BMC Pulmonary Medicine

RESEARCH

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Comparisons between In-Check DIAL® and PF810® in evaluation and training inspiratory capacity for using dry powder inhalers

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Abstract

Background Dry powder inhalers (DPIs) rely on both internal resistance and patients' inspiratory capacity for effective operation. Optimal inspiratory technique is crucial for DPI users. This study assessed the accuracy and repeatability of two available devices, PF810® and In-Check DIAL®, and analyzed their measurement errors and consistency in detecting inspiratory capacity.

Methods The accuracy and repeatability of peak inspiratory flow (PIF) and forced inspiratory vital capacity (FIVC) against various internal resistances of the two devices were assessed using standard waveforms generated by a breathing simulator. The agreement of PIF measurements between the two devices in healthy volunteers and chronic obstructive pulmonary disease (COPD) patients was analyzed with the intraclass correlation coefficient and Bland–Altman graphical analysis.

Results PF810® showed great accuracy and repeatability in measuring PIF, except for square waveforms at the lowest flow rate (20 L/min). In-Check DIAL® exhibited poor accuracy against high resistance levels. In scenarios with no resistance, In-Check DIAL® had significantly smaller measurement errors than PF810®, but larger errors against high resistance levels. The two devices showed excellent agreement (ICC > 0.80, $P < 0.05$), except for healthy volunteers against medium to high resistance (R3-R5) where the ICC was insignificant. Bland–Altman plots indicated small disagreements between the two devices for both healthy volunteers and COPD patients.

Conclusions In-Check DIAL® exhibited poor accuracy and larger measurement errors than PF810® when detecting PIFs against higher internal resistances. However, its good performance against lower internal resistances, along with its cost-effectiveness and convenience made it appropriate for primary care. PF810® showed good accuracy and repeatability and could detect additional parameters of inspiratory capacity beyond PIF, though required further studies to confirm its clinical benefits.

Keywords Chronic obstructive pulmonary diseases, Asthma, Inhalers, Inspiratory capacity, Peak inspiratory flow, Medical devices

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Introduction

Inhalation therapy is the first-line treatment for Chronic Obstructive Pulmonary Disease (COPD) and bronchial asthma (asthma), as recommended by the Global Initiative for Chronic Obstructive Lung Disease (GOLD) [1] and the Global Initiative for Asthma (GINA) [2]. Various inhalation devices are available, including pressurized metered-dose inhalers (pMDIs), dry powder inhalers (DPIs), and soft mist inhalers (SMIs). DPIs containing bronchodilators and corticosteroids are commonly used in clinical practice for treating asthma and COPD [3–5]. DPIs are recommended for asthma and COPD patients who can achieve a forceful and deep inhalation [1]. DPIs are breath-actuated, relying on the interaction between the device's internal resistance and the patient's sufficient inspiratory capacity, which encompasses specific levels of inspiratory volume, flow rates, and post-inhalation breath-hold time [6, 7]. Meanwhile, the internal resistances of DPIs vary significantly, necessitating different minimum and optimal inspiratory flow rates for effective utilization [8]. Therefore, before selecting appropriate DPIs for patients, it is imperative to evaluate their inspiratory capacity across various internal resistances to mitigate the risk of insufficient lung deposition.

Routine pulmonary function tests mainly assess ventilation function, such as forced expiratory volume in one second (FEV_1) and forced vital capacity (FVC). Previous studies have shown a lack of correlation between peak inspiratory flow (PIF) at various device resistance levels and FEV_1, FEV_1% prediction, or FVC [8–10]. More than the severity of airflow limitation, the inspiratory capacity is affected by age, gender, muscle strength, and frailty. Several studies have proved that COPD patients [7, 9, 11–14] and children with asthma [7, 15] have lower PIFs compared to the healthy adults. Men generally have higher PIFs than women [16], and PIFs tend to decline with age [17]. The inspiratory muscle strength and maximum inspiratory pressures are lower in frail compared to pre-frail and non-frail older adults [18, 19]. Consequently, inspiratory capacity may vary among patients with different conditions, and training can enhance the ability to use inhalers [10]. Evaluating and monitoring inspiratory capacity should be an integral part of disease management.

Patients' inspiratory capacity against internal resistances can be measured and trained by using the In-Check DIAL® with mouthpieces [20, 21] or Multi-Function Spirometer System PF810® [22] (Fig. 1). In-Check DIAL® has been used in previous studies to measure PIFs between 15 and 120 L/min [23–25], while PF810® is relatively new in this field. Therefore, this study measured and compared the accuracy, repeatability, and consistency of these two devices. Additionally, their working principles, cost, and application ranges were discussed to determine which device better meets clinical needs.

Methods

Subjects and study design

The subjects were prospectively enrolled for this comparative study. The healthy volunteers and COPD patients were recruited from Zhongshan Hospital, Shanghai Medical College, Fudan University. COPD patients were diagnosed according to the GOLD guidelines [1], with exlusion criterias: patients with other diseases, cognitive disabilities, lack of patient's consent. The healthy volunteers were defined based on clinical investigation and a negative history of any diseases. Demographic characteristics of all participants were collected, and their PIFs against varying levels of resistance were detected through In-Check DIAL® and PF810®. And PIF values detected by In-Check DIAL® and PF810® were compared to assess the consistency between the two devices. The study was approved by the Ethics Committee of Zhongshan Hospital of Fudan University (B2019-142) and all the participants have signed an informed consent.

In order to analyze the in vitro accuracy and repeatability of In-Check DIAL® and PF810®, a breathing simulator was applied to generate specific airflows with fixed inspiratory volumes and flow rates. The PIFs of airflows were measured by In-Check DIAL® and PF810®. The flow volumes, equivalent to forced inspiratory vital capacity (FIVC), were measured by PF810®.

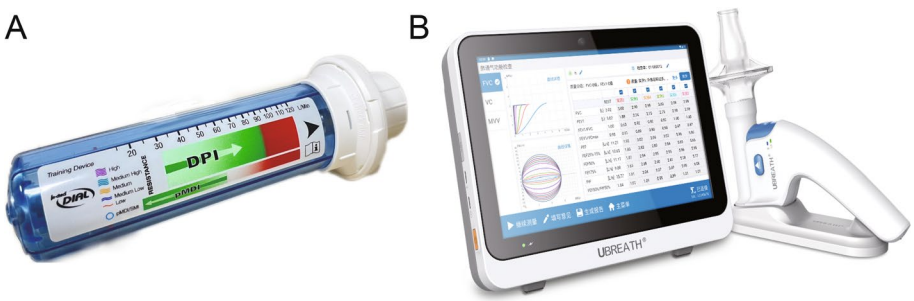

Fig. 1 In-Check DIAL® (**A**) and PF810.® (**B**)

The devices and instruments

In-Check DIAL® (Clement Clarke International, Harlow, UK and Alliance Tech Medical) comprises a resistance generation and a mechanical measurement component to detect the PIF. During the measurement procedure, the resistance generation component was manually adjusted to simulate internal resistances of pMDIs, SMIs, and DPIs, ranging from no resistance (R0) to high resistance (R5) (Supplementary Table S1) [26, 27].

The Multi-Function Spirometer System PF810® (UBREATH, Hangzhou, China), a novel flow sensor-based spirometer, visualizes dynamic real-time inspiratory flow on a flow-time graph and output other parameters reflecting inspiratory capacity (Supplementary Figure S1). The flow sensor inside PF810® was capable of simulating internal resistances from R0 to R5, consistent with In-Check DIAL®.

The breathing simulator (Piston Medical Ltd., Budapest, Hungary) was utilized to simulate patients' inspiratory efforts with specific flow rates, volumes, and times. The mechanical error of the breathing simulator was less than 0.2%.

Measurement of simulated waveforms

The instructions for using In-Check DIAL® and PF810® were obtained from the respective manufacturer websites and product brochures [20–22].

PF810®

Before measurement, the BTPS (body temperature, pressure, water vapor saturated) correction function of PF810® was selected. The software carried by PF810® (Multigunctional Pulmonary Function Testing System v1.1.7) calculated the BTPS correction factor from sensor data and correct the results output of the device. In this way, the PIF and FIVC of airflows generated by the simulator and the participants were BTPS-corrected. Then a certified 3 L syringe (CareFusion Calibration Pump, Germany) was used for calibration. The air outlet of the syringe was connected to PF810®'s filter port with a silicone tube, then volume calibration checks were performed manually using different flow rates between 2 and 12 L/s.

The air outlet of the breathing simulator was connected to PF810®'s filter port using a silicone tube to avoid air leaks. Resistance levels were set via PF810®'s software before operating the simulator to initiate the output of inspiratory waveforms. In this study, C07, C09, C13 inspiratory waveforms from ISO 26782: 2009 international certification, square waveforms with an inspiratory volume of 2 L and flow rates varying from 20 to 100 L/min, and sine waveforms with an inspiratory volume of 3 L and a PIF of 60 L/min were generated using the breathing simulator. The measurement results of the flow rate and volume, equivalent to PIF and FIVC, against different resistance levels were recorded. For each condition, three repetitions were performed.

In-Check DIAL®

The red cursor was reset to the start position before In-Check DIAL® was connected to the simulator's air outlet using a silicone tube. After adjusting the resistance level, the breathing simulator was activated to generate the standard waveforms. The PIF reading, indicated by the position of the red cursor against the scale, was recorded. For each condition, three repetitions were performed.

Measurement of participants' PIFs

After PF810® had completed the BTPS correction and the calibration with the 3 L syringe, In-Check DIAL® and PF810® were both adjusted to the required resistance levels. After connecting the mouthpiece to either the In-Check DIAL® or PF810®, each participant was instructed to (1) sit still, look straight ahead and keep the head vertical; (2) make the mouth close to the mouthpiece; (3) exhale slowly and as completely as possible; (4) inhale deeply and quickly, keep the inhalation as smooth as possible; (5) hold the breath for as long as possible, and then slowly exhale the air in the lungs. Repeat the above maneuvers three times, and the maximum PIF value among three repetitions was recorded before adjusting the device to the next resistance level. Each participant completed PIF measurements at six resistance levels using both devices, with a few minutes of rest scheduled between each inhalation. Additionally, all the participants received detailed instructions on how to use each device from researchers and practiced using them beforehand. Researchers confirmed their proficiency and movements before the actual tests began.

Statistical analysis

The accuracy and repeatability of PF810® and In-Check DIAL® were assessed using three repeated measurements of simulated flows generated by the breathing simulator. The measurement error was defined as the difference between each measured value and the standard value (V_{std}). The average error (V_{err}) was calculated as the mean of the three measurement errors. The reading span (V_{span}) was the difference between the maximum and minimum values among the three readings. The accuracy was expressed as the ratio of V_{err} to V_{std}, and the repeatability was determined as the ratio of V_{span} to the average measured value. A student t-test was applied to determine whether there was a significant difference ($P<0.05$) in measurement error between the two devices.

The agreement of the two devices was assessed using the intraclass correlation coefficient (ICC) and the Bland–Altman graphical analysis. A *p*-value of less than 0.05 indicated a significant ICC, interpreted as follows: zero to 0.20, poor agreement; 0.21–0.40, fair agreement; 0.41–0.60, moderate agreement; 0.61–0.80, good agreement; 0.81–1.00, excellent agreement [28]. Bland–Altman plots were created based on the average differences between PIFs detected by PF810® and In-Check DIAL®.

SPSS (v26.0) and R (v4.2.0) software were used for statistical analysis.

Results

PF810® presented accuracy less than 10% except measuring the lowest PIFs

According to the international standard ISO 23747: 2015 (Anaesthetic and respiratory equipment), V_{err} and V_{span} of both PIF and FIVC should be less than 10 L/min, and accuracy and repeatability should be less than 10%, to meet the requirements. Supplementary Table S2 indicated that when standard waveform C07, C09, and C13 were measured by PF810®, V_{err}, V_{span}, accuracy, and repeatability of both PIFs and FIVCs all met these criteria.

Table 1 PIFs and FIVCs of square and sin waveforms against various resistances measured by PF810®

Waveforms	Resistance level	Standard PIF (L/min)	PIF				FIVC[a]			
			V_{err} (L/min)	Accuracy	V_{span} (L/min)	Repeatability	V_{err} (L)	Accuracy	V_{span} (L)	Repeatability
Square waveforms	R0	20	5.67	28.33%	1.00	3.90%	-0.01	-0.33%	0.03	1.51%
		40	4.67	11.67%	2.00	4.48%	-0.01	-0.50%	0.00	0.00%
		60	5.67	9.44%	1.00	1.52%	-0.01	-0.50%	0.00	0.00%
		80	6.00	7.50%	0.00	0.00%	0.01	0.67%	0.01	0.50%
		100	6.00	6.00%	3.00	2.83%	0.00	0.17%	0.01	0.50%
	R1	20	4.33	21.67%	1.00	4.11%	-0.02	-1.00%	0.00	0.00%
		40	2.33	5.83%	1.00	2.36%	-0.02	-0.83%	0.01	0.50%
		60	1.00	1.67%	0.00	0.00%	0.00	0.00%	0.00	0.00%
		80	1.00	1.25%	0.00	0.00%	0.00	0.00%	0.00	0.00%
		100	1.00	1.00%	0.00	0.00%	-0.01	-0.50%	0.00	0.00%
	R2	20	4.33	21.67%	1.00	4.11%	-0.01	-0.50%	0.00	0.00%
		40	1.67	4.17%	1.00	2.40%	-0.02	-1.00%	0.02	1.01%
		60	0.33	0.56%	1.00	1.66%	-0.01	-0.67%	0.02	1.01%
		80	0.67	0.83%	1.00	1.24%	-0.01	-0.50%	0.02	1.01%
		100	1.00	1.00%	0.00	0.00%	0.00	0.00%	0.00	0.00%
	R3	20	2.67	13.33%	1.00	4.41%	-0.02	-0.83%	0.01	0.50%
		40	0.00	0.00%	0.00	0.00%	-0.03	-1.50%	0.00	0.00%
		60	0.00	0.00%	0.00	0.00%	-0.02	-0.83%	0.01	0.50%
		80	1.67	2.08%	1.00	1.22%	0.00	0.00%	0.00	0.00%
		100	2.00	2.00%	0.00	0.00%	0.01	0.50%	0.00	0.00%
	R4	20	2.67	13.33%	1.00	4.41%	0.02	0.83%	0.01	0.50%
		40	1.00	2.50%	0.00	0.00%	0.00	0.00%	0.00	0.00%
		60	1.00	1.67%	0.00	0.00%	0.00	0.17%	0.01	0.50%
		80	1.00	1.25%	0.00	0.00%	0.01	0.33%	0.01	0.50%
	R5	20	0.00	0.00%	0.00	0.00%	0.01	0.50%	0.00	0.00%
		40	0.67	1.67%	1.00	2.46%	0.01	0.50%	0.00	0.00%
		60	0.00	0.00%	0.00	0.00%	-0.02	-0.83%	0.01	0.50%
Sin waveforms	R0	60	1.33	2.22%	1.00	1.63%	0.02	0.78%	0.01	0.33%
	R1	60	0.00	0.00%	0.00	0.00%	0.01	0.33%	0.00	0.00%
	R2	60	0.00	0.00%	0.00	0.00%	0.01	0.33%	0.00	0.00%
	R3	60	-0.67	-1.11%	1.00	1.69%	0.01	0.44%	0.01	0.33%
	R4	60	-1.00	-1.67%	0.00	0.00%	0.03	1.00%	0.00	0.00%
	R5	60	1.00	-1.67%	0.00	0.00%	0.10	3.33%	0.00	0.00%

PIF peak inspiratory flow, *FIVC* forced inspiratory vital capacity, V_{err} the mean of the difference between the measurement and the standard value, V_{span} the reading span equivalent to the difference between the maximum and minimum measurement value, *R0* no resistance, *R1* low resistance, *R2* medium–low resistance, *R3* medium resistance, *R4* medium–high resistance, *R5* high resistance

[a] The standard FIVC of all the square waves were 2 L and that of sin waves were 3 L. Numbers were presented to two decimal places or two significant digits

Table 1 presented that when the standard PIF of a square wave was 20 L/min, the accuracy of PIFs measured by PF810® exceeded 10% against resistances R0-R4. It also exceeded 10% against resistance R1 when the standard PIF was 40 L/min. In other conditions, both PIFs and FIVCs of square waves measured by PF810® met the criteria. PF810® also met the criteria for detecting PIFs and FIVCs of sine waves with a volume of 3 L and a peak flow rate of 60 L/min against any resistance level. Figure 2 and Fig. 3 showed the real-time square and sine waveforms measured by PF810® from R0 to R5, which closely matched the waveforms output by the simulator.

The accuracy of In-Check DIAL® exceeded 10% against high internal resistances

Table 2 presented the PIF measurements of simulated waveforms against different resistance levels using In-Check DIAL®. The repeatability of In-Check DIAL® met the criteria except for a fixed flow rate of 20 L/min against resistance R5. The accuracy of measuring certain flow rates (20 and 40 L/min against R0, 60 and 80 L/min against R1, 60–100 L/min against R2) was outside the 10% limit against resistances R0-R2. The accuracy of In-Check DIAL® was above 10% for all flow rates against resistances R3-R5, failing to meet the criteria. The V_{err} of In-Check DIAL® mostly exceeded 10 L/min against

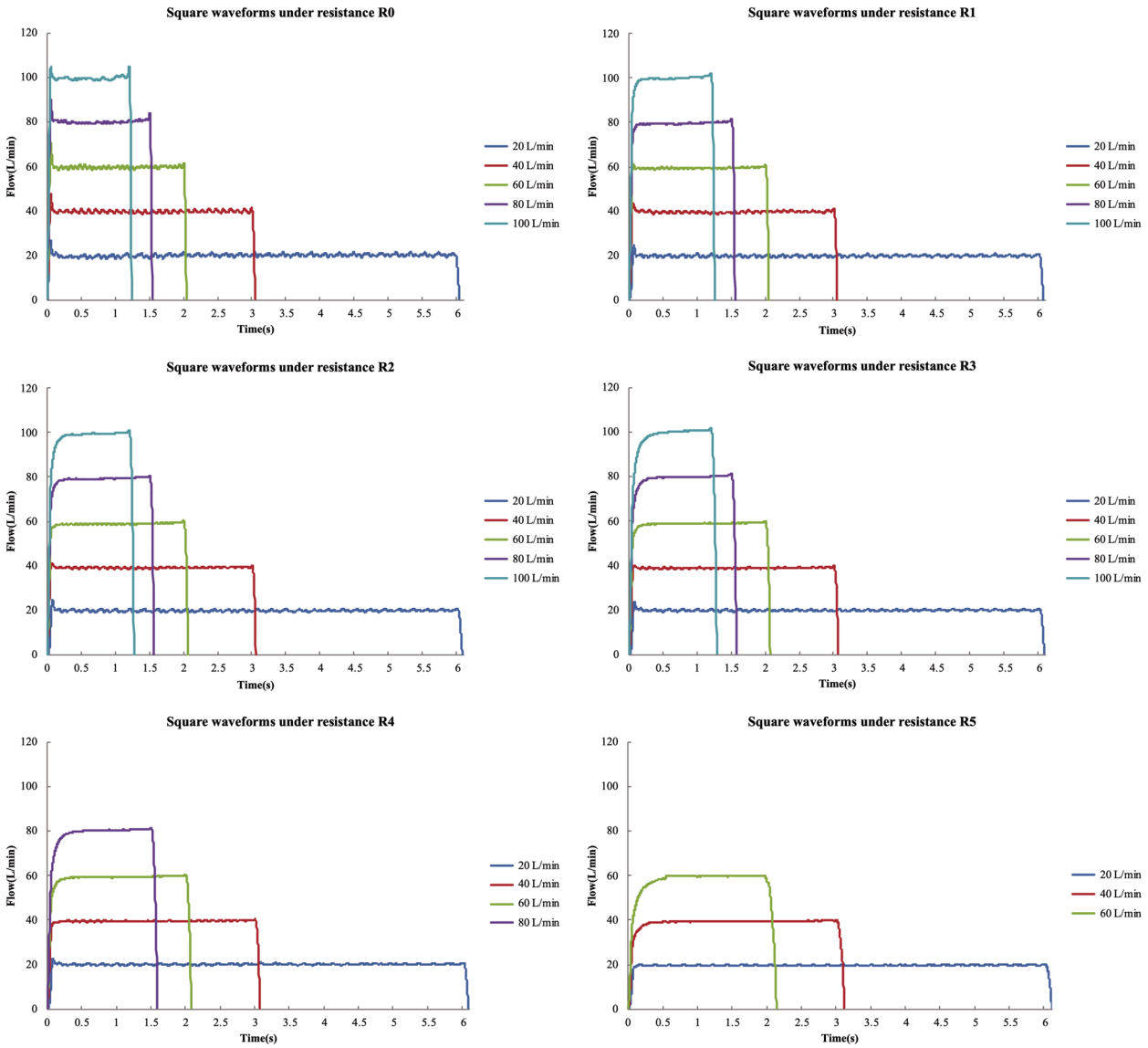

Fig. 2 The flow-time graph of square waveforms detected by PF810®.R0, no resistance; R1, low resistance; R2, medium–low resistance; R3, medium resistance; R4, medium–high resistance; R5, high resistance

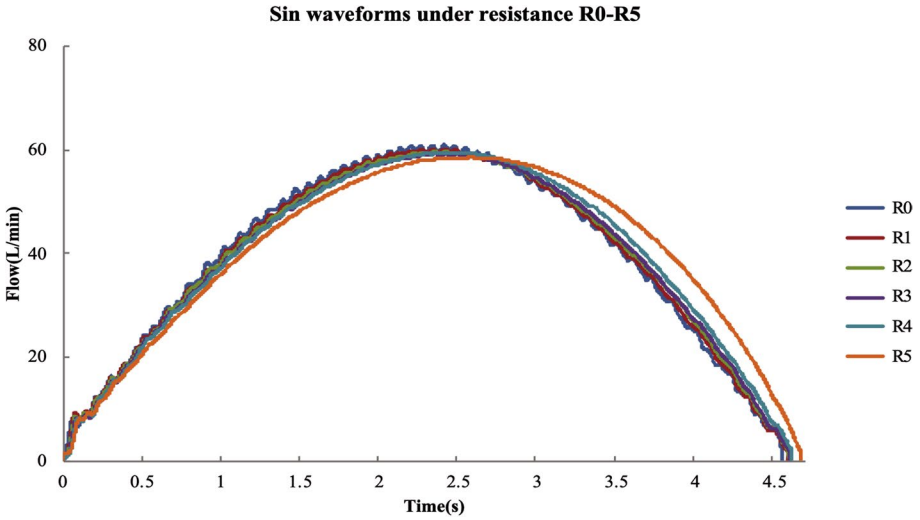

Fig. 3 The flow-time graph of sin waveforms detected by PF810®. R0, no resistance; R1, low resistance; R2, medium–low resistance; R3, medium resistance; R4, medium–high resistance; R5, high resistance

resistances R2-R5, with detected values being lower than the standard values.

The measurement errors between In-Check DIAL® and PF810®

The measurement errors of PF810® and In-Check DIAL® for determining PIFs were compared (Table 3). Against resistance R0, In-Check DIAL® had significantly smaller measurement error than PF810®. Against resistance R1 and R2, with a standard PIF of 20 L/min, In-Check DIAL® also had significantly smaller errors. However, for standard PIFs of 60, 80, or 100 L/min against R1 and R2, In-Check DIAL® had significantly larger errors. Against resistance R3, with standard PIFs from 40 to 100 L/min, In-Check DIAL® also showed significantly larger measurement errors than PF810®. PF810® had notably smaller errors against R4 and R5, regardless of the fixed waveforms' flow rates.

Consistency between In-Check DIAL® and PF810® in measuring participants' PIFs

A total of 10 healthy volunteers and 14 COPD patients participated in this study. Table 4 demonstrated that for COPD patients, PF810® and In-Check DIAL® had excellent agreement (>0.80) from R1 to R5. For healthy volunteers, PF810® and In-Check DIAL® had excellent agreement against R1 (ICC = 0.952, 95% CI: 0.819–0.988, $P < 0.001$) and R2 (ICC = 0.916, 95% CI: 0.654—0.979, $P = 0.001$), but the ICC against R3 to R5 was not significant ($P > 0.05$). From R0 to R5, Bland Altman plots (Fig. 4) all demonstrated small disagreements between PF810® and In-Check DIAL® in PIFs measurement for both healthy volunteers and COPD patients. In COPD patients, the mean difference (In-Check DIAL®—PF810®) was from 2.35 to -6.35 L/s. In healthy volunteers, the mean difference was from 5.50 to -3.00 L/s.

PIFs detected by PF810® against R0 exceeded 120 L/min, the upper limit of In-Check DIAL®, so PIFs against resistance R0 were not included in the consistency analysis.

Discussion

To select appropriate DPIs and assist with inhalation training, the device used to evaluate PIF needs to be accurate, repeatable, convenient, and cost-effective. In this study, the accuracy and repeatability of PF810® and In-Check DIAL® were compared based on standard PIFs and FIVCs of different waveforms generated by the breathing simulator for the first time. Their general performance and consistency between PF810® and In-Check DIAL® in detecting PIF against various resistance levels were evaluated for the first time.

Previous studies have shown that many researchers prefer using In-Check DIAL® over other spirometers to measure PIFs because it can measure PIFs against resistance conditions, which more accurately reflects patients' inspiratory capacity when using DPIs. In-Check DIAL® also assists patients with low PIFs in inhalation training. It has been demonstrated that inhaler technique training using In-Check DIAL® increases patients' PIFs and improves their ability to use DPIs [10]. Accurate measurement of PIFs against resistances was necessary for clinical evaluation and inhalation training. However, few studies have assessed the accuracy of In-Check DIAL®,

Table 2 PIFs against different resistances measured by In-Check DIAL®

Resistance level	Standard PIF (L/min)	PIF			
		V_{err} (L/min)	Accuracy	V_{span} (L/min)	Repeatability
R0	20	2.67	13.33%	2.00	8.82%
	40	4.33	10.83%	1.00	2.26%
	60	3.67	6.11%	1.00	1.57%
	80	3.67	4.58%	1.00	1.20%
	100	3.00	3.00%	0.00	0.00%
R1	20	0.33	1.67%	1.00	4.92%
	40	2.33	5.83%	1.00	2.36%
	60	-6.00	-10.00%	0.00	0.00%
	80	-8.33	-10.42%	1.00	1.40%
	100	-6.33	-6.33%	1.00	1.07%
R2	20	-1.00	-5.00%	0.00	0.00%
	40	-3.00	-7.50%	2.00	5.41%
	60	-8.33	-13.89%	1.00	1.94%
	80	-12.67	-15.83%	1.00	1.49%
	100	-14.67	-14.67%	1.00	1.17%
R3	20	-2.00	-10.00%	0.00	0.00%
	40	-4.33	-10.83%	1.00	2.80%
	60	-7.67	-12.78%	1.00	1.91%
	80	-12.67	-15.83%	1.00	1.49%
	100	-16.33	-16.33%	1.00	1.20%
R4	20	-4.33	-21.67%	1.00	6.38%
	40	-5.33	-13.33%	1.00	2.88%
	60	-8.67	-14.44%	1.00	1.95%
	80	-17.67	-22.08%	1.00	1.60%
R5	20	-3.00	-15.00%	2.00	11.76%
	40	-7.33	-18.33%	1.00	3.06%
	60	-11.67	-19.44%	1.00	2.07%

Numbers were presented to two decimal places or two significant digits

PIF peak inspiratory flow, V_{err} the mean of the difference between the measurement and the standard value, V_{span} the reading span equivalent to the difference between the maximum and minimum measurement value, *R0* no resistance, *R1* low resistance, *R2* medium–low resistance, *R3* medium resistance, *R4* medium–high resistance, *R5* high resistance

indicating a need for further evaluation. *Barnes* found that when In-Check DIAL® was used to detect PIFs at resistant levels of Diskus® or Handihaler®, there was a small mean difference between measurement attempts and a low repeatability limit [29]. Conversely, *Broeders* proved that In-Check DIAL® could not indicate all patients who did not reach the optimal flow rate [30]. Our research also showed that In-Check DIAL® had low accuracy in measuring PIFs at resistance levels of R3, R4, and R5.

PF810® is a new device in this field and has not been applied in reported research. This study demonstrated good repeatability of PF810®, and its accuracy was also confirmed, except for square waves with extremely low PIF values. Meanwhile, its measurement error against high resistance levels was significantly smaller than that of In-Check DIAL®. Although the Bland–Altman plots showed that PIF measurements of PF810® and In-Check DIAL® were in reasonable agreement for both COPD patients and healthy volunteers, the ICCs indicated inconsistencies against high resistances in healthy volunteers, probabaly due to In-Check DIAL®'s larger measurement error against high internal resistances.

Additionally, since inspiratory flow would be affected by ambient conditions, the device should be able to convert the ambient conditions to physiological ones within the lungs before detecting inspiratory capacity [31]. PF810® included a BTPS correction function, while In-Check DIAL® with simple structure was probably affected by environmental factors.

For a comprehensive evaluation of inhalation techniques, indicators such as breath-holding time,

Table 3 Comparison of measurement errors in PIFs between PF810® and In-Check DIAL®

Resistance level	Standard PIF (L/min)	Absolute V_{err} of PF810® (L/min)	Absolute V_{err} of In-Check DIAL® (L/min)	*P*-value
R0	20	5.67	2.67	0.016
	40	4.67	4.33	0.678
	60	5.67	3.67	0.013
	80	6.00	3.67	0.002
	100	6.00	3.00	0.040
R1	20	4.33	0.33	0.001
	40	2.33	2.33	1
	60	1.00	6.00	< 0.001
	80	1.00	8.33	< 0.001
	100	1.00	6.33	< 0.001
R2	20	4.33	1.00	< 0.001
	40	1.67	3.00	0.116
	60	0.33	8.33	< 0.001
	80	0.67	12.67	< 0.001
	100	1.00	14.67	< 0.001
R3	20	2.67	2.00	0.116
	40	0.00	4.33	< 0.001
	60	0.00	7.67	< 0.001
	80	1.67	12.67	< 0.001
	100	2.00	16.33	< 0.001
R4	20	2.67	4.33	0.024
	40	1.00	5.33	< 0.001
	60	1.00	8.67	< 0.001
	80	1.00	17.67	< 0.001
R5	20	0.00	3.00	0.007
	40	0.67	7.33	< 0.001
	60	0.00	11.67	< 0.001

The V_{err} was presented to two decimal places, and the *P*-value was presented to three

PIF peak inspiratory flow, V_{err} the mean of the difference between the measurement and the standard value, *R0* no resistance, *R1* low resistance, *R2* medium–low resistance, *R3* medium resistance, *R4* medium–high resistance, *R5* high resistance

$P < 0.05$ was considered statistically significant

Table 4 Intraclass correlation coefficient of PIFs between PF810® and In-Check DIAL®

	Healthy volunteers			COPD patients		
	ICC	95% CI	*P*-value	ICC	95%CI	*P*-value
R1	0.952	0.819—0.988	< 0.001	0.977	0.932—0.993	< 0.001
R2	0.916	0.654—0.979	0.001	0.979	0.938—0.993	< 0.001
R3	-0.227	-6.654—0.720	0.606	0.974	0.921—0.992	< 0.001
R4	0.493	-0.548—0.863	0.131	0.984	0.952—0.995	< 0.001
R5	0.093	-2.017—0.762	0.439	0.811	-0.164—0.955	< 0.001

The ICC and the *P*-value were presented to three decimal places

ICC intraclass correlation coefficient, *COPD* chronic obstructive pulmonary disease, *R1* low resistance, *R2* medium–low resistance, *R3* medium resistance, *R4* medium–high resistance, *R5* high resistance

$P < 0.05$ was considered statistically significant

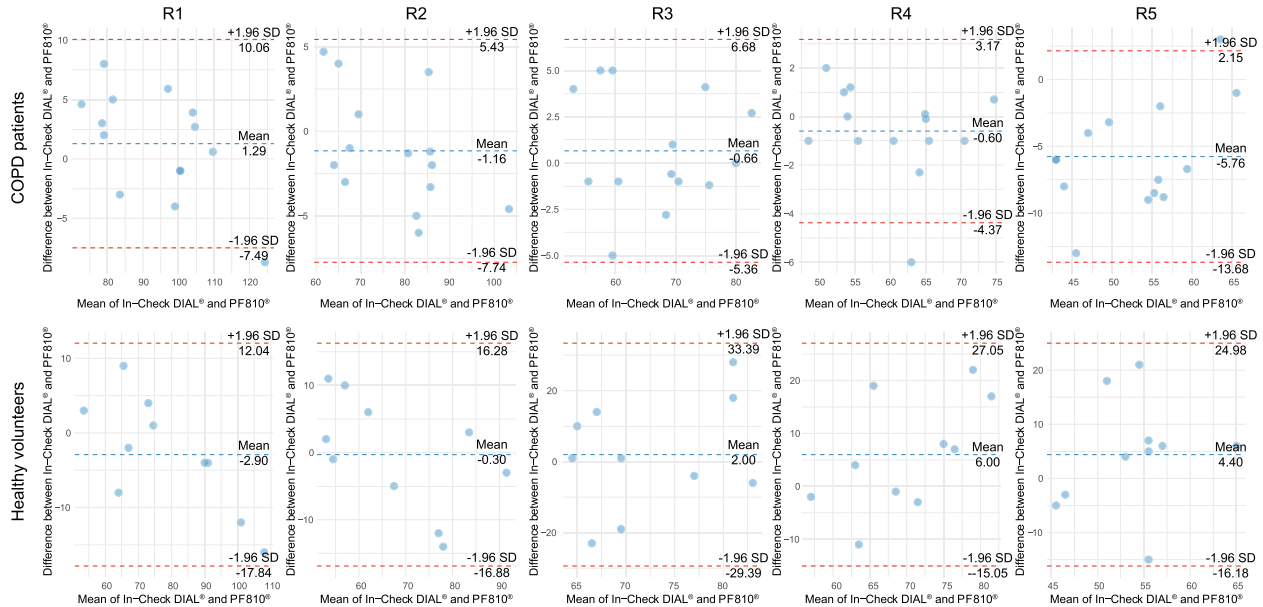

Fig. 4 The Bland–Altman plots of participants' PIFs measured by PF810® and In-Check DIAL®.COPD, chronic obstructive pulmonary disease; PIF, peak inspiratory flow; R1, low resistance; R2, medium–low resistance; R3, medium resistance; R4, medium–high resistance; R5, high resistance; Measn, the average difference between the measurement values of In-Check DIAL® and PF810®; SD, standard deviation

effective inspiratory time and volume were crucial. Excessive flow rate and oral pressure increased the deposition of drugs in the upper respiratory tract due to inertial impaction [32], leading to higher drug deposition in the central respiratory tracts and reduced uniformity of drug distribution throughout the airway [33]. PF810® could measure these parameters and the real-time display of inspiratory flow may aid inhalation training. However, further clinical studies are needed to determine if these technical advantages translate into clinical benefits.

In clinical practice, both cost-effectiveness and safety are important considerations. PF810® was priced at 28, 314 USD, with each disposable mouthpiece costing 4.72 USD. In contrast, In-Check DIAL® costed 37.56 USD, with disposable one-way valved cardboard mouthpieces at 0.42 USD each. Both devices met safety requirements by using replaceable mouthpieces to prevent the transmission of respiratory pathogens. However, due to its high cost, PF810® was more appropriate for specialized hospitals and tertiary hospitals, whereas In-Check DIAL®, being less expensive, smaller, and more convenient, was better suited for use in clinics and at home, where COPD and asthma are commonly treated and managed.

The primary limitation of this study was its small sample size, including only 10 healthy volunteers and 14 COPD patients for comparing the two devices. However, PF810® showed promising advantages in the preliminary study, suggesting further verification. We plan to evaluate the clinical benefits of PF810® in the following studies.

Conclusions

In-Check DIAL® exhibited relatively lower accuracy in detecting PIF against high internal resistances and lacked the capability to measure other indicators of inspiratory capacity. Nevertheless, it was proved to be more cost-effective, convenient, and appropriate for outpatients and primary care settings. PF810®, despite its high cost, exhibited good accuracy and repeatability in measuring multiple parameters. It showed small disagreements with In-Check DIAL®, making it suitable for comprehensive assessments in large hospitals. However, the clinical benefits of PF810® still require substantiation through reliable evidence from clinical trials.

Abbreviations

COPD	Chronic obstructive pulmonary disease
GOLD	The global initiative for Chronic Obstructive Lung Disease
GINA	The global initiative for asthma
pMDIs	Pressurized metered-dose inhalers
DPIs	Dry powder inhalers
SMIs	Soft mist inhalers
R0	No resistance
R1	Low resistance
R2	Medium–low resistance
R3	Medium resistance
R4	Medium–high resistance
R5	High resistance
FEV_1	Forced expiratory volume in one second
FVC	Forced vital capacity
PIF	Peak inspiratory flow
FIVC	Forced inspiratory vital capacity

BTPS	Body temperature, pressure, water vapor saturated
V_{std}	The standard value of airflows' PIFs and FIVCs generated by the breathing simulator
V_{err}	The mean of the difference between the measurement and the standard value
V_{span}	The reading span, equivalent to the difference between the maximum and minimum measurement value
ICC	Intraclass correlation coefficient

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12890-024-03191-7.

Supplementary Material 1.

Acknowledgements
We thank UBREATH (Hangzhou, China) for providing the working principles of PF810®.

Authors' contributions
YW and JZ conceived and designed the study. YW, LL, YG, XL and XY collected the data. YW performed the analysis and wrote the paper. All authors reviewed and approved the final manuscript.

Funding
The study is financially funded by 2021 clinical medicine research navigation project of Shanghai Medical College of Fudan University and Science and Technology Commission of Shanghai Municipality (19DZ1920104).

Availability of data and materials
All data generated or analysed during this study are included in the manuscript and supplementary material.

Declarations

Ethics approval and consent to participate
Authors reporting experiments on humans and/or the use of human tissue samples confirm that all experiments were performed in accordance with relevant guidelines and regulations. This study was approved by the Ethics Committee of Zhongshan Hospital of Fudan University (B2019-142) and all the participants have signed an informed consent.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

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Received: 28 June 2023 Accepted: 30 July 2024
Published online: 02 August 2024

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