

Title: An open source, non-invasive novel assembly for automated real-time monitoring of continuous bladder irrigation.

Running title: Open-source automated CBI monitoring.

Introduction: Continuous bladder irrigation (CBI) is a common intervention following endoscopic manipulations of the GU tracts to prevent clot retention in the early postoperative phase, or for patients with gross hematuria from other causes (benign prostatic hyperplasia, bladder tumor, etc). During CBI, effluent colour is assessed subjectively by attending staff, and adjustments are made to input flow rate to lighten the reddish hue to titrate an adequate irrigative force within the bladder to prevent excessive hemostasis and consequent clot formation. However, repeated subjective assessments tend to be labour intensive, lack standardization, and may be unresponsive to changes in effluent color [1]. Tools such as Hemostick® [2] and the Hematuria Grading Scale [3] offer one solution but still rely on manual assessments to make adjustments to CBI flow.

In this letter, we present an open-source, inexpensive assembly to construct an automatic CBI monitor, featuring 3D-printed enclosures and consumer-accessible hardware (<https://github.com/malyalar/CBI-monitor>). We secondarily validated the colorimetric function of the device in a clinical setting in twenty patients on CBI with agreement analysis versus a human raters. Other groups have developed automated CBI solutions [4-6], but to our knowledge, none are available on-market, and none have opened their designs for inspection and further development.

Open source medical devices carry several advantages over traditionally developed hardware, which include but are not limited to: improved pace of innovation; modifiability for more specific uses; improved repairability; lower cost; and low potential for vendor lock-in [7].

Methods: The *hematuria monitor* (HM) is built with openness and expandability as core principles. The device uses the Arduino open-hardware platform, a popular, easy-to-use development environment that makes it ideal for prototyping devices. HM was also built with secondary goals of being easy to construct, and to keep potential cost-per-unit low. Instructions available on our published *openhardware.io* page include editable CAD files for 3D-printable enclosures (**Figure 1**), circuit schematics, code, and data from validation.

The processing unit for HM is an Arduino Nano V3.0. The spectral sensing module is a white LED mounted opposite an AS7262 spectrophotometer, passing incident light through a catheter outflow tube latched inside the spectrophotometer shroud (**Figure 2**), resulting in a reading of transmitted light at the spectrophotometer inversely proportional to the level of hematuria.

The current implementation of HM uses a lookup table to estimate outflow colour based on readings from the violet (450nm) wavelength of light, as internal tests demonstrated the greatest sensitivity/reliability of this wavelength on the selected spectrophotometer to differentiate grades of hematuria (not shown). Flow rate is detected through rate-of-change calculations from a load cell from which the catheter outflow bag is mounted. Readout data is displayed via a small screen.

We conducted initial laboratory validation of the HM with known serial dilutions of known-hematocrit pig's blood, sealed within portions of catheter outflow bag tubing (**Figure 3**). 8 dilutions were measured in quintuplicate, ranging from 0-1mL in 10mL saline. The range of these dilutions were corresponding to Lee et al.'s Hematuria Grading Scale (HGS) values of 0-10 [3]. A correlation coefficient analysis was undertaken. We also proceeded to validate the

colorimetric function of the device in a ward setting, on twenty patients undergoing CBI. 40 pictures were taken of the spectrophotometer shroud clamped on CBI effluent tubes beside a copy of the HGS, which were rated by three blinded raters on a scale of 0 to 10. These were simplified to an ordinal score from 0 to 5 to match the device readout. The mode of the three human-read grades was taken and compared with device readouts via weighted Kappa. Testing was done under UBC Clinical Ethics Board certificate H20-02012.

Results and Discussion:

The current iteration of the HM can be used completely externally to an existing CBI setup, and is notably compact. 3D print files are offered in varied formats for edit-ability in different software. The device can continuously monitor flow rate. The total lowest-estimate cost for the HM is approximately 45 CAD at the time of writing (**Table 1**). **Future implementations of the device would include components to control irritant flow rate and other modules that may increase the build cost.** **Figure 2** includes pictures of an exemplar build of the HM.

In laboratory testing, the HM achieved a correlation coefficient of 0.97, $p < 0.001$ (Figure 3). In clinical validation, the hematuria grade readouts from the HM (mean, SD $1.95/5 \pm 1.51$) achieved a Kappa statistic of 0.822, $p < 0.001$ (**Table 2**), indicating high agreement with human raters (mean, SD $1.62/5 \pm 1.14$).

A hematuria monitor such as the one proposed may help increase patient comfort by reducing clot retention and catheter blockage during CBI, as well as potentially reducing the more significant complication of a perforated bladder from unrestricted inflow into an outflow blocked catheter. HM lends itself well to future CBI automation, as we have demonstrated its ability to distinguish grades of hematuria analogous to human readouts on standard scales, and providing a means to control the inflow rates to the CBI system based on HM readings may allow for improved patient safety, comfort, and reduction in complications, as well as reducing administrative burden by attending staff. The open-source nature of the device lends itself to easy extensibility, low cost, and feature-richness.

Regulatory approval challenges are a legitimate concern for open-source medical devices.

However, during the COVID-19 pandemic, effort and interest in establishing pathways for open-source devices to play a larger role in healthcare has flourished. Canadian examples of efforts in this space include Glia Medical's research-validated 3D-printable stethoscope [8], and COSMIC Medical's Project Bubble Helmet [9].

Future steps include the addition of a wireless communications module to output alarms to a user's cellphone, motor control of flow-rate to automate the CBI process fully, and exploration of regulatory approval processes.

Key messages:

1. There is **an opportunity** in medical device development that may be addressed by open source development strategies.
2. Properly assembled consumer electronics-based sensors can be capable of differentiating grades of hematuria for research purposes in laboratory or clinical settings.
3. We have **demonstrated the development of an open-source device** to monitor CBI that may serve as a platform for refinement or development of future adjuncts in the name of increasing patient safety.

Table 1. Bill of Materials (BOM).

	Component	Quantity	PPU
Central unit	Arduino Nano V3.0-based CH340 Chip Atmega328p Board, with USB Cable	1	\$5.00
	Momentary push buttons (optional)	3	\$1.00
	1.8" TFT display module ST7735	1	\$9.00
Spectral sensor	AS7262 6-channel visible light spectral sensor breakout	1	\$20.00
	White LED	1	\$0.1
Load cell	TAL220 beam-type load cell	1	\$5.00
	HX711 load cell amplifier	1	\$1.00
Connectors, misc.	PLA filament for enclosures	100g	\$1
	Resistors, dupont connectors, solder, other consumables	n/a	\$1
Total			\$45.05

Table 2. Results of Clinical Validation.

	Average \pm standard dev. ($n = 40$ subjects)	Kappa	p-value
Human grades (0 to 5)	1.65 ± 1.95	0.822	<0.001
Machine grades (0 to 5)	1.11 ± 1.51		

Figure legends:

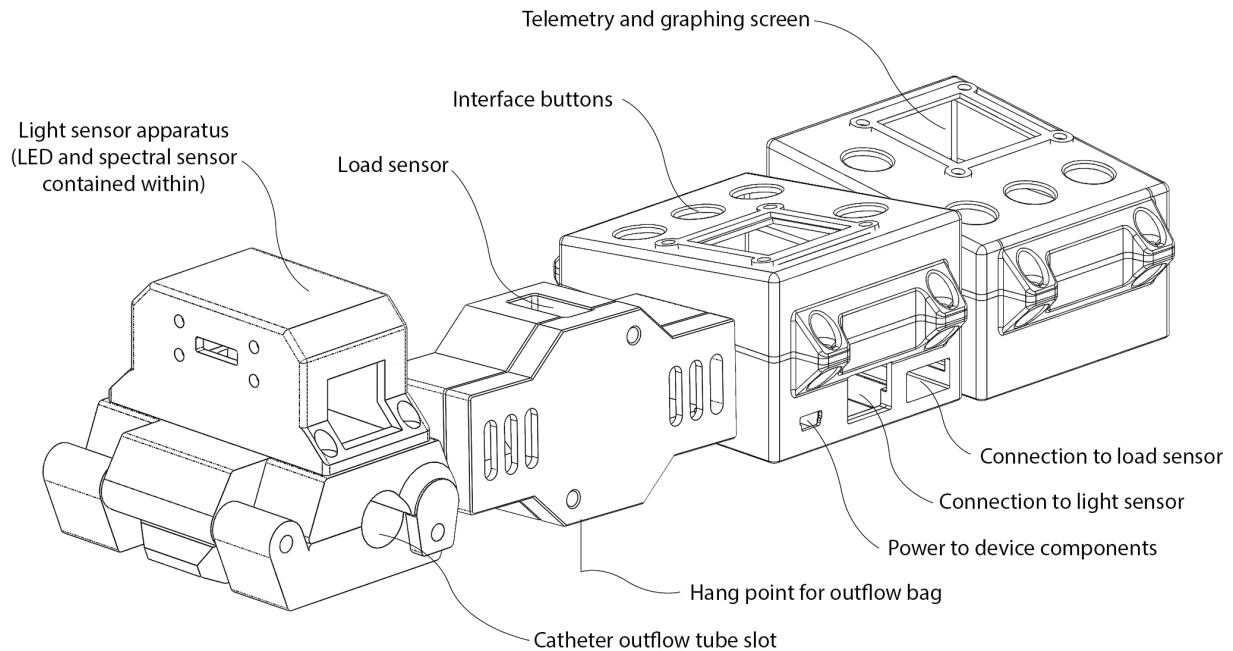


Figure 1: Wireframe diagrams of 3D printable enclosures of the base model, comprising three components. 1) A main body with the Arduino Nano microprocessor, with slots for three buttons, a switch, and a telemetry screen. Next, interfacing with the Arduino through wired connections: 2) a light sensor apparatus comprising a white LED and the AS7262x spectral sensing unit mounted opposite to each other within a folding shroud that clips over a catheter outflow tube, and; 3) a bar-type load sensor (TAL220) with built-in HX711 load cell amplifier with a hang point for the outflow bag.

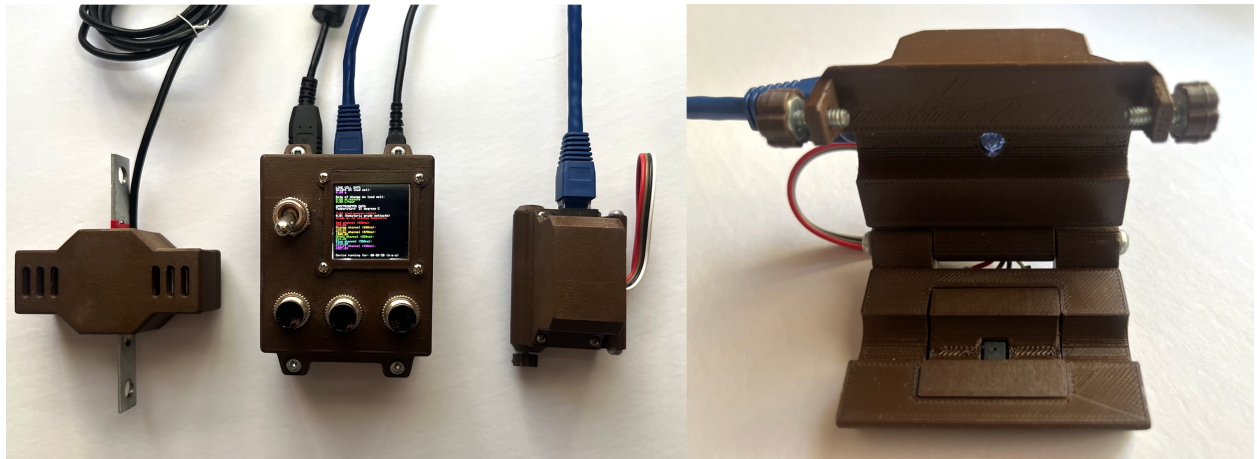


Figure 2. Demonstration of function of an example build. In view: spectrophotometer shroud and main processing unit.

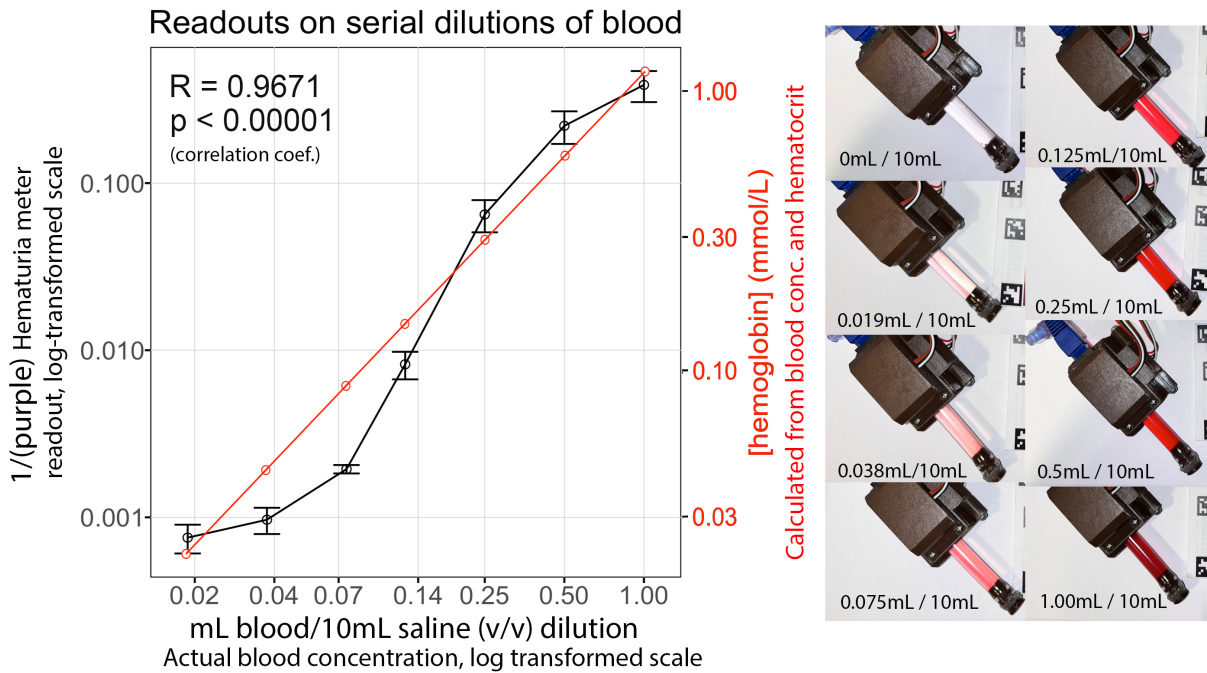


Figure 3. Validation of hematuria monitor across differing concentrations of blood in CBI

effluent. Eight known volume/volume (mL blood to 10 mL saline) dilutions of thawed, heparinized pig's blood in saline were prepared and placed within the spectrophotometer shroud.

On the left y-axis, the internal device calculation based on transmittance at the purple-light wavelength is shown (arbitrary units). As less purple light reaches the spectral sensor, the device estimates there is more hemoglobinuria. Internal arbitrary hemoglobinuria estimates from the device were recorded and plotted alongside values of known dilutions (x-axis is volume/volume dilution, red y-axis is hemoglobin concentration based on volume and hematocrit), and a correlation coefficient is shown. An image of the dilution tubes is included for reference to assess the subjective color range of the tubes.

References:

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