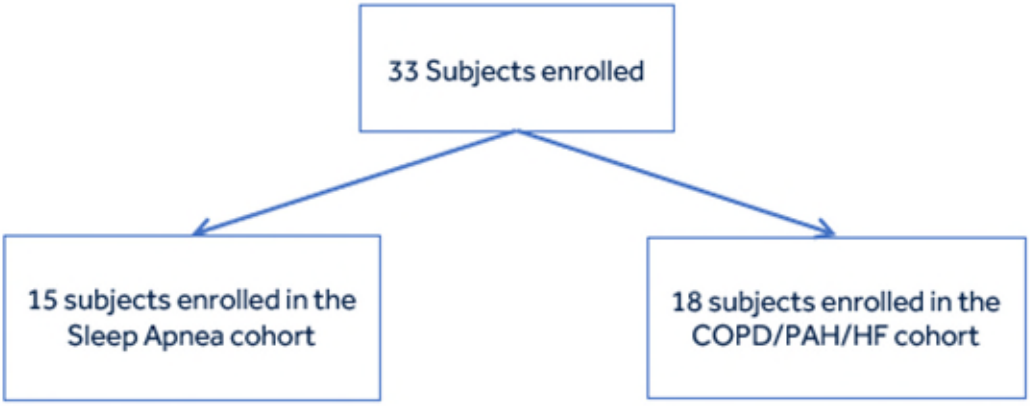
Participant Flow



Baseline Characteristics

Table 1. Subject Demographics

	Total Subjects (N=33)
Gender (N, %)	
Male	17 (52%)
Female	16 (48%)
Age (years)	
Mean ± Standard Deviation	65.8 ± 12.4
Median	67
25^{th}-75^{th} Percentile	56-73
Minimum-Maximum	34-86

Table 2. Baseline Physical Exam Results

	Total Subjects (N=33)
Height (cm)	
Mean ± Standard Deviation	170.75 ± 10.54
Median	170.18
25^{th}-75^{th} Percentile	162.56-177.80
Minimum-Maximum	149.86-195.58
Weight (kg)	
Mean ± Standard Deviation	90.11 ± 21.42
Median	91.17
25^{th}-75^{th} Percentile	79.38-102.00
Minimum-Maximum	55.34-135.00
BMI	
Mean ± Standard Deviation	31.00 ± 7.39
Median	30.54
25^{th}-75^{th} Percentile	26.78-34.23
Minimum-Maximum	17.94-48.65

Table 3. Subject Health Status (N, %)

	Total Subjects (N=33)
None	1 (3%)
Cardiomyopathy, ischemic	4 (12%)
Cardiomyopathy, non-ischemic	4 (12%)
Cardiomyopathy, hypertrophic	1 (3%)
Coronary artery disease	10 (30%)
Hypertension	22 (67%)
Idiopathic structural heart disease	0 (0%)
Left ventricular hypertrophy	3 (9%)
Orthostatic hypotension	1 (3%)
Carotid artery disease	1 (3%)
Deep vein thrombosis	2 (6%)
Peripheral vascular disease	1 (3%)
Pulmonary edema	1 (3%)
Pulmonary embolism	1 (3%)

Raynaud's phenomenon	2 (6%)
Renal artery disease	1 (3%)
Asthma	5 (15%)
Emphysema	6 (18%)
Pneumonia	1 (3%)
Other respiratory	11 (33%)
Diabetes, insulin dependent	3 (9%)
Diabetes, non-insulin dependent	2 (6%)
Renal dysfunction	4 (12%)
Chronic renal dysfunction, requiring dialysis	2 (6%)
Chronic renal dysfunction, not requiring dialysis	3 (9%)
Other renal dysfunction	1 (3%)
Smoker	4 (12%)

Table 4. Disease Classification (N, %)

	Total Subjects (N=33)
Apnea-Hypopnea Index (AHI) classification	
o Subject does not have sleep apnea	**10 (30%)**
o AHI classification not available	**6 (18%)**
o <5 – Normal (no sleep apnea)	**4 (12%)**
o 5-14.9 – Mild sleep apnea	**4 (12%)**
o 15-30 – Moderate sleep apnea	**2 (6%)**
o >30 – Severe sleep apnea	**7 (21%)**
Spirometric classification of COPD (FEV_1^* % of predicted)	
o Subject does not have COPD	**22 (67%)**
o Spirometric classification not available	**5 (15%)**
o FEV_1^* % of predicted: ≥80 – mild COPD	**1 (3%)**
o FEV_1^* % of predicted: 50-80 – moderate COPD	**1 (3%)**
o FEV_1^* % of predicted: 30-49.9 – severe COPD	**2 (6%)**
o FEV_1^* % of predicted: <30 – very severe COPD	**2 (6%)**
Pulmonary hypertension WHO classification	
o Subject does not have pulmonary hypertension	**22 (67%)**
o Pulmonary hypertension WHO classification not available	**1 (3%)**
o Group 1 – pulmonary arterial hypertension	**9 (27%)**
o Group 2 – pulmonary hypertension due to left heart disease	**0 (0%)**
o Group 3 – pulmonary hypertension due to lung disease and/or chronic hypoxia	**0 (0%)**
o Group 4 – pulmonary hypertension due to blood clots in the lungs	**0 (0%)**
o Group 5 - pulmonary hypertension due to blood and other disorders	**1 (3%)**
New York Heart Association (NYHA) classification	
o Subject does not have heart failure	**24 (73%)**
o NYHA classification not available	**4 (12%)**
o Class I	**0 (0%)**
o Class II	**1 (3%)**
o Class III	**4 (12%)**
o Class IV	**0 (0%)**

*FEV_1: forced expiratory volume in one second

Outcome Measures

Table 5. Sleep study results. The time to trough is the time from baseline value to peak minimum. For each of the StO2 channels, this is reported as the lag relative to the trough of SpO2. Note that some subjects had more than one drop to below 90%.

	Baseline SpO2 (%)	Drop in SpO2 (%)	Time to trough of SpO2 (sec)	Baseline Ch1 StO2 (%)	Drop in Ch1 StO2 (%)	Lag time to trough Ch1 (sec)	Baseline Ch2 StO2 (%)	Drop in Ch2 StO2 (%)	Lag time to trough Ch2 (sec)	Ratio Ch1 StO2 drop to SpO2 drop	Ratio Ch2 StO2 drop to SpO2 drop
All Events (n=14)	94.4±2.1	8.2±3.8	369±240	90.3±1.1	1.0±0.9	-1±9	89.1±1.1	1.2±0.9	9±34	0.13±0.14	0.16±0.14
By severity of sleep apnea											
AHI 5-15 (n=5)	94.6±1.6	7.9±2.1	399±196	91.0±0.7	1.1±0.7	1±4	89.1±1.0	1.6±0.6	16±52	0.14±0.09	0.20±0.05
AHI >30 (n=9)	94.3±2.4	8.3±4.6	353±271	89.9±1.1	0.9±1.0	-2±11	89.1±1.1	0.9±0.9	5±22	0.13±0.16	0.14±0.18

Table 6. Summary of Hall Walk Results

	Walk distance (feet)	Baseline SpO2 (%)	Drop in SpO2 (%)	Time to trough of SpO2 (sec)	Baseline Ch1 StO2 (%)	Drop in Ch1 StO2 (%)	Lag time to trough Ch1 (sec)	Baseline Ch2 StO2 (%)	Drop in Ch2 StO2 (%)	Lag time to trough Ch2 (sec)	Ratio Ch1 StO2 drop to SpO2 drop	Ratio Ch2 StO2 drop to SpO2 drop
All Subjects (n=18)	927±228	96.8±2.1	7.9±6.3	377±123	85.5±5.6	4.2±4.1	28±68	83.5±6.3	4.9±4.3	-25±142	0.68±0.58	0.83±0.85
By disease												
COPD (n=10)	874±227	96.2±2.4	8.2±4.1	376±126	86.4±6.9	5.1±5.2	11±78	84.5±5.9	4.3±3.8	-32±150	0.57±0.31	0.48±0.22
HF (n=8)	994±206	97.4±2.0	3.9±1.9	340±89	85.8±2.9	3.0±2.3	50±64	85.1±3.5	3.2±1.6	23±113	0.85±0.77	0.93±0.62
PAH (n=11)	895±204	95.9±2.2	9.8±7.1	404±109	84.6±6.8	4.9±4.9	39±64	81.8±7.5	6.3 ±5.1	-42±149	0.60±0.39	0.86±0.99
By group												
COPD (n=4)	856±315	97.8±0.9	6.7±2.6	344±148	88.5±2.1	3.3±2.3	-17±82	85.6±4.7	3.0±2.0	-39±174	0.51±0.28	0.43±0.20
HF (n=3)	1140±35	98.5±1.0	2.4±1.1	325±161	84.9±2.0	2.5±2.1	48±63	85.9±1.1	2.6±1.2	52±75	1.2±1.2	1.28±0.84
PAH (n=3)	817±310	96.7±0.3	15.0±10.9	458±125	81.9±1.2	3.5±0.4	62±47	77.1±9.2	9.3±6.4	-61±205	0.49±0.53	1.50±1.81
COPD+PAH (n=3)	953±40	93.9±2.3	12.9±3.6	441±168	84.4±13.6	8.9±8.5	-1±67	83.1±9.2	6.9±6.4	-82±141	0.61±0.43	0.47±0.31
HF+PAH (n=2)	1039±4	97.2±2.7	3.7±0.6	345±17	87.7±4.7	2.7±2.3	33±71	84.7	4.2	-80	0.68±0.52	1.01
COPD+HF+PAH (n=3)	818±258	96.3±2.4	5.6±1.9	352±30	85.6±3.2	3.8±3.0	62±85	84.5±5.8	3.3±2.4	29±161	0.62±0.35	0.55±0.20
By supplemental O2 use												
O2 use (n=7)	871±233	96.9±2.4	10.5±6.4	404±118	87.7±4.5	3.8±1.5	16±82	85.3±3.3	3.1±1.3	-38±159	0.47±0.27	0.36±0.19
No O2 use (n=11)	963±228	96.7±1.9	6.2±5.9	360±128	84.1±5.9	4.4±5.1	36±61	82.2±7.7	6.1±5.3	-16±137	0.81±0.70	1.16±0.98
By whether subject rested during hall walk												
Rested (n=6)	717±209	96.8±1.2	11.4±8.1	378±153	87.3±5.9	3.6±2.1	22±61	83.3±9.4	5.0±5.3	29±131	0.38±0.26	0.46±0.27
No Rest (n=12)	1032±157	96.8±2.4	6.1±4.5	377±112	84.6±5.4	4.5±4.8	31±74	83.6±4.5	4.8±3.9	-54±145	0.82±0.65	1.04±1.00

Adverse Events

Subject ID	Site Diagnosis	AE Description	Actions Taken	Outcome	Relatedness
M002967004	Skin irritation	On 17-Dec-2019, site was made aware of skin irritation on finger under oxygen probe/SPO2 sensor. Redness, soreness feeling of heat even after probe was removed. Resolving by mid-day (12pm) on 17-Dec-2019	None Taken	Resolved by mid-day (12pm) on 17-Dec-2019	NONIN SenSmart SpO2 sensor