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Design and Development of a Wireless Medical Device for Blood Leak Detection during Hemodialysis Therapy

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Abstract. Hemodialysis therapy is a clinical intervention by inserting the needles on the arterial and venous blood vessel in the patient's arm. The area where the needle is inserted can cause bleeding and it's harmful for the patient. Previous method for detecting the blood vessel is by using a single point optical detection method. However, this method is not suitable for covering wide area. In this research, an electrochemical based multisensor is used for detecting the blood vessel around area of the inserted AV Fistula needles. This sensor is based on the impedance sensor. The main components of blood leak detection system are a multiplexer, an instrumentation amplifier, an impedance analyzer, microcontroller integrated Wi-Fi communication, and alarm system. An impedance analyzer is used to extract the signals into the real part and imaginary parts. The magnitude of the signals is computed from the real and imaginary parts of the signals. Such signals are computed using an artificial neural network (ANN) algorithm to classify the digitized signal output of the impedance analyzer whether the sample is human blood or not. The classification result in the form of messages is then sent to the alarm system to activate the visual and audio alarms. The messages were also transmitted to the nurse station through Wi-Fi communication system. Such message also consists of information about the location of the patient so the medical staf can go to the patient's bed directly. Various testing activities such functional test, battery life test, transmision test have been performed in this work. The result shows that the system can detect the present of the blood leakage with the sensitivity greater than 90%.

INTRODUCTION

Chronic kidney disease (CKD) is associated with decline of renal function which is mainly related to the patient age. It is accelerated by the hypertension, obesity and diabetes. According to the Report of USRDS 2018, the prevalence of patient with chronic kidney diseases in the US increased from year to year [1]. In the Basic Health Research Report of the Ministry of Health (2013), it is mentioned that the prevalence of chronic kidney disease patients in Indonesia is around 0.2% of the population [2]. Whereas according to the WHO Country Health Profiles 2012 report, kidney disease is ranked as the 10th leading cause of death in Indonesia, which is around 3% of the people [3]. According to the report of the Indonesian Nephrology Association (Pernefri) in 2016, there were around 52835 active patients undergoing hemodialysis therapy, with a new patient number of around 25,446 people. From 2007-2016, the number of hemodialysis patients continued to increase significantly [4].

Hemodialysis is considered as a the most common and well known methods to treat the so-called End Stage Renal Diseases (ESRD). In addition, it is also a process that utilize an artificial kidney or dialyzer to remove waste such as urea from blood and excess water from body. In hemodialysis (HD), to purify the blood, a special filter known as an artificial kidney or a dialyzer are used. The blood was taken from patient body via a needle inserted in the patient's arm. The blood is then pumped to dialyzer for purification and then the purified blood returns to the patient's arm via another needle. During hemodialysis therapy, some bleeding may occur around the needle, which can threaten the patient's life. In addition, the medical staffs cannot constantly check the patients whether bleeding occurs, since it takes around 5-6 hours for completing each hemodialysis therapy.

Venous needle dislodgement has been reported to be a potentially serious complication during the hemodialysis therapy. In 2012, the American Nephrology Nurses' Association (ANNA) carried out an investigation on the venous

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needle dislodgement. The survey results revealed that 76.6% (n = 894) of the 1,166 participants indicated about their observances of venous needle dislodgement in the past five years, and with 8.2% (n = 96) of those having seen five events or more in this time period. Moreover, slightly more than half (57.9%) of the 1,166 participants pointed out that venous needle dislodgement occurs very often or often. An additional 23.1% rated their concern as occasional [5]. From the above report, the venous dislodgement occurred very often. Therefore, the venous dislodgement is the potential problem during hemodialysis therapy [6-8].

It is well-known that there are certain methods used in market for detecting the blood leak. The first method is Hemodialert with the Hemosensor [9], in which the sensing of blood is relied on the change in voltage of the sensor. In this device, we connect two electrodes to generate a source through lead. Thus the sensor achieves a signal processing unit, which activates the alarm. The second method is to use Redsense for blood leak detection [10], which is very sensitive device. It can give good results for 1ml of blood. In this case, the blood leak detection, which is based on electrical conductance, changed in the line. Meanwhile, the sensor is put on the fistula access. So, when the blood leak occurs, the sensor absorb blood and activate the alarm and give a visual indication. The third method or blood leakage detection device is called the capacitive sensor [11]. By using this method, blood leak detection will be identified by the change in capacitance. The change in wetness of blood is then detected by the capacitive sensor when the blood leak occurs. The fourth device, which is also used in the market, is called the photo interrupter sensor with absorbent material [12]. The photo interrupter is a transmission type photo sensor. It consists of light emitting and light sensing element facing each other in a single package. The absorbent material is put on the sensing area. Therefore, when blood leakage occurs the blood is absorbed by the absorbent material very quickly and it brakes the light penetration. This changes the voltage signal and activates the alarm. In this kitchen, the napkin is used as an absorbent material. The benefit of the above methods is that it can operates very well in the small distance. However, it requires a high operating power, bulky circuit arrangements and cannot reuse for same or another patients because of the safety. Thus it needs a very high cost.

In this study to overcome all above drawbacks with the use of conductivity sensor. The conductivity sensor could be used. During hemodialysis when blood leakage occurs due to venous needle displacement the sensor can sense leakage of blood and differentiate blood and sweat. This decreases the chance of confusion and enhances the human services nature of HD patients.

METHOD

This section presents about the architecture of the blood leak detection system, signal processing method, functional test and wireless communication test.

System Architecture

System architecture for a wearable blood leakage detector can be shown in Fig. 1. It consists of impedance sensor, impedance analyzer circuit, microcontroller unit, wireless transmitter module and the alarm unit. The impedance sensor was made by printing the silver conductive ink on the surface of flexible PVC sheet. In the first type of sensor, it has 2 electrodes and the new design, multi electrode configuration was used. Similar design can be found in various literature [13]. Using multi electrode configuration can provide a wider detection area. The main consideration is the sensor should be able to surround the puncture point of the needle and that it should be easy to set up on the patient's alarm. The puncture point of the needle is the place where the leakage point is located.

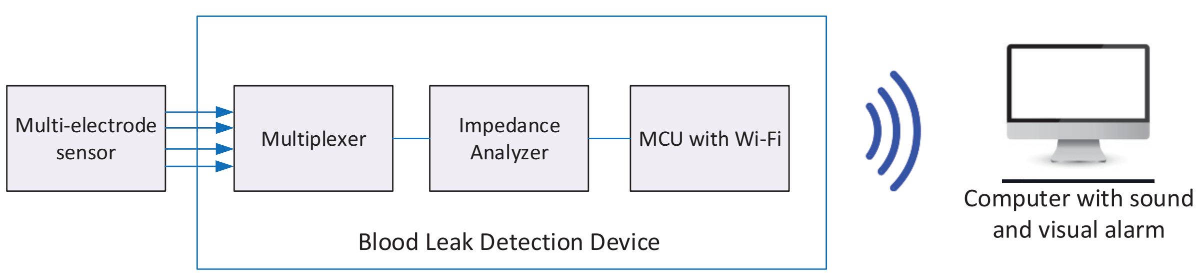
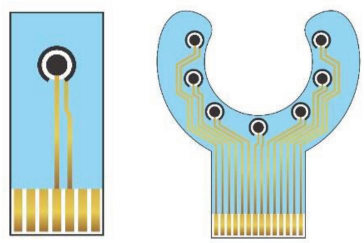


FIGURE 1. Architecture of blood leak detection device

A multiplexer circuit is placed before impedance analyzer module. With the multiplexer circuit, the voltage between two electrodes can be measured. Inside the impedance analyzer, the signals were amplified, filtered, digitized and computed using discrete Fourier transform to obtain the real part and imaginary part of the signals. Further, the micro control unit (MCU) performs the Artificial Neural Network computation and analysis. The module will trigger the local alarm, when the analysis result shows the impedance of the human blood. Through Wi-Fi module, such analysis result will be sent to the nursing station to activate the main alarm. Detailed components of blood leak detector are discussed as follows:

Components of Blood Leak Detectors

Screen Printed Electrodes. To print electrodes on the PVC sheet, it was employed a screen printing method. Silver conductive, Electrodag 725A from Acheson Colloids was used as electronic track and electrode pad. Carbon conductive ink, Electrodag PR405, was printed over the silver electrode pad. The ink was overprinted two or three times on the PVC surface to prevent wiring disconnection because of an overly thin conductive pattern. Screen masks with the desired sensor pattern was fabricated in the local workshop.



(a) (b)

FIGURE 2. Designs of impedance sensor with two electrode (a) and multi electrode configuration (b)

Impedance Analyser. There are many methods to measure impedance of the sample. Conventional impedance analyzers in the market are very expensive and not suitable for field application since it is bulky. Currently, due to the advancement in the microelectronic technology, impedance measurement can be performed using a small and cheap electronic device, AD5933 produced by Analog Device [13]. It is easy to use with any computer. The electrical impedance can be measured by the frequency domain ratio of the voltage to the current. Impedance is a complex number consist of real part or resistance, R and imaginary part or reactance, X. The R and X parameters can be converted into desired parameters such as impedance magnitude, |Z|; phase, θ; admittance magnitude, |Y|; conductance, G; and susceptance,

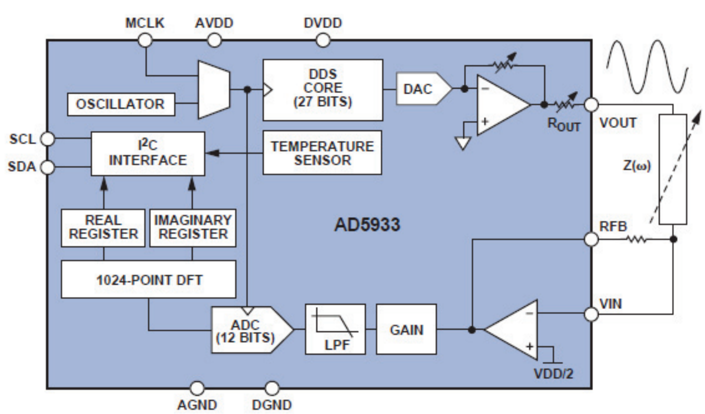


FIGURE 3. Functional Block Diagram of AD5933 [13].

MCU and Wireless Communication. The STM32F411 based microcontroller was used to perform the artificial neural network computation and analysis. This microcontroller was connected to local alarm circuit and Wi-Fi modul of

CC3200MOD manufactured by Texas Instrument [14]. This module includes Wi-Fi network processor, a power management unit, and a ARM Cortex-M4 microcontroller unit, 8M flash memory. It has low voltage requirements of only 2.1–3.7 V and small size. It also uses 802.11 b/g/n protocols, which have an indoor range of up to 100 m according to different specifications of antenna configurations.

Alarm system. The alarm systems were installed in both patient and nursing station. In the patient side, the local alarm system consist of LED and a buzzer. Messages from blood leak detection module were sent to the nursing station through Wi-Fi wireless transmission network to show the warning signals and power level status. This device used the smaller-sized electromagnetic buzzer as the sound warning device. In the nursing station, a user interface was developed to display the visual alarm, power level of the blood leak detectors as well as the location of the patient's bed.

Signal Processing Method

Signals from the sensors were amplified using low noise instrumentation amplifier. These signals were entered to multiplexer before entering to the impedance signal analyzer, AD5933. Inside the AD5933, the signals were digitized and Discrete Fourier Transform algorithm embedded in the chip was used to extract the real and imaginary part of the sampled signal. To compute the real and imaginary part, the sampling rate and the period of the original signals were provided by the AD5933 device. The magnitude of the signal can be computed by making the square root of the square of real part plus square of the imaginary part [13].

Output signals of the impedance analyzer were fed to the MCU board which consist of ARM cortex M4 microcontroller unit and 8 M memory [14]. An algorithm based on Artificial Neural Network (ANN) was used for classification of signals from multi electrode system [15]. In this work, a three layer fully interconnected feed-forward ANN with a back-propagation algorithm is used to update the weights during training to map the input patterns to the corresponding target output. It is a specific technique for implementing the gradient descent method to minimize the error for a multilayer feed forward network. There are three layers in this network [16]. The first one is the input layer, whose number of neurons is the same as the number of the elements of the features set (sensors). The second layer is the hidden layer, where the number of neurons is adjusted accordingly to achieve better classification (fixed by trial). The third layer is the output layer, and the number of neurons equals the number of unit categories of blood sample requiring discrimination [17].

The training algorithm used in this experiment is the backpropagation with Levenberg-Marquardt optimization. It updates the network weights and biases in the direction in which is the negative gradient of the performance function (the is steepest decent training). The learning rate multiplies the negative of the gradient, to determine the changes to the weights and biases. The larger the learning rate is, the bigger the step and if the learning rate is too large, the algorithm becomes unstable. However, if the learning rate is too small, the algorithm takes a long time to converge. Thus, a value of 0.01 was used. The training is done in a batch mode, where the weights and biases of the network are updated only after the entire training set has been applied to the network. The gradients calculated at each training example are added together to determine the change in the weights and biases [18-19].

The training data are based on normalized impedance data for water, sweat, blood, blood with various concentrations of heparin. Input vector and output targets are generated by such samples. A maximum of 4000 epochs and a maximum error of 0.0000001 were used when training this network. Since the impedance of the blood changes during coagulation, impedance measurements were done soon before blood is in the coagulation form [20-22].

Functional Test

The following tests were performed to ensure that blood leak detection system is working based on the requirement. At the beginning, the impedance analyzer inside the blood leak detection system was tested using the 20 RC circuits with known values. High precision resistors and capacitors were used in these experiment. The results were then compared with the impedance measurements conducted using Impedance Analyzer, Solatron1260. Sub sequent tests for impedance measurement with respect for frequencies were performed for phosphate buffer acting for sweat, pure water, bovine blood, human blood with various volume of heparin. These impedance data were collected and used for training data for artificial neural network.

Battery Life Test

The blood leak detection device utilizes a compact rechargeable battery with design specifications of 3.7 V and 1 Ah. A battery life test was performed to determine the usable time of the blood leak detector. Experimental results showed that the microcontroller module has higher power consumption in continuous wireless transmission, but without continuous transmission the power consumption is acceptable. Experiments indicated that the device can be operated for up to 70 minutes for continuous wireless transmission and 8 hours without wireless transmission. The data loss rate is maintained within 1% error. Overall, the device could be used for around 4–9 h without frequent wireless transmissions with a clinical blood leakage scenario.

Wireless Communication Test

In order to obtain the optimal wireless transmission distance, an open space was chosen for performing the experiment. Each experiment was assigned various distances. The received signal strength indicator (RSSI) was measured. If the RSSI is more than 80%, the data lose rate will increase.

RESULTS AND DISCUSSION

This study had been successfully developed wireless medical device for blood leak detection during hemodialysis therapy. The wireless device used an impedance analyzer AD5933, STM32F411 microcontroller and Wi-Fi module based on CC3200 MCU. Figure 5 shows the experimental setup of blood leak detection device for monitoring the presence of blood. To demonstrate the sensor can detect the presence of blood, it is directly connected between blood leak detection device and the personal computer. The sound signal triggered by the device which is also sent to PC is represented using a graph.

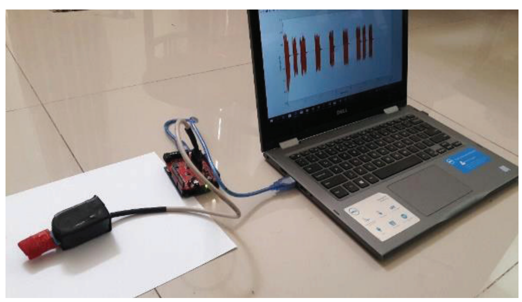


FIGURE 4. Experimental setup of blood leak detection device for monitoring the presence of blood

To validate the wireless device, a set of RC circuit with high precision resistors and capacitor. There are about 20 RC circuits used for validation. The impedance measurements for 20 RC circuits were also performed using Solatron 1260, Impedance Analyser. Figure 5 shows the comparison between impedance measurement for RC circuit using proposed device and Solatron 1260.

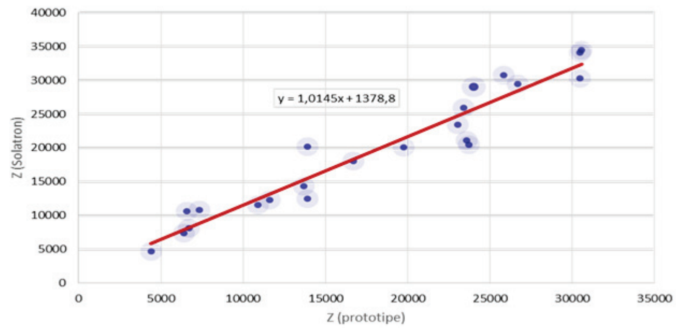


FIGURE 5. Comparison between impedance measurement for RC circuit using proposed device and Solatron 1260.

To demonstrate the ability of the device to measure the impedance, the impedance measurements for bovine blood, bovine blood with heparin, human blood, human blood with heparin and sweat were performed. The measurements were performed for various frequency. Figure 6 shows the impedance of the blood with respect to frequency. It shows that blood impedance increase with respect to frequencies.

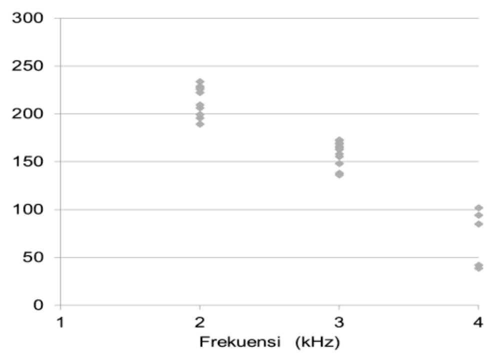


FIGURE 6. Impedance of the blood with respect to frequencies

Application of ANN algorithm for performing the sample classification was also performed in this study. Various samples such as water, sweat, bovine blood, human blood with various concentration of heparin were used for training set. Concentrations of heparin used are 2, 4, 6, 8 and 10 ml. After training set had been performed, experiments were conducted using various blood samples. There are about 5 blood samples for the evaluation.

TABLE 1. Evaluation results

Sample	True Positive	False Negative	Sensitivity (%)
Sample-1	30	1	97%
Sample-2	30	1	97%
Sample-3	30	2	93%
Sample-4	30	3	91%
Sample-5	30	2	97%

The sensitivity of the device is obtained the ration between the true positive and the sum between true positive abd false negative multiply with 100%. It is shown that the sensitivity is greater than 90%. The wireless connection testing was performed using two scenarios. First scenario is performed by setting the transmission distance up between the blood leak detector device with Wifi module and the monitoring panel as shown in Fig. 6. In order to obtain the effectiveness of wireless transmission distance, experimental measurements were conducted in the outdoor space. The distances between the Wi-Fi module and the blood leak detection devices were set to 25, 50, and 75 m.

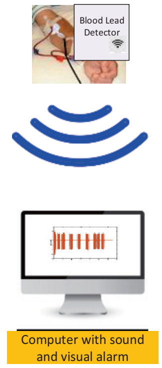


FIGURE 7. Wireless blood leak detection system test.

Tab. 2 shows that data could be received at 75 m, and the received signal strength indicator (RSSI) is -85 dBm. If the RSSI is more than -80 dBm, the data loss rate of the proposed device is below 1%, thus meeting the requirement of this study. According to the actual dialysis ward size of about 10 – 25 m, the results of this experiment confirm the validity of a Wi-Fi wireless transmission system.

TABLE 2. Frequency Propagation Test.

Distance (m)	Wi-Fi (dBm)	Data-loss (%)
25	-70	0x
50	-77	0x
75	-85	<1

After the effective wireless transmission distance test, Fig. 7 shows the experimental set-up of 2 devices connected to Wi-Fi. It is used for testing the transmission stability during the multi-bed monitoring.

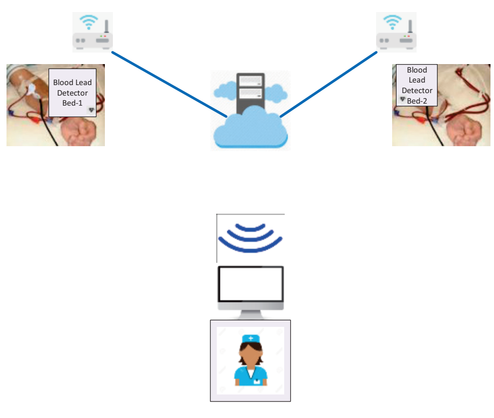


FIGURE 8. Multi-bed monitoring for blood leak detection system.

Test results showed that the system can be used for blood leakage detection in multi-bed dialysis monitoring system. In the nursing station, healthcare workers could view the status of all dialysis patients. It is also possible to integrate the multi-bed dialysis monitoring system into the hospital information system. From the experimental results, it is recommended that a low-power-consumption blood leak detection module is needed to increase the life cycle of the battery.

CONCLUSION

The wireless blood leak detection device had been developed for the monitoring of blood leak or blood loss during hemodialysis therapy. The device consists of multi-electrode sensor, impedance analyzer, microcontroller unit with Wi-Fi communication and alarm system. Artificial Neural Network algorithm was used to classify the detected sample. Various testing had been conducted for to obtain the performance of the device: functional test, battery life test and wireless communication test. The experimental results show that the device be able to detect the various human blood samples. The battery life time is of about 4-8 hours under non continuous operation. The distance between the blood leak detection device and the monitoring panel is of about 75 m with data rate loss is less than 1%.

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