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Comparative study of a novel portable indirect calorimeter to a reference breath-by-breath instrument and its use in telemedicine settings

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Abstract

Background & Aims: Resting Energy Expenditure (REE) quantitatively describes the calories used to support body function (e.g. breathing, blood circulation, etc.) at resting condition. Assessment of the REE is essential for successful weight management and the understanding of metabolic health. REE is typically determined via indirect calorimetry. Current biomedical indirect calorimetry technologies, utilizing assessment of oxygen consumption (VO_2) and carbon dioxide production (VCO_2) rates (which are typically in the form factor of a metabolic cart) are bulky and require on-site calibration and/or trained professionals to operate. We introduce a novel wearable medical device with FDA clearance to determine REE accurately, portable, and user-friendly format, which can be used both by health professionals in a clinical environment and by the patient at home. Previously, we have reported the validation of Breezing Med (also named as Breezing Pro™) through Douglas Bag Method, a gold standard for gas exchange measurement, and excellent agreement has been found between the two methods for the determination of REE, VO_2, and VCO_2 rates.[1] Now we present the validation of Breezing Med against Medical Graphics (MGC) CPX Ultima™, a FDA 510k cleared metabolic cart, which principle is based on breath-by-breath analysis. In addition, we present Breezing Med as a tool for daily measurement of metabolic rate by the lay person at home.

Methods: A) The validation study was executed via parallel measurement of 20 healthy participants under resting conditions using both the Breezing Med and the MGC Ultima CPX™

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[**]In loving memory of Dr. Nongjian Tao; a great professional and scientist, an excellent mentor and exceptional person. His legacy will stay with us forever.

Authors' contributions

MSJ, SM, TVV, WGC, KD, JB, XX and FE participated in the study design, data analysis, and manuscript preparation. MSJ participated in the recruitment of subjects and collection of the data. KD, JB, XX and FE participated in the acquisition of funding for this project.

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Conflict of interest

All authors, excepting Erica Forzani and Xiaojun Xian, currently with Breezing Co., declare no conflict of interest.

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(10 min test). B) Breezing Med measurements were carried out by six subjects at home during stay-at-home order due to COVID-19 for 30 days.

Results: A) The resulting measurements from both devices was compared with correlation slope's and R-squared coefficients close to 1. B) Results were recorded and analyzed for variability. The pilot study demonstrated the advantage of Breezing Med device to be easy-to-use at home by lay people, which make the valuable device for telemedicine applications related to weight management from home.

Conclusions: This result shows that the MGC Ultima CPX™ and Breezing Med are substantially equivalent for REE measurement; and an advantage of this device for metabolic assessment under the current COVID-19 pandemic situation, for people with impaired physical mobility, and for those who lives in rural areas or face impediments that limit physical access to care.

Keywords

Metabolic tracker; Resting energy expenditure; Telemedicine; Point of Care; Breezing Med; Breezing Pro

1. Introduction

Since December 2019, the pandemic due to the novel COVID-19 virus has introduced the world to certain lifestyle changes, where losing, controlling or gaining weight could be a challenge.[2,3] It is been proven that people with overweight or obesity present a higher risk of severe symptoms with COVID-19 infection, and consequently need to be hospitalized.[4–7] In order to prevent the spread of the virus and for protection of the population, stay-at-home, quarantine and isolation were implemented around the world. Working, studying, exercising, and all normal daily activities must be at home, which promoted the demand for innovative technological solutions to meet the current needs of the time. These technological solutions should bring three main associated requirements: accuracy, friendly use, and capability to perform secure data connection via well-known protocols such as HIPAA compliant protocols.

Weight management during lockdown has presented several issues, poor eating habits, stress eating, snacking, and changes in the routine have generally resulted in weight gain and higher incidences of obesity in the general population.[8–10] Total Energy Expenditure (TEE) is the total number of calories burned per day, involving basal energy expenditure, diet-induced thermogenesis, non-exercise activity thermogenesis, and physical activity.[11–15] TEE varies with age, gender, weight, height, and the amount of activity realized as sedentary, moderate, or strenuous. TEE can even be different from person to person having same physical parameters.[16,17] For sedentary population, Resting Energy Expenditure (REE, kcal per day burned during non-active periods), corresponds in average up to 70-80% of the TEE,[18] and its measurement is important to accurately assess a more accurate daily total energy expenditure.[1,19] Values of REE calculated from epidemiological equations can differ up to 900 kcal/day, and therefore, measurements of REE are essential[20–22] to guide caloric intake, and assess metabolic changes such as the metabolic adaptation.

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Telehealth technology is not new but has seen significantly increased adoption as a result of the pandemic.[23] This tool offers an expansion of health services while protecting healthcare personnel and patients. In addition, Remote patient monitoring (RPM) systems or devices have won popularity for patients due to eliminating patient transportation to a facility, increased data collection, and presents improved patient outcomes.[24,25]

In this work, we present the analytical and usability validation of Breezing Med as a wearable medical device with sensing technology capable of determining Resting Energy Expenditure, REE. This device can be used by a professional or the patient. The device performs gold-standard indirect calorimetry, in which the REE is determined by the measured oxygen consumption rate (VO_2) and carbon dioxide production (VCO_2) rate in breath. In comparison with other devices commercially available, Breezing Med uses a mask specially designed to prevent leaks and provide an accurate VO_2 and VCO_2 measurement while breathing by mouth and/or nose. In addition, we avoid the use of nose clips which is very uncomfortable for the patients.

Figure 1 shows a schematic representation of how this device works. Through the user-friendly app, the user, either a professional in his/her office or the patient at home, can perform the measurement and share/manage the data via HIPAA compliant systems. Using this application, a time-stamped and graphical interface is displayed for visualization of longitudinal EE data, which can be used for getting accurate professional care advice. In addition, the Breezing App's records can be exported to CSV (most recent or entire history records) and can be shared to remote locations.

Validation of medical devices must be precise and reliable. Metabolic carts such as the MGC CPX Ultima™, provides a highly accurate determination of REE analyzed breath-by-breath.[26–28] In this work, MGC high technology was implemented for the analytical validation of Breezing Med. In addition, we present the usability validation comprising self-testing results from six subjects during the pandemic, under the stay-at-home orders, which provides evidence of efficacy for the Breezing Med to determine REE of patients as a telemedicine tool.

2. Materials and methods

2.1 Analytical validation's Participants

A total of 20 healthy subjects between 23 and 60 years old were tested. This study included 12 females and 8 males. Table 1 shows the list of individual physical characteristic of the subjects. The subject's heights were ranged from 152 to 189 cm, their weights from 45 to 95 kg, and the body mass indices (BMI) were ranged from 16.9 to 35.3 kg/m^2 (see Table 2). As can be seen from Table 1 and 2, the patient's BMI values ranges from 16.9 to 35.3 which is considered by the Centers for Disease Control and Prevention (CDC) as underweight and obesity Class 2, respectively.[29]

The 10 min tests for determining REE were taken at resting state under specific instructions as no food or caffeine intake in the past 4 hours, no moderate exercise performed 4 hours

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before the test, and no strenuous exercise performed for the past 12 hours. All participants (except one of the home participants) adhered to testing instructions.

All subjects participated voluntarily. Before the test, each person was informed and introduced to the propose of our study, and a consent form was signed.

The tests were carried from September to November 2019, in Mayo Clinic by Arizona State University researchers. The study was approved by the Institutional Review Board of Arizona State University; IRB reference protocols # STUDY00006562.

2.2 Measurements Collected Using the Breezing Med and MGC CPX Ultima™

In collaboration with the Department of Cardiovascular Medicine of Mayo Clinic in Scottsdale, Arizona, a Cardiorespiratory Diagnostic Systems (CPX) Ultima Series™ (MGC Diagnostics Corporation, Saint Paul, MN USA)[30] was used for the determination of VO_2, VCO_2 and REE simultaneously with Breezing Med.

MGC CPX Ultima has been selected as reference instrument because it has received 510k-clearance, which means that had been compared with other formerly cleared or approved FDA-instrument. In addition, this instrument is used for clinical guidance of diets and weight management and has received clinical validity.

MGC Diagnostics' equipment uses advanced gas exchange analysis technology and is an established breath-by-breath reference instrument. Before the use, the equipment was allowed to warm-up for 30 minutes, the flow was manually calibrated using a calibration syringe, and the O_2 and CO_2 sensors (galvanic cell and NDIR absorption, respectively) were calibrated using standard reference gas cylinders that are part of the equipment. In addition, MGC CPX Ultima includes a preVent® flow sensor, which meets ATS/ERS standards and specifications.[27]

A serial connection between the two MGC and the Breezing Med (TF Health, Tempe, AZ US)[31] was designed to guarantee there was no air leakage between the two devices during breathing, and the data was collected simultaneously for the two methods. As can be seen from Figure 2, the mask was connected to the MGC through a custom-made 2 one-way valve adapter followed by a preVent flow sensor. The preVent flow sensor was directly connected to the MGC by an umbilical adapter, and to the mouthpiece with a saliva trap. The Breezing Med analyzer was attached to the subject by a headgear strap and a laboratory jack was used to hold the device at the corresponding height of each subject's face. In this way, discomfort or nuisance during the test was avoided. The subject wore a disposable nose clip to avoid air leaks thorough the nose during the test.

A new preVent flow sensor and mouthpiece were used for each subject. The device was clean and disinfected with 70% isopropanol solution between tests, and a period of 20 minutes was awaited between users.

The Breezing Med device works via measurement of color change from single-use sensors previously calibrated via a QR code. This pre-calibrated QR-code mechanism allows the user to complete the device setting prior to the measurement without use of calibration

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gases. Similarly to MGC, Breezing Med device used oxygen consumption rate and carbon dioxide production rate (VCO_2) to assess the Resting Energy Expenditure through the well-known Weir equation (Equation 1):[32]

$$REE\left(^{kcal}/_{day}\right) = 1.44X[3.9XVO_2 + 1.1XVCO_2]$$

Two different batches of sensors were used for Breezing Med in this study. Each batch was packaged with a desiccant in a plastic bag with a QR code printed on the outside, which was scanned right before its use following the step-by-step and user-friendly procedure indicated by the Breezing-for-professional App (Breezing Pro). The procedure is well explained and indicated photographically in the Breezing iOS App, in order to make this device easy to use. At the end of the test, the screen shows the metabolic parameters obtained as measured REE, respiratory quotient, Mifflin St. Jeor Equation (MSJE) predicted and estimated total energy expenditure, VO_2, VCO_2, exhalation rate, breath frequency, and tidal volume. For each patient, a test history diagram will show the variation of REE along the time the tests were taken. From the app, a pdf with the results can be send by email to the patient, and/or exported to an excel file for further analysis of the professional. Patients and professionals assess their information via HIPPA–compliant methods of data reporting and transmission.

2.3. Data and statistical analysis

The data collected from MGC was analyzed in Microsoft Excel, by taking the average and standard deviation of the last 5 minutes of the breathing test. The first half of the time is required to reach an equilibrium in the breathing frequency. Those results were compared and the correlation between the two methods was analyzed using linear regression for VO_2, VCO_2 and, REE. In addition, the results were analyzed by paired *t*-test to determine the statistical difference by the two methods using GraphPad Prism.[33] Finally, data were reported as Mean ± SD.

2.4. Breezing Med and Telemedicine assessment

A total of 6 subjects, 2 females and 4 males performed the measurements of metabolic parameters by using Breezing Med for self-monitoring for 1 and 4 weeks. The device, mask, sensors and manual were sent to their homes and they were asked to their indirect calorimetry measurement daily. They were also provided with a Samsung tablets (Tab A, 10 inches) or iPads (Mini 1 &2, Pro 2019), where the mobile app was used. Each patient followed the corresponding indications from the app with no additional training.

3. Results and Discussion

3.1. Analytical Validation

The linear regression calculated from the graph for VO_2 and VCO_2 from Breezing Med *vs* MGC is shown in Fig. 3. As can be seen, a value of 1.02 was find for the slope (R^2 = 0.8435) for VO_2 and 0.96 for VCO_2 (R^2 = 0.9194). Similarly, from Fig. 4, the lineal regression for REE was graphed and calculated the slope and R^2, resulting in a value of 1.00 and 0.8817, respectively. The values obtained for $p_{\text{paired } t\text{-test}}$ were 0.9524, 0.0612

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and 0.5745 for VO_2, VCO_2, and REE respectively. In addition, mean of the difference and standard deviation between the Breezing Med device and MGC method were calculated and are summarized in Table 3.

An accurate value for REE is directly proportional to accurate measurement of exhalation rate and the fraction of O_2 and CO_2 in the exhaled gas. In our previous work, the exhalation rate was determined to be accurate for real-time breath flow measurements.[1] The results for VO_2, VCO_2 and, REE over this study's 20 healthy patients were within the expected range of 100-350 ml/min for VO_2 and VCO_2 and 1000-3500 kcal/day for REE, similarly to those values found in a group of 66 subjects in the analytical validation study using the Douglas Bag Method.[1] Therefore, is important to denote that there are not limitations when the test is implemented in an adult population with a wide range of BMI values. As can be seen from Table 1 and 2, the patient's BMI values ranges from 16.9 to 35.3 which is considered by the Centers for Disease Control and Prevention (CDC) as underweight and obesity Class 2, respectively.[29] In addition, by conventional criteria from $p_{\text{paired } t\text{-test}}$ no statistically significant difference between the two data groups was observed.

As was shown in Table 3, the mean difference (%) of the measured VO_2, VCO_2, and REE between the two methods indicated there is no significant difference between them.

3.2. Usability validation for remote patient assessment

All the subjects expressed to be more convenient to take the test in the morning before breakfast, to accomplish the necessary requirements of fasting conditions. All of them reported when a test was forgotten or taken under certain conditions not specified by the manual, as for example after exercising. In that case, REE value out of the normal range was found and was not shown in the final data or analysis. No complaints or issues were reported when using the device or app.

Our study demonstrates that the device can be used properly by users at home guided by the manual and the app. None of the subjects required professional help, indicating the advantage of this medical device for assessing accurate REE measures, and suitability for telemedicine conditions of use.

We could assess the subjects average REE, and other pulmonary parameters captured by the Breezing Med device, in addition to physiological parameters of oxygen saturation (SpO_2) and heart rate (no shown). REE can vary from person to person depending on age, BMI, health, and particular assessment conditions.[34] Typical day-by-day variability of REE for subjects is +/−10%.[16]. As can be seen from Figure 5, we could analyze subject variability of the indirect calorimeter parameters. For the subjects with higher variability than 10%, we interviewed them and determined that exercise conditions and physical activities were identified as factors of REE increase. In this case, we could evaluate, the subject's energy expenditure variability due to specific conditions of testing such us thermogenic effect of food and post-exercise oxygen consumption.

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5. Conclusion

Breezing Med is a FDA 510k cleared medical device designed to perform indirect calorimetry in a mobile, patient-friendly manner. REE is essential for personalized nutrition assessments and individual diet plan creation. Measurements from Breezing Med were compared to measurements from the selected reference instrument, CPX Ultima Series™ metabolic cart from MGC Diagnostics Co., and the comparative analysis concluded that both instruments have equivalent accuracy for measures taken at resting conditions in adults subjects. In addition, Breezing Med device was probed to be user-friendly and useful to assess REE profiles of users at home, which makes the device appropriate for remote metabolic rate assessment, and remote patient monitoring.

Acknowledgments

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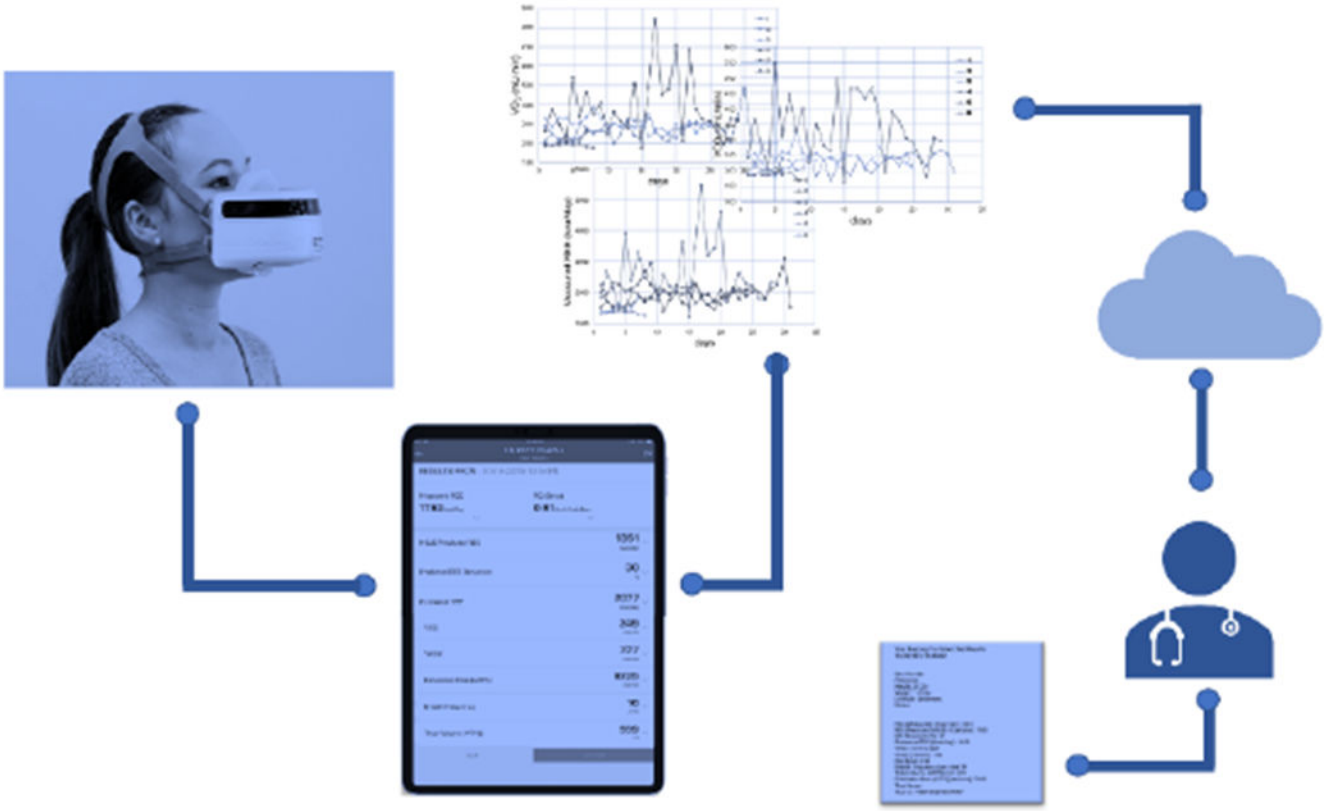

Figure 1.
Schematic representation of Breezing Med Technology

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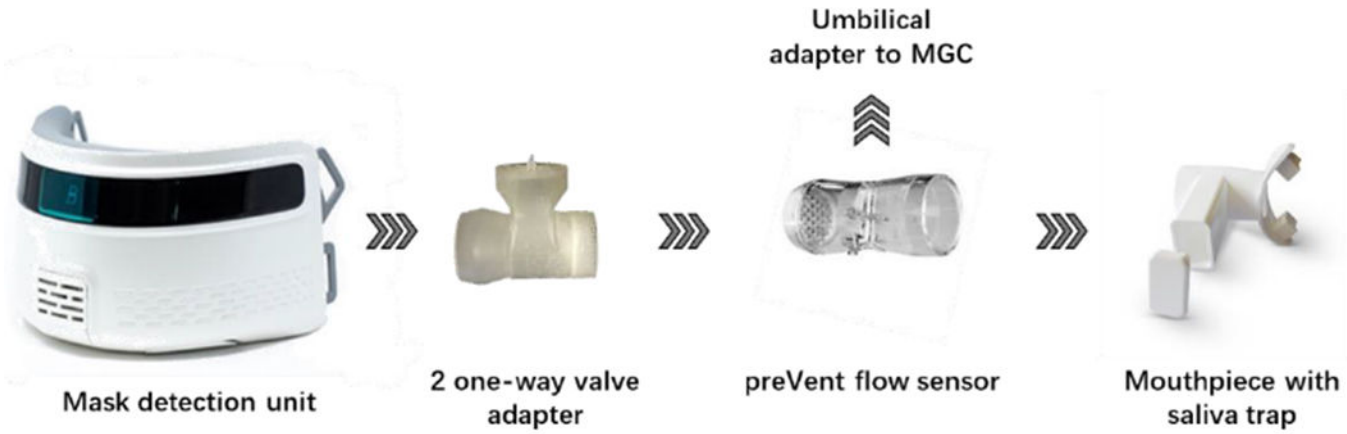

Figure 2.
Schematic representation of the connection between Breezing Med device MCG equipment.

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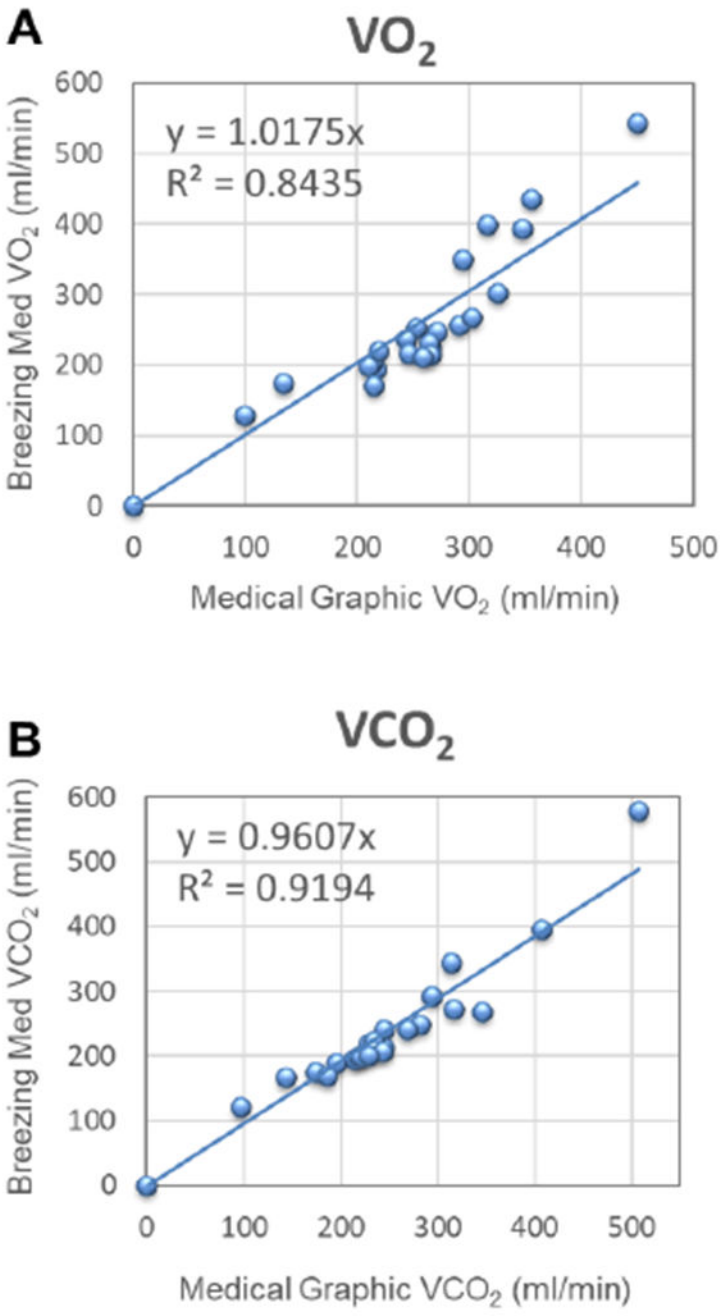

Figure 3.
Validation study for VO_2 (A) and VCO_2 (B), Breezing Med *vs.* Medical Graphic Method (two sensor batches); N=20 subjects; 23 tests.

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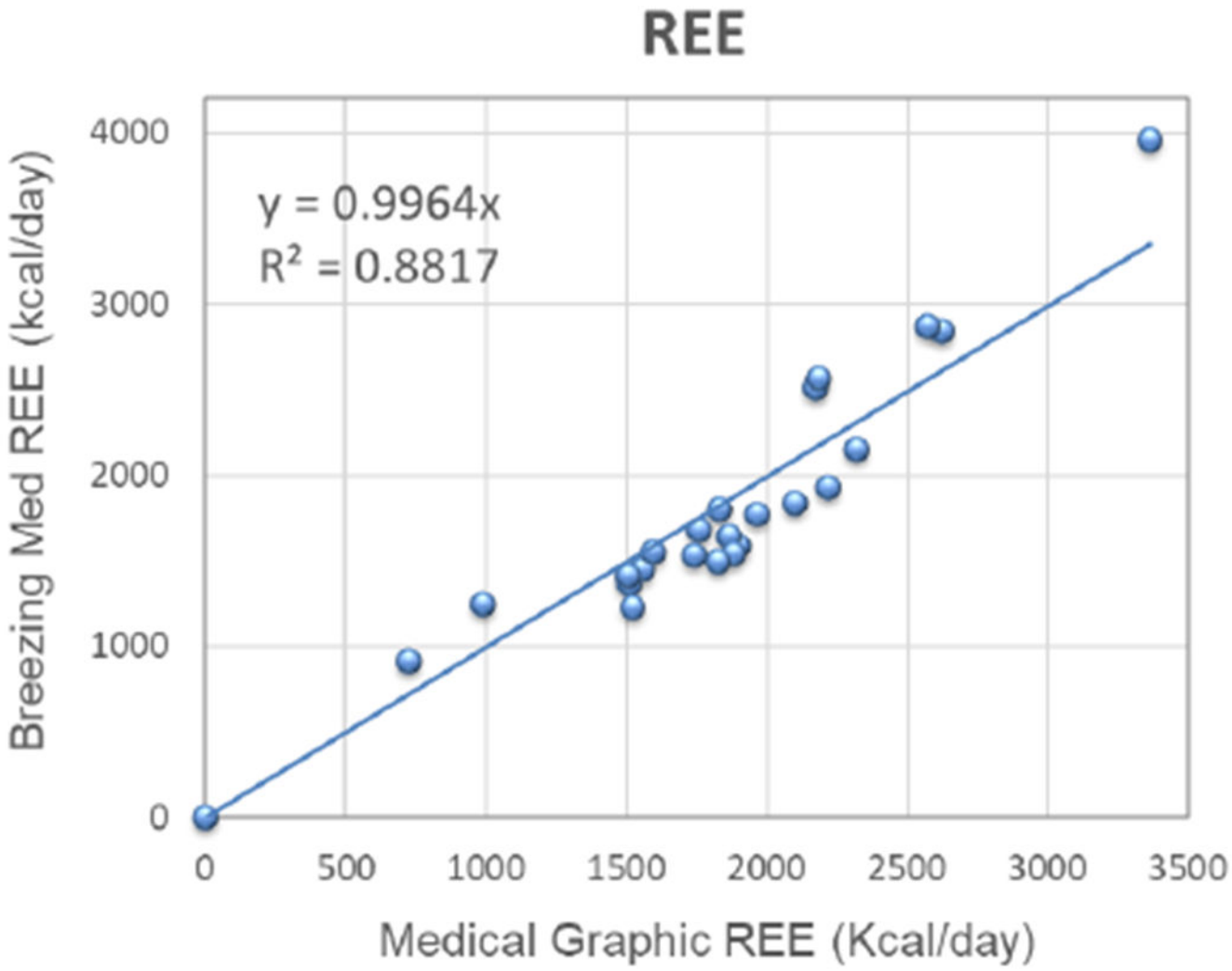

Figure 4.
Validation Study for REE, Breezing Med *vs.* Medical Graphic. N=20 subjects; 23 tests.

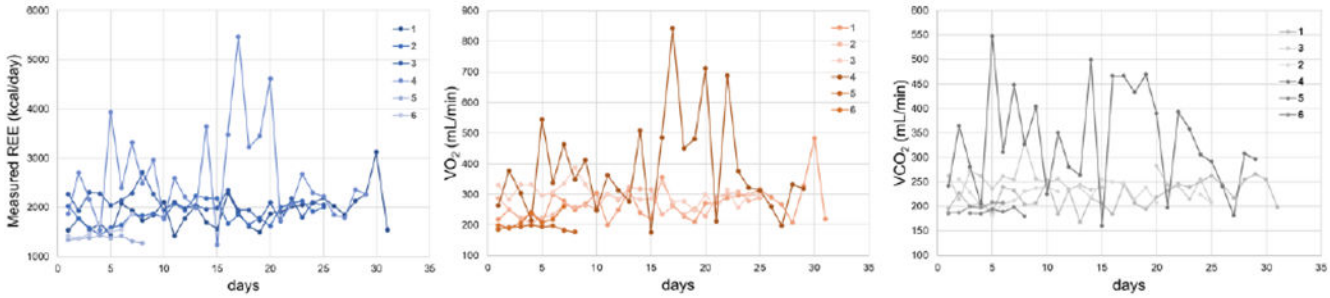

Figure 5.

Usability test of Breezing Med for patient's remote assessment of indirect calorimetry parameter as REE, VO_2 and VCO_2. The figure shows the information collected through the HIPAA-compliant Breezing App by the six subjects for a period of 1-4 weeks.

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Table 1:

Individual physical characteristics of the study's participants

Subject #	Height (cm)	Weight (kg)	Age	Gender	BMI (kg/m^2)
1	158	70	34	F	28.04
2	168	57	48	F	20.20
3	180	95	28	F	29.32
4	152	45	42	F	19.48
5	176	67	60	F	21.63
6	170	49	24	F	16.96
7	164	76	46	F	28.26
8	158	51	34	F	20.43
9	170	66	36	F	22.84
10	170	92	58	F	31.83
11	167	63	31	F	22.59
12	164	95	23	F	35.32
13	178	66	38	M	20.83
14	189	82	37	M	22.96
15	178	92	28	M	29.04
16	173	65	38	M	21.72
17	178	84	23	M	26.51
18	167	62	31	M	22.23
19	173	73	30	M	24.39
20	176	86	32	M	27.76

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Table 2:

Averaged physical characteristics of the study's participants *

Gender	N	Height (cm)	Weight (kg)	Age	BMI (Kg/m^2)
Women	12	166.4 ± 7.5 (152 - 180)	68.8 ± 16.9 (45 - 95)	38.6 ± 11.8 (23 - 60)	24.7 ± 5.4 (16.9 - 35.3)
Men	8	176.5 ± 5.8 (167 - 189)	76.2 ± 10.5 (62 - 92)	32.1 ± 5 (23 - 38)	24.4 ± 2.8 (20.8 - 29)
Total	20	170.4 ± 8.5 (152 - 189)	71.8 ± 15.1 (45 - 95)	36.0 ± 10.1 (23 - 60)	24.6 ± 4.5 (16.9 - 35.3)

* parameters including mean ± SD, and minimum and maximum values.

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Table 3.

Summary and comparison between metabolic parameters Measured by Breezing Med and MGC Ultima CPX™

	VO_2	VCO_2	REE
y	1.02	0.96	1.00
R^2	0.8435	0.9194	0.8817
p paired *t*-test	0.9524	0.0612	0.5745
% Mean difference	−0.1	4	2
SD	± 16	± 11	± 14

a = Correlation slope; R^2 = Squared correlation coefficient; Mean difference and ±SD (standard deviation) expressed as mL/min for VO_2 and VCO_2, and kcal/day for REE.