DEVELOPMENT OF A MONITORING SYSTEM FOR THE MANAGEMENT OF MEDICAL DEVICES

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ABSTRACT

In recent years, according to the sophistication of Medical Devices (MD), many portable MDs have been used and maintained with central management. However, the central management lends hospital staff the MDs only with managing by a ledger, therefore, missing or subletting may be caused. Furthermore, while the demand for the MDs is increasing due to the COVID-19, there is an issue that it is difficult to operate due to the shortage of clinical engineers against management duties of the MDs. In this study, we develop a power strip device which can measure electricity usage of plugged MD and its position and propose a visualization system for position and operation ratio of the MDs. We implemented 75 developed devices in three hospitals and confirmed that the system was effective to evaluate whether the number of the MDs owned by the hospital is appropriate.

KEYWORDS

Internet of Things (IoT), Wireless Network, Indoor Positioning, Medical Device, Management System

1. INTRODUCTION

In today's medical institutions, medical devices become smaller and more sophisticated. Many portable medical devices are used, and the number of devices requiring maintenance and management is increasing. Due to the 2007 revision of the Medical Care Law, the assignment of a medical device safety manager became mandatory, and the importance of medical device management increased in Japan [1-2]. In the case of a large hospital with about 1,000 beds, about 10,500 medical devices are managed, and approximately 90 devices are inspected per day. Because of this, the cost of managing the device is very high. Instead of managing different types of medical devices by department, a centralized management system centred on medical device managers such as medical engineers adopt in recent years [3-4].

The centralized management system manages the lending and returning of devices using a ledger. In this system, it is not possible to obtain the location and usage status of the rented device, but there are cases where the device is sub-leased or taken out temporarily without the lending process. As a result, they are left or lost in the course of medical work. The medical devices left for long periods of time cannot be regularly inspected. Searching for lost devices wastes medical device managers time and leads to lost opportunities.
In 2020, due to the prevalence of COVID-19, the demand for ventilators and extracorporeal membrane oxygenators used in intensive care units for critically ill patients surged. The Japanese government has requested an adequate supply of these medical devices. On the other hand,

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securing enough medical devices leads to an increase in the number of managed and inspections device per day. It increases the burden on medical device managers. In order to reduce the burden of medical device management, it is necessary to obtain the location and operational status of medical devices. Localization and estimate Operation Status of them in hospitals has been widely studied.

One hospital introduced APM (Asset Performance Management) Service to manage device location and operation status. By attaching beacons and power monitors to medical devices and installing receiving stations in various places in the hospital, it is possible to obtain the operation status and location information of them. However, this service only informs that there is a medical device near the receiving station. Namely, it cannot specify the location. The operation status includes the state in which the device is on standby for prompt use to patients. Therefore, it is necessary to be able to measure the actual status of devices, including their maintenance cycle.
In our study, we focused on the fact that portable medical devices are usually transported on a medical wagon and used by connecting them to a power strip attached to the wagon. It supplies power to connected medical devices, measure the amount of current used, and transmit the obtained data to a server. These data are transmitted via LPWA (Low Power Wide Area) communication. LPWA communication is low power consumption and long-distance communication compared to Wi-Fi, which is already used in hospitals. Furthermore, security is safe because there is no Wi-Fi connection, and there is no influence of interference because the communication bandwidth is different. The system also transmits the RSSI (Received Signal Strength Indicator) of the radio waves transmitted by the Wi-Fi and BLE (Bluetooth Low Energy) beacons installed in the hospital. Using these data, we perform indoor position estimation in the hospital.

The estimated position is displayed on the hospital map for visualization. The operation status of medical device is estimated by collecting current consumption. In addition, we developed a system that visualizes the actual operation rate of each medical device category and evaluates the excess or deficiency of the number of medical devices owned.

2. RELATED WORKS

In the centralized management of medical devices, device information is digitized using barcodes to improve the efficiency of medical device lending and returning in general centralized management. This system enables the person in charge of device management, such as a medical engineer, to view logs of lending and returning operations. It contributes to cost reduction in medical device management by making it possible to view and search lending and returning logs. In addition, it improves the efficiency of lending and returning operations [4].

CMDMS (Computerized Medical Device Management System) has be proposed as an IT (Information Technology)-based medical device management system. It focuses on maintenance schedule management for the purpose of preventive and improved maintenance of medical devices. It demonstrated in an actual hospital [6]. This system manages device maintenance schedules based on the downtime and their frequency. These systems do not consider the real operation rate of the devices, such as the operation status or the measurement of the actual power consumption.

Indoor positioning has been studied very extensively, and positioning using image, infrared, ultrasound, Wi-Fi, RFID (Radio Frequency Identification), and even Bluetooth has been proposed [7]. In this paper, we focus on Wi-Fi, RFID, and Bluetooth, which do not have LoS (Line of Sight) constraints, assuming that the structure of a hospital is complex. Indoor positioning system using medical devices equipped with wireless LAN (Local Area Network) has been constructed as a location estimation method [8]. This system performs positioning it by connecting them to Wi-Fi network in a hospital. The medical devices themselves must be capable of Wi-Fi communication, but modifications to the internal structure of existing medical devices, such as enabling Wi-Fi communication, are prohibited under the Pharmaceutical Affairs Law in Japan. Therefore, large-scale replacement is required to apply this system to all medical devices in a hospital. It requires a lot of labour and purchasing costs.

In indoor positioning, the positions of not only medical devices but also patients and medical staffs are estimated. A positioning system was constructed by attaching a bracelet to the patient's arm [9]. In this system, many BLE beacons are installed in the hospital. The bracelet receives the radio waves emitted from them, calculates the distance by measuring the strength of the radio waves, and performs positioning. On the other hand, the problem with this system is that it requires the installation of multiple beacons, gateways, and relay nodes in the hospital, making the system expensive to implement.

The above-mentioned indoor positioning using Wi-Fi and Bluetooth, it is important to conduct a radio wave strength survey at the location where the positioning is performed. Therefore, a system was proposed that tries Wi-Fi communication at each walking step to create fingerprints [10]. It is important guidelines for positioning by communicating Wi-Fi at comprehensive locations within a facility.

UHF (Ultra High Frequency) RFID is also used for indoor positioning because the tags attached to patients and medical devices do not require power [11]. RFID tag-based positioning has the advantage that the tags attached to the target are very inexpensive. However, unlike Wi-Fi-based positioning, which uses communication that has already been introduced, it requires the introduction of a new RFID reader, which increases the introduction cost [12].

On the other hand, indoor positioning using BLE beacons or RFID has the advantage. They can be reinforced after installation by adding their readers in areas where positioning is not possible due to lack of radio wave coverage.

For estimating operation status, a system and device was developed to monitor usage conditions using devices equipped with wireless LAN connectivity in recently years. Predicting future failures and performance of ventilators method has been proposed to optimize costs related to device inspections [13]. In this method, the data from maintenance and periodic inspections, including safety inspections of electrical characteristics and performance inspections, is used to determine whether it will pass inspections. The decision tree method has an accuracy of 98.5%. However, these systems require the replacement of devices to be managed, and the cost of implementation is high.

Recently, due to the prevalence of COVID-19, the development of ventilators as devices and the construction of systems that monitor them remotely [14]. A data model has been constructed for the purpose of improving the efficiency of ventilator management [15]. IT for medical devices has been studied. However, there is not much research on monitoring location information and operation information for medical devices in general.

In these methods, it becomes a new factor of a burden on medical staff such as battery replacement and inspection of IoT (Internet of Things) devices. In addition, the introduction and installation costs are high, and the burden at the time of introduction is heavy.

The current state of hospital management in Japan is that there is no budget to introduce these systems, and there are not enough human resources. Therefore, a system that can be introduced at a low cost and does not require much maintenance after the introduction is required.

3. PROPOSED SYSTEM ARCHITECTURE

Figure 1 shows the architecture of the system we propose in this paper. The IoT device we developed is connected to the power cable of a medical device. It collects current waveforms from medical devices. Wi-Fi access points and BLE beacons periodically transmit radio waves. Our device collects these radio waves. The collected current values and RSSI of these radio waves are transmitted by LoRa (Long Range) communication, which is a type of LPWA communication. The LPWA gateway receives data from IoT devices via LPWA communication. It transmits the received data to the DB (database) server. These collected data are accumulated in the DB server. The Web server acquires these data from the DB server and analyses it.

In the analysis, we estimate the indoor position in the hospital and the operation state of medical devices The analysis results are displayed on the website. Medical staffs view these data and use them for medical device management.

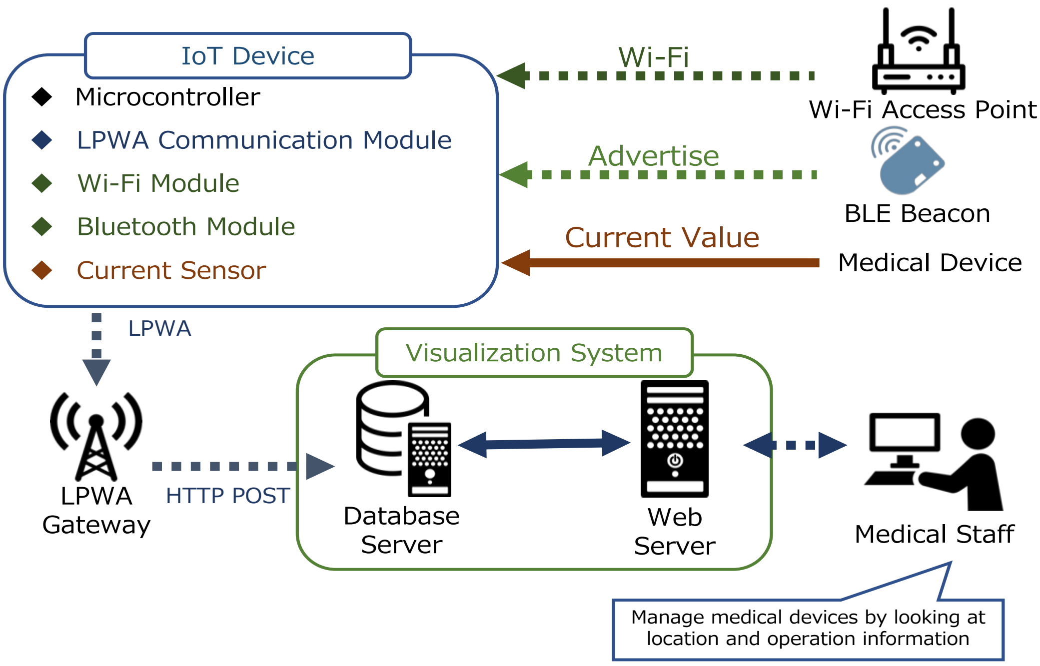

Figure 1. Proposed System Architecture

3.1 IoT Device for Medical Device

The configuration of the IoT device we designed and developed is shown in Figure 2. The device has the shape of a power strip with four outlets. It has an PCB (printed circuit board) inside. It has a MCU (Microcontroller Unit), LPWA Communication Module, Wi-Fi Module, Bluetooth Module, and four current sensors. These sensors measure the current value of each outlet.

The device is used as a power strip. The power cable of the medical device is connected to the outlet in our device. The power cable of our device is connected to the outlet of the hospital. Current is supplied to these medical devices through the current sensor. These current sensors acquire the current and transmits it as analog data to MCU. The MCU converts the acquired value through an A/D (Analog to Digital) converter. The current value is calculated from these values. One current sensor is attached to each outlet. It is possible to acquire the current value of each medical device connected to the outlet.

To track the position of non-operating medical devices, our device is battery-powered and runs without a power supply from the power cable. When the power cable is connected, the AC(Alternate Current) -DC (Direct Current) converter of our device converts AC to DC and charges the litium ion battery.

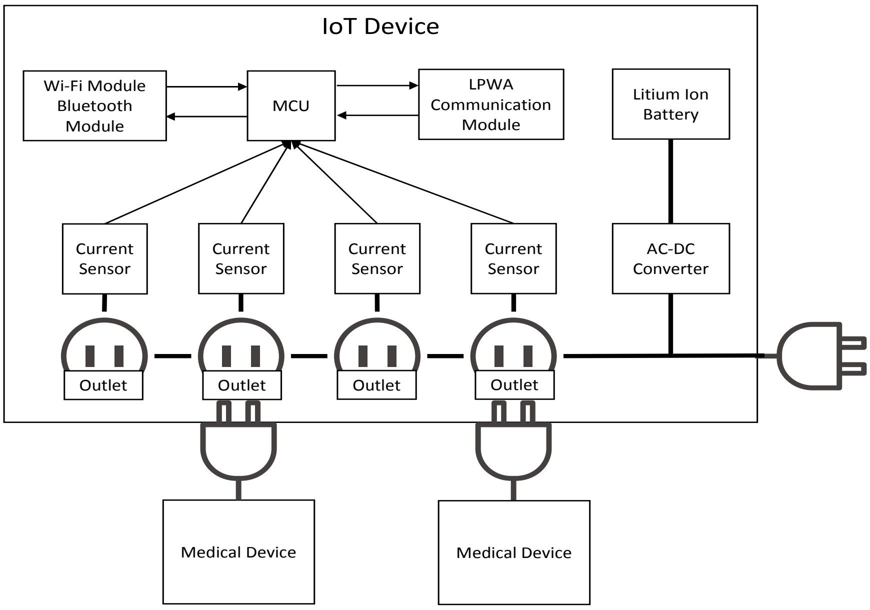

Figure 2. Configuration of IoT Device

3.2 Device Operation Flow

The flowchart of our device is shown in Figure 3. First, the current sensor acquired the AC current value. MCU calculates the RMS (Root Mean Square) of the current and the variance of the AC waveform from those values. When 10 minutes have passed since the operation and the current value and variance value are above the threshold, or when the timer has passed 12 hours, the current value and variance value are transmitted to the LPWA gateway via the LPWA communication module.

The Wi-Fi module and Bluetooth module acquire radio waves of Wi-Fi and BLE beacons. It transmits the acquired radio wave identifier and RSSI to the MCU. It transmits the collected radio wave data to the LPWA gateway via LPWA communication. Finally, reset the timer and repeat the process described above. By performing these processes, data for estimating the location information and operating status of the medical device used in the proposed system is collected.

3.3 Localization Method

We perform indoor location estimation using the RSSI of radio waves of Wi-Fi and BLE beacons (hereinafter referred to as nodes) collected by our device and their location coordinates. These coordinates (Geographic coordinate system) of the node are saved in advance in the DB of the web server. We focused on the fact that RSSI has the property that the farther the receiver (our device) is from the transmitter (node), the weaker the signal strength. The position of the medical device is estimated by the triangulation method using the position of the node and the value of RSSI. This method has been widely studied and is commonly used [16-19].

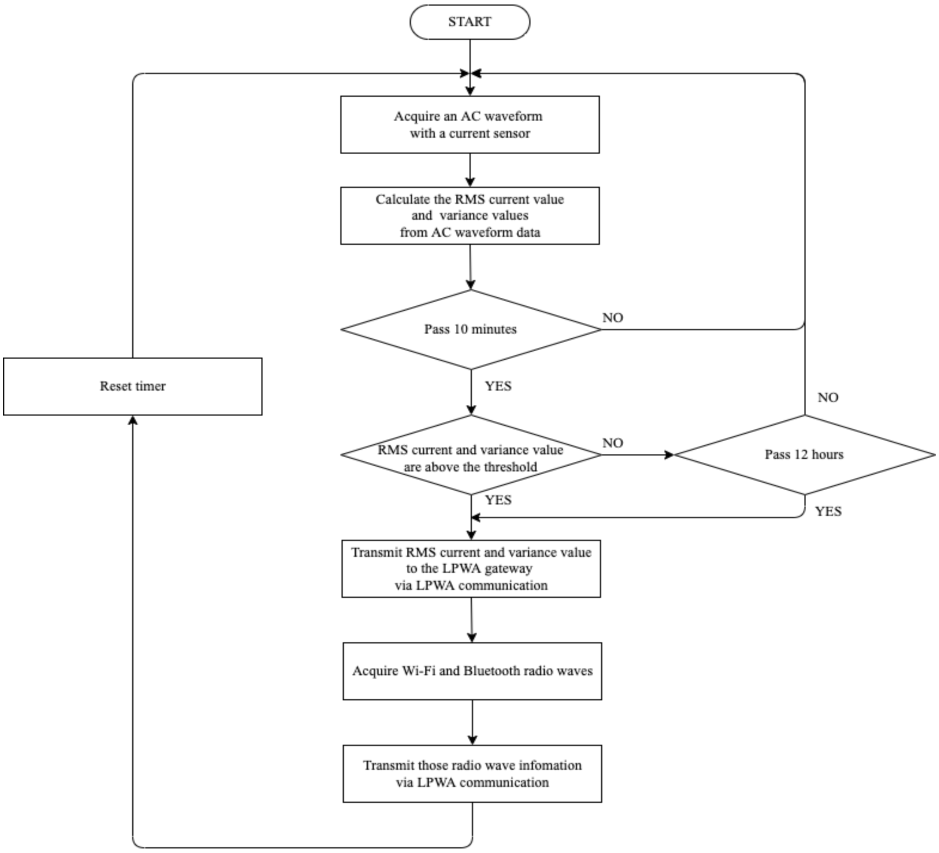

Figure 3. Flowchart of Device

However, since the radio wave characteristics are different between Wi-Fi and BLE beacons, there is a problem that the RSSI values differ greatly when measured from the same distance. Therefore, this method weights the RSSI of both Wi-Fi and BLE beacons. In this study, we conduct a demonstration experiment in hospitals targeting medical devices. In hospitals, Wi-Fi is installed in corridors, whereas medical device is rarely placed in that place. They are often used in a room, and it is important to estimate their location. In this system we propose, BLE beacons are installed in places where medical devices are used and stored, such as hospital rooms and storage areas without Wi-Fi access points. In addition, this system does not require high-precision positioning with an error of several centimetres as position estimation accuracy, and it is important to be able to estimate positions easily and inexpensively. As a result, increasing the RSSI weight for BLE beacons compared to Wi-Fi solves the above problem of having differences in RSSI between Wi-Fi and BLE Beacon.

The equation of the location estimation method considering the importance of Wi-Fi and BLE beacon information is shown below.

$$x = \frac{\sum_{k=1}^{n} w_i x_i}{\sum_{k=1}^{n} w_i} \#(1)$$

$$y = \frac{\sum_{k=1}^{n} w_i y_i}{\sum_{k=1}^{n} w_i} \#(2)$$

$$w_i = \begin{cases} W_{WiFi} \times 10^{\frac{RSSI_i}{10}} \text{ (Node is Wi} - \text{Fi)} \\ W_{BLE} \times 10^{\frac{RSSI_i}{10}} \text{ (Node is BLE Beacon)} \end{cases} \#(3)$$

$$-100 \leq RSSI_i \leq 0 \#(4)$$

Where x and y are the estimated location coordinates of the medical devices. x_i and y_i are the coordinates of node i in the geographic coordinate system. W_{WiFi} and W_{BLE} are the Wi-Fi and BLE beacon RSSI weights, and $RSSI_i$ is the RSSI of node i obtained by our device. (1) and (2) use the weights to calculate x (longitude) and y (latitude) of the device using the triangulation method. (3) converts the RSSI to power and multiplies the weights described above to calculate the weight of the acquired data of each node.

3.4 Device Operation Status Estimation Method

To estimate the operation status of medical devices, we use the RMS of current value and the variance of the AC waveform collected by our device. A medical device has an operation status during charging depending on whether it has an emergency battery, or it has multiple modes depending on the operation. The types and number of operation status to be estimated differ depending on the device. As an example, the operation status determination equation for a medical device that has three statuses, “Not Operating”, “Charging”, and “Operating”, is shown below.

$$\begin{array}{lll} 0 \leq I < \theta_{I1}, & 0 \leq \sigma^2 < \theta_{\sigma^2 1} & \Rightarrow \mathit{Not\ Operating} \\ \theta_{I1} \leq I < \theta_{I2}, & \theta_{\sigma^2 1} \leq \sigma^2 < \theta_{\sigma^2 2} & \Rightarrow \mathit{Charging} \\ \theta_{I2} \leq I \quad , & \theta_{\sigma^2 1} \leq \sigma^2 & \Rightarrow \mathit{Operating} \end{array}$$

In this paper, "Not Operating" is the power cable of our device is not connected to the outlet in the hospital. "Charging" is the power cable of our device is connected to an outlet, the battery installed in the medical device is charging, and the medical device is not in operation. “ Operating” is the power cable of our device is connected to an outlet, and the medical device is in use.

I is the RMS of current value of the medical device calculated by the device. σ^2 is the variance value of the AC waveform. θ_n is the threshold of the RMS I and variance σ^2 value. The more operation status to be estimated for medical devices, the more thresholds are required for the determination.

The threshold is determined using the K-Means clustering method [20]. This method uses at least one week of data. The data are classified into 2 clusters by the K-Means clustering for each RMS of current value and variance value. A histogram of the collected data for one week for the medical device with the status of “Not Operating”, “Charging” and “Operating” is shown in Figure 4. Using K-Means clustering for the one-dimensional data of the current value and the variance value, we performed two-state classification. As a result, by setting 400 as the threshold for the current value and 5000 as the threshold for the variance value, it was shown that it is possible to distinguish between the two statues.

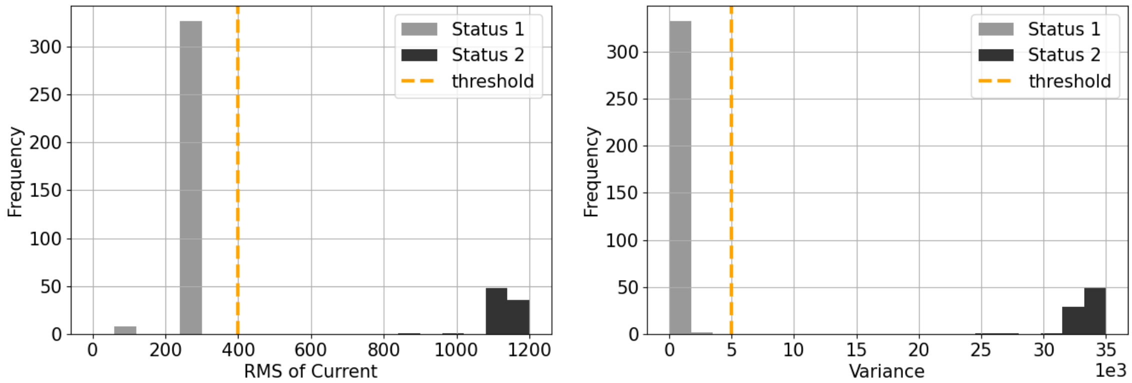

Figure 4. Histogram of current and variance values. It shows all the data. Thresholds are indicated by dashed lines. The RMS of current threshold is 400. The Variance threshold is 5000.

Next, K-Means clustering is performed on these data by dividing the intervals into two groups: those with a variance greater than or equal to 5000 and those with a variance less than or equal to 5000.

The histograms with variance values below 5000 are shown in Figure 5. We perform two-state clustering on these data. As a result, by setting 150 as the threshold for the current value and 500 as the threshold for the variance value, it is possible to distinguish between the two statuses.

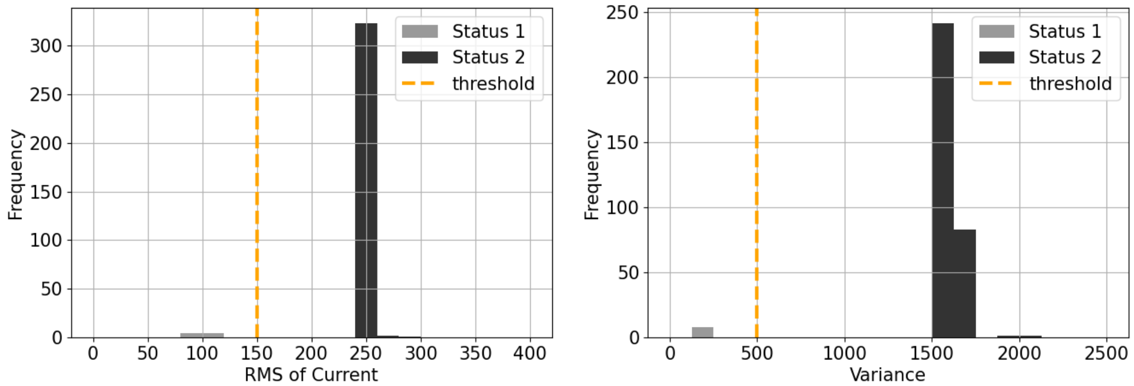

Figure 5. Histogram of current and variance values. It shows data with variance value less than 5000. Thresholds are indicated by dashed lines. The RMS of current threshold is 150. The Variance threshold is 500.

The histograms with variance values above 5000 are shown in Figure 6. We perform two-state clustering on these data. As a result, by setting 1050 as the threshold for the current value and 30000 as the threshold for the variance value, it was shown that it is possible to distinguish between the two statuses. In this identification, there is only one data set with a current value below 1050 and a variance value below 30000, which is classified as one state. We regard this state as noise from the current sensor and call it the undefined status.

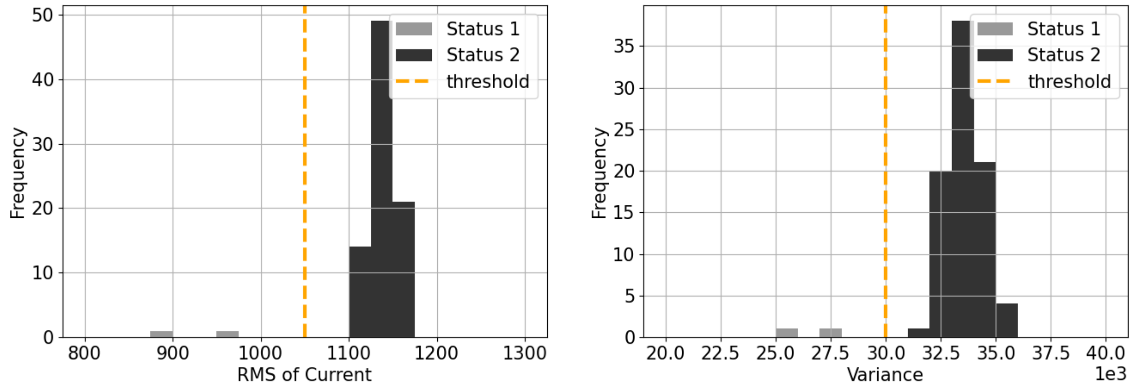

Figure 6. Histogram of current and variance values. It shows data with variance value greater than or equal to 5000. Thresholds are indicated by dashed lines. The RMS of current threshold is 400. The Variance threshold is 5000.

Finally, the following equation is defined.

$$\begin{array}{lll} 0 \le I < 150, & 0 \le \sigma^2 < 500 & \Rightarrow Not\ Operating \\ 150 \le I < 300, & 500 \le \sigma^2 < 5000 & \Rightarrow Charging \\ 300 \le I < 1050, & 5000 \le \sigma^2 < 30000 & \Rightarrow Undefined \\ 1050 \le I \quad , & 30000 \le \sigma^2 & \Rightarrow Operating \end{array}$$

I is the RMS of current value of the medical device calculated by the device. σ^2 is the variance value of the AC waveform. θ_n is the threshold of the RMS I and variance σ^2 value.
The more operation status to be estimated for medical devices, the more thresholds are required for the determination. Undefined status means that the current and variance values are calculated unexpectedly, and if these values appear frequently, we define a new status. These processes are performed periodically and evaluated.

3.5 Visualization Web Site

The visualization page viewed by medical staffs displays the details, location, operation information, and operation rate of medical devices. Visualization page is shown in Figure 7. On the map screen in the centre, the hospital map of the floor specified by the tab at the top is displayed.

Medical staffs can check the location and operation status of medical devices by the icon shown on the map. In the medical device list at the bottom of the map screen, the information and operation rate of the devices on the map are displayed. Detailed information about medical devices can be displayed by selecting the device from the list. The detailed information includes location information, operation information, medical device names, and management numbers within the hospital.

Medical staffs can use this visualization page to check the location and the current operation information and operation rate of the medical devices. Therefore, this system can be used to search for lost medical devices, confirm device that should be used with priority. Furthermore, by using the collected data, we will use it to optimize the number of owned medical devices.

Figure 7. Visualization Web Page. Circle icons in the hospital map indicate the location of medical devices. The color of the icon indicates the status of the device.

4. DEMONSTRATION EXPERIMENT

Experiments were conducted at the following three hospitals in Aichi and Hyogo prefectures, Japan.

- University Hospital A with about 1000 beds (in Aichi Prefecture)
- Civilian Hospital B with about 220 beds (in Aichi Prefecture)
- University Hospital C with about 1000 beds (in Hyogo Prefecture)

Figure 8 shows how the developed device is attached to the medical device. The number of medical devices with the development device installed is shown in Table 1. The most ventilator has a heating humidifier for humidifying the air, which is connected to the outlet of the developed device, but some ventilator connects a heated humidifier to the ventilator itself. There are 6 types of ventilators, 10 types of ultrasound diagnostic equipment, and 2 types of hemodynamic monitoring equipment. Although the ventilator and hemodynamic monitoring devices are equipped with a battery, there are some devices that have the battery removed.

Table 1. List of medical devices that have introduced our system

Hospital	Medical Device	Auxiliary Equipment	Number
Hospital A	Ventilator	Heated Humidifier	36
Hospital A	Hemodynamic Monitoring Device	None	14
Hospital B	Ventilator	Heated Humidifier	2
Hospital B	Ultrasonic Diagnostic Equipment	None	12
Hospital B	Electrocardiograph	None	1
Hospital C	Ventilator	None	10

Figure 8. Our device attached to a medical device

5. RESULTS AND ANALYSIS

Regarding the location information of medical devices, we introduced our system at a hospital where we are conducting a demonstration experiment and evaluated it. The experiment has been conducted since November 14, 2021.

5.1 Evaluation of Localization

At the target hospital, a beacon is installed in each room, and position estimation is performed using radio waves from Wi-Fi and BLE beacons. It was well-received that the accuracy was sufficient for ordinary tasks such as searching for devices.

At Hospital A, a medical engineer provided the following events that demonstrate the usefulness of this system. “With the existing medical device management system, it was not possible to identify the current location of the medical device. I was able to locate it easily by using the system.”

As a result, we obtained the opinion that our system is useful. In the future, we will evaluate the usefulness of this system by comparing it with other highly accurate position estimation systems.

5.2 Evaluation of Operation Status Estimation

In an interview with a medical engineer, we received the opinion that hospital A may have an excessive number of hemodynamic monitoring devices and ventilators before the introduction of this system. Therefore, we focused on the number of hemodynamic monitoring devices in operation each day and evaluated the appropriate number of devices. The data acquisition period is from January 18, 2022 to March 24, 2022. The daily number graphs of two types of hemodynamic monitoring devices are shown in Figure 11 and Figure 12. In the figures, the solid line indicates the total number of units in operation for the day and the dashed line indicates the average number of units in operation during the acquisition period.

Hospital A owns 5 hemodynamic monitoring devices A shown in Figure 9. The number of devices operating simultaneously on February 15 was 5 units. It is the maximum number of devices being used. The average number of devices in operation was 1.8 units. Thus, we thought that the number of 5 units of hemodynamic monitor A was appropriate. The medical engineer commented that it would be possible to acquire data over a longer period and determine whether to add several devices.

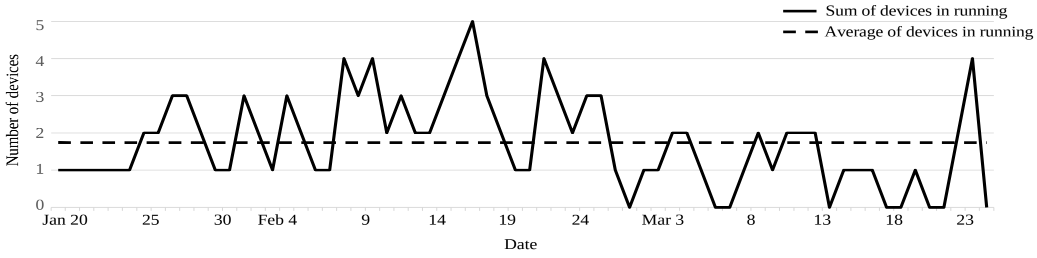

Figure 9. Number of Operating Hemodynamic Monitoring Device A

Hospital A owns the number of 9 units of hemodynamic monitoring devices B shown in Figure 10. During the data acquisition period, the maximum number of devices in operation was 2 units, and the average number of devices in operation was 0.9 units. It is considered that the number of 9 units of hemodynamic monitoring device B owned during this period is excessive for actual operation. Therefore, Hospital A was able to decide to operate fewer devices B.

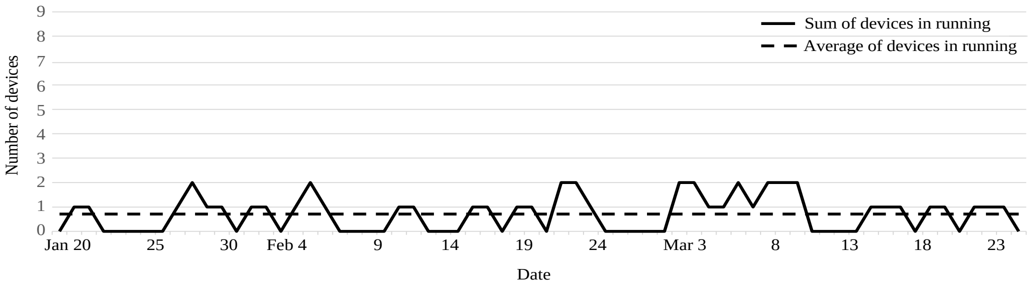

Figure 10. Number of Operating Hemodynamic Monitoring Device B

The system we propose can show real-time operation status and operating rate data of medical devices as a basis for overs and shorts of medical devices in hospitals. It also can propose the optimization of the number of owned units.

6. CONCLUSIONS

In this paper, we developed a medical device management system that supports the management of various medical devices owned by medical institutions, and conducted a demonstration experiment. The IoT device we developed estimates the location information and operation status of medical devices. Our device functions as a power strip, and it can be introduced to various medical devices to collect data without violating medical device approval in Japan.

When the system is introduced, location estimation is performed only with existing Wi-Fi. BLE beacons are installed as necessary in places where detailed location estimation is required. The system we proposed can be operated with only one LPWA gateway installed per target area. For these reasons, it can be introduced inexpensively and easily.

In the demonstration experiment, with the cooperation of three hospitals, the device we developed was introduced for 75 medical devices and evaluated in an actual environment. We interviewed medical engineers and evaluated the system. As a result, we showed that the accuracy of location estimation is sufficient for practical use. We have also shown that the judgment of operation status is useful as data for effectively the management of medical devices, such as optimizing the number of devices.

In the future, we will miniaturize the device to reduce costs and introduce it into small portable medical equipment. We compare our system with a high-precision positioning system and evaluate the estimation accuracy quantitatively. We improve the location estimation accuracy by considering the time series of data and optimizing the BLE beacon placement. In the operating state estimation, a machine learning method is used, and the device infers the operating state on the edge side, so that more states will be automatically judged. Furthermore, it detects anomalies such as equipment failure. In cooperation with the medical device management system, the operating status is evaluated.

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