# **OPERATOR'S MANUAL**



# Millar MPVS Duo<sup>™</sup> Pressure-Volume Measurement System



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MPVS Duo™

# I. Introduction

#### The Millar MPVS Duo is for ANIMAL USE ONLY

## A. Storage and Handling of the Millar MPVS Duo Pressure-Volume Loop Measurement System

- The Millar MPVS Duo system is designed for cardiovascular pressure and volume studies in laboratory animals. The catheter may be introduced via apical insertion after puncturing the myocardium with the appropriate needle, or through an exposed isolated blood vessel, such as the carotid or femoral artery.
- Use of the Millar MPVS Duo system should be restricted to personnel who have been trained to perform catheterization procedures. Failure to do so may result in a damaged catheter and non-valid data.
- Millar MPVS Duo systems are NOT compatible with magnetic resonance imaging due to metal housings in the pressure catheters.
- The Millar MPVS Duo is intended for pre-clinical research ONLY. It is NOT intended for human use.
- The Millar MPVS Duo BNC connections are intended to be coupled to laboratory data acquisition systems. The user takes responsibility to ensure compatibility with their data acquisition system.
- The Millar MPVS Duo USB ports are intended for firmware and software updates Only.
- The Millar MPVS Duo is intended to be used only with the included power supply and cables for your region. DO
  NOT MODIFY OR SUBSTITUTE POWER CABLES. Modification or substitution will compromise the integrity
  and safety of the power supply.
- The Millar MPVS Duo is intended to be used under normal laboratory conditions. The system should be placed on a stable table or cart, with all cables routed to prevent any trip hazards. The MPVS Duo should **NOT** be placed on the floor.
- The MPVS Duo contains multiple sensitive analog and digital processing units. Millar PV Catheters and MPVS Duo Measurement systems must be always handled with care.
- The MPVS Duo is not intended to be modified or serviced by the user. It contains no user-serviceable components.
- Follow the Instructions For Use, included in catheter purchase, for proper care and cleaning of Millar catheters. Damage to the sensors and electronics may occur if instructions are not followed.
- Ambient environmental conditions of the system must be constantly maintained or corrosion to the internal circuits may occur.
- Due to the positioning of the MPVS Duo's internal processor, the top panel of the unit may get warmer at various locations under certain environmental conditions.
- The MPVS Duo system is not waterproof. The top panel can be wiped with a cloth, however, if fluid enters the system, please contact Millar for further instructions.
- Before electrical procedures such as defibrillation, the MPVS Duo must be completely disconnected from the test subject, and the catheter must be disconnected from the HDMI cable.
- For a list of possible warning symbols please refer to "VIII. Symbols & Signs" on page 24.

For Additional Application Information, Surgical Protocols And Customer Support Please Visit ADInstruments.

www.adinstruments.com/contact/technical-support

# **II. Functions & Controls**

## A. About the System

The Millar MPVS Duo Pressure-Volume (PV) measurement system combines the traditional conductance technology with the leading admittance PV loop measurement methods, delivering higher quality, reproducible data compatible with Millar PV catheters.

MPVS Duo provides users with guided steps and a linear menu structure that encompass all aspects of data collection, bringing the benefits of conductance, admittance, and Millar catheters to your studies in a user-friendly design.

## **B. System Components**

The following components are typically included with the MPVS Duo PV system. Please use the specific part numbers in any contact with Millar Support or if ordering replacement parts.

MPVS Duo Control Unit - P/N: 880-200
 Power Supply including Power Cord - P/N: 850-5163-1, Power Cord P/N: 50-5117
 Millar MPVS Duo Micro HDMI Catheter Cables - P/N: 850-5158
 BNC-BNC cable, 6ft - P/N: 850-5164
 Qty. 5



Figure 1: MPVS Duo top down view with LCD and keypad shown.



Figure 2: MPVS Duo BNC Cable



Figure 3: MPVS Duo Power Supply



Figure 4: MPVS Duo with all connections attached



Figure 5: ADInstruments PowerLab: Millar's preferred system for data acquisition.



Figure 6: MPVS Duo Micro HDMI to Full Size HDMI



Figure 7: Millar Ventri-Cath Catheter

# **Functions & Controls**

## C. MPVS Duo Control Unit Layout and Controls

Figure 8 illustrates the MPVS Duo's touch pad controls while Figure 9 shows rear electrical connections. The keypad is used to input system settings and to scroll through menus.

## Front Panel Key Pad User Interface

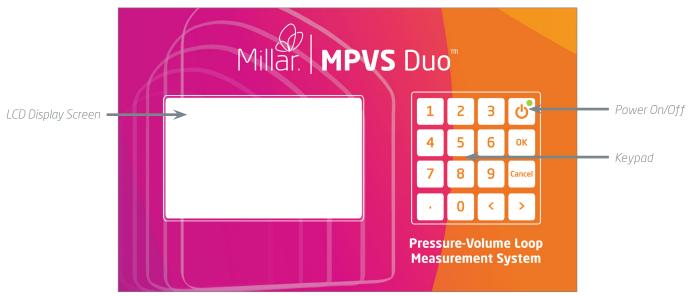


Figure 8: MPVS Duo Front Panel Touch Pad Interface

## ON/OFF 也

Used to turn the system On and Off after the power supply is connected. Note: main analog power is still provided unless disconnected from power input. When the MPVS Duo is Off, a short press on the Power button will turn the device On. The green LED will appear when the MPVS Duo is On. A long press on the Power button to turn the system Off. The MPVS Duo boot up time is approximately 30 sec.

\*Ensure system is properly shut down before removing power connection. Failure to do so could result in corrupt operation.

#### **Keypad**

The MPVS Duo contains a numbered keypad 0 - 9 and allows for decimal input via [.] button. [</>] Arrows provide navigation throughout the MPVS Duo software. [OK] and [Cancel] buttons are used to provide confirmation and value deletion in the user interface (UI).

**NOTE:** All navigation on MPVS Duo is performed via the front keypad.

#### **LCD Screen**

The MPVS Duo contains a 5-inch colored LCD screen where the main User Interface is displayed.

**NOTE:** The LCD screen is a not a touch screen.

System Cable to connect to the MPVS Duo. The cable's electrical properties are matched to the

system. Replacement with a standard HDMI

cable will result in non-valid data.

# **Functions & Controls**

#### **Back Panel Electrical Connections**



Figure 9: MPVS Duo Back Panel

The rear panel of the MPVS Duo control unit contains all the electrical connections for the system. The functions are labeled:

#### **Power 9V Input**

Connect **ONLY** the provided power supply. The MPVS Duo consumes 1.3A at 9V. The included supply is rated for up to 4.5A at 9V.

#### **Unit Serial Number**

Your unit's individual serial number is placed on the back of the unit. When requiring a support call, please have this number ready to share with your customer service representative.

#### **Outputs**

The MPVS Duo system outputs data through 5 individual BNC connectors. Each output is clearly labeled and corresponds to the following:

**Pressure:** Primary pressure channel.

**Calculated Volume:** This output is the mathematical result of the MPVS Duo algorithm. Available only in admittance mode.

**Phase:** This channel tracks the heart muscle present in the electrical field. Used for positional awareness in conductance mode.

**Magnitude:** This channel supplies the magnitude of the measured admittance from the ventricle. This channel is synonymous with the total conductance measured from the heart.

**Pressure #2:** Optional second pressure signal either from a single-sensor pressure catheter plugged into "P2" catheter input or a dual-sensor pressure catheter plugged into the "Catheter" input. A pressure transducer plugged into the Pressure #2 port will have precedence over any second pressure sensors on the main catheter. **Millar Admittance Catheters use a Micro HDMI** 

#### **Inputs**

The MPVS Duo unit has two Micro HDMI input receptacles on the back:

**Catheter:** Input is for a PV catheter, single-sensor pressure catheter.

**P2:** This for the use of a second catheter. Connecting a single-sensor pressure transducer to this input allows for the measurement of pressure from secondary locations. If a PV catheter is plugged into this input, only the pressure data from this catheter will be output via the Pressure #2 output. **Please note that legacy Millar pressure-only catheters are not compatible with the Pressure #2 port on this system. If a second measurement is required, users have the option to utilize an external bridge amplifier or the MPS 2000.** 

#### **Other Connections**

The MPVS Duo unit has additional USB ports located on the front and back:

- Micro USB connection (back): This port is used for debugging and future upgrades.
- Three full size USB connections (front): These are for future software/firmware updates.

# **Functions & Controls**

## D. Variable Segment Length (VSL) Technology

The MPVS Duo system can be used with Millar single-segment, tetrapolar catheters as well as Millar Ventri-Cath Variable Segment Length (VSL) catheters. Single-Segment catheters have 4 electrodes at a fixed distance, staggering the catheter's pressure sensor, as shown in Figure 10. VSL catheters offer a selection of electrode rings to suit different ventricular long axis dimensions. The various segment lengths are user selectable via the MPVS Duo menu structure. The segment being used will be displayed on the "New PV Loop Protocol: Optimize Catheter Position" screen on page 18.

Millar Ventri-Cath catheters contain seven electrodes, five of which are situated proximal to the pressure sensor and two positioned distally. The VSL catheter enables the selection of four different segment lengths for LV volume measurement, providing versatility and flexibility when studying hearts of different sizes as shown in

igure 11.

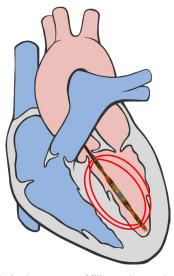


Figure 10: A single-segment Millar catheter shown inside of the left ventricle of a heart with electric field lines shown.

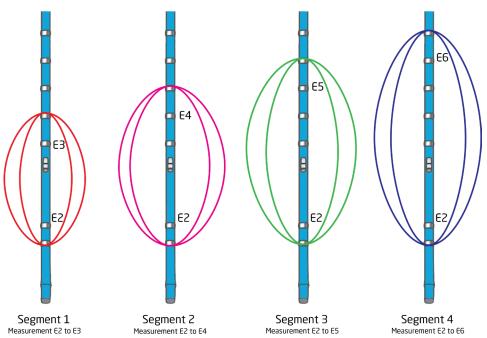


Figure 11: A 5F catheter shown in four different measurement segments 1-4, allowing users to span different ventricular scenarios.

MPVS Duo™

# III. Directions for Use

## A. Quick Setup of MPVS Duo Hardware

- Using the supplied BNC-BNC cables, connect the Pressure, Volume, Phase, and Magnitude outputs to your data
  acquisition system (if necessary, also connect Pressure #2). If using Conductance mode, only Pressure, Phase and
  Magnitude outputs are required. The recommended data acquisition system for the MPVS Duo is ADInstruments Power
  Lab and LabChart products.
- 2. The data acquisition (A/D) system used with the MPVS Duo system must be configured for at least a 0-5V input span. There is an option on the MPVS Duo menu to send the appropriate voltage levels to calibrate the acquisition system. This option is found in the "New PV Loop Protocol: Units Conversion for Data Acquisition" screen, shown in Figure 21 on page 12 or alternatively under "System Settings", shown in Figure 16 on page 10.
- 3. Connect the power jack of the external power supply to the power input on the MPVS Duo. Turn on the MPVS Duo system using the **Power Button** on the MPVS Duo's keypad. Connect a Millar Pressure-Volume (PV) Catheter to the MPVS Duo's "Catheter" port using the supplied Micro HDMI-Full Size HDMI cable. The MPVS Duo control unit will recognize the catheter when it is connected and automatically select the appropriate menu to be displayed.
- 4. **Press 1** to Start a "New PV Loop Protocol". A step by step process will begin by walking you through how to collect PV loops with the MPVS Duo. "New PV Loop Protocol" will be grayed out when no catheter is connected.
- 5. MPVS Duo supports both conductance and admittance measurement modes. **Press 1** on the keypad to select the admittance workflow and **press 2** to select the conductance workflow. See Section "A. Collecting PV Loops" on page 14 for more info on the differences in measurement modes.
- 6. In order to minimize signal drift, immerse the sensing tip in saline (i.e. a saline-filled syringe) for at least 30-minutes to properly hydrate the catheter's pressure sensing membrane.
- 7. Before using the catheter, the pressure signal offset must be adjusted to zero by using the "New PV Loop Protocol: Balance Pressure Sensor" feature and selecting "Balance Pressure Sensor 1", shown in Figure 24 on page 13. Do this immediately prior to inserting the catheter into the vessel, ventricle, or area of measurement. **NOTE:** If using a second pressure sensor, make sure to also "Balance Pressure Sensor 2" from the "New PV Loop Protocol: Balance Pressure Sensor" screen.
- 8. The signals output from the MPVS Duo system will range from approximately 0V to 4V for all channels. Scale the signals appropriately using the physiological values provided in the Low/High calibration screen.
- 9. For additional quick start information please review the included Millar MPVS Duo Quick Start Guide included with your MPVS Duo purchase.

**NOTE:** Power cycle the MPVS Duo if any abnormal technical behavior occurs in the UI or the output data. This includes turning the MPVS Duo off via the power button, then disconnecting the power source. Plug power back in and power on the MPVS Duo. If issues persist, contact Millar technical support.

## **Directions for Use**

## **B.** Navigating the MPVS Duo Menu

To execute a menu option, press the option number on the keypad, or use the navigation arrows [</>) to move between menu screens.

When the MPVS Duo system is first turned on, it will boot up, then display the "Initializing MPVS Duo..." message. as shown in Figure 12.

Once initialized, the system will automatically display a "Home" screen. There are two possible "Home" screen menus depending on whether a catheter is connected to the rear panel. The two possible "Home" screen menus and submenus are:

- 1. Home Please Connect Catheter Figure 13
- 2. Home Catheter Connected Figure 14



Figure 12: MPVS Duo Start-Up Screen







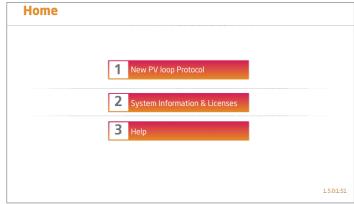


Figure 14: MPVS Duo Home - Catheter Connected

The "Please Connect Catheter" home screen will be displayed until a valid PV or Pressure catheter is connected to the MPVS Duo "Catheter" input. "System Settings & Licenses" and "Help" are selectable from this menu.

**Press 1** on the keypad to select **[1. New PV Loop Protocol]**. This will start a new PV loop protocol and initiate the MPVS Duo PV data collection walkthrough process. This is a guided process with tips and reminders to streamline your data collection process. **Press 2** to access "System Information and Licensing" and **press 3** for "Help" are also selectable from this menu.

## C. Settings and Help

#### Help

Select to view contact info for Millar and ADInstruments support.

## System Settings

Select to view additional menu options and settings related to system information and licensing, System Log, etc., as shown in Figure 15.

# **Directions for Use**

#### **System Settings: Settings**

- **1. System Info and License Keys:** Displays the control unit hardware info, software/firmware info, serial number, and license code. The 20-digit license code determines what features are available in the MPVS Duo system. The code is specific for each control unit and not transferable. This screen contains identifying info about the MPVS Duo system, please refer to this screen if contacting Millar Support.
- **2. System Log:** Status Log of MPVS Duo system info for support use by Millar Technical Staff.
- **3. More Settings:** Displays the "System Settings: Settings and Options" submenu listed below Figure 16

# System Settings: Settings 1 System Info & License Keys 2 System Log 3 More Settings < Back: Main Menu

Figure 15: MPVS Duo System Settings: Settings

#### **System Settings: Settings and Options**

- **1. Send DAQ Calibration Signals:** Outputs a low and high voltage value for calibrating the analog to digital data acquisition systems (DAQ). The calibration signals are also displayed as part of the "New PV Loop Protocol: Units Conversion for Data Acquisition", as shown in Figure 21 on page 12.
- **2. Continuous Auto Scan: Enabled:** This new feature for the MPVS Duo allows the system to continuously scan for baseline while the catheter position is being optimized. With "Continuous Auto Scan: Enabled," blood volume data will be calculated as soon as the catheter is placed into the ventricle. This information can be used as live data feedback to optimize the catheter position. Please see the "New PV Loop Protocol" workflow for more info and **Press 2** to enable or disable this feature\*.
- **3. Set Catheter Position Timing:** This is a series of customizable reminders that prompt users to enter "Experiment Mode" in the "New PV Loop Protocol" workflow, as shown in Figure 17. It is recommended to enter "Experiment Mode" once catheter positioning is optimized and stable. When this mode is selected, the following screen will offer customization of the time notifications.
- **4. Catheter Info:** Displays catheter usage and other catheter identification information for use by Millar technical staff.

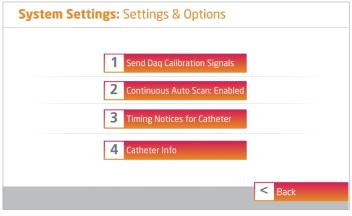


Figure 16: MPVS Duo System Settings: Settings & Options

| Note: All Periods are in full minutes. Setting a Value of 0 will disable prompt. |                       |   |
|--|-----------------------|---|
|  | 1 First Notice Time:  | 1 |
|  | 2 Second Notice Time: | 2 |
|  | 3 Third Notice Time:  | 3 |

Figure 17: MPVS Duo System Settings: Set Catheter Position Timing: Notifications

\*NOTE: When the Continuous Auto Scan feature is disabled, the user will need to manually perform a baseline scan. This option is not available when Continuous Auto Scan is enabled.

# IV. New PV Loop Protocol

## A. New PV Loop Protocol

From the main menu, as shown in Figure 14 on page 9, **press 1** to start a New PV Loop Protocol. This will initiate the Millar PV data collection workflow, which is a guided process with helpful tips and reminders to streamline data collection. Experienced users can quickly and easily navigate through the workflow using the [</>] navigation keys on each screen.

#### **B.** Choose Measurement Mode

MPVS Duo supports both conductance and admittance measurement modes. **Press 1** on the keypad to select the admittance workflow and **press 2** to select the conductance workflow. See Table 1 for more info on basic differences in modes. Full information on each measurement mode are found on page 14.

## C. Catheter Hydration

The "Catheter Hydration" screen prompts users to soak the sensing tip of the PV catheter in a 37°C saline solution for a minimum of 30 minutes, as shown in Figure 19. Proper hydration of the pressure sensor membrane minimizes baseline pressure drift during the experiment.



Figure 20: Example of Catheter Hydration

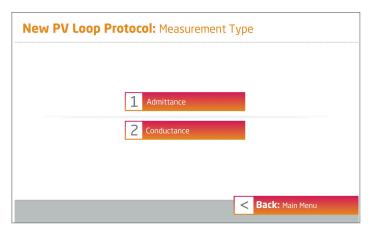


Figure 18: MPVS Duo Select Measurement Type

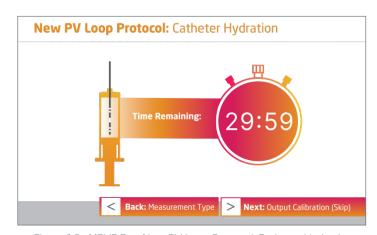


Figure 19: MPVS Duo New PV Loop Protocol: Catheter Hydration

| Table 1 · MPV/S D | )uo Conductance vs / | Admittance ( | omnarison |
|-------------------|----------------------|--------------|-----------|
| Tubic Till VJ D   | ao conductunce vo i  | turrice c    | .ompunson |

|                       | Conductance  | Admittance   |  |
|-----------------------|--|--|--|
| Active Channels       | Only Pressure, Magnitude (conductance), and Phase* channels active   | Pressure, Magnitude, Phase, and<br>Volume Channels activated |  |
| Volume                | Use external calibration method - i.e., ADInstruments PV Loop Module | Wei's Equation   |  |
| Muscle Conductance    | Saline Bolus or Cuvette  | Determined in real-time from phase signal                    |  |
| *Positional Awareness | Phase signal only - new to conductance                               | From phase and volume signals                                |  |

# **New PV Loop Protocol**

## D. Units Conversion for Data Acquisition System

MPVS Duo outputs low and high calibrations voltages that are used for calibrating the analog to digital data acquisition systems (DAQ). Within the users DAQ software, unit conversion can be performed. The MPVS Duo has separate screens for both high and low voltage values.

**Press 1** on the keypad to access the "Output Low Voltages" menu, **Press 2** on the keypad for the "Output High Voltages" menu.

## Output Low Voltages:

**Press 0** to output the low voltage signals from the MPVS Duo to your data acquisition system. The screen provides the reference value, voltage, and units of each output channel for calibration, as shown in Figure 22.

## **Output High Voltages:**

**Press 0** to output the high voltage signals from the MPVS Duo to your data acquisition system. The screen provides the reference value, voltage, and units of each output channel for calibration, as shown in Figure 23.

The physiological values shown in the "Value" column for Volume and Magnitude will change dynamically depending on the catheter used. For example, the magnitude used for a small animal catheter is 5000uS vs 50mS for a large animal catheter. Phase and Pressure remain the same across animal types. Be sure to adjust the DAQ conversion when changing animal types or catheters.

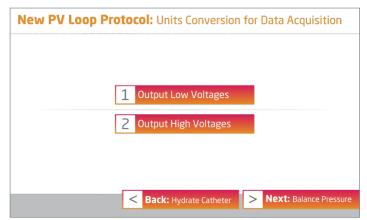


Figure 21: MPVS Duo New PV Loop Protocol: Send DAQ Calibration Signals

| MPVS Duo Chn. | Value | Voltage | Units    |
|---------------|-------|---------|----------|
| Pressure 1    | 0     | ~0.85   | mmHg     |
| Volume        | 0     | 0       | mL       |
| Phase         | 0°    | 0       | Degrees° |
| Magnitude     | 0     | 0       | mS       |
| Pressure 2    | 0     | ~0.85   | mmHg     |

Figure 22: MPVS Duo New PV Loop Protocol: Send DAQ Calibration Signals Low Values. "O" button will highlight green when data is being sent.

| MPVS Duo Chn. | Value | Voltage | Units    |
|---------------|-------|---------|----------|
| Pressure 1    | 100   | ~1.8    | mmHg     |
| Volume        | 300   | 4.095   | mL       |
| Phase         | 20°   | 4.095   | Degrees° |
| Magnitude     | 50    | 4.095   | mS       |
| Pressure 2    | 100   | ~1.8    | mmHg     |

Figure 23: MPVS Duo New PV Loop Protocol: Send DAQ Calibration Signals High Values. "O" button will highlight green when data is being sent.

\*NOTE: Reference your data acquisition and software providers manuals for more information about converting voltage to units.

## MPVS Duo™

# New PV Loop Protocol

#### E. Balance Pressure Sensor

Each pressure sensor should be zeroed or "balanced" prior to use. Use the MPVS Duo's automatic zero feature to balance the pressure sensor. Do this immediately prior to inserting the catheter into the vessel, ventricle, or area of measurement. **Press 1** to balance the first pressure sensor or **press 2** for the secondary pressure only channel, as shown in Figure 24. "Balance Pressure Sensor 2" is only valid while using a catheter with two pressure sensors or a separate catheter connected to the "P2" input. The menu will still be accessible however, the data is only valid for a secondary catheter.

In all scenarios, the catheter must be properly hydrated prior to balancing. For the best outcome, user must ensure that the catheter remains submerged, but any force (weight) from the water must also be minimized (i.e., balancing a catheter at the bottom of a water column will introduce offset into your measurement).

#### Balance Pressure Sensor Sub-Menus

MPVS Duo will display the current raw reading from the pressure sensor in the "Current Reading" box, as shown in Figure 25. Typically, this value will be around a few mmHg. **Press 1** on the keypad to auto-zero the sensor. The current reading box will now read ~0 mmHg. This is the new zero'ed reading of the catheter, as shown in Figure 26. The output voltage on the DAQ signal will also shift down to ~0 mmHg.

The MPVS Duo also has the option to apply a manual offset to the zeroed pressure signal. This must be done after the catheter has been zeroed. **Press 2** on the keypad and then enter the appropriate positive offset. Negative offset is not supported at this time. Note: The use of an offset is not required in a standard protocol, however can be used as a option if desired. The output voltage will shift accordingly based on the new offset value.

**Press 3** on the keypad to reset to the raw pressure reading.

In all cases, the value shown in the current reading box will be the pressure output from the MPVS Duo outputs.

**NOTE:** If the "Current Reading" display shows NAN or a number not close to zero after the "Zero Current Balance" button is selected, **press 3** to reset and try again. This can occur if the pressure data is invalid when attempting to take a measurement.

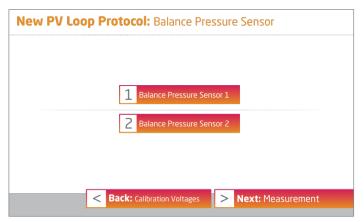


Figure 24: MPVS Duo New PV Loop Protocol: Balance Pressure Sensor

| New PV Loop Protocol: Balance Pressure Calibration 1 |       |           |    |  |
|--|-------|-----------|----|--|
| Current Reading:                                     | -2.50 |           |    |  |
| 1 Zero Current Balance                               |       |           |    |  |
| 2 Manual Offset                                      | 0     |           |    |  |
| Reset Pressure Reading                               |       |           |    |  |
|  |       |           |    |  |
|  | <     | Back > Ne | ct |  |

Figure 25: MPVS Duo New PV Loop Protocol: Balance Pressure Sensor - zero current balance

| New PV Loop Protocol: Balance Pressure Calibration 1 |      |            |  |  |
|--|------|------------|--|--|
| Current Reading:                                     | 0.05 |            |  |  |
| 1 Zero Current Balance                               |      |            |  |  |
| 2 Manual Offset                                      | 0    |            |  |  |
| Reset Pressure Reading                               |      |            |  |  |
|  |      | Nove       |  |  |
|  | < 5  | ack > Next |  |  |

Figure 26: MPVS Duo New PV Loop Protocol: Balance Pressure Sensor - Entering Manual Offset

**NOTE:** The pressure balance will reset following any power outage or reset. Be sure to record the value prior to surgery. If power outage occurs during surgery, the manual offset can be used to adjust during surgery.

## A. Collecting PV Loops

Thus far, each of the steps within the New PV Loop Protocol have been intended to prepare for data collection: catheter hydration, A/D data acquisition calibration, and sensor balancing. The user is now ready to collect PV loops.

The MPVS Duo supports both conductance and admittance PV loop protocols, each with its own walkthrough. The two workflows branch from the main workflow following the pressure balance menus. The specific workflow was chosen after the main menu selection, as shown in Figure 27.

Conductance protocols require external volume conversion typically achieved with 3rd party PV Loop modules, such as ADInstruments PV Loop Module. Whereas admittance protocols require study parameter setup but can output volume directly.

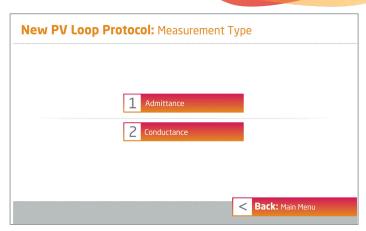


Figure 27: MPVS Duo Select Measurement Type

NOTE: In both workflows, a reference Stroke-Volume (SV) measurement should be completed using external measures such as a flow probe, echocardiography, etc. This value is used both PV loop calculations.

#### **B.** Conductance

The MPVS Duo's conductance mode is very similar to traditional conductance measurement devices where data is collected and analyzed in 3<sup>rd</sup> party software. Single value parallel muscle contribution is removed via saline bolus post experiment. Volume conversion, alpha calibration, and cuvette calibration are done using 3<sup>rd</sup> party PV loop modules.

The MPVS Duo provides the traditional conductance outputs "Conductance (Magnitude channel)" and "Pressure" to provide users a familiar workflow, as shown in Figure 28 and 29.

The MPVS Duo also provides a **phase output channel** to be used to aid in positioning of the catheter during PV loop experiments. Note that in conductance mode, this signal is used for positional awareness only. As the phase signal increases, the catheter's position is closer to the wall of the ventricle. The user can use this information to help center the catheter within the ventricle by reducing the phase seen by the catheter. This signal will look sinusoidal throughout the cardiac cycle and is opposite in direction from the conductance signal.

#### Conductance Mode - Output Signals Used

- Pressure Red
- Phase Used for positioning Blue
- Conductance Magnitude Green



ADInstruments Instrument Interface



Figure 28: MPVS Duo Back BNC Connections for Conductance

For data acquisition and analysis, Millar recommends the ADInstruments PowerLab system and PV Loop Analysis Software Module for LabChart.

Figure 29: Conductance Mode DAQ Connections



Catheter Input

The MPVS Duo has one principle display for the conductance workflow displaying segment select, and other important information indicating that the user must do post-processing in an external 3<sup>rd</sup> party module, as shown in Figure 30.

While on this screen, MPVS Duo will output all conductance related channels that are to be sampled by the users DAQ system. Standard Conductance PV loop analysis can be performed with the users 3<sup>rd</sup> party PV loop Modules. Millar recommends ADInstruments LabChart.

If using a large animal catheter, **press 1** on the keypad to change the segment used. The current segment will be displayed in the text box. The number next to "Segment Select #" is the total available segments for the catheter attached. Small animal catheters are typically single segment and large animal catheters are typically multi-segment.

"Scan Mode" will be set to Conductance Only. This indicator is used to indicate which mode the system is set in. Additional updates are provided here in Admittance mode.

To finish an experiment and go back to the main menu **press 0** on the keypad. A confirmation screen will be displayed asking you to confirm to end the experiment. **Press** > to end the confirm end experiment, as shown in Figure 31.

#### C. Low Pass Filter

The MPVS Duo has an integrated hardware low pass filter with a cut-off frequency of 30 Hz. **Press 5** on the keypad to activate the low pass filter.

The button will change from "Low Pass Filter: Off" to "Low Pass Filter: On" when activated.

The filter will turn to an off state when a new catheter is plugged in. This allows the user to always see the unfiltered data prior to applying any filters.

If additional filtering is required, refer to the 3rd party DAQ's supported filtering features.

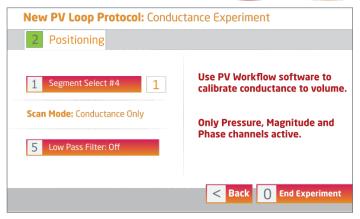


Figure 30: MPVS Duo Conductance Experiment Screen



Figure 31: MPVS Duo Confirm End Experiment

NOTE: The low pass filter is supported in both Conductance and Admittance measurement modes. The low pass filter filters the input analog signal for the magnitude and phase. It has no affect on the pressure signal.

#### D. Admittance

The MPVS Duo admittance workflow mode provides users with live real-time volume output without the need for calibration techniques such as saline bolus or cuvette calibration. This is achieved through various algorithms and by the dynamic separation of the blood and muscle properties of the heart via the magnitude and phase signals.

The admittance method provides instant volume feedback when positioning the catheter in the ventricle. The MPVS Duo Admittance workflow helps qualify your data with real-time measurements, shortening catheter positioning time and makes the units you are interpreting more simplistic and easy to understand. The MPVS Duo contains three specific screens to walk through users in collecting admittance based PV loops.

#### Connections

The MPVS Duo provides four main outputs: "Pressure", "Volume", "Magnitude", and "Phase", as shown in Figure 32 and 33. The Volume channel uses internal algorithms to calculate blood volume from the magnitude and phase channels, dynamically calculating Gb, muscle conductance, etc. This allows users to optimize their catheter position with live volume feedback and PV Loops. Users can use 3<sup>rd</sup> party analysis tools to further process their data.

#### Admittance Mode - Output Signals Used

- Pressure Red
- Volume Yellow
- Phase Blue
- Magnitude Green



Figure 32: MPVS Duo Back BNC Connections - Admittance



ADInstruments Instrument Interface

For data acquisition and analysis, Millar prefers the ADInstruments PowerLab system and PV Loop Analysis Software Module for LabChart.

Figure 33: Admittance Mode DAQ Connections

Catheter Input

## **Basic Theory**

The MPVS Duo's admittance technology is based on the electrical principle that an AC signal in a circuit with capacitance will exhibit a phase shift at the output when compared to the original input signal, as shown in Figure 34. By tracking this phase angle in real-time and mathematically relating it to the resistance of the myocardial tissue, via the heart type ( $\sigma/\epsilon$  ratio), the MPVS Duo allows continuous tracking of the parallel conductance throughout the heartbeat.

The MPVS Duo system employs an improved conductance-to-volume conversion equation to address the non-homogeneous electrical field. Wei's equation replaces Field Correction Factor alpha ( $\alpha$ ) used in the traditional Baan's equation. Wei's equation corrects for the non-homogeneous nature of the catheter's electrical field distribution – it does so by assuming a non-linear relationship between conductance and volume, thus improving accuracy over a wider volume range.

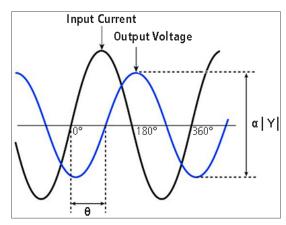


Figure 34: The input/output signal delay is measured in terms of degrees and is referred to as "Phase angle  $\theta$ ".

#### **Calibration Parameters**

This screen prompts users to enter the calibration parameters for the admittance PV Loop Protocol, as shown in Figure 35. The MPVS Duo requires three study parameters.

Defaults are provided for each parameter and users are encouraged to input known values if available. Stroke Volume, for example, is often known from another measurement modality, from prior experimental measurement.

**1. Enter Muscle: Press 1** to change the default muscle parameter. The electrical properties of healthy muscle tissue do not vary significantly. Infarcted heart tissue, however, exhibits an increased heart type value ( $\sigma/\epsilon$  ratio) due to reduced capacitance. Typically, non infarcted tissue averages 800K, while infarcted tissue can return 900K or higher.

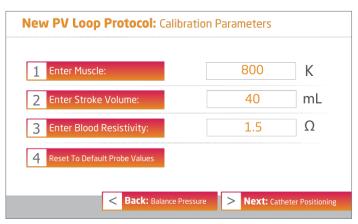


Figure 35: MPVS Duo - Calibration Parameters

2. Enter Stroke Volume: Press 2 to change the default stroke volume. The SV calibration parameter is used to normalize (scale) the computed volume output from the MPVS Duo. As an example, adjusting the Stroke Volume value from the default value of  $25\mu$ L to  $15\mu$ L causes a smaller (approx.  $2\mu$ L) change in the absolute volume calculation of a mouse heart.

When possible, it is recommended to determine SV for each animal or for a small sample population. The SV values can be averaged and input into the MPVS Duo for subsequent experiments. Some of the common methods of determining SV are echocardiography, Swan-Ganz thermo-dilution catheter, aortic flow probe, etc. Good practice dictates acquiring baseline SV values under conditions that mimic those of the experimental protocol, including anesthesia, heart rate, body temperature, and ventilation.

**NOTE:** the units will change based on animal type (catheter connected). For rodent based applications, SV will be enter in  $\mu$ L units, for large animal applications, the units will be entered in  $\mu$ L.

- **3. Enter Blood Resistivity: Press 3** to change the default blood resistivity. These values are loaded directly from the attached catheter. Experimental interventions such as the administration of fluid, can change the blood resistivity of the animal model. To compensate, blood resistivity can be measured and adjusted from the default value.
- **4. Reset to Default Probe Values: Press 4** to restore all system calibrations values to factory defaults. This function is only selectable once a parameter has been changed from the default value.

#### Optimize Catheter Position

The user is now prepared to advance the catheter into the ventricle and optimize the catheter positioning by viewing Pressure vs Volume data on the recording software, as shown in Figure 36. This is in contrast to the Pressure vs Conductance loops that are typically used in the conductance workflow. The MPVS Duo's unique ability to provide immediate feedback, users can view a live PV loop and/or perform online calculations of parameters such as stroke volume, ejection fraction, etc to ensure the data is within expectations.

Once the catheter's position is stable and the resultant PV Loop data is satisfactory, the user can confirm and enter experiment mode by **pressing** > **Next** on the keypad. This locks in the GbES and GbED used in the calculation of volume.

Similar to Conductance mode, the user can adjust the segment of their catheter (if applicable). If using a large animal catheter, **press 1** on the keypad to change the segment used. The current segment will be displayed in the text box. Segment selection should correspond to the largest segment where all the electrode rings fit within the ventricle. With a single segment catheter, only segment 1 will be valid.

The number next to "Segment Select #" is the total available segments for the catheter attached. Small animal catheters are typically single segment (1) and large animal catheters are typically multi-segment (4).

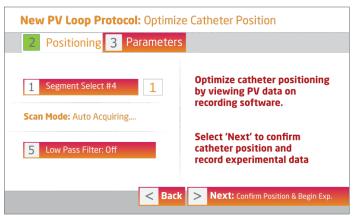


Figure 36: MPVS Duo Optimize Catheter Position

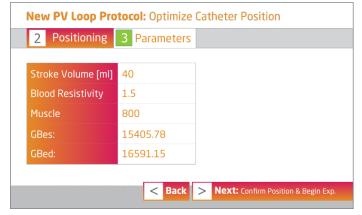


Figure 37: MPVS Duo Optimize Catheter Position - Parameters

Scan mode is set to "Auto Acquiring". This indicates that the MPVS Duo is performing auto base-line scan. The system continuously takes baseline scans, measuring GbED and GbES, calculating volume and outputting to the DAQ. The user can revert to manual mode in the settings. More on this in the following section.

The hardware low pass filter is also available in admittance mode. **Press 5** to turn the low pass filter on or off. More information is found in Section C on page 15.

The "Optimize Catheter Position" screen is tab-based. The user can **Press 3** to view the parameters or **Press 2** to view the positioning screen.

The calibration parameters entered in "New PV Loop Protocol: Calibration parameters" will be visible, as shown in Figure 37, in addition to GbED and GbES blood conductance from the baseline scan. To change the calibration parameters, please use the [</>/>] navigation keys to go back to the previous "New PV Loop Protocol: Calibration Parameters" screen.

**NOTE:** Ensure to **press** > prior to beginning any experimental protocol. This will ensure all calibration parameters are locked and the volume algorithm is executing properly.

## Optimize Catheter Position [With Continuous Auto Scan Disabled]

The same positioning screen will present however, a new, manual reading button will appear, as shown in Figure 38, if users have disabled the continuous auto scan feature in the System Settings: Settings and Options menu, as shown in Figure 16.

With the continuous auto scan feature disabled, users are required to **press 4** to perform a manual baseline scan - "Manual GbES/GbED Reading". The baseline scan will record and report the blood conductance values at end-systole and end-diastole (GbED and GbES).

These values are then used in the calculation of blood volume. Prior to pressing 4 for the first time, the volume output on the MPVS DUo will not be outputting volume. This is unlike the normal catheter positioning screen where volume is continuously being calculated and outputted. Following the manual scan the volume output from the MPVS Duo will become active and the correct LV/RV volume in microliters ( $\mu$ L) or milliliters (mL) will be output.

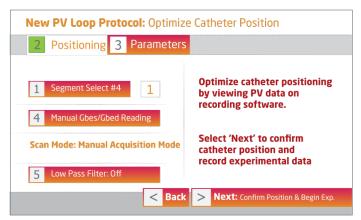


Figure 38: MPVS Duo Optimize Catheter Position - auto scan disabled

The resultant values of a manual baseline scan can be viewed by **pressing 3**, the Parameters tab, as shown in Figure 37. Negative values of Gb would indicate that a baseline scan was rejected and to try again. Erroneous Gb values are usually the result of an incorrectly placed catheter, myocardial artifacts such as PVCs, or noise interference triggering the algorithm at an incorrect point in time.

Please reacquire baseline values during the experiment if the catheter is repositioned. Once the catheter position is stable and the resultant PV Loop data from the manual baseline scan is considered satisfactory, select > **Next** to confirm the catheter position and begin the experiment.

**NOTE:** Millar recommends using the admittance protocol with Continuous Auto Scan Enabled. If disabling auto scan, users must be cautious of incorrect baseline values that can cause incorrect volumes. This is similar to previous generation systems.

#### Optimize Catheter Position [Pressure Only Catheter]

When the user has attached a pressure only catheter, the user will navigate through the menu structure the same as if operating in conductance or admittance mode. When the user reaches the "Optimize Catheter Position" page, "Scan Mode" will show as "Pressure Only", as shown in Figure 39.

**Press > Next** to confirm the catheter position and begin the experiment.

**NOTE:** "New PV Loop Protocol: Experimental Parameters" and subsequent parameters menus are not relevant for pressure only data collection.

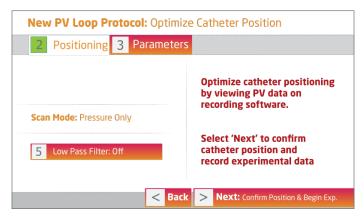


Figure 39: Optimize Catheter Position - Pressure Only Catheter

## **Experiment: In Progress**

At the "Experiment: In Progress" screen, users will have optimized catheter positioning and will be ready to record experimental data, as shown in Figure 40. Entering this screen locks the baseline scan (GbED and GbES) values. They can no longer be changed, regardless of whether continuous auto scan is enabled. This is intended to optimize data stability over the recording protocol. However, if catheter repositioning is required, press < Back to the "Optimize Catheter Position" screen to make changes.

**Press 3** to view the Parameters tab, as shown in Figure 41. The calibration parameters entered in "New PV Loop Protocol: Calibration Parameters" will be visible, in addition to GbED and GbES blood conductance values from the baseline scan. To change calibration parameters, **press < back** navigation key to go back to the previous "New PV Loop Protocol: Calibration Parameters" screen.

**Press 0** on the "Experiment: In Progress" screen to end your experiment. A confirmation screen will be displayed asking you to confirm to end the experiment. **Press >** to end the confirm end experiment, Figure 42.

#### Reference Tables

Table 2: Typical Signal Ranges

| Signal Ranges                | Mouse         | Rat             | Large Animal |
|------------------------------|---------------|-----------------|--------------|
| Systolic Pressure (mmHg)     | 90-120        | 100-130         | 70-100       |
| Diastolic Pressure<br>(mmHg) | 1-6           | 1-6             | 1-6          |
| Heart Rate (BPM)             | >450          | >350            | >50          |
| Magnitude Range              | 900-<br>200uS | 1400-<br>2600uS | 10-20mS      |
| Magnitude Am-<br>plitude     | ≥300uS        | ≥500uS          | ≥2.5mS       |
| Phase Range<br>(deg)         | 2-8           | 2-7             | 1-5          |
| Phase Amplitude<br>(deg)     | 2             | 2               | 2            |

**NOTE:** These are just suggested typical ranges for each measurement. They will vary based on animal type, weight, protocol, etc. It is best to use previous studies or protocols as references.

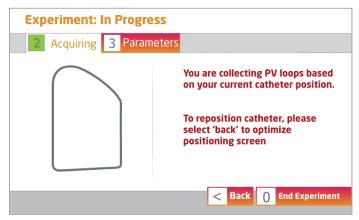


Figure 40: MPVS Duo Experiment In Progress

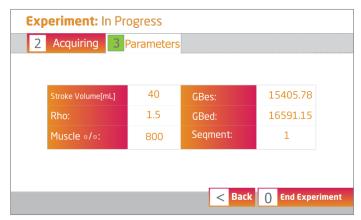


Figure 41: MPVS Duo Experiment In Progress - parameters



Figure 42: MPVS Duo End of Experiment Notice

| <b>Blood Res</b> | Mu        |     |
|------------------|-----------|-----|
| Mouse            | 1.2 ohm-m | Не  |
| Rat              | 1.4 ohm-m | No  |
| Large            | 1.5 ohm-m | Inf |
| Animal           |           | Ну  |

Muscle Properties Heart Type

Normal 800K
Infarcted 900K
Hypertropic 750K

Table 3: Default Study Parameters Table

# VI. Specifications

#### A. Environmental Conditions

The MPVS Duo is designed to operate in standard research laboratories and surgical suites. The MPVS Duo must be kept away from laboratory chemicals to ensure the electronic components operate properly.

#### **OPERATING CONDITIONS**

Temperature Range: 10-35°C Relative humidity = 0 - 90%

Altitude of Operation: up to 2000 m (6561 ft)

Pollution Degree: PD2

Overvoltage Category: Category I

#### **DISPOSAL**



Please contact Millar for disposal instructions or contact local recycler. Items with the Waste Electrical and Electronic Equipment (WEEE) directive symbol requires separate recycling. Please deliver to local recycler or contact Millar.

## **B. MPVS Duo Specifications**

| <b>General Featur</b>          | es  |  |  |  |
|--------------------------------|---|--|--|--|
| Dimensions                     | 3.1" H, 11.4" W, 7.9" D                     |  |  |  |
| Weight                         | 2.27 lb (1032g)                             |  |  |  |
| Display Size                   | 5", 800x480                                 |  |  |  |
| Display Type                   | HDMI LCD Module - Non-Touch                 |  |  |  |
| <b>Power Supply</b>            |   |  |  |  |
| MPVS Duo Power<br>Box Supply   | 9V Input                                    |  |  |  |
| Output                         | 9V DC 4.5A = 40.5W                          |  |  |  |
| Connector                      | Barrel Jack 2.5mm, Positive Center          |  |  |  |
| Power On/Off                   | Front keypad power button                   |  |  |  |
| Operational Technology         |   |  |  |  |
| Pressure                       | Solid-State MEMS Pressure                   |  |  |  |
| Volume                         | Conductance and Admittance PV               |  |  |  |
| Catheter Support               | Millar PV Catheters, Transonic<br>Catheters |  |  |  |
| Inputs/Output                  | S   |  |  |  |
| Catheter Connector             | Micro HDMI                                  |  |  |  |
| Analog Output<br>Type/Channels | BNC / 5 Channels                            |  |  |  |
| Voltage Range                  | 0 - 4.095V                                  |  |  |  |
| USB - For Update<br>use        | 1 - MicroUSB Rear / 3 Full size             |  |  |  |

# VII. Warranty & Liability

#### A. Extent

This Agreement is between Millar, Inc. ("Millar") and the purchaser ("the Purchaser") of any Millar product – software, hardware, catheters, cables and/or accessories – and covers all obligations and liabilities on the part of Millar, the Purchaser, and other users of the product. The purchaser (or any user) accepts the terms of this Agreement by using the product. Any changes to this Agreement must be recorded in writing and have Millar's and the Purchaser's consent.

## B. Copyright and Trademarks

Millar develops proprietary sensor technology, Mikro-Tip® Pressure and Pressure-Volume catheter transducers, signal conditioning hardware and Pressure-Volume acquisition systems. All Millar software, hardware, and documentation are protected by copyright, and may not be reproduced or copied in any way, nor may products be derived from or based on it. Millar retains the exclusive ownership of the trademarks represented by its company name, logo, and product names.

## C. Responsibilities

The Purchaser and any others using any Millar product agree to use it in a sensible manner for purposes for which it is suited, and agree to take responsibility for their actions and the results of their actions. If problems arise with a Millar product, Millar will make all reasonable efforts to fix them. This service may incur a charge, depending on the nature of the problem, and is subject to the other conditions cited in this Agreement.

#### D. General Limitations

Millar products are produced to high standards, and should perform substantially as described in the supplied documentation. There is a limited hardware warranty, and technical support is provided for all products.

Nevertheless, since Millar products could be affected by external factors (for instance, an environment filled with electronic noise or the computer system on which the products are run), absolute performance and reliability cannot be guaranteed. No warranty, either express or implied or statutory; other than contained in this Agreement, is made in respect to Millar products. The Purchaser therefore assumes all risks as to the performance and reliability of the products, and the results gained using them. Millar is not responsible for any problems with the computer system not directly related to Millar products. Millar neither assumes nor authorizes any person to assume on its behalf any liability in connection with the sale, installation, service, or use of its products. Millar shall not be held responsible for special, consequential, or punitive damages of any kind arising out of sale, installation, service, or use of its products.

## **E.** Millar Limited Hardware Warranty

Millar warrants that at the time of sale to the original Purchaser, the MPVS Duo series hardware shall be free from defects in materials and workmanship for a period of one (1) year from its date of shipment to the original purchaser. If there is such a defect, Millar will, at no charge and at its option, either repair or replace the equipment as appropriate.

Millar's limited warranty does not cover damage to the product from alterations, misuse, abuse, negligence, or accident.

There are no user-serviceable parts inside the cabinet and the Purchaser should make no attempts to service the hardware. There is no need for the Purchaser to open the cabinet for inspection or maintenance and doing so within the warranty period will void the warranty. This warranty applies only to the hardware specified in this document and used under normal operating conditions and within specification. It does not cover hardware modified in anyway, subjected to unusual physical, electrical, or environmental stress, used with incorrectly wired or substandard connectors or cables, or with the original identification marks altered.

Since factors beyond Millar's control may directly affect the product and the results obtained from its use, Millar or its agents or employees shall not be liable for any incidental or consequential loss, damage, or expense arising directly or indirectly from the use of this product.

# **Warranty & Liability**

The user shall determine the suitability for use of these devices for research purposes only. Therefore, the user accepts these devices subject to all the terms hereof. Furthermore, Millar does not warrant that equipment is suitable for any specific purpose, other than that explicitly stated by Millar.

Millar hereby excludes all warranties not herein stated, whether express or implied by operation of law or course of dealing or trade usage or otherwise, including but not limited to any implied warranties of fitness or merchantability.

## F. Products Supplied But Not Manufactured by Millar

Millar-supplied products of a third-party manufacturer, i.e. data acquisition systems, amplifiers, computers, monitors, and printers including associated cables, probes, accessories, etc. are not warranted by Millar. These items are covered by the original manufacturer's warranties. Please contact the manufacturer directly if you encounter a defect with a third-party product.

#### **G.** Warranty Service

To obtain service under the terms of this warranty, the Purchaser must notify Millar's exclusive worldwide distributor, ADInstruments through their local office, of the defect before the warranty period expires. The Purchaser must contact ADInstruments to obtain an RMA (Returned Materials Authorization) number and an address to which the Purchaser must ship the defective product at their own expense. The product should be packed safely (preferably in its original packaging) and have the RMA number prominently displayed on the return packaging, preferably beneath the address or shipping label. Millar will make all reasonable efforts to evaluate the product and provide service as necessary within a reasonable amount of time upon receipt of the returned product.

## **H. Technical Support**

Technical support can be provided to the Purchaser through the local support teams of Millar's worldwide exclusive distributor, ADInstruments via the following website address:

https://www.adinstruments.com/contact/technical-support

## I. Jurisdiction

This Agreement shall be governed by the laws of Texas in the United States of America, and any proceedings concerning it shall be heard and resolved in a Texas court of law.

#### J. FCC Certification

The devices comply with part 15 of the FCC Rules. Operation is subject to the following two conditions:

- 1. This device may not cause harmful interference, and
- 2. This device must accept any interference received, including interference that may cause undesired operation.

**NOTE:** This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. 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. Operation of this equipment in a residential area is likely to cause harmful interference, in which case the user will be required to correct the interference at his or her own expense.

# VIII. Symbols & Signs

The following table contains a list of possible symbols with accompanying definitions. Not all symbols are applicable to all products. The term device may refer to any Control Unit, Probe, Catheter or other Millar product.

# FAILURE TO COMPLY WITH ALL WARNINGS BOTH WRITTEN AND SYMBOLIC MAY COMPROMISE SAFETY AND/OR EFFECTIVENESS, AND VOID ANY AND ALL WARRANTIES.

| LEGEND SYMBOL | DEFINITION                                      | Millar NOTATION  |
|---------------|---|--|
|               | Attention, Consult<br>Accompanying<br>Documents | The specific directions in this manual and in the package inserts included with each device must be observed. Periodic testing of devices must be performed to assure the validity of flow measurements. |
| À             | Dangerous Voltage                               | The device must not be modified or serviced except by qualified Millar repair personnel.   |
|               | Waste Electrical<br>and Electronic<br>Equipment | This device contains material that requires special waste handling procedures for disposal. Contact Millar.  |
| C€            | CE Conformity<br>Mark                           | This device conforms to the requirements of applicable EU directives. See the Declaration of Conformity accompanying this device for specific directives.  |
| EC REP        | Authorized<br>Representative                    |  |
| RoHS Pb       | RoHS Compliant                                  | This device was manufactured in accordance with RoHS requirements for applicable hazardous material content.   |
| <del>*</del>  | Keep Dry  | Do not expose the device to excessive liquids. Dry immediately if exposed to any liquids.  |
| °C ∦ °C       | Temperature Limits                              | Do not expose the device to temperatures above or below those listed. Different temperature limits may apply to transportation, storage and use of the device.   |
|               | Manufacture Date                                | This device was manufactured on the date listed.   |
|               | Manufacture<br>Location                         | This device was manufactured by the company listed; at the location listed.  |
|               | Packaging Warning                               | Do not use if the packaging is damaged   |

# **Symbols & Signs**

| LEGEND SYMBOL | DEFINITION       | Millar NOTATION   |
|---------------|------------------|---|
| LOT           | Batch Code       | The number listed is the lot number/batch code for the device.  |
| REF           | Reference Number | The number listed is the catalog, reorder or reference number for the device.   |
| SN            | Serial Number    | The number listed is the serial number for the device.  |
|               | Humidity         | Do not expose the device to humidities above or below those listed. Different humidity limits may apply to transportation, storage and use of the device. |



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