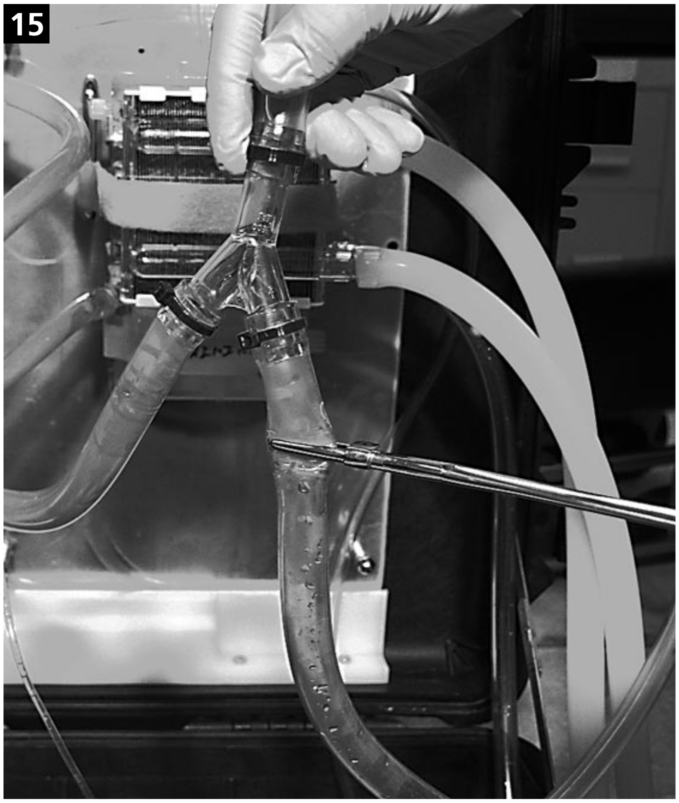
Note that the portion of the loop to the left of points A and B, in the photograph, should remain sterile. In an actual case, place the loop on a sterile field after unwrapping it.

edge of the lid of the ATP case, then clip the manometers to the cord. When you begin perfusing the patient, one manometer should be moved to a location where the surgeon can see it.

The manometers may display readings that are not consistent with each other. If you are not able to calibrate the manometers before using them, you must allow for the different readings when the surgeon instructs you to increase or decrease the pressure to a specified amount.

22. Plug in the thermocouples (temperature sensors).

The thermocouples are already mounted in ports in the plastic tubing of the arterial-venous loop (Photo 13). The wire from the venous thermocoupleplugs into Channel 1 of a DuaLogR data recorder. The arterial thermocouple plugs into Channel 2. See the end of this manual for instructions on setting up and using the DuaLogR.



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C. Prime the Circuit

1. Start the sump pump.

Make sure that the pump is forcing water through the heat exchanger.

2. Clamp the tube to the waste bladder.

Apply a surgical clamp to the tube as high as possible, as in photo 15, immediately below the Y connector near the heat exchanger (position B2 on the Flow Diagram on page 4). Always clamp tubes as close as possible to connectors, to reduce the possibility of backflow into the clamped section of tube.

3. Clamp bypass tubing from heat exchanger to reservoir.

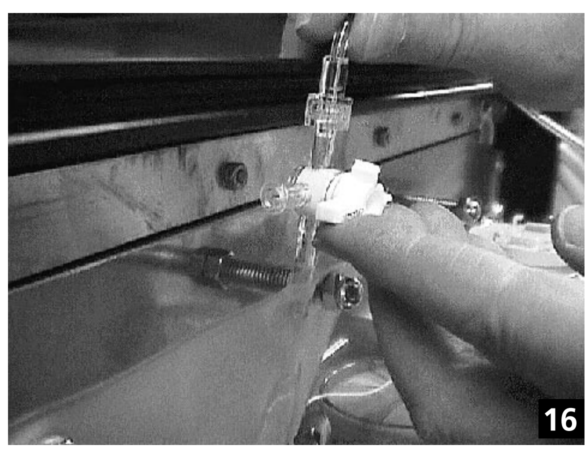
If your ATP does not have this bypass tube, ignore this instruction. If it does have a bypass tube, leave it clamped at all times.

4. Vent air from the circuit.

Make sure the stopcock at the top of the reservoir bladder is OPEN as shown in photo 16. Press the bladder to force air out through the vent line, then close the stopcock. Since the vent is small, expelling air can take time.

5. Verify that the circuit is correct.

Trace the path of the tubing and compare it with the Flow Diagram and photo 12. Make sure that the tube to the waste bladder and the outflow tube from the reservoir are both clamped.



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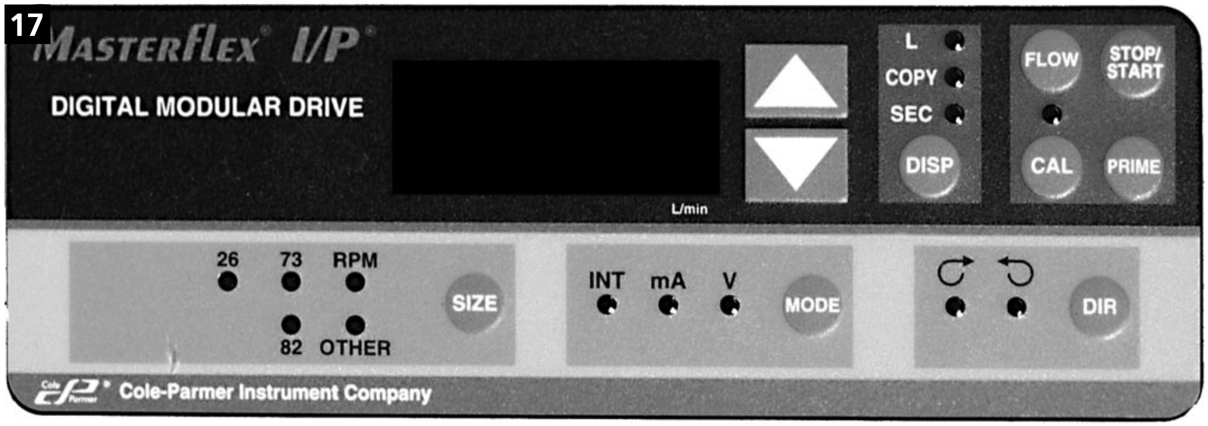

Photo 17: Roller Pump Control Panel.

Press the SIZE button to select the number that matches the code on the tubing that goes through the pump.

Press the DIR button, if necessary, to illuminate the left-hand warning light (clockwise pump rotation, viewed from the tubing end).

Use the up and down arrows to select pump speed. If you maintain steady pressure on one of the arrows, pump speed will increase slowly at first, and then more rapidly.

In emergency, press the STOP/START button to stop the pump immediately.

6. Adjust the pump.

First make sure that the tubing size is correctly indicated on the pump controller. Then adjust the speed to 0.5 liters per minute by pressing the up/down arrows on the digital control pad. If you do not have a digital controller, you will turn a knob to adjust flow.

7. Switch on the pump.

As fluid enters the circuit, it will force air out through vents in the heat exchanger and the reservoir. When the perfusate reaches the embolus filter, remove it from its holder and turn it upside-down to fill it; then replace it on its bracket.

8. Fill the circuit.

Allow the pump to run until the reservoir is half full. Then move the surgical clamp from the reservoir outflow line to the perfusate inflow line (swap the clamp from A1 to A2 on the Flow Diagram on page 4) so that the perfusate inflow is cut off.

CAUTION: Watch the reservoir bladder. You can burst it by overfilling it.

9. Check for leaks and correct as necessary.

D. Purge the Circuit

Air bubbles must be removed from the circuit before you begin perfusion of the patient. Air bubbles may cause embolisms that will block the patient's cardiovascular system, preventing perfusate from reaching parts of the brain, and allowing blood to remain. If this blood coagulates, the patient's chances of successful cryopreservation will be severely compromised.

Always remove all air bubbles!

1. Increase pump speed.

Set the pump to 3 liters per minute to force air out of the circuit, and watch the manometer. If pressure rises above 200 mm of mercury, shut off the pump immediately and look for an obstruction in the circuit.

2. Remove bubbles.

Using a rubber reflex hammer (from the ATP support kit) or the handle of a surgical clamp, sharply tap the tubing of the circuit, moving bubbles along in the direction of the flow. Air from the perfusate supply line can be moved back into the top of the perfusate storage bladder if this is most convenient. Take special care to dislodge bubbles from inside Y connectors. Rap the heat exchanger on the front and on each side. Bleed air out of the manometer line by opening the valve at the isolator end until perfusate runs out. Use a paper towel to catch the liquid.

Purge the arterial-venous loop. Increase the flow pressure to between 100 mm and 150 mm by partially closing the plastic clamp on the bypass line. Chase bubbles from the arterial line around into the venous line.

Remove the embolus filter by lifting it up and out of its bracket. Turn it upside-down and tap it sharply. The filter is crucial, because it is the last barrier against air bubbles before the perfusate flows to the patient. A small amount of air will be able to escape harmlessly from the top of the filter, but you may have difficulty removing all air from this component. Replace the filter in its bracket.

Extract air from the reservoir bag by opening the stopcock at the top and squeezing the bladder. Leave a small amount of air in the reservoir, so that you can see the fluid level. Close the stopcock while maintaining your pressure on the bladder, so that air does not get back into it.

After debubbling for at least five minutes, reduce pump speed to 0.5 liters per minute.

3. Avoid stopping the pump.

To keep the circuit free from air bubbles, maintain some pressure in it at all times. Instead of stopping the pump, maintain it at minimum speed (about 0.5 liters per minute). To maintain the reservoir volume, swap the surgical clamp from the perfusate supply line to the reservoir outlet line (from A2 to A1 on the Flow Diagram) so that more perfusate enters the circuit, and keep the clamp there until the reservoir is between half and two-third full. Then swap the clamp back again.

4. Continue monitoring the circuit until the surgeon is ready.

Watch for leaks and air, and watch the reservoir, which should maintainitself at a constant level while the system is closed. Remove excess water from the bucket and add more ice, as necessary. If a delay seems likely, switch off the sump pump, remove it from the bucket, and place it above the level of the heat exchanger while you are waiting.

E. Cannulation and Perfusion

1. Take precautions against infection.

When the patient is ready for perfusion, use gloves, cap, mask, and eye protection.

2. Check pressure monitor.

Apply light finger pressure to the venous line to slow the flow, and watch the pressure monitor to see if it reacts.

3. Establish working pressure.

With the arterial-venous bypass closed, run the roller pump at sufficient speed to reach a pressure between 25 mm and 40 mm, measured from the manometer on the arterial line. Make a final check for leaks and air bubbles, and check that the sump pump is running.

4. Watch the reservoir during cannulation.

The surgeon will cannulate one femoral artery for infusion and preferably both femoral veins for recovery, and should ligate the cannulae to keep them in place. Allow a small amount of perfusate to enter the cannulae, to avoid taking in air. Be prepared to take initial temperature readings as soon as blood fills the venous line.

5. Switch to open-circuit washout.

Surgeon should open the venous return line and announce loudly to perfusionist, "switch lines." Surgeon will clamp the bypass to force all flow through the patient. Perfusionist should now swap the clamp from B2 to B1 on the Flow Diagram, so that blood from the patient is diverted to the waste bladder. Also swap the clamp from A2 to A1 so that the perfusate supply bladder is able to feed the circuit. The patient is now in open-circuit washout. Perfusate is passing through the patient, displacing blood into the waste bladder. Air bubbles will usually begin to appear in the venous line, and should be cleared down to the waste bladder.

6. Increase pressure.

Increase pump speed to no more than 5 liters per minute, holding the arterial pressure below 80 mm. Estimate the time it will take to wash out with 10 liters of perfusate. This will be the maximum duration of open-circuit perfusion. Be prepared to switch to closed circuit when 10 liters have passed through the patient.

7. Watch for pressure fluctuations.

Continue monitoring the pressure in the circuit. Any sudden drop in pressure may require you to reduce pump speed and swap the surgical clamp from B2 to B1, to close the circuit and stop dumping fluid temporarily. If a cannula is dislodged or perfusate leaks into the patient because of a defect or damage in a blood vessel, you should open the plastic clamp on the arterial-venous loop bypass.

8. Replenish ice.

Observe the ice bucket, remove excess water and substitute more ice as needed.

9. Switch to recirculation to cool patient.

When 10 liters of perfusate have passed through the patient (i.e. half of the contents of the perfusate bladder), switch to closed circuit by moving the clamps from B1 to B2 and A1 to A2 in the Flow Diagram. The source of perfusate has now been cut off, and the dumping of venous return to the waste bladder has also been stopped. The solution is now recirculating through the patient. Much of the blood has been washed out, and the purpose now is to reduce the temperature of the patient.

10. Add and remove perfusate to maintain half-full reservoir.

> *If you allow the reservoir to run dry, air will enter the system. This can cause embolisms which will seriously damage your patient. On the other hand, if you overfill the reservoir, you can actually burst the bladder. Always watch the reservoir carefully and maintain a correct fluid level!*

If the reservoir falls below half-full, move the clamp from A2 to A1 in the Flow Diagram, to allow more perfusate to enter the system. If the reservoir nears three-quarters full, swap the clamp from B2 to B1 to allow some effluent to escape into the waste bladder. NOTE: The clamps need to be swapped only momentarily to correct the volume in the system.

If foam or excess air accumulates in the venous reservoir, vent it to the waste bladder.

F. Shut Down.

1. Perfusion will stop under any of the following conditions:

Venous temperature remains below 10 degrees Celsius after at least 10 minutes of circulation.

Flow remains below 0.5 liters per minute at 110 mm arterial pressure.

Recirculation becomes impossible because the supply of perfusate is exhausted and the reservoir is less than one-quarter full.

Limited availability of air transport for the patient overrides other considerations.

2. Disconnect.

Unclamp the bypass. Use an occlusion clamp to stop flow on the arterial side. Make sure that all cannulae are clamped before cutting or disconnecting lines leading to them. Leave the cannulae in place in the patient to prevent air entering the vasculature. Stitch the cannulae in place and cover the wound with surgical or other adhesive.

3. Prepare for shipment.

Ideally, all ATP equipment should be broken down and prepared for shipment in parallel with preparing the patient. However, the patient should not be delayed because the ATP is not ready to go, and one team member may stay behind to do the cleanup.

Dispose of sharps in the container provided. Strip all tubing and components off the ATP backplate, place in a biohazard bag, and pack with the patient to be returned to Alcor for proper disposal.

Throw away the waste bladder and perfusate bladder, provided this can be done legally (a mortuary will have a hazardous waste collection service). The embolus filter and heat exchanger should be retained with the ATP kit, since they can be reused in training sessions.

4. Take patient to the airport.

Note that since 9/11/2002, commercial air carriers may delay the transport of human remains as a security measure. Your mortician may have made special arrangements with some air carriers to avoid this delay. Do not take the patient to the airport before you are sure that a flight is available. Consider an air ambulance if necessary.