Article

Validation of a Novel Connected "Smart" Stoma Bag to Monitor Output in Ostomates

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Abstract: Over 55% of stoma patients suffer complications such as dehydration. Outcomes may be improved through communicating stoma output data to the patient and their clinical teams. Past artificial neural networks to improve accuracy in fluid level sensing were designed to account for 'slosh' caused by variable acceleration in one or two axes of movement. This paper describes the development of a novel sensor platform for non-invasive monitoring of stoma output in real time through incorporating a volumetric array consisting of thermistors and capacitive sensors into an ostomy appliance. Stoma output which exits the body at core temperature passes into a stoma appliance in a pattern which is dictated by water content, existing effluent within the bag and distortion of the usual bag shape. By using thermistors, a thermal boundary demarcates the accumulated level of fecal material as the effluent settles. A capacitive array allows the measurement of volume of output. The sensing components communicates via near field communication (NFC) and transmits data to a smartphone application by Bluetooth low energy (BLE). Testing of the device on 11 existing ileostomy patients with 51.6 bag hours of data found a correlation between measured volume and predictive value, supporting its use in this population.

Keywords: Ostomy; remote monitoring; stoma bag; machine learning; thermistor; capacitive sensor.

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1. Introduction

Abdominal surgery, which may be done in emergency or elective situations, frequently results in the formation of an intestinal stoma. Most commonly fashioned as ileostomy or colostomy, stomas are artificial openings of the bowel onto the surface of the abdomen and are formed when the usual anatomy has been disrupted or in order to protect distal structures from the flow of feces. Conditions for which stoma may result includes inflammatory bowel disease (ulcerative colitis and Crohn's disease), colorectal cancer and the complications of diverticular disease [1]. Population prevalence rates as high as 2-4 per thousand have been reported [2], with

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approximately 100,000 patients with a permanent stoma in the UK, 750,000 in the USA and 1,000,000 in China [3].

Complication rates for stoma patients exceed 55% [4] and in a review of all US healthcare data, the all cause 30-day readmission rate for ileostomy patients matched kidney transplant at 29.1% [5]. Commonly reported complications include acute kidney injury, skin complications and a reduced quality of life [6]. Dehydration is the most common cause for readmission present in approximately 40% and the subsequent impact on the kidneys can lead to renal failure which is consistently reported in 17-26% of patients [5,7]. Dehydration and acute kidney injury may be precipitated by high output stoma (HOS), defined as ostomy output >1500 ml/d for two or more consecutive days. HOS occurs in up to 17% of stoma patients and results from bowel wall edema and motility changes that follow surgery [6]. Up to 71% of patients who develop HOS develop acute kidney injury. Trace element deficiencies (magnesium, phosphate and calcium) are also common in this group. Patients that develop postoperative HOS stay in hospital longer (18 vs 12 days in one study) [6].

Leakage from over-full appliances results in skin complications, which can range from mild cutaneous inflammation to significant ulceration and are observed in 18-55% of stoma patients [8]. Peristomal skin problems account for more than 1 in 3 visits to ostomy nurses and early intervention can prevent complications and improve outcomes for the patient [9].

The cumulative impact of the complications listed above also imparts a significant burden on the quality of life (QOL) of stoma patients [3]. A systematic review assessed the results of 14 studies investigating quality of life in colorectal cancer stoma patients. Despite variation in methodology, all studies demonstrated that living with a stoma influenced the overall QOL negatively. Painful or irritated peristomal skin, odor, and noise from the appliance were the most commonly reported ostomy-related difficulties [10].

Although some tools exist, there remains a lack of validated and reliable measures of peristomal complications [9]. Equally, efforts to improve outcomes in ostomy patients have focused on education and self-management, often involving manual measurement of stoma output which is unacceptable to many [11]. As a result, patients and healthcare professionals struggle to measure stoma output and monitor skin condition accurately.

Advances in sensor technology and mobile connectivity raise the prospect of continual background monitoring of stoma function. Previously, we designed, fabricated and tested a wireless, flexible and adherent sensor with Bluetooth connectivity capabilities for measuring volume output in ostomy patients [12]. The volume sensor is a flexible polymer strip embedded with conductive materials. When a known voltage is applied to the strip, the resistance can be measured. As the strip is flexed, the conducting particles become further apart, increasing the

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resistance of the circuit through a piezoelectric effect. We were able to demonstrate that a flexible external sensor, affixed to the outside of a stoma bag and wirelessly connected to a patient's smartphone can accurately and reproducibly measure stoma output [13]. The device was also found to be acceptable and usable to patients with newly formed ileostomy [14].

A limitation of the flexible sensor approach is that it requires the volume of the patient's stoma bag to be known. In addition, this method is susceptible to noise and cases were seen where it markedly affected the accuracy of the output recording. Noise was greatest during physical activities and during bag placement. Despite these limitations, it was estimated that such a device could provide a cost saving against current treatment methods up to 33% [15].

In this work we propose and develop a novel sensor platform for the non-invasive monitoring of stoma output in real time. The sensing components, monitoring temperature change and the presence of liquid, are integrated into an otherwise normal stoma bag. Information on the volumetric filling of the bag is relayed to the patient via a Bluetooth connection to a smartphone, and displayed in an installed application to the patient and clinical team.

2. Materials and Methods

2.1. Characterization of Negative Temperature Coefficient Thermistors

Thermistors are a kind of semiconductor for which the resistance changes with temperature. The resistance of some types of thermistors decrease with the increase in temperature and are known as negative temperature coefficient (NTC) thermistors. Properties of high resistivity allow for the design of a small mass unit with a fast response, and high sensitivity of the temperature measuring element allows for accurate temperature measurement in a narrow temperature range, suitable for biomedical applications [15].

Temperature is derived from resistance using the Steinhart and Hart Equation where A_0, A_1, A_3 are constants [16].

$$1/T=A_0+A_1\ell nR_T+A_3(\ell nR_T)^3$$

The relationship between resistance and temperature is linear. The resistance tolerance is reported as +/-1%. The typical size of an NTC thermistor for an industrial or biomedical application is 1.0 x 0.5mm [17].

2.2. Characterization of Capacitive Sensors

Capacitive sensors are used in multiple industrial and consumer applications. Here we describe the use of electrode pads etched from copper and plated with gold for capacitance detection, an

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example of which is shown in Figure 1. The copper pads are connected to a capacitive sensing controller. The controller generates the capacitive value for each electrode in the circuit. Capacitance depends on the dielectric constant, the area of the conducting plate, and the separation distance of the plates. If the properties of a capacitive sensor remain fixed, except for its dielectric constant, then the capacitance in terms of its dielectric constant can be calculated as follows:

$$C(\varepsilon_r) = \varepsilon_r \left(\frac{\varepsilon_0 A}{d}\right)$$

Where C is the capacitance in farads (F), ε_r is the relative static permittivity (dielectric constant) of the material between the plates, ε_0 is the permittivity of free space, A is the area of each plate in square meters, and d is the separation distance of the two plates [18].

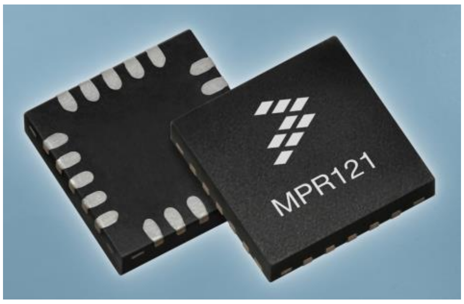
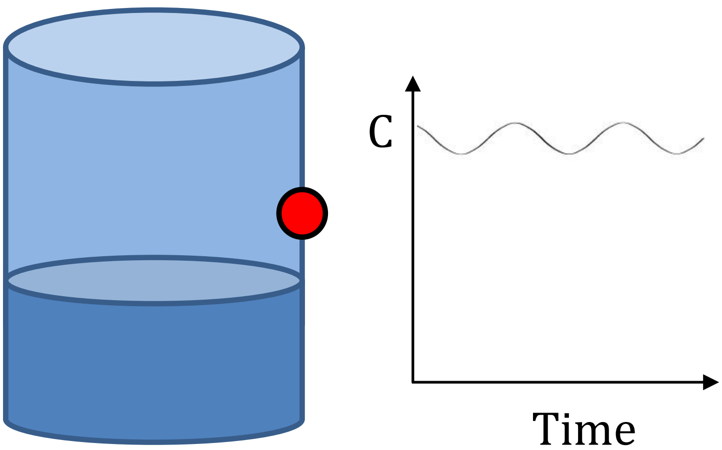


Figure 1. Top and base view of a 20-pin capacitive sensor. The dimensions are 3x3x0.65mm [18].

If mounted on the external layer of a plastic fluid receptacle, the wall of the receptacle becomes the dielectric material. When the receptacle is empty the capacitance will be high. When fluid comes into contact with the layer directly on top of the electrode it forms a simple parallel plate capacitor. In this condition the capacitance will drop providing a measurable event that can indicate the presence or absence of fluid. This is demonstrated in Figure 2.



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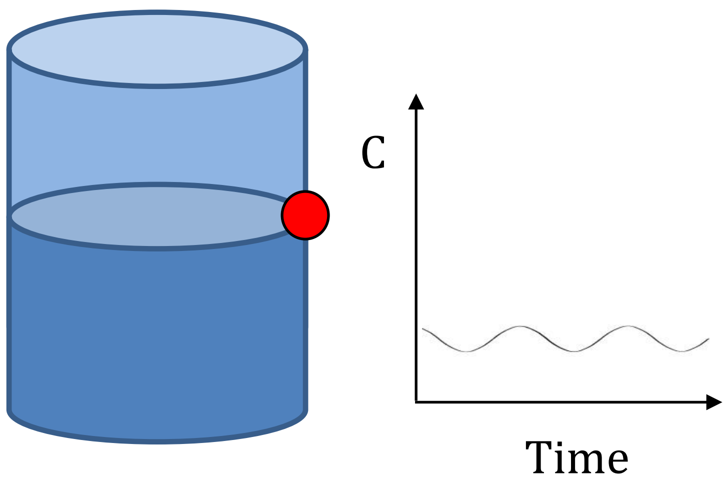

B

Figure 2. The effect of the presence of fluid on a capacitive sensor (red dot) mounted on the outside of a plastic-walled receptical the capacitance (C) is shown on the y-axis of the graph above and can be seen to be elevated when the sensor is uncovered (A) and drop when the capacitive sensor is in contact with fluid (B).

2.3. Rationale of using thermal and capacitive monitoring to monitor human stoma ouput

In health, core body temperature is tightly maintained by physiological mechanisms in a range of 35.5-37.5 °C and the intestinal lumen environment is maintained at core temperature [19]. Feces therefore exits the body at core temperature. In the case of a patient with an intestinal stoma, output is contained by an appliance, usually a stoma bag. Stoma output occurs in discrete episodes and passes into a stoma appliance in a pattern dictated by its water content, existing effluent within the bag, and distortion of the usual bag shape.

As an initial proof of concept, simulated stoma output (oatmeal and apple sauce) was infused into a regular stoma bag and optical and thermal images taken of the process (FLIR E60 thermal imaging camera). This confirmed the hypothesis that as effluent settles within the bag, a thermal boundary will become apparent that demarcates the accumulated level of fecal output. This is demonstrated in Figure 3.

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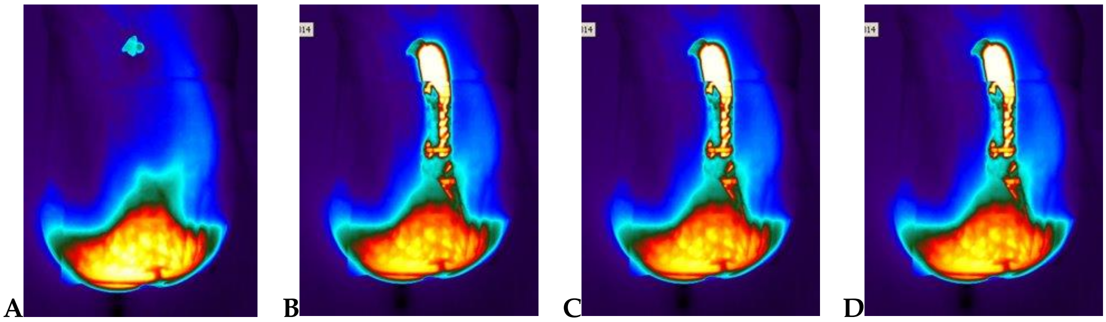

Figure 3. Appearance of a thermal boundary within a stoma bag during infusions of simulated feces. The boundary was still visible 5 minutes after the infusion finished; the path that the effluent flowed through, remained heated 5 minutes after infusion finished. Pictures from left to right are: (**A**) before infusion, (**B**) during infusion, (**C**) right after infusion finished, and (**D**) 5 minutes after infusion finished. Note that bright yellow indicates the highest temperature and dark blue indicates the lowest temperature in these infrared images.

2.4. Development of a volumetric array: proof of concept

The validity of using a thermistor array, externally mounted, to determine dynamic episodes of stoma output and bag filling level was investigated. An array of NTC thermistors mounted on a flexible polymer (Murata Manufacturing, Kyoto, Japan) was adhered to the outer layer of a standard ostomy bag 450ml 2-piece drainable unit, Coloplast, Humlebaek, Denmark). The full set up is demonstrated in Figure 4 below.

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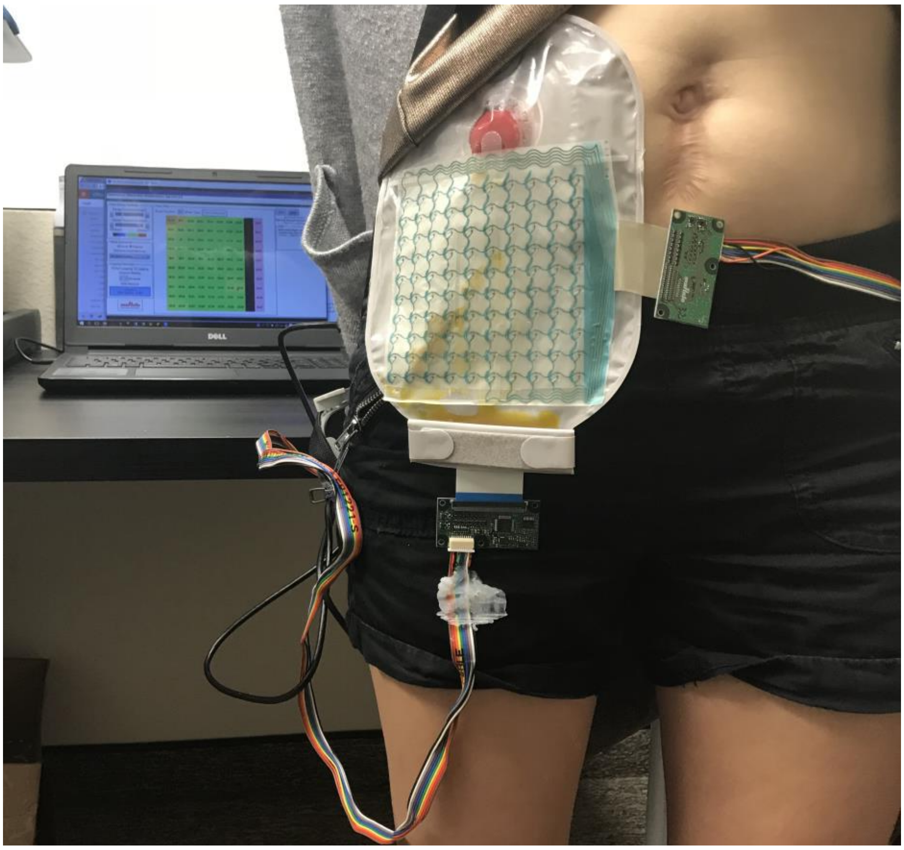


Figure 4: Experimental set up to investigate the performance of a thermistor array as a method of detecting the function and cumulative output of an excretory stoma.

Simulated stoma effluent (Motts Apple Source, Motts LLP, Plano, Texas) was added in 50ml aliquots, previously heated to body temperature (37 °C) whilst temperature change within the bag was monitored in real time. As can be seen in Figure 5, the pattern of temperature change was distinct at different temperature levels at a single thermistor. In addition, the flow-path of the infusion and thermal barrier of effluent settlement was visible across the entire thermistor array in a temperature visualization during sequential simulated outputs. This is shown in Figure 6 below.

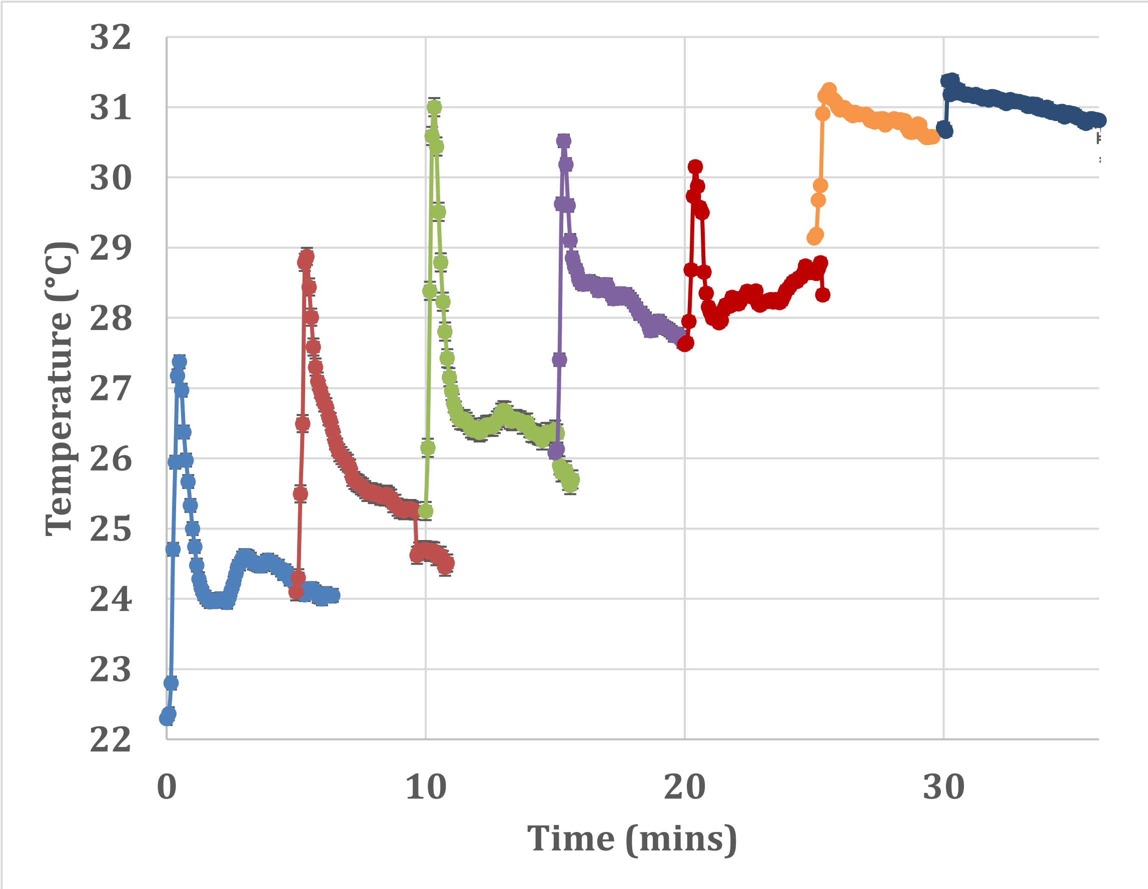


Figure 5: Average temperature at a single thermistor for volumes of simulated effluent infused at body temperature into a prototype 'smart' stoma bag in the up-right/ supine position. Standard error also plotted. Each color represents an additional infusion in 50ml aliquots up to a total of 350ml.

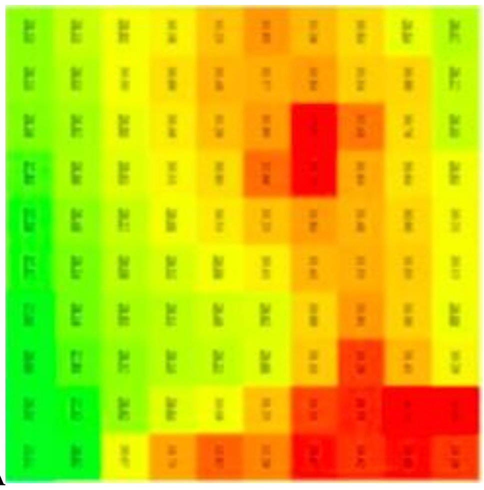
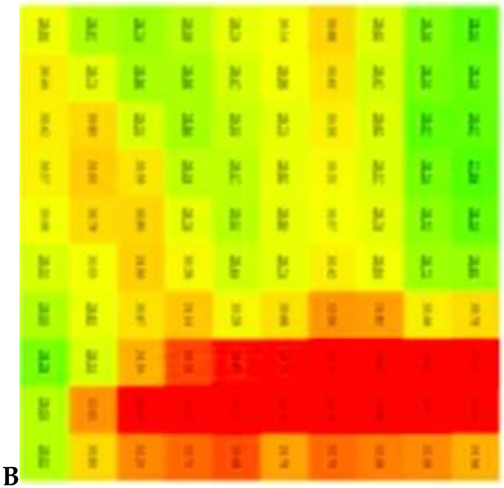
A  B 

Figure 6: 'heat-map' representation of the thermistor array used in the experimental set-up demonstrating the detection of the flow-path of an infusion of simulated effluent **(A)** and thermal

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boundary of settled effluent **(B)** within a stoma bag. Images have been rotated 45° to replicate the physical orientation during the experiment.

2.5. Development of a capacitive array: proof of concept

The validity of using capacitive sensor technology, externally mounted, to determine the amount of volume filled in the bag was tested in early 2018. A Cypress CapSense Liquid Level sensor (20) was mounted on the outer layer of a standard ostomy bag 450ml 2-piece drainable unit (Coloplast, Humlebaek, Denmark) as seen in Figure 7. The bag was worn by a non-ostomate volunteer.

Figure 7: A Cypress CapSense Liquid Level sensor mounted on the outer layer of a standard ostomy bag 450ml 2-piece drainable unit (Coloplast, Humlebaek, Denmark). The bag was worn by a non-ostomate volunteer.

The sensing device used deploys 12 capacitive sensors placed in a vertical strip pattern. The sensor has been designed such that the absolute value of each capacitive sensor is not important for determining whether the liquid is present or absent. The sensor pattern is segmented allowing each sensor element to accurately measure the liquid level in its limited range. The reported liquid height level is the highest sensor covered with liquid.

The mounting on the bag was done via a pre-applied 3M adhesive on the capacitive sensor flex board, which allowed this board to be directly adhered to the outer layer of the bag.

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Fluid was added in 50mL aliquots (to a total of 350 mL). The capacitive flex PCB used, was connected to a Liquid Level Sensing Arduino Shield board and the signal of the sensor, as a function of the infusion was monitored on opensource software. The output of the sensor was in terms of the height of the liquid being measured in mm as a function of time – datapoints were collected every second.

Figure 8 shows a graph of how the capacitive sensor board responded to an incremental increase of volume in the bag in segments of 50 mL. The data shows a stepwise increase as a function of increasing volume in the bag. The step wise increase of the sensors is a result of the binary output of each sensor, resulting in the volume increase to look like an increasing step.

The graph shows that for each infusion, the height fluctuates but eventually plateaus at the corresponding increased height. The noise/fluctuations seen in the data may be as result of the movement of the volunteer, although their basic position was to stand throughout the duration of the test.

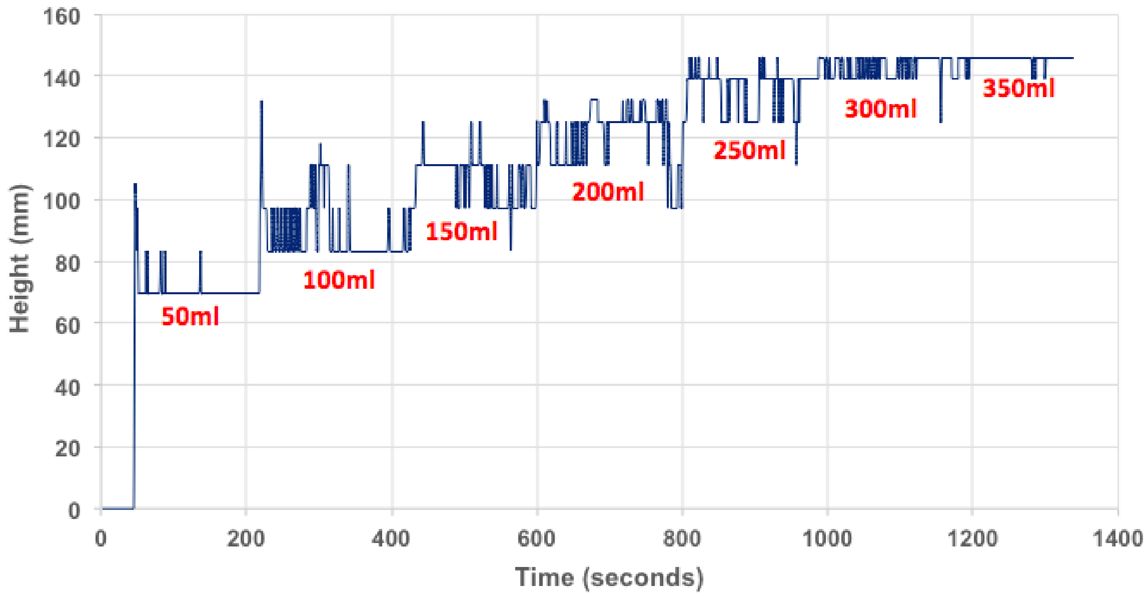

Figure 8: Graph showing the response of the Cypress CapSense Liquid Level Sensing Sensor, in the form of height, as a function of time, during which there was an incremental increase in volume of the ostomy bag, in gaps of 50 mL, up to 350 mL (indicated in red on the graph).

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2.6. Integration of a volumetric sheet into a standard stoma bag

On the basis of this data, an array of thermistors and capacitive sensors was built into a flexible polyamide substrate. This was incorporated into the structure of a stoma bag and detect the thermal and capacitive changes present during stoma output. The board is equipped with a coin-cell battery for power supply and an NFC chip for data transfer. The integrated 'smart' stoma bag is shown in Figures 9 and 10 below.

A **B**

Figure 9: Front **(A)** and back **(B)** images of a 'smart' stoma bag integrated with a volumetric sensor array and wireless connectivity capability.

Figure 10: A 450ml ostomy bag containing an integrated volumetric and capacitive board. In this case a fully wireless 'hub' device (black circular device in the front pocket of the stoma appliance) was used to connect with the volumetric array by NFC and to an installed smartphone application by Bluetooth low energy (BLE).

3. Development of a secure cloud architecture

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3.1. Communication Protocol

The sensing components communicate with themselves via NFC. A BLE chip transmits data to a smartphone application. Data is then transmitted via HTTPS protocol to a secure cloud server. In all cases, the data transfer is HIPAA (The Health Insurance Portability and Accountability Act) compliant and encrypted thus preventing the data from being hacked or compromised by any 3rd party.

3.2. Software Applications

A companion smartphone software application was developed to support use of the integrated sensing device. This incorporates administrative tools, data visualization and access to educational and care resources. Alerts can be set allowing the patient, or the clinicians who are monitoring the patient, to take preventative action to avoid complications.

3.3. Cloud Architecture

The cloud architecture is designed so that data from the sensors can be sent in real time to a patient's or clinician's mobile device. All these data can be accessed through a dedicated HIPAA compliant cloud service. The cloud service and communication system are secured in five layers: all patient data is TLS (Transport Layer Security) secured in transit between smart bag and the cloud and between cloud and software apps; patient personal data in cloud is encrypted at rest; 3rd party cloud service provides its own data protection; all patient data is encrypted again when requested from the cloud and only authorized internal employees and registered users can view the data; internal electronic devices storing trial data are password protected and all data is backed up to a HIPAA compliant cloud library. The communication flow is demonstrated in Figure 11.

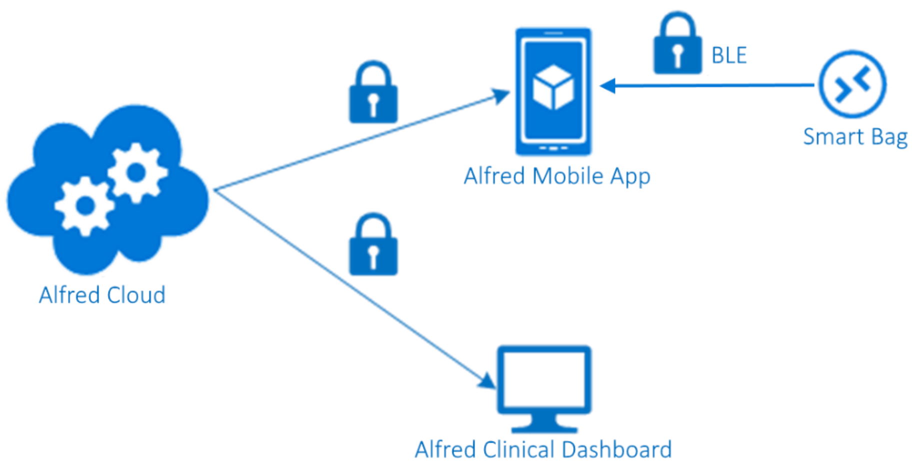


Figure 11. Overview Diagram of data communication flow chart of the connected ostomy bag

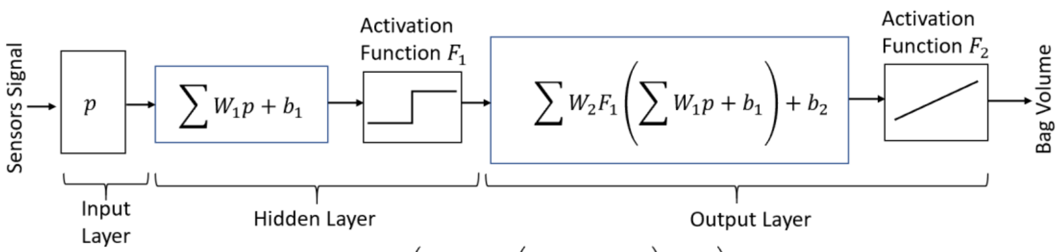
4. Data extraction from volumetric sensor array

4.1. Design of a machine learning algorithm

Direct reading of fluid level by thermistors or capacitive sensors can be inaccurate in dynamic environments. Experience from the use of capacitance for fluid level sensing in industry has also demonstrated the issue of error due to adherence of material, presence of contaminants or movement of the storage vessel. Several methods have been used to compensate for these dynamic effects and artificial neural networks (ANN) have been found to provide an effective method to allow capacitive sensors to function in a dynamic environment without compromising accuracy [21].

We therefore developed a machine learning algorithm to account for the type of output and calculate a reliable volume. For the purposes of processing this data, we selected a static feed-forward neural network to account for both the data from thermistors and capacitive sensors. Resilient backpropagation algorithm (RPROP) was used for supervised training of the multilayer perceptron.

Feed-forward Backpropagation (BP) neural network is a static network, where signals travel in one direction only, i.e. from input to output. There is no loop or feed-back between neurons and their inputs and outputs. Backpropagation network topology is extensively used in pattern recognition. Figure 12 illustrates the structural diagram of the BP network that takes the signal features and produces the fluid volume as the output.



$$Volume = F_2\left(\sum W_2 F_1\left(\sum W_1 p + b_1\right) + b_2\right)$$

Figure 12. Structural diagram of the BP network that takes the signal features and produces the fluid volume as the output.

4.2. Training of a machine learning algorithm

In order to predict volume based on sensors readings, data was acquired corresponding to each vector. Simulated effluent (water and apple sauce) was infused in 50 ml aliquots multiple times in a bag of set volume, producing the volume range from 50 to 350 ml. Multiple cycles resulted in a training set size of about 1500 data points representing 1500 values of volume.

This dataset was used to train the model. Below is the schema for multilayer perceptron architecture designed for that task. It has one input layer and 2 hidden layers of reducing size. The output layer is a single neuron (which is the output volume). Figure 13 illustrates the multilayer perceptron architecture designed for volumetric prediction based on sensor signal.

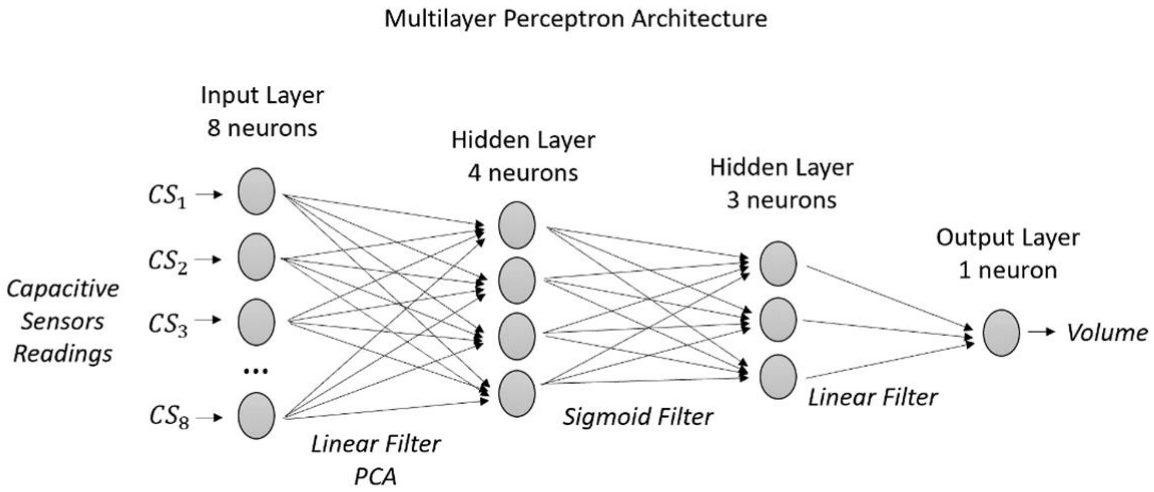


Figure 13. The multilayer perceptron architecture designed for volumetric prediction based on sensors signal.

The model was trained on 80% of the dataset. The cost function for that training is shown on Figure 14. We see that the solution converges within several hundred iterations and the mean square error was reduced to 32.6 ml. The model was validated on the remaining 20% of the dataset with Mean Square Error equal to 35.2 ml. This is equivalent to 10% of the 350 ml maximum effluent volume infused.

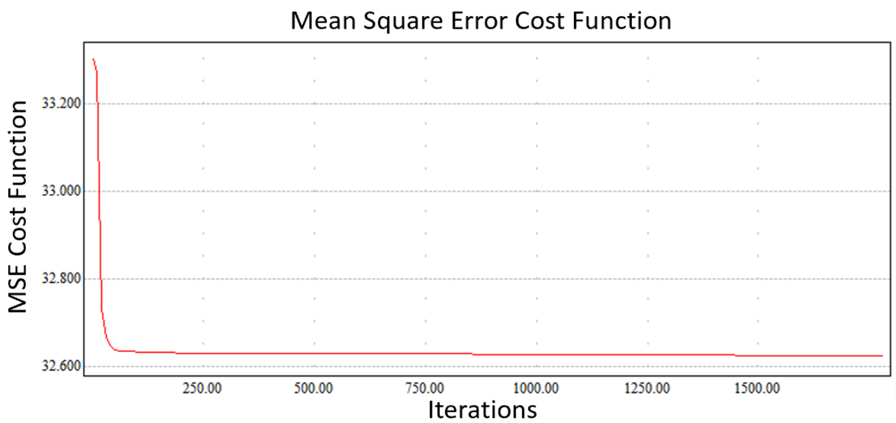


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Figure 14. Mean square error cost function for a training set of simulated effluent infusions into a 'smart' stoma bag at volumes between 50 and 350ml.

5. Results

5.1. Non Ostomate Testing

The prototype combined system integrated into a 450ml two-piece drainable stoma bag was tested in a simulated real-world setting. Two volunteer non-ostomates wore the stoma bag system in a standing, sitting or supine position. Simulated effluent pre-heated to body temperature (37 °C) was added in 50ml aliquots every 3 minutes until 350ml had been instilled. The bag was then drained and the infusion process repeated.

Filling of simulated effluent infused at body temperature, was detectable by temperature increase in all thermistors, greatest in the region of settled fluid. The baseline temperatures were increased compared to bench-testing due to the contribution of body heat. The temperature differentials between filling events was smaller in sitting and supine positions. Capacitance and temperature drop in the lower bag region was found to be an accurate method of detecting bag drainage.

5.2. Testing on Existing Ileostomy Patients

Eleven existing ileostomy patients (7F, median age 33) were recruited to a single center. Data was collected prospectively, and the device performance was described. Participants wore the fully integrated and wirelessly connected smart stoma bag for up to 7.5 hours (median 3.0 hours) and all stoma output was recorded at the point of bag drainage. To mimic real-word conditions, participants were permitted to eat and drink ad-libitum, and could drain their stoma bag when 50% full or greater. Although exhaustive exercise was prohibited, there were no restrictions on position, movement or physical activity. The primary outcome was validation of the algorithm to calculate stoma output volume from thermal and capacitive measurement within the SmartBag system.

A total of 51.6 bag hours of data were collected. In this time 3139ml of stoma output was measured. Mean (standard deviation) stoma output across all participants was 53.3 (42.7) ml/h. The algorithm predicted output of 3332ml in the same time period, providing a predicted mean stoma output per participant of 56.3 (45.5) ml/h. Figure 15 below demonstrates the relationship between measured and predicted stoma output volumes in real ostomy patients.

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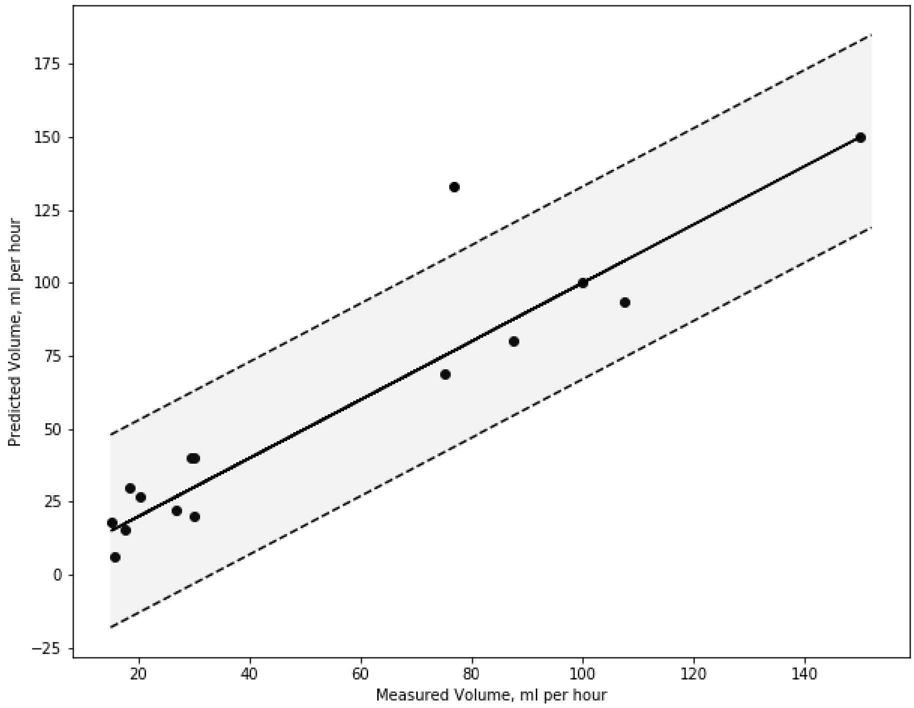

Figure 15. relationship between predicted and measured ileostomy output over 16 bag drain events in 11 ileostomy patients.

6. Discussion

Here we have demonstrated that a volumetric array consisting of thermistors and capacitive sensors can be mounted on a flexible polyimide substrate measuring 18 cm x 12 cm and can be completely incorporated into an ostomy appliance measuring 23 cm x 15 cm. The size and appearance of the device is comparable to currently marketed stoma appliances, as can be seen in Figure 9 above.

The theoretical concept of using thermal and capacitive measurement to determine the characteristics of stoma output and cumulative volume have been described. Data is also shown for how the sensors were integrated into a flexible substrate, and how this sensing model can be used to detect volume in a lab environment through the employment of two separate resilient backpropagation algorithms. Finally, the validity of using these methods to detect ileostomy output in a real-world setting on human volunteer ostomates was shown. Whilst artificial neural networks have been used in industrial settings to improve the accuracy of fluid level sensing in dynamic environments, previous solutions were designed to account for 'slosh' caused by variable acceleration in one or two axes of movement. They were also designed to be mounted on the side-

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wall of a rigid structure [21]. A combination of thermal and capacitive sensing has not previously been described in volumetric sensing applications. Furthermore, no prior approach to sensor deployment has ever been shown to be consistently accurate when mounted to a flexible receptacle such as a stoma appliance.

We previously reported the use of flexible piezoelectric sensors that have been attached to the outside of a stoma bag. As the strip is flexed, the conducting particles become further apart, increasing the resistance of the circuit. The device in-situ can be seen in Figure 16. We were able to demonstrate that the changes in resistance upon flexing, correlated to the filling status of a stoma bag when its capacity is known. In simulated real-world conditions the volumetric data was found to be consistent and accurate in a series of ostomates who used the device. This device was found to be acceptable and usable, but did not provide a consistent accurate reading due to connectivity issues and a high noise to signal ratio in a dynamic environment [14].

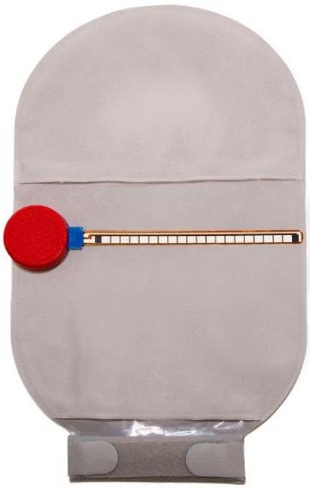

Figure 16 : Example of a flexible piezoelectric sensor in situ attached to a stoma bag.

The solution described here, overcomes these problems by employing two sensing modalities and an artificial neural network to determine accurate volume of bag content in real time, whilst adding to a cumulative total only when a drain is detected.

The ileostomy population suffers disproportionate morbidity, particularly with regards to dehydration and acute kidney injury [6]. Such complications are frequently associated with high output stoma which also contributes to macro and micronutrient losses [22]. The impacts of such complications are significant, with negative effects on quality of life frequently reported in this group [10], particularly in the domains of physical, social, psychological, and spiritual well-being [23]. The cost to the healthcare economy is also great. In an economic analysis, the direct hospital costs of patients with a stoma was over twice as high as similar patients who do not receive a stoma ($26,917 vs. $13,817) [24]. Other studies have also consistently found that acute healthcare resource utilization is higher than expected in stoma patients [25]. Recent studies have advocated better monitoring of ostomates and tailored interventions to reduce complications and improve self-monitoring [5,26]. This does not only apply to the outpatient setting. Length of stay is significantly longer in patients that develop high stoma output and this is at least in part due to the need of the clinical team to have confidence in the accurate monitoring of output volumes [6]. Inpatient documentation of fluid balance is known to be inaccurate and creates a considerable burden for clinical staff to document, not to mention risks involved in handling potentially hazardous bodily waste for extended periods [27]. It is reasonable that a remote monitoring system that can securely communicate instantaneous and cumulative output data to the patient and their clinical team, could contribute to improved outcomes in this population.

6. Patents

The discussion of the foregoing technology is covered by U.S. Patent Application No. 16/184764, 16/184787, and 16/184828, which were published on May 9, 2019, with the United States Patent and Trademark Office.

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