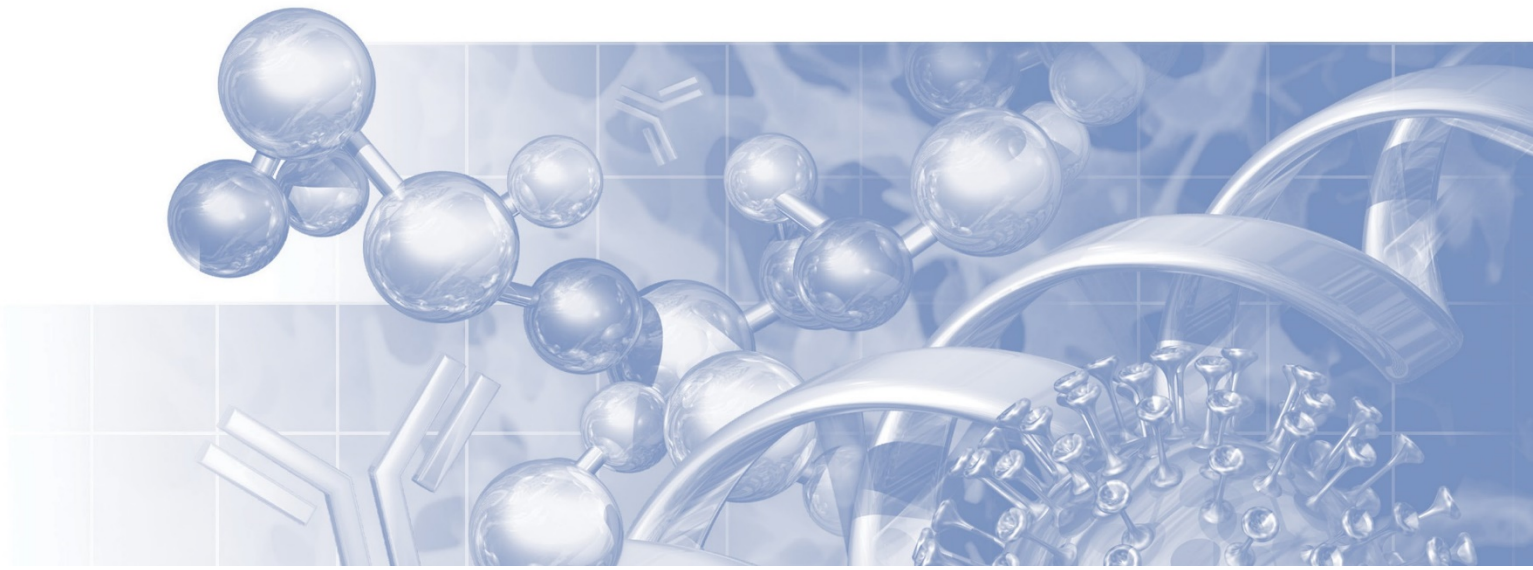
PALL Biotech

Instructions for Use

USD3328

ARTeSYN♦ BioSolutions

Pinch Valve and Diaphragm Replacement Valve



*Filtration. Separation. Solution.*SM

Table of Contents

1. Warnings, Cautions, and Notes

Warning, caution and note statements appear throughout this manual. Attention must be paid to the statements that follow as they are for the safety of the persons operating or working on the equipment to prevent any unnecessary damage being caused.

WARNING

A warning statement identifies a procedural step that, if not followed correctly, will result in injury, loss of life or destruction of equipment.

CAUTION

A caution statement identifies a procedural step that, if not followed correctly, will result in damage of equipment.

NOTE

A notice statement highlights information, procedure that required special emphasis or may be particularly helpful to the reader.

2. Safety

2.1. General Safety Notices

The following general safety warnings apply to the ARTeSYN pinch valve (PV) and the diaphragm replacement valve (DRV).

WARNING

It is extremely important that all personnel operating the PV or DRV read and understand this manual before operating the equipment

WARNING

Modifications to the PV or DRV which have not been approved by ARTeSYN Biosolutions will invalidate the warranty. Furthermore, ARTeSYN BioSolutions cannot accept responsibility for accidents caused by modifications

WARNING

The PV or DRV may only be operated by competent personnel who have been trained to work in the appropriate environment, who are familiar with the equipment and have read and understood the operator/instruction manual.

WARNING

The PV or DRV is only intended to handle group 2 'non-hazardous' fluids as described in the pressure equipment directive

WARNING

Appropriate measures must be applied in the pneumatic system to ensure that default closed actuated PV or DRV do not operate when the valve body is opened.

2.2. Personal Protective Equipment

Personal protective equipment (PPE) is not required for operation or maintenance of the PV or DRV. They are, however, likely to be used in controlled areas where PPE will be required. Always consult the site 'Safe Operating Procedures Manual' or 'Safety Statement' for information on required PPE.

WARNING

Failure to comply with PPE requirements may expose operators and maintenance staff to various hazards

WARNING

The PV or DRV can significantly heat up/cool down during normal operation due to the substances in the pipework/tubing. Apply appropriate safety measures if processing high/low temperature substances

2.3. Danger Zone

A ‘danger zone’ is a section/area (zone) of the product where an operator may be exposed to hazards. The danger zone for the PV and DRV is considered to be the area inside the valve body, when the valve body is shut.

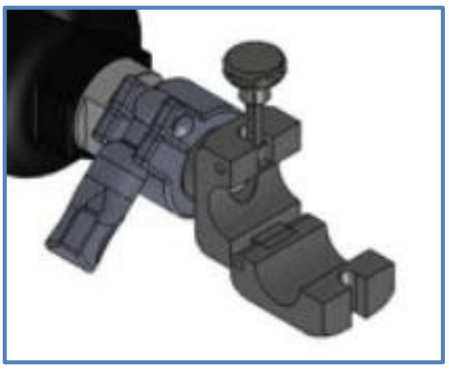


Figure 1: PV valve body during set up
No crush hazard is present when the valve body is open

Figure 2: PV valve body in normal use
Access to crush hazard prevented by pipe, acts as a guard

Figure 3: PV valve body opened (without pipe in place)
Exposed danger zone – finger crush hazard

Operators must be informed of the danger zone and instructed not to place figures in the danger zone under any circumstances during operation of the PV or DRV. An explanation of the danger zone, along with accompanying warning notice, should be added to the user manual.

	WARNING	
	During operation of the PV or DRV, no personnel should be, or have any body part, within the applicable danger zone. While operating the equipment, the operator must remain alert looking out for any possible dangers.	

3. Valve Labelling and Packaging Information

ARTeSYN Pinch Valve (PV) and Diaphragm Replacement Valve (DRV) are laser marked with the following information:

- ARTeSYN logo
- Part number
- Lot number
- Patent number

Figure 4: Shows labelling and packaging of each valve

Each valve will be individually bagged and placed into a cardboard box. Every bag and box will be labelled with the following information:

- ARTeSYN logo
- Part number
- Product description
- Drawing and revision number
- Lot number
- Quantity

	NOTE
	EC Declaration of Conformity will be issued for the Pneumatically Actuated Pinch valves. Refer to Section 10.0 EC Declaration of Conformity

The DRV requires a specific ARTeSYN consumable called the liner. Silicone liners should be ordered separately per product brochure instructions.

Liners are supplied in packs of 10. Each of the liners will be individually double bagged. Each of these double bagged liners will be grouped together in a large over bag.

Labelling is on the primary bag, tertiary bag and the cardboard box. The liner label information is as follows:

- ARTeSYN logo
- Part number
- Product description
- Drawing and revision number
- Lot number
- Quantity

Figure 5: Shows labelling on bag (left) and box (right)

	NOTE
	A Certificate of Conformity will be issued with the liners.

4. Introduction and Technical Description

4.1. Introduction

The ARTeSYN PV and DRV are available in both manual and pneumatic actuation versions. Both the PV and DRV are used to stop/start the flow of fluids or gas. The PV is suited to pinch flexible extruded tubing while the DRV is suited to pinch a specifically designed liner contained within the valve body.

The PV and DRV have been designed for use in the pharmaceutical, biotechnical, food and food product industries with non-dangerous substances/processes.

The primary components of a pneumatic PV and DRV are:

- Pneumatic actuator (cylinder) complete with plunger rod and head
- Valve body
- Assembly clamp – coupling, pneumatic actuator to valve body

The below diagrams show all parts in more detail.

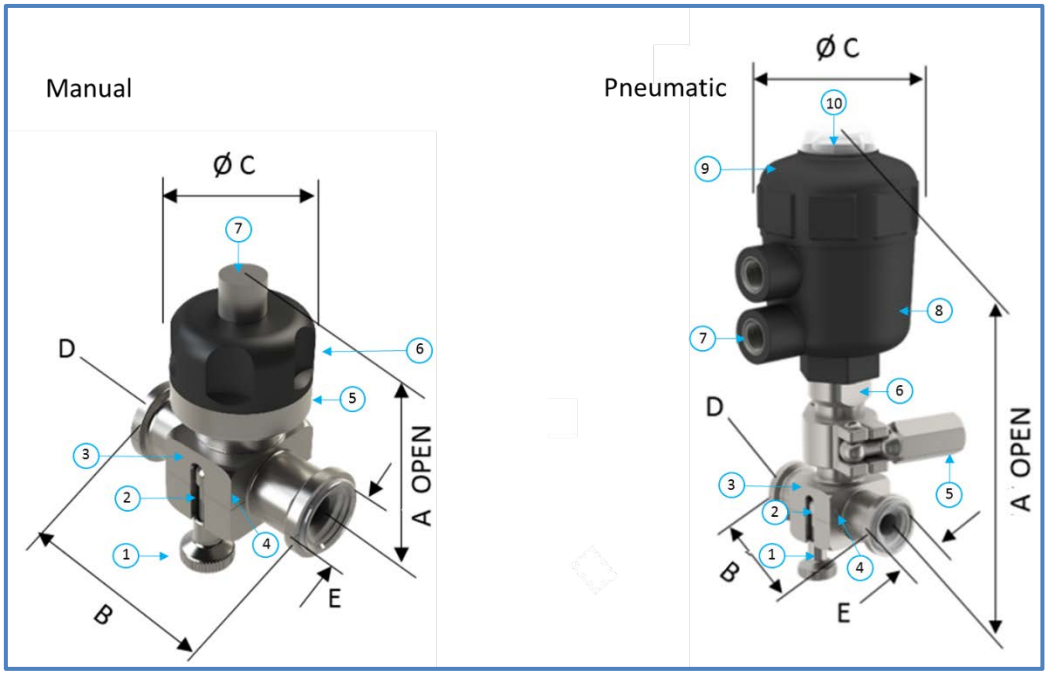


Figure 6: DRV diagram:

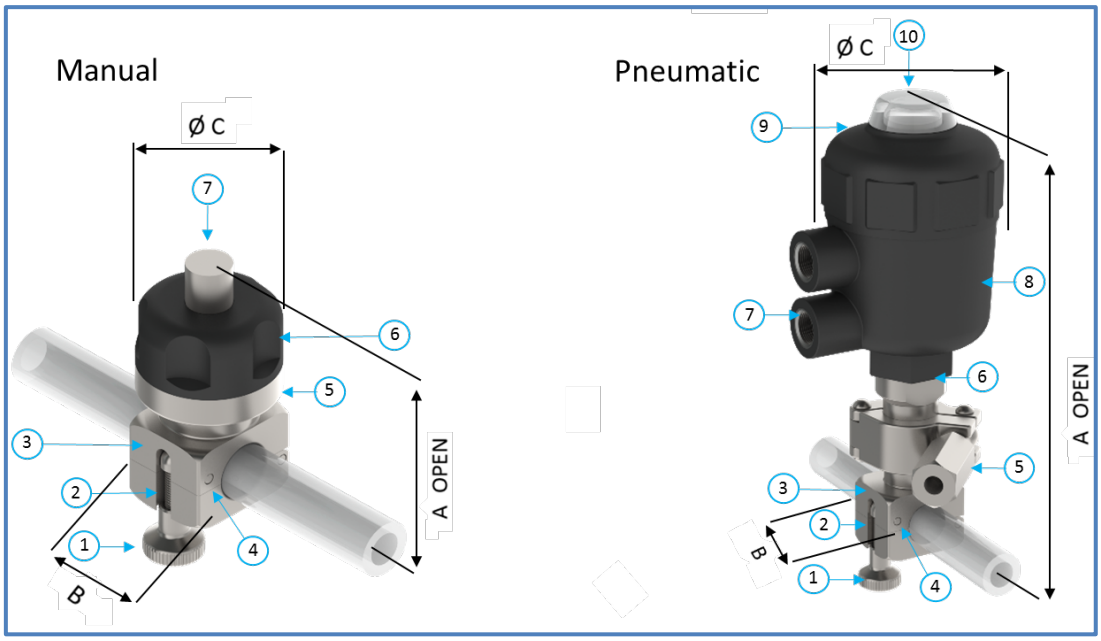


Figure 7: PV diagram:

	Manual valve	Pneumatic valve
Item No°	**Description**	**Description**
1	Lock knob	Lock knob
2	Swing arm	Swing arm
3	Valve body	Valve body
4	Body pins	Body pins
5	Lower handle	Assembly clamp
6	Handle	Actuator body
7	Stem	Air ports (6.3 mm [¼ in.] BSP)
8		Actuator housing
9		Actuator cap
10		Indicator lens

The operation of both manual and pneumatic PV and DRV valves is tool free, no tools should be used when operating the product.

The standard ARTeSYN pneumatic PV and DRV valves are available as normally closed (NC) by default. This means the valve will be in a closed state when no pressurized air is applied onto the lower air port. This is visualized on the below picture:

Figure 8 - Overview of PV & cut-away illustration of an NC unit

Both the PV and DRV have a stem or actuator attached to a separate valve body. When the actuator plunger is extended it seals the flexible tube or liner, respectively, into a 'U' shape against the bottom part of the valve body and in this is designed to close the tube or liner preventing the flow of process liquids or gases.

The PV and DRV products have single-use flow paths and the valves only act externally. As the valves do not contain product contact wetted parts with process liquids or gases, they do not require regular cleaning nor can they cause contamination to the process.

4.2. Intended Use of the Product

The PV can only be operated by technically competent personnel in a highly-controlled environment.

The PV is fully assembled when delivered: the end user removes PV from its packaging, inspects and installs with the dedicated valve support bracket. The mounting instructions for secure mounting are specified under section 6.3.

The actuator air ports must be connected to the pressurized air supply pipework. The air port thread for the PV & DRV pneumatic valves is specified under ection 7.3.

The operation sequence will vary depending on the application process control requirements.

4.2.1. Instructions for Operating Manual PV & DRV

Step 1: Rotate the handle anti-clockwise continuously while observing the stem moving out of the body orifice.

Step 2: Unscrew locking knob, rotate swing arm away from the lower body. Open hinged valve body and place matching tubing or liner into valve body for PV or DRV, respectively.

	WARNING
⚠	Only use the correct size tubing or liner for your particular PV or DRV. Tubing must be as compressible and flexible as silicone tubing.

Step 3: Close the valve body around the tubing or liner for PV or DRV, respectively.

	WARNING
⚠	When inserting tubing or liner into the PV or DRV, respectively, ensure that it is aligned correctly before shutting and locking down the valve body.

Step 4: Rotate swing arm into slotted recess of lower valve body and tighten the locking knob by hand until the body is securely clamped around the tubing or liner for PV or DRV, respectively.

	WARNING
⚠	DO NOT force the valve body locking knob beyond normal manual tightness by using either excessive manual force or tool assist. DAMAGE TO THE LOCKING MECHANISM WILL OCCUR.

Step 5: Cycle the manual valve 3 times between open and closed state. This allows the valve body, stem and tube or liner to achieve a good repeatable seal.

4.2.2. Instructions for Operating Normally Closed Pneumatic PV & DRV

Step 1: Air is connected to the port closest to valve body (normally closed port) which retracts the plunger.

Step 2: The valve body locking knob is loosened and the hinged pin is then swung out of the locking position. The hinged valve body is then opened.

Step 3: The tubing (PV) or liner (DRV) is placed into body curved seat.

	WARNING
	Only use the correct size tubing or liner for your PV or DRV. Tubing must be as compressible and flexible as silicone tubing.

	WARNING
	When inserting tubing or liner into the PV or DRV, respectively, ensure that it is aligned correctly before shutting and locking down the valve body.

Step 4: The valve body is then closed, the hinged retaining pin swung back into position and the knob tightened.

	WARNING
	DO NOT force the valve body locking knob beyond normal manual tightness by using either excessive manual force or tool assist. **This will result in damage to the locking mechanism.**

Step 5: The valve actuator is cycled 3 times to trapped tube allowing the valve body, plunger and tube to achieve a good repeatable seal.

5. Transport & Handling

This section of the manual describes best practices and provides relevant information for transport and handling operations.

5.1. Transport

The PV or DRV will be delivered to the customer packaged in a cardboard box fitted, with foam inserts to prevent damage during transport. The PV or DRV can be transported via a van, truck/trailer, hand carried or similar method of transport. It should be loaded and unloaded using a suitably rated tail-lift, set of ramps etc.

	NOTE
	For packaging information, refer to section 3

	WARNING
	The PV or DRV should always be handled with care!

5.2. Weight & Overall Dimensions

Depending on size and configuration of the PV, it can weigh up to 4 kg. The range would be 0.4kg to 4 kgs, from a 3.18 mm (⅛ in.) to 50.8 mm (2 in.) with actuator & positioner.

6. Installation & Set Up

The PV or DRV are designed to integrate into an existing pneumatic system. It is therefore imperative that this section is consulted when installing the PV to ensure it performs correctly when brought into service.

WARNING

The PV or DRV must only be installed by competent persons who are experienced in the assembly/installation of such machinery. Installers must be trained to work in a pharmaceutical, biotechnical, or food manufacturing environment. Installers must also read and understand the operator/instruction manual.

WARNING

Use caution when closing the valve body! Potential crushing hazard, keep hands and fingers clear from closing gaps!

WARNING

Not suitable for use in vacuum applications!

NOTE

The ARTeSYN BioSolutions valve is designed to be installed in any physical position possible. There are no operational limitations on the orientation of the valve.

WARNING

The PV or DRV are only intended to handle Group 2 ‘Non-Hazardous’ fluids as described in the Pressure Equipment Directive.

WARNING

The PV or DRV can be set to default closed position, consult Section 6.3 of this manual for information.

6.1. Spatial Requirements

When planning and executing the valve installation, allow for sufficient space around the valve so that when the valve body is opened to service the process tube, there is space for safe hand operation of valve components.

6.2. Mounting Requirements

For manual pinch valves, the valve body contains four mounting locations that can be used to secure the PV on the universal bracket for attachment to trolley frames or other surfaces.

The universal bracket has 2 slots through which the manual pinch valve body can be fastened. The 2 threads on the opposite side of the valve knob are to be used with suitable fasteners.

For the manual DRV, the valve should be connected through a sanitary clamp connection to rigid piping on both ends which will provide the desired support.

For pneumatic pinch and diaphragm replacement valves, a supportive bracket is required to ensure secure and simple processing for the operator. The recommendation is to have the pneumatic valve attached via the assembly clamp through usage of a sanitary clamp with a weldable rod end.

Figure 9: With actuator pointing downwards

Figure 10: With actuator pointing upwards

	NOTE
	Mounting the ARTeSYN pneumatic valve with actuator pointing downwards allows easier single-use tubing or liner exchange by the operator.

	WARNING
	Ensure that the ARTeSYN PV or DRV is securely mounted!

6.3. Connecting to the Pneumatic Supply (Pneumatic Valves Only)

The pneumatic actuator should be connected to a clean air supply connection. Recommended operating pressure for standard use is 6 bar (85-90 psig). Supply connections for standard configuration default to close is as shown below. Supply connection for customized default to open valves will be the reverse.

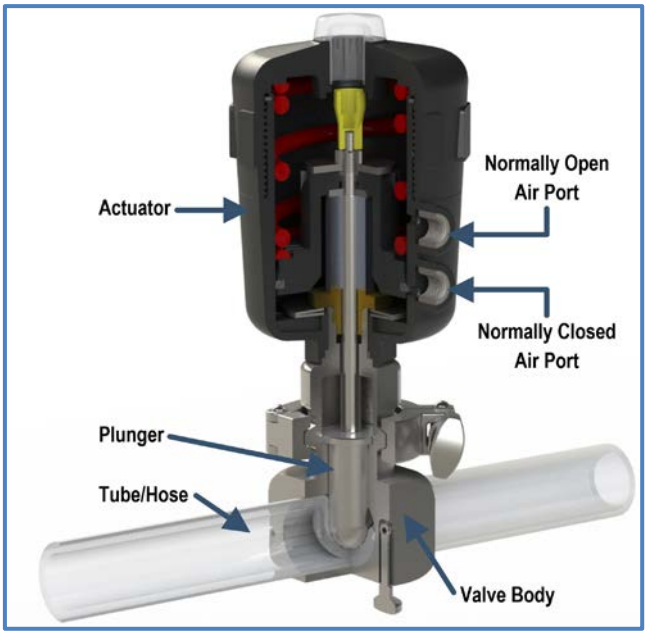


Figure 11: Connecting the PV to the pneumatic system

	NOTE
	For optimum operation, it is recommended that the PV or DRV has a constant pneumatic supply pressure of approximately 6 bar (85-90 psig).

	**WARNING** The top works are rated at 10 bar (150 psig) maximum pressure.
	**WARNING** The pneumatic circuit must be constructed to minimise the risk of un-expected operation of the PV or DRV. A dump valve or similar means of pressure release must also be fitted.
	**WARNING** For ARTeSYN DRV liners installed in its valve body, maximum operating pressure 4 barg. For ARTeSYN PV, maximum operating pressure dictated by tubing manufacturer data but don't exceed 10 bar (150 psig) operating pressure on the valve body.

	**WARNING** Ensure that the pneumatic power supply has been shut off and pressure dumped before connecting the PV or DRV into the system.

6.4. User Responsibilities

ARTeSYN BioSolutions have made every effort to fulfil their responsibilities as the manufacturer of the product by making the PV and DRV as safe and as easy to install and maintain, as possible. The customer (the person(s) in charge of the product) has a responsibility to ensure the following:

6.4.1. General

- Persons involved in the installation of the PV or DRV have read the Instructions for Use and understand all aspects of safety and operational procedures
- Persons involved in the installation have access to the Instruction for Use (or a copy of it) in their first/native language
- Ensure the brackets should be secured using suitable fasteners and positioned in a location which is easy for operators to access for maintenance
- Complete basic commissioning checklist once the PV or DRV is installed
- When installed, maintenance personnel working on the PV or DRV should hold an appropriate technical qualification (maintenance personnel must also read the PV Instruction for Use to understand all safety procedures, operational procedures and the correct maintenance procedures for the PV or DRV)
- The PV or DRV should not be in an area where it may be damaged by vehicular or pedestrian transport during normal operation

6.4.2. Pneumatics

- The pneumatic circuit must be constructed to minimize the risk of unexpected operation of the PV or DRV. Ensure that PVs or DRVs do not operate (open/close) when the valve body is opened
- A means of dumping pneumatic pressure should be provided
- The pneumatic system should not restart the PV automatically in the event of a power failure

6.5. Commissioning Checks

Before operating the PV or DRV, carry out the following general checks:

No.	Item	Check	Complete?
1.	Visual Appearance	• Check for damage upon delivery. • Check for missing, lose or damaged parts	
2.	Nuts and Bolts	• Check all parts are present and fitted correctly (clamp, valve body tube bushings etc.) • Check bolts and other fasteners are present and tightened correctly	
3.	General	• Ensure that the tube (PV) or liner (DRV) has been seated correctly inside the valve body • Ensure that the bonnet and valve body locking tri-clamp is tightened sufficiently.	
4.	Mounting	• Ensure that sufficient operating room has been provided (Consult section 6.1 of this manual) • Ensure that the unit is securly mounted	
5.	Pneumatic System	• Ensure a method of isolating pneumatic pressure to the PV. • Ensure that the correct pneumatic supply pressure is being delivered to the PV or DRV, see section 6.3 of this manual for details. • Ensure Pneumatic Pipework/Tubing has been neatly routed to the PV or DRV and is not creating a trip hazard to passers by. • Document the default actuator setting in Section 6.6 of the Instructions for Use	

6.6. Pneumatic Actuator Setting

Depending on specification the PV can be supplied by default normally closed or as a custom normally open valve.

- **Default to Close** (standard) – upon loss of pneumatic pressure the PV will fully close and stop flow of substance passing through PV
- **Default to Open** (custom) – upon loss of pneumatic pressure the PV will fully open continuing flow of substance passing through PV

Upon installation, the default setting applied should be recorded below for operators and maintenance staff to acknowledge. If any changes are made to the default, these changes must also be recorded.

Date	Setting (tick appropriate)	Completed by
/ /	☐ Default to Close ☐ Default to Open	
/ /	☐ Default to Close ☐ Default to Open	
/ /	☐ Default to Close ☐ Default to Open	

7. Normal Operation

WARNING

During operation of the PV or DRV, no personnel should be, or have any body part, within the applicable Danger Zone.

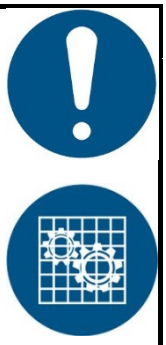
While operating the equipment, the operator must remain alert looking out for any possible dangers.

WARNING

Before operating the PV or the DRV, carry out a brief visual inspection. NEVER operate this unit if there is evidence of any of the following:

- Loose, worn, damaged or missing parts/guarding
- Faults in safety related components
- Damage to locking mechanism

If any of the above or other problems occur, take the unit out of service immediately. If further assistance is required contact your local dealer for further advice and guidance



WARNING

The PV or DRV can be set to default to normally open or closed, consult Section 6.3 of this manual for information

WARNING

Before operating the PV or DRV carry out the routine checks listed in Section 8.1. of this manual.

7.1. Pressure Ratings

The minimum operating pressure requirement of the pneumatic actuator is 6 bar (85-90 psig).

WARNING

The top works are rated at 10 bar (150 psig) maximum pressure.

WARNING

For ARTeSYN DRV liners installed in its valve body, maximum operating pressure 4 barg.

For ARTeSYN PV, maximum operating pressure dictated by tubing manufacturer data but don't exceed 10 bar (150 psig) operating pressure on the valve body.

7.2. Process Tube Pressure Ratings

Please consult tube supplier for tube pressure ratings. Do not exceed PV maximum pressure rating. See Section 7.1.

7.3. Fitting Tubing/Pipework

WARNING

Appropriate measures must be applied in the pneumatic system to ensure that default to close and default to open PV's or DRV's do not operate (open /close) when the valve body is opened.

Pinch valves are designed to work with single-use tubing with defined inner and outer diameter. DRV's are designed to work with specific ARTeSYN single-use liner. Using incorrect tubing or liner in PV or DRV, respectively, will likely cause the PV or DRV to malfunction (i.e. fail to seal the tube/pipe). Please refer to the product datasheet to identify matching tubing or liner for PV or DRV, respectively.

NOTE

Standard valves are designed and supplied to function correctly with a specifically sized tubing or liner. Consult the product brochure to find matching tubing or liner.

7.4. Sterilization

The PV must not be in-line sterilized with the tubing. For sterile applications, the tubing should be pre-sterilized by gamma irradiation or autoclave without the pinch valve. Please keep in mind that no autoclaving is needed for the pinch valve.

The liners can also be supplied pre-gamma irradiated. The DRV with installed unsterilized liner can be sterilized once attached to other process utilities through autoclavation or once by in-line steam sterilization post installation.

Steam used for steam sterilization must be saturated and free from condensation. Superheated steam must not be used. Steam and air pressure should be regulated carefully to avoid over pressurization that can damage equipment.

Adequate means for condensate drainage should be employed to ensure that any condensate that forms is removed from the system and not allowed to collect as it may impact steam flow efficiency resulting in unsuccessful sterilization or over pressurization.

In any case, heat sterilization must not exceed a single cycle of maximum 75 minutes at 130°C.

WARNING

Appropriate measures must be applied to ensure that during in line steaming of DRV's suitable protective measures are employed for operation safety.

NOTE

The ARTeSYN DRVs can be steam sterilized in line both in open or close position but only with the presence of a specific DRV liner.

NOTE

It is recommended to flush the process equipment including the DRV after steaming to remove any residues originating from the steam and/or to remove trace amounts of liner extractables remaining after sterilization.

WARNING

Conditions leading to steam collapse such as rapid cooling must be avoided. Application of compressed air or nitrogen can overcome this risk. This gas should be free of oil, water and particulates.

NOTE

Please note that the procedure and validation of sterilizing DRV's through heat sterilization is the responsibility of the user.

8. Maintenance Instructions

WARNING

Only competent personnel should undertake the installation and maintenance of the PV or DRV. All personnel must follow the safety procedures outlined in this manual

WARNING

Maintenance of the PV or DRV must only be carried out when;

- The pneumatic supply has been disconnected/isolated and locked-out
- Ensure that system pressure is been neutralized/++dumped

WARNING

The use of tools to secure the valve body locking mechanism is strictly forbidden, this may damage the unit

WARNING

The pneumatic actuator should only be factory serviced unless training and tooling have been provided by ARTeSYN BioSolutions

8.1 Pre-Operation Checks

Before commencing operation, the operator should carry out some basic pre-operation checks on the PV or DRV which are both essential to the performance of the overall equipment and the safety of the operator. A (non-exhaustive) list of pre-operation checks has been provided below;

Number	Item	Check
1.	Visual Appearance	• Check for signs of excessive wear and tear • Check for missing, lose or damaged parts
2.	Nuts and Bolts	• Check all parts are present and fitted correctly (clamp, valve body, tube, bushings etc.) • Check bolts and other fasteners are present and tightened correctly
3.	General	• Ensure that the tube/pipe has been seated correctly inside the valve body • Ensure that the bonnet and valve body locking tri-clamp is tightened sufficiently
4.	Mounting	• Ensure that sufficient operating room has been provided (consult section 6.1 of this manual) • Ensure that the unit is securly mounted
5.	Pneumatic System	• Ensure a method of isolating pneumatic pressure to the PV. • Ensure that the correct pneumatic supply pressure is being delivered to the PV, see section 6.3 of this manual for details. • Ensure Pneumatic Pipework/Tubing has been neatly routed to the PV and is not creating a trip hazard to passers by. • Document the default actuator setting in Section 6.6 of the Instruction for Use

8.2 Cleaning

There are no cleaning requirements associated with the PV or DRV for proper functioning other than normal process contact surface cleaning requirements as specified by the user. As the PV could be potentially used in different environments it is recommended the PV is cleaned in line with on-site practices.

CAUTION

The use of certain cleaning agents (specifically bleach) may damage the stainless steel surfaces if used incorrectly; always follow the guidelines provided with the cleaning agents and check their suitability for the PV!

CAUTION

The ARTeSYN PVs should not be autoclaved

The ARTeSYN DRVs should not be autoclaved without liner

8.3 Maintenance Checks

To be carried out by the equipment operator or maintenance technician. In addition to the checks and tasks outlined in section 8.1, the following checks and maintenance tasks should be carried out by a maintenance technician on the basis specified:

Period	Maintenance Checks Required:
Every 3 Months	• Inspect pins, nuts, bolts and washers for signs of damage or wear, replace if necessary.
Annually	• Inspect Valve Body locking knob, continued overtightening of the body locking knob could result in distortion of the swing arm.

8.4. Troubleshooting

Symptom(s)	Possible Cause(s)	Possible Solution(s)
Actuator fails to cycle	• Incorrect connection to appropriate pneumatic port • Insufficient pneumatic supply pressure • Broken return spring • Broken or faulty actuator O-ring seals	• Change pneumatic supply connection • Check pneumatic supply pressure • If actuator stem can be moved manually without an air supply, replace spring • Return to factory for spring and/or seal replacement
Valve does not seal process fluid	• Defective actuator (see above) • Incorrect tubing diameter or liner • Process tubing misaligned in valve • Process tubing not flexible • Valve locking handle not positioned or tightened properly	• Follow above solutions • Check tubing wall thickness against instruction manual • Check alignment of process tube to ensure that it is uniformly positioned in the valve body • Revise tubing material to ensure sufficient flexibility to pinch closed • Examine body locking handle for proper position and tightness

9. Declaration of Incorporation and of Compliance

Declaration of Incorporation

Machinery Directive 2006/42/EC

ARTeSYN Biosolutions. Declares that the full range of its products:

MANUAL & PNEUMATIC PINCH VALVES, "ARTeSYN" branded

are engineered and manufactured according to all Essential Health and Safety Requirements (EHSR), according to applicable titles and conditions, as specified by the EC Machinery Directive 2006/4S/EC Annex I.

Description: Manual and pneumatic pinch valves.

Use: To control the flow of fluids.

Types: PV, DRV.

Serial No.: Each valve bears an identification serial number.

Other applicable directives: (PED) 2014/68/EU

The technical documentation for the manual and pneumatic pinch valve products was written according to Appendix VII, Part B. The assembly instructions mandated by Appendix VI are available in at least one community language and the requisite technical documentation listed in Appendix VII Part B is held by ARTeSYN Biosolutions.

Signed: **February 7th, 2019**

Jun Opiana
Authorized Representative

Statement of Compliance

Sound Engineering Practice

The products listed below conform to the Pressure Equipment Directive (PED) 2014/68/EU Section 4, paragraph 3 and have been designed and manufactured in accordance with Sound Engineering Practice (SEP). According to section 4, paragraph 3 these products must not be identified by a CE-label.

Manual Pinch Valves
Pneumatic Pinch Valves
Manual Diaphragm Replacement Valves
Pneumatic Diaphragm Replacement Valves

It is the responsibility of the user to ensure that the product is installed and operated safely. Detailed product information including installation, operation and maintenance instructions can be obtained from www.artesynbiosolutions.com.

Note: By law, SEP products must not be marked with the CE symbol.

Signed: **February 7th, 2019**

Jun Opiana
Authorized Representative

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