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Development of a Novel Device for Monitoring Incentive Spirometry Performance (Pembangunan Peranti Novel bagi Pemantauan Prestasi Spirometri Insentif)

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ABSTRACT

Lung atelectasis caused by shallow breathing patterns is common after cardiac, thoracic and upper abdominal surgeries. A common method used to address this problem is to encourage patients to perform breathing exercises using incentive spirometers in the postoperative period. However, to be effective, this procedure must be repeated regularly so that adequate lung volumes can be maintained to prevent atelectasis. Current models of single-use, low-cost incentive spirometers do not have features that can track and store data on breathing exercises. This makes it difficult to monitor patients' breathing exercises effectively. We present here a device designed to be interfaced with the Spiro-ball incentive spirometer and programmed to monitor the incentive spirometry performance. Laboratory based validation performed indicate that there were no significant differences between the value obtained from the device and manual reading; p -value > 0.05 and root-mean-square error (RMSE) is 3.882. The device was able to retrieve and display pertinent data on incentive spirometry performance. It was also able to correctly track and register random sets of inspiration data through different dates and timelines. Being a separate entity which is reusable, it does not add to the cost of the single-use incentive spirometer.

Keywords: Breathing exercise; data collection; incentive spirometry

ABSTRAK

Atelektasis paru-paru yang berpunca daripada pernafasan yang cetek adalah satu kebiasaan selepas pembedahan jantung, toraks dan abdomen bahagian atas. Kebiasaannya, kaedah yang digunakan untuk mengatasi masalah ini adalah menggalakkan pesakit menjalankan latihan pernafasan menggunakan spirometer insentif dalam tempoh pasca pembedahan. Walau bagaimanapun, untuk ia menjadi efektif, prosedur ini perlu diulang secara berterusan supaya isi padu paru-paru yang mencukupi dapat dikekalkan untuk mengelakkan atelektasis paru-paru terjadi. Model semasa bagi spirometer insentif adalah sekali guna dan kos rendah serta tidak mempunyai ciri-ciri mengesan dan merekod data untuk latihan pernafasan. Hal ini menyukarkan proses pemantauan latihan pernafasan yang dilakukan oleh pesakit secara efektif. Kajian ini membentangkan alat yang direka untuk diaplikasikan bersama Spiro-ball spirometer insentif dan diprogramkan untuk memantau prestasi insentif spirometri. Validasi menerusi makmal yang dijalankan menunjukkan bahawa tiada perbezaan ketara antara nilai yang diperolehi daripada alat ini dan bacaan secara manual; nilai p lebih besar daripada 0.05 dan punca min ralat kuasa dua (RMSE) adalah 3.882. Alat ini berupaya untuk mendapatkan kembali dan memaparkan data prestasi insentif spirometri. Ia juga mampu mengesan dan menyimpan set data yang rawak melalui tarikh dan masa yang berbeza. Alat ini merupakan entiti yang berasingan daripada spirometer insentif, oleh yang demikian ia tidak menambah kos asal spirometer insentif sekali guna.

Kata kunci: Latihan pernafasan; pengumpulan data; spirometer insentif

INTRODUCTION

Impaired chest wall and lung mechanics due to surgical procedures and pain are common after thoracic, cardiac and upper abdominal surgeries (O'Donohue 1992; Warner 2000). Often, patients resort to shallow breaths postoperatively to avoid pain and discomfort (Warner 2000). If left unresolved, this can cause lung atelectasis which may lead to postoperative pulmonary complications (PPCs) (Duggan & Kavanagh 2005; Wynne & Botti 2004) and substantially increase healthcare costs (Shander et al. 2011). A landmark study by Thoren (1954), demonstrated the effectiveness of deep breathing exercises in reducing

lung atelectasis. This was supported by O'Donohue (1992) who suggested that a simple regimen of regular deep breathing exercises should be sufficient for most postoperative patients to prevent postoperative atelectasis. Deep breathing exercises can be done with or without devices to improve lung expansion and ventilation postoperatively (O'Donohue 1992). A device commonly used for this purpose is the incentive spirometer (IS) (Glover 2010). The main function of using the IS is to facilitate periodic deep breaths which simulate a sigh or a yawn maneuver (Restrepo et al. 2011). The process of performing breathing exercises using the IS is called

incentive spirometry (ISy). This helps to expand lungs to total capacity to prevent or reverse lung atelectasis (Restrepo et al. 2011). Being simple and inexpensive (Duggan & Kavanagh 2010), the IS is used in many healthcare facilities after major surgeries (Carvalho et al. 2011).

However, in order for it to be effective, ISy needs to be performed in accordance with prescribed frequencies and inspiratory volumes (Restrepo et al. 2011). Among the key instructions is that ISy should be done a specified number of repetitions to a preset target volume throughout the day to prevent lung atelectasis (Restrepo et al. 2011). This requires the patient to achieve prescribed inspiratory volumes, even in the absence of healthcare personnel (HCP). Patient compliance with ISy has been highlighted as an important determinant of treatment efficacy (do Nascimento et al. 2014; Gosselink et al. 2000; Overend et al. 2001). If usage is lower than prescribed, there is a probability that the effectiveness of the IS to maintain optimal lung function would be compromised because of underutilization.

Older models of IS, like the Bartlett-Edwards and Spirocare were equipped with counters that recorded successful inspiration maneuvers done by the patient (Gale & Sanders 1977; Glover 2010; Overend et al. 2001) which could be reviewed by the HCP. These costly and non-disposable devices, however, have now given way to single-use disposable low-cost IS devices which are commonly used in many healthcare settings (Duggan & Kavanagh 2010; White 2014). Single-use devices are intended for single patient use only, primarily because of cross-infection concerns (NHS 2012). These IS devices do not possess performance recording features and consequently, they are unable to track and store ISy performance data (Brown & Walters 2012). Any collection of IS performance data from these devices has to be done manually (Brown & Walters 2012). This, in turn, can translate into increased workload for HCP, especially in busy or understaffed facilities, and adversely affect quality of patient care (Carayon & Gürses 2005). As such, there is a need for appropriate innovative and low-cost technologies capable of tracking and storing ISy information that can be used to assist HCP monitor and manage their patients' breathing exercises interventions more effectively.

Thus, the main objective of this paper was to describe the development, features, functionality and laboratory-based validation of a device designed for ISy data collection. This device was able to record and store frequency of deep breaths taken using the IS and the volume achieved in each breath, display ISy information on demand for quick review at the bedside, prevent tampering by patients and unauthorised personnel and eliminate collection of fallacious data.

MATERIALS AND METHODS

The device consisted of four parts (Figure 1), the first part being the conventional incentive spirometer, Spiro

Ball (Leventon S.A.U., Barcelona, Spain): single use, disposable IS with mouthpiece, extensible tubing and a body part that has a volume chamber with a piston (Leventon). The selected model is widely used in many healthcare settings and has a hollow spot at the base of its volume chamber which allows for electronic detection of the piston movements without altering or modifying the original Spiro-ball IS's structure.

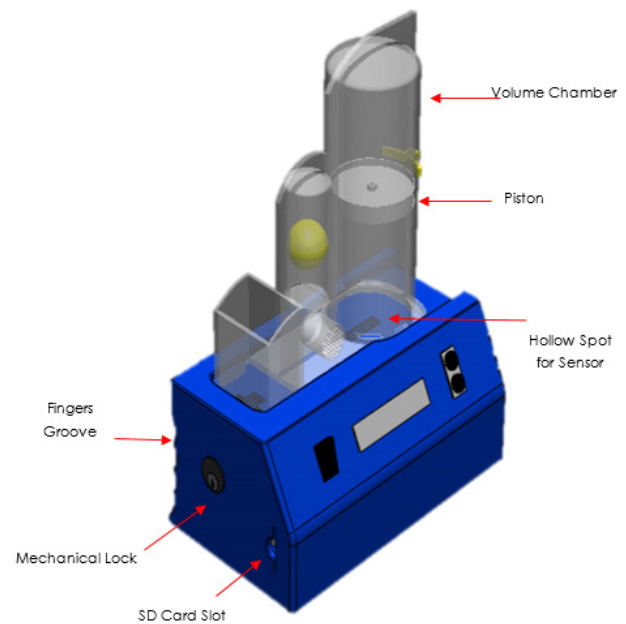


FIGURE 1. Monitoring device with the Spiro-ball IS attached atop

The second part was the distance sensor that measured piston movements in the Spiro-ball IS volume chamber. The infrared (IR) distance sensor, GP2Y0A41SK0F (Sharp, Osaka, Japan) composed of an integrated combination of position sensitive detector (PSD) with infrared emitting diode (IRED) and with a distance measurement range from 4 to 30 cm (Sharp 2002).

The third part was the electronic circuitry with tilt detector, battery, computer interface, memory card reader and timer circuit which were fixed inside the device. The fourth part consisted of additional features included in the device, namely, the mechanical locking system, switch button and liquid crystal display (LCD). The mechanical locking system consisted of a mechanical drawer lock in combination with Omron limit switch (Omron, Kyoto, Japan).

All four parts were held together by a custom casing designed using Solidworks software and developed using 3-dimensional printer technology with Acrylonitrile-butadiene-styrene (ABS) plastic material. The casing was designed in such a way to act as an accessory to the Spiro-ball IS as it could be easily interfaced with it via a sliding-in mechanism as and when necessary. This was to ensure that no changes were made to the commercially available

Spiro-ball IS which could affect its appearance or validated performance. The casing was designed to be compact and had finger grooves for easy handling by users. The system operated using two units of 3.7 V rechargeable batteries. Table 1 shows the technical specifications of the device.

The functional principles of the monitoring device are summarized in Figure 2. The system was conducted by a conventional 8-bit microcontroller (Atmel Corporation, San Jose, CA, USA). This microcontroller was programmed to regulate the whole function of the device and was capable of communicating with a personal computer (PC) via universal asynchronous receiver/transmitter interface for data transmission and device configuration. The microcontroller also communicated with a clock integrated chip to enable time and date tracking function to provide real-time data of the breathing exercises performed.

For the memory function, the microcontroller

communicated with a conventional 4 gigabyte memory card to act as storage for the acquired ISy data together with the date and time. The data was stored in the .txt file format which could be easily viewed and accessed by connecting the memory card to a PC. The device was also configured to read, process and display selected information on the display panel by the operation of a switch button mechanism. This was to facilitate quick review of pertinent ISy performance parameters, such as the target volume, total number of inspirations achieved per day, the number of inspirations achieving target volumes, the highest inspiration volume achieved and its frequency; via a liquid crystal display (LCD).

An infrared (IR) distance measuring sensor was programmed to read the inspiration volume based on the distance the piston moved along the volume chamber during inspiration manoeuvres by the IS user. The IR sensor was placed at the slide-in area (where the IS attached to the

TABLE 1. Specifications for the monitoring device

Specification	Details
Dimension (L × W × H)	20 × 11 × 8 cm
Power supply	DC 7.4V
Weight	300 g
Range distance detection	5.5 - 15.5 cm
Memory	4 gigabyte SDHC external memory

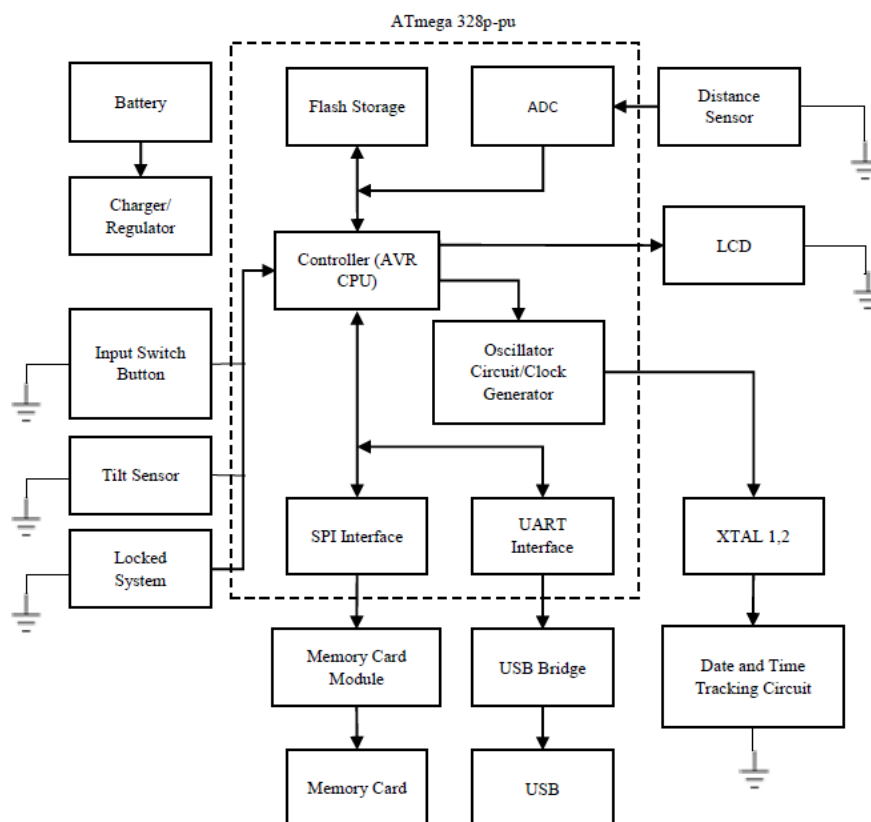


FIGURE 2. Functional principal of the monitoring device

device) which corresponded with the hollow spot at the base of the Spiro-ball IS. This was also the starting point of the piston and allowed the distance sensor to measure the position of the piston as it moved along the volume chamber. Computation of the IS volume using the IR distance sensor was done based on the distance travelled by the piston between the 0 to 4000 mL volume marking on the Spiro-ball IS. The total distance between 0 and 4000 mL measured using a measuring calliper was 10 cm and every 250 mL increment was 0.625 cm as illustrated in Figure 3.

The sensor was placed 1.5 cm below the slide-in

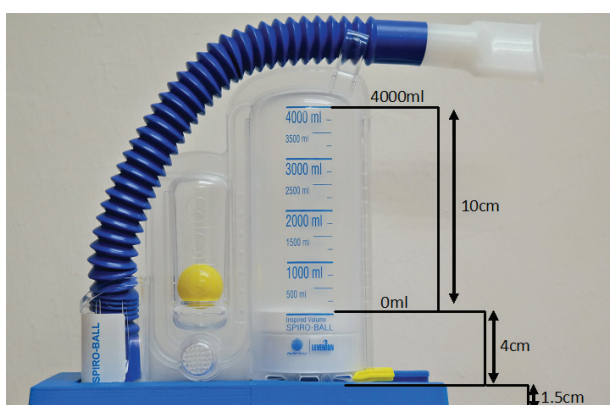


FIGURE 3. Details on positioning of the IR sensor correspond to the Spiro-ball IS

area surface of the device. The distance between the base of the volume chamber up to the top of the piston which was 4 cm was added to this value to give a starting point at 5.5 cm. Hence, the detection range for the sensor was programmed at 5.5 cm (piston position at 0 mL) to 15.5 cm (piston position at 4000 mL). The analogue value of the IR sensor was converted into digital output by a 10-bit analogue digital converter (ADC) microcontroller. The output from the IR sensor for the distance travelled by the piston was in volts. This was computed into distance in cm by using (1) which was derived from the IR sensor datasheet (Sharp 2002).

$$D = -5.16s^3 + 27.11s^2 - 52.05s + 42.93, \quad (1)$$

where s is the IR sensor output in volts; and D is the distance travelled by the piston in cm.

Equation 2 for inspired volume (v) was derived from a linear relationship graph plotted between IS volume from 0 to 4000 mL and the corresponding measured distance where every 250 mL increase in volume was represented by a 0.625 cm increase in distance. The value for (D) from (1) was integrated into (2) to obtain the value for V , as in (3), and these were then programmed into the device.

$$V = 400D - 2200. \quad (2)$$

$$V = -2063.24s^3 + 10844s^2 - 20822s + 14973. \quad (3)$$

A tilt sensor was configured into the system to prevent recording of piston movements which were not vertically upwards and was programmed to issue a 'Place properly!' warning on the LCD if any deviation from the upward motion of the piston was detected.

Additional features of the device included a mechanical locking system and a switch button to enable target inspiration volume setting. The locking system enabled two different operational modes; the administration and the user mode which represented the 'unlocked' and 'locked' state of the device. While in the 'unlocked' administration mode, only authorised personnel would be able to set the target volumes and review ISy performance data by using the switch button. The 'locked' or user mode allowed the user to perform ISy and view his/her volume achievements with each inspiration on a real-time basis; however, they would not be able to change any setting on the device.

TESTING METHODS

Two test procedures were performed to assess the functionality of the newly-developed device. Ethics approval was granted by the Ministry of Health, Malaysia (NMRR-11-898-9888).

TEST 1

The device was tested for its ability and accuracy in collecting inspiration data within 250 mL increments in the range of 250 to 4000 mL, its ability to store this data accurately in the memory card and its ability to prevent collection of fallacious data.

PROCEDURE

The Spiro-ball IS was interfaced with the device via the sliding mechanism and placed in an upright position. Figure 4 shows the summary for the testing procedure, while Figure 5 depicts the experimental setup for the test. In order to ascertain the effectiveness of the locking system, several attempts were made to change the 1000 mL target volume in the user mode using the switch button. Test 1 was performed in a controlled environment and the parameter of interest was the comparison between the datasets obtained from the memory card in the device and the one manually obtained from the Spiro-ball IS. Manual readings were obtained using a digital Samsung camera (NX300) with five times (5 \times) optical zoom which was focused on the piston position corresponding to each 250 mL level marking and was recorded on a log sheet.

The reading from the device was compared to the Spiro-ball IS reading on a 250 mL increment basis. Researcher MAA performed inspirations via the Spiro-ball IS which were repeated 10 times for each 250 mL increment. Each set of 10 inspirations in an upright position for each 250 mL increment level was followed by a 180° upside-down tilt of the Spiro-ball IS with the device. This

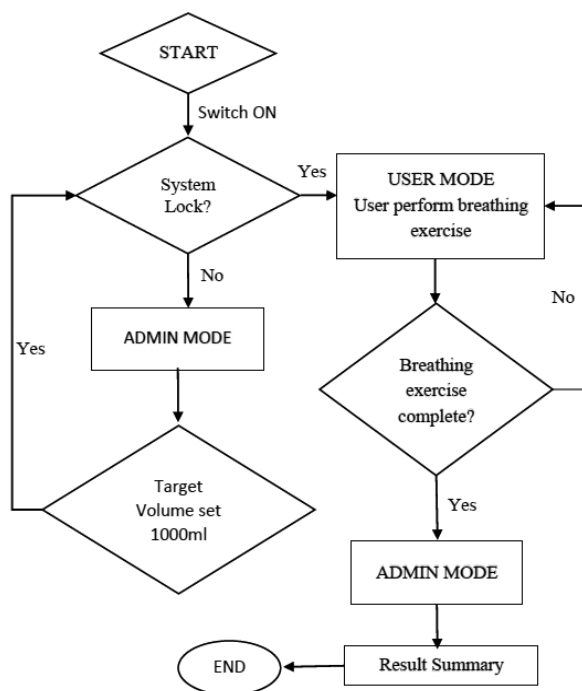


FIGURE 4. The summary of the testing procedure

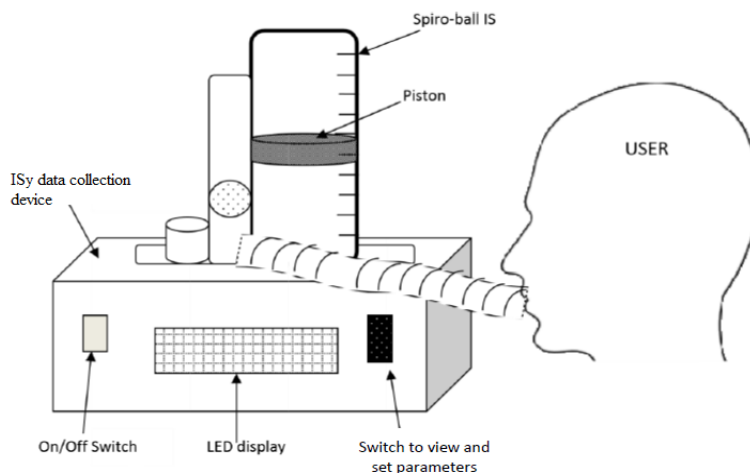


FIGURE 5. The experimental setup illustration

was to test the functionality of the tilt sensor. The data from the device was recorded in the memory card. Once the experiment was completed, the memory card was detached from the device and slot into the PC for data viewing and analysis. The memory card data was compared with the manually obtained dataset.

TEST 2

The device was tested for its ability to retrieve 'quick review' ISy information from inspiration datasets accurately and display this information correctly on the LCD. It was also tested for its ability to correctly track and

register random sets of inspiration data along a timeline.

PROCEDURE

Three faculty staff members volunteered to participate in test 2 and gave written informed consent. A digital watch was attached near the LCD screen of three devices. The watches were adjusted to correspond with the hours and minutes of the clock integrated chip in the individual device, a Spiro-ball IS was secured on each of these three devices. Target volumes were set for each and the devices were 'locked' to enable the user mode. Each volunteer received a Spiro-ball/device set. The volunteers were

asked to perform ISy in a random fashion for three days with the Spiro-ball/device sets. They were told to inspire to the set target volume and to a volume which was slightly higher and lower than the set target volumes several times throughout the three days. Log sheets were provided for them to record frequency of inspirations per day, the number of times the target volumes were achieved, the highest volume achieved and the number of times the highest volume was achieved. This procedure was to determine if the device was able to retrieve and collect accurate 'quick review' information from the inspiration dataset.

The volunteers were also instructed to record the time in hours and minutes from the digital clock and LCD each time they had done an inspiration in these log sheets. This procedure was to gauge the device ability to track inspirations accurately along a continuous timeline. They were told to seal their completed log sheets for each day in individual envelopes. The device was 'unlocked' each morning by researchers MAA and NN to retrieve the 'quick review' ISy data from the LCD. This was recorded and stored in sealed envelopes. Once this was done, a new target volume was set, the device 'locked' and returned to the respective volunteers who were informed of the new target volume. All the sealed envelopes from the volunteers and researchers MAA and NN were labelled according to content and date of data collection and stored in a locked cabinet. At the end of three days, the memory cards from the three devices were retrieved and sealed in an envelope. This was then handed over to ALTN and ARAH, research team members who were not directly involved with test 2, for downloading into a PC.

DATA ANALYSIS

Data from the memory cards were transferred to a PC and viewed separately by researchers ALTN and ARAH. 'Quick review' data for the three days was retrieved from each device, recorded and sealed in individual envelopes. All sealed envelopes (from the volunteers, MAA, NN, ALTN and

ARAH) were handed over to two postgraduate students who were not part of the project team and were not privy to information on the testing procedures in test 2. They were required to compare the 'quick review' parameters from datasets of these three sources; volunteer log sheet, LCD and memory card and document any discrepancies that were elicited (Table 2). All the statistical analysis performed using analysis software SPSS version 16.0 (IBM, USA).

RESULTS AND DISCUSSION

TEST 1

It was not possible to change the target set at 1000 mL once the device was locked and in the user mode. The datasets from the device were stored successfully in .txt file format in the memory card. The dataset in the memory card showed 160 readings in total, same as that was recorded manually from the Spiro-ball IS. The data from the Spiro-ball IS and device in the upside down position was not recorded. The data obtained from the LCD also corresponded with the data from the memory card. It showed that the user completed 160 inspirations and achieved the 1000 mL target volume 130 times. The *t*-test results for test 1 are shown in Table 3. The root-mean-square error (RMSE) is 3.882 and the *p*-values were larger than 0.05, hence there were no significant differences between the measured volumes from device with the set volumes.

TEST 2

All three volunteers were subjected to different target volumes and had different sets of performance data. The memory card registered these random sets of data along a continuous timeline for each test day. There were no discrepancies reported between any of the parameters compared from the different sources. Details of the volunteers' performance are presented in Table 4 and a portion of the raw data record can be viewed in Figure 6.

TABLE 2. Parameters compared from the datasets of the three sources; volunteer log sheet, LCD and memory card

Parameters	Datasets		
	LCD 'quick review'	Volunteer log sheet	Memory card
Set target volume with target volume displayed on LCD	✓		✓
Number of times the target volume was achieved each day	✓	✓	✓
Highest volume achieved each day	✓	✓	✓
Number of times highest volume was achieved each day	✓	✓	✓
Total number of inspirations each day	✓	✓	✓
Date and corresponding time of each inspiration for each day		✓	✓

TABLE 3. One sample *t*-test analysis for every 250 mL increment set volume

Set Volume (mL)	Mean	Std. Dev	<i>t</i> -Value	<i>p</i> -Value
250	250.8	2.65	0.95	0.36
500	500.4	5.01	0.25	0.8
750	751.2	1.93	1.96	0.08
1000	1001.1	2.47	1.41	0.19
1250	1251.4	3.84	1.15	0.27
1500	1501.8	4.89	1.16	0.27
1750	1751.5	3.17	1.49	0.16
2000	2002.3	5.83	1.24	0.24
2250	2252	4.94	1.27	0.23
2500	2502.1	4.18	1.61	0.07
2750	2751.6	3.2	1.57	0.15
3000	3002.3	6.36	1.14	0.28
3250	3251.3	4.16	0.98	0.34
3500	3501.6	2.98	1.69	0.12
3750	3750.4	4.29	0.294	0.77
4000	3997.5	4.22	-1.872	0.09

TABLE 4. The ISy datasets of the three volunteers

Volunteer	Day	Target volume	Total inspirations	Inspirations to target volume	Highest volume achieved	Total inspirations to highest volume
A	1	2000 mL	36	18	4000 mL	1
	2	3000 mL	34	25	4000 mL	8
	3	3500 mL	43	39	4000 mL	11
B	1	2000 mL	37	22	4000 mL	1
	2	3000 mL	43	33	4000 mL	4
	3	3500 mL	40	15	4000 mL	4
C	1	2000 mL	39	38	4000 mL	4
	2	3000 mL	31	21	4000 mL	3
	3	3500 mL	35	17	4000 mL	2

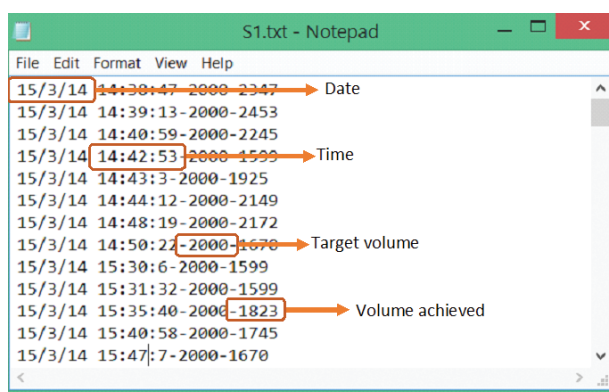


FIGURE 6. A portion of the raw data in .txt file format

DISCUSSION

A device for ISy data collection and storage of this data is presented in this paper. In test 1, there were no significant differences between the measured volumes from the device with the set volumes, demonstrating that the data obtained from the device was reliable. The tilt sensor embedded in the device also demonstrated its ability to eliminate data

when the device was not used in the recommended upright position because volume measurements when piston movements occurred with the device in 180° upside-down tilt positions were absent from the dataset. This feature may be useful in eliminating fallacious data as ISy practice guidelines specify that the IS device must always be used in an upright position (Restrepo et al. 2011). However, further tests are necessary to determine the effects of different degrees of device displacements on the activation of the tilt sensor.

Test 2 demonstrated the ability of the device to retrieve 'quick review' ISy information from inspiration datasets accurately and display this information correctly on the LCD. It was also able to correctly track and register random sets of inspiration data through different dates and timelines. The absence of discrepancies between the datasets of these parameters helped to verify the validity of the dataset collected by the device.

The primary aim of postoperative lung expansion therapies is to restore lung volumes to preoperative levels. Failing which, atelectasis may occur, subjecting the patient to PPCs. ISy is usually the first line of therapy for preventing and addressing problems caused by atelectasis because

of its low cost and ease of administration (Owens et al. 2005). However, it has to be done on a regular basis to prescribed volumes (Restrepo et al. 2011). With current models of IS, it is difficult to objectively monitor and keep track of patients' performance of inspiratory manoeuvres as they lack the necessary features. Any addition of extra monitoring and data storage features to these single-patient use disposable units is not only bound to increase its cost and also have direct implications on healthcare costs.

The newly developed device eliminates this problem because of its concept of design. Being a separate entity, it can be used as an accessory for the Spiro-ball IS as and when necessary by the HCP, thus eliminating the need for adding ISy tracking and storage features to the single-use disposable IS device. This design concept also allows the device to be reused for multiple patients. The conventional memory card, which is easily available, also contributes to the low-cost of this device. Currently, to the best of our knowledge, there is no alternative device available commercially that can fulfil such a role. Furthermore, being a paperless, non-disposable device, it may be a more environmentally friendly option to use.

Postoperative atelectasis due to monotonous, shallow breathing patterns can develop subtly and is often asymptomatic in the early stages (Owens et al. 2005). As such, the device facilitates the usage of ISy as a novel, simple and convenient bedside clinical method for monitoring and detecting early deterioration in lung volumes so that prompt action can be taken to address problems as necessary. The LCD display provides the HCP an option to quickly access and review ISy data of patients at the bedside without the need for data transference. This will allow the HCP to track and manage their patients' ISy performance and regimen more effectively. Additionally, this would also be useful for addressing ISy compliance issues in a timely manner. Furthermore, data on the highest volume achieved would give an indication of patients' actual inspiratory capabilities, especially if they do not perform their best under supervision during evaluation for target volume goal setting. This will enable the HCP to plan more effective volume goals for their patients.

CONCLUSION

A device for ISy data collection has been designed and developed. Deep breathing exercises are very important for preventing atelectasis in patients after thoracic, cardiac and upper abdominal surgeries. Although this is a simple procedure, it has to be done regularly to target inspiratory volumes for optimal effectiveness. Current commonly used single-use IS devices do not have features that can monitor performance of these exercises. Neither do they possess the ability to display pertinent ISy performance information which might be useful in facilitating better patient care. Further research and investigations will be helpful to verify the potential of this device in optimising the use of ISy in postoperative respiratory care for diverse clinical contexts and applications.

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