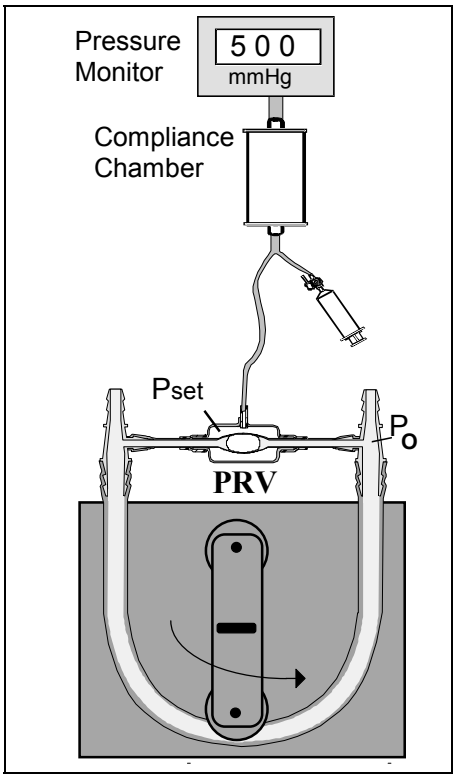
The Better-Header™

Model # PRV14

Catalog Number: BH12 and BH12S with 1/2" ID pump tubing
BH38 with 3/8" ID pump tubing
BH14 with 1/4" ID pump tubing



Description:

The Better-Header™ is a disposable safety device for the roller pump that automatically limits the pressure at the outlet of the pump to a user settable value and provides a simple, improved means to set the occlusion of the roller pump. It consists of a Pressure Relief Valve (PRV) connected across a header of standard pump tubing, see Figure 1. The PRV is made from a tubing with a thin wall section that responds to pressure differences across its wall much like a Starling valve. The thin wall section of tubing is sealed in a housing, which is pressurized to a prescribed pressure (Pset) via a compliance chamber assembly. As long as the line pressure at the pump outlet (P_O) remains below Pset in the housing, the PRV is closed. If P_O approaches Pset, the PRV starts to open, and over pressurization is prevented by diverting blood from the high pressure side of the circuit (i.e., pump outlet) to the low pressure side (i.e., pump inlet).

Indications for Use:

The Better-Header™ is intended for use in the extracorporeal circuit to limit the pressure at the outlet of the arterial roller pump and to set roller pump occlusion.

Contraindications:

The Better-Header™ is designed and sold for use only as indicated.

Precautions:

Read and follow all instructions and descriptive literature carefully and be familiar with the operation of this device before using it clinically.

It is the responsibility of the surgical-pump team to ascertain the suitability of this device relative to the pump, circuit components, and pumping conditions used.

Single-use only. Do not reuse or resterilize. Contents are sterile and non-pyrogenic only if package is not open or damaged. Use aseptic techniques during setup and connection procedures. Store in a cool, dry place.

This device is not recommended beyond 6 hours of use.

If it is desired to effectively remove the PRV from the circuit, clamp the tubing of the PRV at its inlet (outlet side of pump).

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

Warnings:

Secure all connections with nylon ties before use. Tubing should be attached in such a manner as to prevent kinks or restrictions that may alter blood flow.

Avoid direct contact of Better-Header™ components with all halogenated hydrocarbon-based anesthetic agents which attack plastics.

Position the Better-Header™ in the pump head such that the unpainted side of the PRV is facing the user to facilitate observation of blood flow through the valve, see Instructions for Use.

The approximate normal operating pressure in the arterial line should be known before using the Better-Header™ so that an appropriate pressure can be set in the PRV housing, see Instructions for Use. Lower line pressures can be obtained by using a lower resistance arterial cannula.

Pressurization of the PRV housing without the use of a compliance chamber results in significantly higher maximum line pressures.

Changes in ambient temperature may cause changes in the housing set pressure. Monitor the set pressure display periodically and adjust the set pressure as necessary (after verifying that there is no high pressure condition or leak in the housing and compliance chamber assembly).

The PRV should remain closed during normal operation. If blood flow is observed through the valve, a temporary source of high pressure is not identified, and the user wishes to operate at a higher pressure, increase the set pressure in the PRV housing until the valve is closed. Do not exceed a housing pressure of 500 mmHg.

The PRV prevents over pressurization in the extracorporeal circuit due to inadvertent clamping or occlusion of the arterial line. If this occurs, reduce pump speed until the valve closes and then correct the cause of the high pressure. **An open PRV should not be used as a substitute for corrective action; repeated or continuous recirculation of blood through the valve is not recommended**. Additional hemolysis will occur if high flows are directed through the valve for extended times.

Using the Better-Header™ to set pump occlusion results in a nonocclusive setting. It is recommended that the user evaluate various nonocclusive settings to determine the optimum setting for a particular application and its effect on pump flow. If a flow meter is not used, increase pump speed appropriately to correct for the expected retrograde flow, see Instructions for Use.

Device Specifications

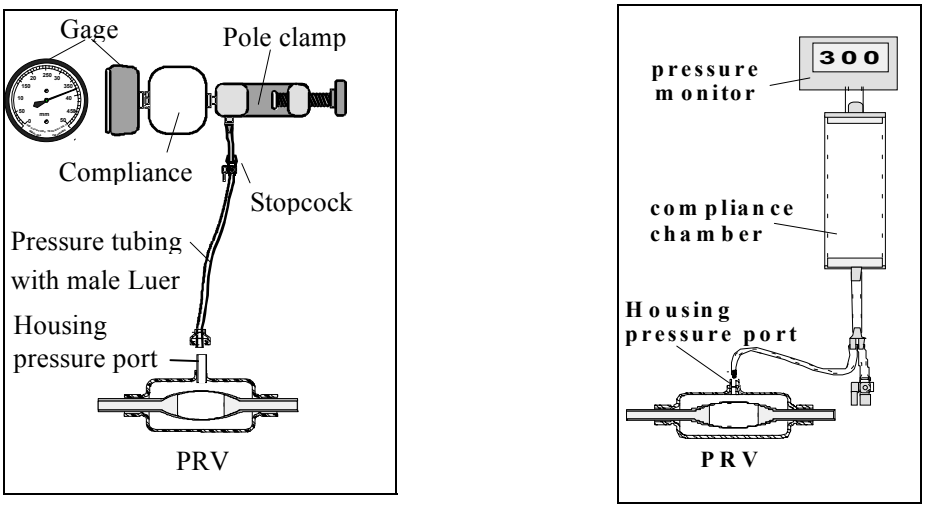
The Better-Header™ incorporates a section of standard pump tubing fitted with a three-way polycarbonate connector at each end. The Pressure Relief Valve (PRV) is connected across the header tubing via the side branches of the connectors. The PRV is made from a unitary length of medical grade polyvinyl chloride tubing having a thin walled, flattened midsection sealed within a clear housing made of PETG. The external wall of one side of the thin section of the PRV is painted white to facilitate viewing of the open or closed state of the valve. The pressure at which the valve opens is set by pressurizing the compliance chamber, part CCT or CCG, see Figure 2. The CCG includes a mechanical pressure gauge without alarms. The CCT is for use with a pressure transducer connected to a monitor with a high (and low) pressure alarm.

Pressure Relief Valve (PRV)	
Model	PRV14
Tubing ID, wall	1/4", 1/16"
Maximum housing set pressure, Pset	500 mmHg
Nominal maximum P_O^+ @ 6 L/min	Pset + 200 mmHg
Maximum flow*	6 L/min
Nominal Leakage rate @ Pset - P_O = 100 mmHg @ Pset - P_O = 50 mmHg	 50 ml/min 100 ml/min

^+P_O - Pump outlet pressure.
* Higher flows can be used if higher maximum P_O is acceptable.

Compliance Chamber		
Model	CCG	CCT
Gauge included	yes	no
Pressure range	0-500 mmHg	as per monitor used
Error	±3%	as per monitor used
Nominal volume	120 ml	70 ml

Blood Pathway Materials:
Header tubing: polyvinyl chloride
Valve tubing: polyvinyl chloride
Connectors: polycarbonate



a. CCG b. CCT

Figure 2. Compliance Chamber Assembly for Setting PRV Housing Pressure. a) Compliance Chamber with Pressure Gauge (model CCG) and b) Compliance Chamber connected to commercial pressure monitor (model CCT).

Instructions for Use

Setup

1) Examine all materials in package. The Better-Header™ is sterile if its package is not opened or damaged.
2) Place the Better-Header™ in the pump raceway. Ensure that the white side of the PRV faces away from the user so flow visualization through the valve is possible at all times. Refer to Figure 3 illustrating the Better-Header™ in a typical arterial pump circuit.
3) Connect the venous and arterial tubing lines to the Better-Header™ connectors. The PRV is bi-directional and therefore the pump may be rotated either clockwise or counterclockwise. Secure all connections with nylon ties or other appropriate method.
4) Prime the circuit according to usual practice, ensuring that all air is removed from the blood path of the PRV. This can be achieved by tilting the PRV downward slightly to allow the air to float to either side of the valve and be purged through the system.

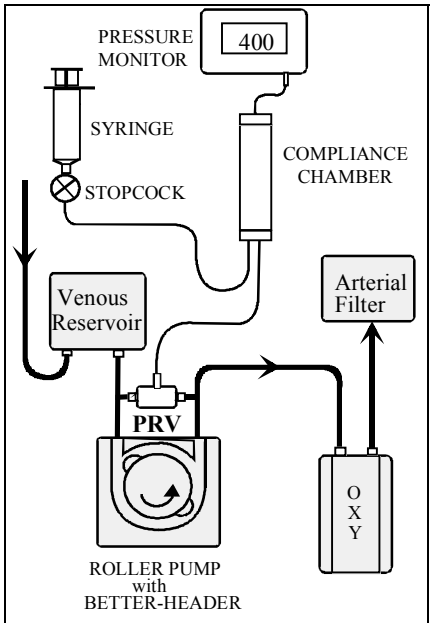


Figure 3. The Better-Header™ in a typical arterial pump circuit.

Establishing PRV Housing Set Pressure (Maximum Line Pressure)

Warning: Pressurization of the PRV without the use of a compliance chamber results in significantly higher maximum pump outlet pressures and should be avoided.

Caution: To assure that the set pressure in the housing is maintained, all connections described below must be made air tight.

5) If using Compliance Chamber model CCT, connect it to the pressure transducer/monitor being used, see Figure 2. With either model compliance chamber, attach apparatus to a pole on the roller pump console.
6) Connect the pressure line of the Compliance Chamber to the housing pressure port of the PRV, see Figure 2.
7) Attach a syringe to the stopcock of the Compliance Chamber and use it to pressurize the chamber to the desired housing set pressure. The PRV housing pressure should be set to 100 mmHg above the maximum desired operating pressure in the arterial line. Exceeding a housing set pressure of 500 mmHg is not recommended. See Figure 4 for nominal maximum line pressure at different pump flows for different set pressures.
8) Observe the pressure indicator to assure its reading does not drift downward, an indication of an air leak in the compliance chamber apparatus. A slight decrease in pressure initially may occur due to expansion of the components. If the pressure continues to drift downward, a leak is indicated. Ensure all gas connections are tight. If a leak is still indicated, disconnect the compliance chamber from the PRV and pressurize the PRV directly. If there is pressure loss, then replace the compliance chamber. If there is no pressure loss, then one of the housing seals on the PRV may be leaking. Either replace the Better-Header or clamp the PRV tubing (on the pump outlet side) to remove it from the circuit.

Caution: If the PRV is clamped out of the circuit, pump outlet pressure should be monitored/limited by other means.

Operation

The normal operating condition of the PRV is closed, with the housing pressure set by the user (Pset) greater than the line pressure at the outlet of the pump (Pset - $P_o \approx 100$ mmHg) and minimal flow through the valve (less than 50 ml/min).

Conditions that cause the PRV to open and must be corrected include:

1) Extreme high pressure condition caused by inadvertent clamping or occlusion of the arterial line. Although the PRV will prevent rupture of circuit tubing and components, reduce pump speed until the valve is closed, and then correct the cause of the high pressure.
2) Loss of housing pressurization as indicated by the pressure gauge/transducer. Clamp the PRV tubing on the pump outlet side to maintain flow to the patient, then repressurize the housing through the compliance chamber. If pressurization is maintained, remove the clamp. Otherwise, maintain the PRV clamped out of the circuit.

Caution: If the PRV is clamped out of the circuit, pump outlet pressure should be monitored/limited by another means.

Setting Rollers Nonocclusively

If desired, the PRV can be used to set roller pump occlusion by the Dynamic Method [1]. This method permits consistent, nonocclusive settings which have been shown to reduce hemolysis [2-4]. Although the Dynamic Method achieves greater degrees of nonocclusiveness than that currently recommended by the pump manufacturers, the retrograde flow is predictable and can be corrected with a slight increase in pump speed [1]. Occlusion setting by the Dynamic Method can be accomplished after priming the Better-Header™, at any time before the patient goes on bypass.

Caution: It is recommended that the user evaluate various nonocclusive settings obtained using the Dynamic Method (e.g., 8 RPM at Pset=500 mmHg) to determine the optimum setting for a particular application. Less occlusive settings allow greater retrograde flow that should be corrected for as described below.

1) Prime the circuit and pressurize the PRV housing to a set pressure of 100 mmHg above normal operating line pressure.
2) If possible, obtain 10 cc of patient blood and pump through circuit. The red color enhances visibility of flow through the valve.
3) Clamp the arterial line distal to the PRV.
4) Set the pump to a slow speed (e.g., 8 RPM).
5) Observe the flow through the PRV over several complete revolutions of the rollers. Ideally, the valve should just start to open for each roller. In addition to flow visualization, the open state of the valve is also indicated by an increase in housing set pressure (fluctuation of the pressure gauge needle if compliance chamber CCG is used, or a slight increase in the readout of a digital pressure monitor, see Audible Alarms to Signal an Open PRV under Additional Safety Measures below).

a) If the valve does not open, the pump is generating insufficient pressure to open the valve at the chosen settings and therefore is too nonocclusive. Stop the pump, if necessary, increase the occlusion, restart the pump, and repeat until proper occlusion is reached.

b) If the valve remains open longer than it is closed, the pump is generating excess pressure at the chosen setting and therefore is over-occluded. Stop the pump, decrease the occlusion, and restart the pump; repeat until proper occlusion is reached.

Note: It is not uncommon for the two rollers to be unevenly aligned. If this is the case, set occlusion by observing the PRV just opening when the more occlusive roller is compressing the tubing. Then slowly increase pump speed until the PRV just opens when the "less" occlusive roller compresses the tubing. To correct for retrograde flow, average the two pump speeds, see 7 below.

6) Remove the clamp from the arterial line.
7) Retrograde flow due to this nonocclusive setting can be corrected by increasing pump speed by the speed used to set occlusion (e.g. 8 RPM, or the average for the two rollers).

Caution: It is recommended that a flow meter be used with very nonocclusive settings at least until the user is familiar with the settings or has verified that flow at the expected operating pressure can be corrected as described. As with any pump, mixed venous saturation should be taken to assure that pump flow meets the patient's metabolic requirements.

Pressure-flow characteristics

Typical pressure-flow characteristics of the PRV for three housing set pressures (Pset) are shown in Figure 4. Even at maximum flow and a completely occluded arterial line, line pressure at the outlet of the pump is limited to 200 mmHg above the housing set pressure. To limit shunting through the PRV, the housing pressure should nominally be set to 100 mmHg above the maximum operating pressure desired in the arterial line. For example, if the user wishes to limit operating pressure to 400 mmHg, the housing pressure should be set to 500 mmHg.

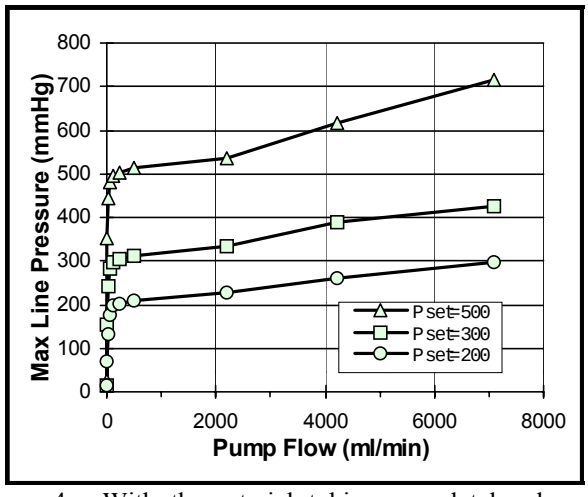


Figure 4. With the arterial tubing completely clamped, typical maximum line pressure at different pump flows and set pressures when using the Better-Header™.

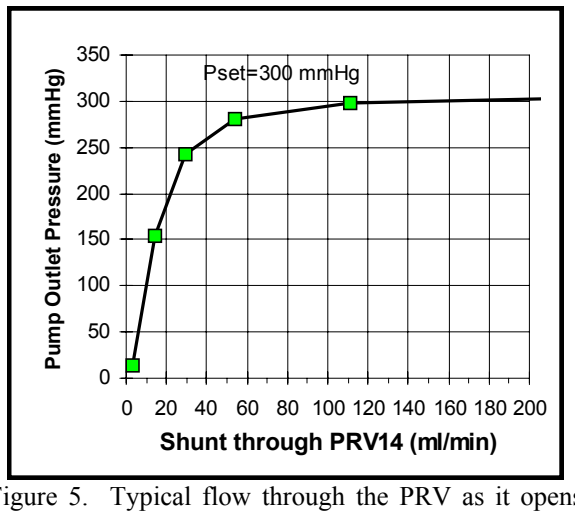


Figure 5. Typical flow through the PRV as it opens (at Pset = 300mmHg).

Under normal operation, the PRV remains closed (see Flow and Pressure Indication below). If the line pressure approaches the set pressure in the housing, the valve begins to open and some of the pumped fluid is diverted through the valve to the pump inlet as shown in Figure 5. Shunt flow through the PRV is less than 50 ml/min when the arterial line pressure approaches 100 mmHg of the set pressure.

Flow and pressure indication

Flow indication through the PRV is illustrated in Figure 6. A closed valve, shown in the leftmost diagram, is indicated by visualization of the entire white painted section of the valve (because the walls of the thinned section of tubing are compressed against each other by the housing pressure).

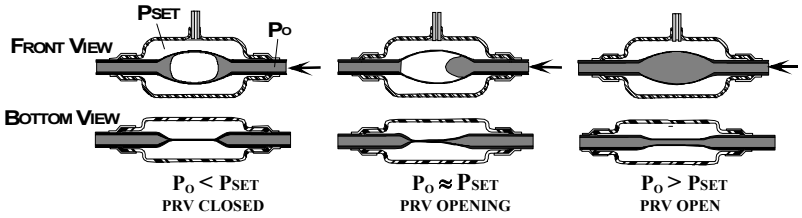


Figure 6. Flow indication through the PRV.

The appearance of blood pulsing across the valve (see middle diagram) indicates that the pressure in the arterial line is approaching the housing set pressure. As long as a portion of the valve remains closed (white is visible), leakage through the valve is minimal. Blood flow across the entire valve, even if intermittent, signifies an open valve. The degree of blood flow through the valve is indicated by the length of time blood travels across it: the longer it persists per pump cycle, the greater the blood flow through the valve and the closer the arterial line pressure to the housing set pressure. The rightmost diagram in Figure 6 illustrates the appearance of a fully open valve, which would occur if the arterial line was inadvertently clamped.

Caution: If the line pressure approaches the housing set pressure, the valve will open and allow some of the pump flow to recirculate through the valve. This is not a normal operating condition in as much as the valve should remain closed. Reduce the flow until the cause for the higher pressure is identified (e.g., a kink in the arterial line) and corrected. If operation at a higher line pressure is acceptable, the PRV set pressure may be increased until the valve closes. If flow through the PRV continues at a set pressure of 500 mmHg, clamp the PRV tubing to remove it from the circuit. Do not use the PRV if normal operating line pressures are greater than 400 mmHg. A lower resistance arterial cannula should be used to reduce the line pressure.

Caution: Temperature Changes

Changes in ambient temperature may cause changes in the housing set pressure of the PRV. The set pressure should be monitored intermittently. If the pressure is elevated from its initial setting but the valve is not open (i.e., there is no high pressure condition in the circuit), clamp the inlet of the PRV, **REMOVE** a small volume of air from the compliance chamber to restore Pset to its original desired value, and then remove the clamp. Similarly, if Pset decreases, clamp the inlet of the PRV, **ADD** volume to the compliance chamber to restore the desired Pset, and then remove the clamp.

Caution: Pulsatile Flow Conditions

Pulsatile flow with roller pumps results in significant peak line pressures. If the PRV is to be used with the roller pump in pulsatile flow mode, the user is urged to verify that the peak pressure is lower than the maximum operating pressure of the PRV. If the housing pressure is set to the maximum of 500 mmHg and flow is observed through the PRV (see Instructions for Use), clamp the PRV tubing at the outlet side of the pump to effectively remove it from the circuit.

Additional Safety Measures

Audible Alarms to Signal an Open PRV

A pressure monitor with user-settable low and/or high pressure limits and alarm capabilities could be used in conjunction with the compliance chamber to signal the open state of the valve. This alarm would be in addition to the visual indication provided by flow through the valve.

The low pressure alarm could be used with any model compliance chamber to alarm if Pset drops below an acceptable level, which could cause the PRV to open prematurely. A drop in Pset may occur due to poor connection between the PRV and compliance chamber, resulting in loss of pressure, or by a decrease in ambient temperature.

The high pressure alarm in combination with smaller volume compliance chamber model CCT would alert the user when the valve opens. The system should be calibrated each time it is set up as follows:

1. Connect the pressure monitor to the compliance chamber.
2. Prime the circuit and stop the pump.
3. Clamp the tubing at the pump outlet.
4. Establish set pressure (e.g., Pset= 500 mmHg).
5. Run pump at RPM corresponding to the desired minimum detectable flow through the valve (Qmin, e.g., 8 RPM).

6. Notice increase in indicated Pset (e.g. Pset = 410 mmHg). Record the change in pressure (e.g. 10 mmHg).
7. Set high pressure alarm limit to this value (e.g. alarm = 510 mmHg).
8. Remove clamp (Pset should return to initial value, e.g., 500 mmHg).
9. To test the alarm system, clamp tubing at pump outlet again and run pump at a flow greater than Qmin. The Pset reading should increase and trigger the high pressure alarm. Remove clamp (Pset should drop back to initial value, e.g., 500 mmHg).

With this setup, if the flow through the PRV exceeds Qmin, the high pressure alarm would alert the user.

Caution: Temperature Changes
The set pressure should be monitored intermittently. As noted above, changes in ambient temperature may cause changes in the housing set pressure of the PRV, possibly resulting in a false alarm. If the set pressure increases above the initial setting, increase the alarm level above the new set pressure by the change in pressure noted during calibration (see step # 6 above). The original set pressure (step # 4) can be obtained by adjusting the volume in the compliance chamber: add volume to increase pressure and remove volume to decrease pressure.

Pump Shut-Off System
An additional measure of safety can be provided by using the pressure shut-off feature available with some pumps in conjunction with the PRV.

References

1. Lee-Sensiba KJ, Tortolani AJ, King RS, and Tamari Y: A New Method for Setting Roller Pump Occlusion Lowers Hemolysis, AmSECT Proceedings, 1995.
2. Rawn DJ, Yoda DN, Harris DK, Blakwell MM, and Riley JB: An Under Occluded Roller Pump is Less Hemolytic than Centrifugal Pump, Abst. AmSECT Proceedings, 1995.
3. Noon GP, Kane EL, Feldman L, Peterson JA, and DeBakey ME: Reduction of blood trauma in roller pumps for long term perfusion. World J. Surg 9(1):65-71, 1985.
4. Bernstein EF, Blackshear PL, Keller KH: Factors Influencing Erythrocyte Destruction in Artificial Organs. Am J of Surgery, 114:126-138, 1967.

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 US Patents 5,186,431 and 5,249,483 and 5,814,004