A Better Bladder for ECMO Controls
Pump Flow as a Function of Inlet Pressure

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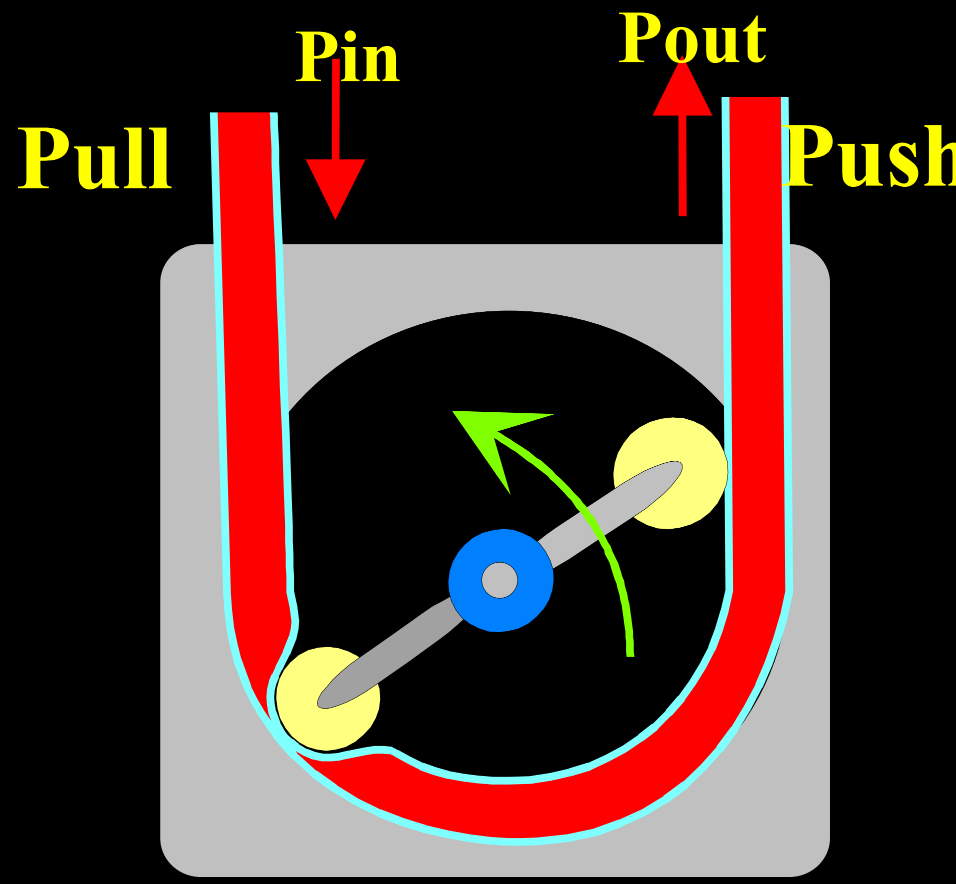
The most popular pump used for ECMO is the roller pump. The RP is a positive displacement pump that is insensitive to inlet or outlet pressure.

The pump can generate:

- Pin –600 mmHg
- Pout > 2,000 mmHg

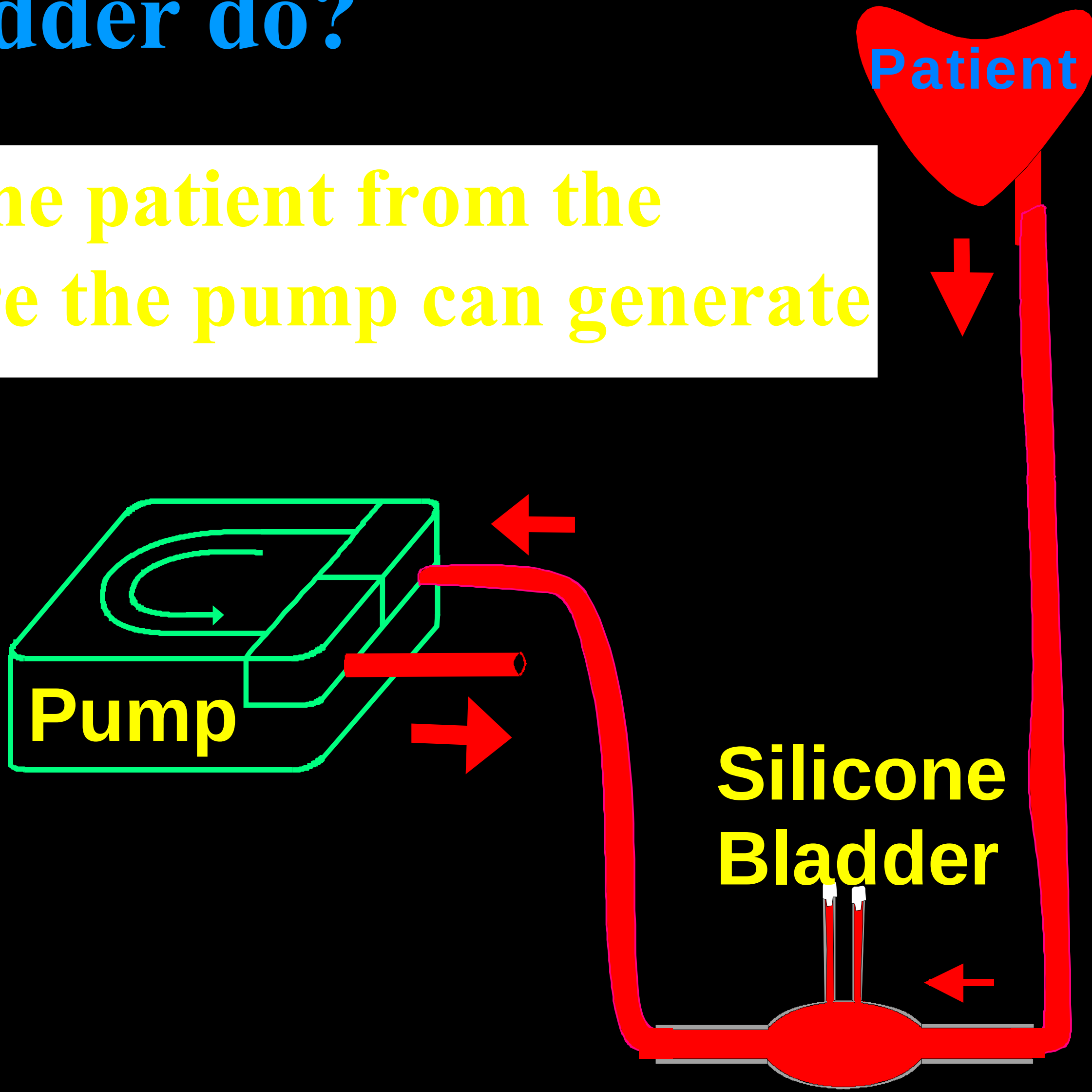
The Roller Pump



What does the Bladder do?

The Bladder protects the patient from the excess negative pressure the pump can generate

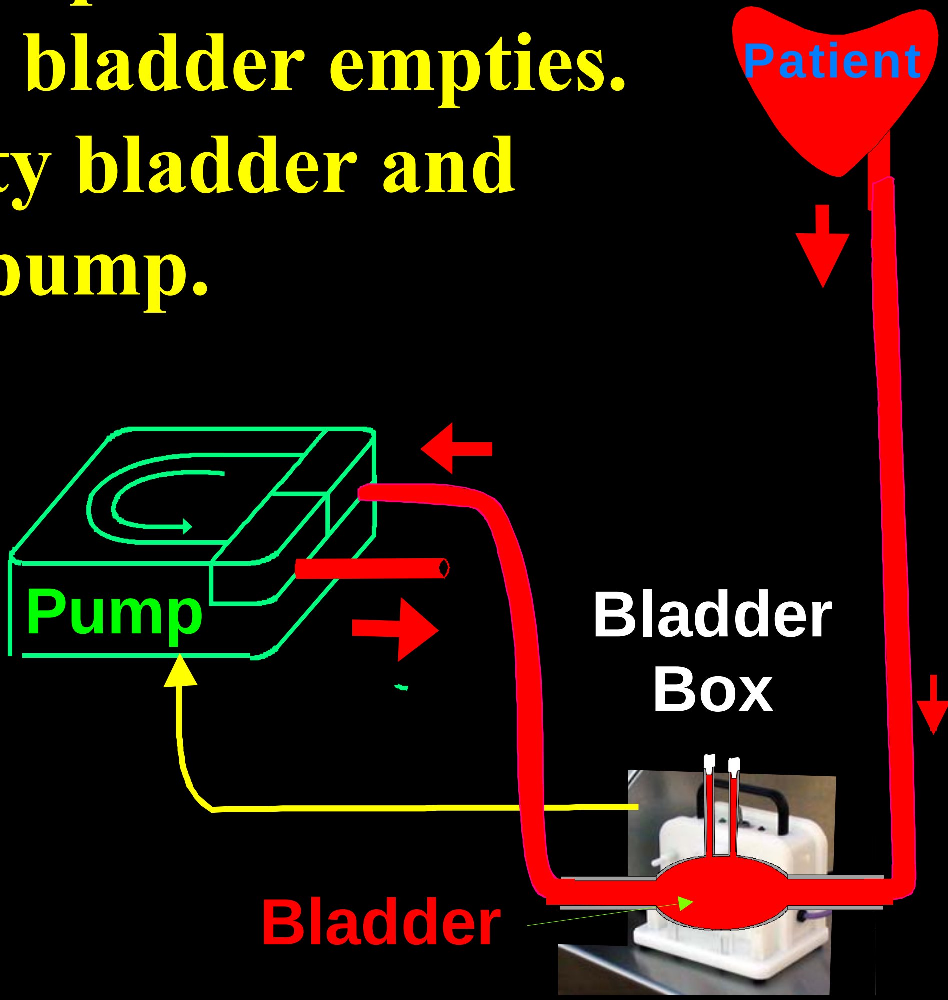
and that can damage the blood as well as the cannulated blood vessel.



How does the Bladder/Bladder Box Work?

When inlet pressure to the pump falls below ambient pressure, the silicone bladder empties. A microswitch senses an empty bladder and switches off the power to the pump.

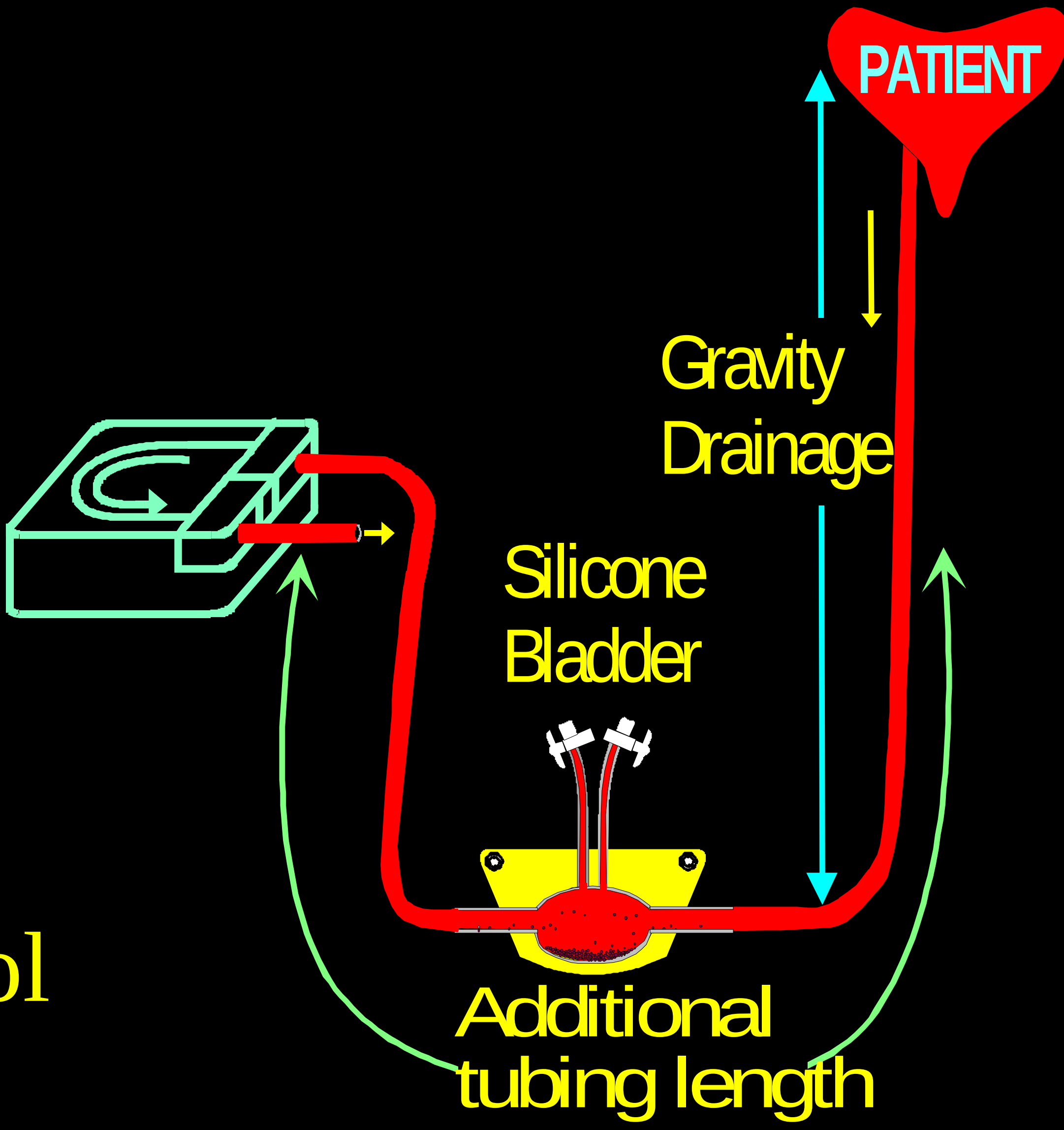
When the bladder refills the pump restarts.



Silicone Bladder/Bladder Box Limitations

Flow Control

- Gravity Drainage
  Dependent = Bladder
  on Floor



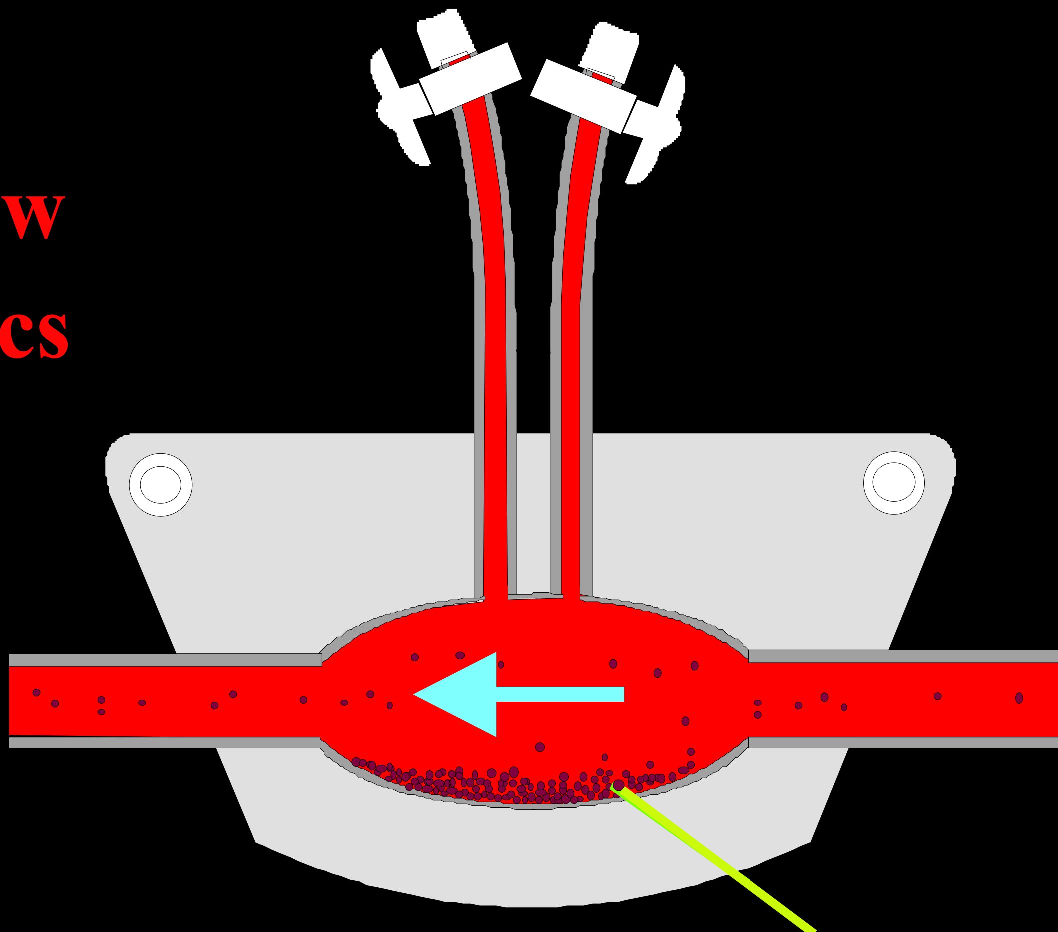
- On - Off Flow Control

Silicone Bladder + Bladder Box Limitations

Long Tubing (Patient to Floor)

- Greater prime volume
- Larger foreign surface
- Blood resides in tubing for a longer time (greater heat loss and greater blood/surface interaction)

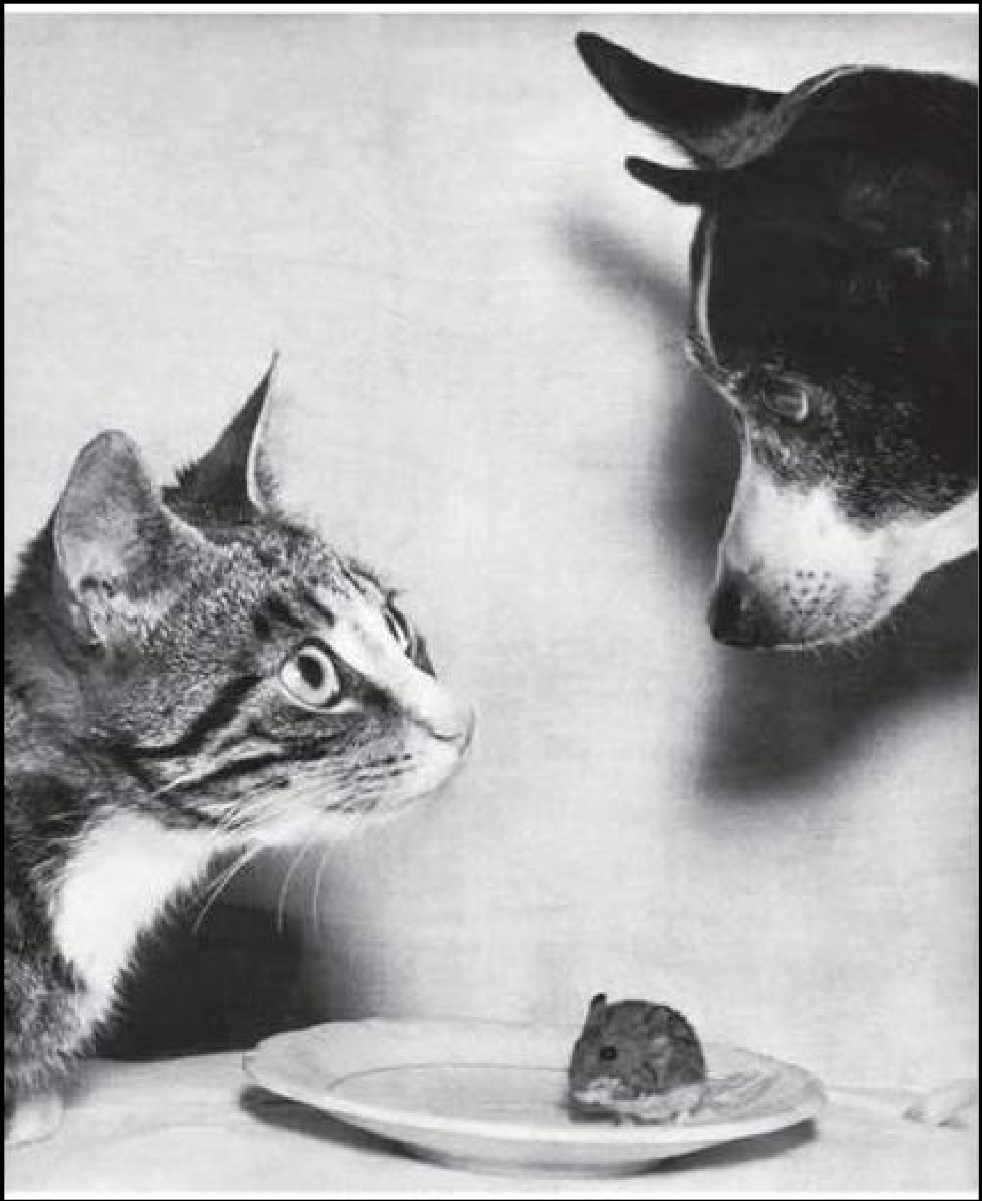
Silicone Bladder + Bladder Box Limitations



Limitations of the Silicone Bladder, Summary

1. Maximum flow is limited to the height of the the patient above the floor
2. On/Off control does not takes advantage of computer controlled roller pumps
3. Poor flow dynamics - more prone to clotting.
4. Placement on the floor can be hazardous
5. Difficult to use when transporting a patient

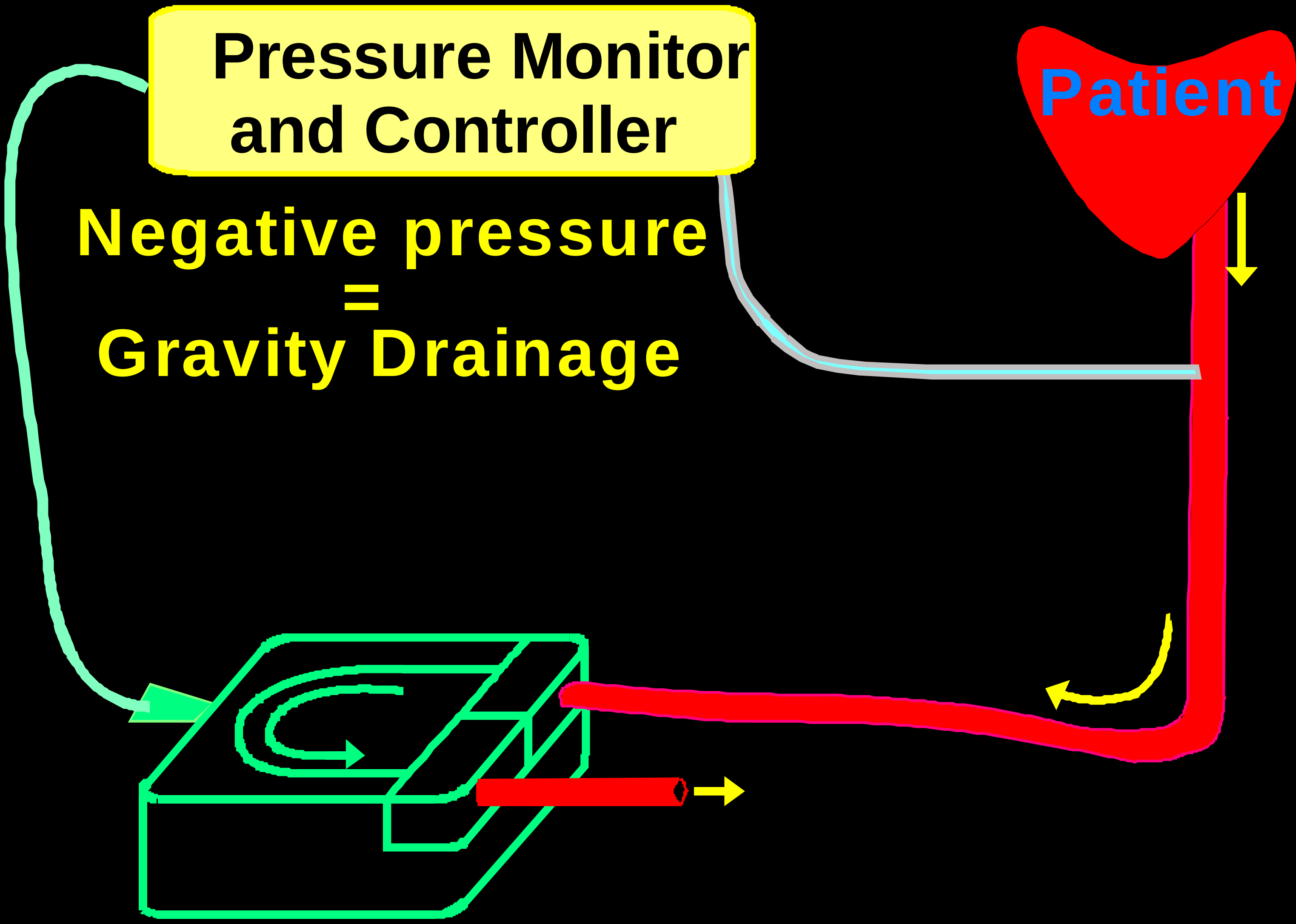
What to do?



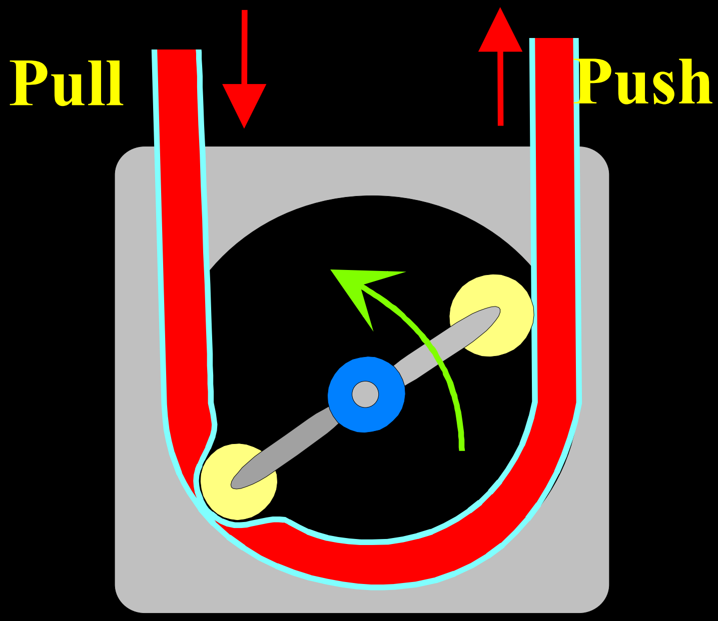
Develop a Better-Bladder System that provides:

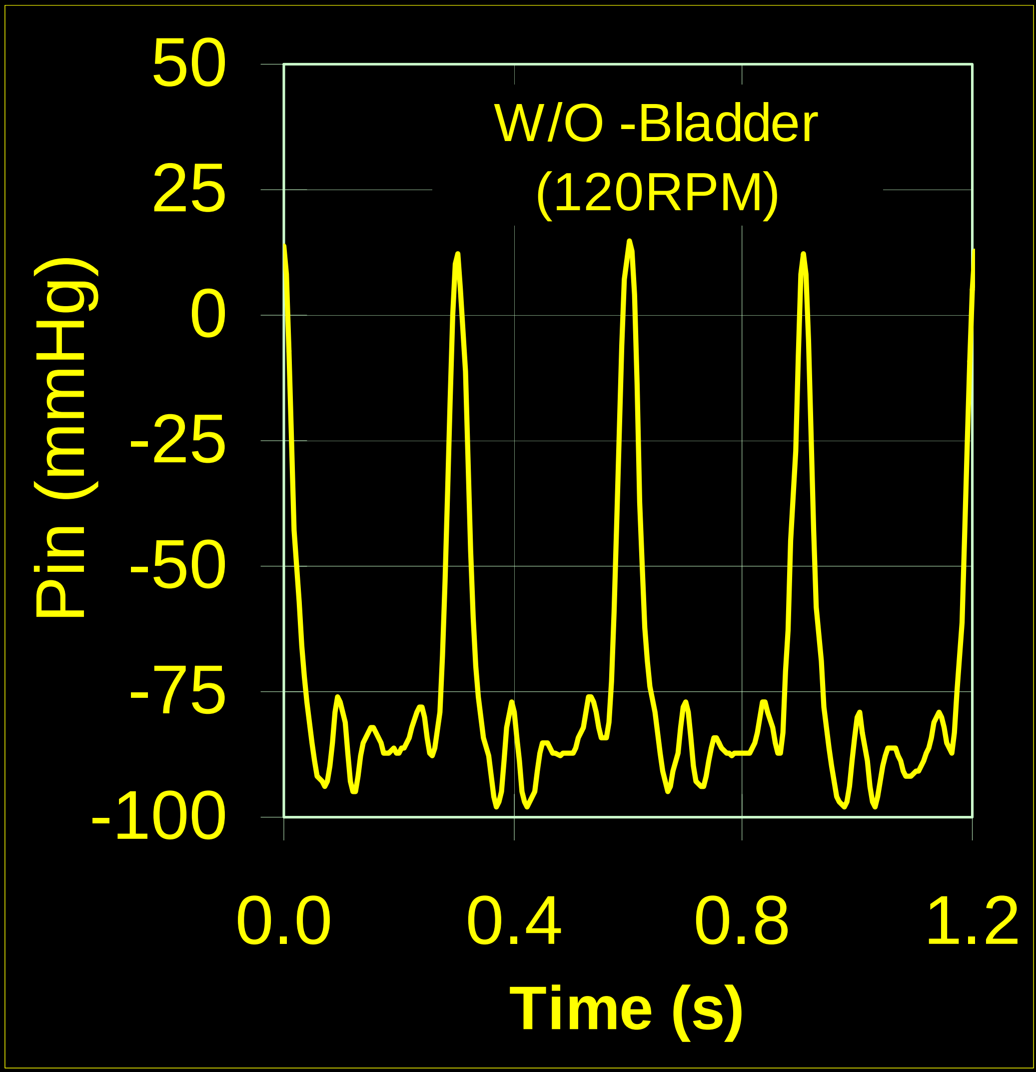
- VAVD for roller pumps that increases flow
- On/Off *or* Continuous flow control
- Flow pattern less conducive to cell settling
- Shorter tubing
- Need not be placed on the floor

Control pump speed as a function of inlet pressure



The Inlet Pressure of a Roller Pump is Pulsatile

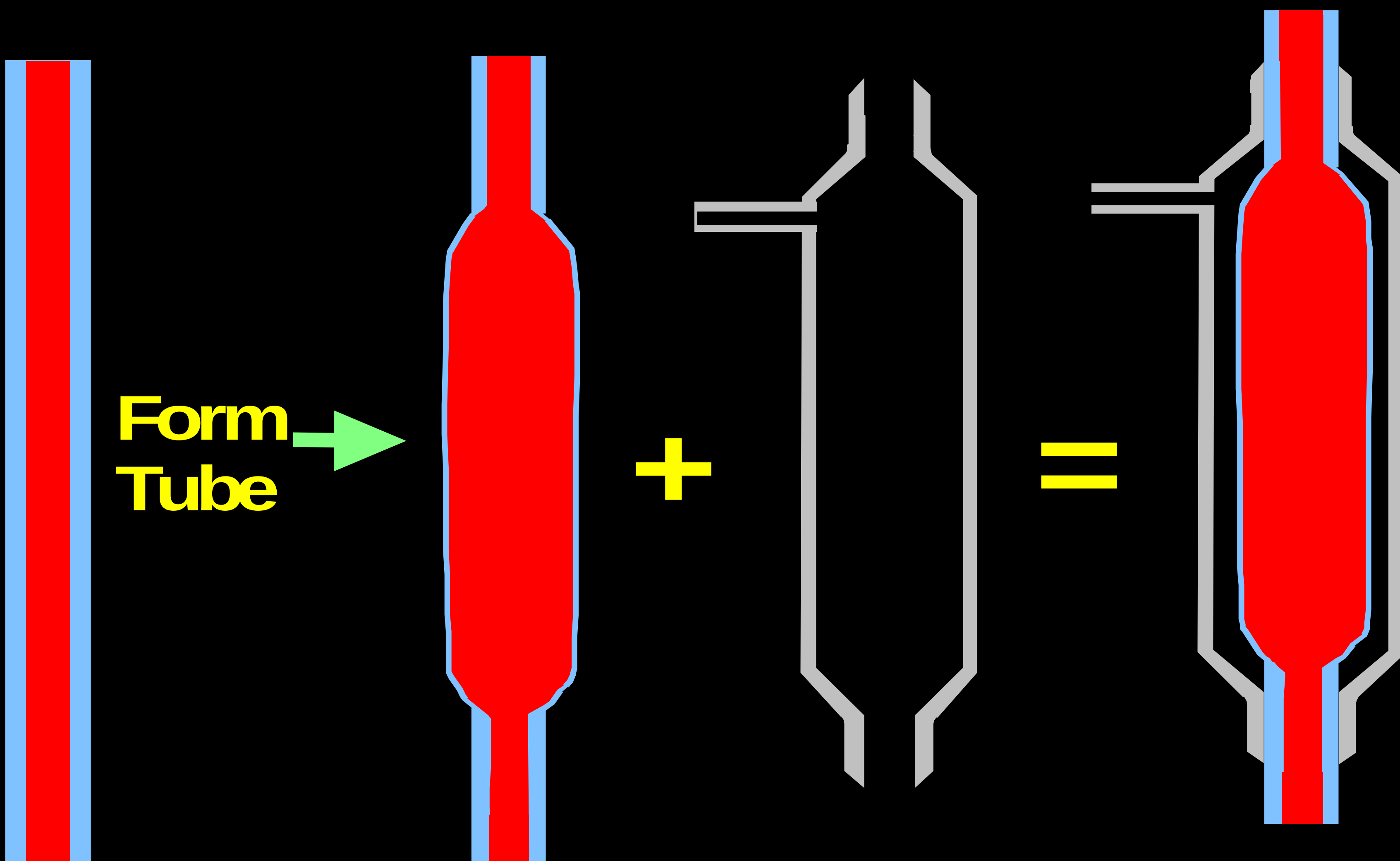




Pulsatile pressure at pump inlet prevents smooth pump control

How the Better-Bladder™ is Made

Tube Balloon + Housing = BB



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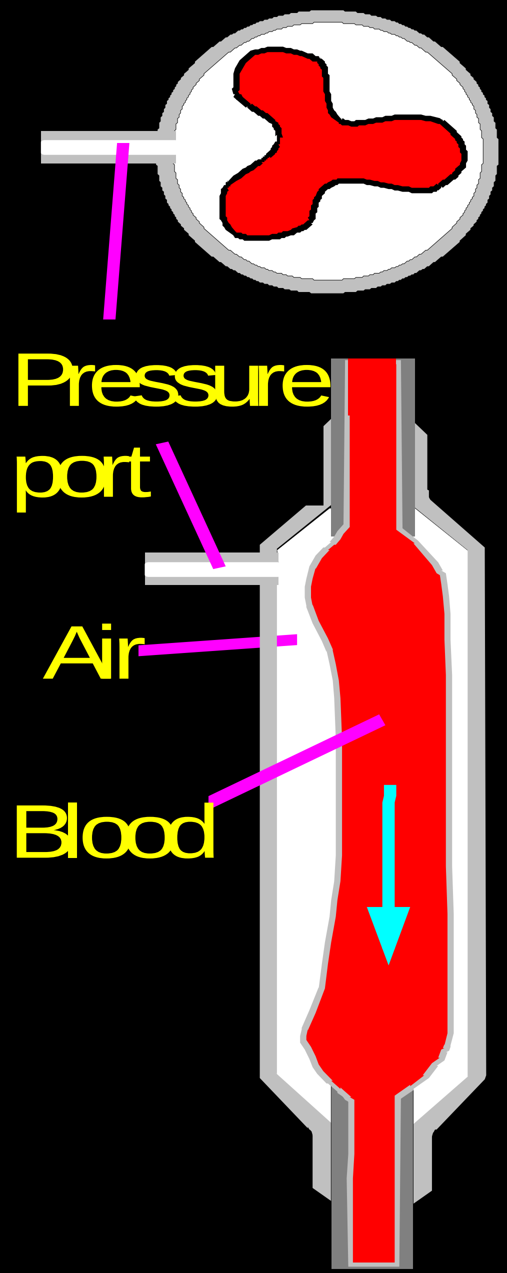
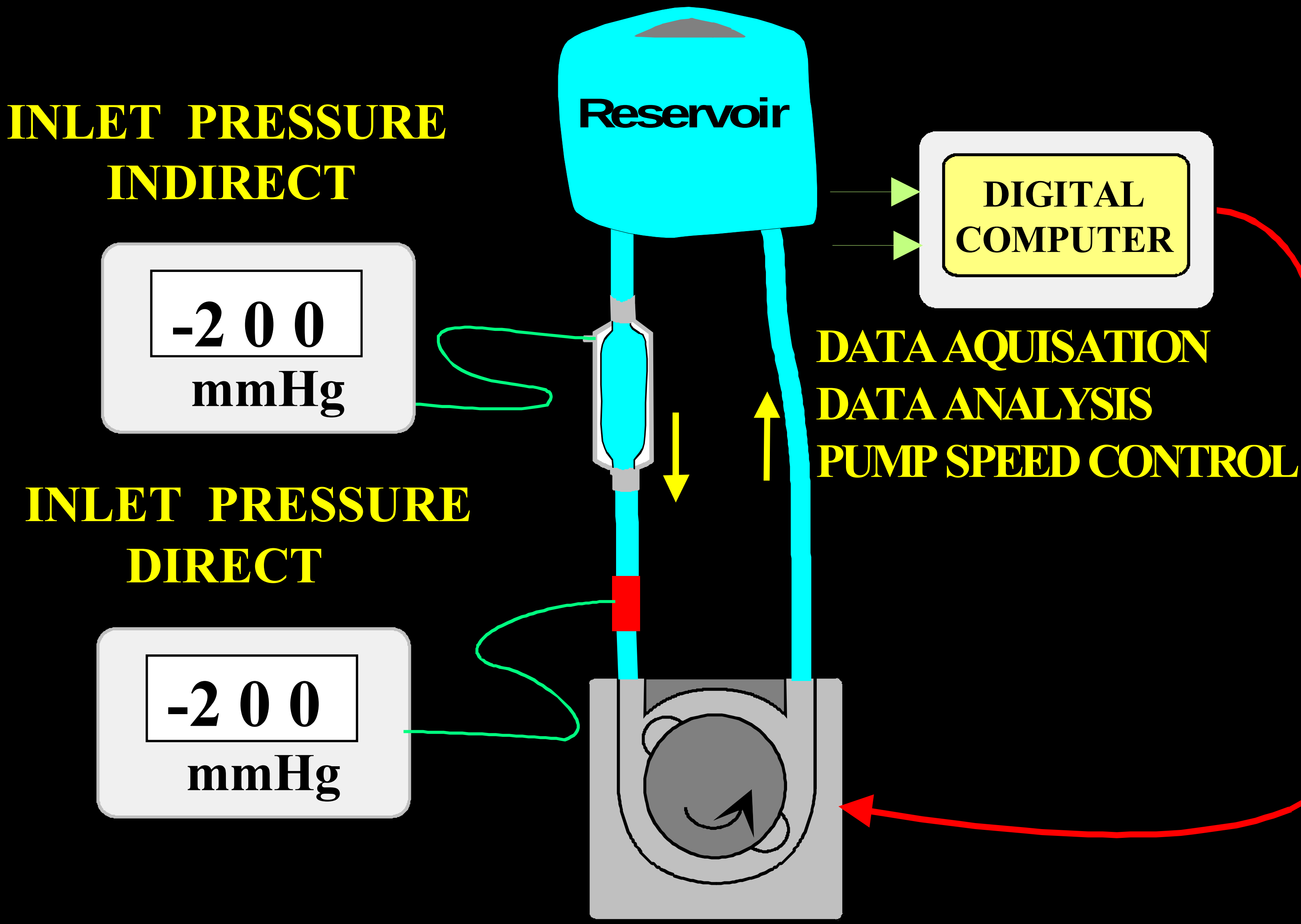
The Better-Bladder

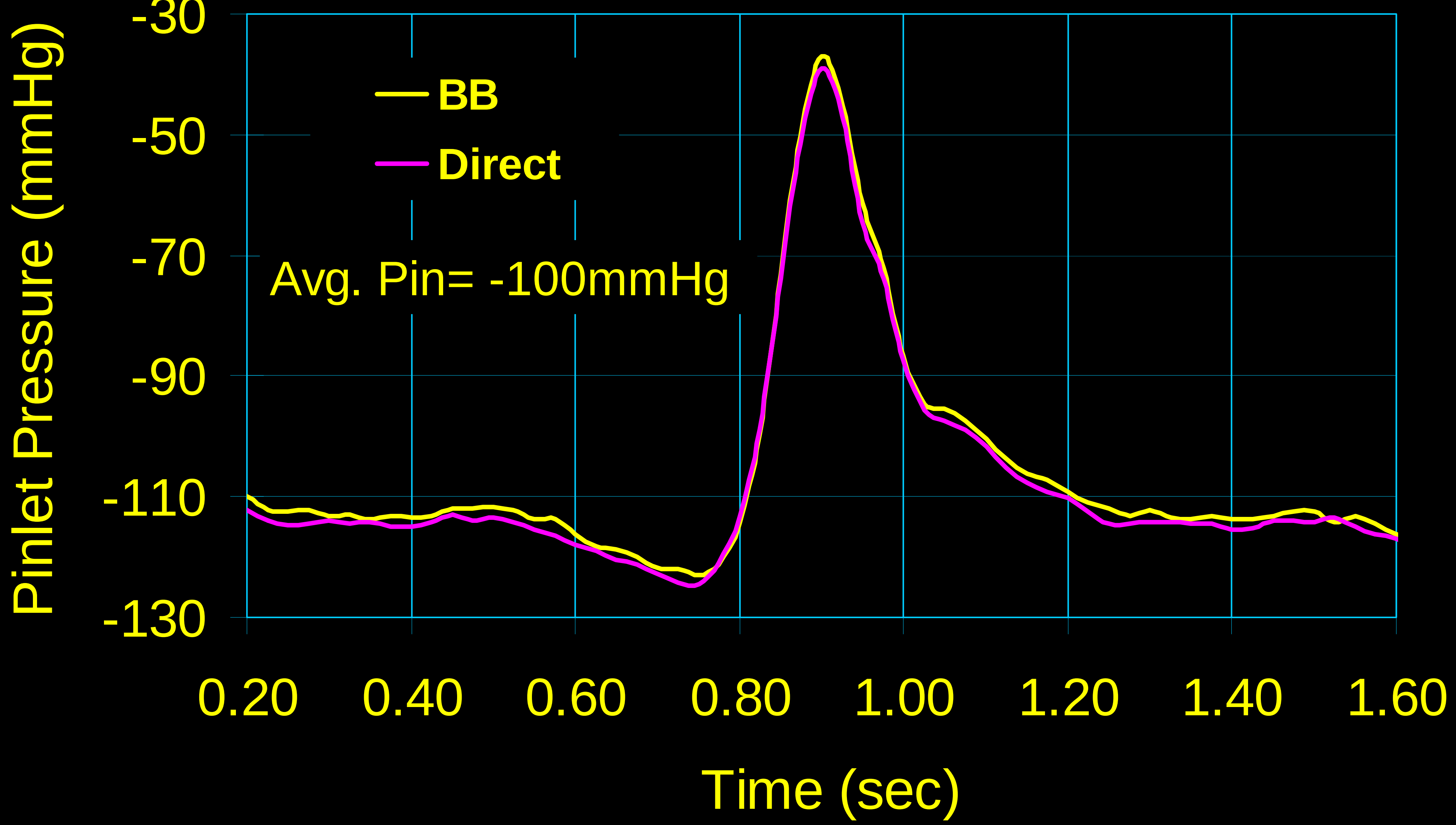
- Senses Pressure
- Provides Compliance



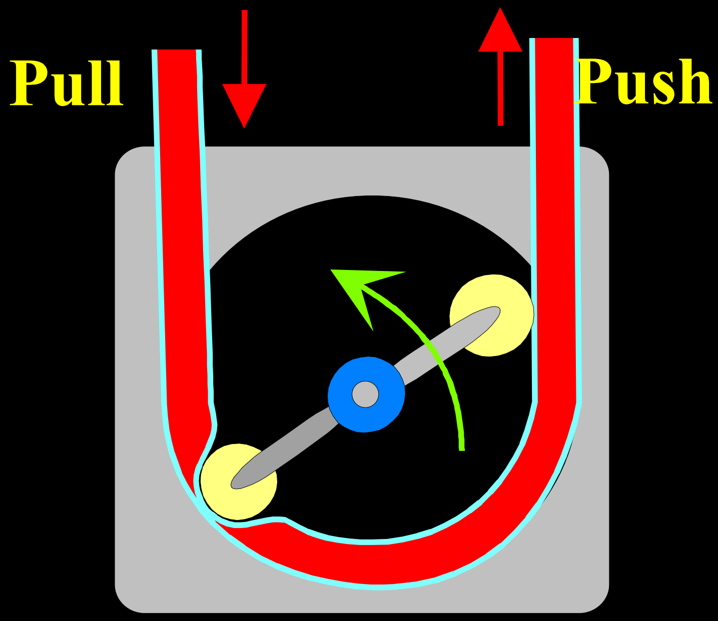
Functional Tests: Experimental Setup

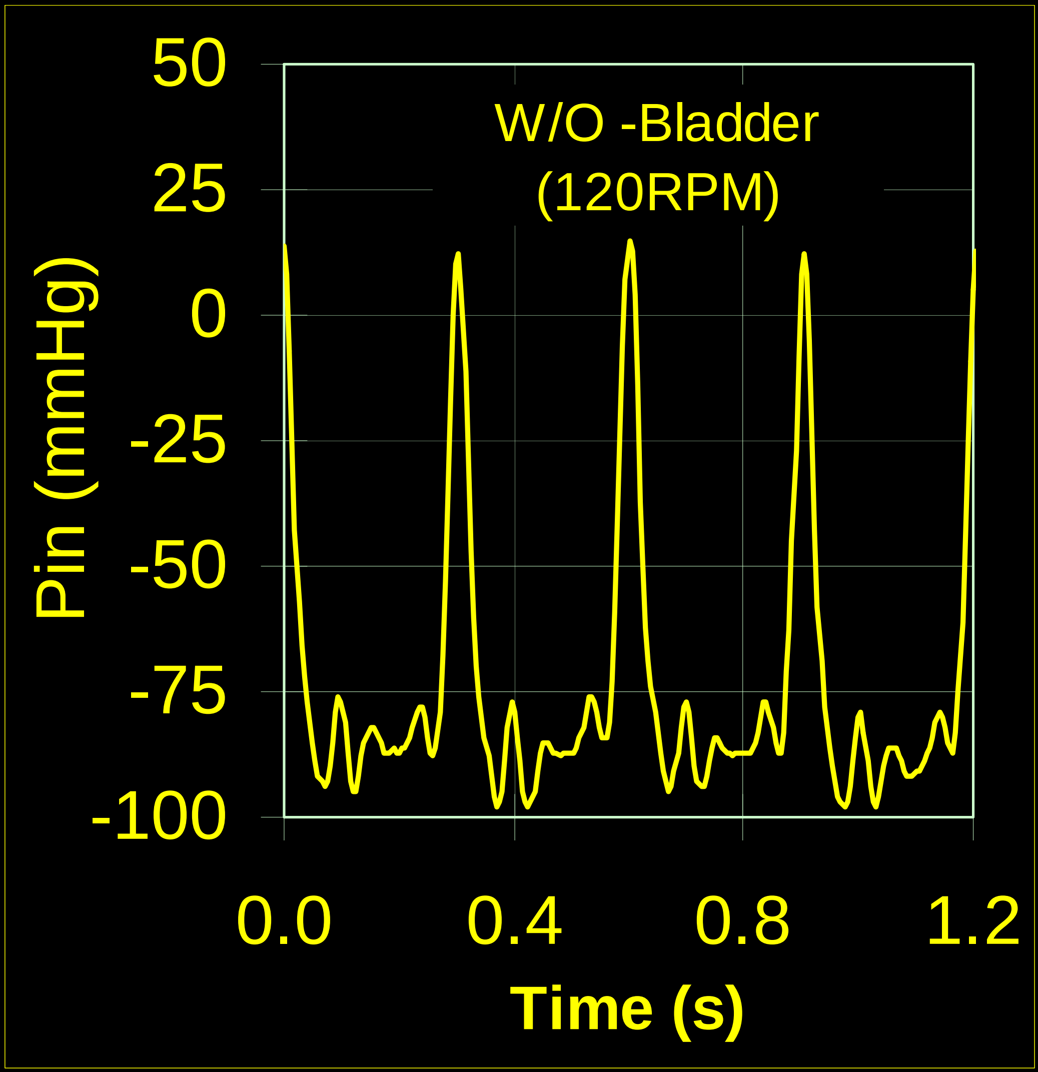


BB Provides a High Fidelity Pressure Signal



The Inlet Pressure of a Roller Pump is Pulsatile

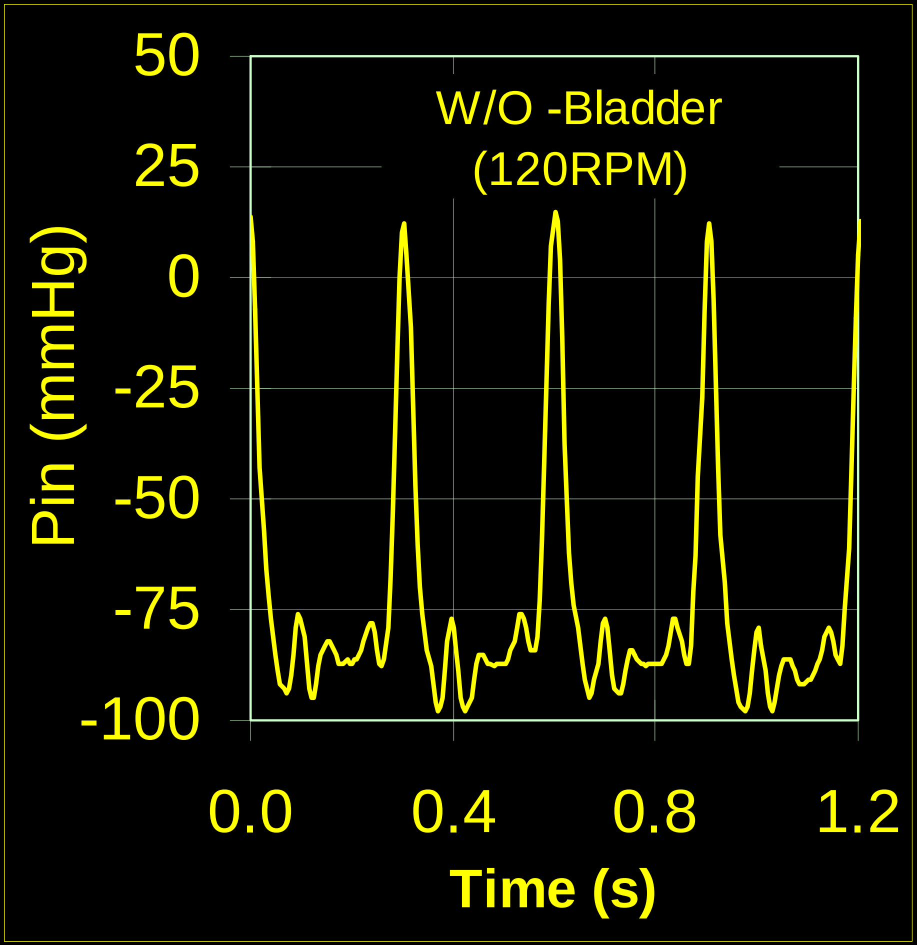


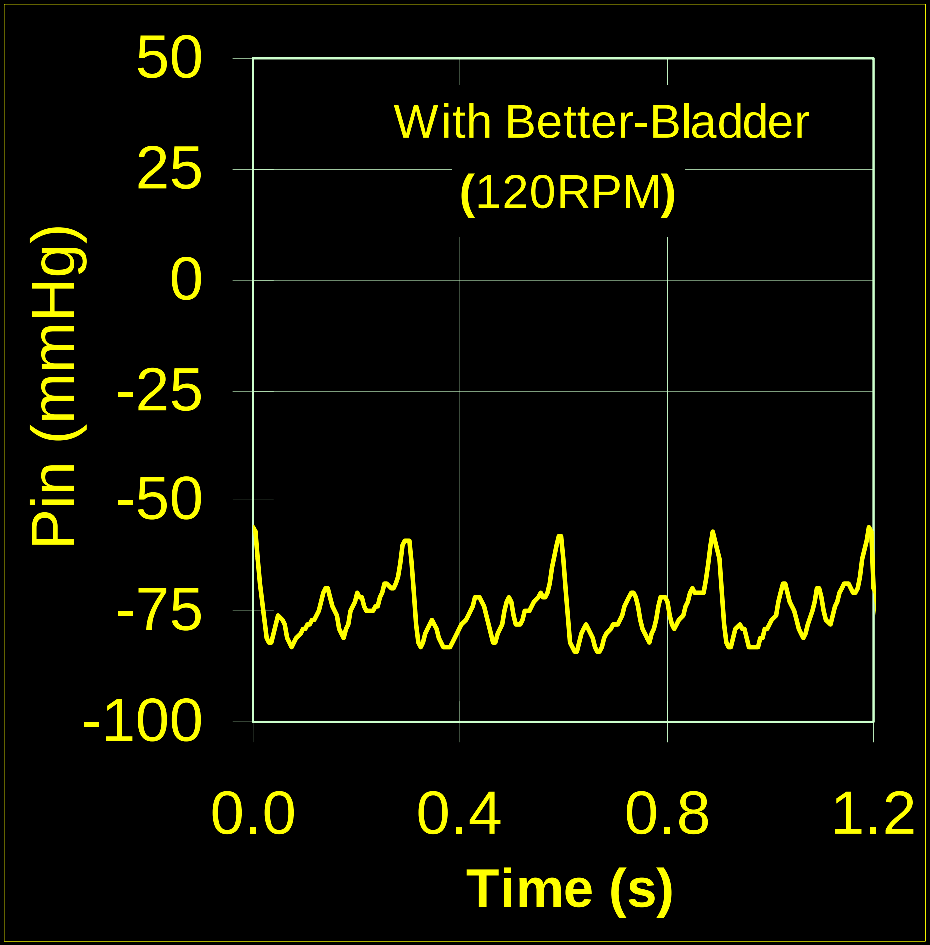


Pulsatile pressure at pump inlet prevents smooth pump control

Roller Pump + BB

Inlet Pulse Pressure is Dampened





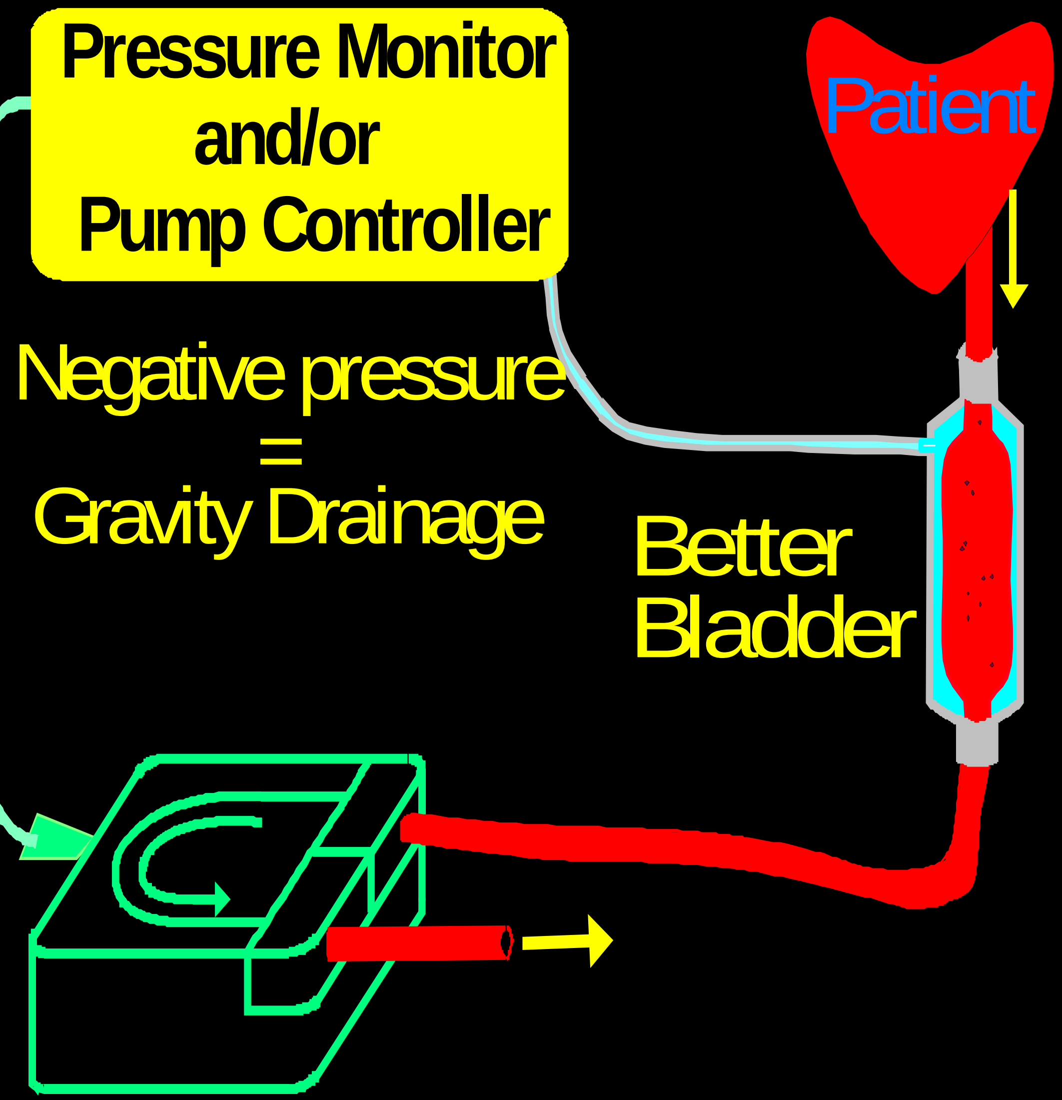
Pump Control with the Better-Bladder:

Inlet pressure signal controls pump speed:

- On/Off

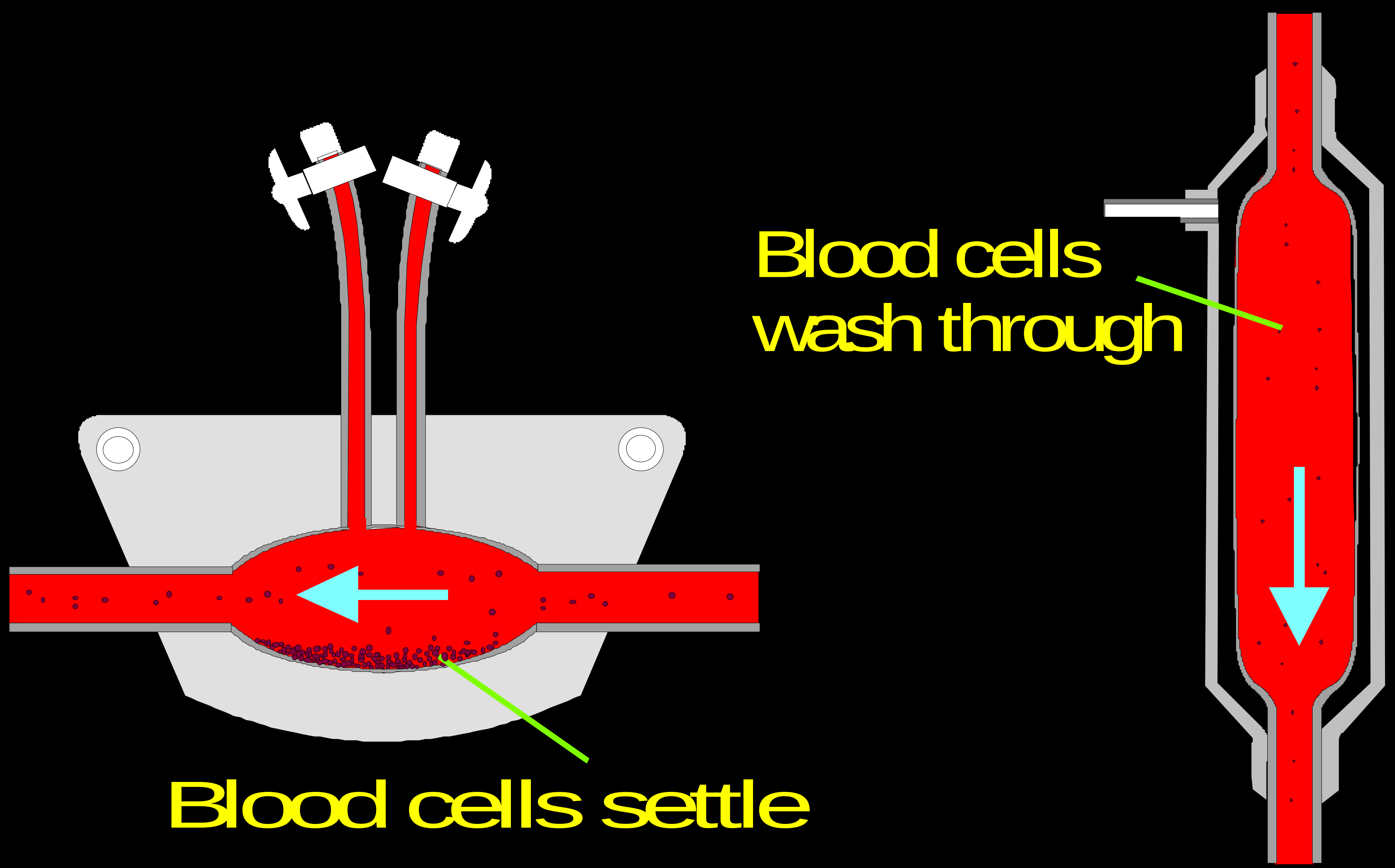
  or

- Continuos (e.g. CAPS)



Better Flow Dynamics

Silicone Bladder | Better-Bladder™

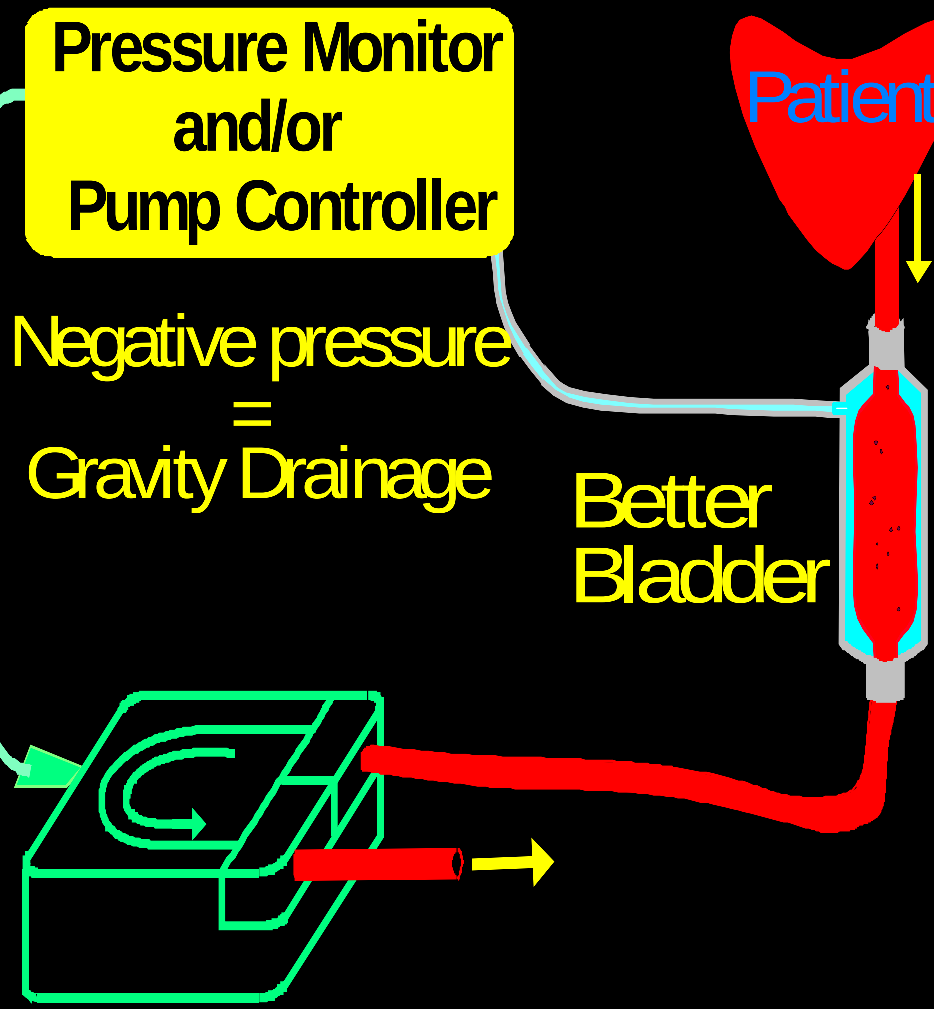


The BB Allows Increased Flow

Flow = ΔP/Resistance

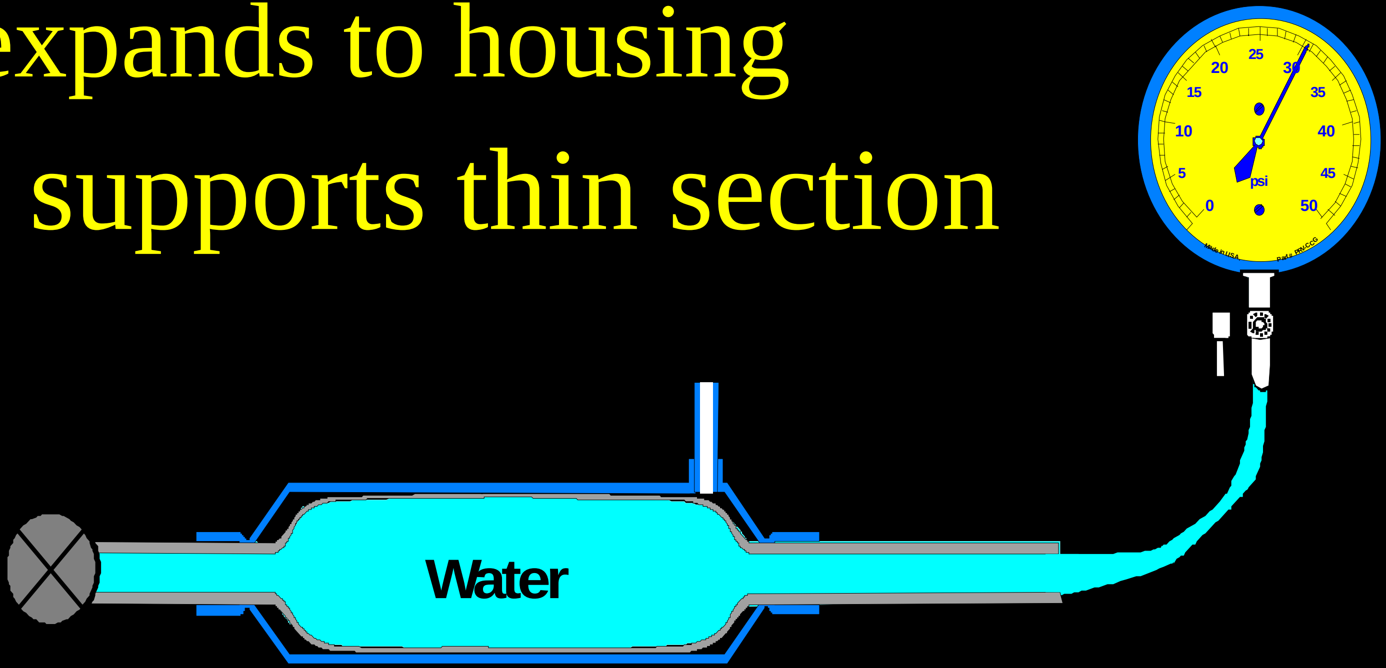
The older bladder collapsed at ambient pressure. The BB collapses at the negative pressure set by the user. Blood can be actively pulled from the patient.

No need to raise the bed or drop the bladder to the floor.

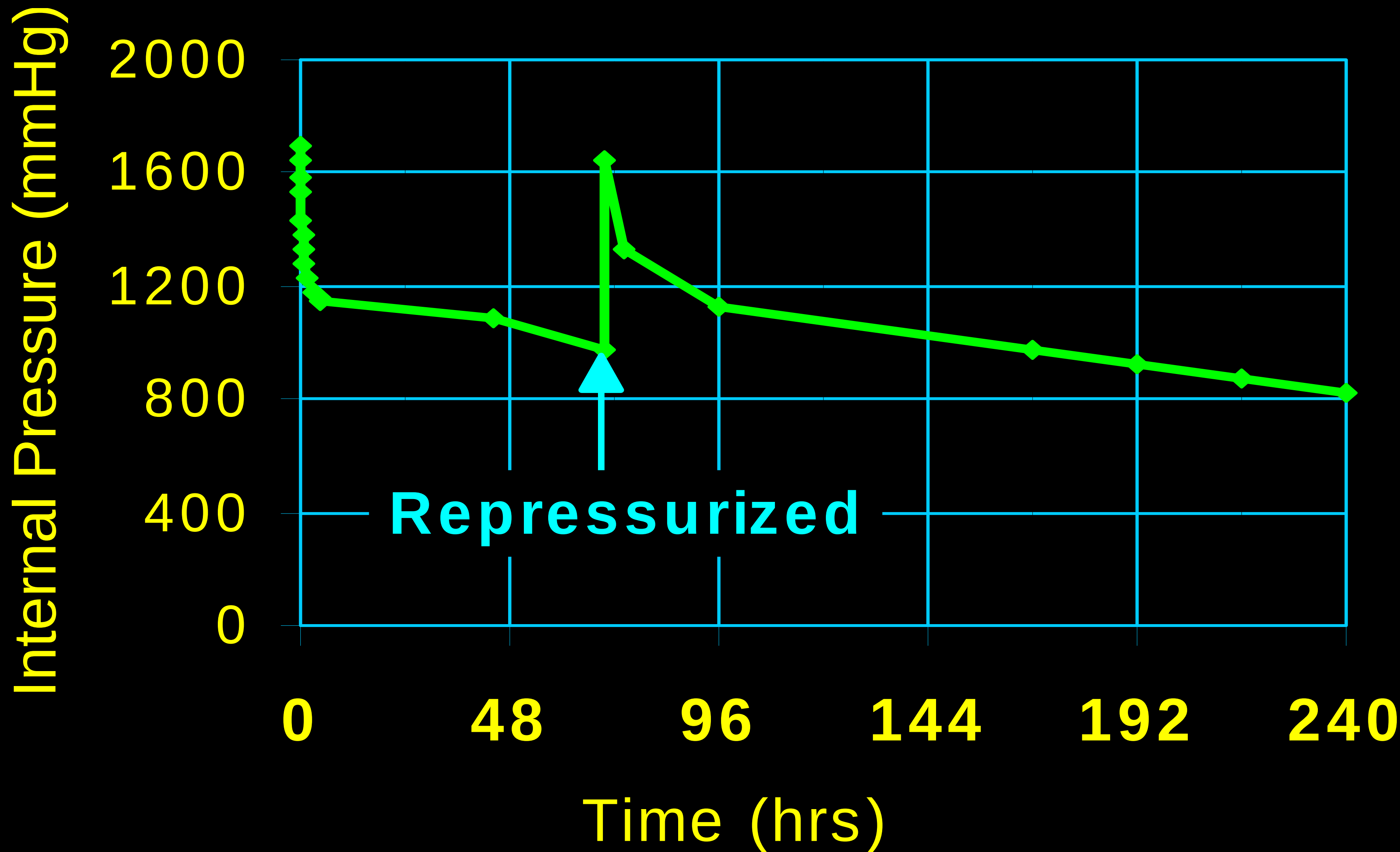


High Pressure Tests of Balloon

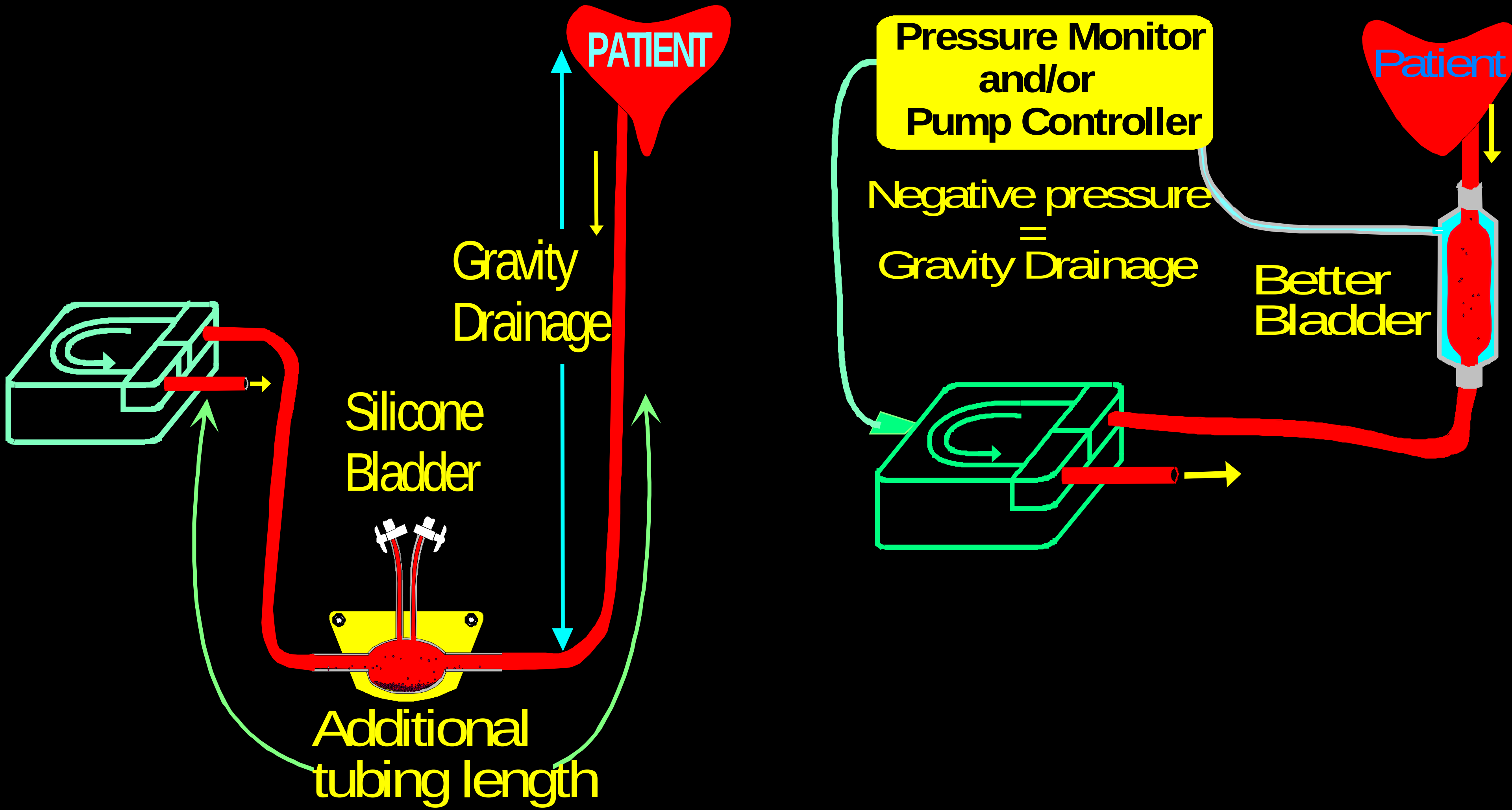
- Housing side is open to atmosphere
- 1500 mmHg applied to blood side
- Balloon expands to housing
- Housing supports thin section



The BB Withstands Large Internal Pressures

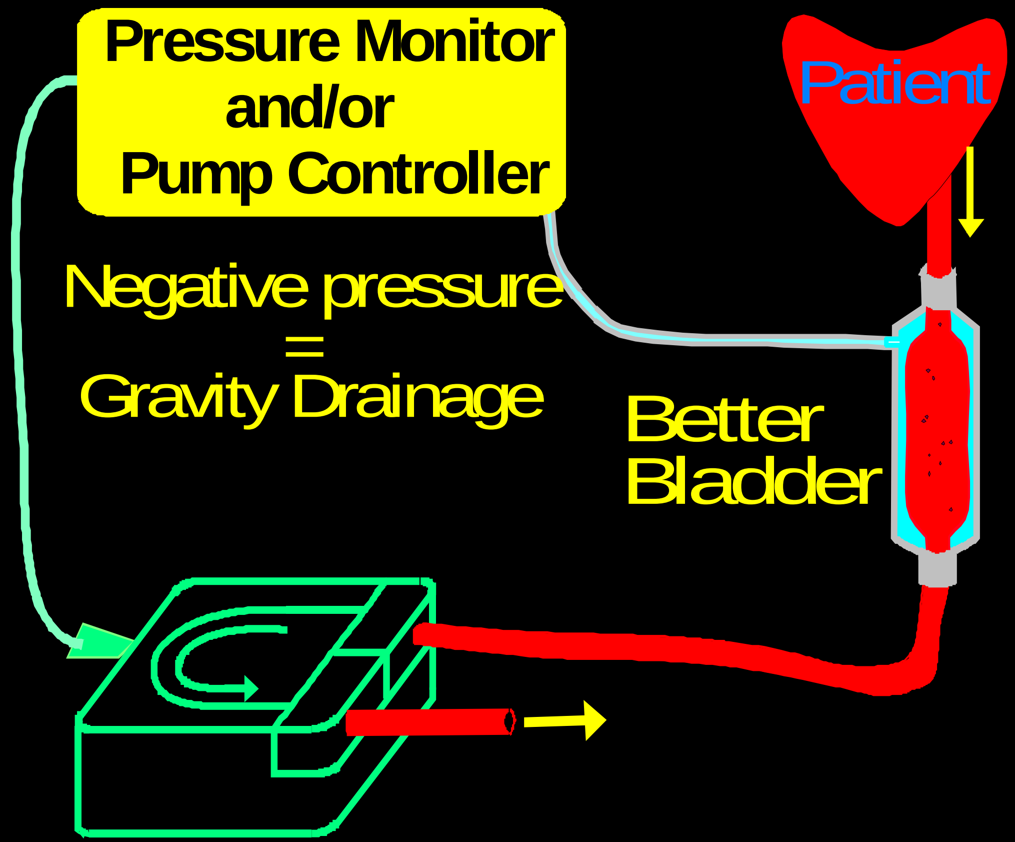


The BB Requires Shorter Tubing



The Better-Bladder Provides:

- "Adjustable" gravity drainage - VAVD
- Flow less conducive to cell settling
- On/off *or* continuous flow control (e.g. CAPS system)
- Shorter circuit tubing



The Better-Bladder Provides

Shorter Tubing

- Lower prime volume
- Reduced foreign surface
- Blood resides in tubing for a shorter time (lowers heat loss and blood/surface interaction)

510(k) Number K98-1284
Device Name Better-Bladder™

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm

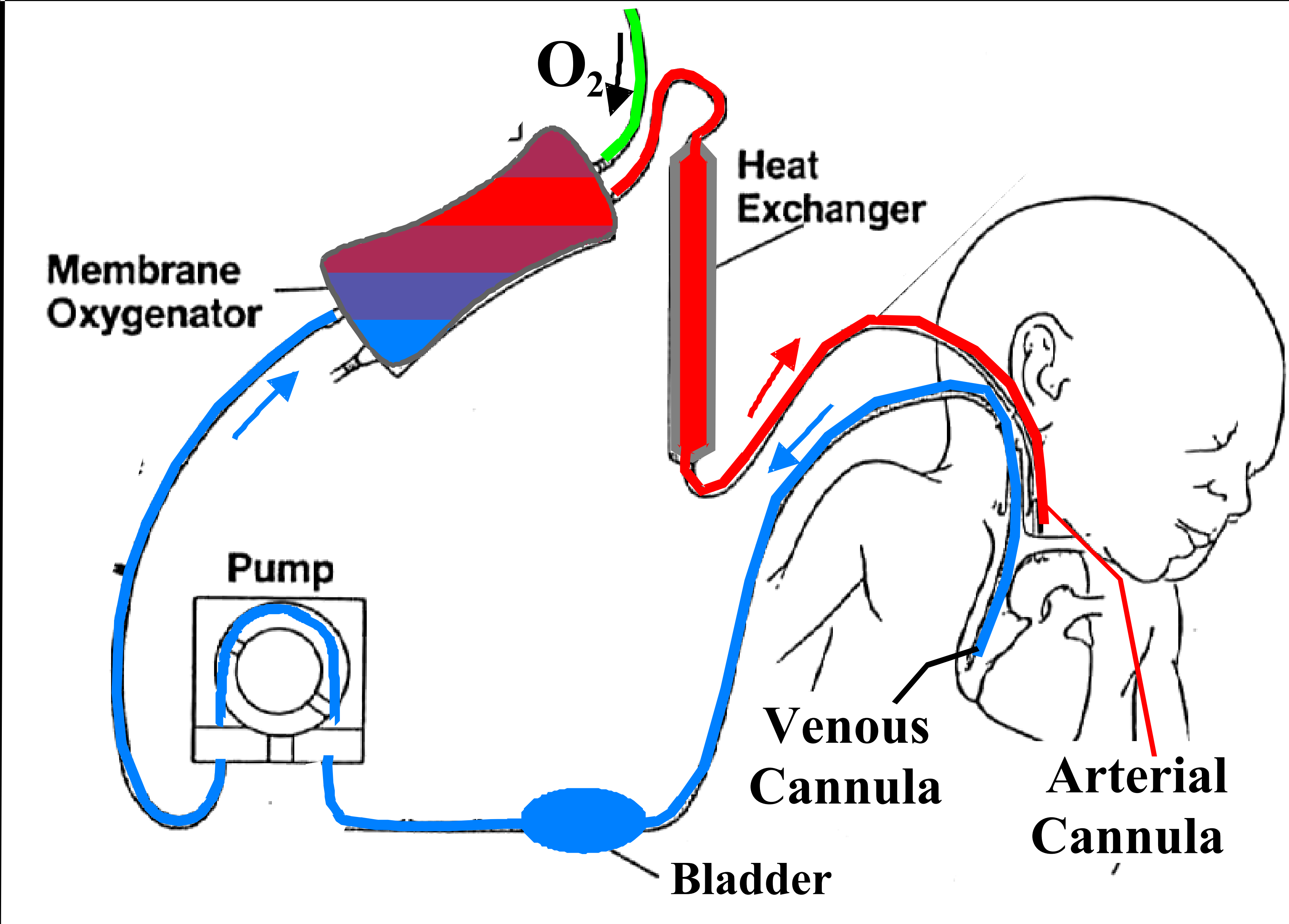
Indications for Use – The Better-Bladder™ is a device that isolates pressure transducers form blood contact when measurements of blood pressure in extracorporeal circuits are made during short and ***long term*** procedures. The pressure signal can be used to control pump speed. It is also used as an inline reservoir to provide compliance in the circuit during short and ***long term*** term procedures.

To Bladder or not to Bladder?

Yehuda Tamari

Circulatory Technology Inc. Oyster Bay, NY

Why use a Bladder for ECMO?

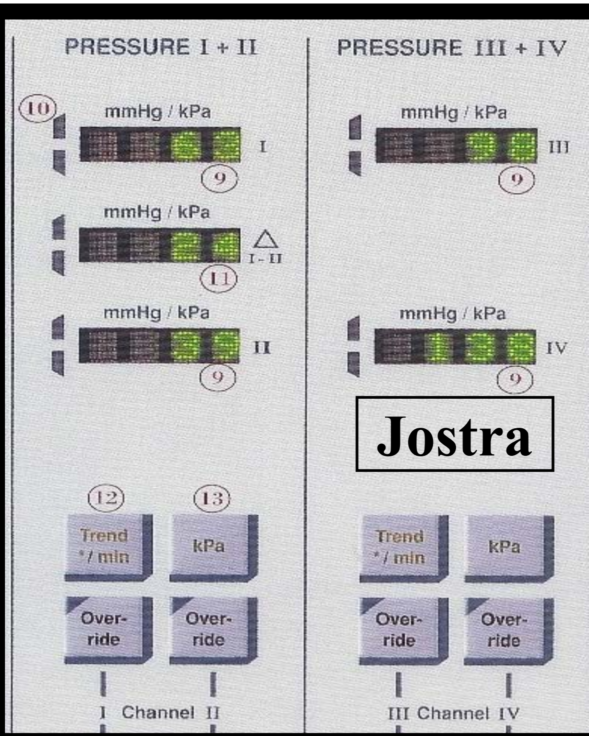


Computerized Roller Pumps

Blood flow is controlled as a function pump inlet pressure.

When inlet pressure drops below a settable pressure the pump slows down or stops.

When inlet pressure increases above the set point, pump flow returns to its set value.



Recent comments/questions from the ECLS-Net

- **"Is anyone removing or considering removing the bladder out of their ECMO circuit that uses roller pumps?"**
- **"We have PVC tubing in place of the bladder and it has worked very well."**
- **"We have a collapsible Silastic bridge."**

No reasons were given for eliminating the bladder.

Cost? Complexity? reliability?

There were no mentions of using a bladder with centrifugal pumps.

When making changes to a circuit

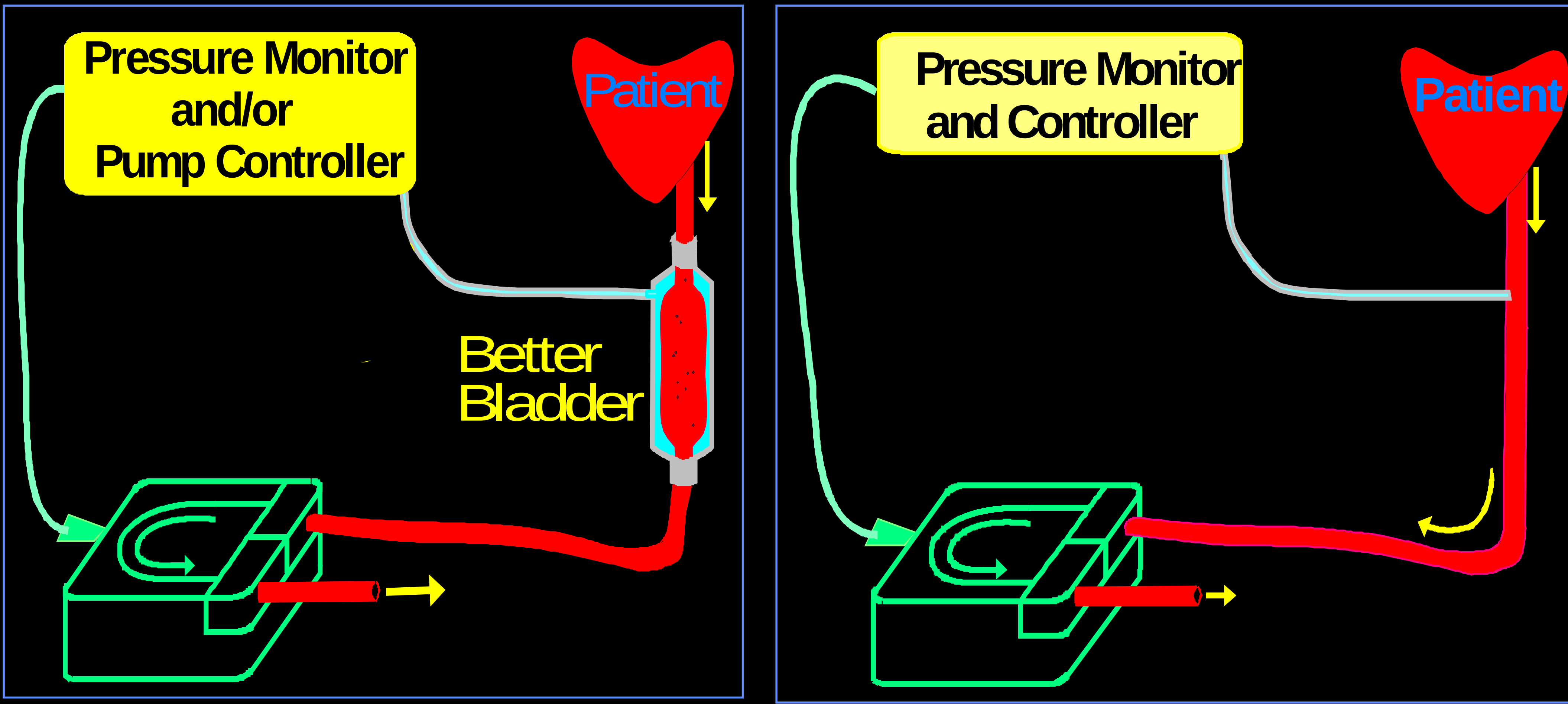
Practice Caution

- What follows are results of some tests that we conducted with and without a bladder under ECMO settings.
- Serve as an outline for the type of tests that should be conducted prior to removing or replacing the bladder.

Pump flow is controlled as a function of inlet pressure

Should we pump

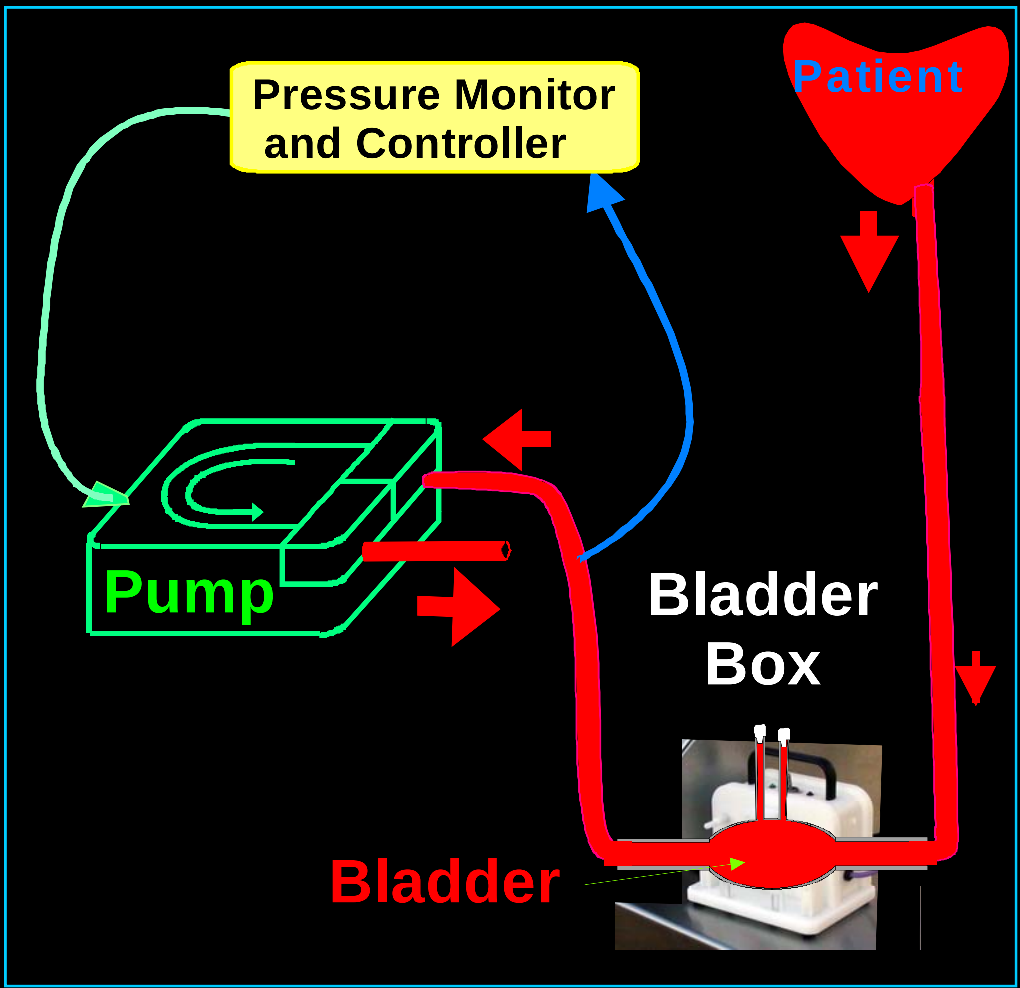
with a bladder or without a bladder



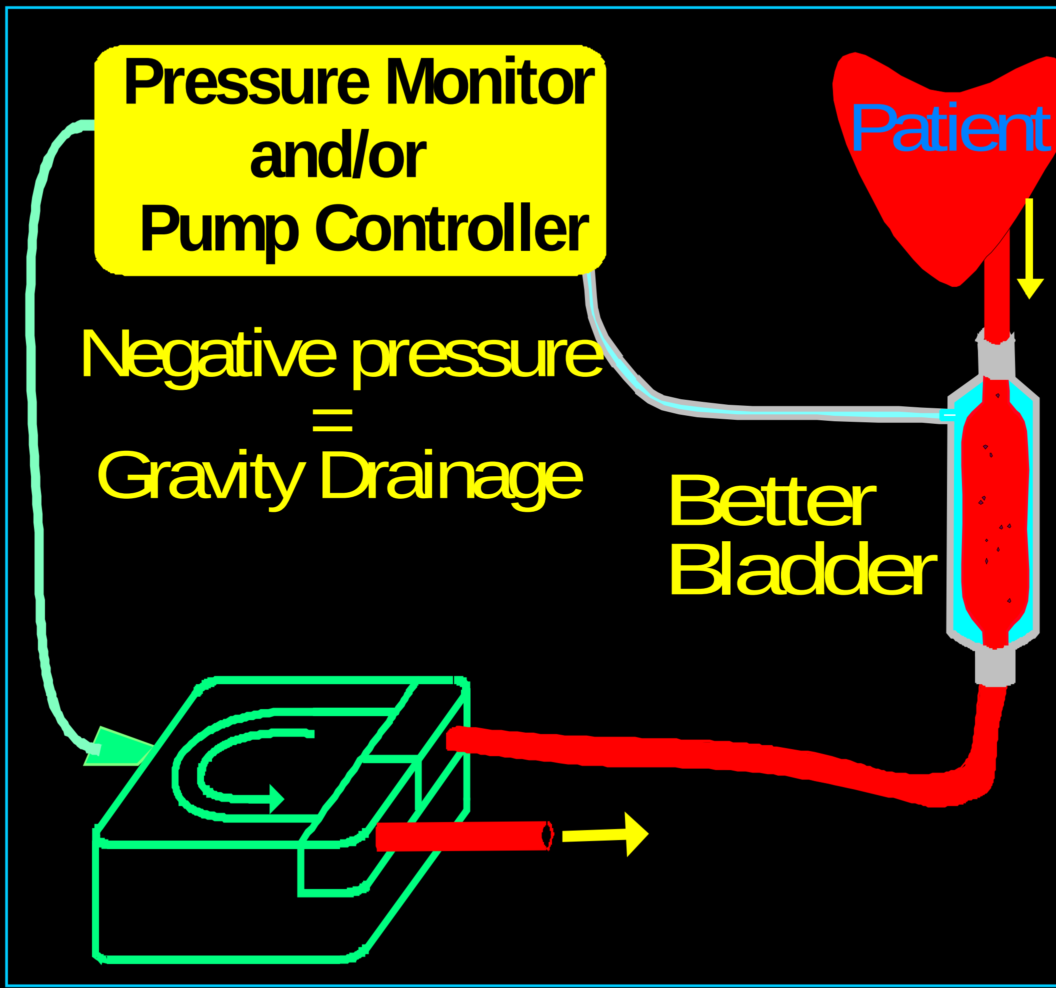
Pump flow is controlled as a function of inlet pressure

Compliance can be provided by

The Silicone Bladder



The Better Bladder

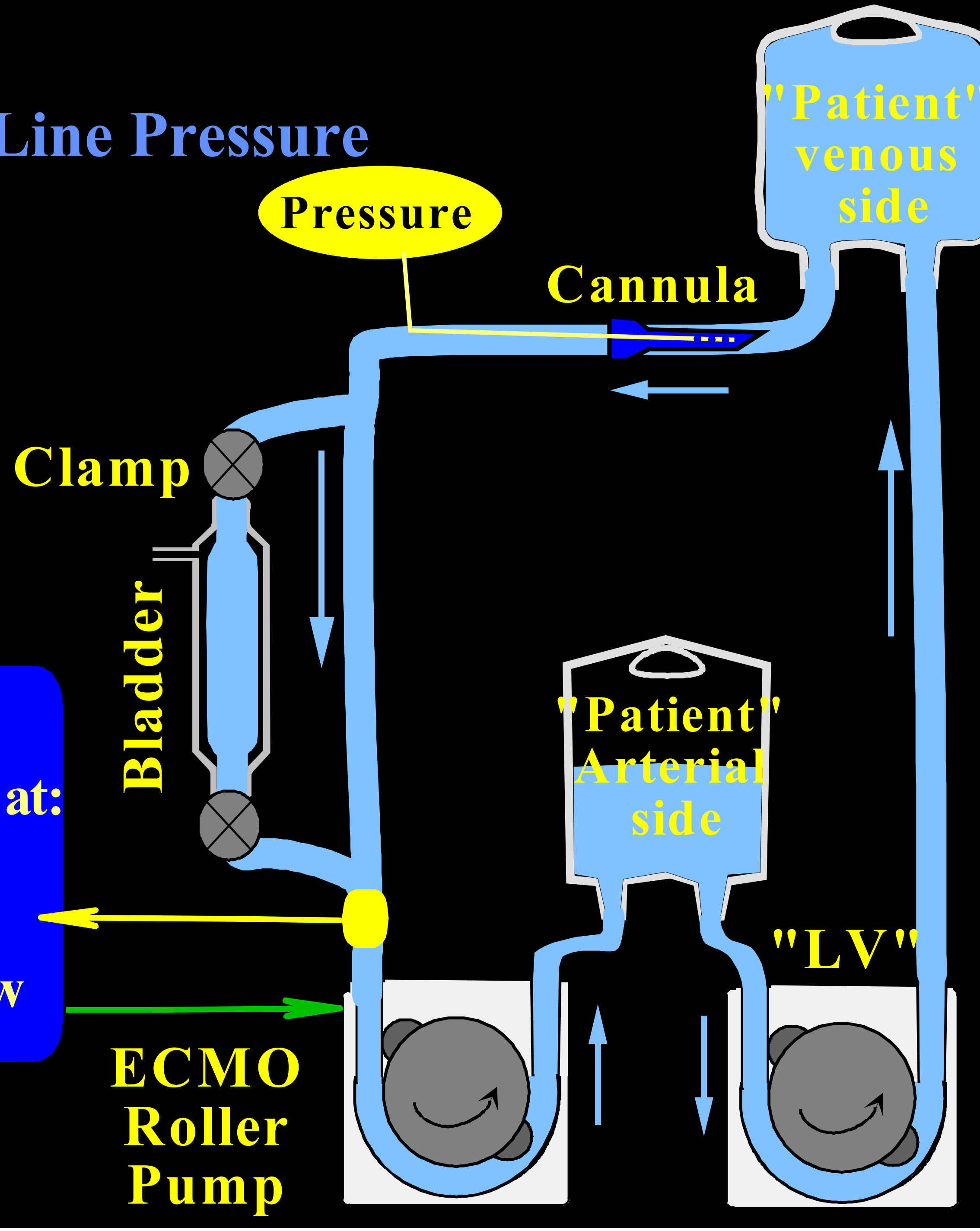


Experimental Setup
Pump Controlled by Venous Line Pressure

Controller set to stop flow at Pin = -30mmHg
Reduce venous flow below pump flow and record the pressures

Sample rate- 1000/sec

Data Acquisition
Measure pressure at:
Cannula tip
Pump inlet
Control Pump flow



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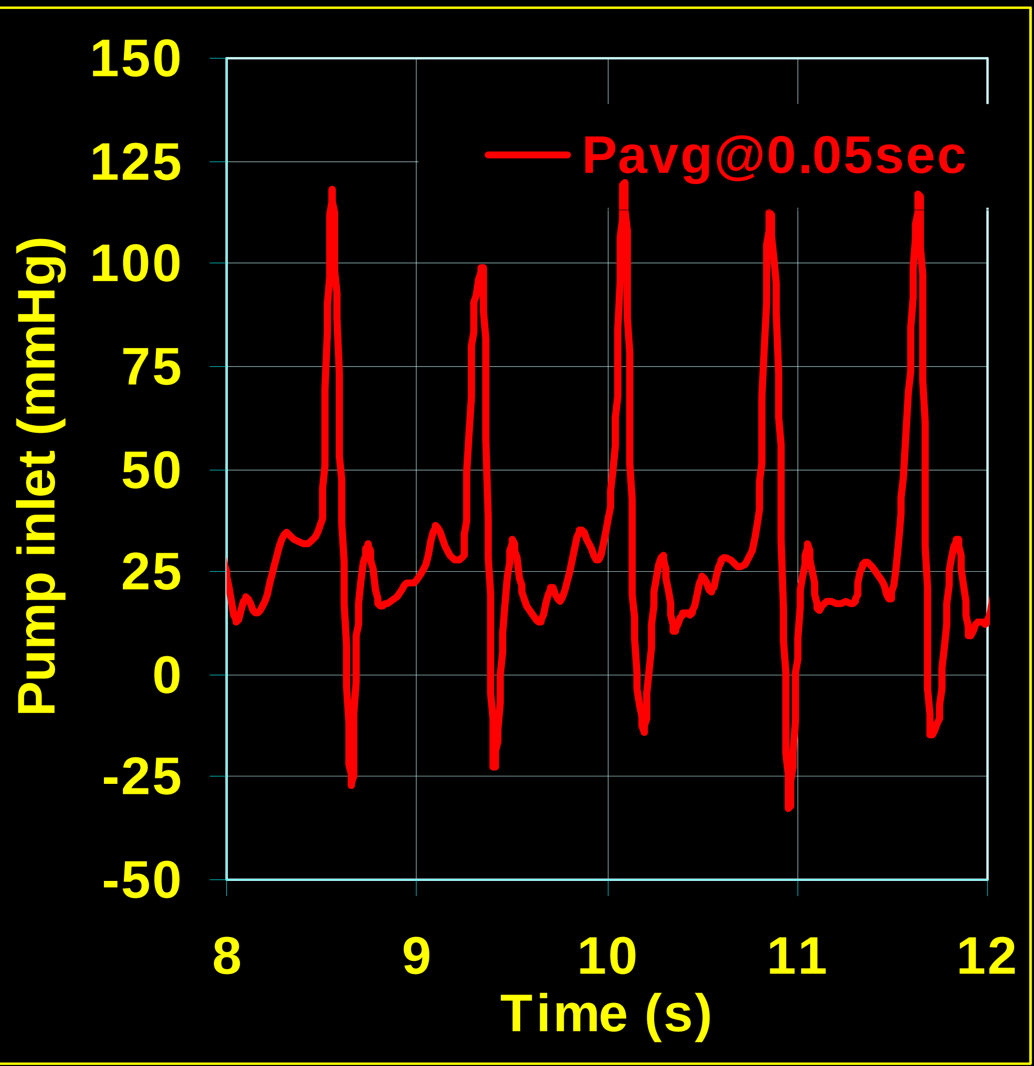
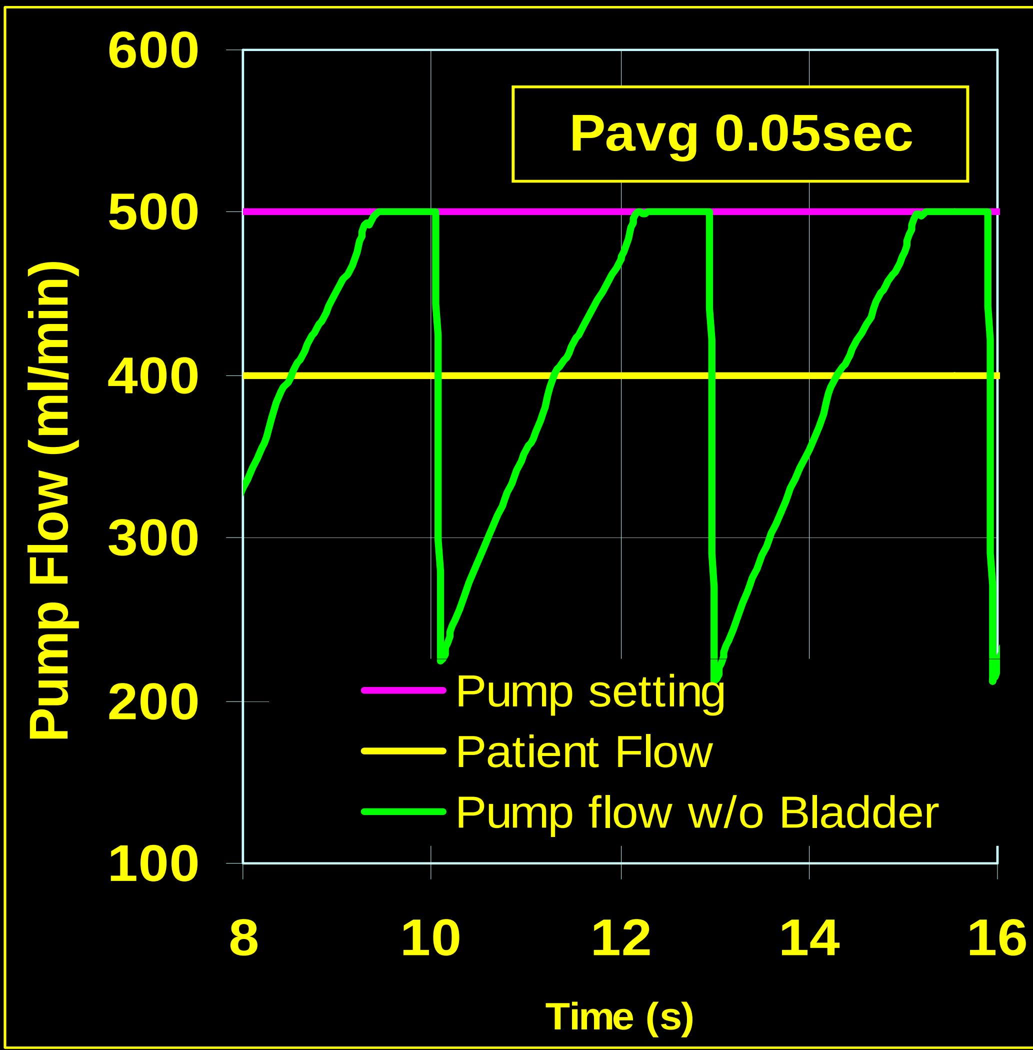
Pump Controlled by the Instantaneous Inlet Pressure:

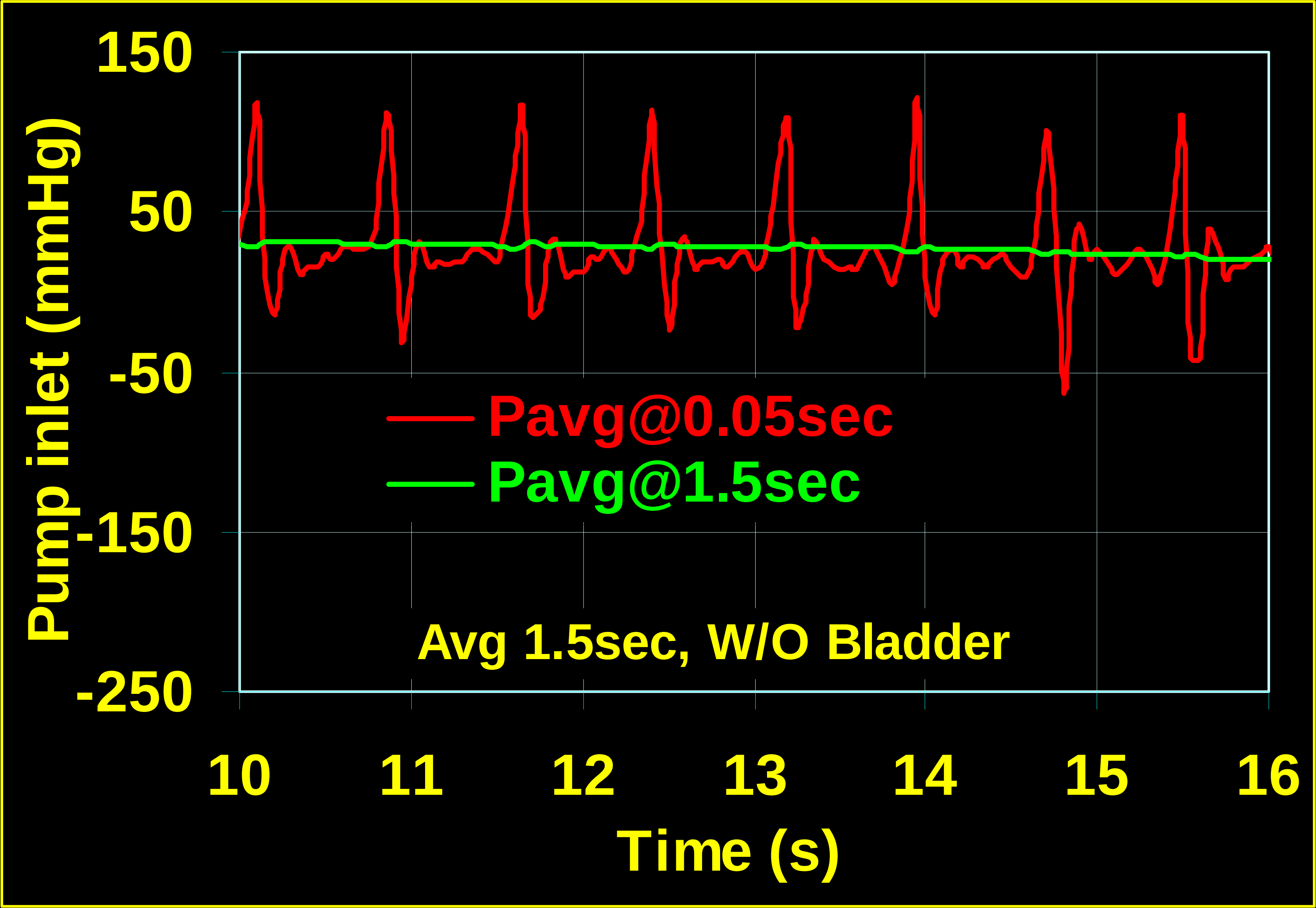
w/o a Bladder Results in Erratic Pump Flow



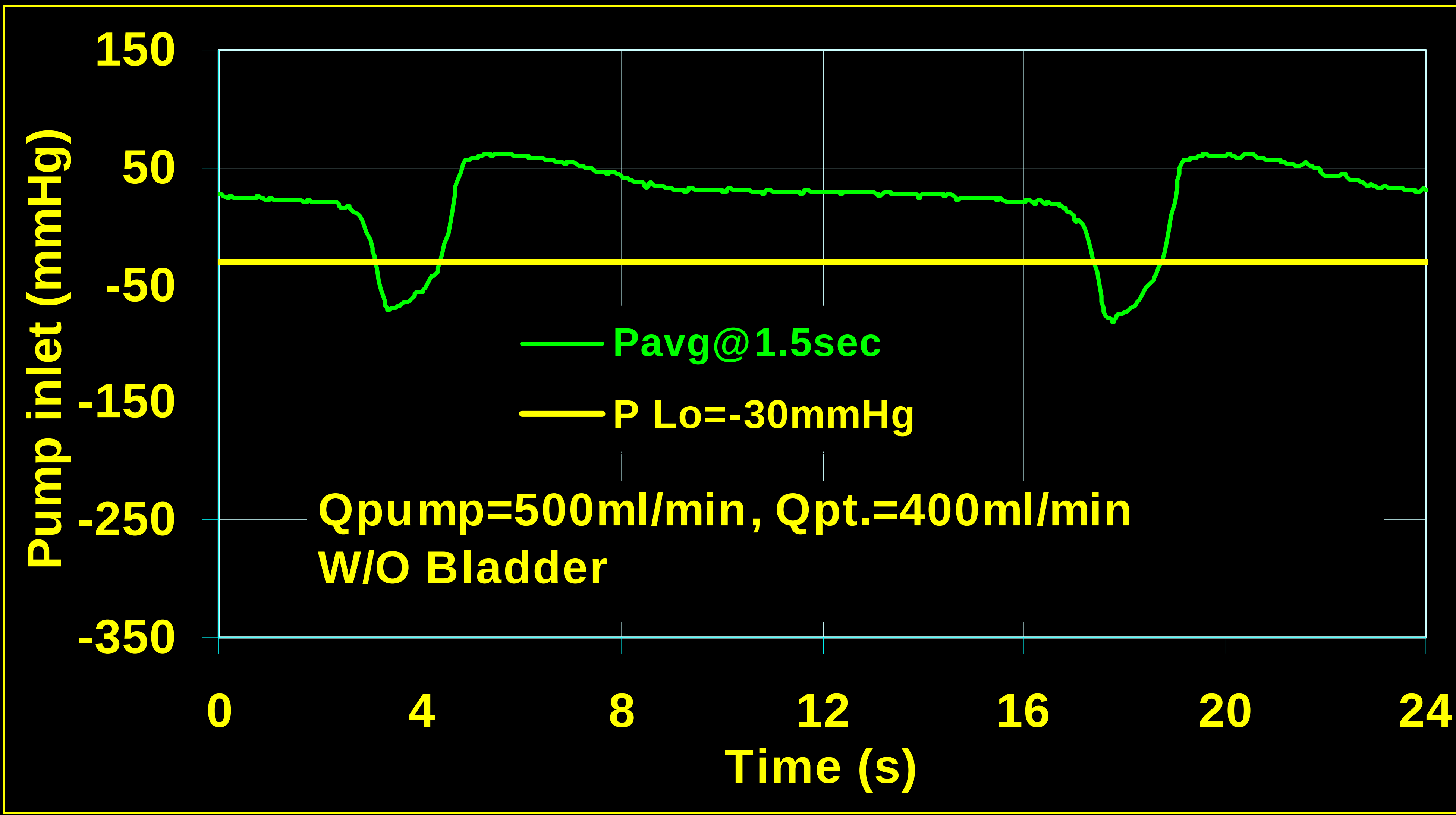


Pump Controlled by the Instantaneous Inlet Pressure:

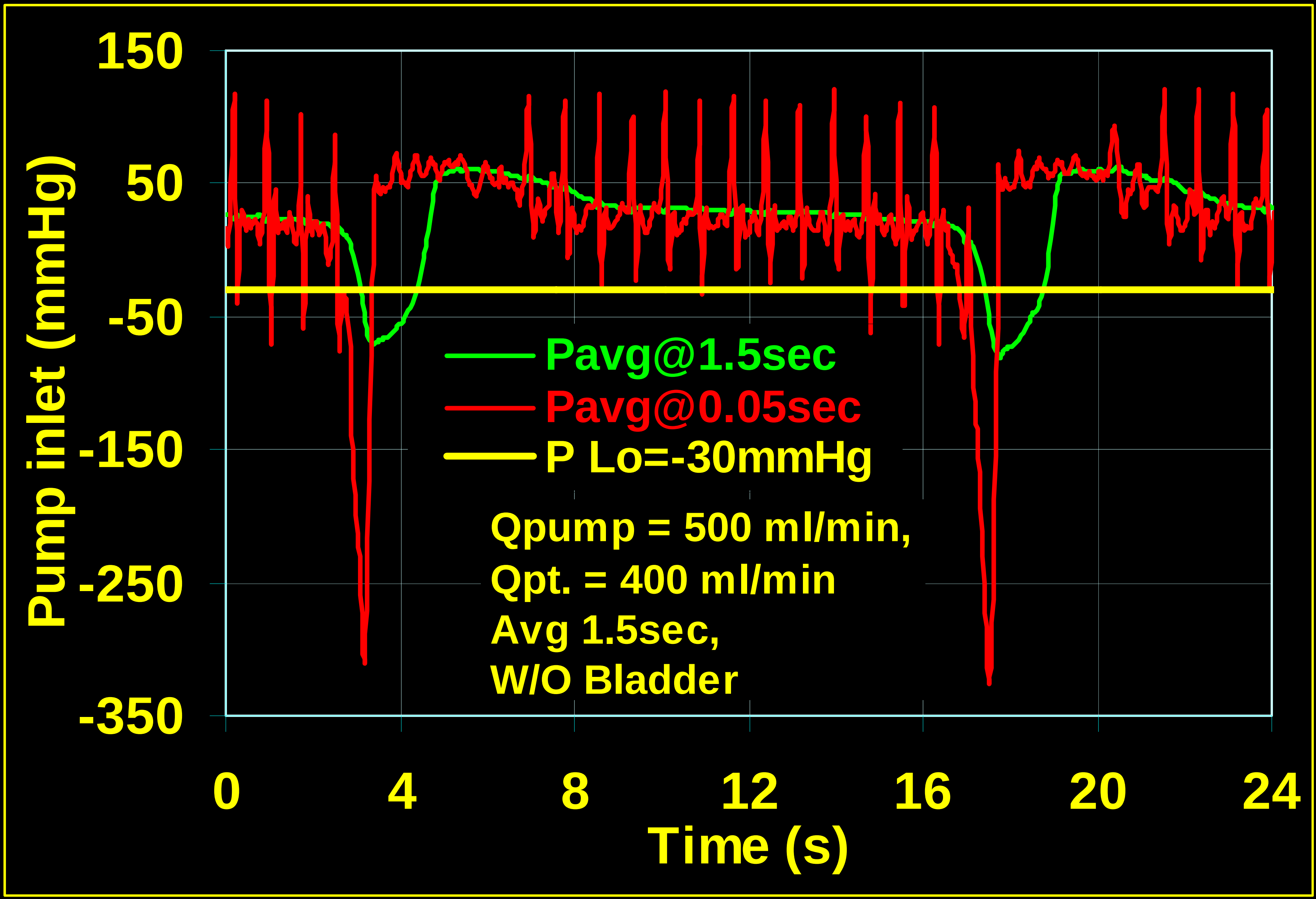
Electronic Pressure Averaging



Pump Controlled by Electronically Averaged Inlet Pressure

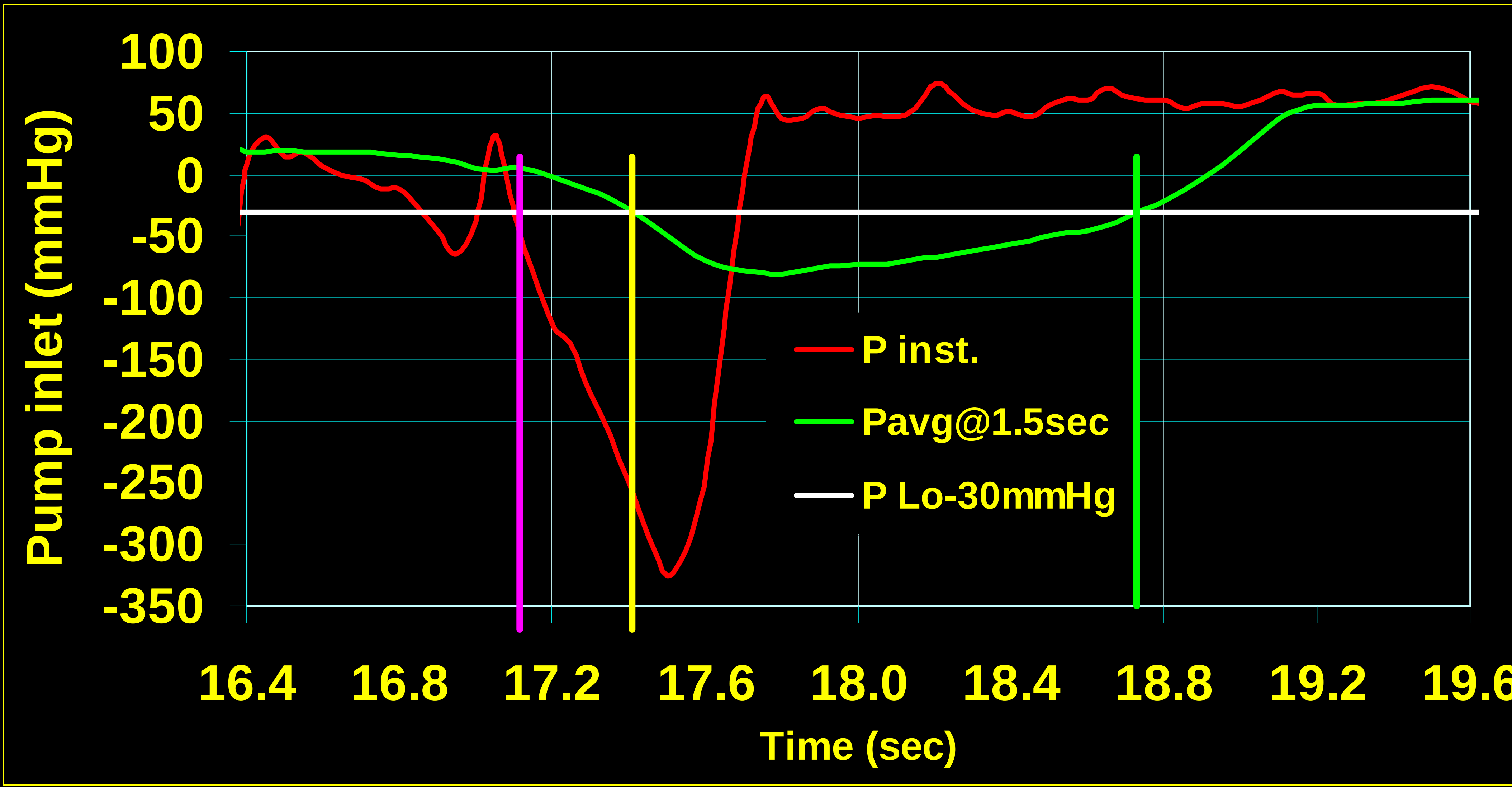


Pump Controlled by Electronically Averaged Inlet Pressure



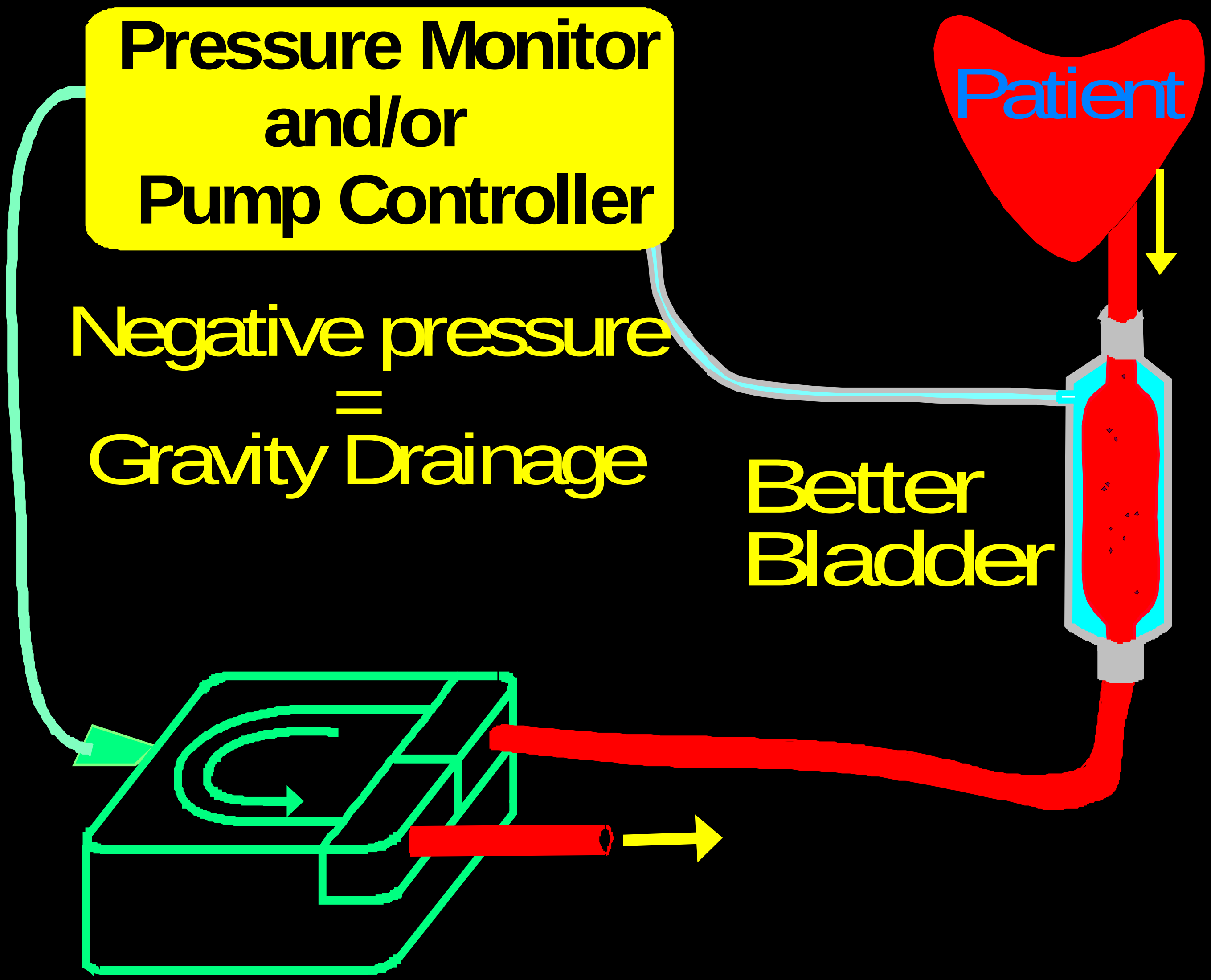
Pump Controlled by Electronically Averaged Inlet Pressure

w/o a Bladder



The BB at the Pump Inlet

Provides compliance and reduces pressure pulsation.



Roller Pump with a Bladder at its Inlet

Bladders Absorb the Pressure Fluctuations of the Roller Pump

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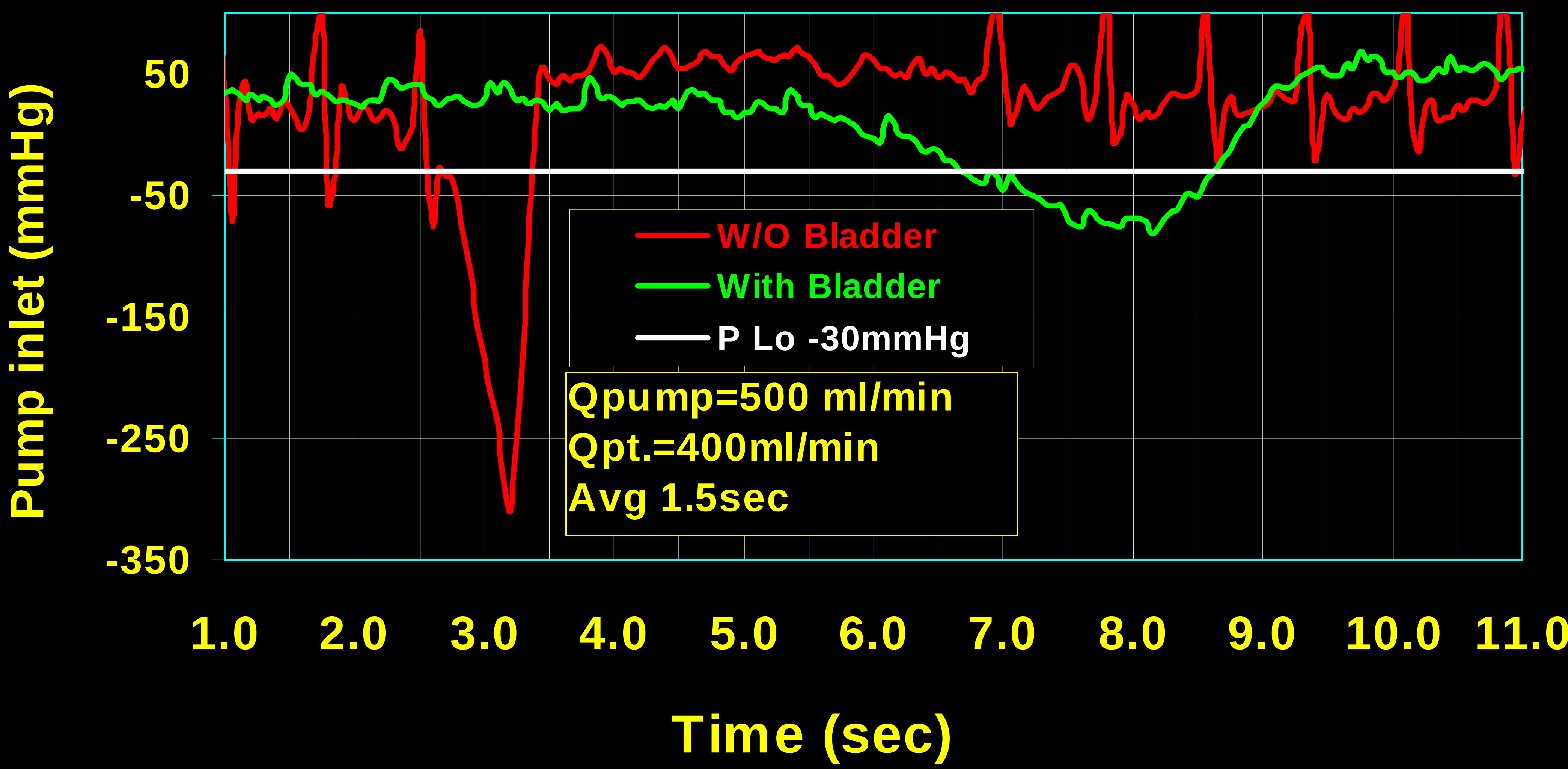
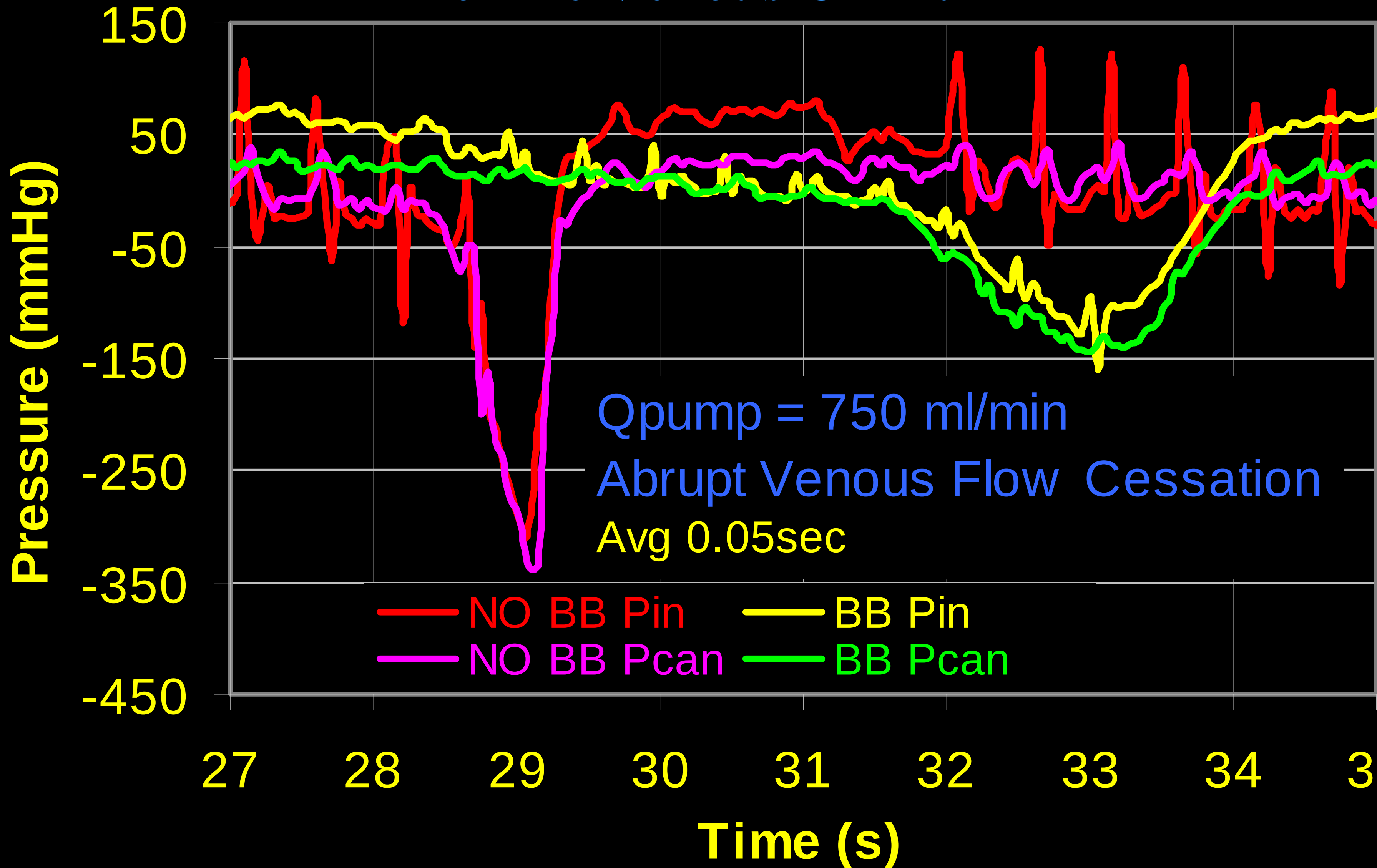
Pump Controlled by Electronically Averaged Inlet Pressure

With a Bladder

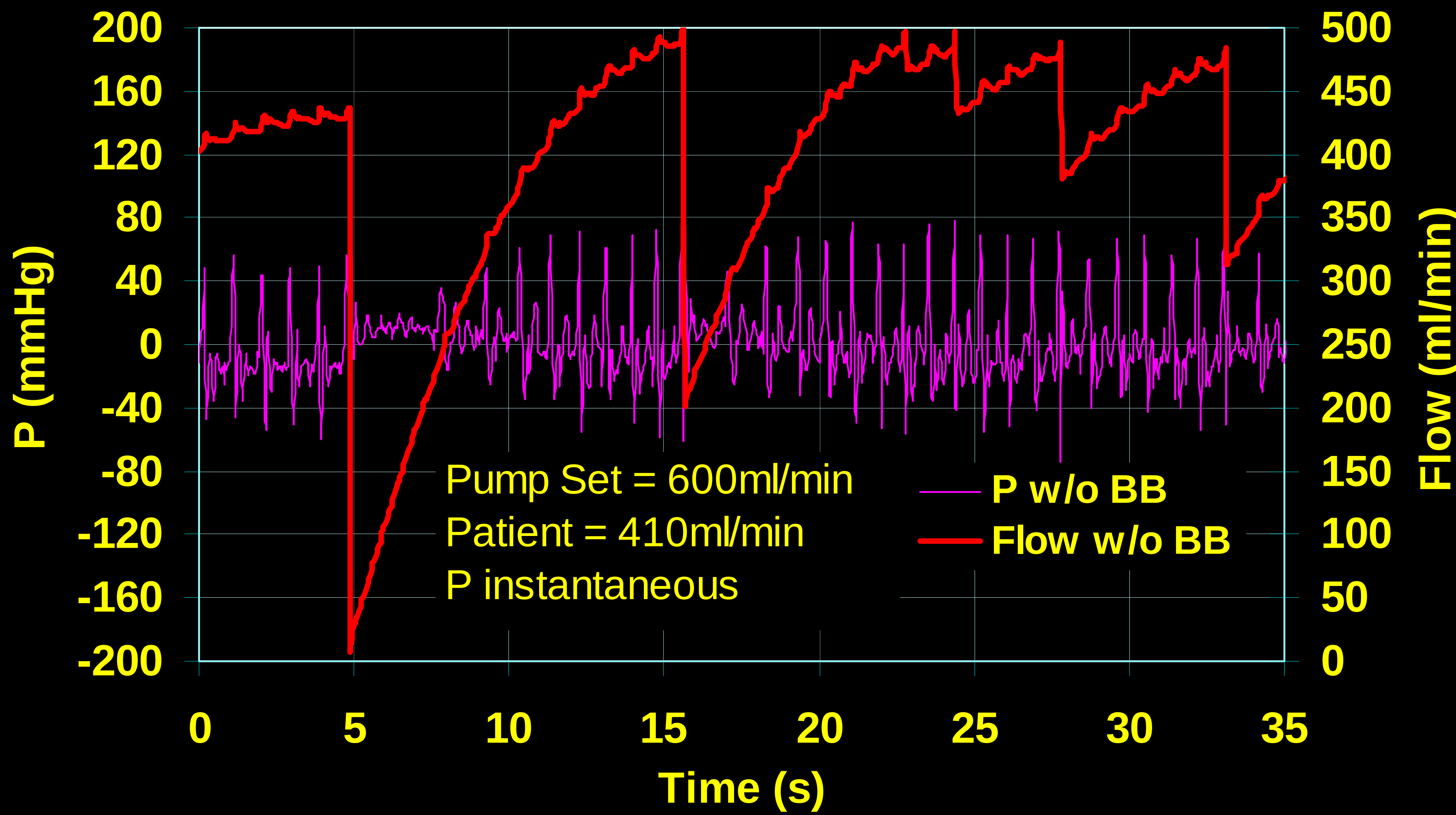


High Negative Pump Inlet Pressure is also Seen at the Tip of the Venous Cannula

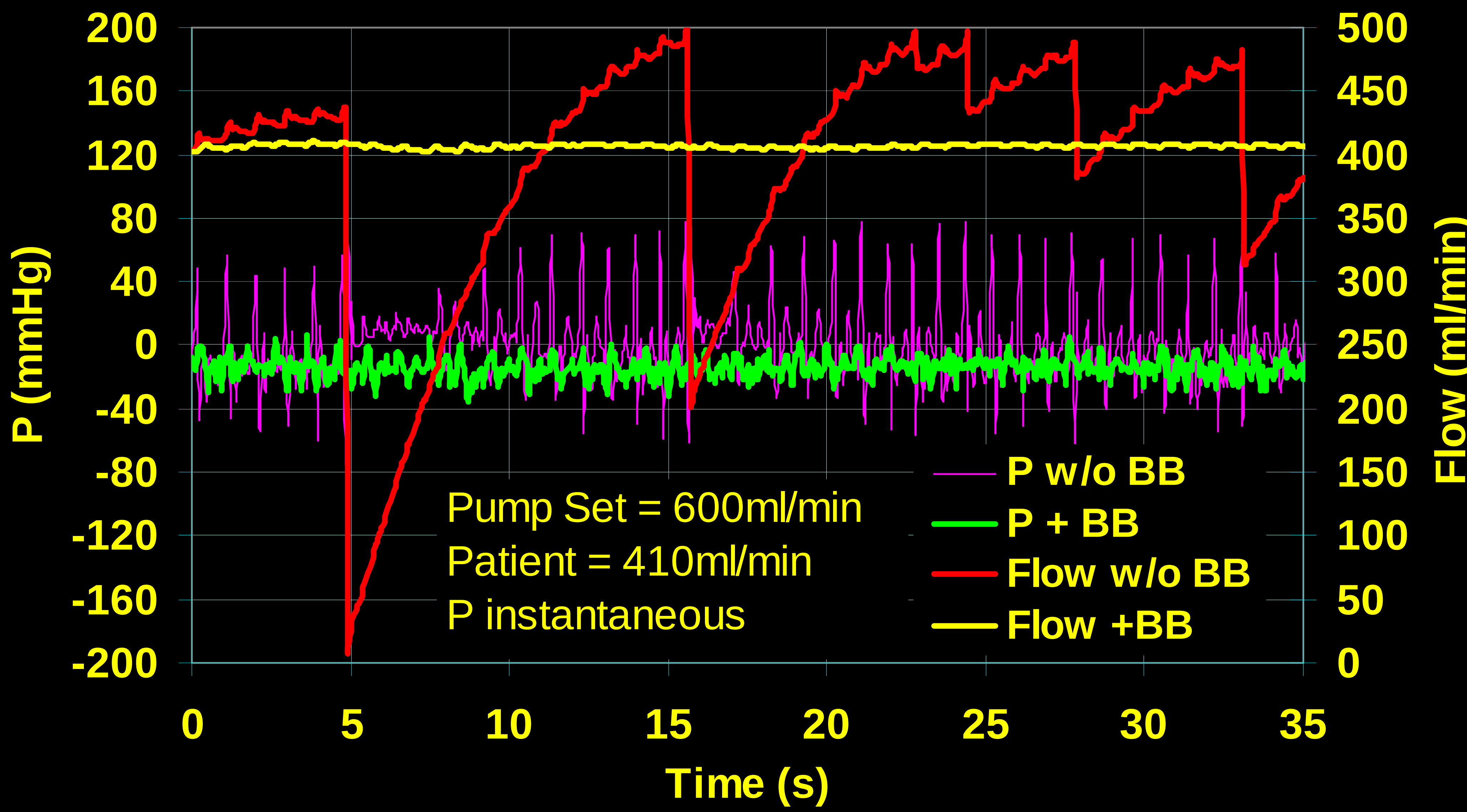


Pump Controlled by the Instantaneous Inlet Pressure:

Results in Erratic Pump Flow



Pump Controlled by the Instantaneous Inlet Pressure



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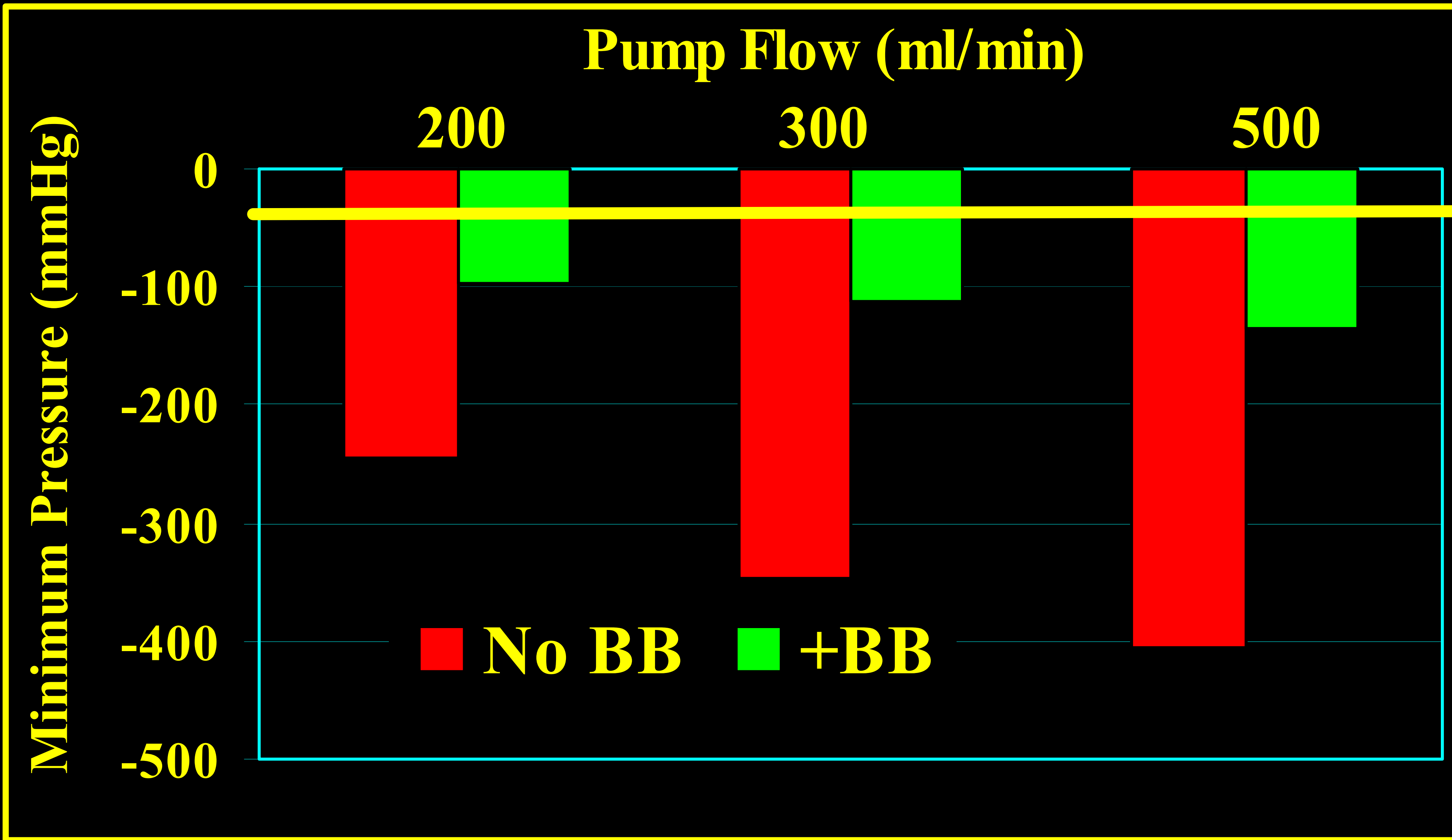
Maximum Suction due to Abrupt Stoppage of Venous Flow. Using the Jostra roller pump with and w/o a bladder

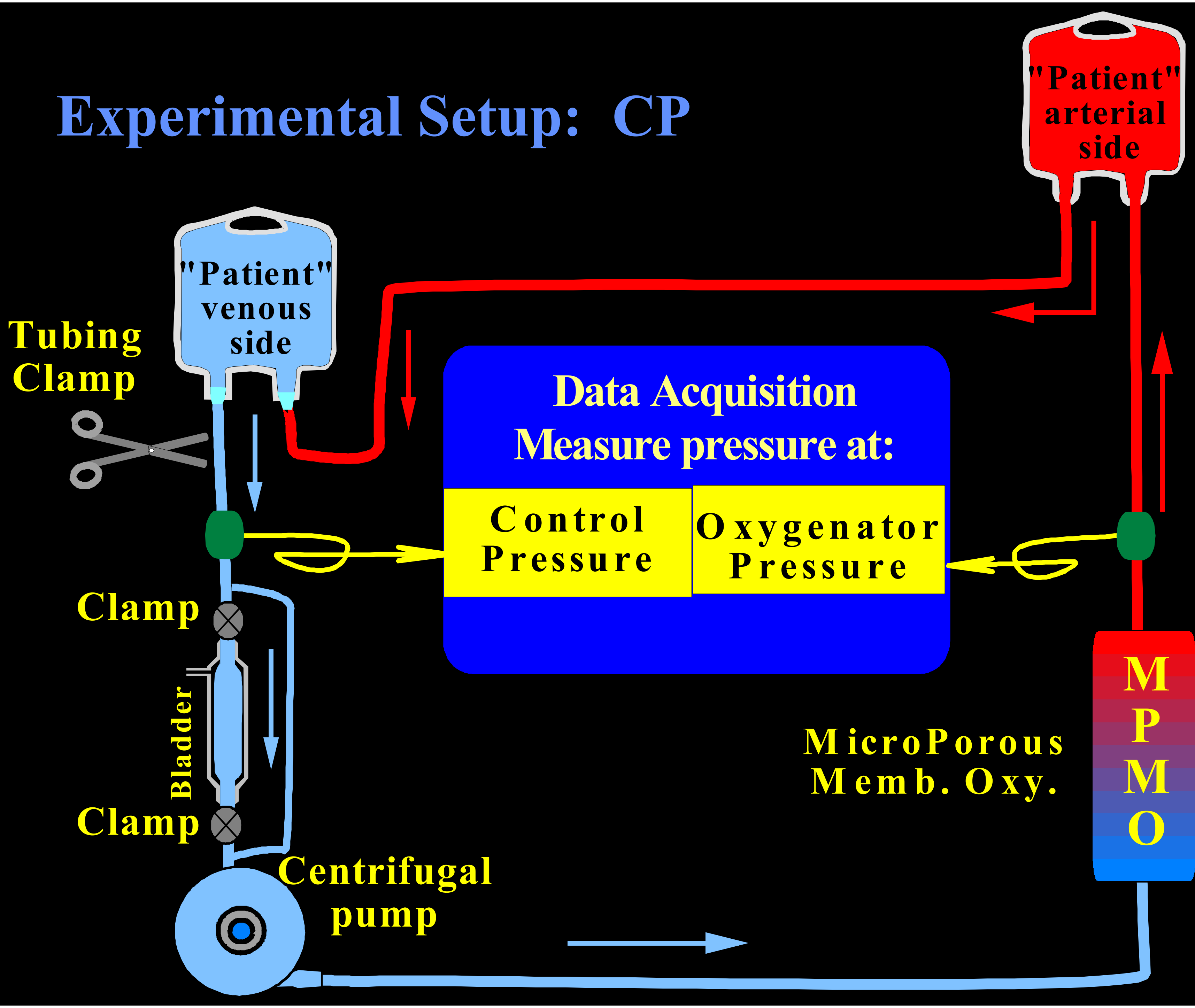


Are Bladders Required
When Centrifugal Pump are Used for ECMO?

Effects of a bladder placed at the pump inlet on:

- **the maximum negative pressure at pump inlet due to abrupt stoppage of venous flow.**
- **the pump outlet pressure due to abrupt stoppage of venous flow.**
- **the air handling of a CP.**

Experimental Setup: CP



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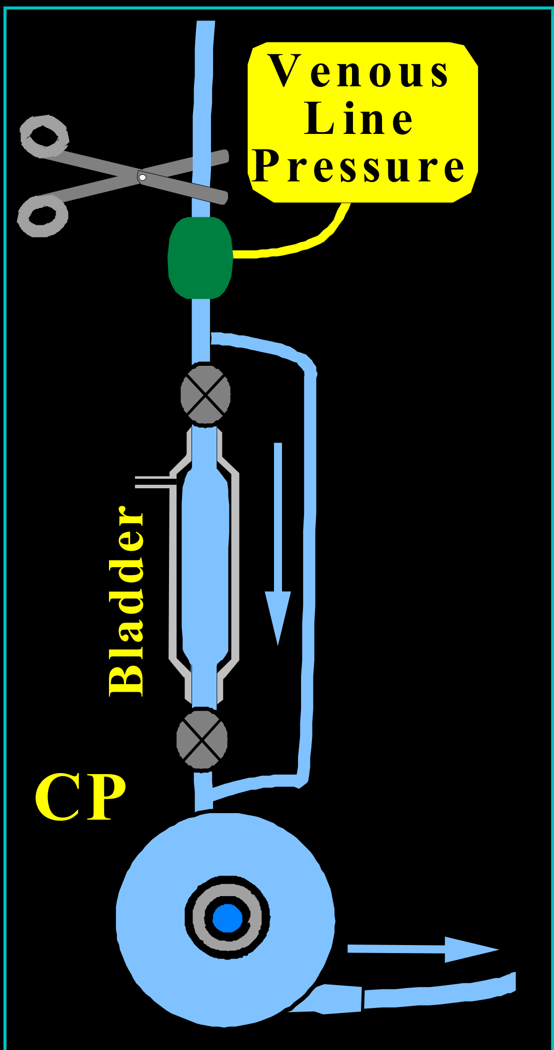
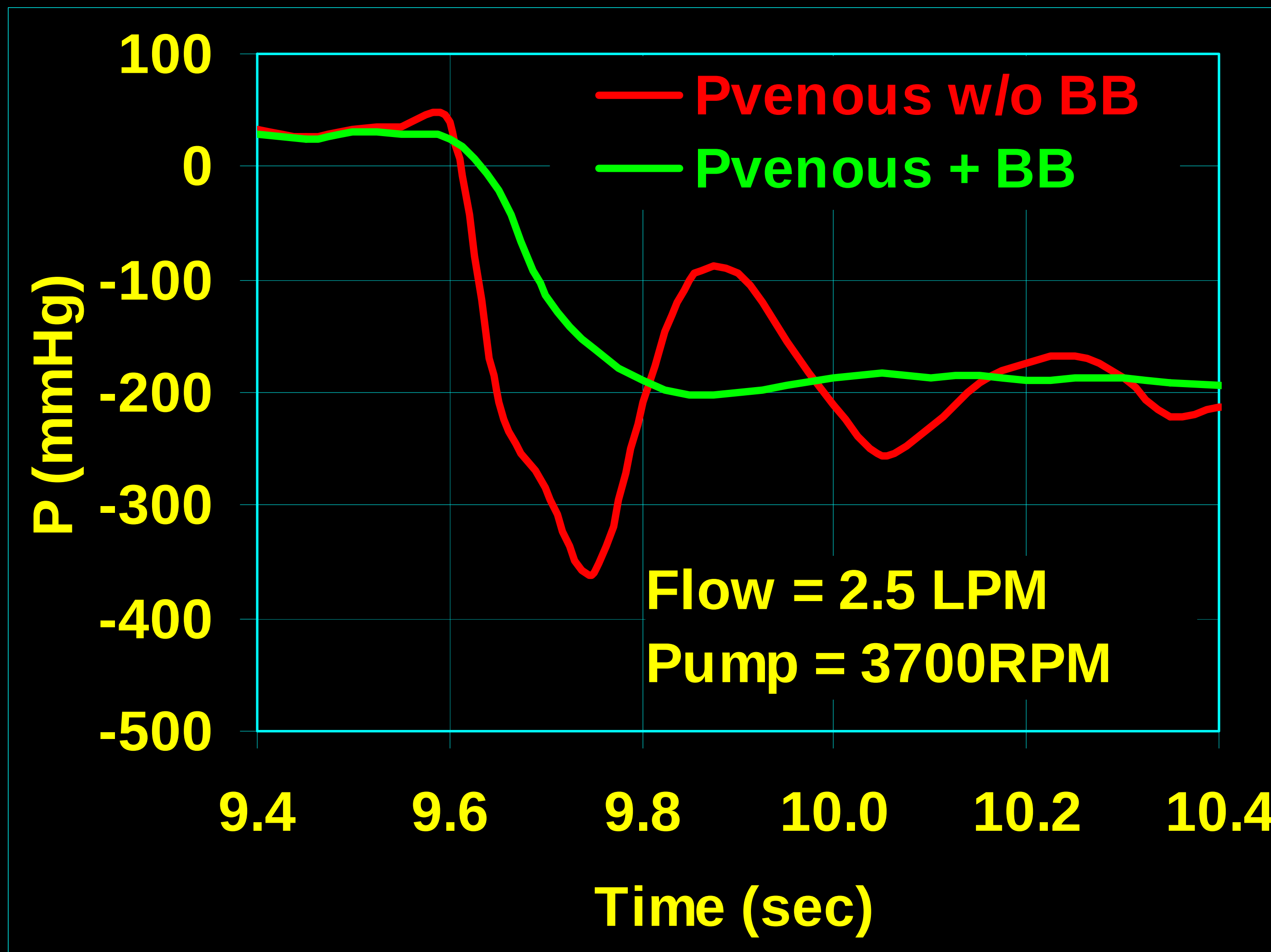
Inlet Pressure to a CP - Abrupt blockage of Venous Flow

Pressure drops faster and lower w/o a bladder





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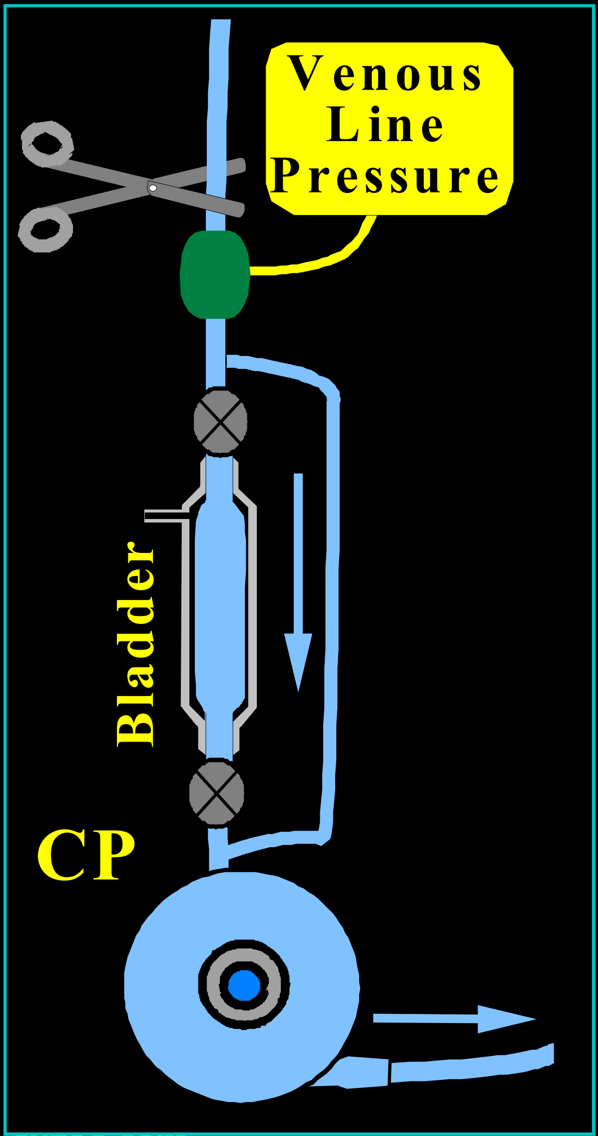

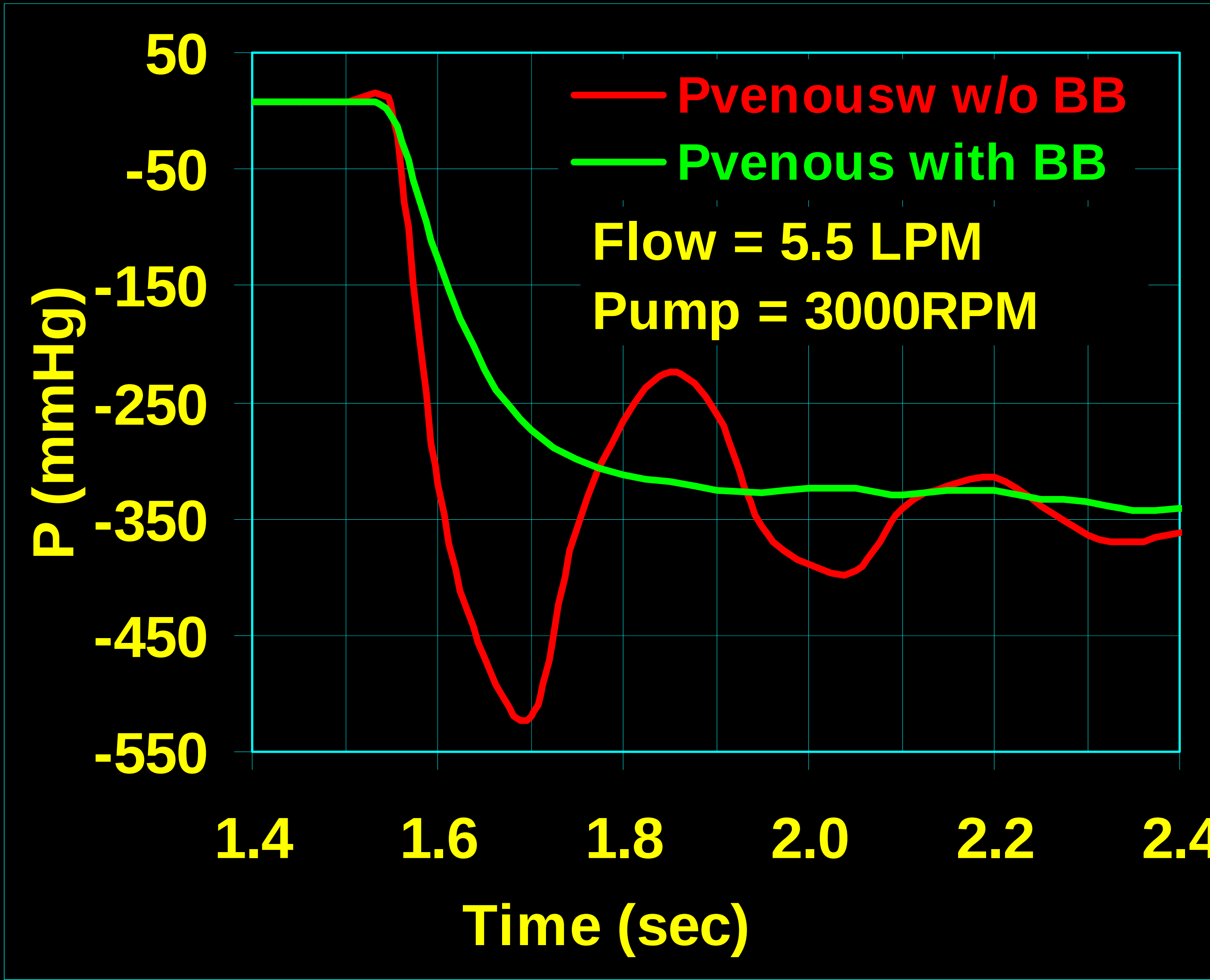

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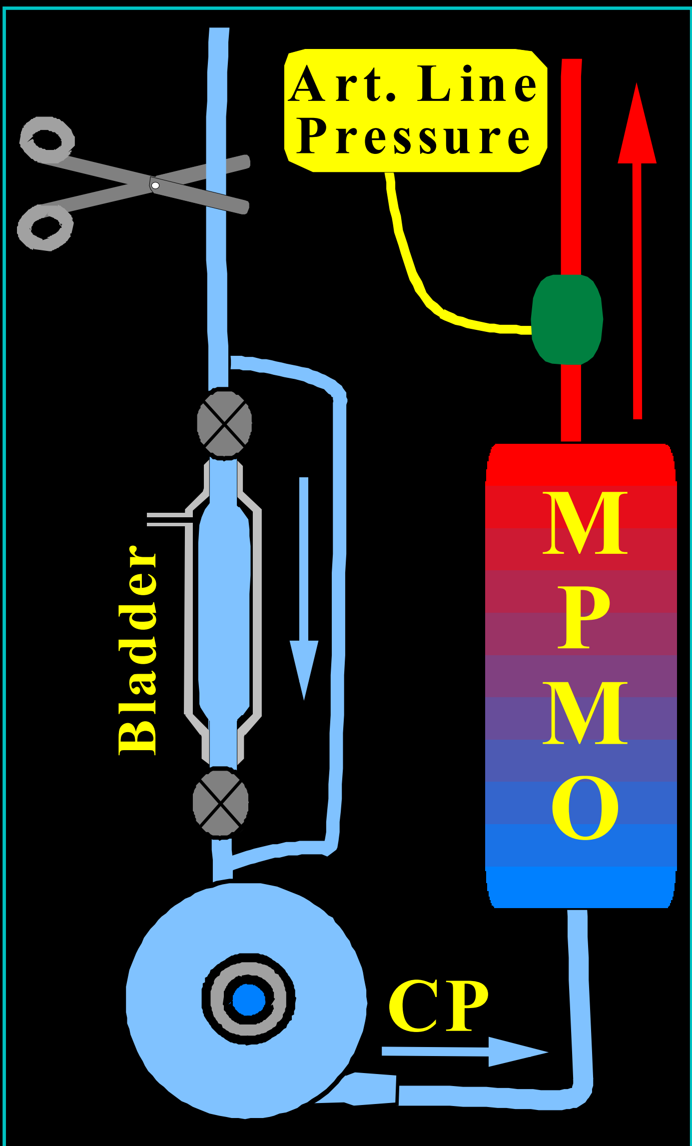
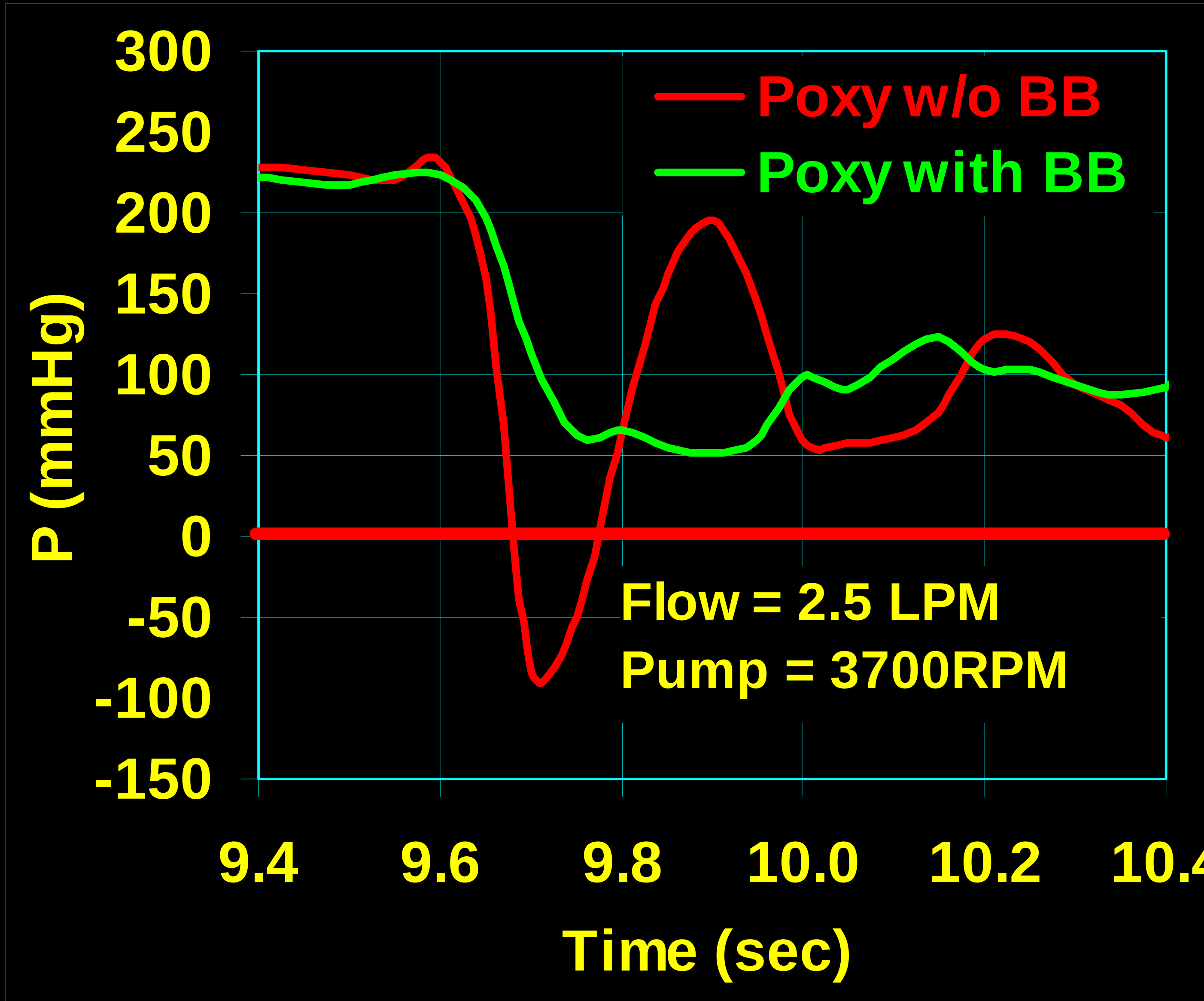
Pressure at Oxygenator can Become NEGATIVE





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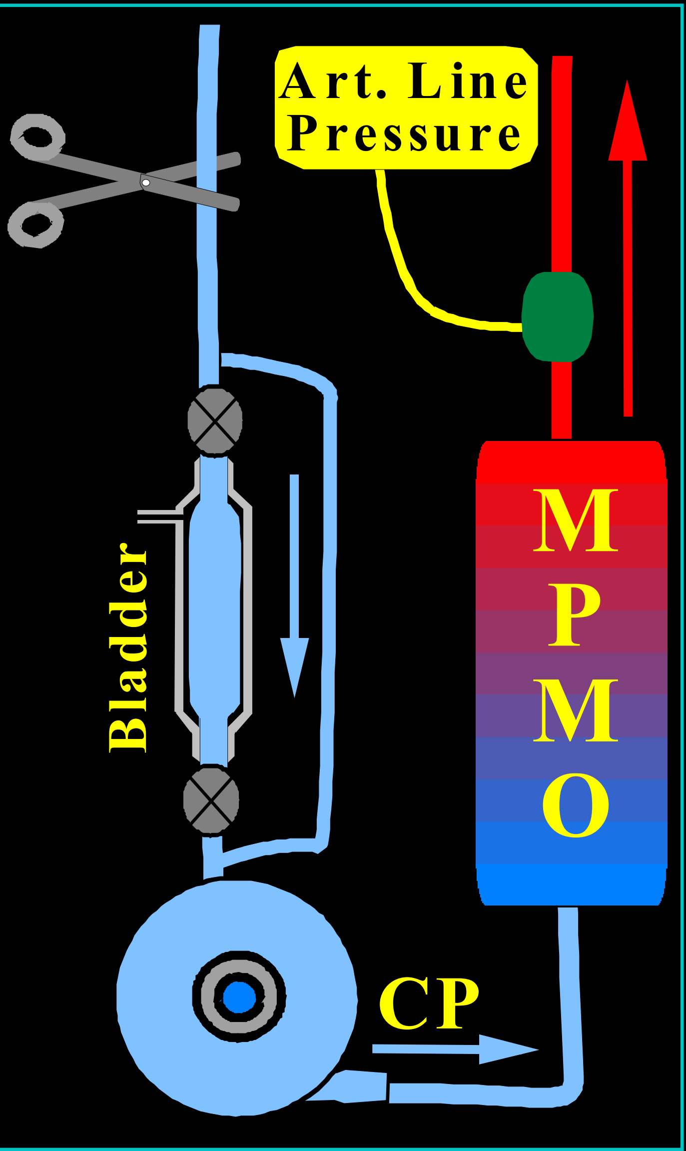
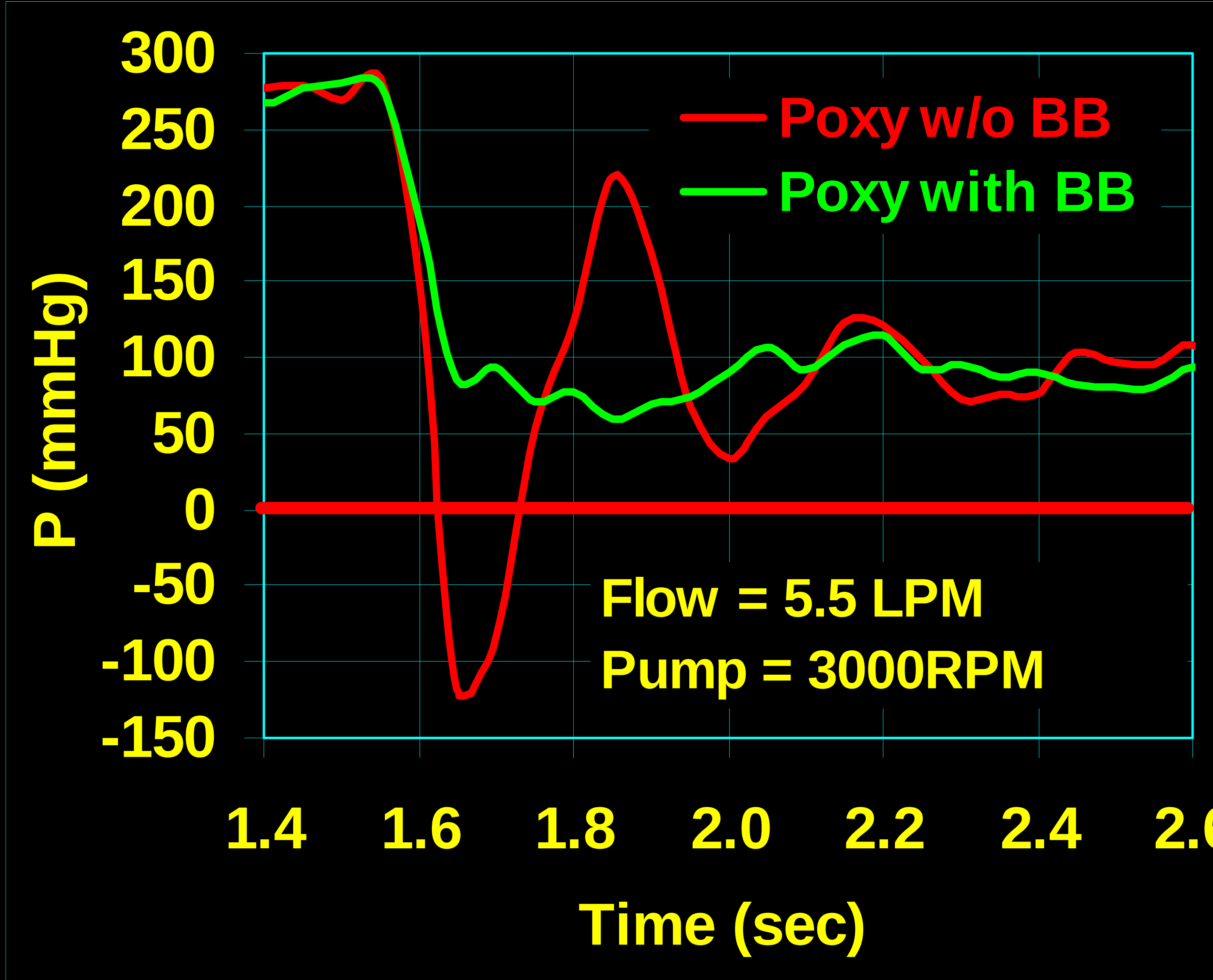
Abrupt stoppage of Venous Flow can Cause the Pressure at Oxygenator to go NEGATIVE





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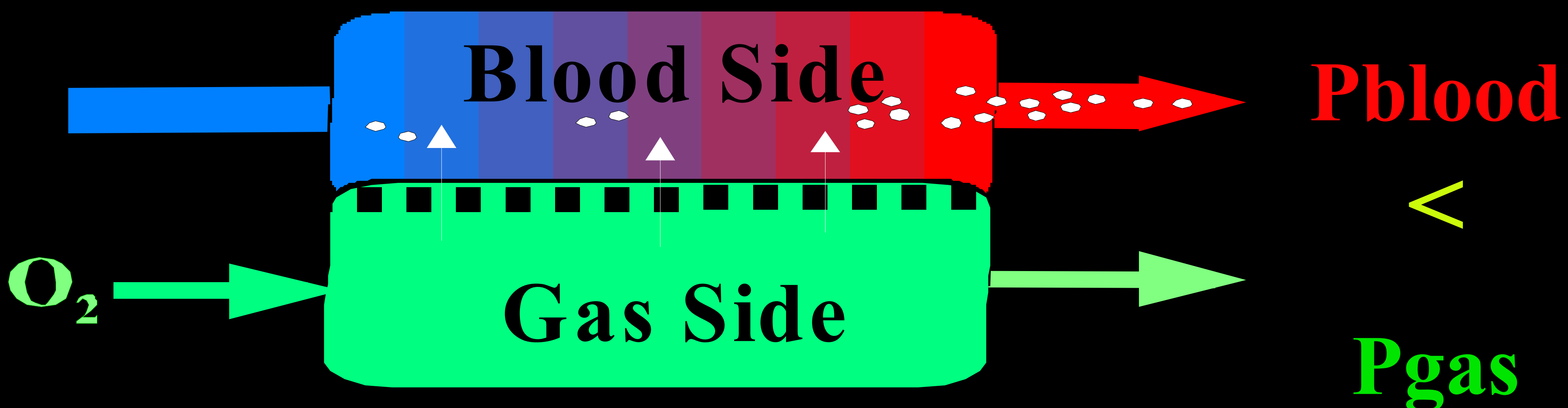
Abrupt stoppage of Venous Flow can Cause the Pressure at Oxygenator can Become NEGATIVE

When pressure on blood side of a MPMO falls below the gas pressure then there is a significant possibility that gas will flow across the porous membrane into the blood side of the oxygenator and into the arterial line.



MicroPorous Mem. Oxy

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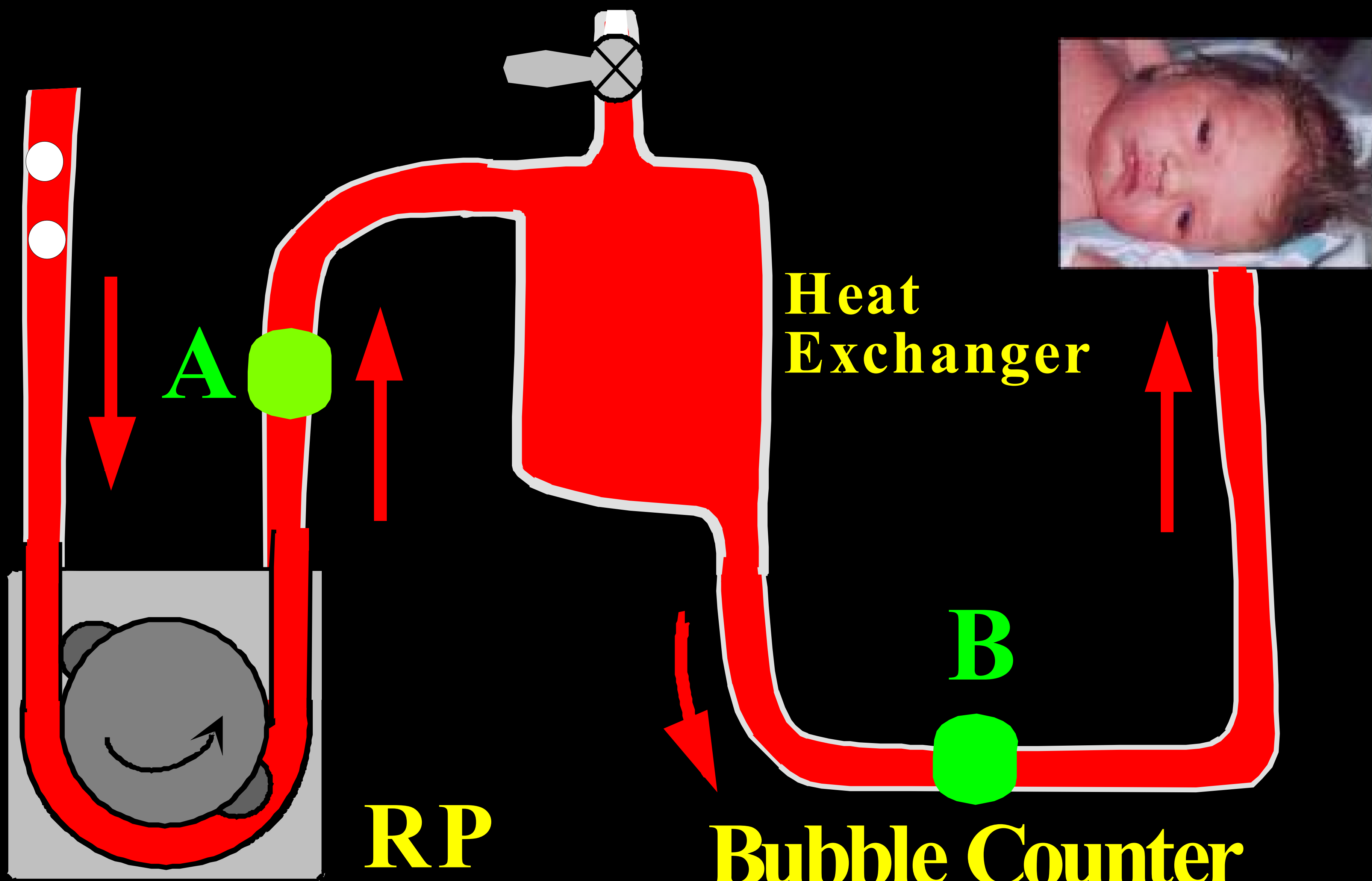
Air handling of roller pumps



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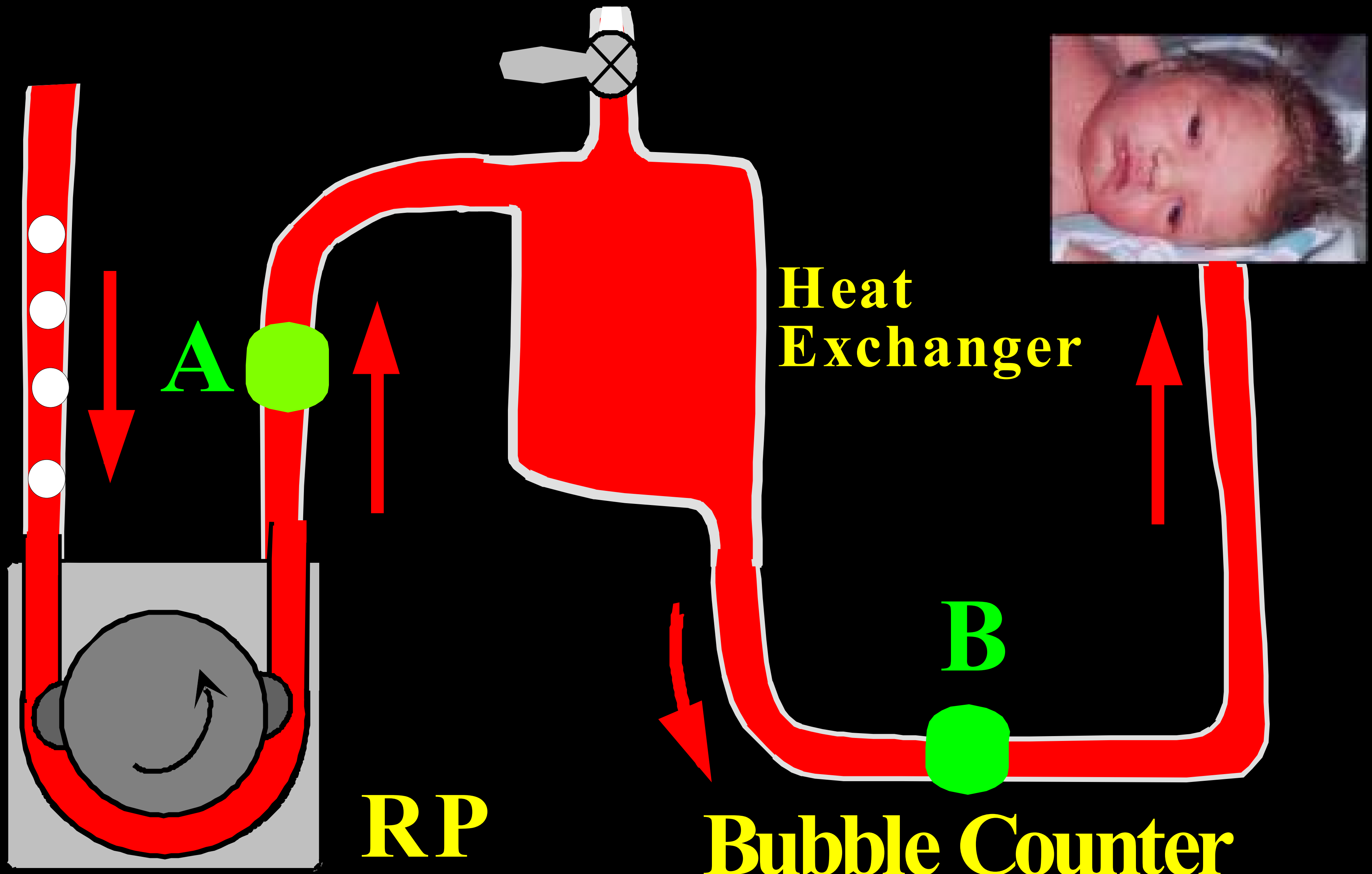

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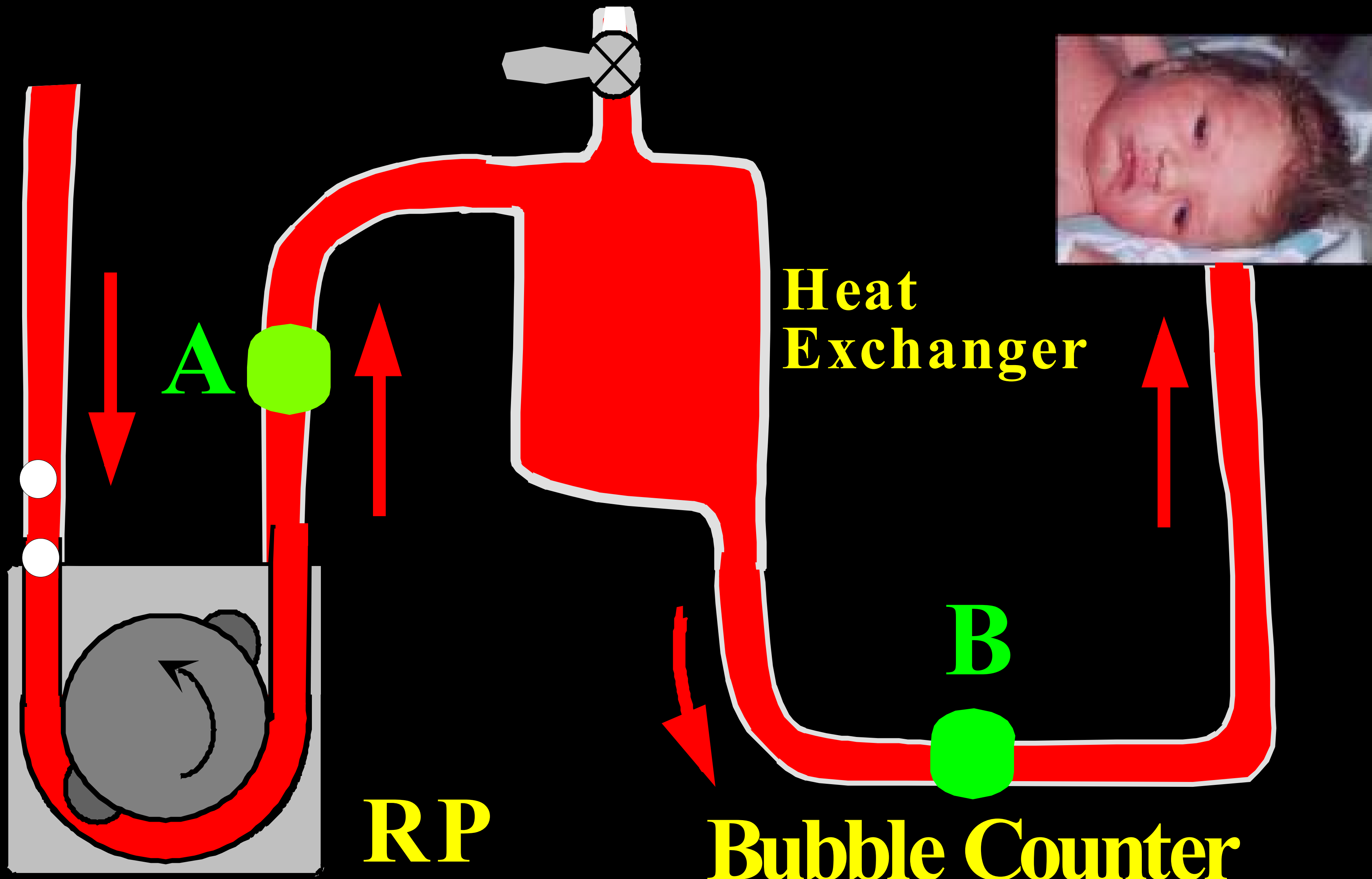

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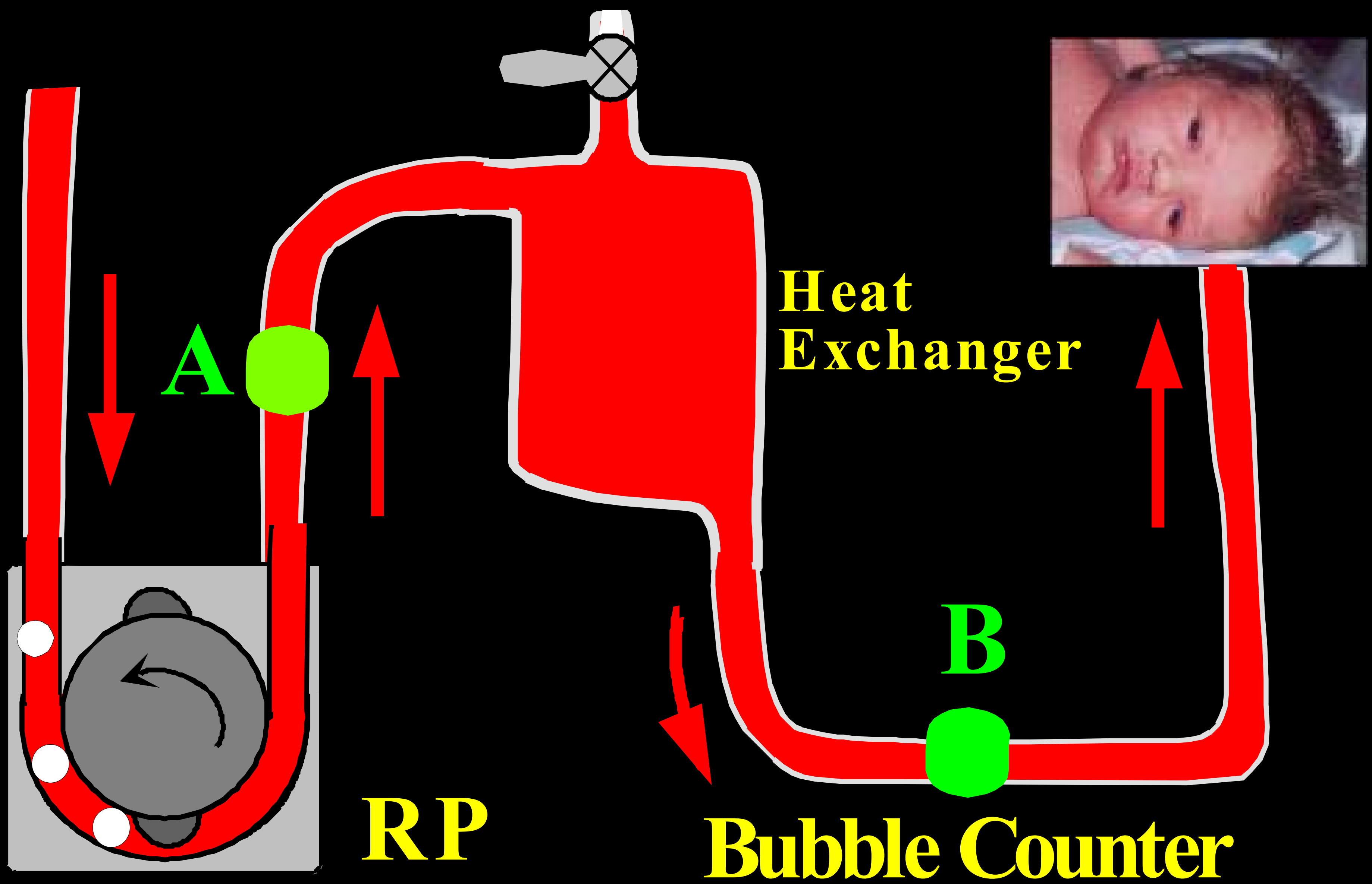

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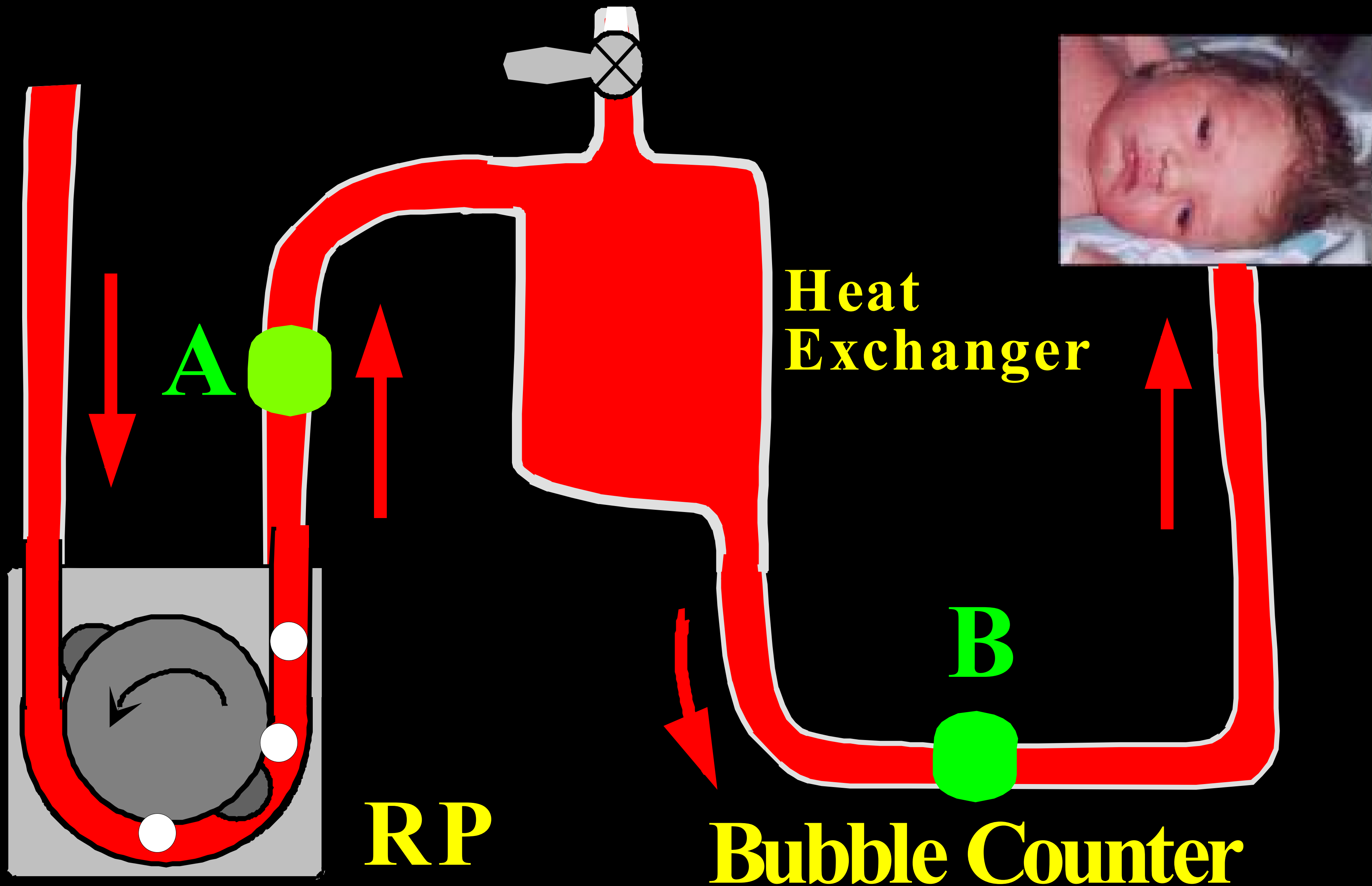
Air handling of roller pumps



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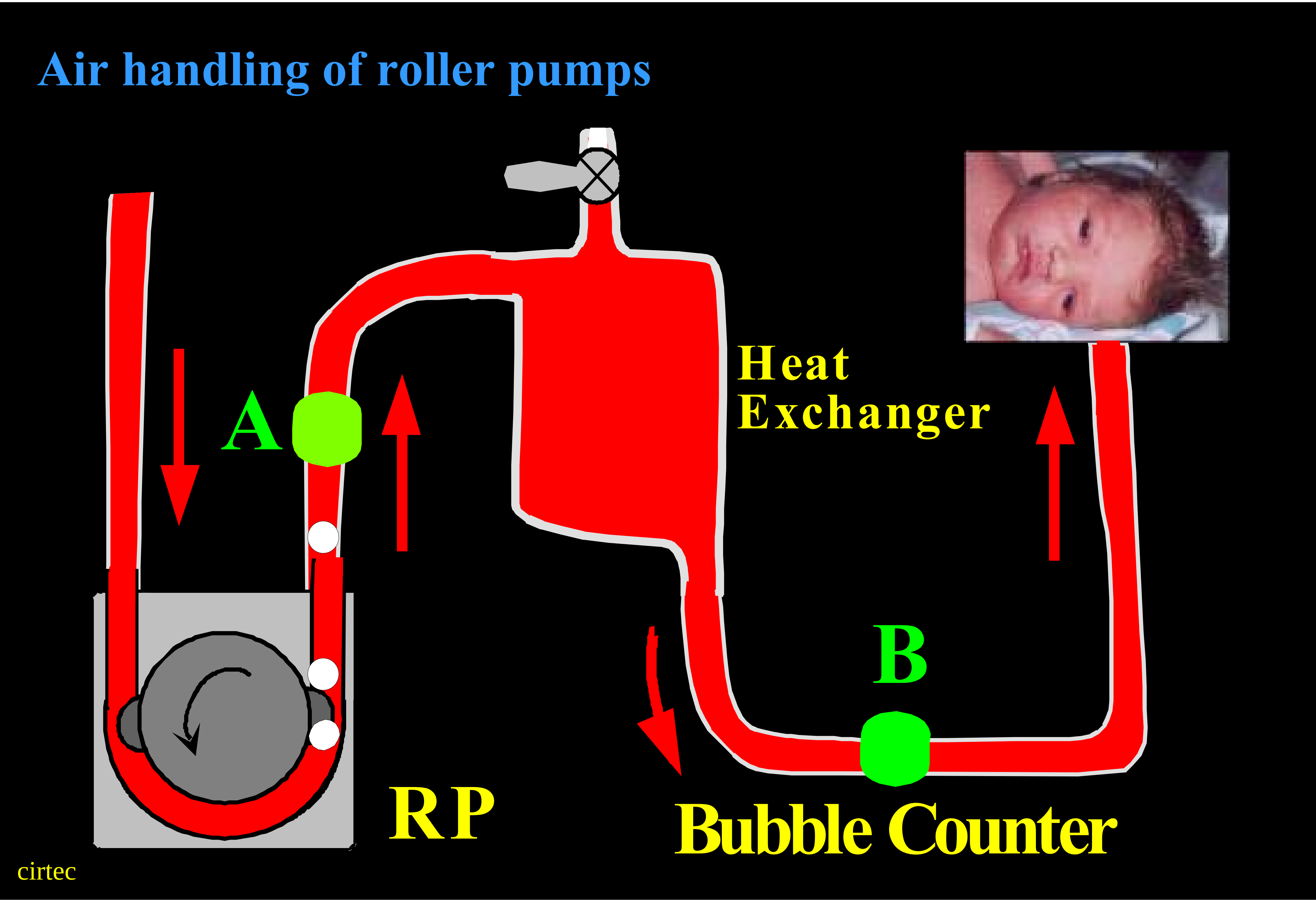

Air handling of roller pumps
A
Heat
Exchanger
B
RP
Bubble Counter
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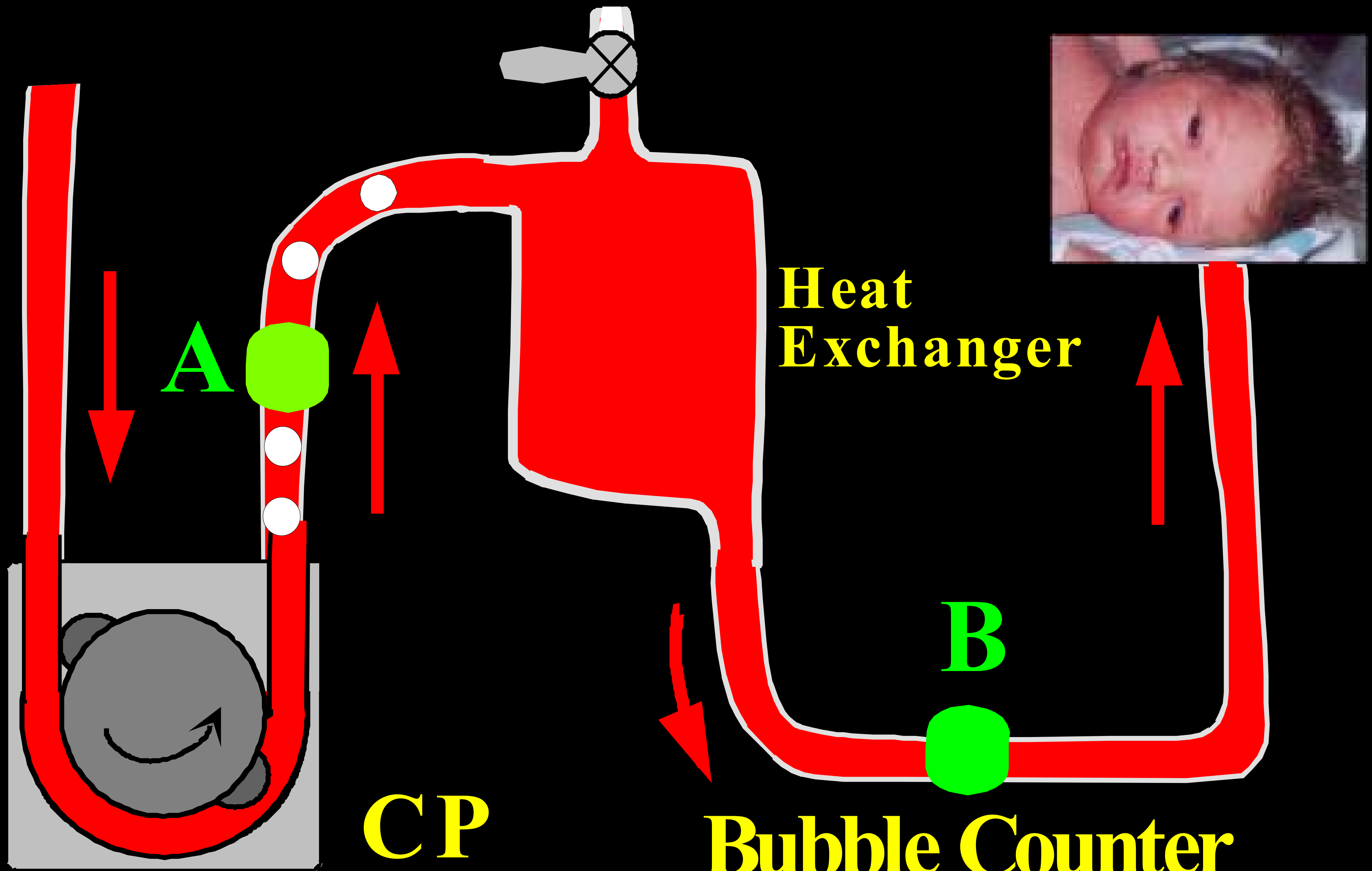
Air handling of roller pumps



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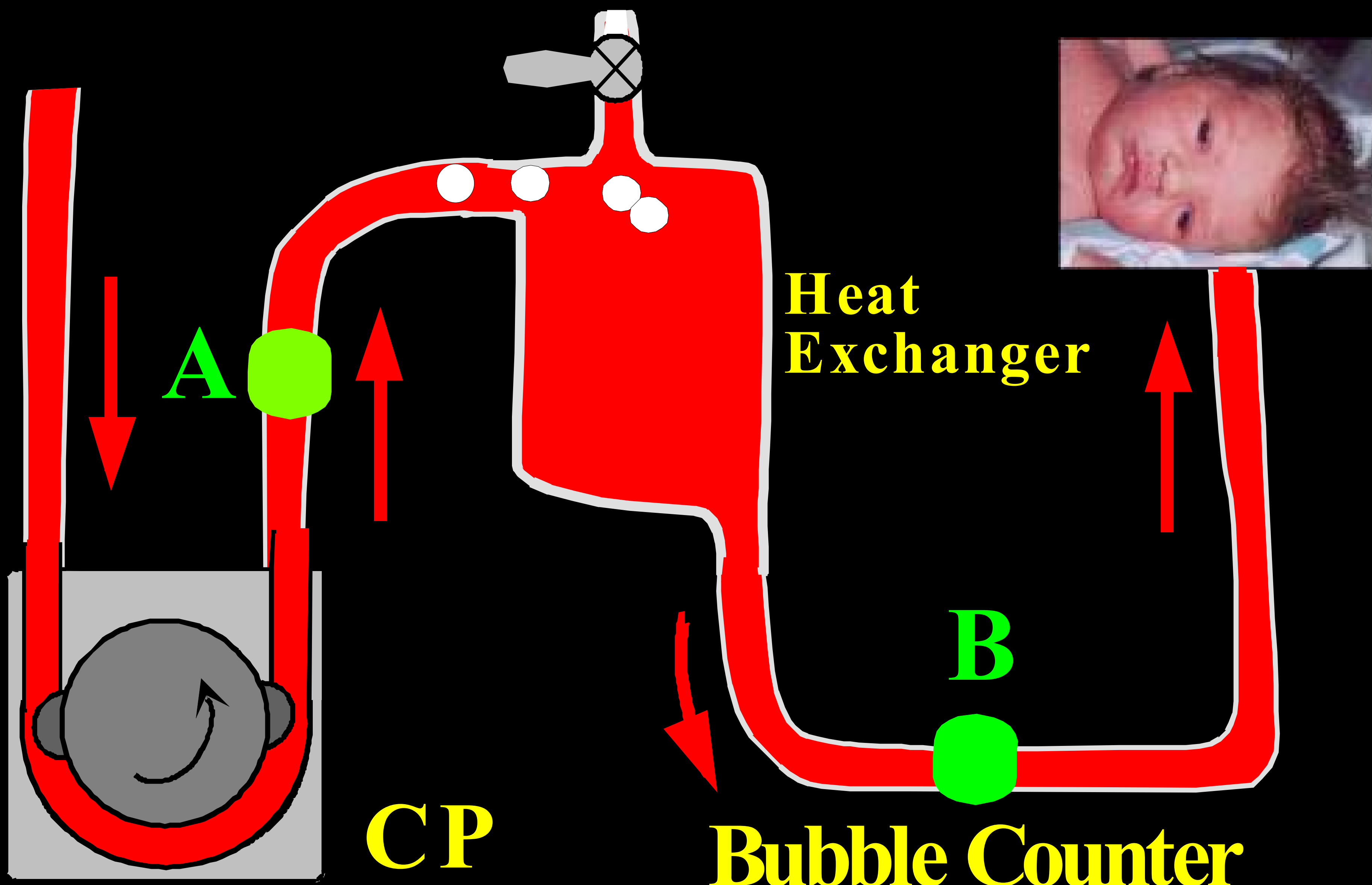
Air handling of roller pumps



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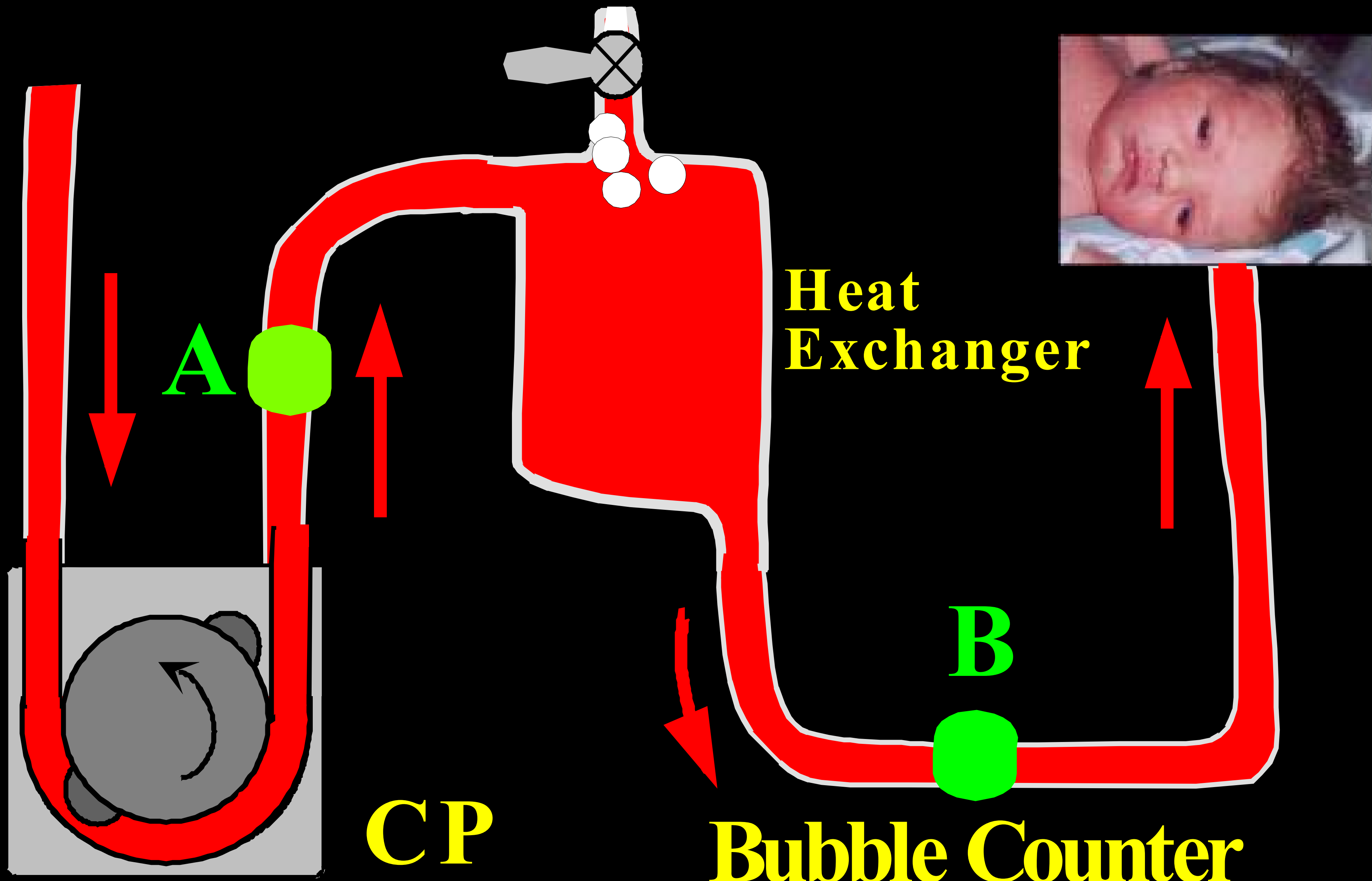
Air handling of roller pumps



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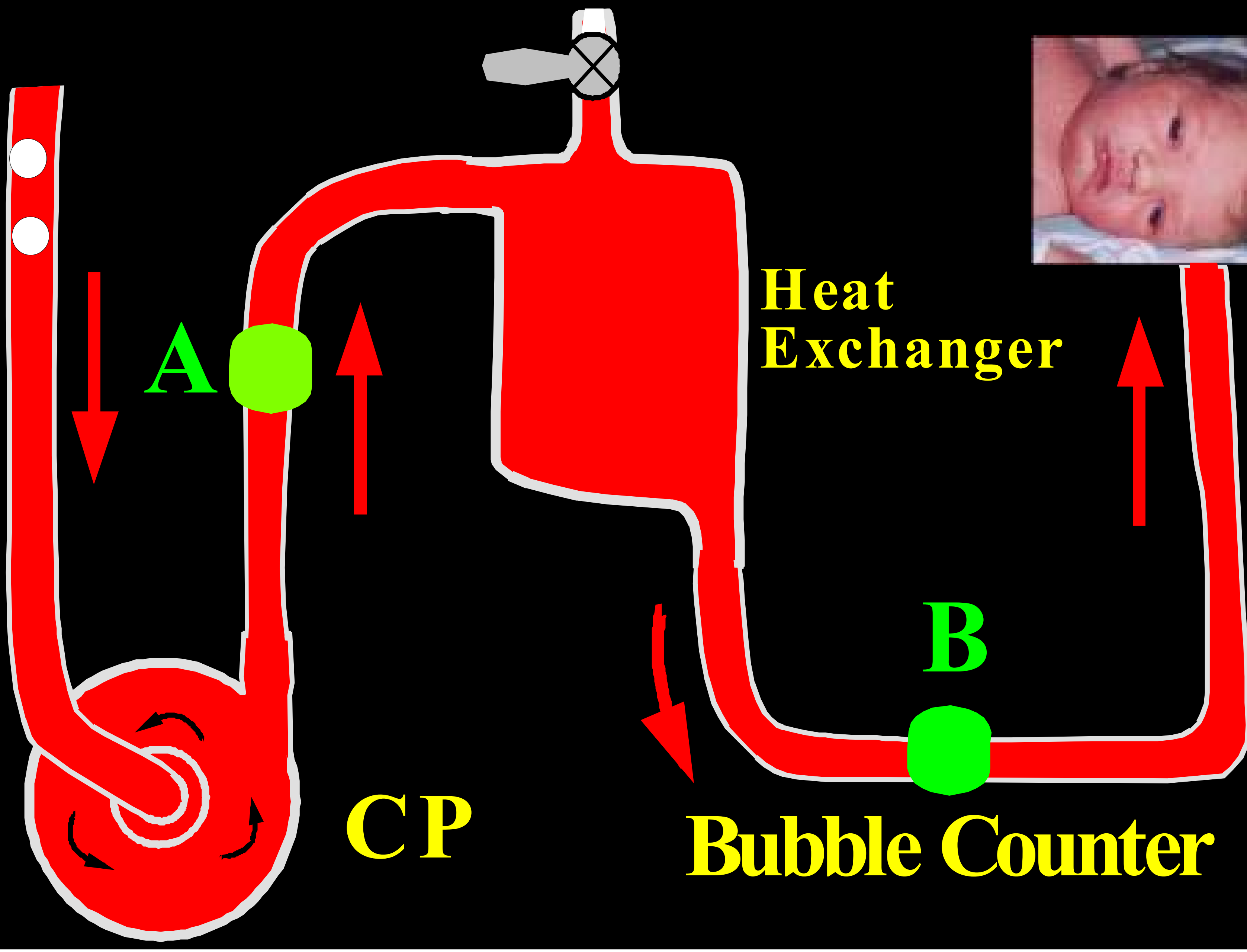
Air handling of centrifugal pumps



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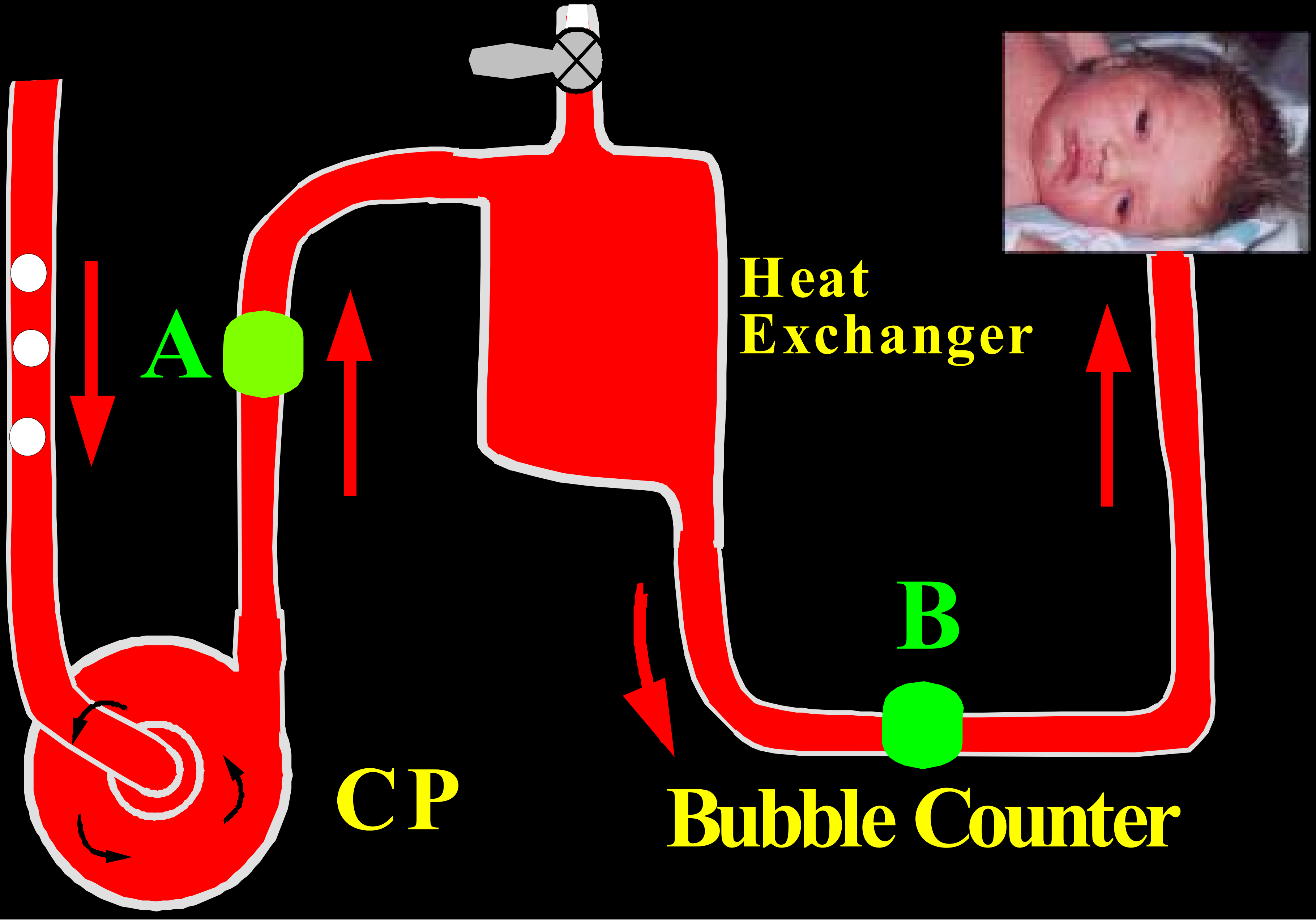
Air handling of centrifugal pumps



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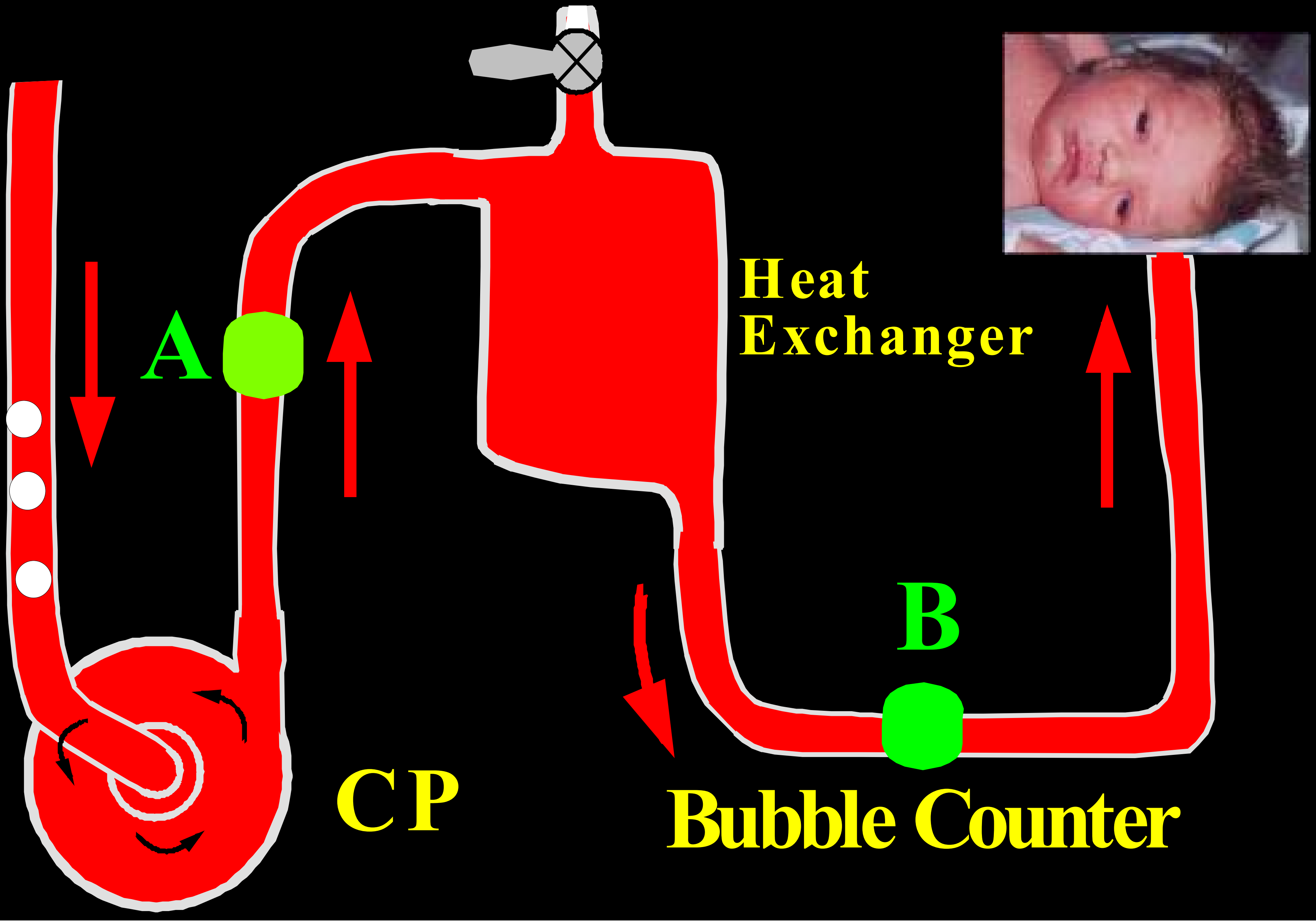
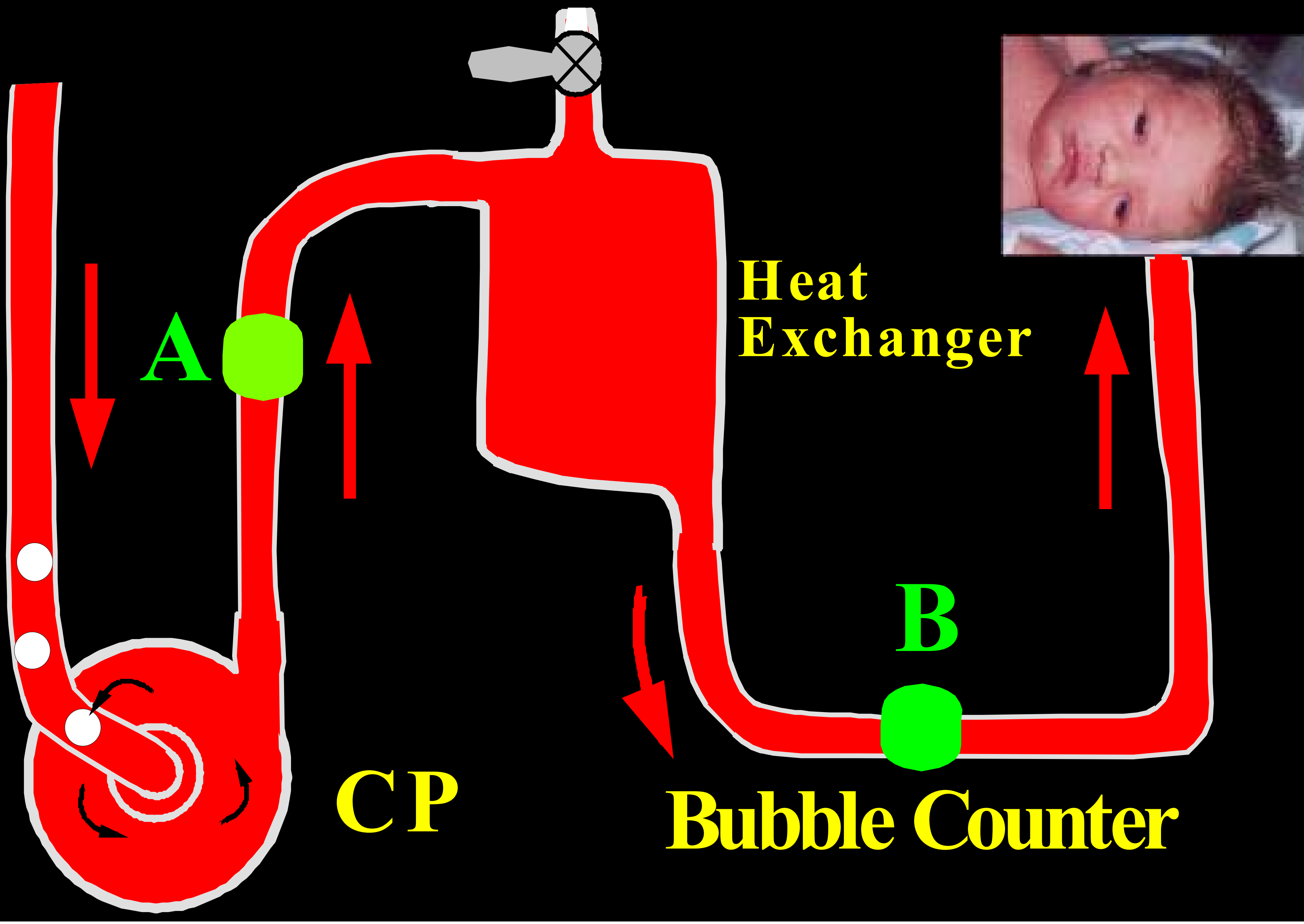
Air handling of centrifugal pumps



Air handling of centrifugal pumps



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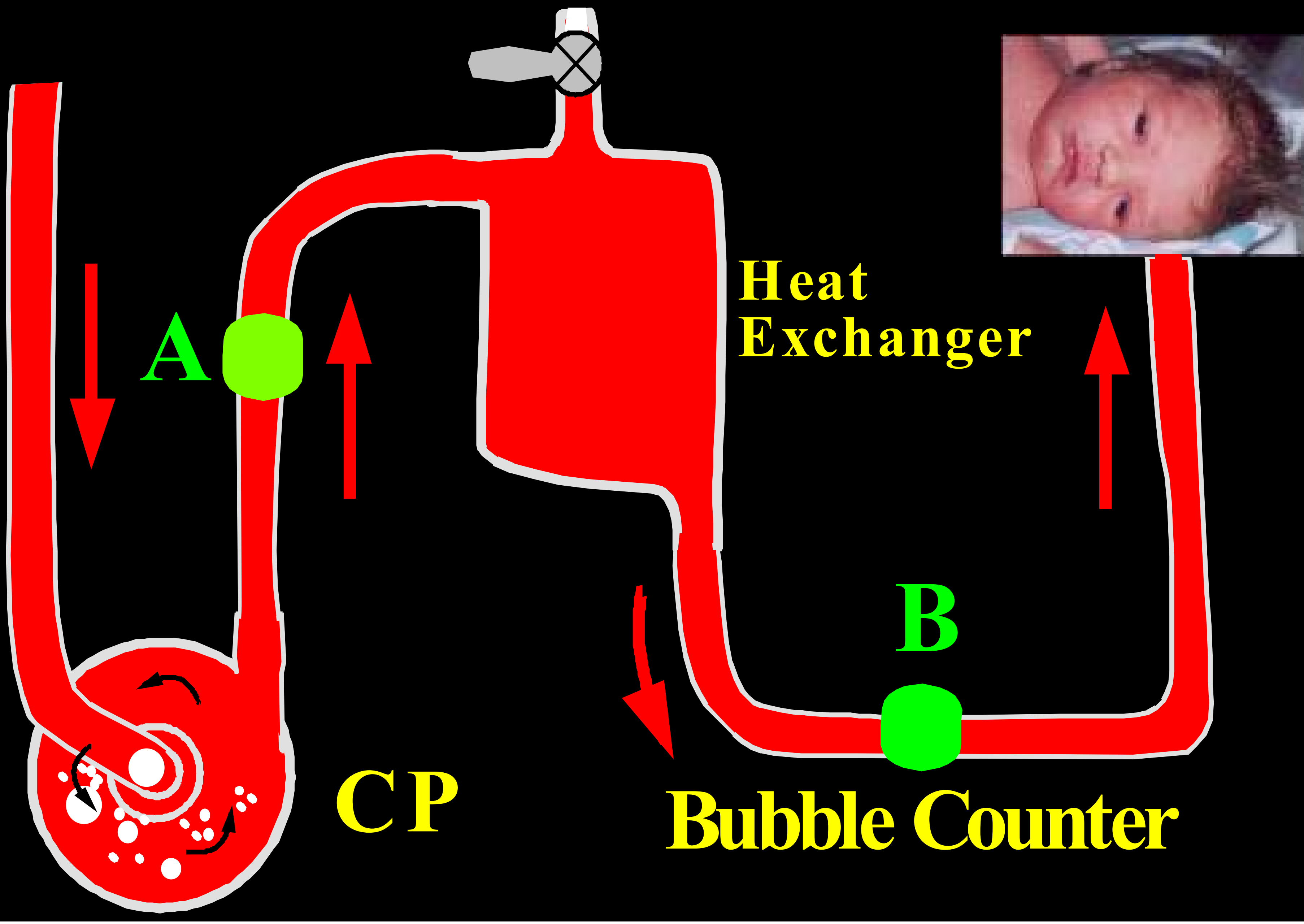
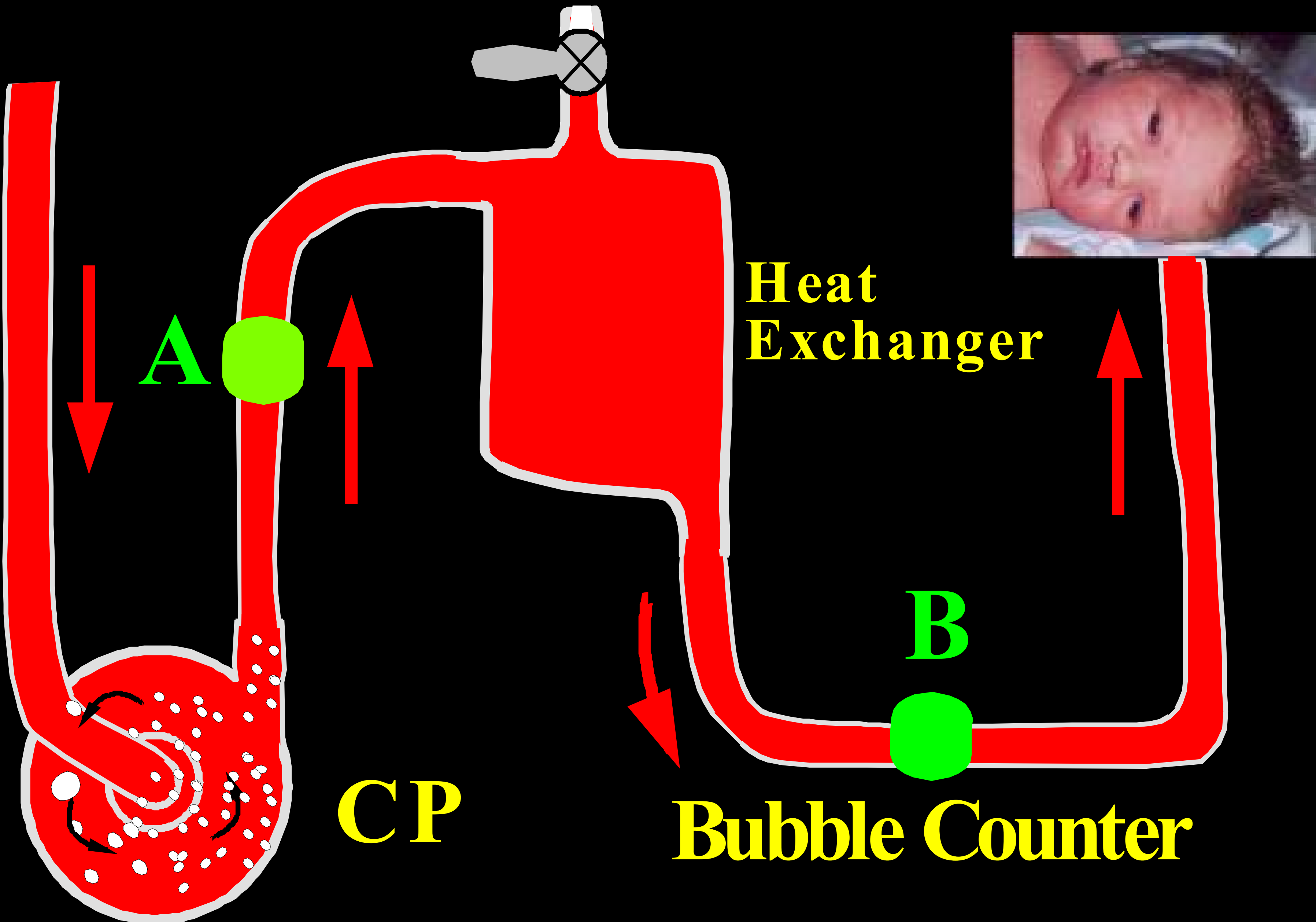
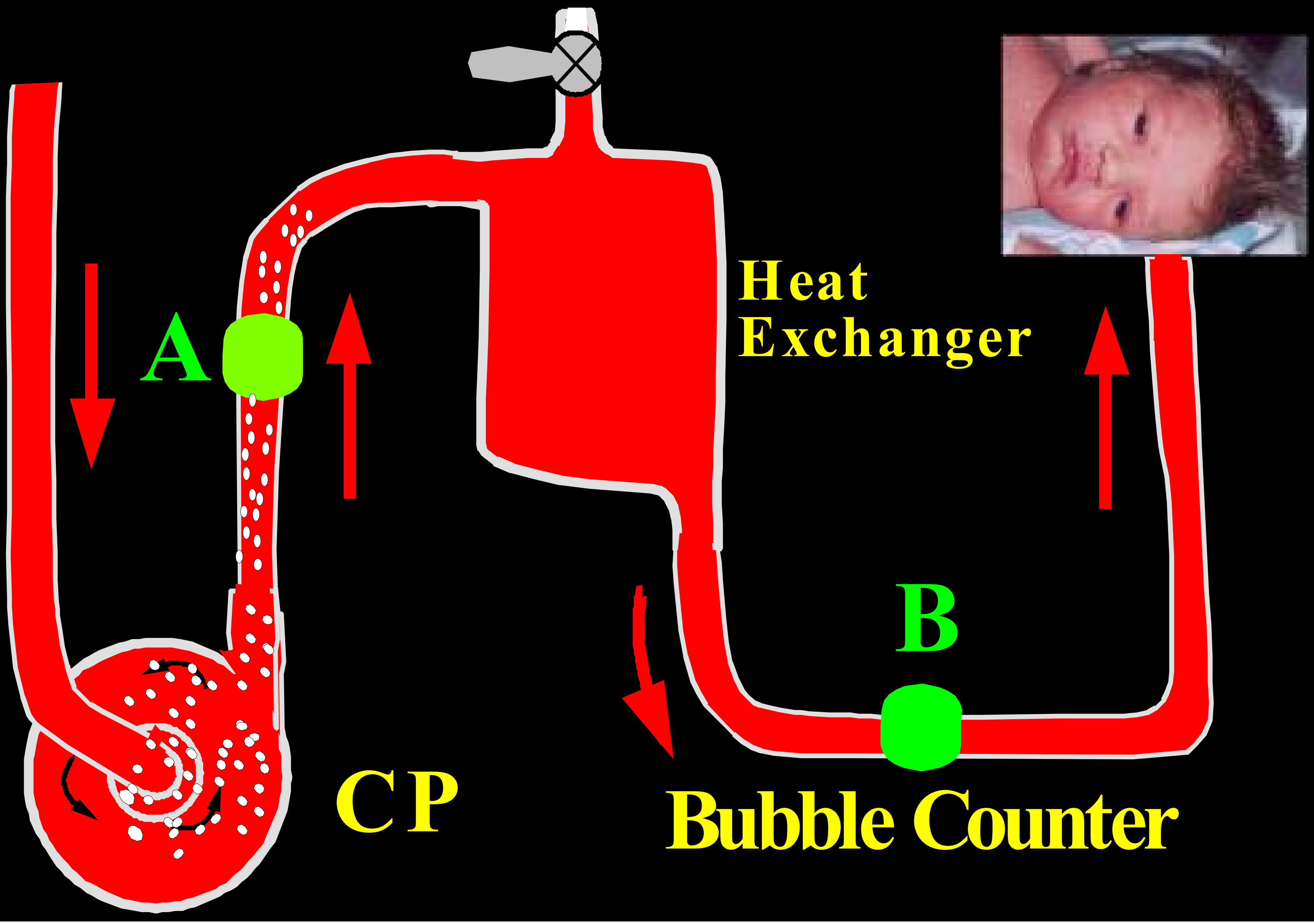
Air handling of centrifugal pumps



Air handling of centrifugal pumps



Air handling of centrifugal pumps



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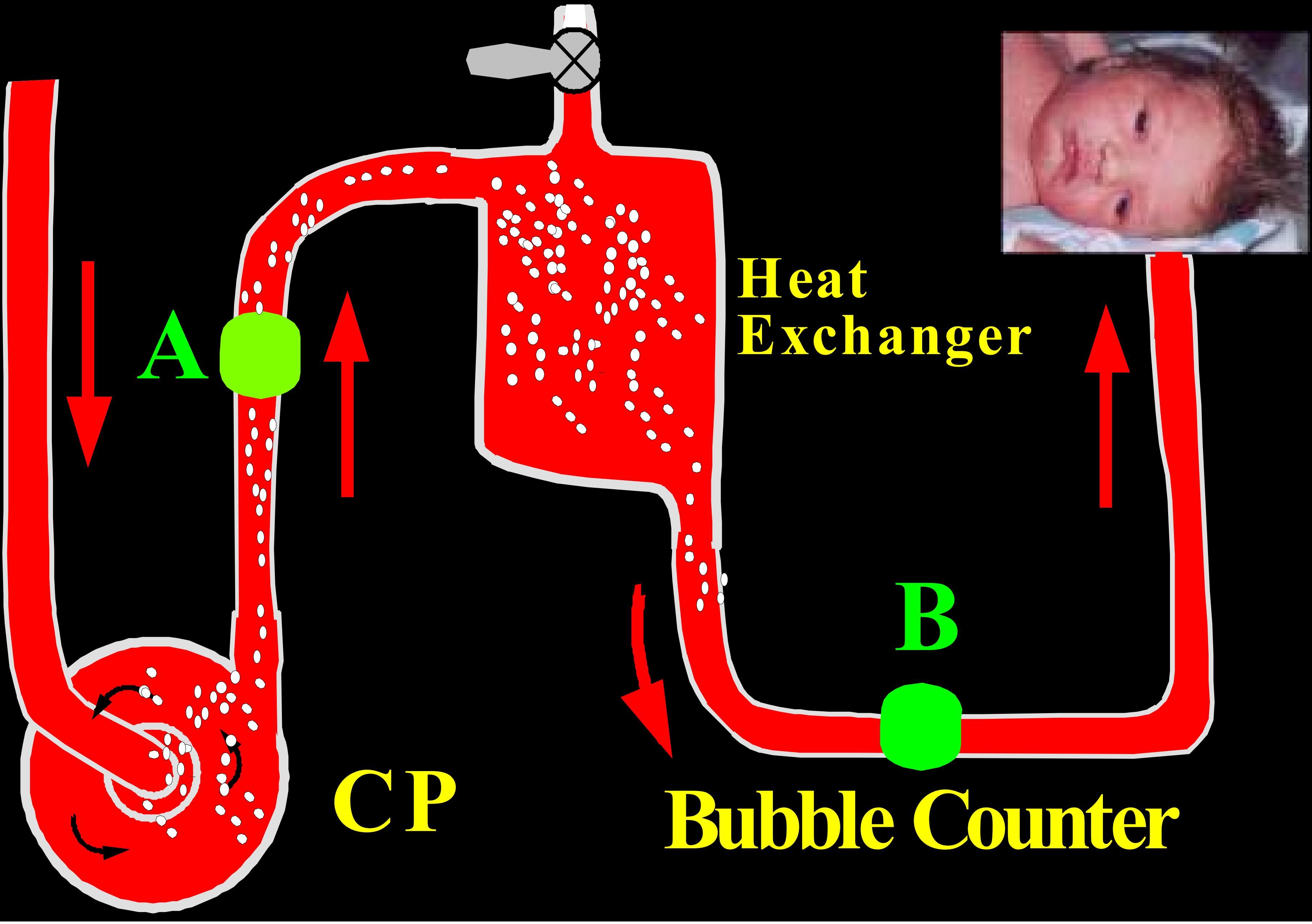
Air handling of centrifugal pumps



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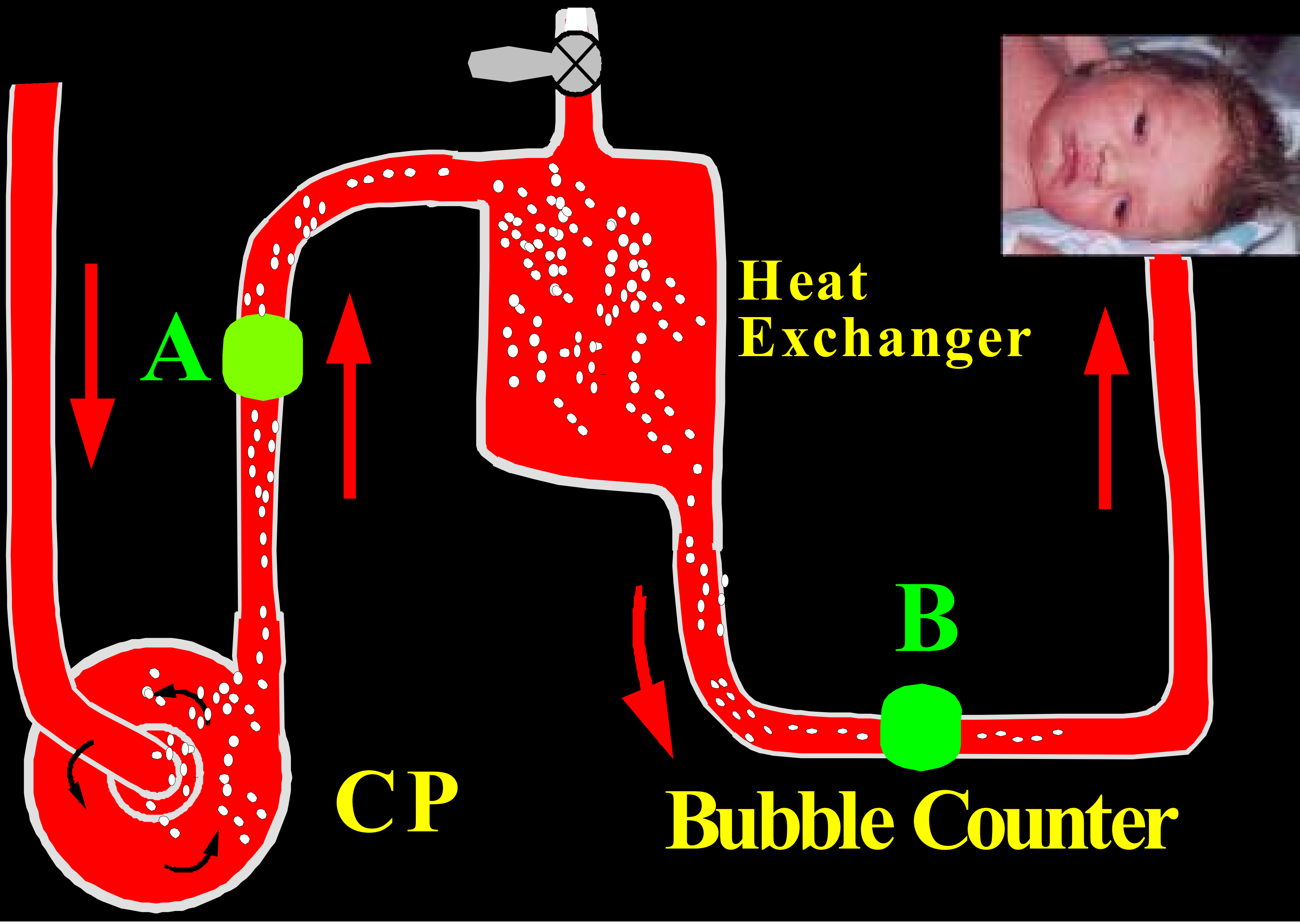
Air handling of centrifugal pumps



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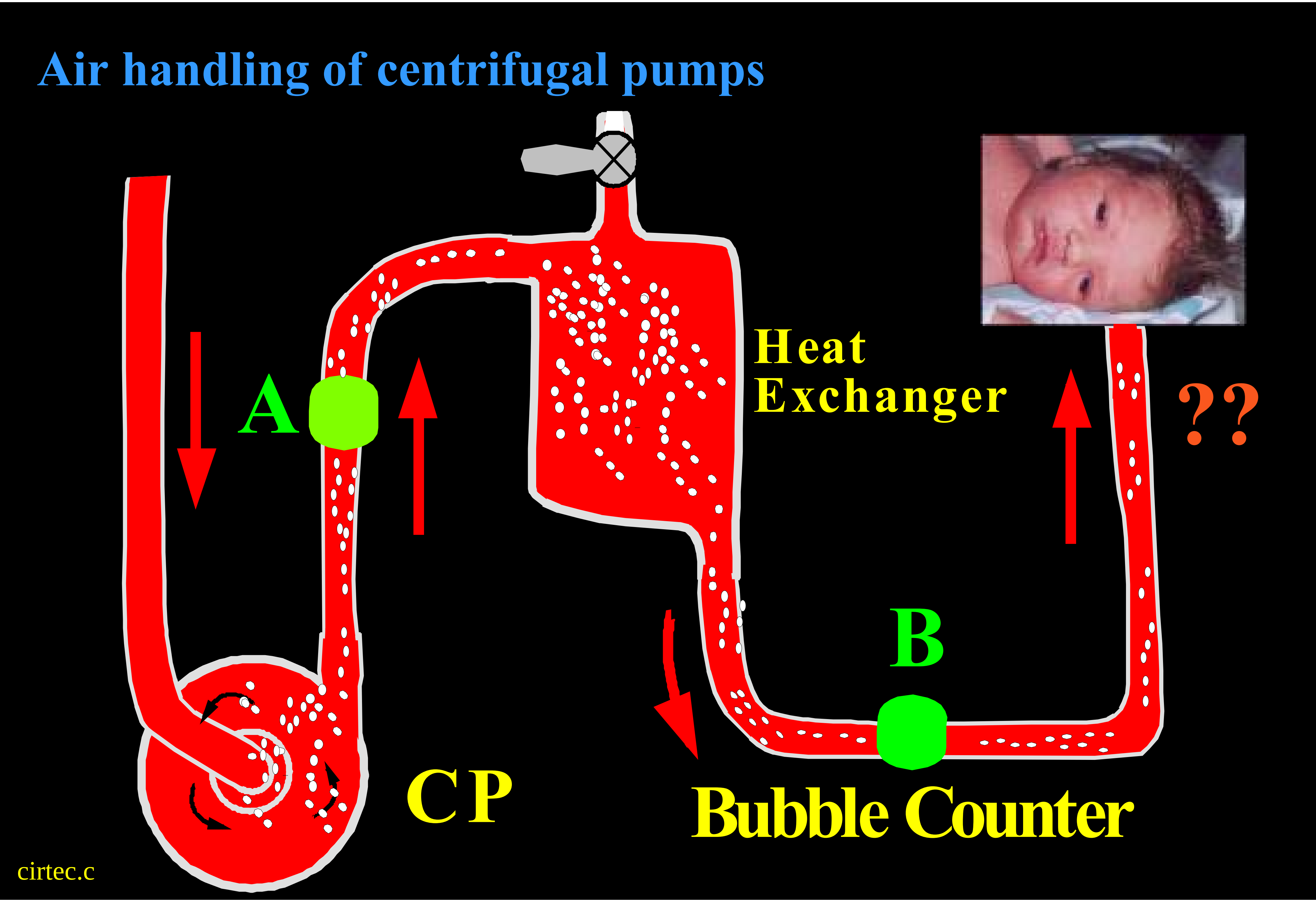

Air handling of centrifugal pumps
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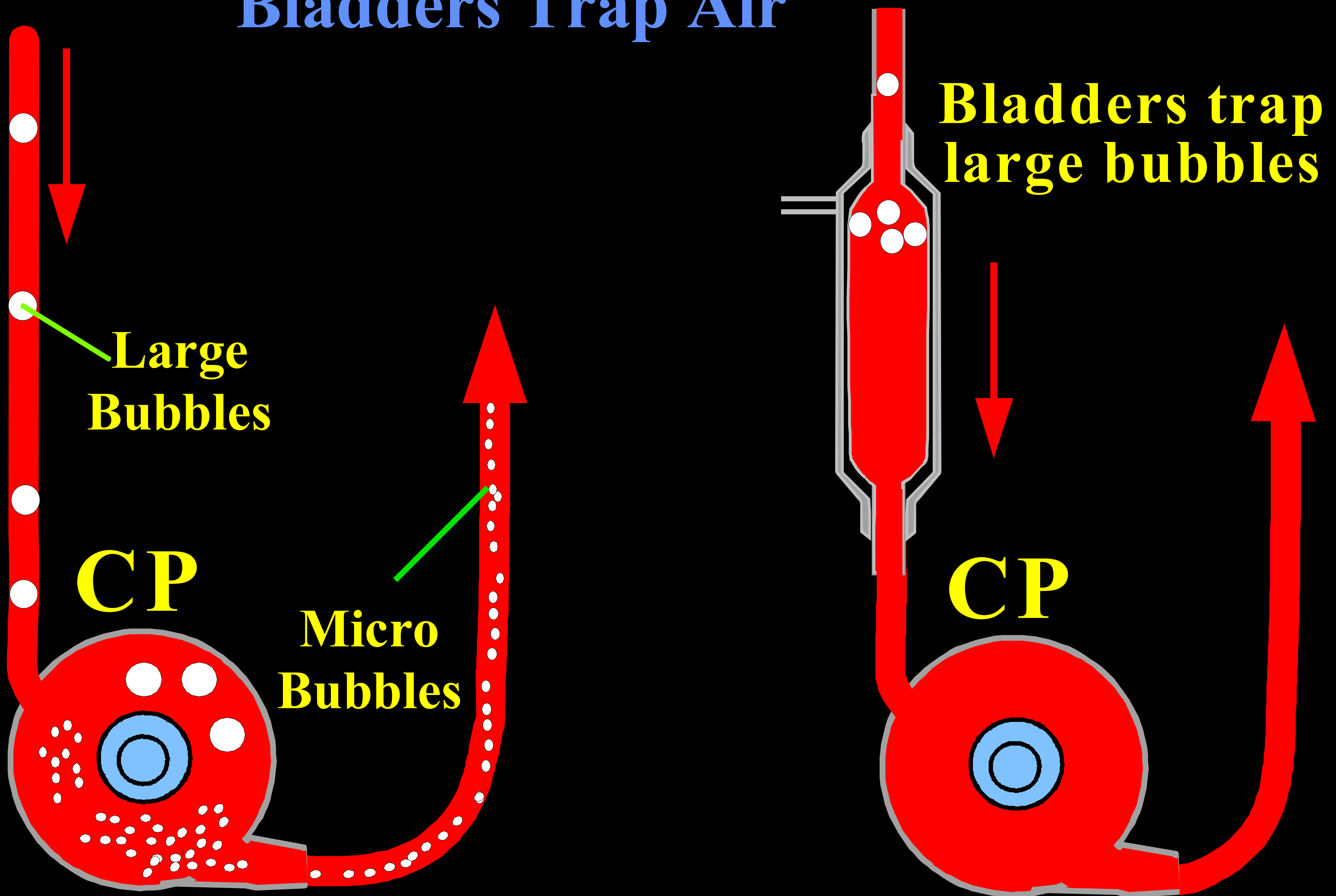
Bladders Trap Air



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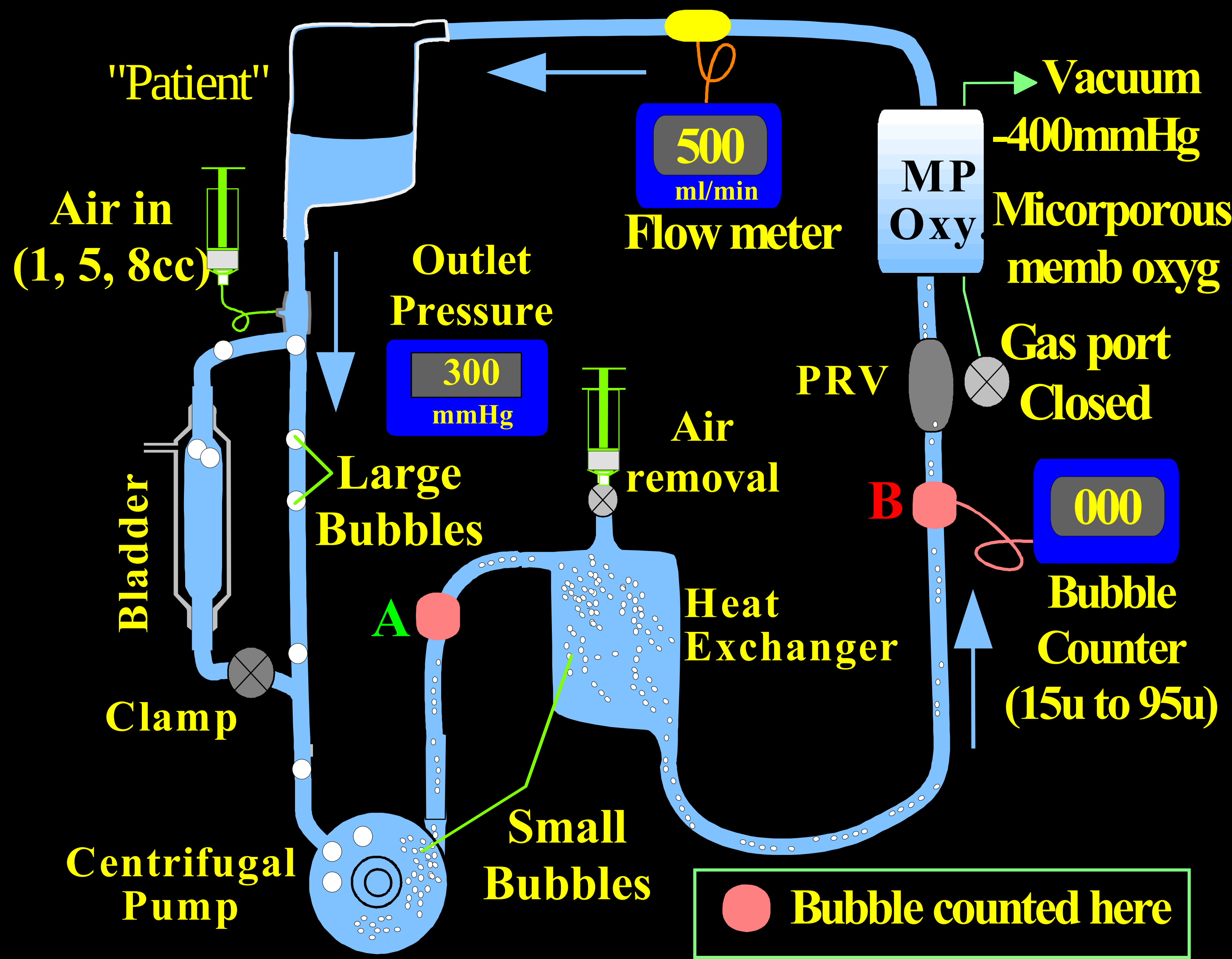
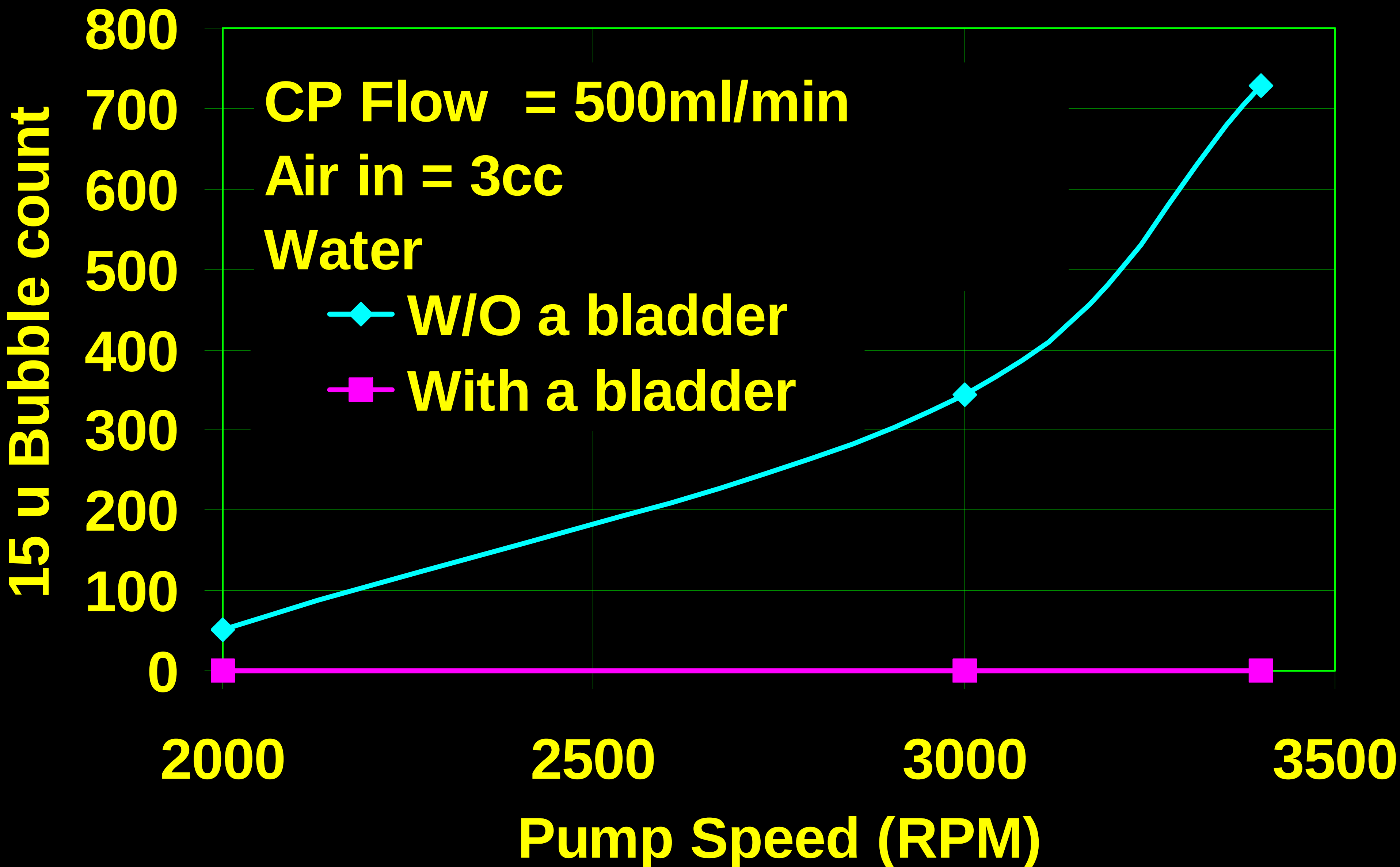
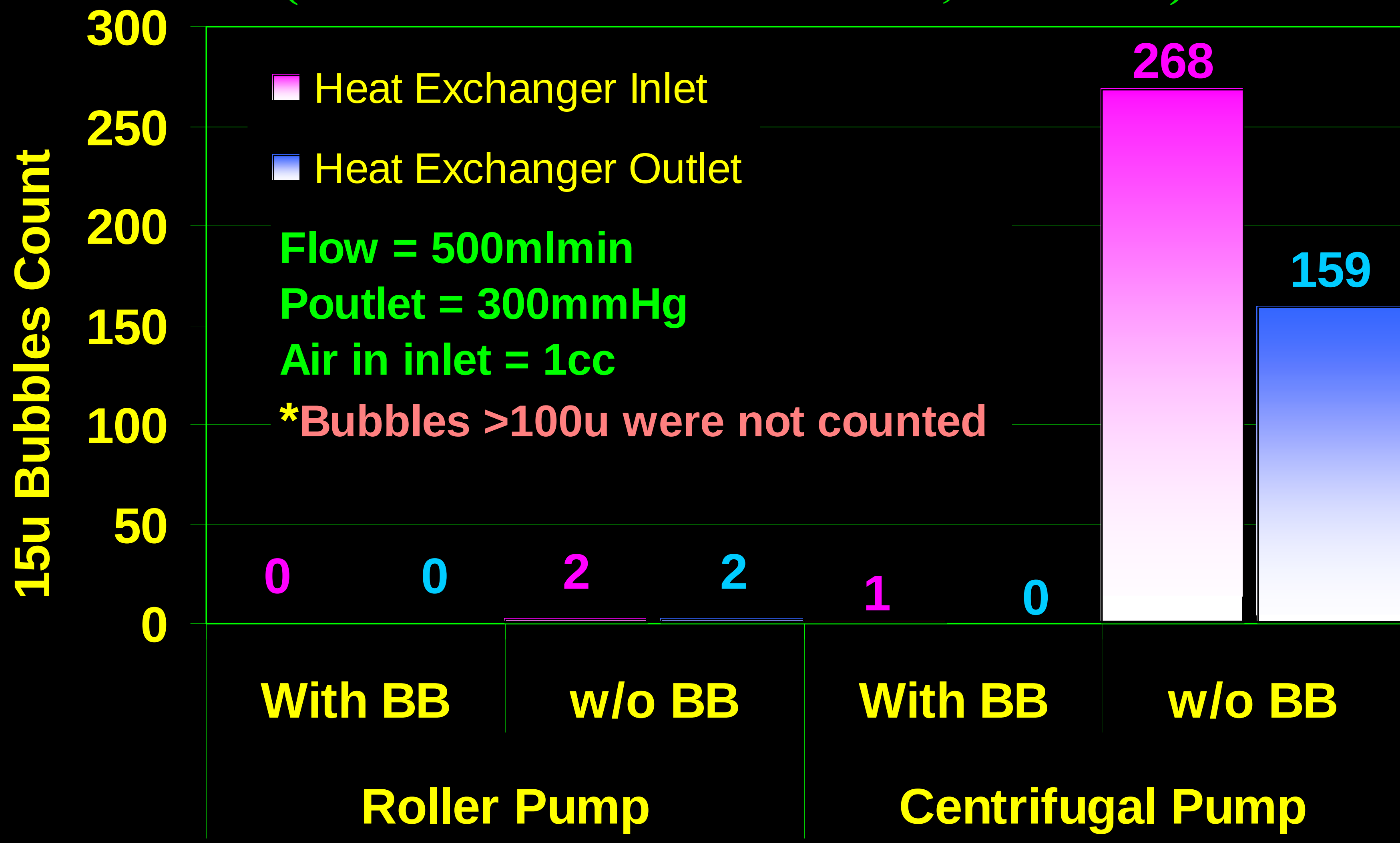
Air handling of centrifugal pumps – Experimental setup



Centrifugal Pump for ECMO – The Air Study



Centrifugal Pump for ECMO – The Air Study
(Blood Flow = 500 ml/min, 1 cc Air)



Bladders Add a Safety to Centrifugal Pumps Used for ECMO

- Provide compliance that reduces rate of change in pressure and allow better pump control as a function of venous line pressure.
- Reduce the maximum negative pressure due to abrupt stoppage of venous flow.
- Eliminate negative pressure at the outlet of the pump due to abrupt stoppage of venous flow.
- Reduce microbubbles generation by the pump.

To Bladder or not to Bladder? - Costs Considerations

Avg. cost for a neonatal ECMO ~ $100,000/wk.
Peds, post-op cardiac cases, adults, etc. are much higher.

Avg. Cost of ECMO pt. - entire hospital stay ……..... $300,000

West Coast hospital
Average hospital cost during ECMO ……………….... $195,860
Avg. Cost of ECMO pt. - entire hospital stay ………. $427,027

The bladder cost is about 0.1% of the total cost.

To Bladder or not to Bladder? - Costs Considerations

Costs of post hospital care are also significant.

52% ECMO infant survivors have abnormal neuro-imaging
(Bulas &Glass Semin Perinat 29:58-65 2005)

12 % have severe mental handicap (FSIQ < 70) and 37% are at risk for school failure.
(Rais-Bahrami et. al. Clin Pediatr: 39(3):145-52, 2000)

The bladder cost is less then 0.1% of the total cost.

To Bladder or not to Bladder?

Costs Considerations

Since the bladder's cost less then 1/1000 of the total cost of ECMO,

If the bladder prevents a single patient from being exposed to microbubbles or vessel damage due to excess negative pressure at the cannula

Then its cost has been justified for hundreds of patients.

Bladders placed at the pump inlet

- Dramatically reduce the maximum negative pressure at the pump inlet and at the tip of the venous cannula. Reduced vessel damage?
- Reduce pressure pulsations at the pump inlet and at the tip of the venous cannula. More Physiological?
- Provide smoother pump operation. Less clotting?
- Cleared by the FDA for that purpose.
- Standard of care - reduce liability.

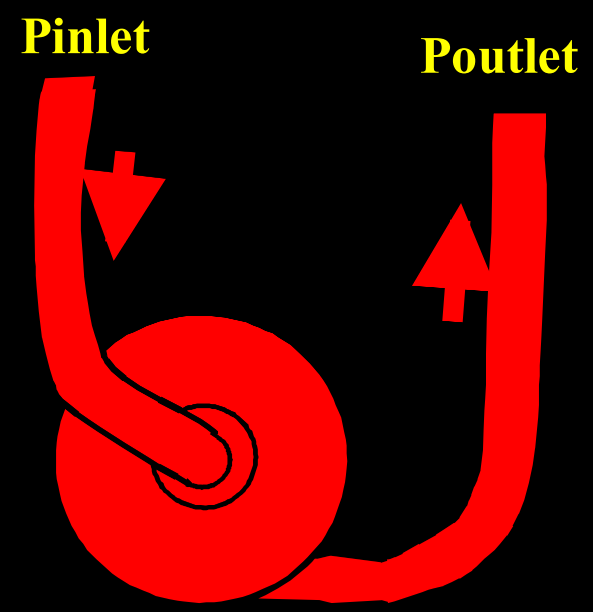
To change a circuit/procedure the user must answer to the affirmative the following :

- Is it as safe or safer then current practice?
- Is it standard of care?
- Is it supported by publications in a peer reviewed journal?
- Could it introduce other problems?
- Do we have the team with the educational background to properly evaluate the effects of the change?

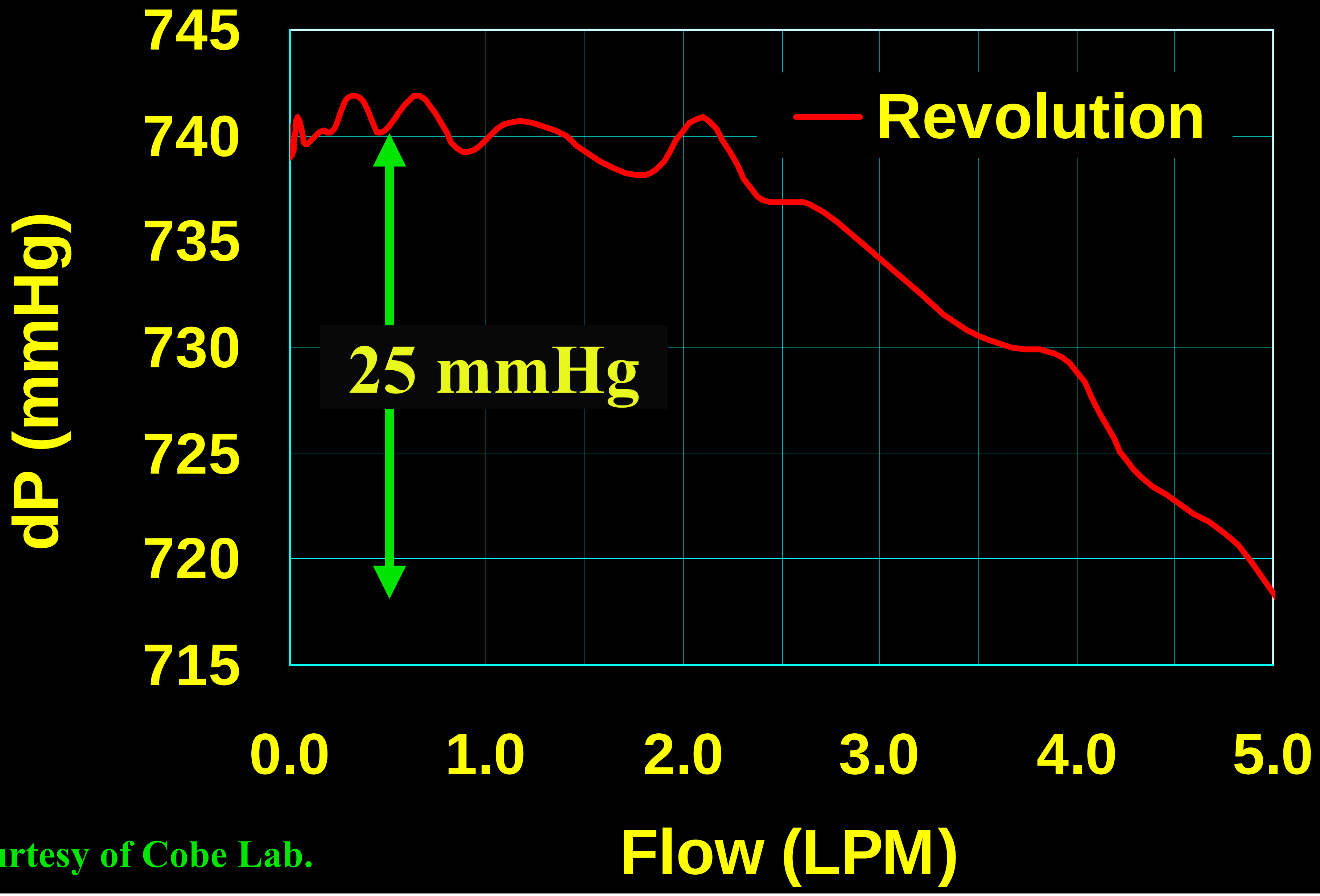
Blood damage: The Centrifugal Pump

Depends on shear stress (*i.e.* RPM) and exposure time.

The greater the shear and the longer the exposure time the greater the damage.



CP's Flow Characteristics*



*Courtesy of Cobe Lab.

Blood damage: The Centrifugal Pump

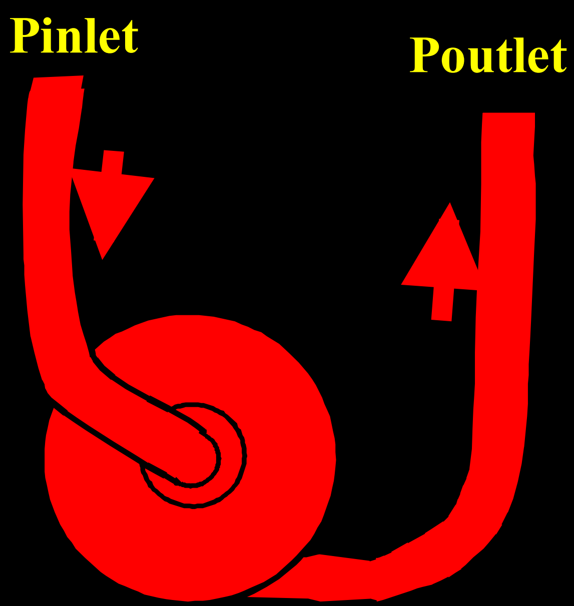
Since the line pressure in the adult and neonate circuits are similar.

And, since the pump speed varies little with flow but is mostly dependent on line pressure.

Then, we can conclude that the shear stress within the pump for neonates approximates that for adults.

Any difference in blood damage between adults and neonates flow conditions is due to differences in exposure times to that shear.

Blood damage by CPs



Patient	*Pout* *mmHg*	*Flow* *LPM*	*Time* *sec*
Adult	*250*	*5.0*	*0.6*
Neonate	*250*	*0.5*	*6.0*

For a CP with a prime volume of 50 ml, the residence time at 5.0 LPM is 0.6 sec.

At 0.5 LPM it is 10 times longer or 6.0 sec.

The finger damage test

= Little or no damage.

Exposure to 0.6 sec

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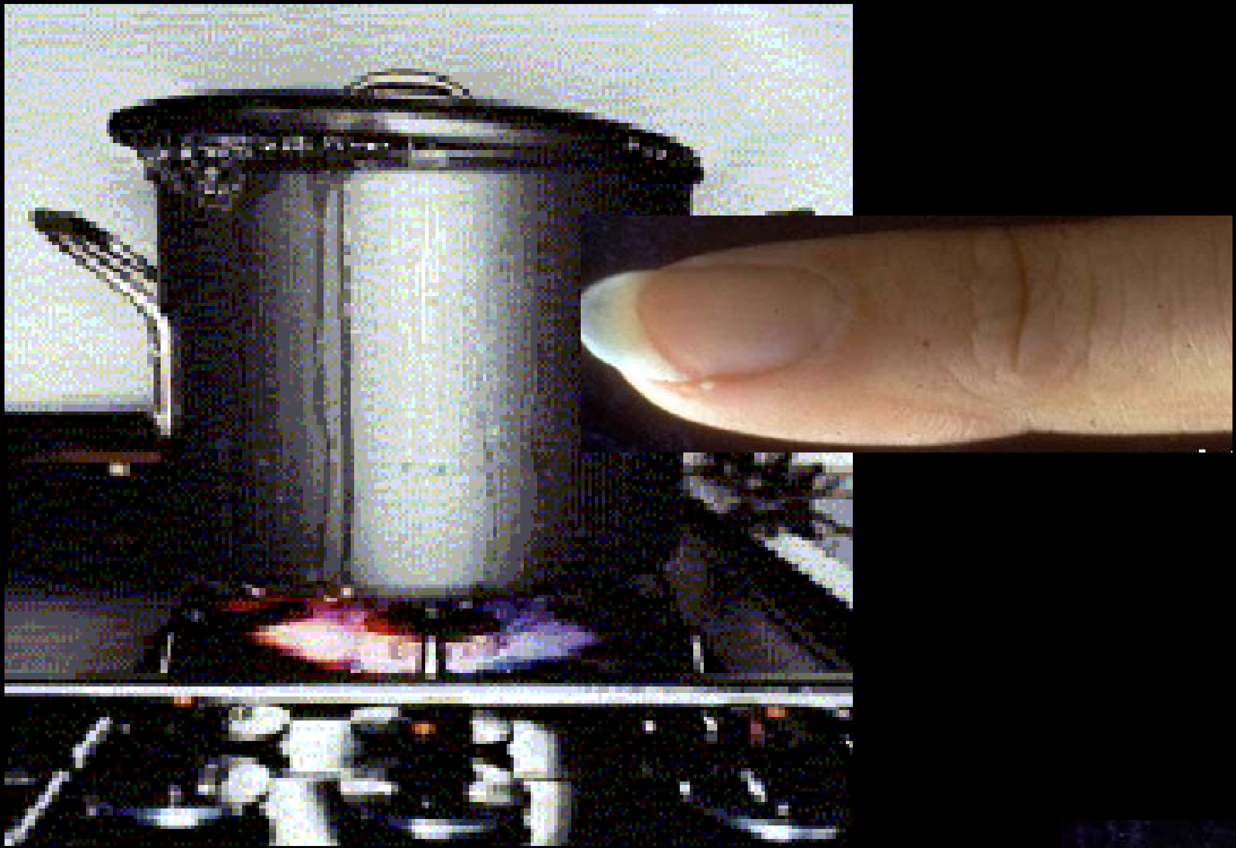
The finger damage test

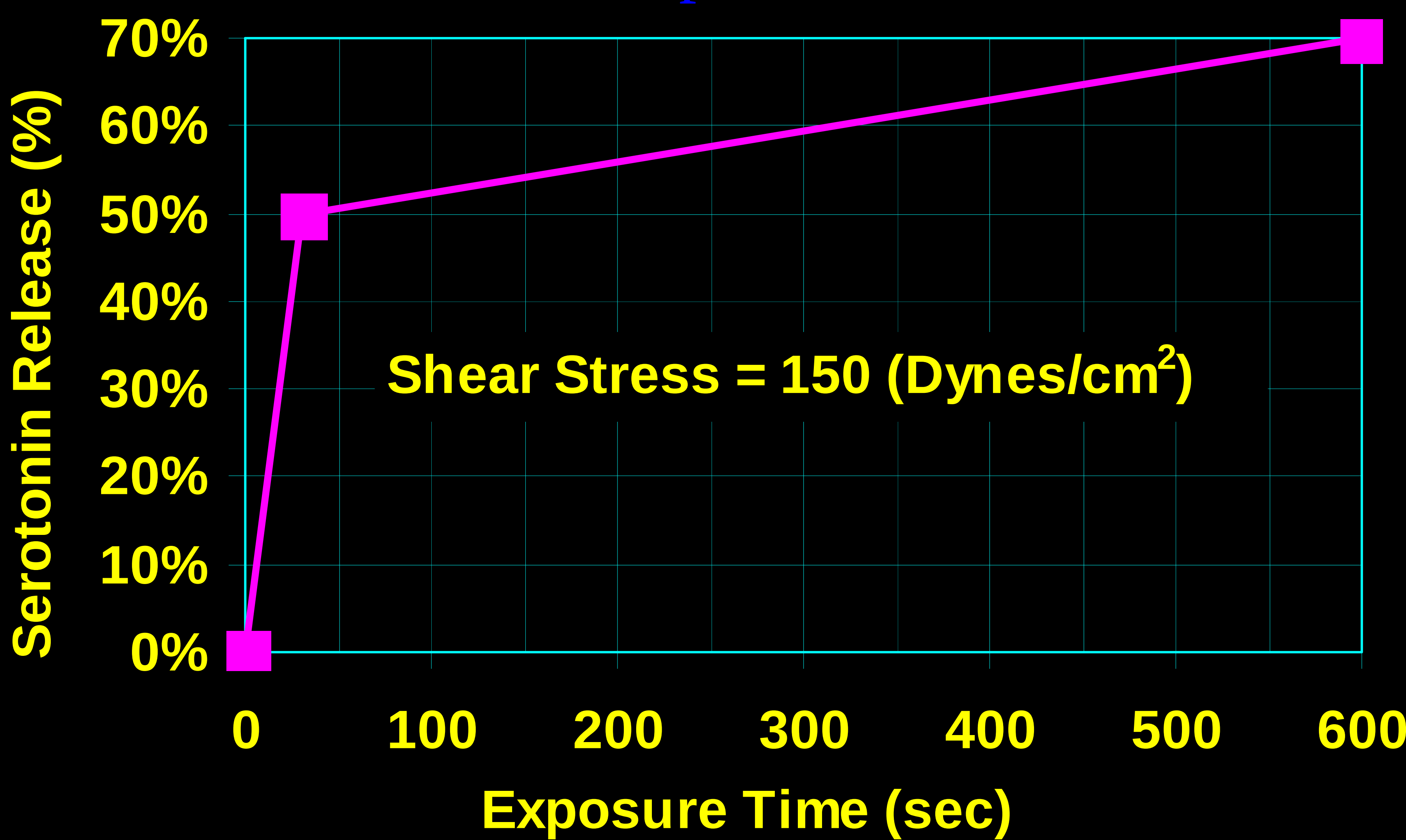


=

Major damage

Exposure to 6.0 sec

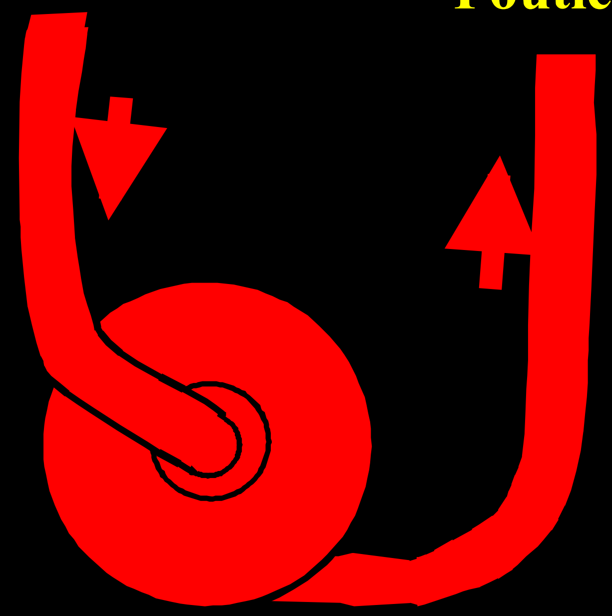
Serotonin released from sheared platelets relates to exposure time*



*Brown *et.al.* Trans. ASAIO 21:35, '75

Blood damage: Comparing RP to CP

Hemolysis:
Shear stress (*i.e.* RPM)
Exposure time.



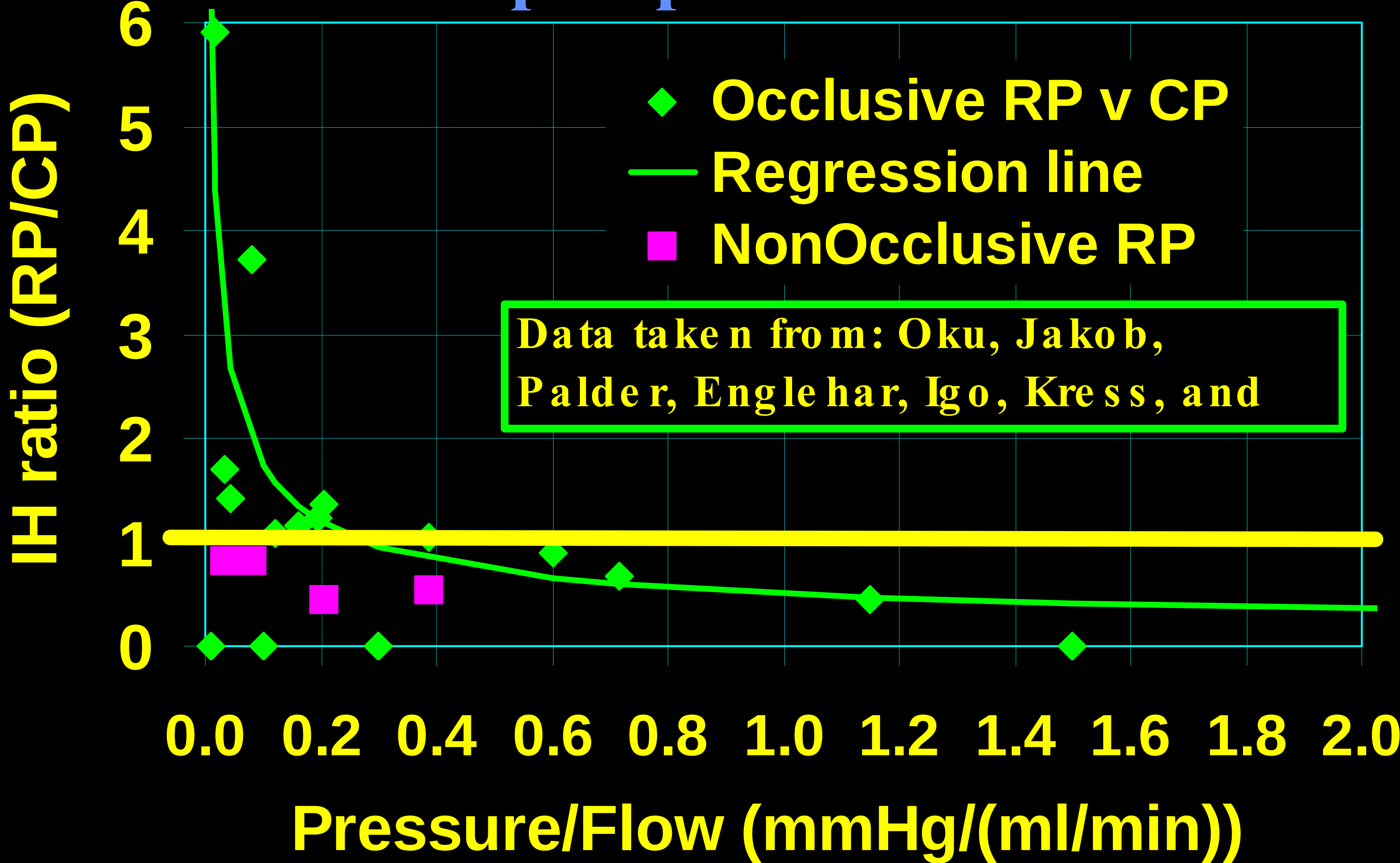
RPM = *f* (pressure)
Exposure time = *f* (1/Flow)

Shear x Time ≅ Pressure x (1/Flow)

The effects of pressure and flow on hemolysis caused by Bio-Medicus centrifugal pumps and roller pumps. Guidelines for choosing a blood pump.

Tamari Y, Lee-Sensiba K, Leonard EF, Parnell V, Tortolani AJ. J Thorac Cardiovasc Surg. 1993 Dec;106(6):997-1007.

Guidelines for choosing a blood pump: RP v. CP



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Guidelines for choosing a blood pump: RP v. CP

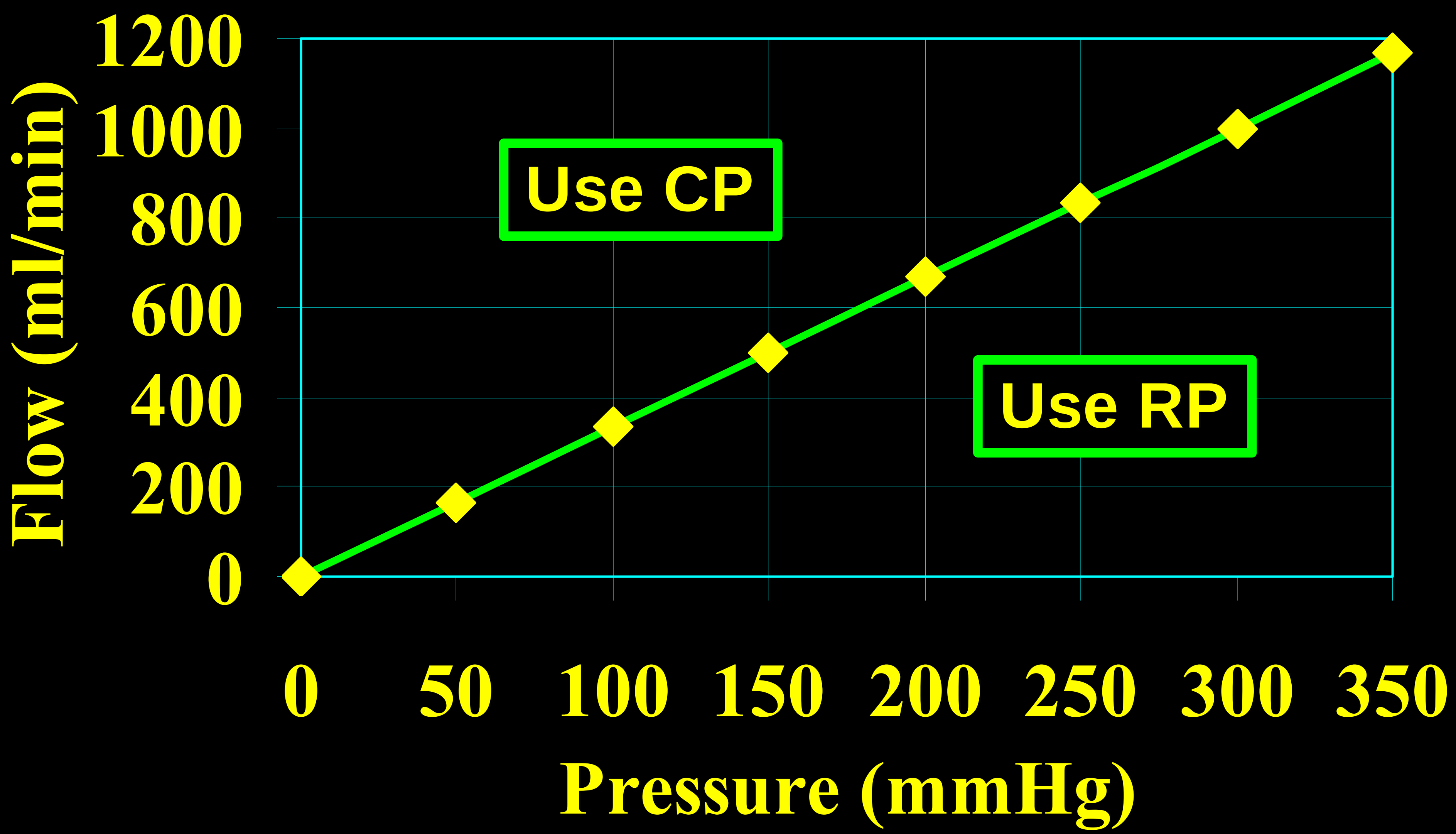
Hemolysis for the Biopump is higher than that of the roller pump when the ratio of the pressure divided by the flow is less than 0.35

When:

$$\text{Pressure(mmHg)}/\text{Flow(ml/min)} > 0.35$$

use the roller pump.

Hemolysis – Choosing between RP and CP



Hemolysis – Choosing between RP and CP

It is important to note that in later studies, when the RP was set nonocclusively, the RP was always less hemolytic than the CP*.

*A dynamic method for setting roller pumps nonocclusively reduces hemolysis and predicts retrograde flow.

Tamari Y, Lee-Sensiba K, Leonard EF, Tortolani AJ. ASAIO J. 1997 Jan-Feb;43(1):39-52.

Questions?

Information@cirtec.com