
Hospital Risk Control

Risk Analysis:

Cardiopulmonary Perfusion Equipment

Dear Readers:

We are fortunate to have obtained the permission of ECRI to reprint the article entitled "Cardiopulmonary Perfusion Equipment." The article is reprinted from *HOSPITAL RISK CONTROL, Surgery and Anesthesia 10, 1984*.

Several professional groups such as ECRI have taken the responsibility for publishing minimum standards for perfusion and related technologies. Rightly so. Perfusionists have not been able to date to create a single document that addresses content similar to this ECRI article, on which the majority of our profession can agree.

Please read with interest how one professional group, ECRI, views our professional obligations to cardiopulmonary perfusion equipment risk analysis.

JBR

Cardiopulmonary perfusion equipment, commonly referred to as heart-lung machines, provides cardiopulmonary support for a patient during open-heart surgery. The equipment allows cardiovascular surgeons to isolate the heart from the circulatory system so that they may perform necessary cardiac repairs or valve replacements, and still supply vital organs with oxygen. Cannulas are inserted into the great vessels leaving (aorta) and returning to (venae cavae) the heart, thus creating an external (extracorporeal) circuit to provide circulation and oxygenation while the heart and lungs are bypassed. Cardioplegia solution, infused through a delivery system, is used to stop the rhythmic contractions of the heart during bypass and to decrease its metabolic requirements, allowing surgeons to operate.

Cardiopulmonary perfusion systems normally consist of blood pumps, control and monitoring devices, disposable oxygenators, cardiotomy reservoirs, filters,

and tubing sets. [These components are described and shown schematically.]

HOW IT WORKS

Blood pumps propel the blood through the extracorporeal circuit and return it to the total volume of blood in the circuit via suction. Usually, three pumps are used. The arterial pump returns oxygenated blood to the patient and may operate at a flow rate of up to 6 L/min, depending on the size of the patient. A backup arterial pump is usually provided. The two other pumps in the system are used to generate suction to return blood from the surgical site to the cardiotomy reservoir. Since continuous operation is imperative, a backup battery pack as well as connection to the emergency power system are necessary. [Hand cranks should also be kept with all pumps.]

The oxygenator,* cardiotomy reservoir, arterial filter, and tubing are the disposable components that form the extracorporeal blood circuit for the perfusion. Blood taken from the venae cavae normally flows by gravity to the venous side of the oxygenator where it is oxygenated and its temperature is controlled. This blood flows through the defoamer of the oxygenator to the arterial reservoir of the oxygenator. The arterial blood pump returns the blood to the patient, and then may pass it through a blood line filter before it reaches the patient. A shunt is incorporated around the blood line filter to permit flow if the filter must be changed.

Blood at the surgical site is returned to the patient by suction pumps. Intracardiac suckers return blood to the cardiotomy reservoir where it is filtered and then drained or pumped to the venous side of the oxygenator. Blood from the cardiotomy reservoir may be passed through an additional blood line filter before it is returned to the oxygenator. The tubing set described is usually specified by the perfusionist and made up as a sterile custom pack by the tubing manufacturer.

*This discussion pertains to bubble-type oxygenators. A second pump may be used to propel venous blood if a membrane oxygenator is used instead.

Copyright 1984 ECRI. All rights reserved. Used by permission. Reprinted from *Hospital Risk Control*, ECRI, 5200 Butler Pike, Plymouth, PA 19462

RISKS TO THE PATIENT _____

One of the greatest risks to the patient during cardiopulmonary bypass is embolism—the inadvertent introduction of air (or other gas or particulate matter) into the patient's circulation. Gross air emboli (1 mL or greater) in the arterial circulation can cause serious injury and death. The effects of smaller emboli are not fully understood; however, small emboli (gaseous and particulate) have been implicated as causes of neurological disorders and of gross pathological changes of downstream organs.

There are devices that are intended to prevent the inadvertent infusion of air, including extracorporeal blood filters, bubble traps, one-way valves, and air bubble and level detectors (i.e., devices attached to the extracorporeal tubing or oxygenator which give audible and/or visual alarms and which may shut off the arterial blood pump when air is detected in the tubing or the level of blood in the oxygenator falls below a predetermined level). Nevertheless, emboli do occur, primarily as a result of operator error or failure to continuously monitor changes in the extracorporeal blood circuit.

Some situations in which emboli can occur are the following:

- A partial vacuum is created as the arterial pump draws blood from the oxygenator during cardiopulmonary perfusion. Any defective or improper connections in this negative pressure area can suck in air.
- Inadequate or improper filtering of blood returned from the surgical site (suction) can result in air and particulate emboli.
- A rapid, inadvertent emptying of the oxygenator and a subsequent infusion of air can occur if there is an inadequate flow of venous blood to the oxygenator.
- Rupture of the arterial line in the pump head can also introduce air and cause blood loss.
- Other sources of embolism, besides air, may be fat, platelets, foreign materials, gas, silicone, anti-foam compounds, fibrin, silica, or other aggregates which can gather in the oxygenator. The oxygenator does not filter blood; it provides oxygen to the blood and defoams it. The literature contains many reports of disorders linked to particulate matter from extracorporeal circulation. Changes in the blood due to extracorporeal circulation and particulate matter from tubing sets and oxygenators have been reported. [This is known as spallation, the breaking off of small bits of tubing from repeated blood pump stress.]

The presence of particulate matter in the extracorporeal blood circuit has led some perfusionists to perform prebypass filtration. Although there is some controversy concerning extracorporeal blood filtration during perfusion, many experts believe that it is safer to filter than not to filter. The extracorporeal blood circuit should

have at least one filter (arterial line) in addition to the filtration provided by the cardiotomy reservoir. An additional blood filter may be required, depending on the level of filtration provided by the cardiotomy reservoir.

MONITORING SYSTEMS _____

There are several patient and equipment variables that must be controlled and monitored during perfusion. The temperature of the blood in the extracorporeal circuit is altered to produce hypothermia or normothermia in the patient's body. A heat exchanger is normally incorporated in the oxygenator and water must be delivered to the exchanger at a specified temperature. A mixer is used to proportion the incoming hot and cold water to be delivered to the exchanger. These mixers usually incorporate a thermometer to give temperature readings.

Oxygen, used to oxygenate the venous blood, may be delivered from tanks or a central piped oxygen system. A flowmeter and bacteriologic filter are usually incorporated into the oxygen circuit. The oxygen content of the blood may be monitored by blood gas determinations from drawn samples or by using an in-line differential oxygen monitor.

Temperature monitors may be used, with probes placed at various points on the patient and/or in the extracorporeal circuit, and the temperature is displayed at the main console.

Level detectors may be used to monitor the blood in the oxygenator. These detectors may give audible and visual alarms and may also stop the arterial blood pump if the blood level in the oxygenator is low, in order to avoid pumping air into the patient, or too high to prevent excessive blood in the exsanguinator.

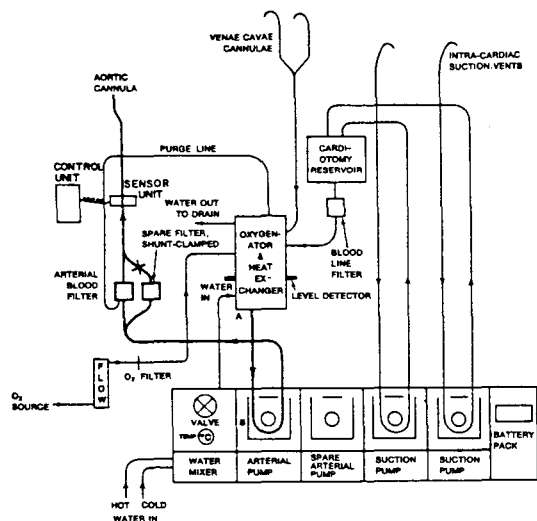
Pressure monitors record left atrial, pulmonary artery, and systemic arterial pressures. These monitors may be included in a central console or they may be attached to other pressure monitoring equipment.

Blood contact with foreign surfaces (extracorporeal circulation) requires alteration of the body's normal coagulation (clotting) mechanism. The clotting mechanism must be controlled and monitored to a point where coagulation is inhibited, but in a reversible manner. Heparin is the anticoagulant drug used in perfusion, and its level must be monitored throughout the perfusion to prevent either clot formation or overheparinization, which would cause uncontrolled bleeding.

THE ROLE OF THE PERFUSIONIST _____

The most important monitor for air or other matter in the extracorporeal circuit that can cause emboli is the

perfusionist. Cardiopulmonary perfusion is not a straightforward, predictable, controlled procedure. Constant vigilance by the perfusionist is required, and, if other responsibilities or activities distract the perfusionist during the procedure, the risks to the patient are increased. Some surgical personnel may wrongly assume that the perfusion equipment runs itself once it is set up, and so may ask the perfusionist to perform other tasks during surgery. This is a very dangerous practice, and should be avoided. There have been many patient injuries or deaths because of operator inattention during the procedure, improper connection of the equipment, or defective equipment. [The arterial pump, operating at 6 L/min, can empty the oxygenator of 1000 cc of blood in 10 seconds. During the short amount of time that the perfusionist may turn away from the machine, air may be allowed to enter the system.] It is possible that many of these incidents could have been prevented had the equipment been thoroughly checked for integrity and proper connection, and had the perfusionist continuously monitored the equipment during the procedure.*



Components of a Heart-Lung Machine

This is a general schematic; not all perfusion systems are configured in this manner. Some components have been left out for clarity. The tubing configuration and disposable products may vary, depending on the perfusionist. Some components of the system are for single use only.

*See, for example: Mills NL, Ochsner JL. Massive air embolism during cardiopulmonary bypass: Causes, prevention, and management. *J Thorac Cardiovasc Surg* 80:708; 1980 Nov; Heart-lung machines & air bubbles, a potential cause of death and lawsuits. *Biomed Saf Stand* 11:16; 1981 Feb 15; Legal review, *Hosp Risk Mgmt* 3:50-51; 1981 Apr; and A momentary diversion proves a fatal mistake. *Case Alerts* (Pennsylvania Hospital Insurance Company/Pennsylvania Casualty Company). No. 81-4; 1981 May.

NEED FOR PERFUSION PROTOCOLS

ECRI has conducted many investigations of injuries and deaths related to cardiopulmonary perfusion equipment and found that many hospitals do not have clearly defined, written perfusion protocols. Practices are often inconsistent, and when incidents occur, proper investigations are difficult to carry out because procedures have not been systematically documented. To ensure an acceptable and uniform practice of cardiopulmonary perfusion, protocols describing the conduct of perfusion should be developed jointly by the perfusionists, surgeons, and anesthesiologists with appropriate input and review by hospital administrative and medical staff. The protocols should describe the procedures for preparing, performing, and concluding bypass. These policies should consider all aspects of the perfusion and should be periodically reviewed and updated. As a minimum, they should address:

- Responsibilities (who does what)
- Surgical protocols
- Anesthesia protocols
- The extracorporeal and cardioplegia circuits
- Equipment selection and use
- Monitoring of coagulation activity, perfusion pressures and rates, suction procedures, acid base balance, blood gases, and temperature

In addition to describing the conduct of normal perfusion, procedures should be described for dealing with emergencies that arise during cardiopulmonary bypass. These include, but are not limited to:

- Air embolism
- Defective extracorporeal component(s)
- Electrical power failure
- Inability to wean from bypass
- Altered hemodynamics
- Excessive blood loss
- Blood damage
- Other clinical manifestations

There should also be protocols describing high risk equipment and recommending supervision during their use. This equipment includes:

- Autotransfusion devices
- Defibrillators
- Intra-aortic balloon pumps
- Plasmapheresis equipment
- Pacemakers

Development and implementation of these protocols will allow better communication and more effective responses from the surgeon, perfusionist, and anesthesiologist during open-heart surgery procedures.

DOCUMENTATION

A perfusion record that is complete and provides all relevant information should be kept for each procedure. General information should be included regarding date, patient, medical record, diagnosis, surgical team (surgeon, anesthesiologist, perfusionist), and procedure. Specific information should be listed concerning starting and stopping of bypass, priming volumes, partial bypass time, and fluids and drugs administered. [If blood products are given, serial numbers should be recorded.] Flow rates (blood and gas), pressures, temperatures, blood chemistry data, heparin status (Activated Coagulation Time), and urine output should be charted at regular intervals throughout the procedure (every 10-15 minutes), or when measurements of these factors change. Disposition of blood volume remaining in the oxygenator and any other components pertinent to the perfusion should be noted. The lot and serial number of all disposable components used in the procedure should be recorded, including the tubing set, filters, and oxygen electrodes. If a prosthesis is involved, its type, model, and serial number should be listed. [A sample perfusion record is included in this Risk Analysis. Readers may copy this form for use in their hospitals.]

In addition to the perfusion record, a protocol and preoperative checklist should be developed. The protocol should describe the steps necessary to prepare for the perfusion. The checklist should be used to detect problems or to verify that all components and systems have been checked prior to perfusion.

EQUIPMENT

The perfusionist must have access to the perfusion setup and to information on blood pressure and blood chemistry throughout the perfusion. The perfusion setup and pressure monitoring equipment must be in the direct view of the perfusionist. The perfusionist should be able to view the mean arterial and left atrial pressures (value and waveform) while simultaneously viewing the oxygenator, cardiotomy reservoir, arterial blood filter, and extracorporeal tubing. Team perfusion may help prevent or minimize the severity of perfusion problems. Information on blood clotting time and chemistry (pH and electrolytes) and blood gases should be available on a "stat" basis (within 5 minutes). If this cannot be achieved using the hospital lab, the hospital should consider purchasing blood gas equipment for the surgical suite.

In some hospitals, perfusionists maintain their own equipment. It is kept in the OR between procedures, and may never be inspected by anyone other than the user. This is not a safe practice. Care of cardiopulmo-

nary perfusion equipment should be part of the hospital's equipment control program. If perfusion is provided by an outside contract service, the hospital should make sure that the equipment is properly maintained.

As part of a preventive maintenance program, the following should be considered:

- Complete inventory of all equipment used in perfusion
- Initiation and documentation of inspection (including performance testing), preventive maintenance, and repair of equipment used in perfusion
- Establishment of complete documentation for all equipment in the form of an Equipment Control Record (ECR). This record should include equipment history, operator's and service manuals, maintenance service and repair information, and hazard and recall information.
- All equipment maintenance and repair data should be communicated between biomedical engineering and the perfusion staff periodically to ensure proper preventive maintenance and confidence in equipment performance. All vendor-provided services should be carefully monitored.
- A specific pump room should be designated for the purpose of storing the console and associated supplies. This will provide a controlled access area for setup and storage of the console as well as an area for performing inspection, preventive maintenance, and repair.

DEFINED RESPONSIBILITIES

The hospital should develop protocols for obtaining backup perfusion support should sudden illness or personnel changes necessitate substitution. The protocol should describe:

- Qualifications (education, experience, familiarity with equipment)
- Available resources (contract perfusion services, designated backup)
- The credentialing process
- Necessary practice perfusions
- Contract conditions (contract perfusion)
- Certificates of liability (contract perfusion)

The perfusionist's responsibilities and reporting relationships must be clearly defined. While this can be defined through the delineation of clinical privileges and appropriate job descriptions, it is important to understand that most perfusionists employed by surgeons often provide additional services to the hospital other than perfusion (such as autotransfusion, plasmapheresis, intra-aortic balloon pumping, and hemodynamic monitoring). Reporting relationships must be clearly defined in these situations.

PERFUSION RECORD

DATE _____
 PATIENT _____
 MEDICAL RECORD # _____
 DIAGNOSIS _____
 PROCEDURE _____
 ALLERGIES _____
 PERFUSIONIST _____
 SURGEONS _____
 ANESTHESIOLOGIST _____

	MANUFACTURER _____	MODEL/SERIAL # _____
OXYGENATOR _____		
FILTERS _____		
TUBING _____		
RESERVOIR _____		
PT. HEIGHT _____ m WEIGHT _____ kg		
PT. BSA _____ m ² FLOW RATE _____ cc/kg/min		
PRIME COMPOSITION _____		
HEPARIN DOSE _____ TIME _____		

TIME	COMMENT	PRESSURES			TEMPERATURES			FLOWS			LABORATORY DATA					ACT	URINE (CC)
		Art.	CVP	LAP	Eso.	Rect.	H ₂ O	O ₂	Syst.	PO ₂	PCO ₂	pH	Hgb	Hct	K		
Pre Bypass																	
Post Bypass																	

TOTALS

Fluid acellular _____
 Cardioplegia _____
 Urine volume _____
 Time on bypass _____
 Time on aortic clamp _____
 Volume, pt. oxygenator _____
 Volume left in oxygenator _____

BLOOD PRODUCTS
 SERIAL # _____

PROSTHESIS DATA

TYPE _____
 MANUFACTURER _____
 MODEL _____
 SERIAL (Lot) # _____

MEDICATIONS

Signed _____ PERFUSIONIST

NOTE: Hospitals should feel free to reproduce this form or modify it to meet their particular needs.

INCIDENT INVESTIGATION _____

The hospital's incident reporting and investigation system should be reviewed to be certain that it can deal with perfusion incidents. Incident reports should contain all relevant facts, and supposition or speculation should be clearly identified as such. Speculation could unjustifiably limit the future use of the equipment if an exact cause for the incident is not determined.

When any incident (abnormal, unusual, or unanticipated event) occurs, all equipment, solutions, accessories, disposables, and packaging involved should be impounded and kept as they were when the incident occurred. There should be a mechanism by which all staff involved in the incident can write down their observations or have them written down (depending on the circumstances) before the details of the incident are forgotten. The model, serial, and lot numbers of all devices used should be recorded.

Supplies involved in every procedure should not arbitrarily be sequestered after each procedure. This would

create problems of documentation and secure storage. Identifying information on all disposables used in perfusion should always be recorded. If a problem arises, or is suspected, the components should be identified and sequestered.

Selected Bibliography _____

1. ECRI. Evaluations: Sarns air bubble detector and Delta automatic shut-off valve. *Health Devices*, Vol. 10, No. 3; 1981 Jan.
2. Galletti PM and Brescher GA. Heart lung bypass, principles and techniques of extracorporeal circulation. New York: Grune and Stratton; 1962.
3. Ionescu MI, ed. Techniques in extracorporeal circulation, second edition. London: Butterworths; 1981
4. Mills NL and Ochsner JL. Massive air embolism during cardiopulmonary bypass; causes, prevention, and management. *J Thorac Cardiovasc Surg* 80:708-717; 1980.
5. Mortenson JD. Cardiopulmonary Bypass Systems: A Study of Safety and Performance. Final Report. April 2, 1981. Contract 223-80-5081, FDA Bureau of Medical Devices.
6. Reed CC and Clark DK. Cardiopulmonary perfusion. Houston: Texas Medical Press; 1975.
7. Stoney WS, et al. Air embolism and other accidents using pump oxygenators. *Ann Thorac Surg* 29:336; 1980 Apr.