Flow Sensor Calibration

Note: The test fluid used is blood analog fluid (BAF). Please prepare the BAF by following detailed instructions outlined in the document, 'Preparation of Blood Analog Fluid (BAF)'. For preliminary or feasibility testing, De-ionized (DI) water may be used in place of BAF as the test fluid. While all test protocols in this document are written for BAF, they are also directly applicable to DI water, when used as the test fluid.

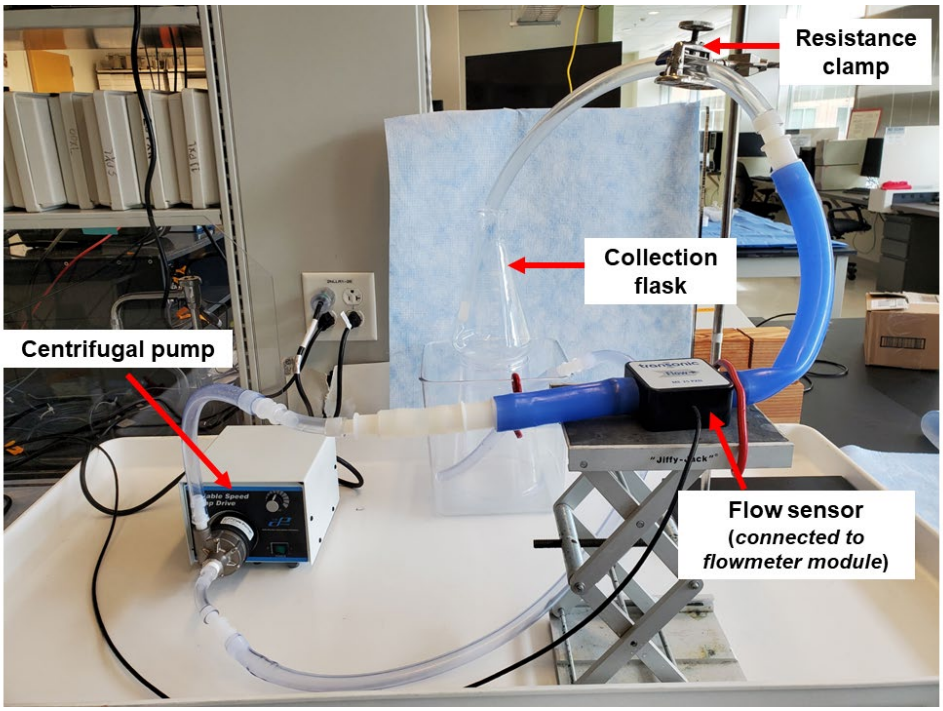
The following flowmeter-flow sensor options can be used to measure the BAF flow rates at various locations within the mock circulatory loop (MCL):

Flowmeter	**Flow sensor**
T402 (dual channel), Transonic Systems, Inc., Ithaca, NY	ME-25PXN, ME-11PXL, ME-16PXL
FM501, Carolina Medical Electronics, East Bend, NC	EP688 (size 88 mm cir)

Note: Since the EP688 flow probe requires a conductive fluid, sodium chloride (NaCl) would need to be mixed with DI water when it is used as the test fluid.

Note: This document lists specific flow sensors and flowmeter modules used in the mock circulatory loop (MCL) described in this regulatory science tool. Please note that the calibration procedure below can be adopted for all ultrasonic and electromagnetic in-line and clamp-on (compatible with flexible and semi-flexible PVC or silicone tubing) flow sensors that are intended for blood flow measurement and produce a voltage output when sensing a flow rate input. Please note that the calibration flow rate range (0 – 5 L/min) adopted below may need to be customized when using a different make/model of flow sensors.

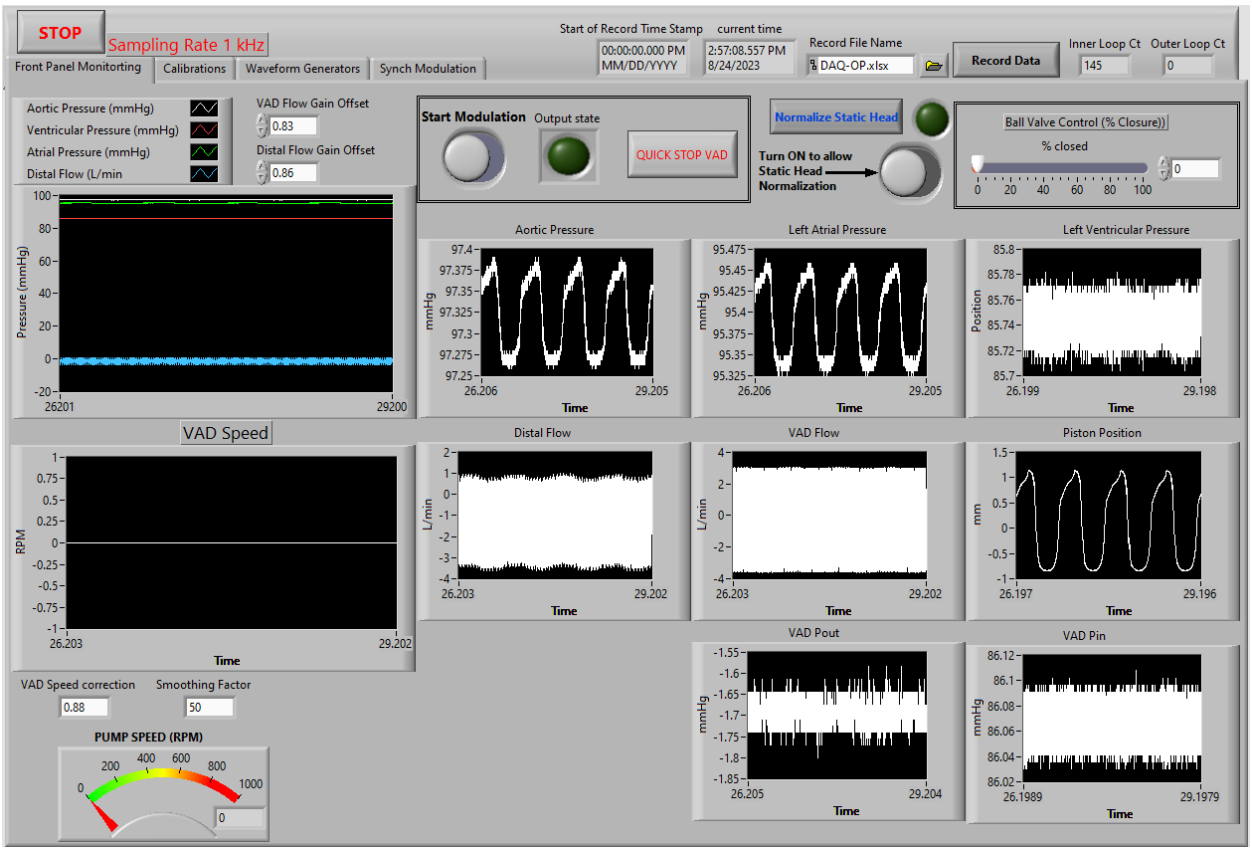
1. Connect the simplified flow loop per the diagram shown below to calibrate the flow sensors.



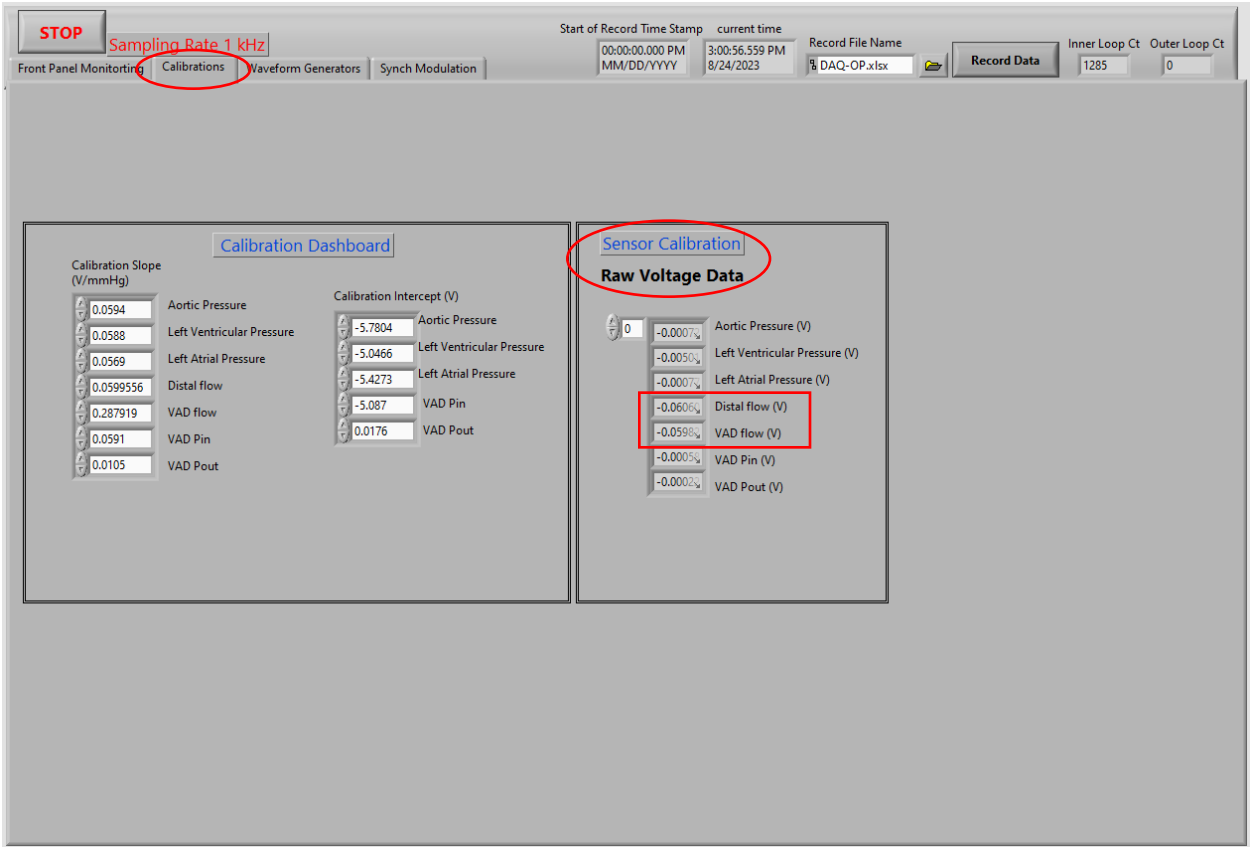
2. Make the appropriate electrical connections:
   a. Connect the flow sensor(s) to the corresponding flowmeter module(s).
   b. Connect the output channel(s) on the flowmeter module(s) to the channel(s) on the analog input (AI) module [NI-9205, National Instruments, Austin, TX] of the data acquisition system [cDAQ-9174, National Instruments, Austin, TX] per the table below.

Instrument Channel	**AI Channel on cDAQ-9174**
T402 output channel	AI 4, NI-9205
FM501 output channel	AI 5, NI-9205

   c. Connect the USB data cable from cDAQ-9174 to the mock circulatory loop (MCL) laptop.
3. Power ON all equipment.
4. Set the low pass filter on the flowmeter module to the following: T402 – 10 Hz (recommended), FM501 – 30 Hz (recommended)
5. For setting up FM501, follow step by step instructions provided in the instrument's user manual.
6. Set the sensor Gain value on the TS402 to 100%. Please refer to the instrument's user manual.
7. Open and Run the LabVIEW VI (or Virtual Instrument) that executes the custom MCL software (snapshot graphical user interface (GUI) shown below).



8. In the software, select the Calibrations tab to read the raw voltage values (Sensor Calibration > Raw Voltage Data) corresponding to the two AI channels which the flowmeter modules are connected to.



<u>Note</u>: The MCL software has been developed with the goal of evaluating ventricular assist devices (VADs) within the MCL, which is the reason for the nomenclatures, 'Distal flow' and 'VAD flow'. The MCL is designed to incorporate a maximum of 2 flow sensors at any given time of testing. Thus, in the absence of a VAD connected to the MCL, the 'VAD flow' AI channel is used to record cardiac output (CO) using the EP688 flow probe. 'Distal flow' represents the aortic (Ao) or systemic flow recorded by the ME-25PXN flow sensor.

<u>Note</u>: Please ensure that the VAD Flow Gain Offset and Distal Flow Gain Offset (in the Front Panel Monitoring tab) are set to 0.00.

9. With the resistance clamp in the fully open position, start the centrifugal pump (with variable-speed pump drive) [Model 75211-60, Cole-Parmer Instrument Co., Vernon Hills, IL] and increase the speed until the upper limit of flow rate (~ 3.5 L/min – 5 L/min) is read on the flowmeter module digital/analog display. This pump speed setting will be maintained constant for the entire flow sensor calibration.
10. Record the time (s) to fill 1 L of fluid in the collection flask. Record the raw voltage reading(s) on the analog input channel(s). Record the flow rate reading(s) displayed on the flowmeter module(s).
11. Compute and record the true flow rate, Q_{true} (L/min), as 1 L / (fill time (s) / 60).
12. For TS402, if the displayed flow rate on the flowmeter module does not match Q_{true}, adjust the Gain on the flowmeter module until a match is achieved. Re-record the raw voltage reading(s) on the analog input channel(s).
13. Decrease the flow rate in steps of 0.5 L/min by closing the resistance clamp and repeat steps 9 – 10 at each flow rate till the lower limit of flow rate (~ 0.5 L/min – 0.7 L/min) is reached.

14. Compute the slope of the voltage (V) *vs.* Q_{true} (L/min) data line for each flow sensor channel and record it (in the Laboratory Notebook and MCL software (see Calibration tab snapshot above)) as the flow sensor Calibration Slope in units of V/L/min. Record the final Gain set on the TS402. Record the settings used on the FM501. Record the date of calibration.