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Mock Flow Loop Generated Database for Characterization of Pulse Contour Cardiac Output Monitoring Systems

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Introduction

- Minimally and noninvasive cardiac output (CO) estimation methods based on pulse contour analysis of arterial blood pressure (BP) waveforms enables tracking rapid changes in CO and/or stroke volume variation (SVV) to understand patient responses to treatment.
- Testing of CO monitoring systems is generally limited to comparing the device measurements against traditional, well-established methods such as triplicate thermodilution readings of CO using central catheters.
- However, the "gold standard" thermodilution method has practical limitations when evaluating the performance of CO devices in tracking rapid changes of parameters such as SVV and CO.

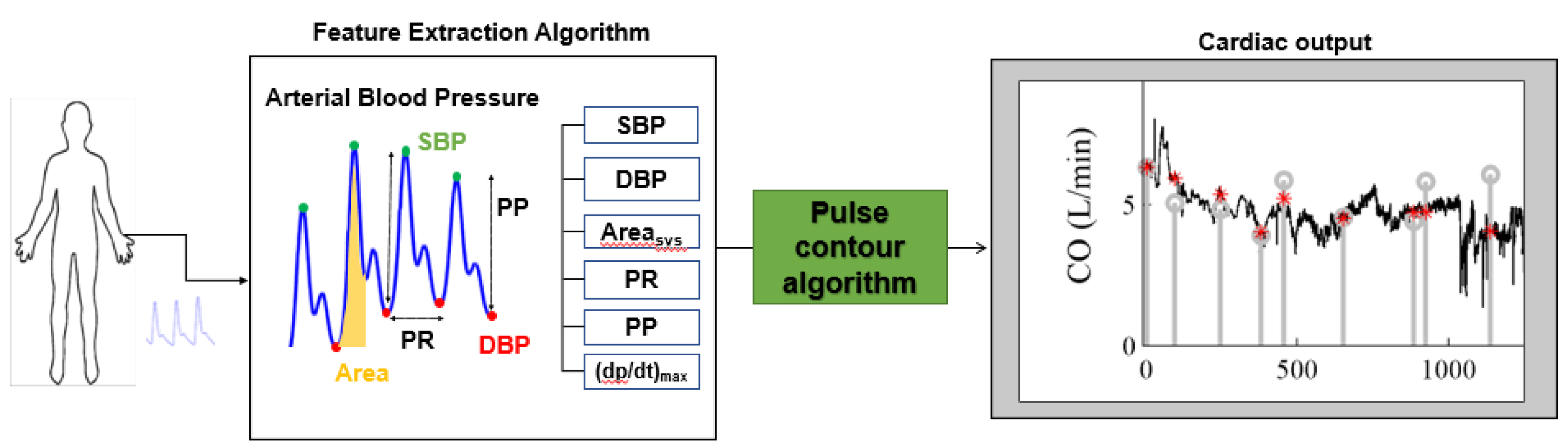


Figure 1. Block diagram illustrating the procedure for obtaining pressure-derived cardiac outputs using pulse contour analysis (PCA) method. SBP: Systolic BP; DBP: Diastolic BP; PR: Pulse Rate; PP: Pulse Pressure.

Objective

- Create a database of physiologically-relevant pressure and flow waveforms under known conditions for characterizing the following attributes of arterial blood pressure based cardiac output monitoring devices
  - ❑ CO resolution,
  - ❑ SVV resolution and,
  - ❑ CO time response

Method for Simulating Radial Arterial Pressure

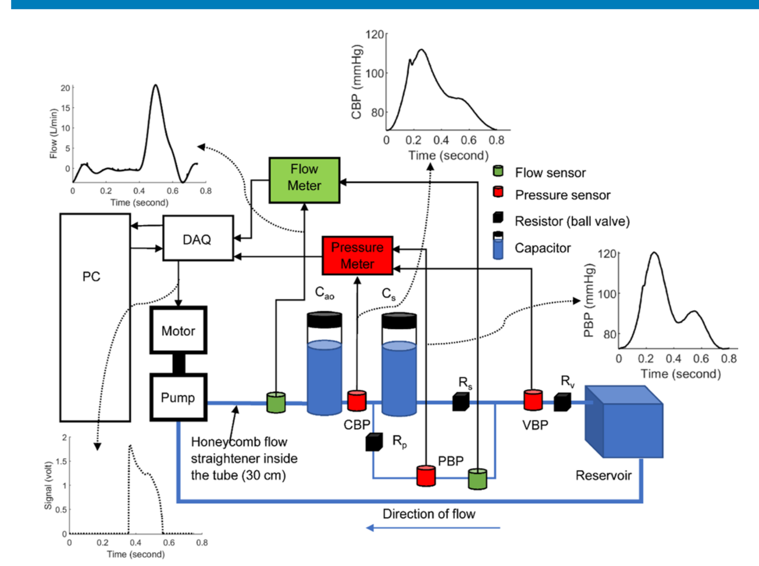
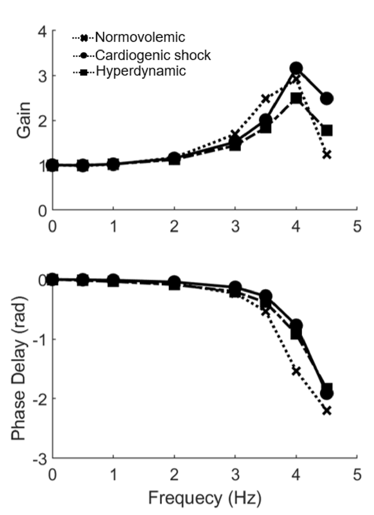


Figure 2. Schematic diagram of the mock circulation loop (MCL). CBP: Central (aortic) blood pressure; PBP: Peripheral (radial) blood pressure; VBP: Venous blood pressure; Rs: Systemic resistance; Rp: peripheral (radial) resistance; Rv: Venous resistance; Cao: Aortic compliance; Cs: Arterial compliance.

- **Mock Circulatory Flow Loop (MCL):** We configured the physical elements (capacitors, resistors, tube lengths) to simulate three hemodynamic states including Normovolemic (NV), Hyperdynamic (HD), and Cardiogenic shock (CS).



- Bode plots are obtained by performing sinusoidal frequency sweeps from 0.5 Hz to 4.5 Hz using the MCL for each hemodynamic state (**Figure 3**). Plots show the relationship between the aortic pressure and peripheral radial pressure. These relationships were compared against those reported in the literature.
- The MCL generated aortic flow and radial pressure waveforms under each hemodynamic state (**Figure 4 and Table 1**) with high repeatability.

Figure 3. The MCL characterization results. Central aortic to peripheral pressure transfer functions for the normovolemic, cardiogenic shock, and hyperdynamic states.

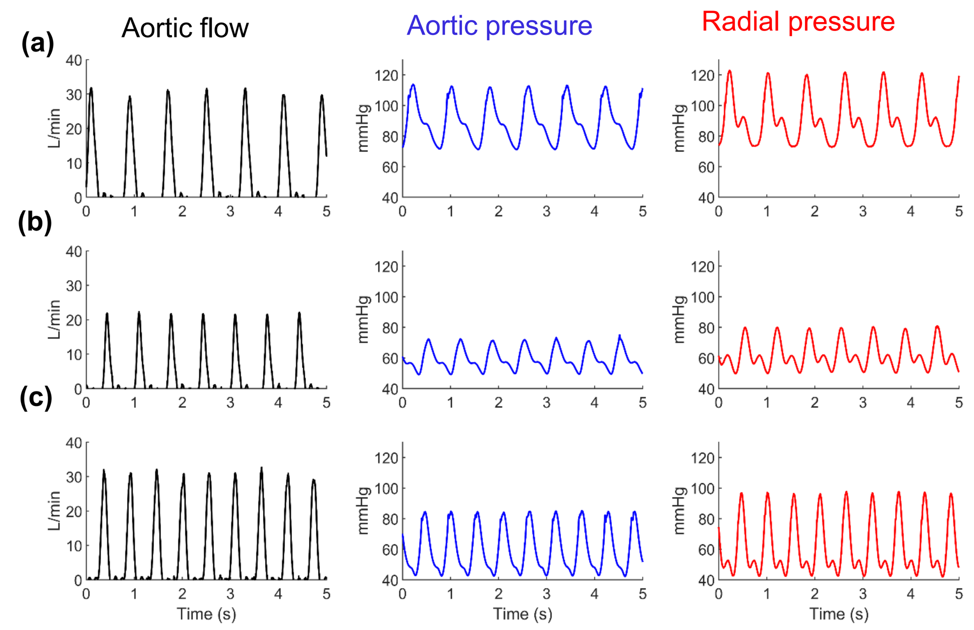
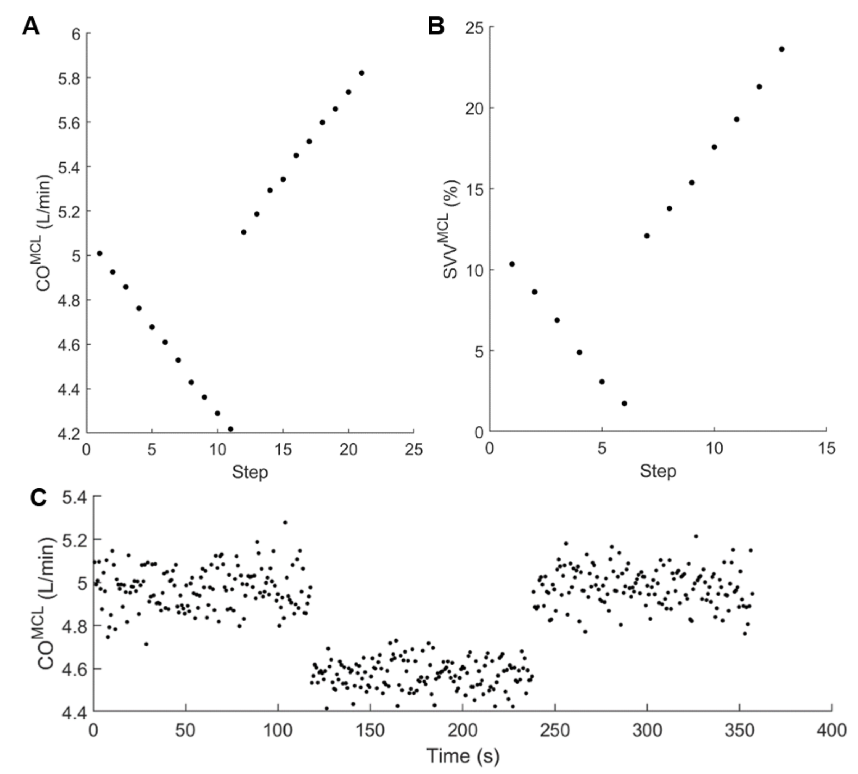


Figure 4. Baseline flow and corresponding pressure waveforms produced by the MCL for **(a)** normovolemic, **(b)** cardiogenic shock and **(c)** hyperdynamic states. Shown only five seconds of data.

	NV	CS	HD
PR (BPM)	75	90	110
CO (L/min)	4.97	3.03	6.93
RF (mL/min)	122	75	93
Aortic Pressure (mmHg)			
Systolic	113.3	72.7	84.1
Mean	89.2	59.7	59.5
Diastolic	71.7	49.7	42.6
Peripheral Radial Pressure (mmHg)			
Systolic	122.2	80.2	96.1
Mean	90.4	62.4	61.1
Diastolic	73.5	50.4	42.4
Venous Blood Pressure (mmHg)			
Mean	9.5	10.7	10.2
Total Resistance (mmHg.min/L)	16.00	16.17	7.12

Table 1. Range of physiologic parameters produced by the MCL for each hemodynamic state. RF: Radial Flow.

Dataset for the Normovolemic State



- Stepwise change in the MCL flow was simulated and datasets were for characterizing CO resolution and SVV resolution of pressure-based CO systems.
- Rapid change in MCL flow rate was simulated for characterizing CO Response time of a system

Figure 5. Normovolemic datasets for quantifying three dynamic attributes of pressure-based CO monitoring systems. Figure shows normovolemic datasets for (**A**) CO resolution, (**B**) SVV resolution (respiration rate of 20 times/min), and (**C**) CO response time (beat-to-beat flow data are shown).

Example Application of the Database

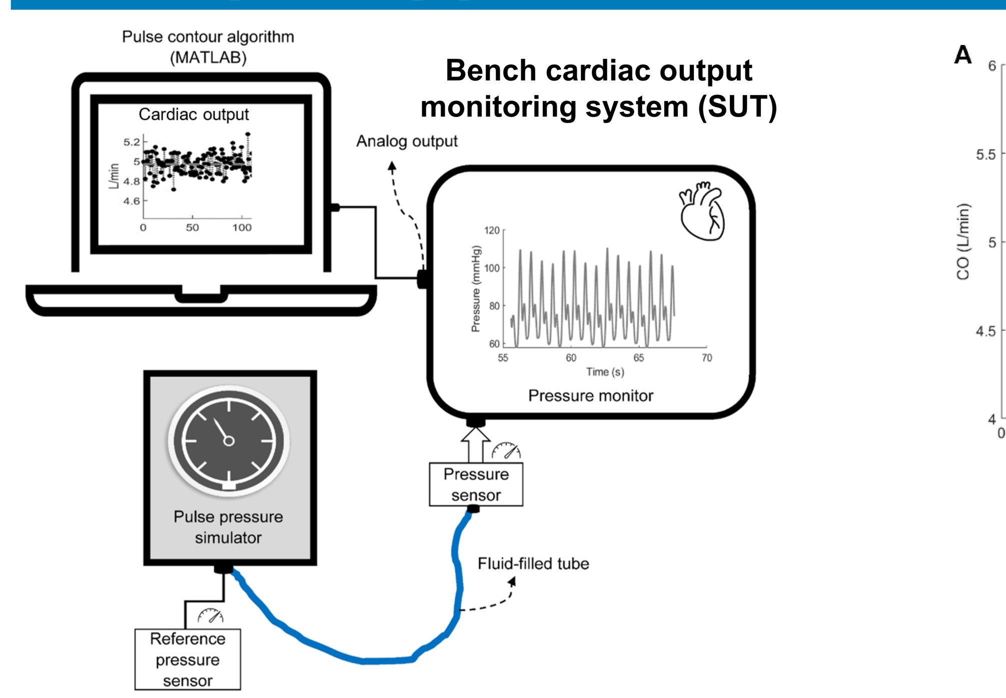


Figure 6. The schematic diagram of the setup for evaluati bench pulse contour CO monitoring system. Pulse pres simulator generates the peripheral pressure waveforms from the MCL. The pressure-based cardiac outputs are estimated by applying a pulse contour algorithm to the pressure outputs from the monitor. The system consists of a fluid-filled tube, a disposable pressure transducer, a pressure monitor, and a pulse contour algorithm coded in MATLAB.

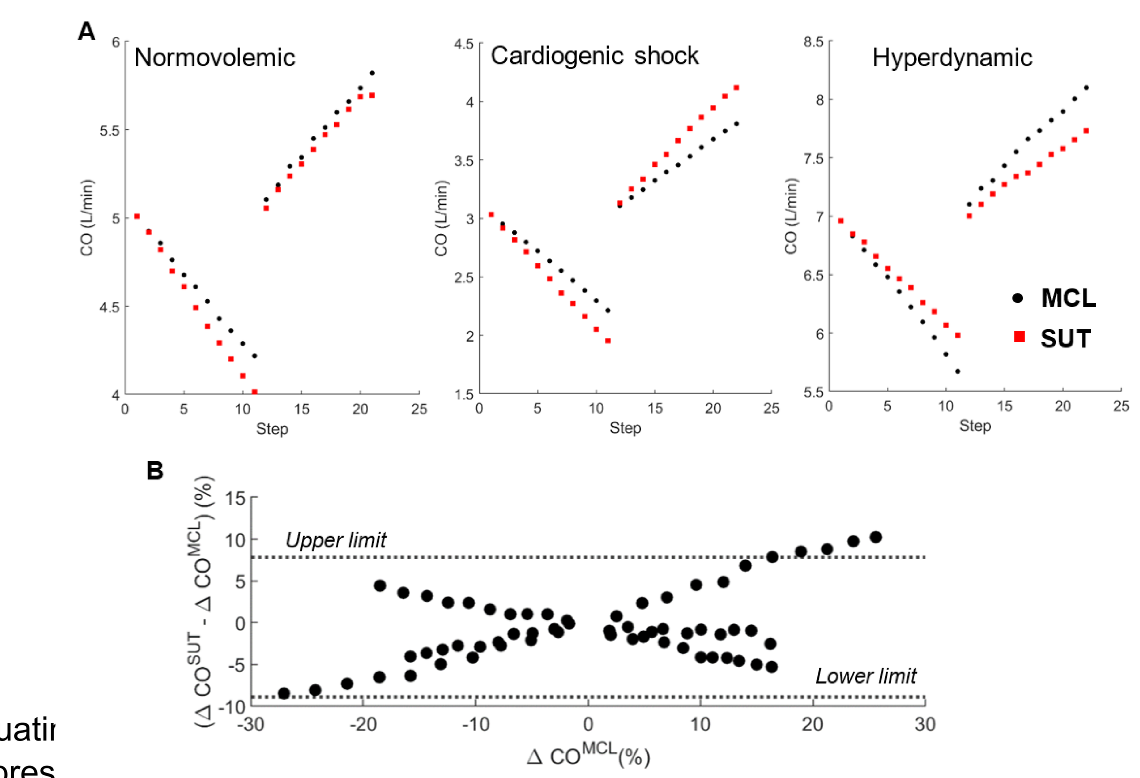


Figure 7. CO resolution assessment of the SUT. **(A)** Pressure-based CO measurements by the benchtop pulse contour CO monitoring system under test (SUT) vs. MCL flow data for each hemodynamic state. **(B)** Plot of the difference between ΔCO^{MCL} and ΔCO^{SUT} for all three hemodynamic states.

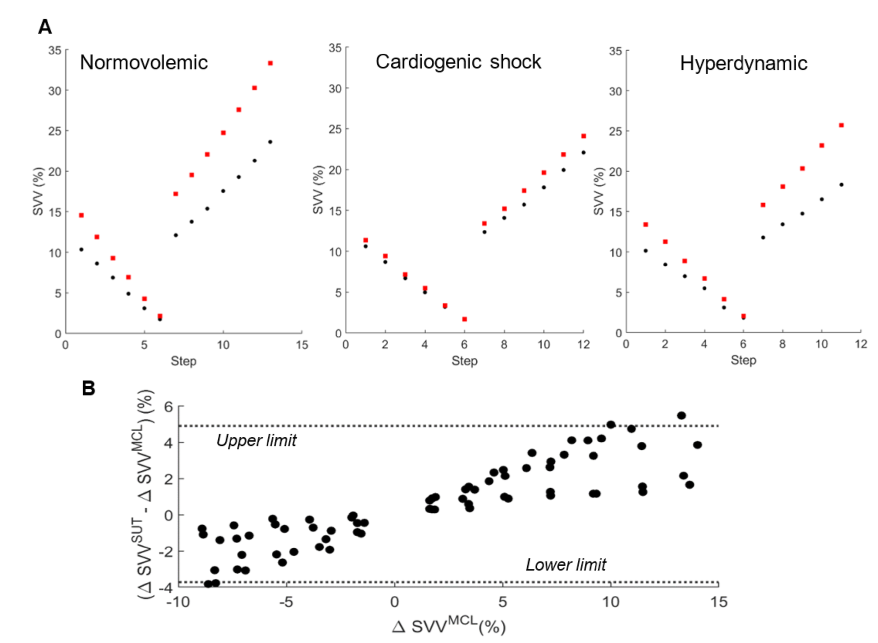


Figure 8. SVV resolution assessment of the SUT. (**A**) Pressure-based SVV measurements by the benchtop pulse contour CO monitoring system under test (SUT) VS. SVV derived from MCL flow data for each hemodynamic state. (**B**) Plot of the difference between ΔSVV^{MCL} and ΔSVV^{SUT} for all hemodynamic states

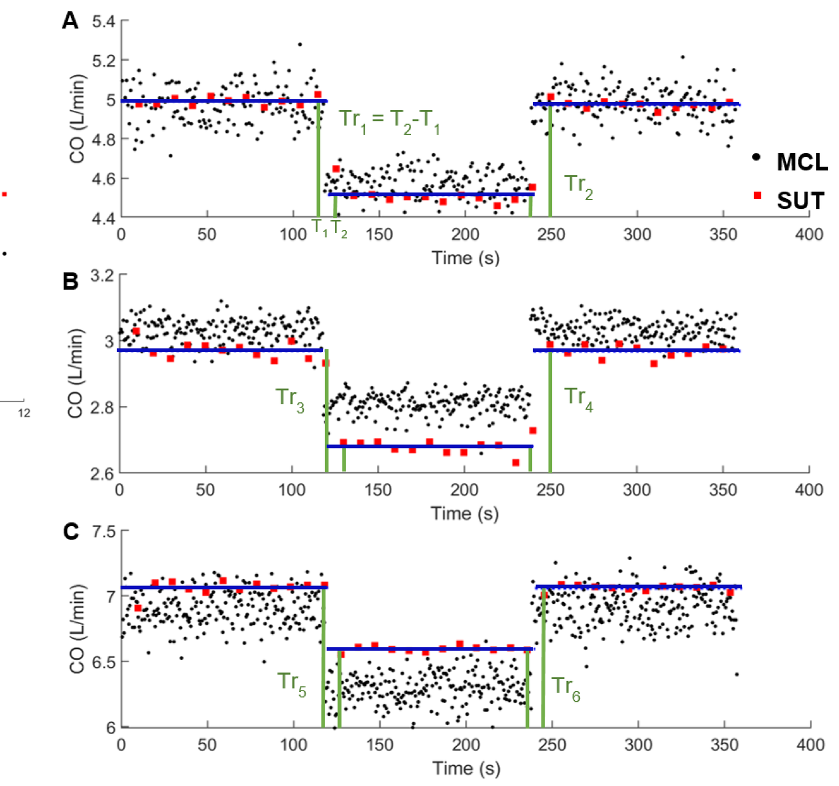


Figure 9. CO response time assessment of the SUT. (**A**) normovolemic (**B**) cardiogenic shock, and (**C**) hyperdynamic state. Horizontal lines display average measurements by the SUT in each step. The average CO response time of the SUT [Tr_{SUT} = avg ($Tr_{1,..,6}$)] is 10 seconds.

Uncalibrated CO = (MAP/60) × ln(SBP/DBP)×PR
Calibrated CO (CO^{SUT}) = k × Uncalibrated CO

Where k is the calibration factor from MCL flow data.

$\Delta CO_j (\%) = 100\times(CO_j-CO_1)/ CO_1$

$\Delta SVV_j (\%) = SVV_j-SVV_1$

$SVV (\%) = 100\times(SV_{max}-SV_{min})/(0.5\times(SV_{max}+SV_{min}))$

where "j" is the step number.

Lower limit (LL) = b^- - 2×SD

Upper limit (UL) = b^- + 2×SD

Where b^- and SD are the mean and standard deviation of the difference between ΔCO^{SUT} and ΔCO^{MCL}.

Characterization Results

- **CO resolution:** 95% LoA (limits of agreement) were UL: 8.4% (95% CI: [6.1%, 9.9%]) and LL: -9.1% (95% CI: [-11.0%, -7.2%]).
- **SVV resolution:** the 95% LoA were UL: 5.0% (95% CI: [4.0%, 5.9%]) and LL: -3.8% (95% CI: [-4.7%, -2.9%]).
- **CO response time:** 10 seconds for the system.

Conclusion: Database presented here may be used to quantify key dynamic characteristics of pressure-based hemodynamic algorithms. This will support a more comprehensive assessment of these devices while assuring that valid scientific evidence supports the performance of devices used in the care of critically ill patients.

Limitation: While we tuned the MCL to simulate the realistic transfer functions between pressures and flows at different locations, it does not simulate the nonlinear relationship between arterial compliance and pressure, which can affect the testing of certain algorithms.

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