





An Inhalation Device With Inertial Measurement Unit for Monitoring Inhaler Technique

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I. INTRODUCTION

Abstract—Inhalers are commonly used to treat asthma and chronic obstructive pulmonary disease. Regular and correct usage of inhalers is necessary for effective use. However, approximately 70% of patients do not use their inhalers as directed. This is due to a lack of understanding about the medication and misunderstanding of directions. Assessment of patients' inhaler techniques are usually conducted in person. However, doctors or pharmacists have no objective information regarding how patients use their inhalers at home. Therefore, monitoring daily inhaler use is necessary for precise medical treatment. This article proposes an inhalation monitoring device using an inertial measurement unit (IMU). The IMU is used to measure a patient's inhalation motion. Incorrect inhalation usage can be determined by comparing the measurement data against data that indicate correct usage. The experimental results show the utility of the proposed device.

Index Terms—Asthma, chronic obstructive pulmonary disease (COPD), inertial measurement unit (IMU), inhaler technique.

Manuscript received 19 January 2022; revised 26 March 2022; accepted 1 May 2022. Date of publication 3 June 2022; date of current version 16 August 2022. Recommended by Technical Editor D. Shi and Senior Editor X. Chen. (Corresponding author: Shunya Takano.)

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This work involved human subjects or animals in its research. Approval of all ethical and experimental procedures and protocols was granted by the ethics committee of Keio University School of Medicine under Authorization No. 20190308, and performed in line with the principles of the Declaration of Helsinki.

Color versions of one or more figures in this article are available at <https://doi.org/10.1109/TMECH.2022.3175851>.

Digital Object Identifier 10.1109/TMECH.2022.3175851

ASTHMA and chronic obstructive pulmonary disease (COPD) are two of the most common respiratory diseases. These diseases cause the airway to the lungs to constrict due to inflammation. According to the World Health Organization (WHO), 262 million people suffered from asthma in 2019. Moreover, COPD, which is the third leading cause of death worldwide, resulted in 3.23 million deaths in 2019.

A common method for the treatment of asthma and COPD are inhaled medications. Medications, such as corticosteroids are used to treat the symptoms of asthma and COPD. Pressurized metered dose inhalers (pMDIs) and dry powder inhalers (DPIs) are commonly used to deliver medication directly to the lungs. Inhalers must be used regularly and correctly to be effective. However, approximately 70% of patients do not use their inhalers as directed [1]–[3]. This is due to a lack of understanding about medication and misunderstanding of directions. In addition, patients forget how to use their inhalers correctly as time passes after receiving directions.

The assessment of patients' inhaler technique is usually conducted face-to-face by a doctor or pharmacist [4]. However, doctors or pharmacists have no objective information about how patients use their inhalers at home. Usually, inhaler usage is recorded by the patients' self-reports or dose counters. However, this information only shows the total usage of an inhaler and is usually unreliable. Therefore, monitoring daily inhaler usage is necessary for precise medical treatment.

Studies have been conducted on monitoring inhaler usage using sensors. The pMDI with an air flow sensor and pressure sensor monitors the inhalation and motion of the pressing canister [5]. An inhaler with a microphone monitors inhalation and exhalation by analyzing the audio of the breathing sounds [6]–[8]. In addition, the microphone monitors the preparation process of Diskus by monitoring the sound of the foil blister packs containing the medications [9]. However, monitoring sound is easily affected by surrounding noises. Therefore, another method for monitoring inhalation usage is needed.

This article proposes an inhalation monitoring device using an inertial measurement unit (IMU) to track inhalation motion. The IMU measures 3-axis acceleration and 3-axis angular velocity. Incorrect inhalation usage is detected by comparing the measurement values with the correct inhalation usage. Ellipta, a type of DPI device, is used to verify the proposed method.

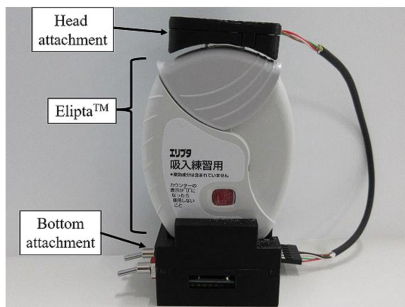


Fig. 1. Structure of proposed sensing device.

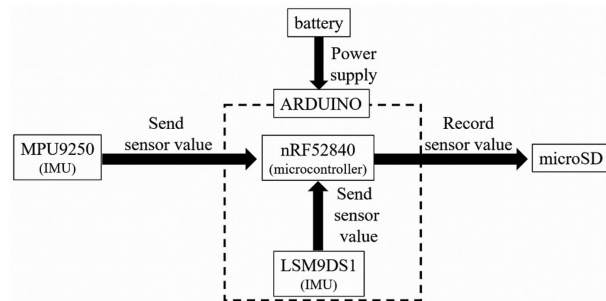


Fig. 3. Schematic of proposed device.

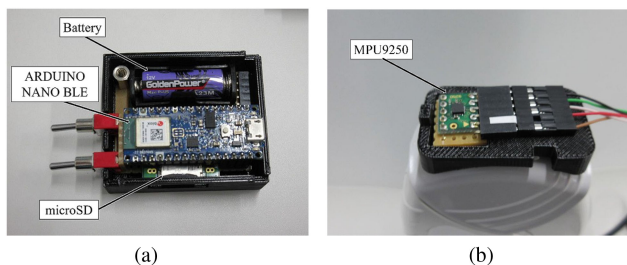


Fig. 2. Structure of each attachment. (a) Structure of bottom attachment. (b) Structure of head attachment.

Frequent errors in the use of DPI devices include incorrect preparation, no full expiration before inhalation, and no postinhalation breath-hold, which occur 29, 46, and 31% of the time, respectively [1]. The preparation motion in Ellipta involves opening the cover to fill up the medication. This preparation motion can be monitored directly by using an IMU. In addition, the full expiration motion before inhalation and postinhalation breath-hold motion can be monitored indirectly by monitoring the interval time of each motion. Therefore, the proposed device with an IMU is suitable for monitoring these frequent errors.

The rest of this article is organized as follows. In Section II, the structure and method of the proposed device are presented. In Section III, confirmation of the proposed device is described. In Section IV, the results of a clinical trial of the device on four patients are shown. In Section V, the advantages of the proposed device and the problematic issues are discussed. Finally, Section VI concludes this article.

II. PROPOSED SENSING DEVICE

A. Structure

Fig. 1 shows the overview of the proposed inhalation monitoring device attached to Ellipta and Fig. 2(a) and (b) shows the structure of each attachment. The device consists of an ARDUINO NANO 33 BLE, a micro SD, a battery, and an MPU9250. The ARDUINO NANO 33 BLE is a single-board electronics platform containing a built-in microcontroller (nRF2840), an IMU (LSM9DS1), and Bluetooth low-energy technology (NINA-B206). The MPU9250 and LSM9DS1 are IMUs that combine a 3-axis gyrometer, 3-axis accelerometer, and 3-axis magnetometer. Fig. 3 shows the schematic of the

TABLE I
INHALATION USAGE OF ELLIPTA

Step	Procedure
1	Check the counter value to confirm the quantity of medication remaining.
2	Open the cover completely.
3	Hold the device away from your mouth and breathe out completely.
4	Put the mouthpiece into the mouth.
5	Breathe in with one brisk inhalation, and inhale deeply.
6	Hold the breath for more than 5 seconds.
7	Remove the inhaler from mouth and breathe out slowly and gently.
8	Return the cover to the original position.

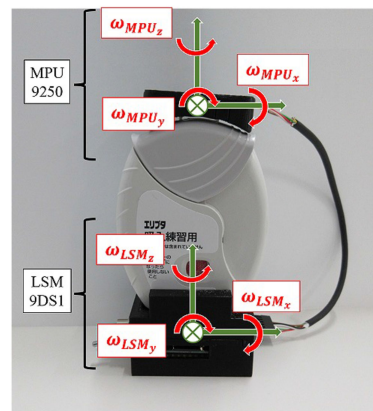


Fig. 4. Axial directions of gyrometer.

proposed device. The microcontroller reads the sensor values of the two IMUs and writes them to the microSD. The MPU9250 is attached to the cover of Ellipta, and the others are attached to the bottom of the device. Attachments were made of PLA resin using a 3-D printer. Thus, the MPU9250 measures the cover movement and the LSM9DS1 measures the device posture. Therefore, the two IMUs measure inhalation movement.

B. Methods

Table I shows the inhalation usage of Ellipta. Fig. 4 shows the axial directions of the gyrometers of the two IMUs.

In the cover opening motion in procedure 2, the cover turns to approximately 110° , as shown in Fig. 5(a). Therefore, the cover

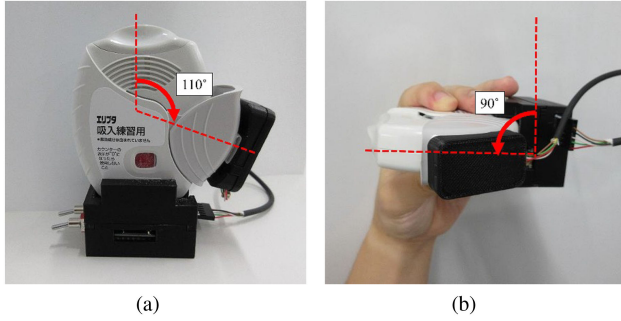


Fig. 5. Posture of device at each motion. (a) Posture after cover opening. (b) Posture at inhale motion.

angle is used to monitor the cover opening motion. The angle value was estimated by integrating the angular velocity given by the following equation:

$$(\theta_{IMU_{axis}})_n = (\theta_{IMU_{axis}})_{n-1} + (\omega_{IMU_{axis}})_n \times \Delta t. \quad (1)$$

θ and ω are the angle and angular velocity of IMU. IMU is the sensor name that represents MPU9250 or LSM9DS1. $axis$ is the sensor axis, and n is the number of data elements in the measurement. Δt is the time period of reading the sensor values by the microcontroller. The Y -axis gyrometer of MPU9250 corresponds to the cover opening motion. However, the measurement values of MPU9250 include the device posture. This posture angle is measured by LSM9DS1. Thus, the cover angle is obtained by estimating the difference between the Y -axis angles of the two IMUs, given as

$$\theta_{cover_y} = \theta_{MPU_y} - \theta_{LSM_y}. \quad (2)$$

θ_{cover_y} , θ_{MPU_y} , and θ_{LSM_y} are the cover angle, Y -axis angle of MPU9250, and Y -axis angle of LSM9DS1, respectively. Therefore, θ_{cover_y} is used to monitor the cover opening motion.

The full expiration motion at step 3 was monitored indirectly at different intervals of motion. Basically, the device is stable during expiration. Therefore, full expiration is monitored indirectly, while the sensor value is stable after the cover is opened.

After full expiration, the device was turned approximately 90° to put the mouthpiece into the mouth, as shown in Fig. 5(b). This motion is monitored by measuring the device angle, which corresponds to the X -axis gyrometer of LSM9DS1 given by the following equation:

$$\theta_{device_x} = \theta_{LSM_x}. \quad (3)$$

θ_{device_x} and θ_{LSM_x} are the device angle and X -axis angle of LSM9DS1. Thus, θ_{device_x} is used to monitor the motion of placing the mouthpiece into the mouth.

The breathing motion, breath-hold motion, and breathing out motion are monitored while θ_{device_x} is stable at approximately 90° .

Fig. 6 shows the schematic graph of how the angle values are changed in inhalation motion. Therefore, the inhalation usage of Ellipta is monitored using θ_{cover_y} and θ_{device_x} .

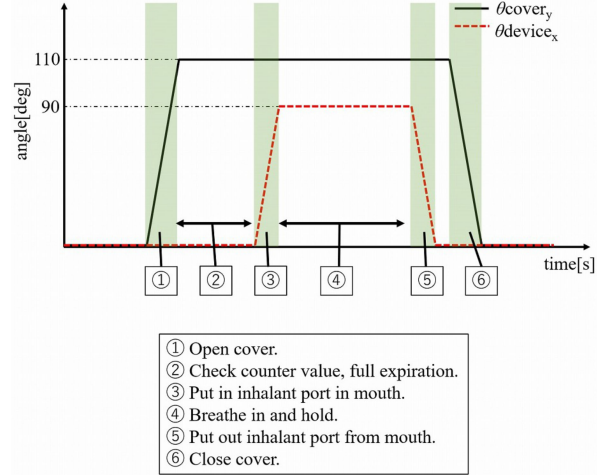


Fig. 6. Schematic graph of proposed device.

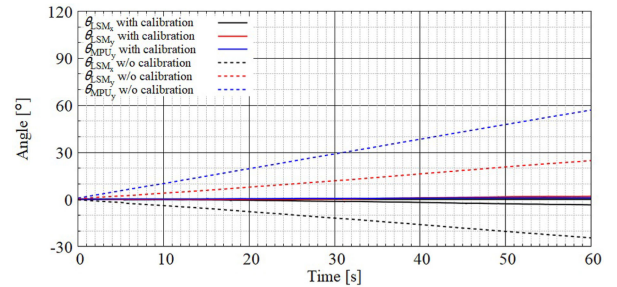


Fig. 7. Effect of calibration: Comparison of angle value in static state.

C. Sensor Calibration

Generally, the sensor value includes error. Thus, the angle value includes the accumulated error of the angular velocity. This accumulated error increases as time passes. Therefore, sensor calibration is conducted before the inhalation to reduce the sensor error.

First, the device is stabilized for 1 s to measure the offset value of the sensor. The average value of the angular velocity is used as the offset value, given by the following equation:

$$\varepsilon_{IMU_{axis}} = \frac{1}{k} \sum_{i=1}^k (\omega_{IMU_{axis}})_i. \quad (4)$$

ε and k represent the offset value and the number of data elements in the calibration. Therefore, the calibrated angle value $\hat{\theta}$ is estimated using (5) instead of (1)

$$\begin{aligned} (\hat{\theta}_{IMU_{axis}})_n &= (\hat{\theta}_{IMU_{axis}})_{n-1} \\ &+ ((\omega_{IMU_{axis}})_n - \varepsilon_{IMU_{axis}}) \times \Delta t. \end{aligned} \quad (5)$$

A confirmation of the decreasing error by calibration is shown in Fig. 7. The device was stable in this confirmation. Therefore, the transition of accumulated error in angle values was measured. Three types of angle values that are used for θ_{cover_y} and θ_{device_x} were measured. The solid lines represent the angle value after

TABLE II
ANGLE ERROR AFTER 60 SECONDS AT EACH CALIBRATION TIME

Calibration time [s]	0	1	3	5	10	20
θ_{LSM_x} [°]	24.02	5.17	6.36	6.12	6.05	5.63
θ_{LSM_y} [°]	23.61	1.35	1.65	1.95	1.76	1.53
θ_{MPU_y} [°]	46.14	0.78	0.18	0.15	0.28	0.43
Average [°]	31.26	2.43	2.73	2.74	2.70	2.53

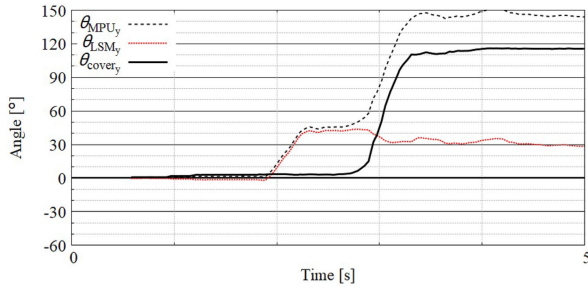


Fig. 8. Effect of using two sensors: Comparison of angle values in cover opening.

calibration, and the dotted lines represent the angle values before calibration. As time passed, the angle values without calibration increased because of the accumulated error in the angular velocity. By contrast, the angle values obtained after calibration were stable around 0°. Therefore, it can be confirmed that sensor error can be decreased by calibrating the sensor.

Moreover, the calibration time must be set as short as possible. The proposed device must conduct calibration before every inhalation. This is because the sensor error is not constant. Therefore, patients must wait for the calibration before using this device. Thus, we determined the calibration time at which the angle error was no longer decreased. Table II shows the angle errors of each calibration time. The device was stable in this measurement. The angle values during 60 s intervals were measured. The measurements were conducted three times. The results show that after 1 s, the angle error stabilizes and no longer decreases. Therefore, the calibration time of the proposed device was determined as 1 s.

D. Effect of Using Two IMUs.

In the previous research, the inhalation device using a single IMU was proposed [10]. This device monitors inhalation by one sensor attached to the cover of Ellipta. However, the sensor value includes the posture of the device. Therefore, the measurement values are deviated according to the device posture. Thus, the posture angle must be measured to determine the cover angle. For this reason, the second IMU was attached to the proposed device to measure the posture angle of the device.

Fig. 8 shows the result of opening the cover while the device is tilted. The proposed device was used in this verification. The two dotted lines show the Y-axis angle of the two sensors, and the solid line shows the cover angle estimated by (2). First, the device was tilted to approximately 40°. Next, the cover was opened while the device was tilted. In the previous research, the cover angle is monitored by using θ_{MPU_y} . However, θ_{MPU_y} is

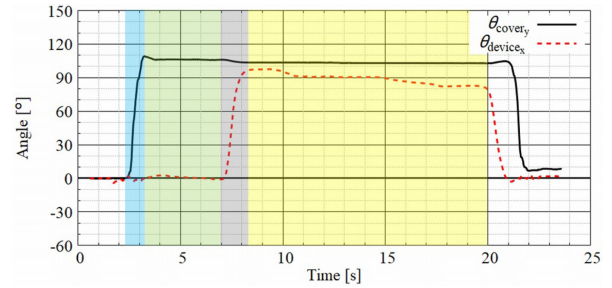


Fig. 9. Measurement result in correct inhalation usage.

increased to approximately 150° owing to the device posture. Thus, an accurate cover angle cannot be measured if the device is tilted. In contrast, θ_{COVER} was stable even though the device was tilted. In addition, θ_{COVER} was increased to approximately 110° after the cover was opened. Therefore, the proposed device will be able to measure the cover angle regardless of the device posture. Thus, the effect of using two IMUs was confirmed.

III. CONFIRMATION OF MONITORING INHALATION BY PROPOSED DEVICE

A. Transition of Sensor Value in Correct Usage.

This section describes the measurement in correct inhalation usage. The measurement was conducted by the author. Fig. 9 shows the result of the cover angle and the device angle in correct inhalation usage of Ellipta. First, the blue shaded area at 2–3 s represents the cover opening motion. The cover angle was increased to approximately 110°, which represents that the cover was opened completely. Second, the green shaded area represents the full expiration motion. The cover angle and the device angle were stable during expiration. Third, the grey shaded area represents the motion of putting the mouthpiece into the mouth to breathe in (inhalation). The device angle was increased to approximately 90° in this motion. Fourthly, the yellow shaded area represents the breathing motion, breath-hold motion, and exhalation motion. The device angle was stable for 12 s. Therefore, the result shows the breath-hold was conducted sufficiently. Finally, the device angle and the cover angle were decreased to 0°, which indicates that the device was removed from the mouth and the cover was closed. From the result, it was confirmed that monitoring each inhalation usage by the proposed device was possible.

B. Confirmation of Detecting Error

In this section, the measurement of inhalation, including the error, was conducted to confirm that the error can be measured using the proposed device. The frequent errors of DPI device usage are incorrect preparation, no full expiration before inhalation, and no postinhalation breath-hold [1]. The preparation error in Ellipta usage is opening the cover incompletely. Therefore, three types of inhalation errors were observed.

- 1) Opening the cover incompletely.
- 2) No full expiration before inhalation.
- 3) No postinhalation breath-hold after breathing in.

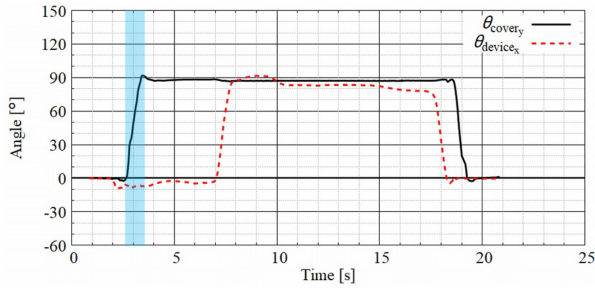


Fig. 10. Result of opening the cover incompletely.

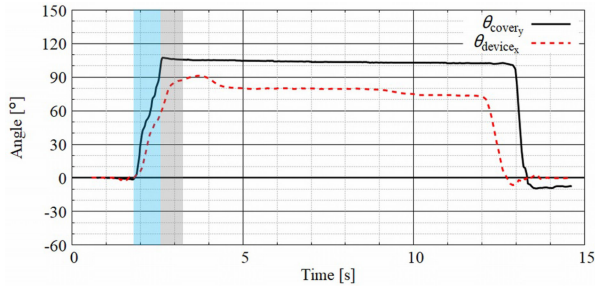


Fig. 11. Result of no full expiration before inhalation.

1) *Open the Cover Incompletely*: In this experiment, measuring the motion after opening the cover incompletely was conducted. In the experiment, the cover was stopped approximately 90° from its initial position. Fig. 10 shows the experimental result. From the result, the cover angle was increased up to 90° , as shown in the blue shaded area. Therefore, the sensor value shows the cover was not opened completely. If the cover is not opened completely, the dry powder is not filled up, which causes a critical error. Thus, the proposed device detects the errors in opening of the cover.

2) *No Full Expiration Before Inhalation*: Second, measurement of inhalation with no full expiration before the inhalation is confirmed. The full expiration was monitored indirectly, while the sensor value was stable after opening the cover. Fig. 11 shows the experimental result with no full expiration. From the result, the cover angle and the device angle increased at the same time, as shown in the blue and grey shaded areas. Therefore, the cover opening motion and the motion of putting the mouthpiece into the mouth were conducted simultaneously. Thus, the result indicates that the exhalation motion was not conducted. Therefore, the proposed device detects the exhalation error.

3) *No Postinhalation Breath-Hold After Breathe In*: Finally, measurement of inhalation with no postinhalation breath-hold is confirmed. The breath-hold motion was monitored while the device angle was stable after inhalation. Fig. 12 shows the experimental result when there is no breath-hold. From the result, the device angle was stable at 90° for only 4 s, as indicated by the yellow shaded area. The breath-hold time must be at least 5 s in a correct procedure. Therefore, the results show that sufficient breath-hold was not conducted during inhalation. Thus, the proposed device can detect the no-breath-hold error.

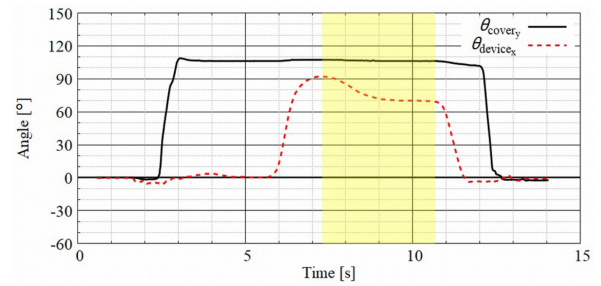


Fig. 12. Result of no postinhalation breath-hold after breath in.

TABLE III
COMPARISON BETWEEN PROPOSED DEVICE AND PHARMACIST'S ASSESSMENT FOR EACH CLINICAL TEST

Patient	Gender	Check point	Proposed device	Pharmacist's assessment
A	male	Open the cover.	○	○
		Breathe-out completely.	○	○
		Hold the breath after inhalation.	×	○
B	male	Open the cover.	○	○
		Breathe-out completely.	○	○
		Hold the breath after inhalation.	×	○
C	female	Open the cover.	×	○
		Breathe-out completely.	○	○
		Hold the breath after inhalation.	×	○
D	male	Open the cover.	○	○
		Breathe-out completely.	×	×
		Hold the breath after inhalation.	○	○

As a result, the detection of inhalation errors was verified using the proposed device. Because the proposed device can detect inhalation errors, a pharmacist can provide precise medical treatment to the patients. The device can inform both patients and the pharmacist about inhalation errors. Thus, the pharmacist can provide treatment to the patients before exacerbations of inhalation occur. Therefore, the device can enhance the effectiveness of treatment.

IV. EXPERIMENT

This section describes the experimental results of the clinical tests. For these clinical tests, approval was obtained from the ethics committee of Keio University School of Medicine (authorization number: 20190308). The tests were conducted on four patients. The pharmacist observed the patients' inhalation motion while using the proposed device. Thus, the comparison of the measurement data and the assessment by the pharmacist is described here.

Fig. 13(a)–(d) shows the measurement results from the clinical test and Table III shows the comparison of inhalation results. The color-shaded areas in the graph represent each motion of inhalation; specifically, the blue shaded area represents the cover opening motion, the green shaded area represents the exhalation motion, the grey shaded area represents the motion of putting the mouthpiece into the mouth for breathing in, and the yellow shaded area represents the breath-hold motion.

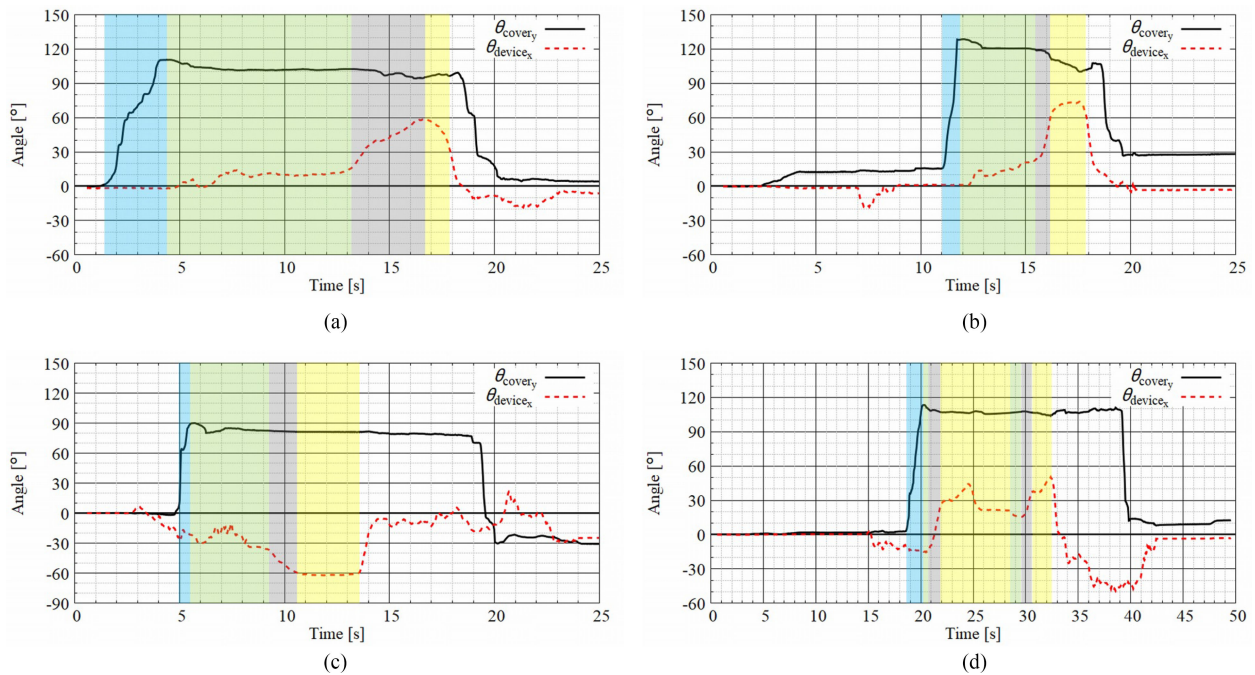


Fig. 13. Measurement results of clinical tests involving four patients. (a) Patient A. (b) Patient B. (c) Patient C. (d) Patient D.

In the results for patients A and B, the proposed device indicates that the cover opening motion and the exhalation motion were conducted successfully. However, the breath-hold motion was not measured by the proposed device. In fact, the patients did conduct the breath-hold motion. The reason for this is that the patients removed the device from their mouth and closed the cover while holding their breath. Therefore, the breathe-hold motion was not observed using the proposed device.

For patient C, the proposed device indicates that the cover angle was opened incompletely. In fact, the patient opened the cover completely. This occurred because of errors in measurement of angular velocity due to the rapid movement. In Fig. 13(c), the blue shaded area is narrower than in the other charts' implying that patient C opened the cover very rapidly. Thus, a large measurement error occurred. In addition, the device angle changes to a negative value. The reason for this is that the patient held the device backwards during inhalation. However, the inhalation motion could be monitored because the device angle was reversed only in this situation. Therefore, the breath-hold motion measurements recorded by the proposed device differed from those of patients A and B.

Finally, in patient D, the proposed device indicates that the exhalation motion was not conducted. In Fig. 13(d), the time interval of the exhalation motion, which is indicated by the green shaded area, is less than 1 s. In fact, the patient did not breathe-out completely before inhalation. This result is the same as in the pharmacist assessment. Therefore, the proposed device detects the nonfull-expiration error before the inhalation. In addition, the proposed device indicates that the inhalation motion was conducted twice. In fact, the patient conducted inhalation twice to inhale medication completely. Therefore, the proposed device could monitor this unusual motion.

As a result, monitoring inhaler usage was verified by comparing the measurement data results and the pharmacist's assessment. However, improvements in the accuracy of monitoring breathe-hold motions are needed.

V. DISCUSSION

This article presented a method of monitoring a patient's inhaler adherence by using two IMUs. The algorithm was designed to identify each step of inhalation usage by monitoring the cover angle and the device angle of Ellipta. For instance, the cover opening motion was monitored by measuring the cover angle, and the inhalation motion was monitored by measuring the device angle. In addition, the full expiration and breath-hold motions were monitored indirectly during the interval time of each motion. However, breath-hold motion cannot be measured if the patient moves the device while holding their breath. Therefore, improvement of the device to measure breath-hold motion is required.

Research has been conducted on monitoring inhaler usage using microphone sensors. Table IV summarizes the advantages and disadvantages of current methods of monitoring inhaler technique. Conventional methods of monitoring inhaler usage, such as patient self-reporting and checklist assessments by pharmacists, cannot monitor a patient's daily inhaler technique. In contrast, sensing devices are suitable for monitoring daily usage. However, monitoring of sound is easily affected by surrounding noises. Therefore, audio-based sensing devices are difficult to use in different environments, such as homes. Although some studies have extracted breath signals by analyzing audio signals, their accuracy is insufficient. In addition, audio-based sensing devices have difficulty in monitoring the preparation motion.

TABLE IV
SUMMARY OF ADVANTAGES AND DISADVANTAGES OF CURRENT METHODS OF MONITORING INHALER TECHNIQUE

Method of monitoring adherence	Advantage	Disadvantage
Patient's self-report	Simple and low-cost.	Only shows the total usage of inhalation. Usually unreliable.
Checklist assessment by pharmacist	Provides information on user technique.	Only can obtain information in the clinic.
Audio-based sensing device	Obtain information on the daily inhaler technique. Can quantify inhaler drug delivery.	Affected by surrounding noise. Inaccurate measurement of preparation motion.
Proposed sensing device with IMU	Obtain information on the daily inhaler technique. Can quantify preparation and inhalation motions. Not affected by surrounding noise.	Inaccurate measurement of breathing motion. (Breathing motion is measured indirectly from the intervals of each motion.)

Some devices measure the preparation indirectly using sound; for instance, detecting of click sounds is done by detection of the opening of the cover of Ellipta. In contrast, the proposed device with IMUs can monitor the preparation motion and is not affected by surrounding noise. However, measurements of exhalation motion and breath-hold motion are not accurate. This is because the motions are measured indirectly at various intervals of each motion. To improve the accuracy of monitoring breathing motions, we are considering integrating other sensors such as a microphone. The proposed device has disadvantages in monitoring breathing motions. However, some studies have successfully used microphones to quantify breathing motions. Therefore, we are considering sensor fusion as a future work.

Therefore, improvement in the accuracy of monitoring inhalation and more clinical trials must be conducted in future studies. Because the experiments were conducted with a small number of patients, a greater quantity of data is needed to verify the utility of the proposed device in the medical field. In addition, the patients stated that the proposed device was difficult to use owing to the head attachment. Therefore, improvement of structure is also needed. Moreover, detection errors were confirmed only in the three types of studied inhalation errors. Thus, confirmation of other types of inhalations, such as plural errors in one inhalation or inhalation with other errors, is needed.

Furthermore, an automatic algorithm that can identify inhalation errors from measurement data is needed. In the experiment, inhalation errors were detected by observing the graph from the measurement data. This manual evaluation is not quantitative and is a significant burden on the pharmacists. Thus, an automatic algorithm is needed to allow pharmacists to provide efficient inhaler adherence. Monitoring daily use of inhalers is utilized for improving patient treatment. These measurement data can assist pharmacists in providing the patient a more personalized inhaler therapy and enhancing medication efficacy.

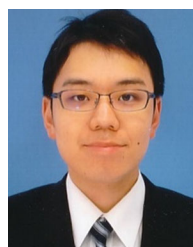
VI. CONCLUSION

In this article, an inhalation monitoring device using IMUs was proposed to track inhalation motion. Ellipta was used to verify the proposed method. Each inhalation procedure was monitored by the proposed device with two IMUs. In the experiment, three types of inhaler errors were studied. The error in preparation motion was detected by monitoring the cover angle. Errors of no full expiration before inhalation and no

postinhalation breath-hold were detected by monitoring the time interval between the cover angle movement and the device angle movement. Therefore, the proposed device can be utilized for monitoring the patient's daily usage.

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