HHS Public Access

Author manuscript

Conf Proc IEEE Eng Med Biol Soc. Author manuscript; available in PMC 2020 January 28.

Published in final edited form as:

Conf Proc IEEE Eng Med Biol Soc. 2018 July ; 2018: 1592–1595. doi:10.1109/EMBC.2018.8512582.

A Conductance-Based Sensor to Estimate Bladder Volume in Felines

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Abstract

New research tools are essential to help understand the neural control of the lower urinary tract (LUT). A more nuanced understanding of the neuroanatomy of bladder function could enable new treatment options or neuroprosthesis to eliminate incontinence. Here we describe the design, prototyping and validation of a sensing mechanism for a catheter-free fluid volume estimating system for chronic neurophysiological studies of the lower urinary tract and ambulatory urodynamics. The system consists of two stimulation electrodes, one sensing anode, and a microcontroller for control and recording. The packaged device is small enough to be surgically implanted within the bladder lumen, where it does not inhibit bladder function nor inflict trauma. Benchtop evaluation of the conductance-sensing system in simulated bladder-like conditions has demonstrated that the system can predict intra-vesical fluid volume to within ±20 *mL* (40%) from 0 to 50 mL with root-mean-square error of 11.32% over the same range. These results indicate that conductance-based volume sensing of the urinary bladder is a feasible method for real-time measurement.

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I. Introduction

Neural control of the lower urinary tract (LUT) in health and disease is not well understood [1]. Bladder pressure and volume are biomechanical variables that reflect LUT responses to peripheral nerve activity and understanding these variables and their response to neural activity during ambulation and activities of daily living is essential to future mechanistic investigations of autonomic control of the LUT. Current studies are limited by the necessity of catheter placement because they require acute and/or anesthetized preparations to avoid intractable bladder and urethral irritation. These preparations confound data acquisition and are entirely unrealistic for chronic applications. Systems exist to measure bladder pressure in ambulating animals via a microtip catheter implanted across the bladder wall [2]. However, they do not measure bladder volume and constrain animals when using the external recording system.

Furthermore, laboratory-based urodynamics is the current standard for diagnosing voiding dysfunction but provides only a snapshot examination during retrograde bladder filling and resultant voiding. [3] Because of its brief nature and nonphysiological conditions, it can be difficult to reproduce symptoms during urodynamic examination. [3,4] Ambulatory urodynamics, performed using indwelling catheters (Fig. 1) for continuous measurement of pressure and portable ultrasound for snapshot measurements of volume [3,5,6], has the potential to provide bladder function measurement during activities of daily living. However, it has not gained clinical popularity, in part, due to the need for extended catheterization and the lack of real time volume measurement [3].

Therefore, there is a critical need for catheter-free sensing that enables real-time bladder volume estimation in both research and clinical applications. This technology will significantly enhance data collection in neurophysiological studies of autonomic control of the LUT as well as in evaluation and diagnosis of bladder dysfunction in clinical settings. Previously, conductance can be used to estimate bladder fluid volume [7]. This method was susceptible to changes in concentration of the intra-vesical solution, likely due to changes in solution conductivity. To address this vulnerability, we propose a new sensor topology which measures both intra-vesical conductance and conductivity, to compensate for changes in concentration. The sensor form factor was designed for use in_feline bladders. This technology enables real-time, catheter-free volume sensing for animal studies of the LUT, and provides a foundational design allowing translation to clinical applications.

II. Sensor Design

A. Design Concept

The sensor consists of two cathodes and a common anode (Fig. 2). Conduction between the electrodes occurs via ionic polarization, where the total cathodic current is proportional to the total number of ions. Therefore, the sensor current is determined both by the volume of urine (number of ions) and the concentration of urine (density of ions). Further, the cathode-anode distance $D_{C1\text{-}A}$ determines the volume in which ionic current flows; sensor sensitivity is therefore proportional to $D_{C\text{-}A}$. The sensor is designed with $D_{C1\text{-}A} \gg D_{C2\text{-}A}$ so that I_{C1} current flows through a roughly constant, small volume. Therefore, I_{C1} is determined solely

by urine concentration, while I_{C2} is proportional to both urine volume and concentration. A corrected sensor current, I_S, can be computed simply as

$$\frac{I_{C2}}{I_{C1}} = I_S. \quad (1)$$

The dependence of I_S on urine concentration is greatly reduced by this calculation, although error in the I_{C1} measurement is amplified. To limit the magnitude of this error, I_{C1} is truncated to a fixed resolution (binned), and the sensor response is linearized using a 2D look-up table (LUT) discussed below.

The overall accuracy of this sensor is primarily limited by the physical size constraints imposed by the feline bladder environment. Because the sensor is an implant, it must be small enough to minimize discomfort or trauma in the feline, but large enough to provide useful bladder volume measurements from C_2. Existing devices can distinguish between an empty and full bladder [6], failing however to detect a partially-full bladder. The sensor design in Fig. 2 offers the advantage of volumetric knowledge between empty and full states. Because there is widespread variation in bladder capacities, bladder fullness must only be quantized within +/− 25% of full bladder capacity to offer meaningful clinical insights. A minimum accuracy benchmark of ±20mL is sufficient to divide bladder fullness into 4 quartiles, assuming 50 mL capacity for felines. Thus, sensed volumes are ultimately used to determine if the bladder is empty (0 mL), less-than-half, more-than-half, or at full physiologic capacity.

B. Prototype Fabrication

Prototypes were fabricated for validation of the sensing approach (Fig. 3). Sensors comprised of 2-by-2 mm electrodes (0.5mm diameter stainless-steel 314, 200 mesh, Alfa Aesar), wire for measurement connections (A-M Systems, Inc. 0.055” diameter coated stainless steel), and medical-grade silicone (VST-50HD Silicone Elastomer, Factor II, Inc.) to represent the sensor body’s form factor. Each prototype uses a three-electrode design, with two cathodes and one anode. Each electrode is soldered to a coated stainless-steel wire, which is sutured through the silicone body of the prototype and connected to the measurement circuit.

As urine contains both chloride and sodium ions, the sensor uses Platinum-Iridium for the electrode material, due to its extremely robust corrosion resistance properties. All electrode-to-wire solder joints were covered in silicone and cured to the sensor body to minimize any effects on the measurement that may have occurred due to corrosion of the solder material.

III. Experimental Results

A benchtop test phantom was used to test the performance of the prototypes (Fig. 4). To simulate the environment of a bladder, the prototypes from Fig. 3 were inserted into a 5” white latex balloon and submerged into a bath of 5% saline. A Kent Scientific GenieTouch™ syringe pump infused and withdrew a flow rate-controlled volume of cat

urine or saline into the balloon, while an Arduino Due stimulated the cathodes with a 500 Hz, 3.3V TTL square wave and recorded the anode voltage with a 12-bit ADC input. A 2.7 kΩ sense resistor measures the current passed through the fluid, and subsequently, the conductance.

A commercial conductivity probe was used as a calibration reference, with a resulting conversion factor of 1.89 (Fig. 5). The prototype shows sufficient ability to distinguish between changes in concentration, indicating that the conductivity correction described in Section II is feasible. A calibrated look-up table (Table 1) converts sensor output voltage (Fig. 6) to linearized estimated volume (Fig. 7).

The look-up table (Table 1) is comprised of two parameters: conductivity and output voltage. Expected values of conductivity C_1-C_m are discretized into bins along the rows. The average of the corresponding volume-dependent voltage response curve at each conductivity value populates a discretized transfer function vector along the columns. Subscripts n,m denote the granularity of the look-up table with respect to conductivity and volume. For a given conductivity value and conductance electrode voltage, a calibrated volume estimate is returned.

A set of linearized predicted volumes from a sample of cat urine (Fig. 7) demonstrate the feasibility of the sensor approach. The estimated volume outputs return values to within $\pm 20 mL$ for the bladder volume range of interest (550mL). Each of the datasets nears the $\pm 20 mL$ error limit towards high volumes, however this is expected based on the visible drop in sensitivity at maximum infused volume in Fig. 6. I_{c2} is directly related to the total number of ions polarized by the electric field between C_2 and A, so an increase in $D_{c2\text{-}A}$ lengthens the volume of fluid affected by the field, polarizing more ions. Because the strength of the resultant fringe fields diminishes rapidly with distance from the sensor body, sensitivity depends strongest on $D_{C2\text{-}A}$. However, $D_{C2\text{-}A}$ is constrained by the physical limitations of the cat bladder (Table II), so this loss of sensitivity at high volumes is unavoidable.

Look-up table granularity limits the resolution of the sensor but reduces the memory and computation requirements as shown in Fig. 8. Discretization of the volume elements should be kept at its maximum of one point per bin to achieve the necessary resolution. Even rounding to two points per bin yields error outside of the acceptable $\pm 20 mL$ benchmark.

Granularity in conductivity also heavily affects the accuracy of the linearized output. However, recent data implicates a linear sensor output response with respect to conductivity (Fig. 9), possibly enabling the removal of the conductivity axis of the look-up table. Because the span of the C2 output response over the full-scale volume range is consistent under the urine conductivity range of interest, in this case the transfer function vector F for any conductivity can simply be expressed as an offset from a single reference vector F_{ref} by the difference in C_1 output voltage V_{C_1} :

$$F = F_{ref} + \Delta V_{C_1}. \tag{2}$$

Fig. 9 shows linearity in conductivity values out to more than twice the upper bound of the urine conductivity range. Fig. 10 shows linearized volume estimation error from offset correction of a reference transfer function vector, demonstrating performance within the required error margin. The reference vector was built from recordings of sensor response in cat urine (21.31 mS/cm), and the comparison data is from 4% saline (60.85 mS/cm). Measurements of linearity over the range of interest will determine the feasibility of this approach.

IV. Conclusion and Ongoing Work

The bladder volume sensing system was designed, prototyped, and tested in benchtop phantoms simulating a feline bladder model to within to the specifications of Table 1. The intra-vesical volume predictions agree with the known infused vesical volume to within the $\pm 20 mL$ accuracy requirement, indicating the feasibility of conductance with conductivity correction as a novel approach to catheter-free bladder volume estimation. A catheter-free bladder volume sensor would improve neurophysiological studies of the LUT and provide a translatable technology platform for clinical applications.

Acknowledgments

This research is funded by the NIH SPARC program.

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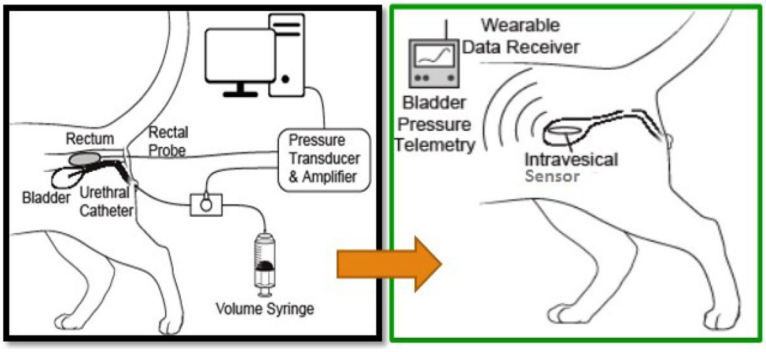

Fig. 1:

(Left) Standard urodynamics method. A urethral catheter is used for pressure monitoring and for fluid infusion. A rectal balloon catheter is used to measure abdominal pressure (Right) The proposed sensor enables wireless, catheter-free bladder volume and pressure measurements.

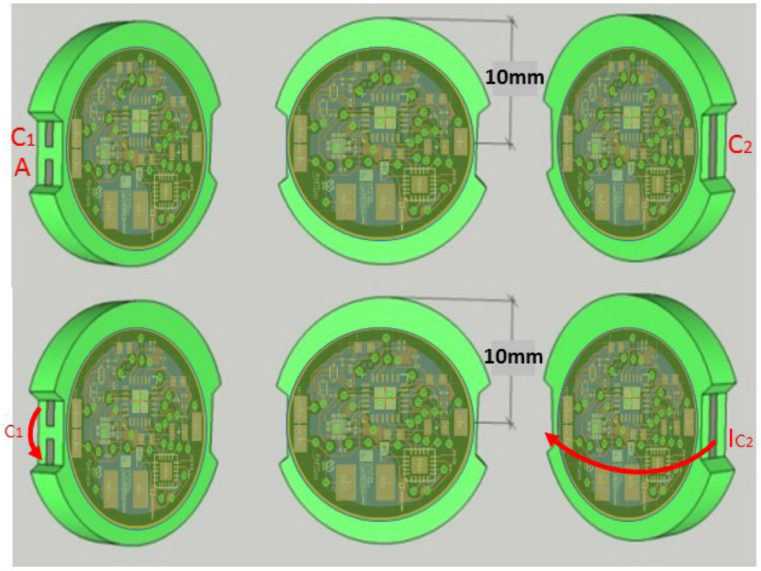

Fig. 2:

The conductance sensor uses two cathodes ($C_1$and C_2) and one anode (A). The different electrode spacings are used to distinguish between changes in urine volume and concentration which occur naturally throughout the day.

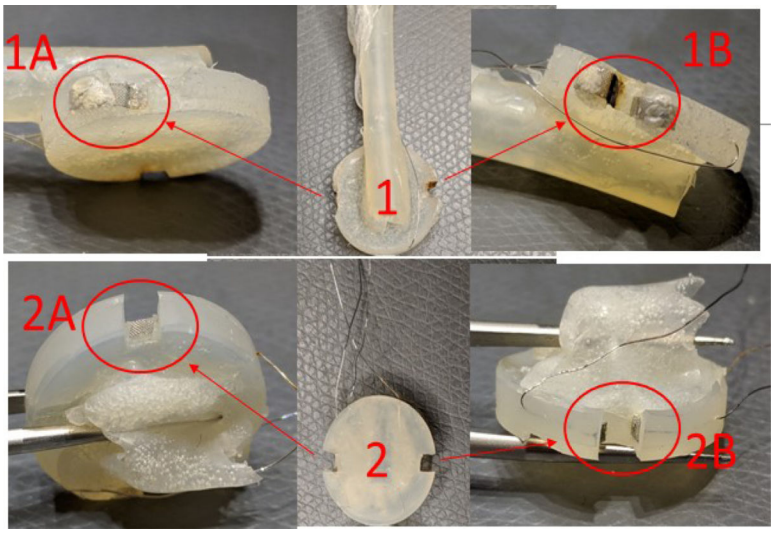

Fig. 3:

Prototype sensors were fabricated with medical-grade silicone and attached to silicone tubing for benchtop testing. Prototypes 1 and 2 each have a conductance cathode (1A, 2A), a conductivity cathode and a common anode (1B, 2B). Electrodes are soldered to insulated wires for wired measurements.

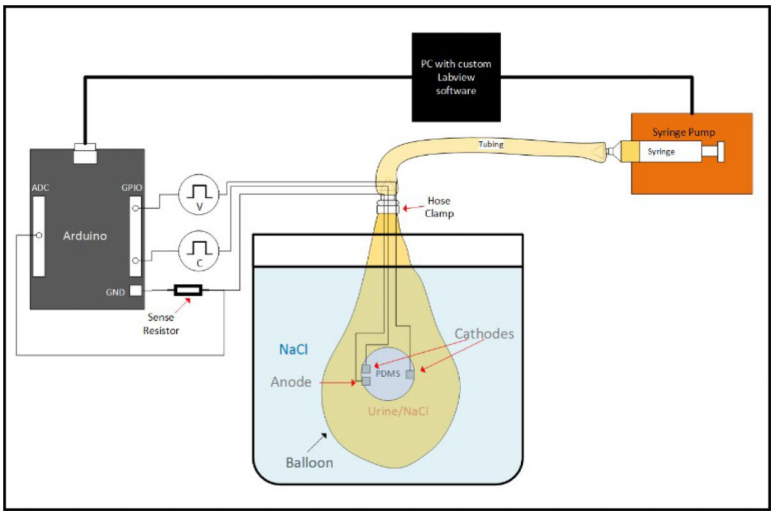

Fig. 4:

A schematic of the benchtop test phantom. The PDMS prototype (bottom center) inserted into a balloon and submerged into a bath of NaC to simulate the bladder in the body. An automated syringe pump (top right) infuses and withdraws urine or NaCl. An Arduino (left) supplies stimulation and records the anode voltage.

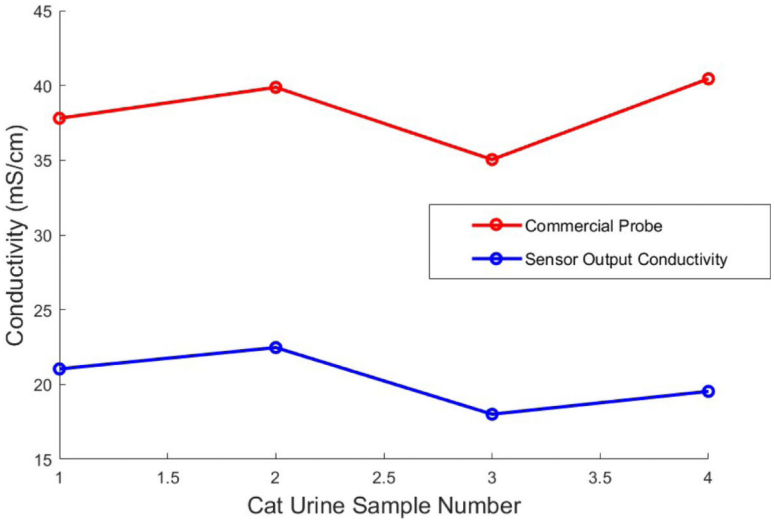

Fig. 5:

A plot of measured conductivity from a commercial conductivity probe overlaid with measured conductivity from a sensor prototype, from four different cat urine samples. The sensor prototype is able to distinguish between changes in conductivity with about the same sensitivity as the commercial probe, with a conversion factor of 1.89.

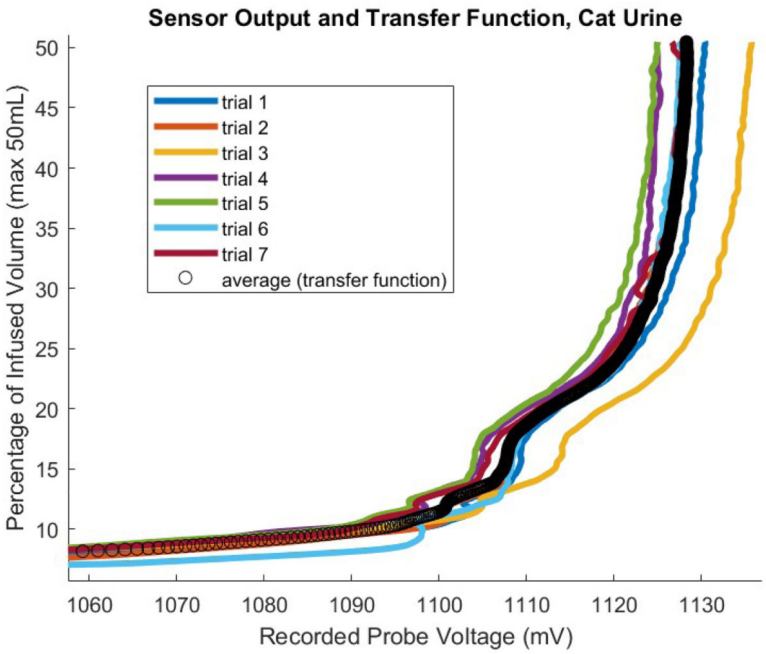

Fig. 6:

Conductance cathode output (colored lines, millivolts) versus percentage of infused volume in a sample of cat urine, overlaid with the linearized transfer function (black).

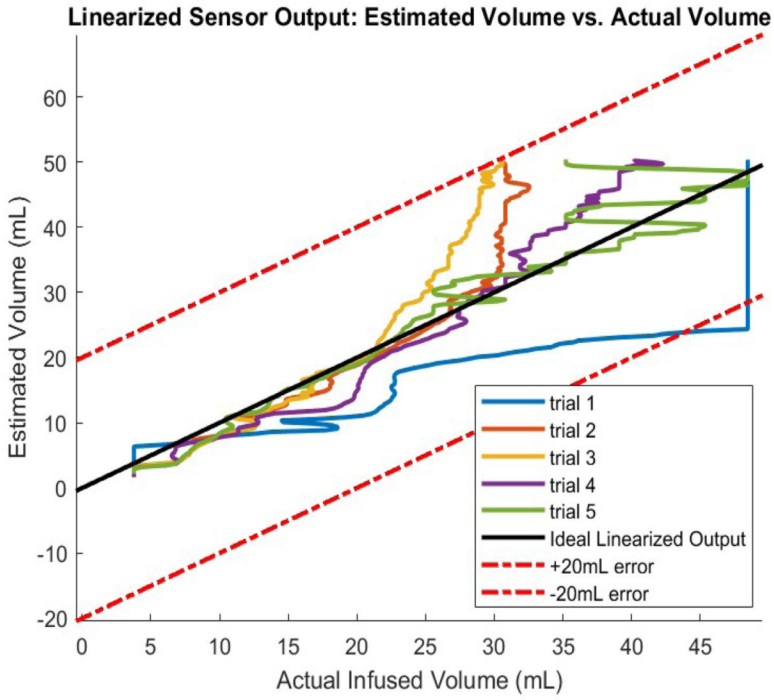

Fig. 7:

Linearized sensor output of volume predictions in a sample of cat urine, with ideal linearized output (black line) and $\pm 20 mL$ error margins (dashed red lines) overlaid.

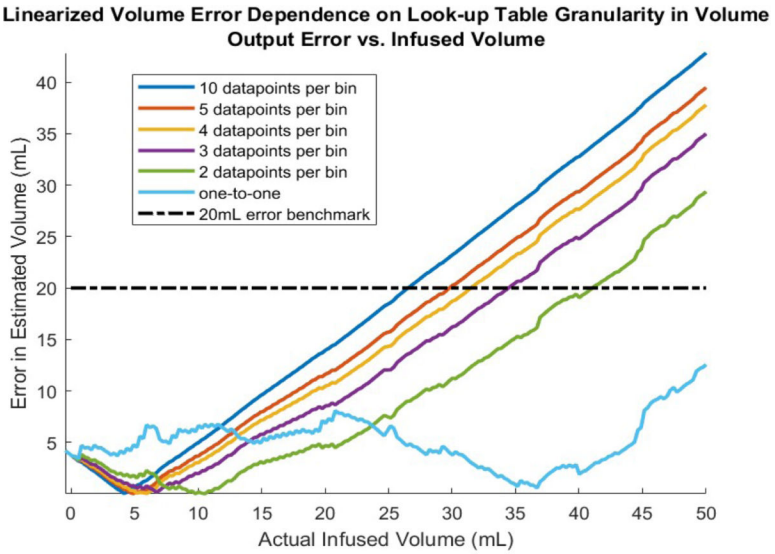

Fig. 8:

Linearized volume estimation error vs. infused volume, with dependence on granularity of look-up table in volume.

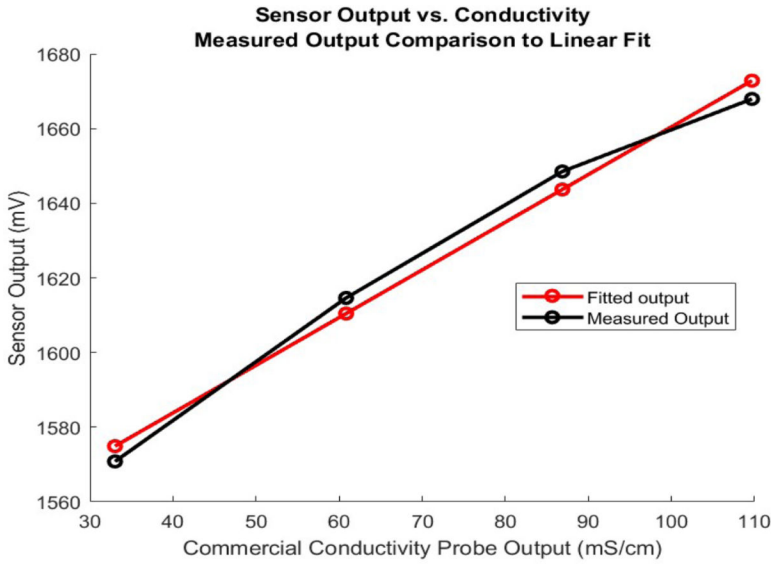

Fig. 9:

Linearity of C_1 output voltage response to changes in conductivity. Enables offset correction of reference transfer function vector.

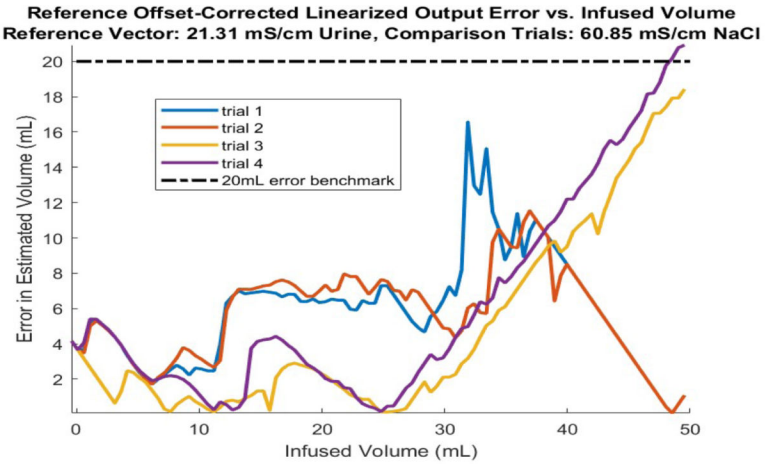

Fig. 10:

Linearized volume error of offset-corrected reference transfer function vector F_{ref} from 21.31 mS/cm urine compared to trial data from 60.85 (4% saline).

Table 1:

A diagram of the look-up table structure.

Voltage → / Conductivity ↓	V_1	V_2	...	V_n
C_1	Vol_{11}	Vol_{12}	$Vol_{1...}$	Vol_{1n}
C_2	Vol_{21}	Vol_{22}	$Vol_{2...}$	Vol_{2n}
⋮	$Vol_{...1}$	$Vol_{...2}$	⋱	$Vol_{...n}$
C_m	Vol_{m1}	Vol_{m2}	$Vol_{m...}$	Vol_{mn}

Table II:

SENSOR FUNCTIONAL RANGE AND PARAMETER REQUIREMENTS.

Size	*<2cm in all directions*
Volume Accuracy	±20*mL*
Urine Conductivity Range	*10 mS/cm - 50 mS/cm*
Equivalent NaCl Concentration Range	*0.5%−4%*
Full Scale Volume Range	*5 mL - 50 mL*
Operating Temperature	38°C — 40°C