The Feasibility of Integrating Flexible Sensor and Virtual Self-Organizing DC Grid Model in an Embedded System for Blood Leakage Detection During Dialysis Treatment

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Abstract—Blood leakage or serious blood loss is a frequent life-threatening complication that occurs during dialysis treatment. When these events occur, it takes only a few minutes for blood loss in an adult patient, resulting in mortality. As an early-warning design, this study proposes integrating a flexible sensor and a virtual self-organizing DC (Direct Current) grid model for blood leakage detection. A flexible sensor is made using a screen printing technique, and a self-organizing algorithm is used to automatically construct a virtual DC grid from an existing grid to an extending grid. That is, a virtual blood leakage detector can be modeled, which is intended for detection of blood leakage or serious blood loss. The feasibility is verified, and the model is implemented in an embedded system.

Index Terms—Blood Leakage, Flexible Sensor, Self Organizing, DC (Direct Current), Virtual DC Grid Model.

1. Introduction

According to the 2016 statistics, in Taiwan, more than 80,000 patients with end-stage renal disease and chronic kidney failure have received dialysis therapy. In a routine dialysis treatment, certain complications occur frequently, including vascular access stenosis [1], venous needle dislodgment, body fluid/blood leakage, and serious blood loss [2-3]. Among these events, blood leakage or serious blood loss is a life-threatening complication. With blood flow rates of 400–500 ml/min, it takes only a few minutes to lose more than 40% of the adult blood volume. In a lecture in 2012 [4], the American Nephrology Nurses' Association (ANNA) venous needle dislodgement (VND) survey reports revealed that more than 75% of the surveyed candidates indicated that they had observed a VND event in a hemodialysis room with more than 8% having observed five events or more in the last 5 years. The reports also revealed that more than half of the surveyed candidates concerned about VND or serious blood loss indicated that they were concerned about VND very often (>30%) or often (>20%). Six risk levels were identified in the ANNA

Figure 1. The proposed configuration of an integrating flexible sensor and virtual DC grid

VND survey results [3], and practice recommendations were also implemented to prevent VND [3, 5-7], including selecting an adequate access cannulation site, which serves a dual purpose, taping the needles securely, assuring access visibility, using a safety dialysis machine, and monitoring the devices.

In addition, various alarms have been built into a hemodialysis machine that can warn system malfunction through pressure (pump pull and push), blood leaks, pump flow, and temperature monitors. Measuring venous pressure helps in detecting VND, whereas pressure drops act to stop the roller pump. Pad sensors, optical sensors, and wetness sensors [8-10] can also be used as an early warning detector, such as the customized product Redsense® monitor (CE mark, Halmstad, Sweden, approved by the FDA) for high-risk patients and home HD. It is placed at the access cannulation sites around the venous and arterial needles to detect blood leakage or blood loss. It relies on an optical sensor (infrared light) and is not sensitive to clear but conductive fluids such as saline. A pad sensor [9] comprises upper / lower membrane layers and an electrical circuit connection. When blood comes in contact with the circuit connection, electrical connection changes produce electrical

Figure 2. The configuration of proposed flexible sensor

signals that are sent to the analytical circuit (alarm unit) or analytical method [10]. These base membrane layers need to be made of a medical-grade and biocompatible material. Electromagnetic compatibility (EMC), circuit electrical performance, and electrical tests should be validated (IEC 60601-1, medical design standards) for medical electrical equipments and compliances. Wetness sensors are sensitive to not only blood but also saline and other fluids in the patient's body environment [2]. However, these alarm tools cannot stop the blood pump as there is no interface with the hemodialysis machine.

Hence, this study proposed integrating a flexible sensor [11-13] and a virtual DC grid model [14-15] for body fluid / blood leakage detection during dialysis treatment, as shown in Figure 1. The virtual DC grid model with a sensing unit and a wireless communication [16] can be implemented in an embedded system. The virtual DC grid model is a manner to design a virtual self-organizing analytical circuit / alarm unit. It can automatically build up an impedance matrix by adding the analytical circuit's connecting branches one at a time to construct a complete DC grid that is formed from an existing impedance matrix to extend a new large-scale impedance matrix. Its advantage is that it can be easily implemented on a digital tablet (PC) or an intelligent mobile devices. The so-called "rake equivalent circuit" is applied for short circuit analysis in a grid using the current injection method [17-18]. A flexible sensor consists of an electrical connection circuit and is made using a screen printing technique with elastic and metallic materials. A detector integrating a flexible sensor and a virtual DC grid can then be implemented into an embedded

Figure 3. The configuration of proposed virtual DC grid for blood leakage detection

system and WiFi wireless local area network (WLAN, IEEE 802.11 Standards) [16]. The feasibility of the proposed model is verified in this study.

2. Methodology

A. The Proposed Configuration of Flexible Sensor

Flexible sensors have been applied in several fields, including biomedical engineering, industrial automation controls, robotic sensing controls, communication security, human-robot interaction, and human-machine interfacing [11-13]. Capacitive-based, piezoresistive-based, and piezoelectric-based sensors are commonly used to measure pressure, force, and temperature and for tactile examination. They are thin, soft, flexible, and stretchable and can integrate a mobile and a wearable device on the human body. For healthcare applications, noninvasive sensing systems and health-monitoring appliances are widely used for clinical needs and biomedical diagnostic procedures. An advantage of the flexible sensor is that it can be placed anywhere on the patient's body.

Therefore, a printed circuit board (PCB) was mounted in a flexible planar, with a size of 60 mm × 40 mm body-fluid-sensitive element with 9 nodes. It is a configuration of an 8-position switch that manipulates the open and closed states through blood leakage / serious blood loss. Interface conductors connect directly to embedded system connectors (digital inputs, DIs) without using any additional components, because of using the pull-up on MXP (port) connectors or pull-down on MSP (port) connectors. MSP connectors (DI-01 ~ DI-08) are used to measure 0 – 3.3 V signal [16]. Each connector has an internal 40kΩ pull-down

resister. For a constant voltage source, $V_{cd} = +3.3$ V, eight connecting conductors will appear as short circuit in any position. On the MSP connectors, each DI has a connection from V_{cd} to pull-down resistor, as shown in Figure 2. Hence, each DI has one terminal tied high to the voltage, V_{cd} , and then the numerical values or binary patterns can be obtained. The eight-bit binary patterns can be defined as (1)

$$C_l = \begin{cases} 1, & \text{if } V_l = V_{cd} (\text{High}) \\ 0, & \text{if } V_l = 0 (\text{Low}) \end{cases}, l = 1, 2, 3, \dots, 8 \quad (1)$$

where the 8-bit binary patterns are control signals, which are used to control the resistor, R_g , tied to the virtual ground, as shown in Figure 3.

Then, a WiFi WLAN is used for linking mobile devices (smart phones, personal digital assistant, or iPad) and portable computers (laptops), while operating on 2.4-GHz industrial, science, and medical frequency bands. It is employed to transit the control signals for portable devices with short-range communications in common household and mobile appliances.

B. Virtual DC Grid Model in an Embedded System

As shown in Figure 3, consider a virtual DC grid consisting of 10 nodes ($n = 10$) and 11 branches ($b = 11$), whose DC grid has the following connecting matrix, M_C , as follows:

$$M_C = \begin{array}{c} \begin{array}{cccc} \text{Node} & \text{Node} & R & C \\ \text{No.} & \text{No.} & & \end{array} \\ \begin{array}{cccc} 1 & 0 & R_s & 1 \\ 1 & 2 & R_{ref1} & 1 \\ 2 & 0 & R_{ref2} & 1 \\ 2 & 3 & R_1 & 1 \\ 2 & 4 & R_2 & 1 \\ 2 & 5 & R_3 & 1 \\ 2 & 6 & R_4 & 1 \\ 2 & 7 & R_5 & 1 \\ 2 & 8 & R_6 & 1 \\ 2 & 9 & R_7 & 1 \\ 2 & 10 & R_8 & 1 \end{array} \end{array} \quad (2)$$

where Column 1# and Column 2# are the branches with resistors, including additional resistors between two nodes (①# - ②# to ③# - ⑩#), and an additional resistor from one node to the reference node (⑩#); Column 3# indicates the resistors in the DC grid; and Column 4# describes the connecting state, the symbol “ $C = 1$ (High)” indicates the connecting state; otherwise, it is symbol “ $C = 0$ (Low).”

The constant R_s is the internal resistor in the current source, I . Resistors, R_{ref1} and R_{ref2} ($R_{ref1} = 2 \times R_{ref2}$), are used to determine the normal output voltage, V_{out} , using the voltage divider rule, as follows:

$$V_{out} = (1 + \frac{R_{ref1}}{R_{ref2}}) \times (\frac{R_{ref2}}{R_{ref1} + R_{ref2}}) \times (I \times R_s) \quad (3)$$

where $(1 + R_{ref1}/R_{ref2})$ is the magnification of a virtual amplifier. The voltage level is 3.3 V for further wireless communication application via the WiFi WLAN (IEEE

802.11 Standard). Constants R_1 to R_8 are the branch resistors. The ground connection matrix, M_g , is defined as follows:

$$M_g = \begin{array}{c} \begin{array}{cccc} \text{Node} & \text{Node} & R & C \\ \text{No.} & \text{No.} & & \end{array} \\ \begin{array}{cccc} 3 & 0 & R_g & 0 / 1 \\ 4 & 0 & R_g & 0 / 1 \\ 5 & 0 & R_g & 0 / 1 \\ 6 & 0 & R_g & 0 / 1 \\ 7 & 0 & R_g & 0 / 1 \\ 8 & 0 & R_g & 0 / 1 \\ 9 & 0 & R_g & 0 / 1 \\ 10 & 0 & R_g & 0 / 1 \end{array} \end{array} \quad (4)$$

where Column 1# and Column 2# describe the short circuit between one node to virtual ground (grounded branch: $g = 8$), due to blood leakage. Constant R_g is the virtual ground resistor, as described below:

$$R_g = R_l = R_{ref}, l = 1, 2, 3, \dots, 8 \quad (5)$$

When the blood leakage is detected by the flexible sensor, the control signal will be “ $C = 1$ ” and the grounded branch will be connected. The connecting matrix and the ground connection matrix are combined, whose virtual DC grid has the following admittance matrix, as shown below [14, 17]:

$$M = \begin{bmatrix} M_C \\ M_g \end{bmatrix}_{h \times 4}, h = 1, 2, 3, \dots, (b + g) \quad (6)$$

$$Y = [Y_{ij}] \in R^{n \times n}, Y_{ij} = \begin{cases} (y_{ij} + \sum_{k \neq i} y_{ik}), & \text{if } i = j \\ -y_{ij}, & \text{if } i \neq j \end{cases} \quad (7)$$

$$y_{ij} = \frac{1}{M_{h3}}, i = 1, 2, 3, \dots, n, j = 1, 2, 3, \dots, n, \quad (8)$$

where node number, $n = 10$; branch number, $b = 11$; and grounded branch, $g = 8$; y_{ij} is the admittance ($y_{ii} \neq 0$) between the node, i , and node, j .

In the virtual DC grid, only the current source is injected into node ①#, and the nodal equations for the grid are:

$$YV = I \Rightarrow [Y]_{10 \times 10} \begin{bmatrix} V_1 \\ V_2 \\ V_3 \\ \vdots \\ V_{10} \end{bmatrix}_{10 \times 1} = \begin{bmatrix} I_s \\ 0 \\ 0 \\ \vdots \\ 0 \end{bmatrix}_{10 \times 1} \quad (9)$$

$$ZI = V, Z = Y^{-1} \quad (10)$$

where I_s is the injection current into node ①#; Z is the impedance matrix; and both Z and Y are symmetric matrices; the nodal voltages at each node can be obtained using the current injection method [18-19], as follows:

$$\begin{bmatrix} z_{11} & z_{12} & z_{13} & \cdots & z_{1n} \\ z_{21} & z_{22} & z_{23} & \cdots & z_{2n} \\ z_{31} & z_{32} & z_{33} & \cdots & z_{3n} \\ \vdots & \vdots & \vdots & \ddots & \vdots \\ z_{n1} & z_{n2} & z_{n3} & \cdots & z_{nn} \end{bmatrix} \begin{bmatrix} I_s \\ 0 \\ 0 \\ \vdots \\ 0 \end{bmatrix} = \begin{bmatrix} V_1 \\ V_2 \\ V_3 \\ \vdots \\ V_{10} \end{bmatrix} \quad (11)$$

where nodal voltages, V_3 to V_{10} , are used to identify the

Figure 4. The graphical programming user interface

blood leakage, while their grasp drops have blood leakage occurrence, as follows:

$$V_{\min} = \min\{V_3, V_4, \dots, V_{10}\}, V_{\max} = \max\{V_3, V_4, \dots, V_{10}\}$$

$$V_{ref} = \frac{1}{2}(V_{\min} + V_{\max}) \quad (12)$$

$$S_j = \begin{cases} 0, & V_j > V_{ref} \\ 1, & V_j \leq V_{ref} \end{cases}, j = 3, 4, 5, \dots, 10 \quad (13)$$

where state variable, $S_j = 1$, indicates that one or more nodes have detected a blood leakage event. Therefore, signal "1" acts to drive an alarm unit. In addition, the power flow equations of the grounded branches can be represented as

$$P = V_i \times \sum_{l=1}^8 \left(\frac{V_l}{R_l} \right), i = 3, 4, 5, \dots, 10, R_l \neq 0 \quad (14)$$

where grounded branch, $R_l \neq 0$, while the connecting state " $C = 1$ "; otherwise " $C = 0$ " indicates that the grounded branch is not connected, and resistor, $R_l = 0$. When several grounded branches are connected, the power flow will increase.

There are two grasp changes that can be used to quantify the level of blood leakage and can be summarized as follows:

- nodal voltage drops: nodal voltages, V_3 to V_{10} , are drops, while one or more sensing points in a flexible sensor have detected blood leakage using equations (12) and (13),
- power flow increases: one or more ground branches are connected, resulting in power flow increases.

3. Experimental Results

The proposed prototype detection model has been developed in an embedded system (National InstrumentsTM myRIO-1900, Austin, Texas, U.S.A). The virtual DC grid model was coded as a "self-organizing algorithm" in an embedded system, including matrix methods for large-scale network and a current injection method. The flexible sensor (60 mm × 40 mm) was made using a screen printing technique with elastic and metallic materials. As shown by the connecting topology in Figure 3, the DC grid has 10

Figure 5. Experimental results. (a) Nodal voltage distributions in a 60mm × 40mm region, (b) Nodal voltages, V_2 , versus blood leakage events at node 2#

nodes and its connecting injection current, inductance, and resistors are shown as follows:

Injection Current: $I_s = 1\text{mA}$,
 $R_1 = 100\Omega$, $R_{ref1} = 100\text{k}\Omega$, $R_{ref2} = 50\text{k}\Omega$, $L = 5\text{mH}$,
 $R_{ref4} = 99 \times R_{ref1}$, $R_{ref3} = 1\text{k}\Omega$,
 $R_l = R_g = 50\text{k}\Omega$, $l = 1, 2, 3, \dots, 8$

Hence, considering the connecting states, C , of the connecting matrices, M_C and M_g , the original impedance matrix, Z , was constructed at the top of the next page, where the square matrix, Z , was a symmetric and nonsingular matrix that was equal to transpose, $Z = Z^T$ and $|Z| \neq 0$. The connecting states were obtained from the flexible sensor. The proposed prototype model was designed using a LabVIEW graphical programming user interface (NITM Corporation, Austin, Texas, U.S.), as shown in Figure 4, and was carried out in a development platform, such as a tablet PC or mobile intelligent vehicles.

$$Z_{10 \times 10} = \begin{bmatrix} 100 & 33 & 33 & 33 & 33 & 33 & 33 & 33 & 33 & 33 \\ 33344 & 33344 & 33344 & 33344 & 33344 & 33344 & 33344 & 33344 & 33344 & 33344 \\ 83344 & 33344 & 33344 & 33344 & 33344 & 33344 & 33344 & 33344 & 33344 & 33344 \\ 83344 & 33344 & 33344 & 33344 & 33344 & 33344 & 33344 & 33344 & 33344 & 33344 \\ 83344 & 33344 & 33344 & 33344 & 33344 & 33344 & 33344 & 33344 & 33344 & 33344 \\ 83344 & 33344 & 33344 & 33344 & 33344 & 33344 & 33344 & 33344 & 33344 & 33344 \\ 83344 & 33344 & 33344 & 33344 & 33344 & 33344 & 33344 & 33344 & 33344 & 33344 \\ 83344 & 33344 & 33344 & 33344 & 33344 & 33344 & 33344 & 33344 & 33344 & 33344 \\ 83344 & 33344 & 33344 & 33344 & 33344 & 33344 & 33344 & 33344 & 33344 & 33344 \\ 83344 & 33344 & 33344 & 33344 & 33344 & 33344 & 33344 & 33344 & 33344 & 33344 \end{bmatrix}$$

$$Z_g = \begin{bmatrix} 100 & 14 & 7 & 7 & 14 & 14 & 14 & 14 & 7 & 7 \\ 14288 & 7144 & 7144 & 14288 & 14288 & 14288 & 14288 & 7144 & 7144 & 7144 \\ 28572 & 3572 & 7144 & 7144 & 7144 & 7144 & 3572 & 3572 & 3572 & 3572 \\ 28572 & 7144 & 7144 & 7144 & 7144 & 7144 & 3572 & 3572 & 3572 & 3572 \\ 64288 & 14288 & 14288 & 14288 & 7144 & 7144 & 7144 & 7144 & 7144 & 7144 \\ 64288 & 14288 & 14288 & 14288 & 7144 & 7144 & 7144 & 7144 & 7144 & 7144 \\ 64288 & 14288 & 14288 & 14288 & 7144 & 7144 & 7144 & 7144 & 7144 & 7144 \\ 28572 & 3572 & 7144 & 7144 & 7144 & 7144 & 3572 & 3572 & 3572 & 3572 \\ 28572 & 3572 & 7144 & 7144 & 7144 & 7144 & 3572 & 3572 & 3572 & 3572 \end{bmatrix}$$

Figure 6. Voltage distributions. (a) Nodal voltage distributions for case study, (b) Nodal voltage distributions for serious case

For normal condition and eight blood leakage events, nodal voltages, V_2 to V_{10} , can be calculated using equations (6) to (11), and the nodal voltage distributions are illustrated in Figure 5(a). Therefore, local or global information can be characterized by the binary sensing/communication matrix using equations (12) and (13), while state signals are further used to drive an alarm unit. The nodal voltages versus blood leakage events are depicted in Figure 5(b). Nodal voltage, V_2 , is regarded as a reference voltage, while the voltage levels were from 3.33 V to 0.91 V. That is, the binary sensing matrix can be determined.

Suppose a blood leakage event as shown in Figure 6; blood leakage covered the nodes, 3#, 4#, 9#, and 10#, and caused the short circuit. Then, the flexible sensor detected the connecting states and transited the control signals to the

Table 1. The specification of the proposed integrating sensor

Constant Voltage Source	$V_{cd} = +3.3V$
Virtual Injection Current	1mA
Connector	MXP (port) or MSP (port)
Pull-up or Pull-down Resistor	40k Ω
Wireless Communication	2.4GHz, WiFi, WLAN, IEEE 802.11 Standards
Virtual Circuit Element	$R_1=100\Omega$, $R_{ref1}=100k\Omega$, $R_{ref2}=50K\Omega$, $L=5mH$, $R_{ref4}=99 \times R_{ref1}$, $R_{ref3}=1K\Omega$, $R_l=R_g=50K\Omega$, $l=1, 2, 3, \dots, 8$
Voltage Level for Identifying Normal Condition	Virtual Voltage: +3.33V
Voltage Level for Identifying Blood Leakage / Blood Loss	The Range of Virtual Voltage: +2.50V ~ 0.45V
Power Flow	0.1248mW ~ 0.0303mW

virtual DC grid, as shown below:

$$[C_1, C_2, C_3, C_4, C_5, C_6, C_7, C_8] = [1, 1, 0, 0, 0, 0, 1, 1]$$

The self-organizing algorithm acted to construct the impedance matrix, Z_g , at the top of the next page. The nodal voltages were calculated using equation (10), as shown in Figures 5 and 6(a). Their grasp drops can be identified using equations (12) and (13), as follows:

$$V = [V_2, V_3, V_4, V_5, V_6, V_7, V_8, V_9, V_{10}] = [1.4273, 0.7137, 0.7137, 1.4273, 1.4273, 1.4273, 1.4273, 0.7137, 0.7137],$$

$$V_{min} = \min(V) = 0.7137, V_{max} = \max(V) = 1.4273,$$

$$V_{ref} = 1.0705,$$

$$[S_3, S_4, S_5, S_6, S_7, S_8, S_9, S_{10}] = [1, 1, 0, 0, 0, 0, 1, 1].$$

State variables indicate “signal 1” to identify the blood leakage event and to drive an alarm unit. In addition, power flow was calculated using equation (14) and its value increased from 0.0000mW to 0.1019mW at the grounded branches. Figure 6(b) shows the nodal voltage distributions for a serious case. Overall nodal voltages dropped and power flow also increased from 0.0000 mW to 0.0303 mW. These findings confirmed that the proposed model could detect blood leakage or serious blood loss during dialysis treatment.

4. Conclusion

Medical electrical equipments need to be validated for safety and effectiveness before their commercialization. The standard of IEC 60601 series [20] covers the design methodology, verification, and risk assessment. Considering the biocompatibility and electrical safety, the design of the flexible sensor reduced a large amount of electrical circuits used to produce the analytical circuit and the alarm unit.

The flexible sensor was made using a screen printing technique with elastic and metallic materials. The analytical and alarm units were virtualized and implemented in an embedded system. A self-organizing algorithm using a large matrix method was employed to construct the virtual DC grid. Its variable structure can construct a virtual DC grid for handling various conditions. Table 1 shows the specification of the proposed integrating sensor. The feasibility of the proposed prototype has been verified and this simple technique can be easily implemented on a tablet PC or a mobile appliance via wireless connection, cloud computing, and cloud storage for clinical applications.

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