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INVESTIGATION OF ELECTRICAL CHARACTERISTICS IN NOVEL NEEDLE DISLODGEMENT DETECTION ELECTRODES FOR DIALYSIS THERAPY

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Abstract. *Hemodialysis (HD) is essential for patients with renal failure; however, venous needle dislodgement (VND) during the procedure can lead to significant blood loss. Current HD devices do not offer effective preventive measures against this risk. In response, we have developed a noninvasive system for automatic VND detection. This research enhances the usability of the detection electrode and testing its electrical characteristics to prevent complications. Our updated electrode successfully identified VND. Moreover, the frequency response showed that utilizing a wide range of frequencies may be more effective for VND detection than relying on a single frequency. Finally, its one-touch detachability feature is expected to enhance usability and patient safety associated with HD.*
Keywords: Venous needle dislodgement (VND), VND detection, Hemodialysis (HD), Dialysis, Patient safety, Blood loss

1. **Introduction.** Approximately 350,000 patients in Japan undergo chronic dialysis therapy, with this number reportedly increasing by about 2,000 annually [1]. For dialysis patients, sustaining life is challenging without either receiving treatment to replace kidney functions or undergoing kidney transplantation. However, a statistical survey conducted from January 1 to December 31, 2022, revealed that of the 14,080 transplant recipients nationwide, only 198 kidney transplants were performed [2]. Consequently, a significant

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proportion of patients either continue with hemodialysis treatment or are newly introduced to it. Hemodialysis plays a crucial role in maintaining their lives. This treatment involves the extracorporeal circulation of the patient's blood, removal of excess fluid and waste products via an artificial kidney called a "dialyzer", and returning the purified blood to the body (Figure 1). A major risk associated with this process is significant blood loss due to unintended dislodgement of the venous indwelling needle, referred to as venous needle dislodgement (VND). Accidents from needle dislodgement are reportedly among the most common in dialysis treatment and can sometimes be life-threatening [3,4].

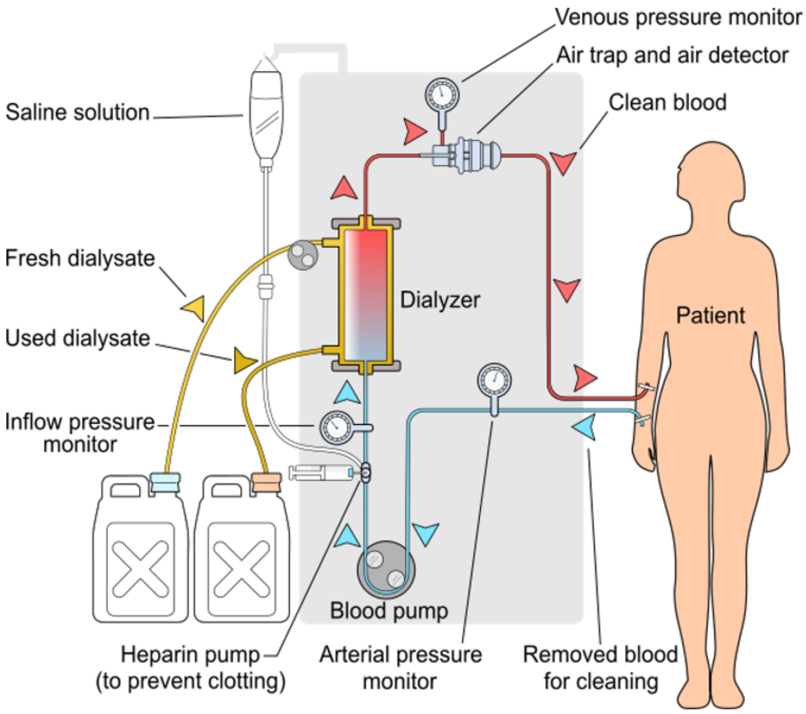


FIGURE 1. Schematic diagram of hemodialysis [8]

Two primary methods exist to prevent VND accidents: human and machine intervention. However, current systems lack a dedicated VND detection mechanism. The prevalent method detects pressure variations on the return side and relies on resistance within the needle's narrow tubing. The resulting intravascular pressure difference is often minimal and challenging to detect [5]. Moreover, human preventative measures have not been wholly effective against VND accidents, which constitute a significant portion of dialysis treatment mishaps.

To address these challenges, we designed a VND detection system using a reusable capacitive coupling sensor [6,7]. The VND detection circuit has electrodes attached at two points in the blood circuit and applies an alternating current signal, which causes a capacitive coupling between the VND detection circuit, the blood circuit, and the human body. When the VND detection circuit detects a needle removal, it sounds an alarm and immediately stops the blood pump of the dialysis machine. Furthermore, the VND detection circuit is wirelessly connected to a VND detection web system, and the monitoring status is notified to a PC installed at a nurses' station or other location. However, conventional electrodes increase the workload of medical personnel, as they require conductive tape to be wrapped around the circuit before being clipped in place. To mitigate this issue, we developed an electrode that can be attached with a single touch, reducing the workload and enhancing patient safety.

This study examines the electrical characteristics of three detection electrodes: two redesigned for improved usability and one conventional detection electrode.

2. Methods.

2.1. **Needle dislodgement detection circuit (electrodes testing circuit).** Figure 2 provides an overview of the electrodes testing circuit.

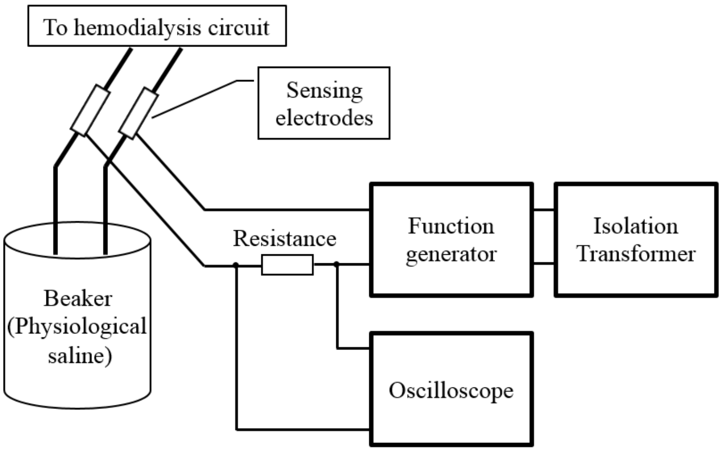


FIGURE 2. Detection of electrodes testing circuit

The dialysis circuit is comprised of a dialysis machine (TR-3000S: Toray Medical), a hemodialysis circuit (H-502-ATU: Toray Medical), indwelling dialysis needles (HappyCath V (16 G), with a side hole: Medikit), and a dialyzer (APS15EA: Asahi Kasei Medical).

The needle dislodgement detection circuit includes a clip-type detection electrode (conventional type), a newly developed detection electrode (offered in two types), a load resistance (200 kΩ), a function generator (AFG31000: Tektronix), an oscilloscope (DSO-X 2024A: Agilent Technologies), and an isolation transformer (DF2UL022AH216: ANIMA). The detector electrodes are positioned at two locations on the arterial (blood collection) and venous (blood return) sides of the blood circuit, specifically 30 cm from the needle's tip or at the bottom of the arteriovenous chamber. They are connected to the function generator via a series-connected load resistor. The function generator is connected to the power supply through an isolation transformer to negate any interference on the measured values due to electrical coupling with the oscilloscope.

When the needle tip is submerged in a saline solution inside a beaker that simulates a human body, the electrode and beaker become capacitively coupled, leading to a very minute current flow. Conversely, if the blood circuit is disconnected, the electrical characteristics of the needle tip alter, and the voltage value observed at the resistor's two ends diminishes. In its function as a needle dislodgement detection circuit, the voltage drop across the resistor is half-wave rectified, and the direct current (DC) voltage value is monitored by a microcomputer to facilitate needle dislodgement detection.

For this study, aiming to emphasize the electrode's electrical characteristics, the voltage drop across the load resistance was measured directly using an oscilloscope for comparison.

2.2. **Detection principles.** Figure 3 shows a model diagram for application to an actual patient and electrical equivalent circuit.

As shown in Figure 3, the detection electrode is attached to the arterial (blood collection side) and venous (blood return side) sides of the blood circuit. Therefore, an insulator such as a blood circuit or an indwelling dialysis needle connects the detector electrode and the patient. Thus, the electrical equivalent circuit between the two detector electrodes can be expressed as shown in Figure 3.

R is the extremely large impedance component due to the human body and blood circuit, and C is the capacitance component due to the electrostatic capacitance that exists between the electrodes. Since these are connected in parallel, the current hardly flows

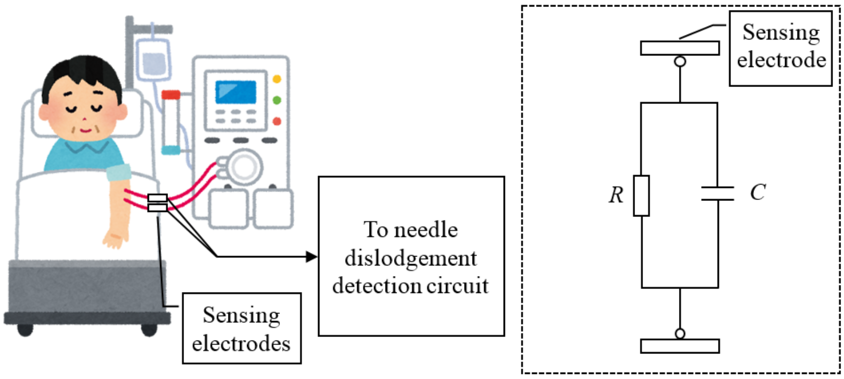


FIGURE 3. Model diagram for application to a patient and electrical equivalent circuit [6]

into the impedance component, and the capacitance component dominantly determines the current value.

The capacitive reactance is expressed by the following equation. Furthermore, j is the imaginary unit and ω is the angular frequency, $2\pi f$ [rad/s].

$$X_C = \frac{1}{j\omega C} = -j\frac{1}{\omega C} \ [\Omega] \tag{1}$$

From Equation (1), it is known that the capacitive reactance has a low electrical impedance to alternative current (AC) signals. Therefore, when a weak AC signal that does not affect the human body is applied to the sensing electrode, a very small amount of current is flowing due to capacitive electrical coupling. However, if one side of the indwelling needle becomes disconnected from the patient, the dielectric material between the electrodes (like human blood) is substituted with a model that traps some air.

The dielectric between the electrodes is replaced by a model in which air is partially sandwiched between the electrodes. The capacitance of a single dielectric capacitor using a metal parallel plate is shown by the following equation, assuming the area of the electrode plate as S [m^2], the dielectric constant in vacuum as ε_0, the relative dielectric constant of the material between the electrodes is ε_r, and its thickness is l [m].

$$C = \frac{\varepsilon S}{l} = \frac{\varepsilon_0 \varepsilon_r S}{l} \ [\mathrm{F}] \tag{2}$$

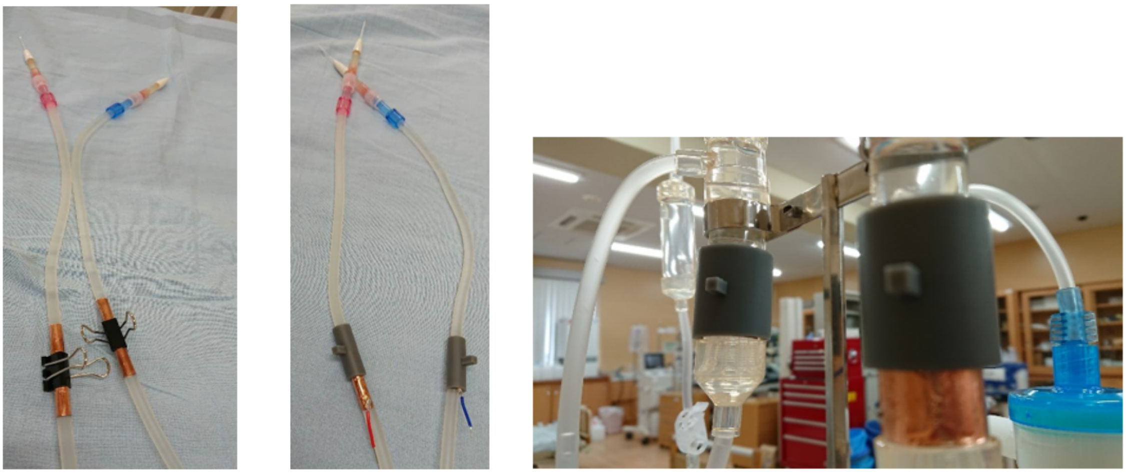
If the dielectric is partially replaced by air, the dielectric constant of the original dielectric is ε_1 and that of air is ε_2, and the thicknesses are l_1 and l_2 [m], respectively, Equation (3) shows that the capacitance C is smaller than that of Equation (2).

$$C = \frac{S}{\frac{l_1}{\varepsilon_1} + \frac{l_2}{\varepsilon_2}} \ [\mathrm{F}] \tag{3}$$

As the capacitance C becomes smaller, the capacitive reactance increases according to Equation (1), and the electrical impedance between the electrodes also increases. This impedance change decreases the voltage drop across the load resistance shown in Figure 2. By monitoring this voltage drop using tools like a microcomputer, the circuit can detect needle dislodgement.

2.3. **Detection electrodes.** Figures 4(a)-4(c) show the conventional clip-type electrode, the newly developed slip-on type electrode, and the chamber-mounted type electrode used in this study.

The contact areas of the different electrodes were as follows: conventional electrodes at 25 cm^2, slip-on type at 4.5 cm^2, and chamber-mounted type at 13.2 cm^2.



(a) Conventional type (b) Slip-on type (c) Chamber-mounted type

Figure 4. Photograph of each detection electrode

3. Results and Discussion.

3.1. **Experimental procedure.** We used the electrodes testing circuit and dialysis circuit shown in Figure 2. High-frequency signals (sinusoidal, 1 kHz to 10 MHz, 10 $V_{\text{p-p}}$) were applied to the tip of the dialysis circuit. Measurements were taken with the needle tip immersed in a beaker of saline solution (normal condition) and with one side of the needle disconnected (termed VND). The dialysis circuit was primed with saline solution. The dialysis machine used a sodium chloride solution, adjusted to match the conductivity of regular dialysate. The machine was set to a dialysis mode without dehydration. The blood pump operated at 200 ml/min. The detector electrode was placed 30 cm from the needle tip or in the lower part of the arteriovenous chamber (Chamber-mounted type). Under these conditions, we compared the voltage drop differences between the normal and VND states across a signal frequency range of 1 kHz to 10 MHz. We took an average of 10 measurements at 10 kHz, the frequency at which the largest voltage difference was observed in a previous study [7], and examined if there was a statistically significant difference between the normal and VND conditions.

3.2. **Frequency characteristic experiment.** The frequency characteristics of various electrodes during normal operation and when the needle is dislodged are shown in Figures 5-7.

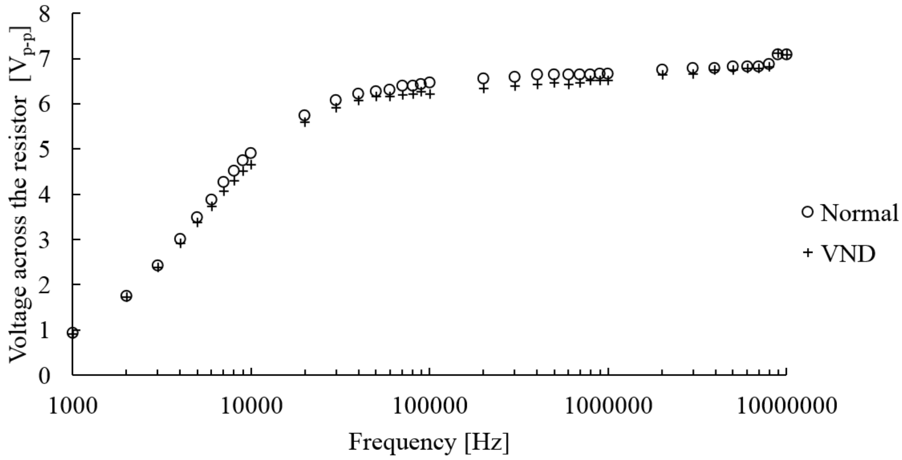


Figure 5. Frequency characteristic experiment on conventional electrode

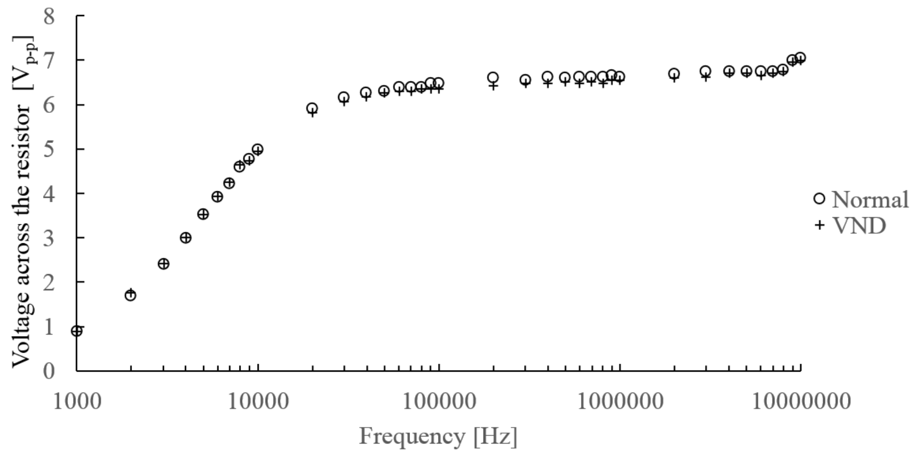


FIGURE 6. Frequency characteristic experiment on slip-on type electrode

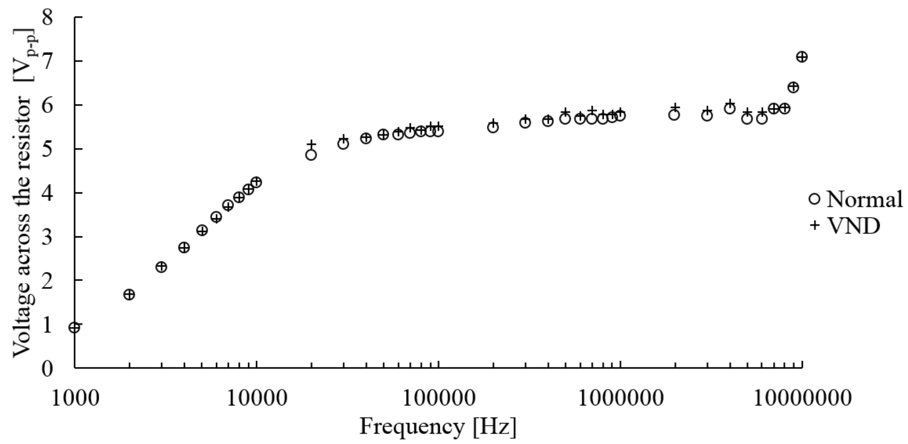


FIGURE 7. Frequency characteristic experiment on chamber-mounted type electrode

The frequency response of the conventional electrode mirrored our previous study, exhibiting a peak detection voltage difference at 9 kHz and 10 kHz. The detection voltage difference was 0.24 $V_{p\text{-}p}$ at the peak.

For the slip-on electrodes, the detection voltage difference peaked at 200 kHz, 400 kHz, 600 kHz, and 800 kHz, instead of 10 kHz. The detection voltage difference for these was 0.16 $V_{p\text{-}p}$ at the peak.

The chamber-mounted type electrode had its detection voltage difference peak at 6 kHz, with a difference of 0.04 $V_{p\text{-}p}$ at the peak.

From the experiments on the frequency characteristics presented in Figures 5 to 7, it is evident that the characteristics during normal operation and VND differ significantly for each type of detection electrode. Therefore, when using the needle dislodgement detection system, it is crucial to assess differences not just at a single frequency but across the entire frequency spectrum.

3.3. **Statistical comparison of the average voltage drop during normal and VND.** Figure 8 illustrates the average voltage drop across various detection electrodes operating at 10 kHz during normal and VND conditions. On the other hand, the slip-on type of electrode developed in this study had a smaller difference compared to the conventional electrode. The conventional electrode showed a voltage of 5.005 ± 0.026 [V] in the normal condition and 4.949 ± 0.044 [V] during VND.

The voltage difference across the load resistance, during both normal operation and VND, revealed statistically significant differences for all electrodes. The discrepancy was

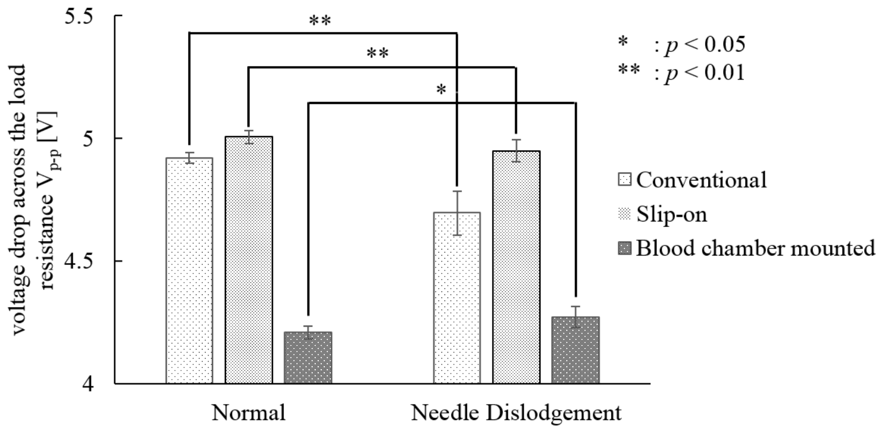


Figure 8. Average voltage drop during normal and VND (10 kHz)

notably vast for the conventional electrode compared to the others, aligning with findings from prior research.

In contrast, the slip-on electrode developed in this study exhibited a smaller difference. According to past research, there exists a positive correlation between electrode area and voltage difference during both normal operation and VND. The reduced contact area of the slip-on electrode, compared to the conventional type, might be responsible for these differences.

On the other hand, the slip-on type electrode can be applied with a single touch and reduces the workload compared to the conventional electrode, which requires wrapping conductive tape around the electrode and then inserting a clip.

Furthermore, chamber-mounted electrodes presented an inversion phenomenon where the VND voltage was larger than in normal circumstances, complicating VND detection. Past research has indicated a negative correlation between the distance from the needle's puncture site to the electrode's position and the voltage difference in both normal and VND states. Given the smaller contact area of chamber-mounted electrodes compared to conventional ones, these results suggest that detecting VND with chamber-mounted electrodes is difficult.

4. **Conclusion.** In this study, we compared two newly developed types of needle dislodgement detection electrodes with conventional electrodes to assess their practicality. As a result, the newly developed detection electrodes had issues with the electrode contact area and distance from the puncture site, and the voltage difference between normal and VND conditions was smaller than that observed with the conventional electrode. The frequency response experiments also indicate that utilizing a wide range of frequencies may be more effective for VND detection than relying on a single frequency.

On the other hand, the slip-on type electrode can be applied with a single touch and reduces the workload compared to the conventional electrode, which requires wrapping conductive tape around the electrode and then inserting a clip.

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