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TECHNICAL NOTE

The reliability and validity of the Affinity Altitude hypoxic generators in acute and chronic conditions

Ashley G. B. Willmott[1,2,3] · Henry C. Chung[4] · Justin D. Roberts[1] · Neil S. Maxwell[2,3]

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Abstract

This study investigated the reliability of the Affinity Altitude hypoxic generator within-day, between-day and between-generator under acute and chronic hypoxic conditions. An additional objective was to assess the validity of the fraction of inspired oxygen (FiO_2) values in relation to the claimed manufacture's reference values to ensure the accuracy and safety of the product. Three altitude generators (Affinity Altitude Ltd., Sussex, UK) were assessed across all available settings during a test–retest design for equivalent FiO_2 and output volume. This consisted of two phases: 1) acute exposure (10 min per setting) and 2) chronic exposure (8 h per setting). FiO_2 and volume data were calculated from 1 min collection samples using the Douglas bag method for acute and chronic exposures. There were low variations in FiO_2 data across all settings within the acute exposure for within-day (coefficient of variation [CV] range: 0.0–2.6%), between-day (0.2–1.3%), and between-generator analysis (0.7–1.4%). This was similarly found for volume data within-day (0.1–3.7%), between-day (0.7–5.4%), and between-generator (1.2–3.0%). Equally, for chronic exposure trials, CV for FiO_2 (< 4.0%) and volume (< 5.0%) across each of the generators presented low variations. The FiO_2 values were similar to reference values, however, significant differences were found for settings 4 (−0.3% [17.6% *vs.* 17.9% reference value]) and 5 (−0.1% [15.8% *vs.* 15.9% reference value], both $p < 0.05$). A '*good'* level of reliability (CV < 5%) and validity were found within and between the Affinity Altitude's generators. However, a review of the reference values is warranted, and long-term experimental studies are required to determine the efficacy of this device for the purpose of physiological adaptations.

Keywords Altitude simulator · Altitude training · FiO_2 · Hypoxia · Accuracy · Precision

1 Introduction

For over half a century, expedition enthusiasts and endurance athletes alike continue to explore traditional (e.g., terrestrial) and alternate (e.g., simulated) altitude training strategies, in an attempt to improve athletic performance under altitude (hypoxic) and sea-level (normoxic) conditions. Adaptations following chronic exposure to hypobaric hypoxia (HH), commonly 'live-high, train-low' [1], include a range of haematological, metabolic, and neuromuscular improvements [2]. However, those unable to visit terrestrial altitude for training, may seek to use alternate normobaric hypoxia (NH) methods to simulate altitude exposure, where the fraction of inspired oxygen (FiO_2) is < 0.21. This is achieved when using altitude generators, by reducing the concentration of oxygen (O_2) in the air through a filtration mechanism, resulting in NH. These NH methods include passive exposure to hypoxia (e.g., via the use of masks or

✉ Ashley G. B. Willmott
Ash.willmott@aru.ac.uk

Henry C. Chung
henry.chung@essex.ac.uk

Justin D. Roberts
justin.roberts@aru.ac.uk

Neil S. Maxwell
n.maxwell@brighton.ac.uk

1 Cambridge Centre for Sport and Exercise Sciences (CCSES), Anglia Ruskin University, Cambridge, UK

2 Environmental Extremes Laboratory (EEL), University of Brighton, Eastbourne, UK

3 Para-Monte Altitude Awareness Charity, Eastbourne, East Sussex, UK

4 School of Sport, Rehabilitation and Exercise Sciences (SRES), University of Essex, Colchester, Essex, UK

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tents for rest and sleep) or in combination with exercise via intermittent hypoxic training or conditioning [3, 4].

Home-based altitude generators are a growing market and widely accessible to the public, with demand created through the proposed benefits to performance [5] and health [6] following NH training [7]. Altitude generators are also marketed as a cost-effective, time-efficient and more accessible method than sojourns at natural altitude, with the added mitigation of unpredictable weather and mode/speed of ascent [8]. However, it is important to recognise that users are unlikely to meet the desired, minimum daily exposure to hypoxia to elicit meaningful adaptations (e.g., > 8–12 h) [9] and that barometric pressure must also be considered independently due to its differing effects on physiological responses within hypoxia [10]. Furthermore, there is limited evidence on whether the use of hypoxic tents may effectively reduce AMS or assist with acclimatisation and summit success, specifically in mountaineering [11]. This is important to recognise as anecdotal reports and marketable information may persuade the public, athletes and/or climbers to purchase and use these generators for personal use, yet scientific evidence is lacking.

There is also a lack of research investigating the reliability and validity of portable home-based NH generators, with research limited to one brand (Hypoxico®) [12, 13]. While FiO_2 and output volume were found to be consistent over an 8 h period using HYP-100 models (demonstrating a 'good' level of coefficient variation [CV: < 5%]), discrepancies in output volume were observed compared to the manufacturer claims [12]. Similarly, the Everest Summit II models were considered reliable (CV: < 1.2% for both FiO_2 and output volume), yet differences were found in both FiO_2 and output volume when compared to manufacturer reference values [13]. As such, self-validation of the equipment's level of NH were recommended using an accurate ambient O_2 sensor for both accuracy and safety purposes.

As altitude generators grow in popularity, regulations are necessary and companies should produce equipment that is fit-for-use, particularly because of the risks associated with hypoxia. While elite athletes are likely to be supervised during NH training, amateur athletes are not [14]. This stresses the importance of testing to ensure a reliable and safe product, to eliminate any dangerous effects of prolonged hypoxic exposure (e.g., hypercapnia while sleeping in the tents). UK based retailers have also appeared on the market (e.g., Affinity Altitude Ltd., Sussex, UK. [www.affinityaltitude.com]), with the proposed ability to reduce FiO_2 to 9.6% (equivalent to an altitude of ~ 6000 m), although this hypoxic generator has not been scientifically investigated. Therefore, the aims of this study were to assess the Affinity Altitude generator's reliability within-day, between-day, and between-generator within an acute and chronic hypoxic exposure. The authors also investigated the validity of FiO_2 data in relation to claimed reference values by the manufacturer.

2 Methods

2.1 Study design

This study consisted of two phases: 1) acute hypoxic exposure (10 min per setting) and 2) chronic hypoxic exposure (8 h per setting), as outlined in Fig. 1. Three altitude generators of the same model (Affinity Altitude Ltd., Sussex, UK) were used to assess all available settings (from 4–10 as outlined below) during the test–retest design for equivalent FiO_2 and output volume within-day (am *vs.* pm), between-day (day 1 *vs.* 2) and between-generators (generator 1 *vs.* 2 *vs.* 3) in phase 1. This protocol followed previous research [13]. Between-generator (generator 1 *vs.* 2 *vs.* 3) analysis were also undertaken over 8 h exposure to each setting for phase 2. This protocol was informed by Pedlar et al. [12] and Harwood et al. [13], and represents a duration typically used for hypoxic generator intervention when sleeping [3]. Equivalent FiO_2 data for each altitude setting were compared against reference values in phase 2. There were 24 h between testing trials for each phase.

2.2 Data collection

The data currently available from the Affinity Altitude generator settings (from 4–7), as outlined in the manufacturer guidelines, include an estimated FiO_2 of; 17.9% (~ 1200 m), 15.9% (~ 2200 m), 14.8% (2800 m) and 13.7% (3400 m), respectively. Information on settings 8–10 were unavailable at the time of investigation. Setup guidelines and setting adjustment were followed and replicated across each of the three generators. FiO_2 (%) and output volume ($L \cdot min^{-1}$) data were assessed across all settings for phases 1 and 2. All trials were completed in a controlled laboratory environment at sea level (~ 7 m), minimising the effect of barometric pressure. For health and safety purposes, an ambient O_2 sensor (Crowcon Gasman Detector, Oxford, UK) was activated if room conditions for O_2 fell below 20.0% (zero incidences) and standing oscillating electric fans (Dudley Fan SSF-16″) were used to circulate airflow. Atmospheric conditions (barometric pressure, room temperature, relative humidity) were controlled digitally, with data recorded at the start and end of each visit (ClimeMET, CM9098, Suffolk, UK). The gas analysis system (Servomex, MiniHF 5200, East Sussex, UK) was calibrated according to the manufacturer guidelines. Oxygen and carbon dioxide (CO_2) settings were calibrated against known concentrations of gas (15% O_2, 5% CO_2) (Cranlea and Company, Birmingham, UK).

Phase 1					
Generator	Day	Time	Reliability Analysis		
1	1	10 am	Within-day	Between-day	Between-generator
		3 pm			
	2	10 am	Within-day		
		3 pm			
2	1	10 am	Within-day	Between-day	
		3 pm			
	2	10 am	Within-day		
		3 pm			
3	1	10 am	Within-day	Between-day	
		3 pm			
	2	10 am	Within-day		
		3 pm			

Phase 2					
Setting (FiO_2 %)	Generator			Reliability Analysis	Validity Analysis
4 (17.9%)	1	2	3	Between-generator	FiO_2 *vs.* reference value
5 (15.9%)	1	2	3		
6 (14.8%)	1	2	3		
7 (13.7%)	1	2	3		
8 (unknown)	1	2	3		-
9 (unknown)	1	2	3		
10 (unknown)	1	2	3		

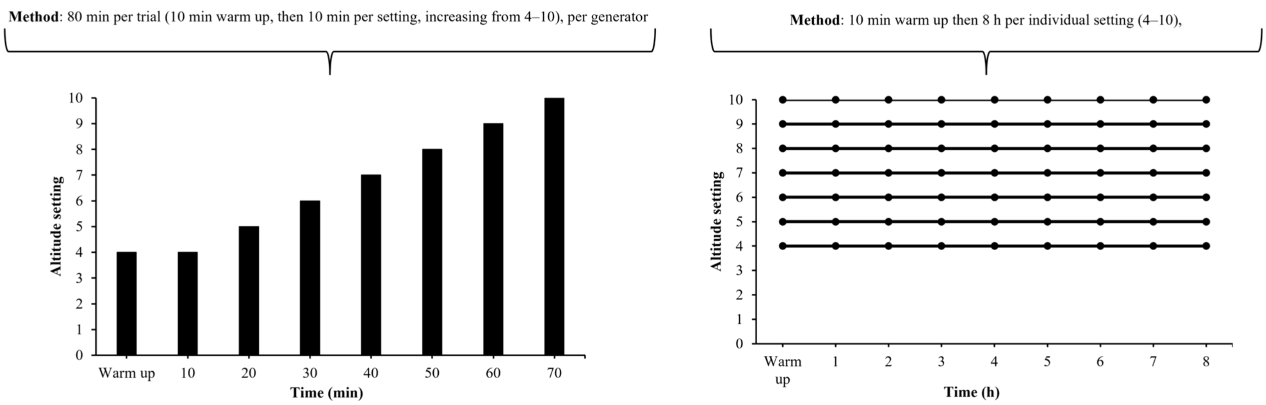

Fig. 1 Study design for phase 1 and phase 2

Prior to collection, Douglas bags were checked for sealant issues and evacuated using a dry gas meter (Harvard Apparatus, UK). The altitude generators were manually connected to the Douglas bags using customised manufacturer tubing (Affinity Altitude Ltd., Sussex, UK) and secured with hose clips (Jubilee®, Kent, UK). Generators underwent a 10 min warm-up at setting 4 (17.9% [~ 1200 m]) prior to the start of each trial. Baseline ambient air was also sampled for O_2 and CO_2. Air from the generators were pumped into the Douglas bags, and at the end of each stage, a 1 min collection period was manually timed via a stopwatch where the bags were then opened (Fastime, AST Ltd., England, UK). The same Douglas bags were used for each generator across each trial. The sample period included nine expirations of air from the generator. The Douglas bags' contents were individually analysed immediately after collection by the same experimenter. Douglas bags were then completely evacuated via a dry gas meter.

2.3 Statistical analyses

Data are presented as mean ± standard deviation (SD) and conformed to normality and sphericity. Statistical analyses were conducted using SPSS (v28.0, IBM, USA), with statistical significance set at $p < 0.05$. Two-way repeated ANOVA were preformed to assess for differences between generator setting (4–10) and time (1–8 h) for phase 2 data. A Bonferroni post hoc test for multiple comparisons were also used. Typical error of measurement (TEM) and CV were used to measure absolute and relative levels of reliability, respectively [15]. TEM and CV were calculated for each setting for all trials in both phase 1 and 2. CV results, which determined the level of reliability, were categorised as: '*Poor*' = > 10%, '*Moderate*' = 5–10%, and, '*Good*' = < 5% [16]. For validity purposes, one-sampled *t* tests were used to compare FiO_2 data at each setting with Affinity Altitude's reference values.

3 Results

3.1 Phase 1: Acute hypoxic exposure trials

Mean ± SD atmospheric pressure, room temperature, relative humidity and bag collection time were 766 ± 1 mmHg, 20.4 ± 0.7°C, 42.8 ± 6.2% and 60.27 ± 0.20 s, respectively. Table 1 provides the TEM (CV) data for FiO_2 and volume across the varying altitude settings from 4–10 for the within-day (am *vs.* pm), between-day (days 1 *vs.* 2) and between-generator analyses (generators 1 *vs.* 2 *vs.* 3). The TEM (CV) for FiO_2 ranged from 0.01% to 0.40% (0.0–2.6%) for within-day, 0.02–0.22% (0.2–1.3%) between-day and 0.08–0.27% (0.7–2.2%) for between-generator analyses, respectively. Likewise, the TEM (CV) for output volume ranged from 0.04 to 3.14 L·min^{-1} (0.1–4.3%) for within-day, 0.26–3.46 L·min^{-1} (0.4–5.4%) for between-day and 0.80–2.08 L·min^{-1} (1.2–3.0%) for between-generator analyses, respectively.

Table 1 Within-day, between-day and between-generator reliability data

Setting	Generator	Day	TEM (CV)					
			FiO_2 (%)			Volume ($L{\cdot}min^{-1}$)		
			Within-day (am *vs.* pm)	Between-day (day 1 *vs.* 2)	Between-generator (generator 1 *vs.* 2 *vs.* 3)	Within-day (am *vs.* pm)	Between-day (day 1 *vs.* 2)	Between-generator (generator 1 *vs.* 2 *vs.* 3)
4	1	1	0.12% (0.7%)	0.03% (0.2%)	0.16% (0.9%)	0.46 $L{\cdot}min^{-1}$ (0.7%)	1.72 $L{\cdot}min^{-1}$ (2.6%)	2.08 $L{\cdot}min^{-1}$ (3.0%)
		2	0.09% (0.5%)			0.09 $L{\cdot}min^{-1}$ (0.2%)		
	2	1	0.07% (0.4%)	0.04% (0.2%)		1.61 $L{\cdot}min^{-1}$ (2.1%)	3.04 $L{\cdot}min^{-1}$ (4.1%)	
		2	0.14% (0.8%)			2.31 $L{\cdot}min^{-1}$ (3.1%)		
	3	1	0.17% (1.0%)	0.22% (1.3%)		1.83 $L{\cdot}min^{-1}$ (2.6%)	0.88 $L{\cdot}min^{-1}$ (1.3%)	
		2	0.19% (1.1%)			2.25 $L{\cdot}min^{-1}$ (3.2%)		
5	1	1	0.03% (0.2%)	0.06% (0.4%)	0.16% (1.1%)	0.97 $L{\cdot}min^{-1}$ (1.5%)	1.66 $L{\cdot}min^{-1}$ (2.6%)	1.60 $L{\cdot}min^{-1}$ (2.3%)
		2	0.02% (0.1%)			0.50 $L{\cdot}min^{-1}$ (0.8%)		
	2	1	0.01% (0.0%)	0.03% (0.2%)		0.27 $L{\cdot}min^{-1}$ (0.4%)	0.48 $L{\cdot}min^{-1}$ (0.7%)	
		2	0.03% (0.2%)			0.40 $L{\cdot}min^{-1}$ (0.6%)		
	3	1	0.17% (1.1%)	0.13% (0.8%)		1.65 $L{\cdot}min^{-1}$ (2.4%)	3.16 $L{\cdot}min^{-1}$ (4.4%)	
		2	0.40% (2.6%)			3.14 $L{\cdot}min^{-1}$ (4.3%)		
6	1	1	0.22% (1.6%)	0.18% (1.3%)	0.15% (1.0%)	1.41 $L{\cdot}min^{-1}$ (2.3%)	3.46 $L{\cdot}min^{-1}$ (5.4%)	1.79 $L{\cdot}min^{-1}$ (2.7%)
		2	0.08% (0.6%)			2.41 $L{\cdot}min^{-1}$ (3.7%)		
	2	1	0.00% (0.0%)	0.19% (1.3%)		2.01 $L{\cdot}min^{-1}$ (2.9%)	1.29 $L{\cdot}min^{-1}$ (1.9%)	
		2	0.08% (0.5%)			0.87 $L{\cdot}min^{-1}$ (1.2%)		
	3	1	0.05% (0.3%)	0.08% (0.5%)		0.19 $L{\cdot}min^{-1}$ (0.3%)	1.98 $L{\cdot}min^{-1}$ (2.9%)	
		2	0.11% (0.7%)			1.42 $L{\cdot}min^{-1}$ (2.0%)		
7	1	1	0.02% (0.2%)	0.06% (0.5%)	0.12% (0.8%)	0.19 $L{\cdot}min^{-1}$ (0.3%)	1.33 $L{\cdot}min^{-1}$ (2.2%)	1.09 $L{\cdot}min^{-1}$ (1.7%)
		2	0.06% (0.5%)			0.20 $L{\cdot}min^{-1}$ (0.3%)		
	2	1	0.00% (0.0%)	0.08% (0.6%)		0.04 $L{\cdot}min^{-1}$ (0.1%)	0.68 $L{\cdot}min^{-1}$ (1.0%)	
		2	0.06% (0.4%)			0.24 $L{\cdot}min^{-1}$ (0.4%)		
	3	1	0.00% (0.0%)	0.12% (0.9%)		0.24 $L{\cdot}min^{-1}$ (0.4%)	1.05 $L{\cdot}min^{-1}$ (1.5%)	
		2	0.22% (1.6%)			0.89 $L{\cdot}min^{-1}$ (1.3%)		

Table 1 (continued)

Setting	Generator	Day	TEM (CV) FiO$_2$ (%) Within-day (am *vs.* pm)	FiO$_2$ (%) Between-day (day 1 *vs.* 2)	FiO$_2$ (%) Between-generator (generator 1 *vs.* 2 *vs.* 3)	Volume (L·min^{-1}) Within-day (am *vs.* pm)	Volume (L·min^{-1}) Between-day (day 1 *vs.* 2)	Volume (L·min^{-1}) Between-generator (generator 1 *vs.* 2 *vs.* 3)
8	1	1	0.03% (0.3%)	0.07% (0.6%)	0.14% (1.1%)	1.61 L·min^{-1} (2.7%)	0.89 L·min^{-1} (1.5%)	0.80 L·min^{-1} (1.2%)
		2	0.09% (0.7%)			0.25 L·min^{-1} (0.4%)		
	2	1	0.04% (0.3%)	0.10% (0.8%)		0.62 L·min^{-1} (0.9%)	0.68 L·min^{-1} (1.0%)	
		2	0.00% (0.0%)			0.87 L·min^{-1} (1.3%)		
	3	1	0.08% (0.6%)	0.11% (0.8%)		0.68 L·min^{-1} (1.0%)	0.74 L·min^{-1} (1.1%)	
		2	0.02% (0.2%)			0.35 L·min^{-1} (0.5%)		
9	1	1	0.06% (0.5%)	0.11% (1.0%)	0.16% (1.4%)	1.59 L·min^{-1} (2.7%)	0.54 L·min^{-1} (0.9%)	1.22 L·min^{-1} (1.9%)
		2	0.04% (0.4%)			0.42 L·min^{-1} (0.7%)		
	2	1	0.03% (0.3%)	0.06% (0.5%)		0.44 L·min^{-1} (0.7%)	1.03 L·min^{-1} (1.6%)	
		2	0.06% (0.5%)			1.00 L·min^{-1} (1.5%)		
	3	1	0.12% (1.0%)	0.05% (0.4%)		0.33 L·min^{-1} (0.5%)	1.76 L·min^{-1} (2.7%)	
		2	0.15% (1.2%)			1.45 L·min^{-1} (2.2%)		
10	1	1	0.00% (0.0%)	0.02% (0.2%)	0.08% (0.7%)	0.04 L·min^{-1} (0.1%)	0.56 L·min^{-1} (1.0%)	1.10 L·min^{-1} (1.7%)
		2	0.03% (0.2%)			0.62 L·min^{-1} (1.1%)		
	2	1	0.02% (0.2%)	0.04% (0.3%)		0.41 L·min^{-1} (0.6%)	0.26 L·min^{-1} (0.4%)	
		2	0.01% (0.1%)			1.01 L·min^{-1} (1.5%)		
	3	1	0.02% (0.2%)	0.16% (1.3%)		0.63 L·min^{-1} (1.0%)	1.87 L·min^{-1} (2.8%)	
		2	0.17% (1.4%)			1.59 L·min^{-1} (2.3%)		
Combined mean ± SD	1	1	0.12% (0.9%)	0.12% (1.0%)	0.27% (2.2%)	1.74 L·min^{-1} (2.7%)	1.78 L·min^{-1} (2.8%)	1.39 L·min^{-1} (2.2%)
		2	0.11% (0.9%)			2.15 L·min^{-1} (3.3%)		
	2	1	0.09% (0.7%)	0.16% (1.1%)		1.33 L·min^{-1} (1.8%)	1.25 L·min^{-1} (1.7%)	
		2	0.11% (0.7%)			1.03 L·min^{-1} (1.5%)		
	3	1	0.12% (0.8%)	0.12% (0.9%)		0.96 L·min^{-1} (1.4%)	1.77 L·min^{-1} (2.5%)	
		2	0.19% (1.3%)			1.85 L·min^{-1} (2.6%)		

3.2 Phase 2: Chronic hypoxic exposure trial

Mean ± SD atmospheric pressure, room temperature, relative humidity and bag collection time were 765 ± 4 mmHg, 20.2 ± 1.0°C, 38.7 ± 8.6% and 60.31 ± 0.37 s, respectively. Table 2 provides the mean ± SD FiO_2 and volume data, mean bias ± SD, and TEM (CV) for altitude settings 4–10 for the between-generator analyses (generator 1 *vs.* 2 *vs.* 3). Across the hypoxic settings, TEM (CV) ranged from 0.09% to 0.24% (0.6–2.0%) for FiO_2 and 0.81–1.57 L·min^{-1} (1.2–2.3%) for volume data. Table 2 also includes the within-generator CV, which ranged from 0.5% to 4.6%. Table 3 provides the combined FiO_2 and volume data for the three generators across all settings (4–10), and the one-sample test data for FiO_2 *vs.* the reference values. There were significant differences ($p < 0.05$) between FiO_2 data and reference values for settings 4 (−0.3% [17.6% *vs.* 17.9%]) and 5 (−0.1% [15.8% *vs.* 15.9%]), respectively.

Figure 2A presents the mean ± SD FiO_2% data for each setting across 8 h. There were significant main effects for FiO_2% between settings ($F_{(6)} = 1252$, $p < 0.001$) and time points ($F_{(7)} = 13$, $p < 0.001$). FiO_2% data significantly differed between each setting ($p < 0.001$): 4 = 17.61 ± 0.23%, 5 = 15.83 ± 0.16%, 6 = 14.77 ± 0.25%, 7 = 13.75 ± 0.39%, 8 = 12.78 ± 0.40%, 9 = 12.19 ± 0.28% and 10 = 11.71 ± 0.32%. There was also an interaction effect for FiO_2% between settings and time points ($F_{(42)} = 3$, $p < 0.001$). Within-setting differences in FiO_2% between time points were found for setting 7 (1 *vs.* 8 h [+ 0.2%]), 8 (1 *vs.* 2–7 h [+ 0.4 ± 0.0%], 9 (3 *vs.* 4 h [-0.4%]) and 10 (1 vs. 5–6 h [+ 0.4 ± 0.0%]) (all $p < 0.05$) (Fig. 2A). No differences were found between time points for setting 4, 5 or 6 ($p > 0.05$). Figure 2B displays the mean output volume and altitude setting data.

Table 2 Chronic exposure for between-generator reliability and within-generator variation data

Setting	Variable	Generator			Between-generator		Within-generator (CV)		
					Mean Bias ± SD	TEM (CV)	Generator		
		1	2	3			1	2	3
4	FiO_2 (%)	17.58 ± 0.29	17.55 ± 0.21	17.71 ± 0.12	0.07 ± 0.26	0.18% (1.0%)	1.7%	1.2%	0.7%
	Volume (L·min^{-1})	69.45 ± 0.72	71.36 ± 1.56	69.75 ± 0.86	0.15 ± 1.66	1.17 L·min^{-1} (1.7%)	1.0%	2.2%	1.2%
5	FiO_2 (%)	15.66 ± 0.13	15.94 ± 0.08	15.87 ± 0.11	0.11 ± 0.13	0.09% (0.6%)	0.8%	0.5%	0.7%
	Volume (L·min^{-1})	68.56 ± 2.10	70.31 ± 1.09	68.21 ± 1.31	0.17 ± 1.66	1.17 L·min^{-1} (1.7%)	3.1%	1.5%	1.9%
6	FiO_2 (%)	14.47 ± 0.13	14.94 ± 0.12	14.89 ± 0.14	0.21 ± 0.17	0.12% (0.8%)	0.9%	0.8%	0.9%
	Volume (L·min^{-1})	67.93 ± 1.48	69.56 ± 1.29	67.37 ± 1.40	0.28 ± 1.21	0.85 L·min^{-1} (1.2%)	2.2%	1.9%	2.1%
7	FiO_2 (%)	13.25 ± 0.14	14.15 ± 0.09	13.85 ± 0.11	0.30 ± 0.15	0.11% (0.8%)	1.1%	0.6%	0.8%
	Volume (L·min^{-1})	68.08 ± 1.22	69.71 ± 0.94	67.10 ± 1.14	0.49 ± 1.44	1.02 L·min^{-1} (1.5%)	1.8%	1.3%	1.7%
8	FiO_2 (%)	12.28 ± 0.20	13.01 ± 0.12	13.04 ± 0.17	0.38 ± 0.14	0.10% (0.8%)	1.7%	1.0%	1.3%
	Volume (L·min^{-1})	67.33 ± 1.32	68.15 ± 1.33	65.86 ± 0.75	0.74 ± 1.15	0.81 L·min^{-1} (1.2%)	2.0%	2.0%	1.1%
9	FiO_2 (%)	12.01 ± 0.39	12.30 ± 0.17	12.27 ± 0.14	0.13 ± 0.34	0.24% (2.0%)	3.2%	1.4%	1.2%
	Volume (L·min^{-1})	66.08 ± 1.73	66.66 ± 1.24	66.53 ± 1.32	0.23 ± 2.00	1.42 L·min^{-1} (2.2%)	2.6%	1.9%	2.0%
10	FiO_2 (%)	11.44 ± 0.33	11.76 ± 0.23	11.90 ± 0.20	0.23 ± 0.26	0.18% (1.6%)	2.9%	1.9%	1.7%
	Volume (L·min^{-1})	67.22 ± 3.09	65.28 ± 1.26	67.13 ± 1.87	0.05 ± 2.22	1.57 L·min^{-1} (2.3%)	4.6%	1.9%	2.8%

Table 3 Combined data across settings for the three generators and one-sample test *vs.* reference values for FiO_2 data

Setting	Combined FiO_2 (%)	Reference FiO_2 (%)	Mean bias (95% upper, lower CIs)	*t* test	Combined volume (L·min^{-1})
4	17.6 ± 0.2	17.9	−0.3 (−0.4, −0.2)	$t_{(47)} = -8.8$, $p < 0.001$	70.18 ± 1.38
5	15.8 ± 0.2	15.9	−0.1 (−0.1, 0.0)	$t_{(47)} = -3.1$, $p = 0.004$	69.03 ± 1.79
6	14.8 ± 0.3	14.8	0.0 (−0.1, 0.0)	$t_{(47)} = -0.8$, $p = 0.452$	68.28 ± 1.66
7	13.8 ± 0.4	13.7	+ 0.1 (−0.1, 0.2)	$t_{(47)} = 0.8$, $p = 0.403$	68.30 ± 1.53
8	12.8 ± 0.4	–	–	–	67.11 ± 1.49
9	12.2 ± 0.3	–	–	–	66.43 ± 1.44
10	11.7 ± 0.3	–	–	–	66.55 ± 2.34

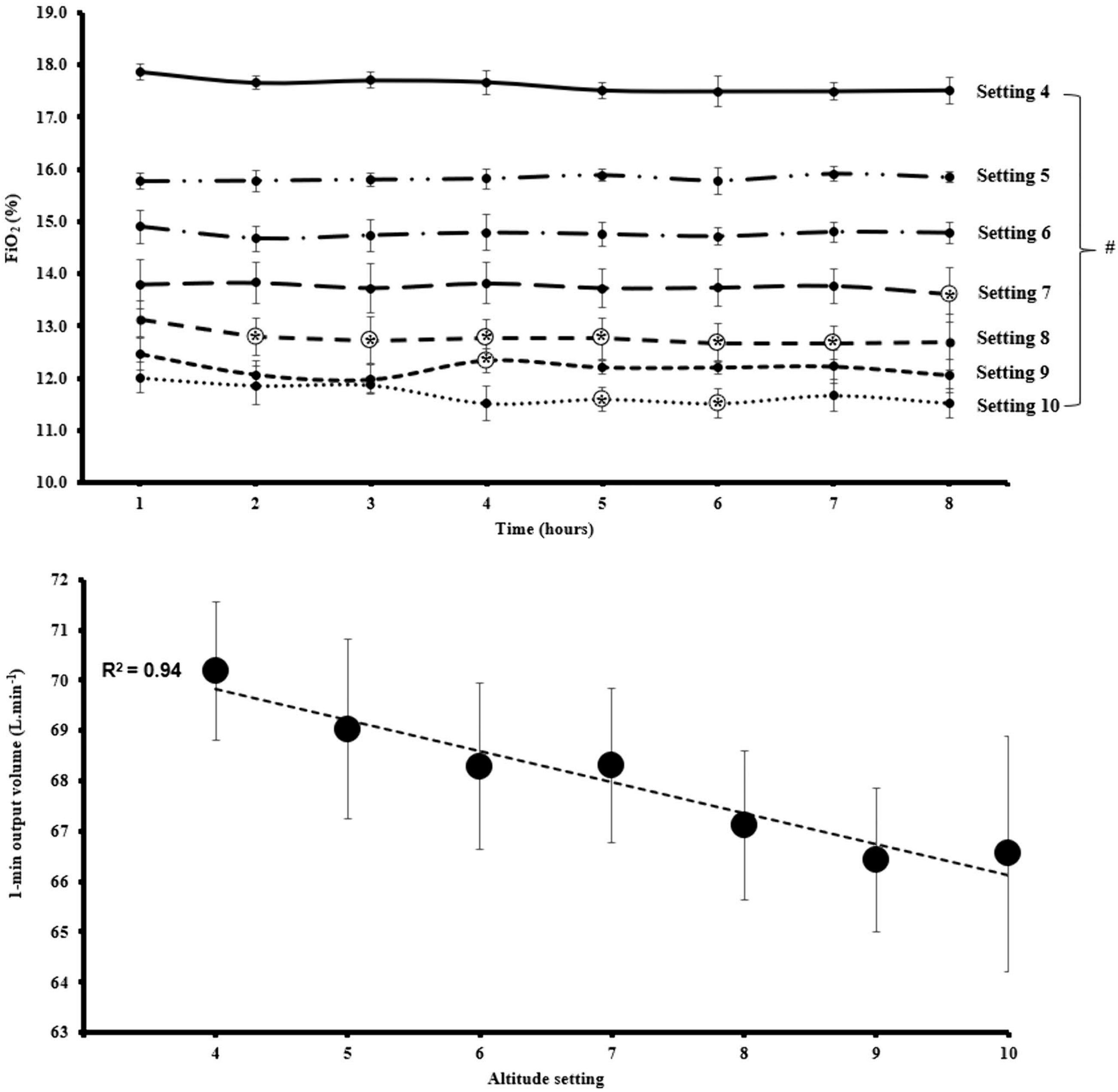

Fig. 2 **A—top)** Combined mean ± SD FiO_2 data for each setting from all three generations across 8 h. Note: $^{\#}=p<0.05$, where each setting's FiO_2% significantly differed to each other overall and between each time point, and $*=p<0.05$, where differences between time points were found for setting 7 (1 *vs.* 8 h), 8 (1 *vs.* 2–7 h), 9 (3 *vs.* 4 h) and 10 (1 *vs.* 5–6 h). **B—bottom)** Combined mean ± SD 1 min output volume across altitude settings

4 Discussion

4.1 Overview

This study aimed to investigate an altitude generator's reliability within-day, between-day and between-generator within an acute hypoxic exposure. In addition, the authors aimed to investigate the between-generator reliability during chronic hypoxic exposure and the validity of FiO_2 in relation to the claimed manufacturer reference values. The following sections outline the acute and chronic exposure hypoxia trials, which were undertaken to determine the reliability and validity of the altitude generators.

4.2 Acute exposure hypoxia trials

Results showed low variation for FiO_2 data across settings 4–10 both within- (0.0–2.6%) and between-days (0.2–1.3%), and also between-generators (0.7–1.4%) (Table 1). Similarly, low variation findings were also observed for volume data within (0.1–3.7%) and between-days (0.7–5.4%), and between-generators (1.2–3.0%) (Table 2). For FiO_2 and the majority of volume data, the level of reliability was categorised as '*Good*' (< 5%). The only exception was related to generator 1 for between-day volume data at setting 6 (63.0 ± 0.9 *vs.* 65.1 ± 4.9 L·min^{-1}), with a CV of 5.4% ('*Moderate*'). Nevertheless, it appears the generators provide reliable data across a range of settings during acute hypoxic exposure, that are reliable within-, between-days, and between-generators. These results are similar to the work conducted using the Hypoxico® Everest Summit II altitude generators [13], where low CVs were found for both FiO_2 and output volume within-day (0.0–0.9% and 0.2–1.6%), between-day (0.2–1.0% and 0.4–1.3%) and between-generators (0.5–1.1% and 1.0–1.4%), respectively.

4.3 Chronic exposure hypoxia trial

Results demonstrated low variation, TEM and mean bias in FiO_2 across settings 4–10 between-generators (CV < 2.0%, TEM < 3.0%, bias < 0.4%). This was similarly observed for output volume data between-generators (bias < 0.8 L·min^{-1}, TEM < 1.6 L·min^{-1} and CV < 2.5%). There were also low within-generator CV for FiO_2 (< 4.0%) and output volume (< 5.0%) across each of the generators, where all reliability data are categorised as '*Good*'. As such, it appears the generators provide reliable and stable FiO_2 and output volume data across a range of settings during chronic hypoxic exposure (~ 8 h). As expected, there were significant differences in FiO_2 (Fig. 2A) across each of the altitude settings, although this was also true of output volume (Fig. 2B). While the authors observed that over the 8 h exposure there were variations in FiO_2 within settings 7, 8, 9 and 10, these are only minor fluctuations in O_2 concentration (mean difference ~ 0.4%), as confirmed by the low TEM and CV. Nonetheless, where reference values are not provided (e.g., 8–10), hypoxic generator brands and manufacturers have the responsibility to inform their users of this information and outline risks associated with these extreme conditions (e.g., FiO_2 < 13.0), especially where higher variations exist.

Mean FiO_2 data were also compared with the reference values from the altitude generator for settings 4–7. Interestingly, our data significantly differed compared to the FiO_2 reference values for settings 4 (−0.3%) and 5 (-0.1%), but not for the higher settings 6 (0.0%) and 7 (+ 0.1%) (Table 3). Previously, differences between collected FiO_2 data compared to Hypoxico® reference values have been reported, where the largest difference was equivalent to an increase in altitude of approximately 473 m (− 1.0% for a programmed 17% FiO_2) [13]. Output volumes were also found to be lower by 21.8–35.4 L·min^{-1} compared to Hypoxico® reference values of 126.6 L·min^{-1} [13]. The study suggested a possible reason for this was due to a restricted increase in hypoxic intensity as generators reach their maximal output [13]. The authors observed a strong, negative correlation (R^2 = 0.94) between output volume and altitude setting, where volume fell ~ 3 L·min^{-1} from setting 4–10. This is comparable to the results from Harwood, Wright and Burnet [13], where R^2 = 0.99 was found over 6 settings when using the Hypoxico® altitude generators. While the current study may provide suitable reference ranges for all available settings (4–10), at the time of investigation there were no reference values for settings 8–10, nor output volume data. Therefore, further investigations are warranted for individuals wishing to use FiO_2 of < 13.7 and to assess adjustments in the generator's flow meter and altitude level.

4.4 Application

The investigated altitude generators appear to provide reliable and stable levels of simulated altitude conditions during acute and chronic exposures. These findings may be applicable across the same branded devices, although verification can be achieved following the same methodology provided herein. These findings are also informative and applicable for athletes wishing to use these generators as a tool for at-home altitude training, whether that be in the form of exercise or sleeping. However, in addition to the standard participant risk stratification procedures that are necessary when using any equipment that simulates environmental extremes, the authors stress the importance of supervision for all users and emphasise recommendations that an accurate ambient O_2 sensor is necessary alongside continuous and alarmed pulse oxygen saturation monitoring. It is also recommended that O_2 sensors are built into these devices or provided alongside generators. These recommendations should be included for health and safety reasons due to potential risks associated with hypoxia, especially if users operate the generators alone. The authors also suggest professional advice and educational guidance are sought prior to using altitude generators, and that these generators are well maintained with routine safety testing as the generator ages.

4.5 Future research

Future research should focus on the generators' long-term application and to investigate equipment development. In an applied setting, a comprehensive assessment of human responses and adaptations is required, and to assess if the physiological benefits of altitude training can be replicated when using these generators. Manufacturers may also seek to improve the usability and programme setting accuracy of these generators (e.g., reporting a full range of reference values for settings 8–10 and transitioning from a manual dial to an automated digital setting).

4.6 Conclusion

The work produced in this study demonstrates comprehensive testing of the Affinity Altitude's generators, which is the first of its kind, outside of the traditional branded systems. The results demonstrate good reliability and validity when the altitude generators are used within- and between-days, in both acute and chronic timeframes, and presented results are comparable to manufactures reference values. However, more extensive experimentation is required to investigate altitude-related adaptations following their long-term use in applied settings.

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Data availability All relevant data is publicly available and within the contents of this manuscript or supporting documents and cited.

Declarations

Conflict of interest All authors declare that there are no competing interests.

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