

# FOR BCV-980 Bio-Pharmaceutical Proportional Pinch Control Valve

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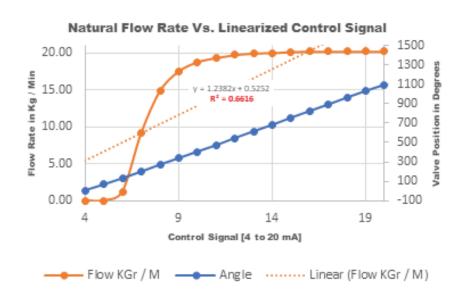
# **INTRODUCTION:**

The BCV-980 is an intelligent, Proportional Control Valve intended for BioPharmacutical applications. The BCV is an electrically operated Pinch Valve with built-in, sophisticated control capabilities. Electrically operated Pinch valves offer several advantages over other valve constructions. For BioPharama applications these advantages include:

- No added materials in contact with the media; only the tube-manifold contacts the media
- No crevasses, cracks, clogging or dead spots
- Unaffected by particulates in the stream
- Simple, robust & straight through design
- No Pneumatic complications or facilities required for operation
- Self-cleaning
- Tight shutoff
- Minimal turbulence & friction
- Minimal maintenance required. No bearings, seals or packings
- Low Total Cost of Ownership; other than the single use manifold there are no other consumables

Classic pinch valves provide minimal throttling control capabilities; most of the control occurs during the first 1/4 to 1/3 of the control range [Coefficient of Determination, i.e.: R2 values around 66%]. Malema utilizes a complex polynomial algorithm

expanding upon the classic performance of pinch valves. By linearizing valve performance [flow rate] Vs. control signal rather than linearizing valve position Vs. control signal. While using Malema's linearization scheme a slight change in control signal results in a similar [linear] change in flow rate [Coefficient of Determination, i.e.: R2 >95%]. This proprietary linearization scheme can be disabled from Malema's GUI.



Control Resolution: The BCV-980 utilizes a ten(10) pitch [i.e.: ten(10) threads per inch] Acme screw and an eight thousand (8,000) count per revolution optical encoder monitoring valve position. A sixteen(16) bit ADC converts the command setpoint signal into 65K steps between fully OPEN and fully CLOSED positions. Assuming one hundred LPM is the max flow through a 1" ID tube, individual step resolution is about 5 ccm or  $\approx$  0.5% of Full Scale.

Resolution varies with tube size. Smaller sized tubes may have fewer total steps available. Malema offers a high resolution version for these applications.



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# **INTRODUCTION (CONTINUED)**

The BVC-980 is an intelligent, proportional, pinch, control valve.

- 1. The BCV-980 Supports 1/8" through 1"I.D. tubing
- 2. The BCV-980 supports virtually any biopharma tube construction including:
  - a. Unreinforced tubing
  - b. Braid Reinforced tubing, or
  - c. Double Braid Reinforced tubing

#### **OPERATING MODES:**

The product has two(2) operating modes:

- **1. REMOTE Mode:** In this mode, the device responds to an external 4 to 20 mA signal generated by a remote operator or control system [i.e.: 4 mA = FULLY CLOSED; 20 mA = FULLY OPEN]. Valve position is software adjusted to approximately linearize flow rate Vs. signal [I.e.: 12 mA ~= 50% FLOW]
- **2. TFF Mode:** Based on an analog Setpoint signal, the device monitors up to three(3), external analog transducer signals, adjusting valve position based on the TFF Equation. On application, other algorithms can be supported. Confirm that you have the following items:

When panel mounted in a standard 1/4 DIN panel cut-out [88 mm X 88 mm], the BCV-980 provides IP65 (protection against water jets) *NOTE: Care must be taken in a panel layout as the flexible tube running through a BCV-980 may obscure adjacent panel cut-out locations.* The BCV-980 supports mounting in any orientation.

The BCV-980 accepts tubing of virtually any size between 0.125" ID through 1.000" ID. Factory pre-configuration for any size or tube configuration is available and recommended. One(1) finger guard is supplied with each BCV-980. Several finger guards are available depending on tube OD

# STORAGE AND HANDLING

# **Storage conditions**

Store the product under packed conditions in an anti-static bag. The storage place shall be free from moisture, mechanical shock and vibration. The ambient temperature shall be between 3°C and 60°C and the humidity between 5% and 80% R.H. without condensation

# **Unpacking and Product Inspection**

On delivery, check the product for damage. Confirm that the model code on the label matches the specification in the purchase order.



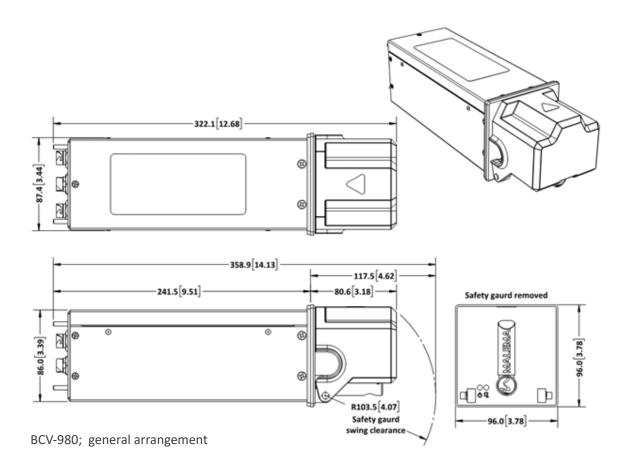
# **SAFETY CAUTIONS**



The BCV-980 is a Pinch Valve: use care keeping fingers, etc. out of the pinch mechanism! Severe & painful damage is possible.

# **DIMENSIONAL DRAWINGS: BCV-980**

**For Reference Only** 





# **Performance Specifications**

Fluid Temperature	4° – 60°C *
Ambient: Temperature/Humidity	0° – 40°C / 30% – 80% RH, non-condensing
Maximum Expected Operating Pressure	6 bar (g)
Differential Pressure range	0 - 6 bar

<sup>\*</sup> Consult the factory for higher temperature applications

# **Electrical Specifications**

Power Supply Input	24 Vdc 10%
Current Consumption	4 A max, 1A typical
Alarm Signals	Max 30 Vdc, 200 mA NPN open collector
Signal Out (Valve Position)	4 - 20 mA

<sup>\*</sup> Up to four external analog signals. Implements standalone TFF control

# **Material Specifications**

Wetted Parts	None
Non Wetted Parts, Enclosure	Non-magnetic 316L Stainless Steel, Non-magnetic Powder-coated Stainless Steel

# **Physical Specifications**

Mounting Orientation	Performance unaffected by mounting orientation
Fluid Connections	1/8" - 1" ID flexible tube, braided or un-braided
Ingress Rating	IP65
Panel Mounting	Universal thickness — accommodates any panel thickness
Panel Cutout	1/4 DIN (90mm x 90mm)
Mass	2.6 kg – 3.3 kg



# **GETTING STARTED**

Unpack and mount the BCV-980, using the included Silicon Sponge Gasket, through a standard ½ DIN panel cut-out [88mm X 88mm]. Panel or surface mounting is essential to achieve IP65 ingress protection. The BCV-980 is fully connectorized using shielded Hirose connectors. [Hirose connectors are readily available from Digikey, Farnell, Mouser, Newark, and others.] Fully assembled cables are available. Consult Malema factory for details

#### FINGER GUARD INSTALLATION:

The FINGER GUARD is packaged separately. Using provided 3/16" Allen wrench and provided PIN SCREWS, install the FINGER GUARD. Finger tight is adequate.

#### **FINGER GUARD INTERLOCK:**

The FINGER GUARD is magnetically interlocked with the BCV-980 crush mechanism. The DRAW BAR will not move until the FINGER GUARD is replaced. Various FINGER GUARDS are available depending on the tube size in use. Contact Malema for the FINGER GUARD(s) required for your applications.

#### **POWER, CONTROL & SIGNALING**

A male, twelve(12) pin, Hirose connector supports device power along with primary signaling. A twelve(12) core, three(3) meter long, connectorized cable with stripped ends is provided with each BCV-980.

The BCV-980 accepts up to four(4) external analog signals and provides two(2) discrete, OPEN Collector STATUS / ALARM Outputs [NPN, 30 VDC, <200 mA], one(1) discrete Input along with two(2) analog Output signals. One(1) of these analog outputs is proportional to valve position and provides CLOSED Loop feedback to a remote controller. The other analog output reports  $\mu$ P temperatures or alternatively, this output can be utilized to drive other components in your system [i.e.: Pump speed(?), consult Malema factory for details].

The device communicates over [Malema Addressable Sensor Network] MASN (RS-485 serial). Up to two hundred fifty(250) devices can be supported by a single RS-485 master controller. MASN supports viewing & setting of device configuration along with near real-time data logging on a customer supplied computer or laptop.

#### **GROUNDING**

The four(4) rear mounted 4 mm studs provide for a convenient GROUND or EARTHING connection. A thumb nut is provided for this essential electrical connection. Failure to properly GROUND the BCV-980 voids the warranty and CE Compliance.



# **EXTERNAL SENSORS**

If ordered separately, Three(3), female, twelve(12) pin connectorized cables support up to three(3) attached, external sensors. [These are often pressure transducers, or flow meters monitoring the conditions surrounding a TFF module.] The BCV-980 provides +24 VDC, [up to 100 mA] power to these external sensors and accepts Discrete & Analog signals in return. If utilizing TFF Mode, these external signals are then utilized, internally by the BCV-980, to modulate valve position. Additionally, these external sensor interfaces provide:

- A POWER Cycling capability
- A Zero RESET signal
- Discrete signal "Hand Shaking"
- RS-485 Serial Communication based on the Malema Addressable Sensor Network Protocol (MASN):
  - o Baud Rate = 115,200
  - o Data Bits = 8
  - o Parity = NONE
  - o Stop Bits = 1
  - o Flow Control = NONE

#### **TUBE SIZE SELECTION**

The standard BCV-980 ships pre-linearized for several standard tube sizes. These sizes can be selected from a "drop down" menu accessible from the Malema GUI.



# **TUBE INSTALLATION**

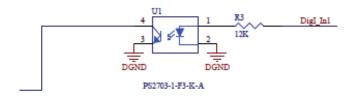
Tubing installation proceeds from the front of the BCV:

- 1. Ensure the DRAW BAR is OPEN. A remote panel mounted key switch accomplishes this function.
- 2. OPEN the FINGER GUARD
- 3. Insert the tube-manifold
- 4. CLOSE the FINGER GUARD
- 5. RESTORE the key switch to the normal or operate position
- 6. The BCV-980 executes an initialization routine locating the zero(0) flow location
- 7. The BCV-980 is now ready to operate

## REMOTE MANIFOLD INSTALL COMMAND

This unit is provided with REMOTE MANIFOLD INSTALL COMMAND. An external +24 VDC signal applied to the DI pin [PIN #8, WHITE/BLACK] on rear panel mounted connector P0 causes the DRAW BAR to fully OPEN so, manifolding can be easily installed or removed. When this signal is removed the BCV-980 slowly closes under reduced torque until motor stall occurs. At this point a new ZERO position is established and the system returns to Normal operation.

The internal circuit for this function is shown here:



#### **VALVE LINEARIZATION**

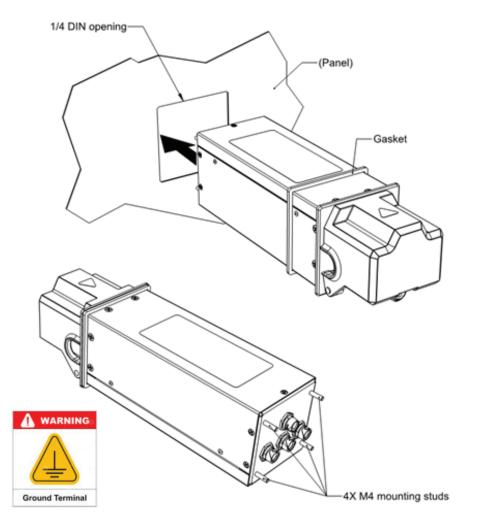
The BCV-980 ships with Malema's linearization scheme enabled. The feature can be disabled by unchecking the "Enable LIN function" Check Box in the Bio Control Valve settings Window of the GUI. A Valve Linearization Vs. Flow Rate Procedure is provided [see page 11] should you require a unique linearization result



# **PANEL MOUNTING**

The BCV-980 panel mounts through a standard ¼ DIN panel cutout [88mm X 88mm].

An ORANGE Silicone Rubber sponge gasket is provided with each BCV-980. When properly installed with the gasket the BCV-980 provides IP65 ingress rating; i.e.: protection against water jets.



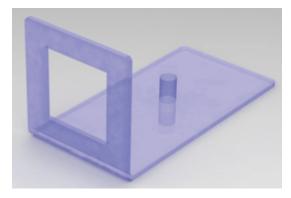
CAUTION: [The front of the BCV-980 provides IP65. IP30 protection is provided for the portion behind the panel or when not panel mounted.]



Any of the four(4), 4 mm Rear Mounting studs can be used for GROUNDING.

# [OPTIONAL, BENCH TOP-MOUNTING]

A clear, blue tint, PVC Bench-Top mounting accessory is available. Consult Malema for details.





# **VALVE LINEARIZATION VS. FLOW RATE PROCEDURE**

#### Scope:

To set the BCV angles for minimum and maximum flow rates

#### Setup requirement:

- PC with GUI to indicate flow rate
- Calibrated Flow meter
- BCV-980 with power/signal cable
- 4-20mA signal generator
- Hose to test
  - o Use the same tubing / hose that will be used in production

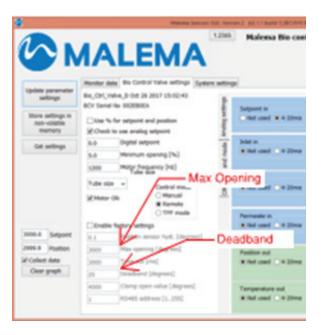
#### **Procedure:**

- 1. Place the tubing into BCV-980 with no pressure and power-up the unit
  - a. On initial POWER-UP the BCV-980 slowly closes while seeking full closure. This is automatic and requires several seconds.
- 2. After the fully closed point is located, set the BCV to remote mode.
- 3. Set maximum valve opening of BCV-980 allowing maximum flow thru the tube.
- 4. Establish flowrate thru the flow meter equal to 110% of desired flowrate:
  - a. [i.e.: if 2L max desired; set flow to 2.2L]
- 5. Slowly decrease the maximum valve opening of the BCV-980 Valve angle until the flow meter reported flow rate is 2L/min
- 6. Enter this angle value in the GUI Maximum opening field 420 Max opening [degrees]
- 7. Continue to decrease the angle until no flow is observed
- 8. Enter this angle value in the GUI Deadband field120 Deadband [degrees]
- 9. Set the BCV to remote operation mode:
  - a. The Status LED turns BLUE in Remote mode
- 10. Hook-up a 4-20ma analog signal generator to the the Analog setpoint input of main power cable
- 11. Set input setpoint signal to 20ma
  - a. Confirm the BCV-980 opens to the GUI maximum opening angle
  - b. Confirm flow rate equals the maximum desired flowrate
- 12. Set setpoint to 4ma
  - a. Confirm the BCV-980 closes to the GUI Deadband angle
  - b. Confirm minimum flow rate or pressure observed.

Note: The Deadband angle adjustment is an iterative process

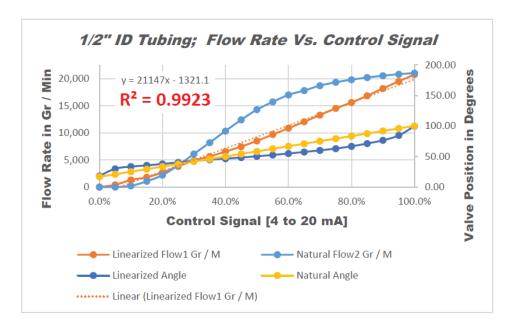
- 13. Power cycle the unit and verify the setpoint and flowrates are correct
- 14. Record flowrates for the following setpoints:

a. 4ma	
b. 5ma	
c. 8ma	
d. 12ma	
e. 16ma	
f. 20ma	



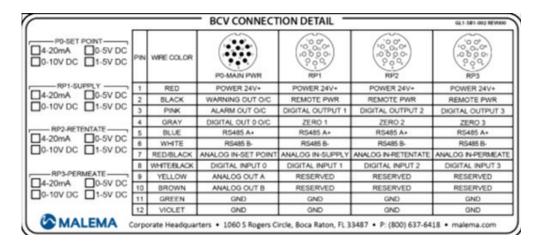


# **Typical Linearization Results**





# **Connector PINOUTS**



# **Connector FUNCTIONS:**

MAIN POWER / CONTROL CONNECTOR [twelve(12) Pin, Male]:

1. **RED** +24 VDC ±10%; POWER INPUT; 2 AMP 2. **BLACK** WARNING OUT; OPEN COLLECTOR

3. PINK ALARM OUT; OPEN COLLECTOR; this line shorts to GROUND in the event of drive motor stall.

4. GRAY DIGITAL OUTPUT; FINGER GUARD OPEN

5. **BLUE** RS485 A+; serial communications utilizes Malema Addressable Sensor network protocols; up to two hundred fifty(250) devices can be supported on a single channel

6. **WHITE** RS-485 B-

7. **RED / BLACK** SETPOINT INPUT; a configurable analog INPUT VIA the Malema GUI; could be 4 to 20 mA; 0 to 5 VDC; 0 to 10 VDC or 1 to 5 VDC

8. WHITE / BLACK DIGITAL INPUT 0; A +24 VDC signal applied to this PIN implements the REMOTE MANIFOLD INSTALL COMMAND [see line 132 on page 7 of this USER GUIDE]

9. **YELLOW** ANALOG OUT 1; An analog output signal proportional to valve position, 4 mA = valve closed, 20 mA = valve fully opened.

10. **BROWN** ANALOG OUT 2; Analog output signal proportional to  $\mu$ P temperature<sup>2</sup>; 4 mA = 0° C, 20 mA = 100° C; could be configured to mirror one(1) of the remote sensor inputs or some calculated value

11. GREEN GROUND12. VIOLET GROUND

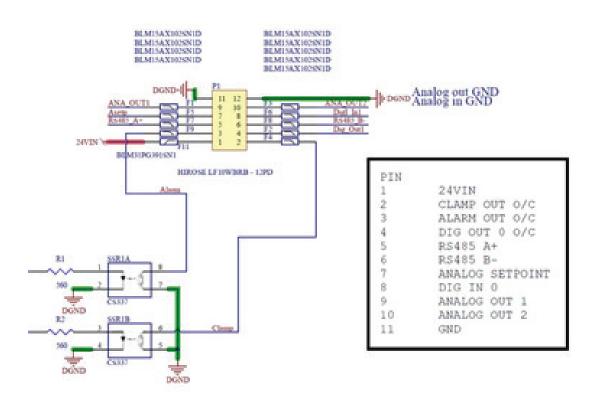


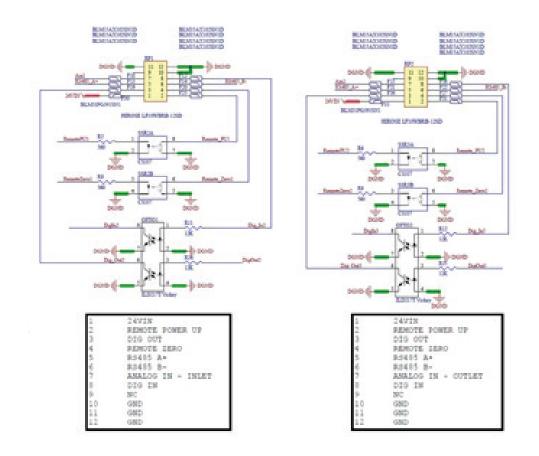
	322 - 4	S 75	BCV CONNECT	TON DETAIL		GL1-581-002 REV000
P0-SET POINT	PIN	WRE COLOR	PO-MAIN PWR	(0 0'0' (0 0'0') (0 0 0 0') (0 0 0 0') (0 0 0 0') (0 0 0 0') (0 0 0 0')	10 00 00 10 00 10 00 00 10 00 10 00 00 10 00 10 00 00 10 00 10 00 00 10 00 10 00 00 10 00 10 00 00 10 00 10 00	1000 1000 1000 1000 1000 1000 1000 100
RP1-SUPPLY	1	RED	POWER 24V+	POWER 24V+	POWER 24V+	POWER 24V+
□4-20mA □0-5V DC	2	BLACK	WARNING OUT O/C	REMOTE PWR	REMOTE PWR	REMOTE PWR
0-10V DC1-5V DC	3	PINK	ALARM OUT O/C	DIGITAL OUTPUT 1	DIGITAL OUTPUT 2	DIGITAL OUTPUT 3
12-10-22-00-20-0	4	GRAY	DIGITAL OUT 0 O/C	ZERO 1	ZERO 2	ZERO 3
RP2-RETENTATE	5	BLUE	RS485 A+	RS485 A+	RS485 A+	RS485 A+
4-20mA	6	WHITE	RS485 B-	RS485 B-	RS485 B-	RS485 B-
0-10V DC1-5V DC	7	RED/BLACK	ANALOG IN-SET POINT	ANALOG IN-SUPPLY	ANALOG IN-RETENTATE	ANALOG IN-PERMEAT
	8	WHITEBLACK	DIGITAL INPUT 0	DIGITAL INPUT 1	DIGITAL INPUT 2	DIGITAL INPUT 3
RP3-PERMEATE	9	YELLOW	ANALOG OUT A	RESERVED	RESERVED	RESERVED
4-20mA	10	BROWN	ANALOG OUT B	RESERVED	RESERVED	RESERVED
0-10V DC	11	GREEN	GND	GND	GND	GND
	12	VIOLET	GND	GND	GND	GND

#### REMOTE SENSOR CONNECTORS [i.e.: RP 1; RP 2 and RP 3] [twelve(12) Pin, Female]:

- 1. **RED** +24 VDC ±10%; POWER INPUT; 1 AMP
- 2. **BLACK** REMOTE POWER; +24 VDC ±10%; 0.100 AMP; these circuits are controlled by the BCV-980 allowing interruption or POWER Cycling of connected sensors
- 3. **PINK** DIGITAL OUTPUT 1 thru DIGITAL OUTPUT 3; these are OPEN COLLECTOR circuits enabling the BCV to send command signal to attached sensors; unimplemented
- 4. GRAY ZERO 1 thru ZERO 3; these signals allow the BCV-980 to force a ZERO function for remote sensors; these signals are configurable in firmware either supplying +24 VDC or GROUND as required by the remote sensors
- 5. **BLUE** RS485 A+; serial communications; utilizes Malema Addressable Sensor network protocols; up to two hundred fifty(250) devices can be supported on a single channel
- 6. **WHITE** RS-485 B-
- 7. **RED / BLACK** ANALOG INPUT 1 thru ANALOG INPUT 3 [or SUPPLY, RETENTATE or PERMEATE]; configurable analog signal carrying the values generated by the remote sensors
- 8. WHITE / BLACK DIGITAL INPUT 1 thru DIGITAL INPUT 3; these signals allow the remote sensors to report ALARM or FAULT conditions to the BCV-980
- 9. YELLOW RESERVED
  10. BROWN RESERVED
  11. GREEN GROUND
  12. VIOLET GROUND

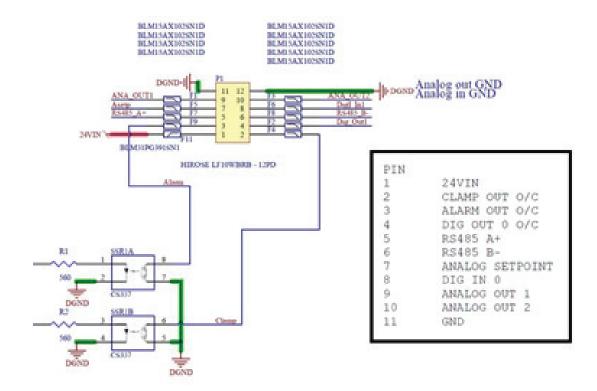


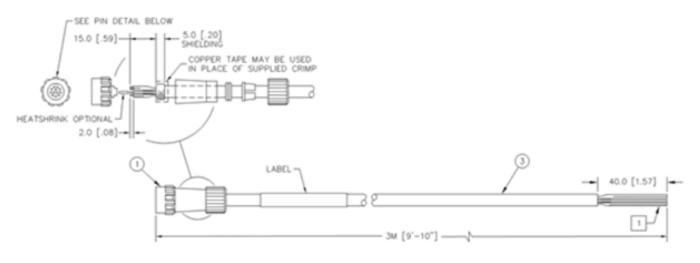






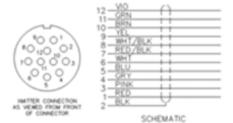
# **CABEL DETAILS**





#### NOTES:

- SPLICE Smm [.20"] FROM END OF WIRES AND LEAVE JACKETS ON FOR CUSTOMER.
  - TEST EACH CABLE ASSEMBLY AND SEAL IN BAG WHICH INCLUDES THE PART LABEL. THE LABEL SHOULD INDICATE THE PART NUMBER, REVISION AND ASSEMBLY DATE CODE (MMYY). THE CABLE IS ALSO REQUIRED TO INCLUDE ASSEMBLERS INITIAL AFTER PASSES TESTING.





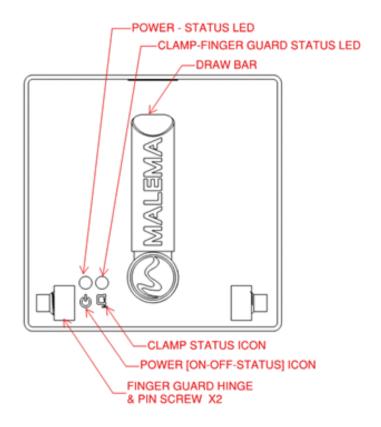
# **FRONT PANEL STATUS DISPLAY**

The front panel of the BCV-980 supports two(2) LEDs:

• **POWER** – This LED glows when adequate 24 VDC power is applied. LED color changes based on currently selected operating mode:

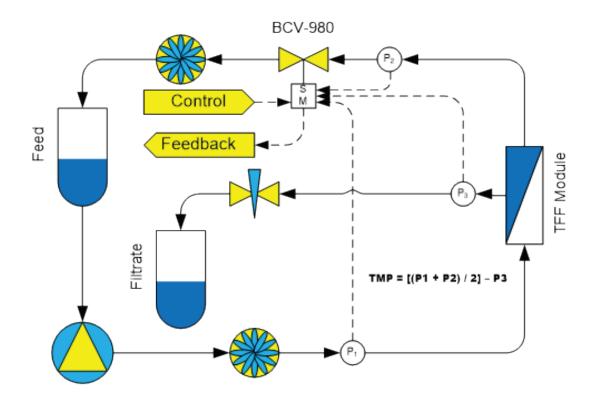
o BLUE – Remote Mode o GREEN – TFF Mode

• **CLAMP** – The CLAMP LED glows RED when the FINGER GUARD is OPEN or missing. At these times all operating modes are disabled. To restore function replace & CLOSE the FINGER GUARD.





# TYPICAL, STAND-A-LONE, TFF APPLICATION





# **CONTROL STRATEGY**

Malema has manufactured Liquid Flow Controllers for many years. Over this time, we have developed sophisticated, proprietary, expert, self-learning, rule based, PID control algorithms. These algorithms overcome the shortcomings typically found in PID process control.

Quick responses to process upsets or changing conditions are not followed by overshoot, undershoot and delays associated with quarter wave decay. Malema flow controllers typically achieve stable control in less than one(1) second after a process upset or step change in control setpoint. Systems have normal responses to these events. By observing and recognizing these disruptions as they occur, Malema flow control algorithms take the appropriate steps early on, reestablishing and restoring control quickly. Just like a truck driver in the mountains knows to conserve his brakes and momentum as he descends so, he'll need less additional energy ascending the next hill.

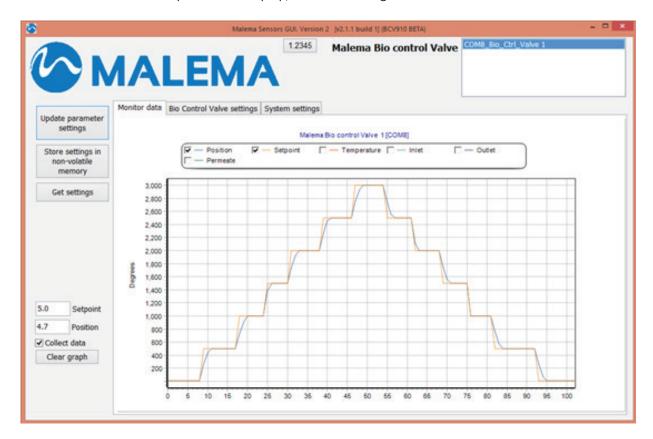
# **MALEMA GUI**

Copy the Malema Sensors application from the CD to a local drive and create shortcut to desktop.

Open the Malema application, click on the text field labeled with the COM port number to connect PC app to BCV-980 located in the upper right-hand corner.

To capture a graph, check the Collect data checkbox.

Graph below shows Position and Setpoint with ramp up/down of 500 deg.





#### Using the GUI to control Digital setpoint:

- Connect the RS485 to the cable.
- Open the Bio Control Valve Settings tab.
- Set the control mode to Remote.
- Click checkbox "Motor ON".
- Enter a value in degrees or percent to the Digital setpoint window.
- Click the "Use % for Setpoint and position" if entering percent valve.
- Click on Update parameter settings button.

Note: Update parameter settings button must be clicked when any setting has changed.

#### Controlling the Valve using 4-20mA analog signal:

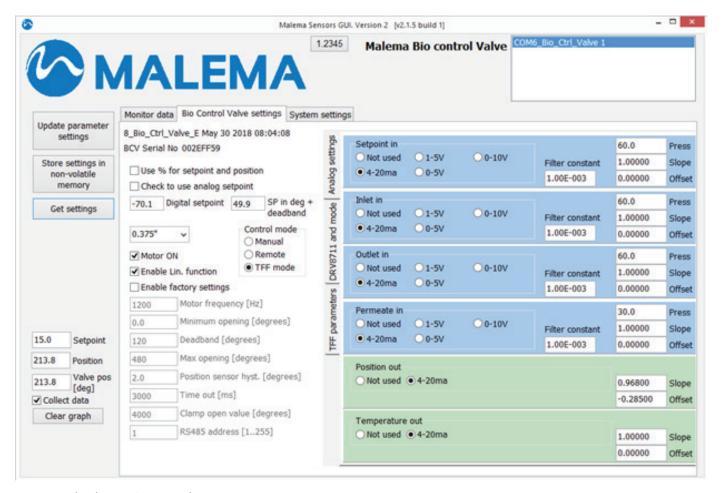
- Hook up the 4-20mA connections to the command signals of control cable provided.
- Set the control mode to Remote.
- Click checkbox "Check to use analog setpoint".
- Select Setpoint input type: 4-20mA, 1,5V, 0-5V, or 0-10V.

#### Using TTF mode:

- Set the control mode to TFF.
- Connect the other inputs.
- Select the input type for each input: 4-20 mA, 1,5 V, 0-5 V, or 0-10 V.



#### **GUI CONTROL WINDOW**



Bio Control Valve settings Window



#### WARRANTY

Malema Sensors warrants to the buyer that its products are free from defects in materials and workmanship at the time of shipment and during the WARRANTY PERIOD. Malema Sensors obligation under this warranty is limited to the repair or replacement of the product(s) at Malema Sensors facility. Malema Sensors products are sold with the understanding that the buyer has determined the applicability of the products to its intended use. Performance may vary depending upon actual conditions.

#### Warranty Period

This warranty is in effect for thirteen (13) months from the date of shipment from Malema Sensors place of business.

#### Warranty Claim

If Malema Sensors products are found to be defective in materials or workmanship within thirteen (13) months of the shipment date, they will be repaired or replaced with the same product at the discretion of Malema Sensors at its place of business at no charge to the buyer.

#### Service and Repair

To return the products, please obtain an RMA number for the product by contacting Malema Sensors Corporate Office, Boca Raton, Florida at +1 (800) 637-6418 or +1 (561) 995-0595. Kindly return the products as specified in the RMA document.

#### **Installation Support**

Contact Malema Sensors in California during US West Coast business hours for installation and operating support.

Tel: +1 (408) 970-3419

Email: malema@malema.com

#### Compliance



Compliance to the following standards is indicated by the corresponding mark on the product. This product complies with the applicable harmonized standards of EU Directives 2011/65/EU (RoHS), 2014/30/EU (EMC) and 2014/35/EU (LVD). The EU Declaration of Conformity is available online at www.malema.com



### **Disposal**

In conformance with the European Directive 2002/96 EC on Waste Electrical and Electronic Equipment (WEEE) this device may not be disposed of in domestic waste. This also applies to countries outside the EU, per their specific requirements. Please dispose of this product in accordance with local regulations at the collecting point specified for electrical and electronic equipment. If you have any questions, please contact the responsible authority or the distributor from which you purchased this device. Should this device be passed on to other parties (for private or professional use), the content of this regulation must also be related. Thank you for your contribution to environmental protection.

#### **FCC Note**

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures: reorient or relocate the receiving antenna. Increase the separation between the equipment and receiver. Connect the equipment into an outlet on a circuit different from that to which the receiver is connected. Consult the dealer or an experienced radio/TV technician for help.

# ISO 9001 Registration for Malema Engineering Corporation

Malema Engineering Corporation (MEC) obtained ISO 9001:2000 registration in April 2000. Malema's QMS is in full compliance with the ISO Quality Management System Standard. All three(3) Divisions of MEC (HQ in Fla., the West Coast Division (Malema Sensors), and the Singapore Division (MSIPL)) are now registered to current ISO 9001:2015 Standards. To ensure continuing compliance, all three(3) sites undergo annual audits by ANAB/IAF sponsored registrars.



### **Certificate of Compliance**

Date: July 7th, 2018

Part Number: This document applies to products with model code BCV & BRV followed by numerical values

including: 910, 980

**Product Description: BIOPHARMA VALVE Product Line** 

This product utilizes software, techniques and methods developed by Malema Engineering Corp. and covered by Trade

Secrets, US & foreign patents.

The product(s) covered by this certificate comply with the following standards:

- 1. Directive 2011/65/EU (RoHS) Restricting the use of certain hazardous substances
- 2. Regulation (EC) No. 1907/2006 of the European Parliament concerning the Registration, Evaluation, Authorization, Restriction of Chemicals (REACH).
- 3. IEC standard 60529 IP Protection Class. When panel mounted the BIOPHARMA VALVE products conform to class IP65 for electrical enclosure protection, i.e.: water projected by a nozzle (6.3 mm) against enclosure from any direction shall have no harmful effects. The front mounted FINGER GUARD provides IP20 protection, i.e.: exclusion of finger sized objects from the crushing mechanism.

**BIOPHARMA VALVE Products** These products are serialized and traceable. They are produced and calibrated using NIST traceable calibrated equipment. Assembly/Testing documentation is retained.

**Storage & Shipment:** Products are protectively stored and shipped.

**Electronics Compliance:** CE Compliance via the following testing:

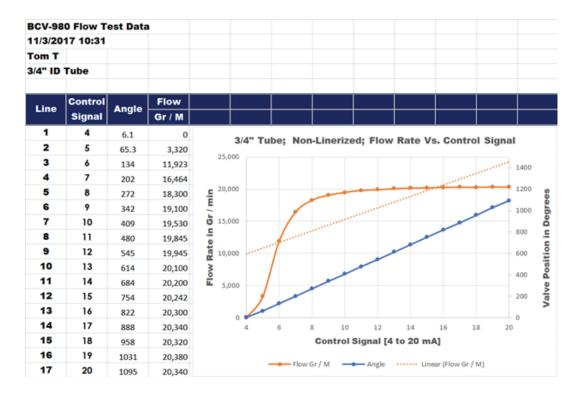
- 1. EN61000-4-2: Electrostatic Discharge
- 2. EN61000-4-3: Radiated Immunity (and Radiated Emissions)
- 3. EN61000-4-4: Electrical Fast Transients
- 4. EN61000-4-5: Surge Power Line
- 5. EN61000-4-6: Conducted Immunity

This document was prepared by Malema Engineering Corporation:

Brian Williams Quality Manager (408)-970-3419



# **APENDIX; SELECTED DATA**

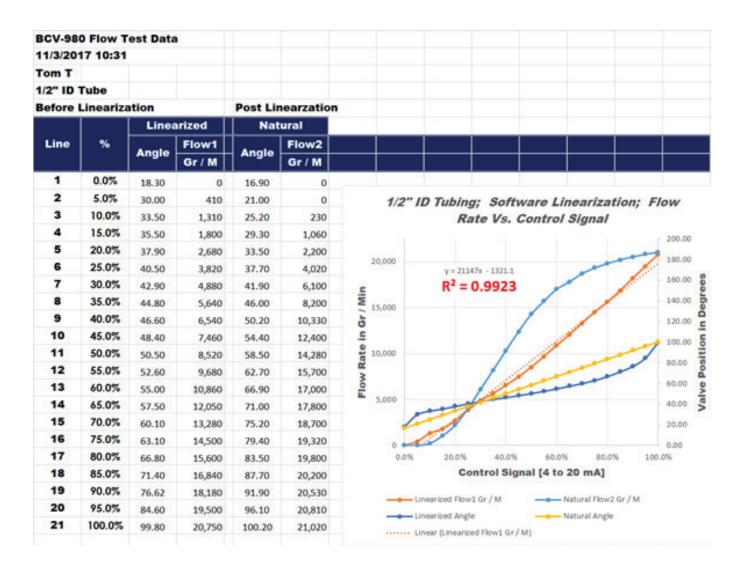


As can be seen in the above chart, the "natural", non-linearized flow, through a tube is highly asymmetric with a long "tail" at the higher flows where essentially no flow rate change occurs over much of the control signal. Malema addresses this situation by first limiting the control signal to the region of maximum control then by software linearization utilizing a ninth(9th) order polynomial equation, with the target of obtaining a ten(10%) percent change in flow rate based on a ten(10%) percent change in control signal over the central sixty(60%) to eighty(80%) percent of the control range. Typical Malema linearization results in R2 values exceeding 0.97.

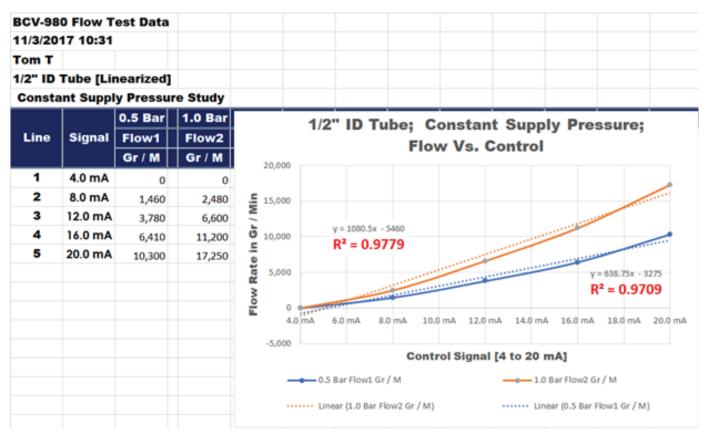


BCV-98	0 Flow Te	st Data							
11/3/201	17 10:31								
Tom T									
3/4" ID '	Tube								
Softwar	e Lineari	zation							
Line	% An	Ammin	Flow						
Line		Angle	Gr / M						
1	0.0%	2.2	0		2/4" ID Tabas Flow Bata Va Control Clarel				
2	5.0%	12.2	305		3/4" ID Tube; Flow Rate Vs. Control Signal				
3	10.0%	16.1	955	25,000	13				
4	15.0%	18.9	1,570		- 13				
5	20.0%	21.8	2,510	20.000					
6	25.0%	24.4	3,570	20,000	11				
7	30.0%	26.4	4,050	i.					
8	35.0%	28.3	5,030	Flow Rate in Gr / min	y = 20800x - 1424				
9	40.0%	30.3	6,000	5	R <sup>2</sup> = 0.9927				
10	45.0%	32.9	7,350	9	- 70				
11	50.0%	35.8	8,800	10,000					
12	55.0%	38.8	10,530	<b>%</b>	- 50				
13	60.0%	41.7	10,930	ū.	- 30				
14	65.0%	44.3	11,880	5,000	31				
15	70.0%	47.2	12,920		- 10				
16	75.0%	50.9	14,020	<b>✓</b>					
17	80.0%	56	15,330	0 📥	.1				
18	85.0%	62.2	16,530	0.0%					
19	90.0%	69.3	17,630		Control Signal [4 to 20 mA]				
20	95.0%	79.3	18,700	Flow Gr / M Angle Linear (Flow Gr / M)					
21	100.0%	98.7	19,890						









NOTE: Specifications are subject to change without notice.

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