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Original Article

Confidence, ease of use, satisfaction and preference of spacers in patients with asthma and COPD: Results from three open-label, prospective studies

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ABSTRACT

Errors with the use of pressurized metered-dose inhalers (pMDIs) reduces lung deposition and increases the local and systemic side effects. The use of a spacer reduces these errors. The studies aimed to assess the usability, confidence, preference and satisfaction with the use of three spacers (Zerostat, Zerostat V and Zerostat VT) in three different, identically designed studies. The three studies were open-labelled, prospective and multicentric in subjects with mild obstructive disease like asthma and COPD. In these two visit studies, the subjects were trained to use the device at visit 1 and again at visit 2, and the average time taken for three consecutive correct attempts was reported (primary endpoint). The secondary endpoints included number and type of errors (critical and non-critical), and scores on usability, confidence, preference, and satisfaction questionnaires. A total of 90 participants (30 participants per study, 1:1 healthy volunteers: subjects with asthma/COPD) completed these studies. The average time taken for three consecutive correct attempts in subjects with asthma/COPD in the three studies decreased at visit 2 (2.99, 4.65 and 1.91 minutes) from visit 1 (3.58, 4.99 and 2.23 minutes), respectively. The critical and non-critical errors also decreased at visit 2 from visit 1. Overall reduction in the scores at visit 2 was also observed on the usability, confidence, preference and satisfaction questionnaires. The results from the three studies demonstrated that Zerostat, Zerostat V and Zerostat VT spacers are easy to learn, understand and operate. This highlights the fact that the spacer devices can be recommended for all patients using a pMDI.

Keywords: spacers, inhalation spacers, valved holding chamber, aerosol holding chamber, patient preference, patient satisfaction, asthma, metered dose inhaler

INTRODUCTION

Inhalation therapy has been the most effective and safest mode of delivering drugs to patients with obstructive airways diseases, such as asthma and chronic obstructive pulmonary disease (COPD)[1]. Effective management of obstructive respiratory conditions such as asthma and COPD has been recommended and recognised with aerosol-based therapy [2, 3]. Pressurized metered-dose inhalers (pMDIs) are the most widely prescribed dosage forms because of several factors including convenience, portability, multiple doses in a single formulation, storage in any orientation and a cheaper cost[1, 4]. Additionally, pMDIs are not dependent on the inspiratory flow of the patient; they provide highly reproducible dosing; have no contamination risk, and require a short treatment time[5]. However, some patients find it difficult to co-ordinate inhalation with actuation in the simple "press and breathe" technique of the pMDI[6]. The high speed of aerosol delivery with a pMDI hits the throat and causes cough in some patients due to the cold freon effect, and high amounts of drugs get deposited in the oropharynx, especially with the use of inhaled corticosteroids, causing local side effects [7]. Many studies discussed such "errors" in the use of pMDIs, with the other most common errors being too short breath-hold after inhalation; a rapid inspiration; abrupt discontinuation of inspiration as the aerosol hits the throat (probably due to the cold freon effect) etc.[6, 8]

A spacer device is a tube extension or a holding chamber with a port at one end to which a pMDI is attached, and a mask or mouthpiece fitted at the

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other end. Using a spacer reduces the cold freon effect and oropharyngeal deposition, thus, reducing local side-effects like cough, hoarseness, throat discomfort and oral candidiasis[9]. A pMDI with spacer eliminates the need for actuation-inhalation co-ordination for both adults and children, and has also been recommended by guidelines[2-4]. The spacer creates some distance between the point at which the aerosol is released and the patient's mouth. This allows the inactive propellant to evaporate and the rapidly moving aerosol cloud to slow down before it is inhaled[10]. Valved spacers or valved holding chambers contain a one-way, low-resistance valve which allows the aerosol to remain in the chamber until the patient's inhalation effort opens the valve, allowing for multiple inhalations without the aerosol being lost[1]. Use of a spacer improves drug delivery, increases lung deposition, and reduces local and systemic side-effects[2].

Zerostat, Zerostat V and Zerostat VT are spacer devices (Cipla Ltd., India) that are made of non-metallic antistatic thermoplastic polymer. They act as a reservoir where the actuated aerosol cloud can be held prior to inhalation. Additionally, Zerostat V and Zerostat VT are fitted with a flow-gate valve to provide unidirectional flow from the holding chamber. Zerostat VT is a transparent holding chamber to provide visual confirmation of drug delivery. The acceptance of an inhaler device is strongly influenced by factors such as patient confidence in the use of the device, the ease to understand, learn and operate the working of the device, and the satisfaction with the results provided in terms of drug delivery by the device. These patient-related factors, in turn, reflect compliance and adherence to the prescribed treatment. Hence, it is important to evaluate if patients using the spacers are comfortable with the add-on device.

The aim of the study was to assess the confidence, usability, preference and satisfaction with the use of the Zerostat, Zerostat V and Zerostat VT spacers (all manufactured by Cipla Ltd.). Three identically designed studies were conducted with each of the three different spacers in healthy volunteers and in subjects with either asthma or COPD.

SUBJECTS AND METHODS

Design: All the three studies were open-labelled, prospective and assessed the confidence, usability, preference and satisfaction of the use of Zerostat spacer (study 1), Zerostat V spacer (study 2) and Zerostat VT spacer (study 3) in healthy volunteers and in subjects with mild obstructive airway disease such as asthma and COPD. Enrolment in the study was done after the patients gave written informed consent. During the study, each participant had to complete two visits on an outpatient basis. The three studies were conducted at two outpatient clinics in different cities in India.

At visit 1, the study investigator explained and demonstrated the use of the spacer twice and the participants repeated the procedure until they achieved three consecutive correct attempts. A correct attempt was defined as demonstration of all the steps involved in proper use of the spacer. [Appendix I] During the 2nd visit, which was two days after visit 1, the participants were asked to demonstrate the use of spacer devices. Irrespective of whether they used the spacer device correctly or not, the participants were trained twice on the correct use of the technique. At both visits, the time taken to reach three consecutive correct attempts were noted. The number and type of errors till three consecutive correct attempts were also recorded [Appendix I]. After this evaluation, a questionnaire was administered to each participant and they were requested to fill in their responses for the nine questions, which were divided into four domains of confidence, usability, preference and satisfaction [Appendix II]. The evaluation to the nine questions were assessed using a Likert scale where the responses ranged from 1 to 6 (score of 6 implied positive response; score 1 implied negative response), and for satisfaction assessment from 1 to 5 (5 = positive response; 1 = negative response). At all instances, placebo inhalers were used.

Patient Population: Only subjects 18 years of age, of both genders, were enrolled in all the three studies. Equal number of healthy volunteers and patients of mild obstructive airway diseases were recruited amongst those patients who visited the outpatient clinics. Each subject with a respiratory condition (prior experience of using of an inhaler) was matched as far as possible with an individual without a respiratory condition (inhaler naïve) with respect to age, gender and literacy status. To avoid bias, subjects with a prior use of Zerostat, Zerostat V or Zerostat VT spacer, as well as those with co-ordination problems (Parkinson's disease, mental illness, tremors, etc.) were excluded from the study.

Outcome Measures: The primary endpoint for all the three studies was the average time (measured in minutes) taken by the participants to achieve three consecutive correct attempts in using the spacer device at visit 1 and 2. The secondary endpoints included: type and number of errors during visit 1 and 2; assessment of confidence, usability, preference and satisfaction with the use of Zerostat, Zerostat V or Zerostat VT spacer devices; and the number of attempts required to achieve the first correct attempt.

The study was performed in accordance with the Good Clinical Practices and Declaration of Helsinki,

and ethics committee approvals were obtained prior to the initiation of the study. The participants were explained the purpose of the study, the study procedures and a written informed consent was obtained. The data management and statistical analysis were performed by an independent agency.

Statistical Analysis: The baseline characteristics were analysed descriptively per treatment group in the three studies, and the subject disposition was summarized. The demographic and baseline data were presented descriptively. The continuous variables like age, height, weight were represented by mean and standard deviation. The categorical variables were presented as counts and percentages. The mean difference in time taken for three consecutive correct attempts during first and second visit was analysed using the paired t test at 5% level of significance. Confidence, preference, usability and satisfaction assessment scores were described in terms of frequency and percentages of each event. The analysis was done by unpaired and paired t-test (for normally distributed data) Wilcoxon's test and mann-whitney test was used to for non-normally distributed data. The number of attempts required to achieve the first correct attempt was analysed using paired t test at 5% level of significance. The primary outcome measures were based on the patients who have completed visit 1 and participated in the follow-up visits, thus, having a baseline and end-point evaluation.

RESULTS

Patient disposition from the three studies is shown in Table 1. The demographic and baseline characteristics for study 1 and 2 are presented for two groups (group 1 = healthy volunteers; group 2 = subjects with mild asthma and COPD), and for study 3, these are presented in the overall population (Table 2).

Table 1. Patient flow-through study.

	Zerostat	Zerostat V	Zerostat VT
Screened, N	31	30	30
Healthy volunteers, n	15	15	15
Subjects with mild OAD	15	15	15
Asthma, n	12	14	13
COPD, n	3	1	2
Sex			
Male	10	13	15
Female	20	17	15
Dropout	1*	0	0
Completed	30	30	30

*OAD: Obstructive airway disease; * Drop out due to protocol violation*

The average (± SD) time taken for three consecutive correct attempts at visit 1 by healthy volunteers in study 1, 2 and 3 was 3·8 (±1·1) minutes, 4·11 (±1·36) minutes and 1·51 (±0·12) minutes, respectively, and for patients with asthma/COPD, it was 3·58 (±0·93) minutes, 4·99 (±1·46) minutes and 2·14 (±0·21) minutes (Figure 1). At visit 2, healthy volunteers took an average (± SD) time of 3·52 (± 1·32) minutes, 3·58 (± 1·23) minutes and 1·48 (±0·08) minutes for three consecutive correct attempts and patients with asthma/COPD took an average (± SD) time of 2·99 (± 1·21) minutes, 4·65 (± 1·41) minutes and 1·55 (±0·15) minutes, in studies 1, 2 and 3, respectively (Figure 1) The overall number and type of errors in using the spacer device in all the three studies is shown in Table 3. The classification of critical and non-critical errors for individual spacers is mentioned in the Appendix I.

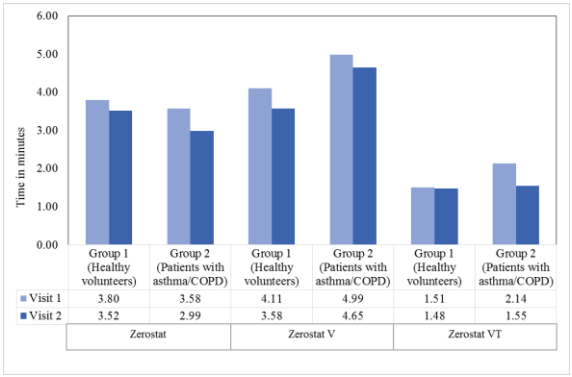

Figure 1. Time taken for three consecutive correct attempts in the three studies.

At visit 1, 86·67% of healthy volunteers in both study 1 and 2, and 40% in study 3 felt confident in using the spacer, and this increased to 93·33%, 80% and 66·70%, at visit 2. The percentage of patients with asthma/COPD that felt confident in using the device at visit 1 and 2 was 86·67% in study 1. The percentage of patients that felt confident at visit 1 was 80% and 40% in study 2 and 3, respectively, and this increased to 93·33% and 86·67% at visit 2. The overall confidence scores, out of a maximum score of 6, in the three studies are shown in Figure 2.

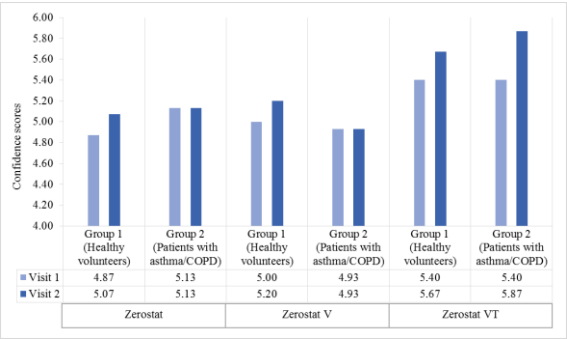

Figure 2. Overall confidence assessment scores (out of a maximum score of 6) in the three studies.

Table 2: Baseline characteristics of participants (all values are mean ± SD).

Parameters	Zerostat		Zerostat V		Zerostat VT	
	Group 1* (n=15)	Group 2# (n=15)	Group 1* (n=15)	Group 2# (n=15)	Group 1* (n=15)	Group 2# (n=15)
Sex						
Male	1	9	6	7	9	6
Female	14	6	9	8	6	9
Age ± SD (years)	34·60 ± 9·20	50·47 ± 11·92	34·67 ± 9·08	45·40 ± 18·34	30.0 ± 6.02	39.73 ± 12.53
Weight ± SD (kg)	54·47 ± 6·88	68·86 ± 13·34	53·87 ± 8·14	65·57 ± 14·30	61.87 ± 12.40	58.33 ± 13.02
Height ± SD (cms)	155·73 ± 4·22	160·60 ± 4·84	157·07 ± 5·96	158·27 ± 5·56	160.60 ± 6.73	159.80 ± 9.38
Severity of disease for asthma and COPD	NA	Mild	NA	Mild	NA	Mild

SD: Standard Deviation;
** group 1 = healthy volunteers; # group 2 = subjects with mild asthma and COPD*

The usability assessment for the two groups in the three studies is shown in Table 4. Out of a maximum score of 6, the overall average (± SD) usability scores in healthy volunteers at visit 1 were 5·02 (±0·15), 5·07 (±0·31) and 5·53 (±0·43), and at visit 2, they were 5·13 (±0·21), 5·13 (±0·48) and 5·62 (±0·43) in the three studies. The overall usability scores in patients with asthma/COPD at visit 1 were 4·93 (±0·31), 5·09 (±0·41) and 5·51 (±0.33), and 5·22 (±0·41), 5 (±0·38) and 5·71 (±0·21) at visit 2, in the three studies (Figure 3).

Table 3: Errors during the two visits by healthy volunteers and asthma/COPD patients in the three studies.

	Type of Error	Healthy volunteers		Patients with asthma/COPD	
		Visit 1	Visit 2	Visit 1	Visit 2
Zerostat	Critical	16	4	19	4
	Non-critical	33	24	58	26
Zerostat V	Critical	16	4	21	8
	Non-critical	44	24	61	34
Zerostat VT	Critical	0	2	3	3
	Non-critical	5	2	8	8

Out of a maximum score of 6, at visit 1 the overall average (±SD) preference scores in healthy volunteers were 4·97 (±0·49), 5·08 (±0·42) and 5·53 (±0·45), and in patients with asthma/COPD, the scores were 4·87 (±0·21), 5 (±0·35) and 5·52 (±0·46) in the three studies. The preference assessment is shown in Table 5. At visit 2, the overall average (±SD) preference scores in healthy volunteers were 5·13 (±0·36), 5·22 (±0·48) and 5·58 (±0·43), and in patients with asthma/COPD, the scores were 5·10 (±0·30), 4·9 (±0·31) and 5·75 (±0·30) in the three studies.

The satisfaction assessment for the two groups in the three studies is shown in Figure 4. Out of a maximum score of 5, at visit 1 the overall average (± SD) satisfaction scores in healthy volunteers were 4·47 (±0·64), 4·27 (±0·46) and 4·60 (±0·63), and in patients with asthma/COPD, the scores were 4·07 (±0·26), 4·2 (±0·41) and 4·67 (±0·49) for the three studies. At visit 2, the overall average (±SD) satisfaction scores in healthy volunteers were 4·67 (±0·49), 4·53 (±0·52) and 4·80 (±0·41), and in patients with asthma/COPD, the scores were 4·27 (±0·46), 4·2 (±0·41) and 4·87 (±0·35) in the three studies. At visit 1, the average number of attempts required for the first correct attempt after training were 5, 5 and 1·13 in healthy volunteers, and 6, 6 and 1·53 in patients with asthma/COPD in the three studies, and at visit 2, the healthy volunteers took an average of 5, 5 and 1·07 attempts and patients with asthma/COPD took an average of 5, 6 and 1·27 attempts in the three studies.

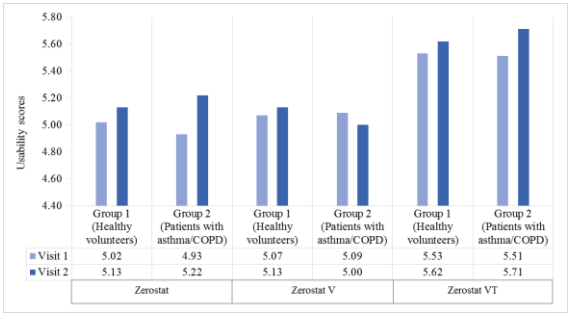

Figure 3. Overall usability assessment scores (out of a maximum score of 6) in the three studies.

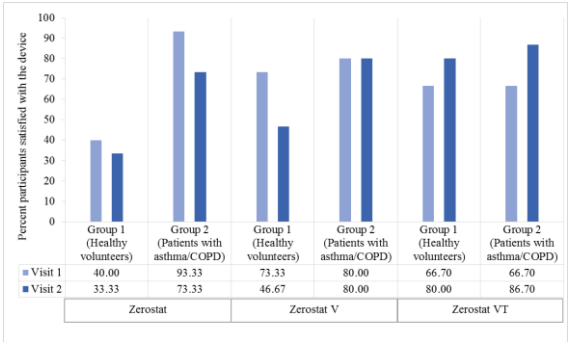

Figure 4. Percent participants satisfied with using the respective devices in the three studies.

Table 4: Usability assessment in healthy volunteers and patients with asthma/COPD from the three studies. Values are percentage of participants reporting a score of 5 (agree) on the Usability Assessment Questionnaire.

Usability Assessment	Zerostat				Zerostat V				Zerostat VT			
	Healthy volunteers		Asthma/COPD		Healthy volunteers		Asthma/COPD		Healthy volunteers		Asthma/COPD	
	Visit1	Visit 2	Visit 1	Visit 2	Visit 1	Visit 2	Visit 1	Visit 2	Visit 1	Visit 2	Visit 1	Visit 2
Easy to understand	93·33	80	86·67	86·67	86·67	80	80	93·33	46·70	53·30	60	60
Easy to operate	80	100	73·33	60	66·67	73·33	53·33	86·67	53·30	66·70	40	80
Easy to remember	93·33	66·67	66·67	60	86·67	66·67	73·33	53·33	66·70	73·30	53·30	73·30

Table 5: Preference assessment for healthy volunteers and patients in asthma/COPD in the three studies. Values are percentage of participants reporting a score of 5 (good/comfortable) on the Preference Assessment Questionnaire.

Preference Assessment	Zerostat				Zerostat V				Zerostat VT			
	Healthy volunteers		Asthma/COPD		Healthy volunteers		Asthma/COPD		Healthy volunteers		Asthma/COPD	
	Visit 1	Visit 2	Visit 1	Visit 2	Visit 1	Visit 2	Visit 1	Visit 2	Visit 1	Visit 2	Visit 1	Visit 2
Liking the device	73·33	73·33	93·33	73·33	80	73·33	86·67	100	53·30	66·70	73·33	86·70
Comfort of mouthpiece	60	86·67	93·33	73·33	66·67	66·67	53·33	53·33	53·33	53·33	73·33	80
Inhalation manoeuvre	66·67	73·33	53·33	86·67	40	46·67	66·67	53·33	60	60	40	46·7
Overall handling	66·67	60	93·33	86·67	60	33·33	73·33	86·67	60	66·70	60	86·7

DISCUSSION

These are the first and to our best knowledge, only studies till date, to assess the four parameters of confidence, usability, preference and satisfaction with Zerostat, Zerostat V and Zerostat VT in groups who have used inhaler devices earlier, and those who were naïve.

pMDIs are the most widely prescribed inhaled device, with over 70 million patients using them either alone, or with a spacer device [1, 4, 9]. Despite a number of advantages, pMDIs have some limitations, the major ones being large and rapidly moving propellant particles that impact on the oropharynx and lead to side-effects, and inability of patients to use the pMDI correctly [11]. Previous studies have conclusively shown that poor inhalation technique with a pMDI can be corrected with the use of a spacer device [9, 10, 12]. Spacers may improve the clinical effectiveness of the medications, thus increasing patient compliance and treatment adherence [12]. Previous studies on spacer devices assessed the efficacy and safety of drugs with or without the spacer [13], comparison of pMDI-spacer with a DPI [14], comparison of pMDI-spacer with nebulization therapy [15], poor asthma control due to incorrect use of pMDI [11, 16], drug deposition with pMDI-spacer [17], and lung bioavailability with the use of pMDI-spacer [18, 19]. Jarvis et al., in their study, observed that 85% of the 79% patients prescribed a spacer with their pMDI device, were not using it. This stresses the need for communicating the importance of the use of spacers in patients [20].

The primary outcome in our study was to assess the time taken by the participants for three consecutive correct attempts. This ensured that the patients learnt the correct technique to use the spacers. The time taken by the participants was under 4, 5 and 2 minutes to learn the correct use of the three spacers. It was observed that the patients took less time for three consecutive correct attempts on the second visit, as compared to the first visit, and this was even less after re-training. These results emphasize that re-training not only helps the patients to memorize the correct steps to use the spacer, but also ensures that the errors while using the spacers are minimized. A retrospective analysis by Levy et al. observed that out of a patient population of 6,573, who were prescribed a reliever or preventer treatment through a pMDI (with or without spacer), only 50% could achieve asthma control. This was attributed to incorrect inhaler technique [11].

Many patients modify the technique of using the device. This could be unintentional, either they forget the correct steps to use or because they were never taught the correct steps. This may lead to errors [21], and these errors potentially affect drug delivery to the lungs. It was noted that the number of critical errors decreased by 25% in the study participants while using the spacers, at the second visit. This decrease could be attributed to re-training by the investigator, and highlights the importance of re-training the patients at every follow-up visit.

Correct use of the spacer plays a vital role in the control of symptoms and the overall management of obstructive airway disease [11]. In our study, the percentage of participants feeling confident with the use of spacer was observed to be either same or increased at the second visit. Ease of use of a device influences the satisfaction and preference of patient towards the device. These factors determine the extent symptom improvement with the use of an inhaler device [22]. In our study, a higher percentage of participants remembered the steps to use the spacers, and found the spacer device ease to operate, at the second visit. Healthy volunteers were included in the study to get an unbiased opinion about the spacer devices. We assumed that patients with asthma or COPD had used devices like inhalers, spacers and masks previously, whereas healthy participants would be device naïve. Their opinion on understanding the usability of the device would help us identify the perception of patients who would use the spacer for the first time.

Patients in this study were asked about their preference of the spacers – whether they liked the device and the inhalation manoeuvre; whether the mouthpiece is comfortable and the overall handling of the device. These scores were high at the first visit and increased at the second visit not only in patients with asthma or COPD, but also in the healthy volunteers, who might have had a first ever experience with any spacer. The satisfaction assessment scores at the second visit were increased, in the patients using Zerostat VT spacer. This can potentially be explained by the transparency of the spacer and an in-built one-way valve-design.

One of the determinants of treatment non-adherence in COPD patients is incorrect inhaler technique. Patients do not have a high inspiratory flow rate to inhale a pMDI directly [23]. A holding chamber and the valve of the Zerostat VT spacer helps these patients to overcome this difficulty. The holding chamber reduces the velocity of the drug particles and reduces oropharangeal deposition [12]. The valve is unidirectional and allows the patient to inhale the accumulated dose multiple times. These are factors that may increase pulmonary deposition. Another important feature of a spacer in COPD patients is to eliminate the need to co-ordinate actuation-inhalation [6]. A limitation of this study was the low number of COPD patients. Hence, there is a need for further research to evaluate the advantages of using spacers in patients with COPD.

CONCLUSION

The results of the study show that the three spacers Zerostat, Zerostat V and Zerostat VT are easy to learn, use and operate. The confidence, usability, preference and satisfaction with the use of spacers, especially in the patients with mild obstructive airway disease confirms that spacers should be an important inclusion in the treatment prescription to improve symptom control and treatment adherence in patients with asthma and COPD on pMDIs.

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APPENDIX I

Steps to use Zerostat spacer and classification of critical and non-critical errors.

Step No.	Description	Critical/non critical
1	To assemble Zerostat spacer, push the two halves of the spacer together firmly.	**Non Critical**
2	Remove the protective cap from the mouthpiece of the inhaler. Shake the inhaler well.	**Non Critical**
3	Place the inhaler firmly into the narrow end of the spacer.	**Non Critical**
4	Place the protective cap over the mouthpiece of the spacer, while holding it with the inhaler firmly.	**Non Critical**
5	Holding the inhaler, press down on the canister to release a dose into the spacer.	**Non Critical**
6	Remove the protective dust cap.	**Non Critical**
7	Close your lips firmly around the mouthpiece to create a good seal. Do not bite.	**Non Critical**
8	Inhale deeply through your mouth from the spacer.	**Critical**
9	Remove the spacer from your mouth and hold your breath for 10 seconds, or as long as is comfortable.	**Critical**
10	Breathe out slowly. If a second dose is required, wait for at least one minute. Remove the inhaler and shake it well.	**Non Critical**

Steps to use Zerostat V and Zerostat VT spacer and classification of critical and non-critical errors.

Step No.	Description	Critical/non critical
1	To assemble Zerostat V/ Zerostat VT spacer push the two halves of the spacer together firmly with dust cap in place.	**Non Critical**
2	Remove the protective cap from the mouthpiece of the inhaler. Shake the inhaler well.	**Non Critical**
3	Place the inhaler firmly into the opposite end of the spacer.	**Non Critical**
4	Place the protective cap over the mouthpiece of the spacer, while holding it with the inhaler firmly.	**Non Critical**
5	Holding the inhaler, press down on the canister to release a dose into the spacer.	**Non Critical**
6	Remove the protective dust cap.	**Non Critical**
7	Close your lips firmly around the mouthpiece to create a good seal. Do not bite	**Non Critical**
8	Inhale deeply through your mouth from the spacer.	**Critical**
9	Remove the spacer from your mouth and hold your breath for 10 seconds, or as long as is comfortable.	**Critical**
10	Breathe out slowly. If a second dose is required, wait for at least one minute. Remove the inhaler and shake it well.	**Non Critical**

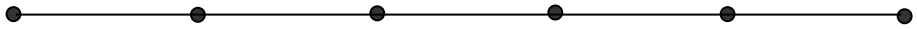
APPENDIX II

QUESTIONNAIRE

(Please encircle the appropriate option)

I. Confidence assessment

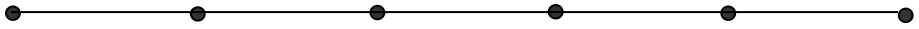
1. Overall I feel confident about using the device.



6	5	4	3	2	1
Very confident	Confident	Somewhat confident	Somewhat not confident	Not confident	Definitely not confident

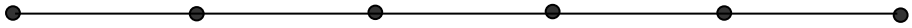
II. Usability assessment

1. I found it was easy to understand how to use the device.



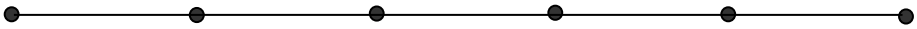
6	5	4	3	2	1
Strongly agree	Agree	Somewhat agree	Somewhat disagree	Disagree	Strongly disagree

2. I found it was easy to operate the device.



6	5	4	3	2	1
Strongly agree	Agree	Somewhat agree	Somewhat disagree	Disagree	Strongly disagree

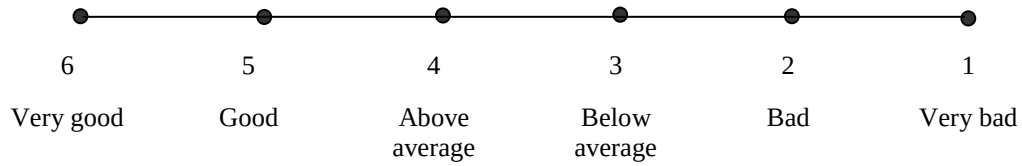
3. I found it was easy for me to remember how to use the device.



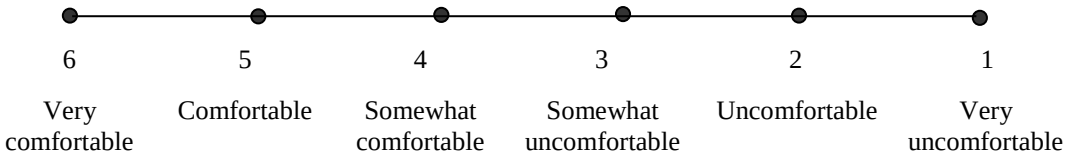
6	5	4	3	2	1
Strongly agree	Agree	Somewhat agree	Somewhat disagree	Disagree	Strongly disagree

III. Preference assessment

1. How do you like the device?

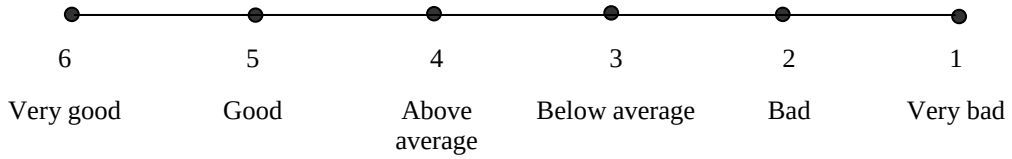


2. Is the mouthpiece of the device comfortable?



3. How did you like the inhalation manoeuvre with this device?

4. How did you like overall handling the device? (preparation, handling, inhalation manoeuvre, storage & cleaning)



IV. Satisfaction assessment

1. Overall, considering your responses to the previous questions, were you satisfied with the inhaler?