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510(k) Summary K021490

In accordance with the Safe Medical Devices Act of 1990 (SMDA), this is a summary of the safety and effectiveness information for this premarket notification upon which an equivalence determination could be based (510(k) summary) [21 CFR ξ 807.92(c)].

1. Applicant Information

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Date Summary Prepared: .....October 1, 2002

2. Device Name and Classification

Trade name: ..... REEVUE Indirect Calorimeter
Model: 8100
Common Name:.....Indirect Calorimeter
Classification name:.....Computer, Oxygen-Uptake
Classification Code.....CFR Section: 21 CFR ξ 868.1730
Product Code:..... AN-BZL
Panel:.....Anesthesiology
Class:.....2

3. Identification of Legally Marketed Predicate Device

Device: .....BodyGem (also marketed as MedGem)
Marketing Company: .....Healthetech Inc.
510(k) Number:.....K010577

Contents of Summary:

4. Description of the Device

The REEVUE is an indirect calorimeter. The REEVUE device measures oxygen consumption (V_{O2}) and estimates Resting Metabolic Rate (RMR) based on the measured V_{O2} using an assumed respiratory quotient (RQ=0.83). Resting metabolic rate can also be referred to as Resting Energy Expenditure (REE).

Measurement of energy requirements can be used for nutritional assessment. A typical application would be for counseling obese patients on their caloric intake requirements.

During a test the patient breathes through a mouthpiece with unidirectional breathing valves. These valves allow the patient to breath in ambient air and then direct the expiratory gas down a hose to the device. The flow rate of the expiratory gas is measured and the patient's tidal volume and respiratory rate is calculated. The expiratory gas passes through a mixing chamber so that the mixed expiratory oxygen concentration can be found. The oxygen concentration of the mixed expiratory gas is measured.

Oxygen consumption can be expressed as the volume of oxygen breathed in minus the volume of oxygen breathed out. This can be described as:

$$V_{O2} = V_I F_{IO2} - V_E F_{EO2} \qquad [1]$$

where V_{O2} is the oxygen consumption, V_I is the inspiratory volume, F_{IO2} is the inspiratory oxygen fraction, V_E is the expiratory volume, and F_{EO2} is the expiratory oxygen fraction.

Since the REEVUE only measures the expiratory volume of gas breathed out, the inspired volume must be estimated. This is similar to other legally marketed medical devices. When measuring both CO_2 and O_2 this is often referred as the Haldane method.

To estimate the inspired volume, the components of the expiratory and inspiratory volumes need to be accounted for. In estimating the inspiratory volume the REEVUE requires an estimate of the Respiratory Quotient (R_Q). The REEVUE uses an assumed R_Q of 0.83. The R_Q is defined as:

$$R_Q = \frac{V_{CO_2}}{V_{O_2}} \qquad [2]$$

where V_{CO2} is the carbon dioxide eliminated by the patient's breathing.

An estimate of Resting Energy Expenditure (REE) is calculated using the Weir Equation with the assumed R_Q value of 0.83. Substituting for the V_{CO2} using the R_Q and the V_{O2} the Weir Equation can be expressed as:

$$Calories = \left(3.941\, V_{O2-STPD} + 1.106 R_Q\, V_{O2-STPD}\right) \times \left(1 - 0.082\, P_F\right) \qquad [3]$$

Where
Calories .....is the calories burned per liter of oxygen consumed.
P_F.....is the fraction of total energy production due to protein oxidation.

Typical values for P_F range from 0.08 to 0.2, corresponding to 8 to 20% protein. We selected a default value of 0.125 for our calculations. In reporting (REE) in Kcal/day, this simplifies to:

$$RMR_{Kcal/day} = 6.925 \times V_{O2-ml/\min-STPD} \qquad [4]$$

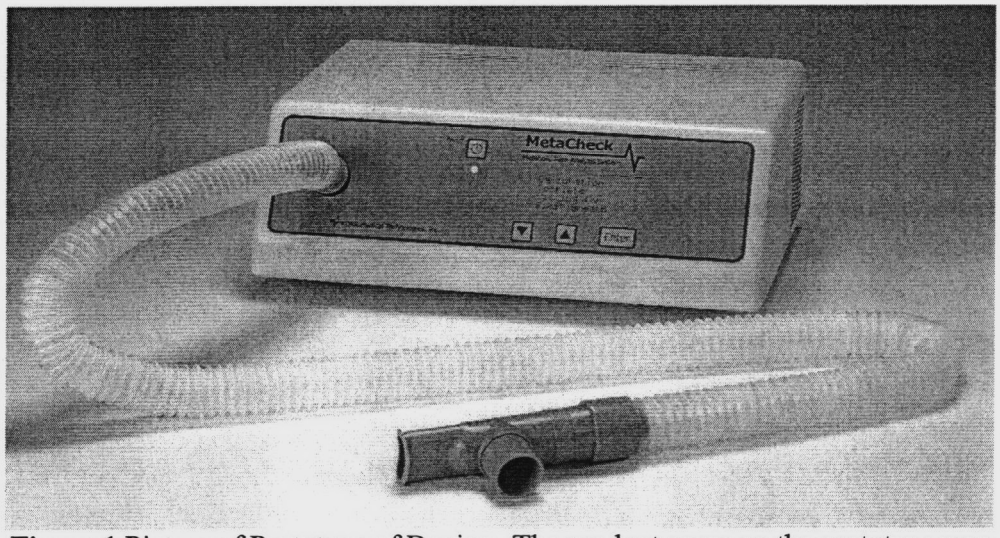


Figure 1 Picture of Prototype of Device. The product name on the prototype was "MetaCheck".

Figure 2 Example of a test with the Device

5. Intended Use / Indications for Use

The device is intended for use in clinical and research applications to measure oxygen uptake.

5.1 Typical Applications Where the Device may be Used

The device could be used in applications where oxygen consumption or measurements of indirect calorimetery would typically be used. This could include:

- Diseases where patients may be at risk for malnutrition
- Burn Patients
- Weight Management
- Parenterally Fed Patients
- Enterally Fed Patients
- Inflammatory States: Sepsis

Since the device does not measure carbon dioxide, and hence respiratory quotient, it could not be used in applications that require a measure of the respiratory quotient. Since the device assumes the patient is breathing ambient air, it is not intended for patients where supplementary oxygen is being given.

6. Technological Characteristics Compared to Predicate Device

Both the device and the predicate device measure oxygen consumption and then estimate resting metabolic rate using the Weir Equation and an assumed respiratory quotient (R_Q). Both devices measure gas flow, oxygen concentration, barometric pressure, temperature, and relative humidity. Both devices use a single-use mask or mouthpiece.

The main difference between the current device (REEVUE) and the predicate device (BodyGem) is that the predicate device is a handheld device that measures oxygen concentration and gas flow near the patient's mouth. The current device (REEVUE) is a "bench top" unit that uses a traditional mixing chamber approach, which allows the expiratory gas to mix. Since the gas is mixed, the oxygen sensor does not need to have a high frequency response since it is continuously measuring the mixed expiratory oxygen concentration.

6.1 Comparison Table to Predicate Device

Parameter	REEVUE (Current Device)	BodyGem (Predicate Device)	Comparison Notes
Indications for Use	For use in clinical and research applications to measure oxygen uptake	For use in clinical and research applications to measure oxygen uptake	Intended use statements are similar. Both products are intended for oxygen consumption and indirect calorimetery measurements.
Target Population	Weight > 33 kg (73 pounds) Pediatric to Adult Patients Device is not compatible with mechanical ventilation or patients on supplemental oxygen. Specified for breath rates of 5 to 40 breaths per minute and for tidal volumes ranging from 200 ml to 3000 ml.	Device is not compatible with mechanical ventilation or patients on supplemental oxygen. Specified for breath rates of 5 to 25 breaths per minute and for tidal volumes ranging from 500 ml to 1500 ml.	The minimum tidal volume of the predicate device is 500 ml. This is a typical tidal volume for an adult male.
Sterility	All patient contact elements are single-patient use. These accessories are considered as clean, non-sterile.	The patient holds the reusable device in his/her hand. A filter is placed in the device to prevent cross-contamination of the gas breathed by the patient.	Neither device uses sterile components. Both devices use clean, non-sterile single patient use components.
Biocompatibility	All patient contact components are legally marketed medical devices used as defined by their intended use statements.	No known issues.	
Mechanical Safety	No mechanical safety risks identified.	No mechanical safety risks identified.	Same.
Chemical Safety	No chemical safety risks identified.	No Known Issues.	
Anatomical Sites	Measures the respiratory gases at the patient's mouth and nose.	Measures the respiratory gases at the patient's mouth and nose.	Same.
Human Factors	Requires patient to keep mouthpiece/mask sealed about mouth/nose.	Requires patient to keep mouthpiece/mask sealed about mouth/nose.	Same.
Energy Used	External 12-volt power supply from device.	External 12-volt power supply from device.	Same.
Energy Delivered	No energy delivered to patient.	No energy delivered to patient.	Same.
Compatibility with Environment	No known issues.	No known issues.	Same.
Compatibility with Other Devices.	No known devices for compatibility issues.	No known devices for compatibility issues.	Same.
Where used	Doctor's office. Hospital nutritional assessment.	Doctor's office. Hospital nutritional assessment.	Same.

Parameter	REEVUE (Current Device)	BodyGem (Predicate Device)	Comparison Notes
Standards: Electrical Safety	EN60601-1 (1996) UL2601-1 (2nd edition) CSA C22.2 NO 601.1-M90 Class 1, Type BF applied part Drip proof equipment (IPX1)	EN60601-1 (1996) UL2601-1 CSA601-1 Class II, Type B	Similar safety. The Class 2 on the predicate device is due to the plastic enclosure. The Class 1 on the current (REEVUE) device is due to the grounded metal enclosure.
Standards: EMC Testing	EN60601-1-2	EN60601-1-2	Same.
Standards: Voluntary	No applicable voluntary standards.	No applicable voluntary standards.	Same.
Thermal Safety	No known thermal safety issues.	No known thermal safety issues.	Same.
Radiation Safety	No known radiation safety issues.	No known radiation safety issues.	Same.
Design - General	Device measures expiratory flow and oxygen concentration. Inspiratory volume is estimated. Ambient (inspired) oxygen concentration is assumed 20.93. Device is a desktop unit that connects to the patient via 1.5 meters of breathing circuit hose and a single-patient use mouthpiece. The display shows the Resting Metabolic Rate and VO2.	Ambient (inspired) oxygen concentration is assumed 20.93 for device calibration. Inspiratory and expiratory flow and oxygen measurements are integrated to obtain VO2. The device is handheld. The display shows the Resting Metabolic Rate and VO2.	The predicate device, the BodyGem, measures VO2 on a breath-by-breath basis whereas the current device uses a mixing chamber design. The mixing chamber is comparable to other legally marketed devices indicated in this 510(k) notification.
Specification Comparison			
Barometric Pressure Sensor			
Accuracy	± 5 mmHg	± 4 mmHg	Not a significant Difference
Resolution	1 mmHg	0.05 mmHg	Not a significant Difference
Min/Max Range	500 to 800 mmHg	515 to 795 mmHg	Not a significant Difference
Temperature Sensor			
Accuracy	± 1 °C	± 1 °C	Not a significant Difference
Resolution	0.1 °C	0.01 °C	Not a significant Difference
Min/Max Range	10 to 40 °C	5 to 50 °C	Not a significant Difference
Humidity Sensor			
Accuracy	± 10 %RH	± 10 %RH	Not a significant Difference
Resolution	1 %RH	1 %RH	Not a significant Difference
Min/Max Range	10 to 95 %RH	10 to 98 %RH	Not a significant Difference
Oxygen Sensor			
Type	Galvanic Fuel Cell	Florescent Quenching	
Accuracy	± 0.2 %O2	± 0.4 to 0.8 %O2	
Resolution	0.01 %O2	0.03 %O2	Not a significant Difference
Min/Max Range	0 to 30 %O2	10 to 21 %O2	Not a significant Difference

Parameter	REEVUE (Current Device)	BodyGem (Predicate Device)	Comparison Notes
Nominal Sensor Life	> 30 months	Not reported. However, the user manual does describe that an error message will be given when the sensor needs to be replaced.	The REEVUE notifies the user when the oxygen sensor is nearly depleted. When the senor is depleted device will lockout user operation.
Flow Sensor			
Type	Fixed-orifice Differential Pressure Pneumotach	Ultrasonic time-of-flight	Flow technology is different, but should not be significant if each works within the published specifications. The REEVUE flow sensor is also used in other legally marketed medical devices for measuring expiratory respiratory gas flow.
Accuracy	± 2% of reading	± 1%	Not a significant difference since the REEVUE estimates the inspired volume from the expired volume. (i.e. similar to traditional Haldane Equation) If both the expiratory and inspiratory volumes are measured, a higher flow sensor accuracy is required.
Resolution	10 ml / sec (0.01 LPM)	1 ml / sec	Not a significant Difference
Min/Max Range	- 40 to 150 LPM (-600 to 2500 ml / sec)	0 to 2100 ml / sec	Not a significant Difference
Respiratory Tidal Volume Measurements			
Breathing Rate	5 to 40 breaths/min	5 to 25 breaths/min	Not a significant Difference
Tidal Volume	200 to 3000 ml	500 to 1500 ml	Not a significant Difference
VO2 Measurements			
Range	< 70 to > 720 ml /min O2	72 to 721 ml /min O2	Not a significant Difference
Resolution	1 ml/min O2	1 ml/min O2	Same.
RMR Measurements			
Calculation Method	Weir Equation with assumed RQ = 0.83	Weir Equation with assumed RQ = 0.85	Not a significant Difference.
Range	500 to > 5,000 kcal/day	500 to 5,000 kcal/day	Same.
Resolution	7 kcal/day	10 kcal/day	Not a significant Difference.
Measurement Time	10 minutes	10 min max	Not a significant Difference.
Size & Weight			
Size	20 x 30 x 10 cm	5.5 x 5.5 x 11.5 cm	REEVUE is a desktop unit. The predicate device is a handheld device.
Weight	5.75 lbs. (2.6 kg)	4 oz.	REEVUE is a desktop unit. The predicate device is a handheld device.
Disposables			

Parameter	REEVUE (Current Device)	BodyGem (Predicate Device)	Comparison Notes
Mask Sizes	N/A	Small, medium, large	REEVUE does not have a mask.
Mouthpiece	One size	One size	Same.
Filter Efficiency	Bacterial Filtration 99.999+% Viral Filtration 99.99+%	Better than 99% of particles at 2 microns at flow rates up to 30 liters per minute	Due to the uni-directional gas flow in the REEVUE, a filter is only recommended, but not required by the REEVUE.
Operating Environment			
Temperature Range	15 to 30 °C (59 to 86 °F)	15 to 30 °C (59 to 86 °F)	Same.
Elevation Range	-30 to 3040 meters (-100 to 10,000 feet)	-30 to 3040 meters (-100 to 10,000 feet)	Same.
Barometric Pressure Range	525 to 780 mmHg	525 to 780 mmHg	Same.
Relative Humidity Range	10 to 95% RH non-condensing	10 to 88% RH non-condensing	Not a significant Difference
Storage Environment			
Temperature Range	-20 to 60 °C (-4 to 140 °F)	-20 to 60 °C (-4 to 140 °F)	Same.
Barometric Pressure Range	375 to 800 mmHg	140 to 780 mmHg	Not a significant Difference.
Relative Humidity Range	10 to 95% RH non-condensing	0 to 100% RH non-condensing	Not a significant Difference.

7. Non-clinical Performance Data to Establish Equivalence

General performance testing for hardware and software is presented in the body of the 510(k) notification. The non-clinical bench test that establishes equivalence is summarized here.

The accuracy of the REEVUE device was analyzed using the nitrogen injection method. In this method, a motorized piston or other device simulates patient breathing. A precisely measured flow of pure nitrogen (N_2) is added to the gas that is pumped into the device under test (REEVUE). Injecting nitrogen simulates expired air, which has a lower concentration of oxygen than fresh air. By exactly measuring and controlling the flow of nitrogen, the amount of oxygen consumed can be exactly controlled and known.

Methods and Materials - A motorized patient ventilator (Harvard model 608, Harvard Apparatus, South Natick, MA) is used to draw in room air and pump it into the device under test. The ventilator can be adjusted to simulate various flow rates and minute volume levels. The nitrogen flow is adjusted using a needle valve. The exact flow of N2 is measured using a gas flow analyzer (VT Plus, BioTek Instruments, Winooski Vermont).

Test Range - VO2 accuracy was tested over minute volume levels between 3 and 20 liters per minute. Simulated VO2 levels for these respiration levels were selected such that tests were taken using expired oxygen fractions between 12 and 20 percent.

Pass/Fail Criteria
Bias: (Average error) should be less than 3 ml/min or 1% of reading
Precision (1 standard deviation): Less than 5 ml/min or 2% of reading for all tests.

Results - For each measurement the VO_2 measured by the REE-VUE and the simulated VO_2 was recorded. The percent difference was calculated as:

$$\%\text{Difference} = 100\% * (VO2_{\text{REE-VUE}} - VO2_{\text{simulated}})/VO2_{\text{simulated}} \qquad [5]$$

The device was tested under 26 separate conditions with an average simulated VO_2 of 231.3 ml/min. The average of the percent difference across all measurements was 0.84% (1.89 ml/min). The standard deviation of the error was 1.3% (3.70 ml/min). The Plot below shows the measured value plotted against the actual values. Regression analysis shows the correlation between the actual and measured values was $r^2 = 0.9992$ and the factor (slope) relating the two values was 1.0088.

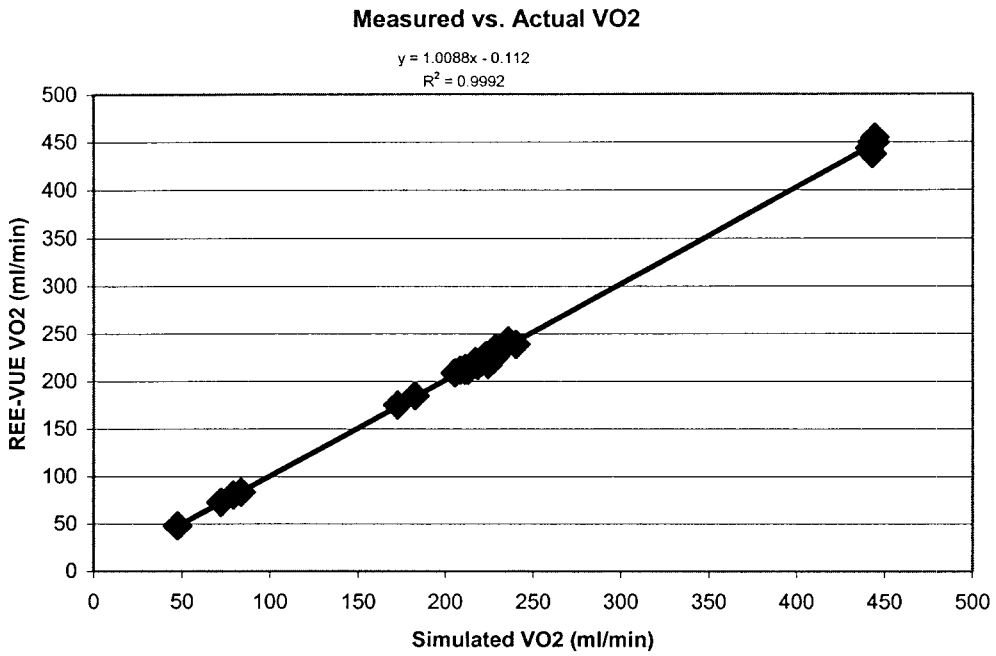


Figure 3 - Regression Plot of Nitrogen Dilution Test

The plot below shows the percent difference of the measurements vs. the minute volume. Note that the percent difference is similarly low regardless of the simulated minute volume (minute volume is amount of air breathed in one minute).

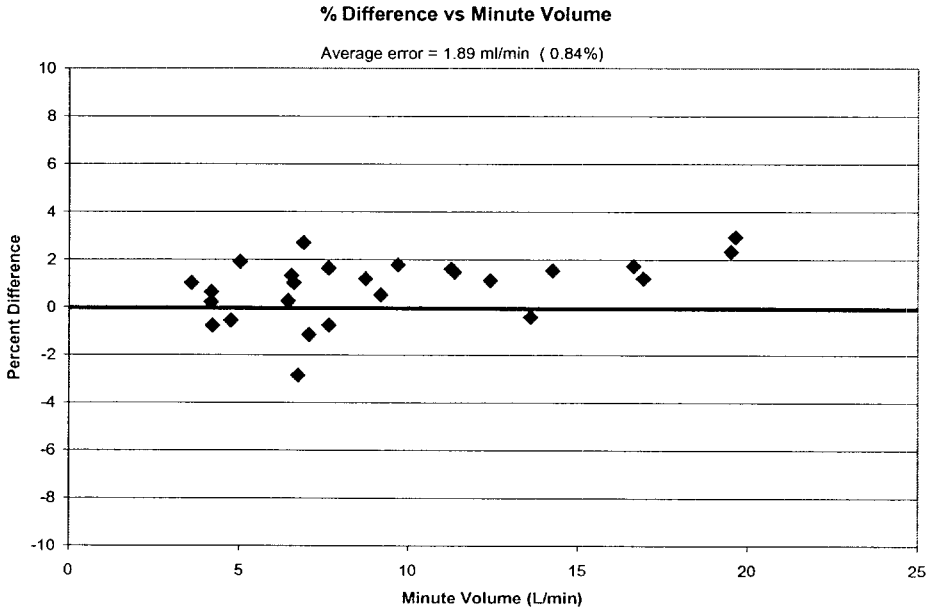


Figure 4 - Independence on ventilation demonstrated from nitrogen dilution tests.

The next plot shows the percent difference plotted against the concentration of oxygen in the expired air. Note that the error is consistently low even at the extremes of oxygen concentration.

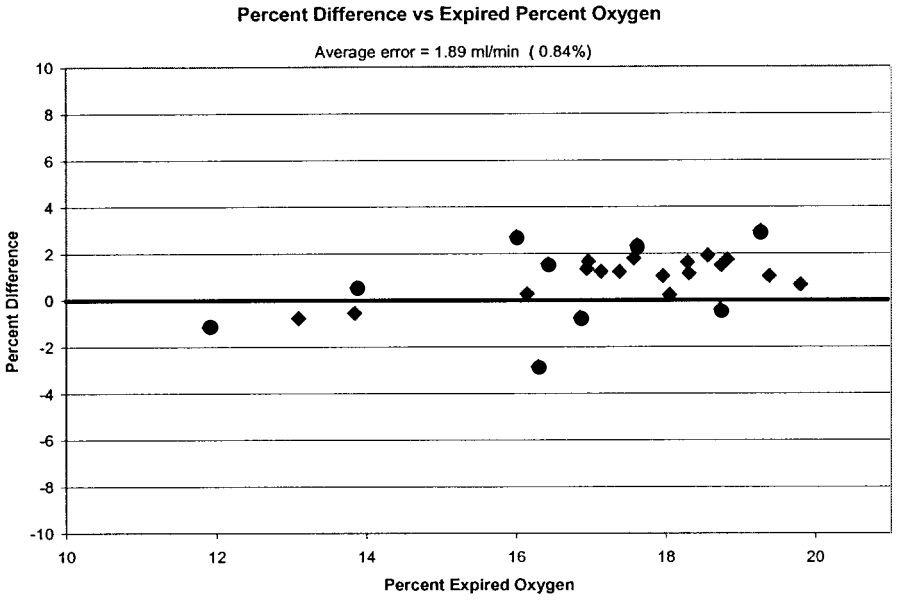


Figure 5 - Independence on expiratory oxygen concentration demonstrated from nitrogen dilution tests.

Inter-device Variability - We also tested a set of five REE-VUE systems to assess the variability of the results between systems. In this test, the N_2 dilution technique was set up using two standard oxygen consumption and minute volume conditions. The table below shows the measured results:

Unit #	Simulated VO2	Measured VO2	error	% error
1	200	198	-2.0	-1.0%
2	206	201	-5.0	-2.4%
3	211	214	3.0	1.4%
4	196	192	-4.0	-2.0%
5	206	203	-3.0	-1.5%
1	369	368	-1.0	-0.3%
2	377	382	5.0	1.3%
3	375	375	0.0	0.0%
4	370	364	-6.0	-1.6%
5	372	372	0.0	0.0%

Note: values are in ml/min

The average error across all units was 0.6% (1.3 ml/minute) with a standard deviation of the error of 1.3% (3.46 ml/min). There is no significant difference between measurements made with different REE-VUE systems.

Long Term Stability - We also tested the REE-VUE to assess the stability of the measurements over multiple days. Simulated oxygen uptake rates were simulated at approximately the same in 10 separate tests distributed over a 22-day period. Simulations were done using the nitrogen dilution technique as discussed above. The table below lists the date of each test along with the simulated and measured oxygen consumption values.

Date	Simulated VO2 (ml/min)	Measured VO2 (ml/min)	Error (ml/min)	Percent Error
22-Apr	352	347	-5	-1.4%
24-Apr	326	326	0	0.0%
26-Apr	318	315	-3	-0.9%
30-Apr	336	337	1	0.3%
2-May	318	321	3	0.9%
6-May	323	327	4	1.2%
8-May	323	327	4	1.2%
9-May	342	344	2	0.6%
10-May	320	320	0	0.0%
14-May	339	342	3	0.9%

The average error was 0.9 ml/min (0.3%) with a standard deviation of the error of 3 ml/min (0.9%). Over the entire period of the tests, the worst-case error was 1.4% of reading.

Discussion on Performance Testing -

The pass fail criteria for nitrogen dilution testing is:

- *Bias: (Average error) should be less than 3 ml/min or 1% of reading*
- *Precision (1 standard deviation): Less than 5 ml/min or 2% of reading for all tests.*

Test	Results	Pass/Fail Status
VO2 Accuracy over a range of 50 to 450 ml/minute	Bias = 1.89 ml/min (0.84%) Std. Dev. = 3.7 ml/min (1.3%)	Pass
VO2 accuracy over range of Minute volume from 3 to 20 L/min	Bias = 1.89 ml/min (0.84%) Std. Dev. = 3.7 ml/min (1.3%)	Pass
VO2 accuracy over range of FeO2 (mixed expired O2) from 12% O2 to 20% O2	Bias = 1.89 ml/min (0.84%) Std. Dev. = 3.7 ml/min (1.3%)	Pass
Inter-device variability over 5 REE-VUE devices	Bias = 1.3 ml/min (0.6%) Std. Dev. = 3.46 ml/min (1.3%)	Pass
Long-term stability, Device tested on 10 separate occasions over a period of at least 21 days	Bias = 0.9 ml/min (0.3%) Std. Dev. = 3 ml/min (0.9%)	Pass

These results indicate that the REE-VUE meets or exceeds the pre-determined pass criteria for each test.

8. Clinical Performance Data to Establish Equivalence

Introduction - The "Douglas bag" is considered a "gold standard" method of validating the accuracy of oxygen consumption measurement devices. The Douglas Bag method uses a large, non-porous bag to collect all of the gas expired by the individual being tested. After the gas is collected, the volume, and the concentration of oxygen and carbon dioxide of the gas collected in the bag are analyzed. This analysis gives the total volume of oxygen in the bag. Based on the bag contents and amount of time over which the bag was filled, the rate at which oxygen was consumed can be calculated.

Methods - Tests were conducted using a protocol approved by the University of Utah Institutional Review Board (IRB). Each subject provided informed consent.

For each test, the REEVUE system was calibrated using the standard automatic calibration before each test. Following auto-calibration, subjects breathed through a standard disposable mouthpiece and hose connected to the REEVUE system. Breathing was allowed to stabilize for at least 1 minute before data collection began.

After stabilization, expired gas exiting the REE-VUE was collected in a 100 Liter Douglas Bag (Hans Rudolph P/N 112377, Hans Rudolph inc, Kansas City, MO). Oxygen consumption (VO2) for each breath along with the breath rate measured by the REEVUE were stored digitally for each breath during the test. Expired gas was collected for at least 2 minutes and at least 20 Liters of gas was collected for each test. After the gas was collected, the bag was sealed. Average oxygen consumption for all of the breaths measured during the data collection period was calculated. The total time of data collection was recorded as well.

The volume and contents of the Douglas bag were analyzed following each individual's data collection. The volume of oxygen inspired by the subject was calculated using the measured ambient relative humidity and temperature. Further compensation was made to account for the difference in the rate of oxygen consumption to carbon dioxide production (respiratory quotient or RQ). The oxygen consumed during the test is the difference between oxygen consumed by the subject and the volume of oxygen that was collected in the bag. The total oxygen consumed divided by the collection time gives the rate of oxygen consumption measured by the Douglas Bag method. This rate of oxygen consumption can then be compared to the average oxygen consumption rate measured simultaneously by the REEVUE.

Results - Thirteen comparisons were made using 8 subjects. Tests were repeated in some subjects at various levels of physical activity to produce a wider range of test conditions. Measured oxygen uptake rates ranged from 138 to 545 ml/min. The average difference between the REE-VUE and the Douglas bag method was –3.22% (-7.6 ml/min). The standard deviation of the error was 3.4% (6.7 ml/min). The data plot below shows the relationship between Oxygen consumption using the Douglas bag and the REE-VUE.

The line relating REE-VUE oxygen consumption measurements to the corresponding Douglas bag values has a slope of 1.0081 with an offset of –10 ml/min. The correlation coefficient between the two methods was $R^2 = 0.99$.

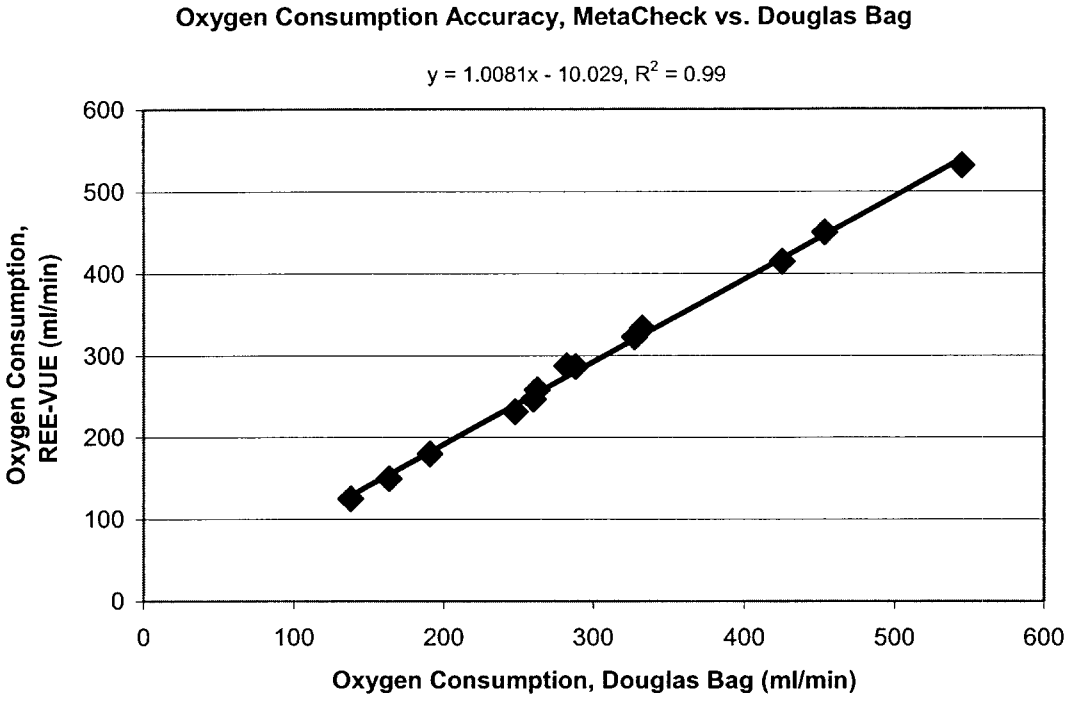


Figure 6 - Regression Plot of Clinical Data using Douglas bag

The minimum respiratory quotient (RQ) values observed during test was 0.76, the maximum value was 1.05, and the average value was 0.93.

Discussion - This data shows very good agreement between the REE-VUE and the Douglas Bag method. Linear regression shows a good correlation between REE-VUE and Douglas bag measurements of $R^2 = 0.997$ and a slope factor of 1.0081. The range of respiratory quotients (RQ) was quite wide (0.76 to 1.05).

9. Substantial Equivalence Conclusion

This section 9 provides a decision tree was used to determine if the current device (REEVUE) is substantially equivalent to the predicate device (BodyGem).

9.1 Does the new device have same indication statements?

Yes. The new device and the predicate device are intended for use in clinical and research applications to measure oxygen uptake. Both devices report oxygen consumption and resting metabolic rate.

9.2 Does the new device have same technological characteristics in design and materials?

Yes. Both the current device (REEVUE) and the predicate device (BodyGem) measure oxygen consumption and estimate caloric expenditure (metabolic rate). Both devices use an assumed respiratory quotient for estimate of caloric expenditure (metabolic rate).

The key technological characteristics that can affect product safety and efficacy are:

- Flow Measurement Technology
- Oxygen Measurement Technology
- Integration of Flow and Oxygen measurements to obtain V_{O2} estimate.
- Estimation of metabolic rate from the V_{O2} using an assumed respiratory quotient.

The current device (REEVUE) and the predicate device (BodyGem) vary in the implementation of the first three items. The differences are summarized as follows:

Technological Characteristic	Current Device (REEVUE)	Predicate Device (BodyGem)
Flow Measurement Technology	Fixed-orifice pneumotach design	Ultrasonic time-of-flight flow measurement
Oxygen Measurement Technology	Galvanic Fuel Cell	Illuminescent Quenching
Integration of Flow and Oxygen measurements to obtain VO2 estimate	The expiratory gases are mixed in a mixing chamber. The mixed expiratory oxygen concentration is multiplied by the measured volume to obtain VO2.	Flow and oxygen is measured directly at the patient's mouth. The two instantaneous signals are multiplied together to perform the integration.

To more fully demonstrate substantial equivalence, we have included the following reference to other legally marketed devices that share the same technological characteristics.

Technological Characteristic	Predicate Device with same Technological Characteristic
Flow Measurement Technology. Fixed-orifice pneumotach flow sensor to measure respiratory volumes.	MFG: Novametrix Medical Systems Tradename: CO2SMO PLUS 510(k) Number: K963380 Product Code: BZC NOTE: Current Device uses same flow measurement technology.
Oxygen Measurement Technology. Galvanic oxygen sensor.	MFG: AeroSport Tradename: TEEN 1000 510(k) Number: K945213 Product Code: BZC
Integration of Flow and Oxygen measurements to obtain VO2 estimate. Mixing chamber to obtain a mixed expiratory oxygen concentration.	MFG: PARVO MEDICS, INC Tradename: MMS-2400 (TRUEMAX 2400) 510(k) Number: K941843 Product Code: BZC
Estimate caloric expenditure (metabolic rate) from VO2 and assume a respiratory quotient of 0.85.	MFG: HealtheTech Tradename: BodyGem / MedGem 510(k) Number: K010577 Product Code: BZL

9.3 Are the descriptive characteristics precise enough to ensure equivalence?
No. Since the devices consist of measurement technologies that may differ slightly in the individual implementation, performance data is also required.

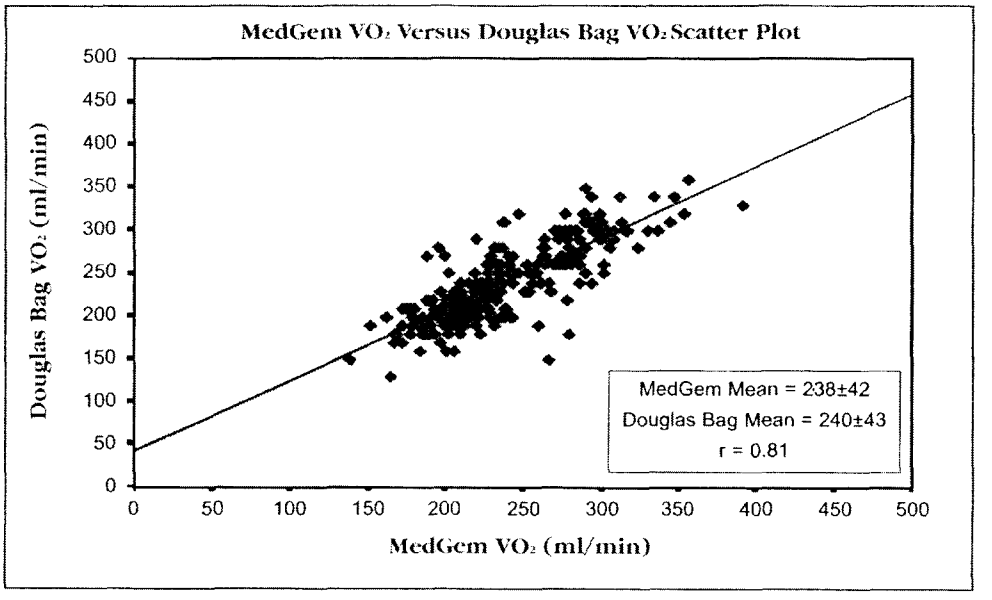
9.4 Are performance data available to assess equivalence?
Yes. A summary of the performance data is given in section 7 and 8.

9.4.1 Predicate Device Performance Data

The predicate device advertising literature shows the accuracy for testing versus a Douglas bag. The following is a plot of the predicate device data:

Clinical Validation Study Compares MedGem to the Classic Douglas Bag

A study completed at Appalachian State University demonstrated that the resting metabolic rates of 63 men and women, of diverse ages and sizes, were measured accurately and reliably by the MedGem. The study was presented at the North American Society for the Study of Obesity and has been submitted for publication. A scatter plot demonstrating the high level of agreement between the MedGem and the reference system is shown below.



Summary of Comparison Data

Range of VO_2 Values:

MedGem: 138.9 ml/min to 391.4 ml/min.

Douglas Bag (gold standard of reference method): 130.0 ml/min to 360 ml/min.

Key Statistics:

n = 252, r = 0.81, r^2 = 0.65, slope = 0.83, intercept = 41.0, standard error of estimate = 27.1 ml/min.

Figure 7 - Predicate Device (BODYGEM) Published Accuracy. Scanned Image from predicate device product literature.

The regression analysis statistics reported show that:

- n = 252 tests
- $r^2 = 0.65$
- Slope of regression Line = 0.83
- Intercept of Regression Line = 41.0 V_{O2} (ml/min)
- The standard error of the estimate was 27.1 ml/min
- Mean value was 238 ± 42 ml/min

9.5 Does performance data demonstrate equivalence?

Yes. The performance data demonstrates that the current device meets the product specifications and will provide equivalent results to the predicate device.

9.6 Substantially Equivalent Determination:

From the above information we conclude that the new device (REEVUE) is substantially equivalent to the predicate device (BodyGem).

End of 510(k) Summary

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 02 2003

Dr. Scott A. Kofoed, Ph.D.
President
Korr Medical Technologies, Incorporated
3900 East 3300 South, Suite 100
Salt Lake City, Utah 84109

Re: K021490
Trade Name: REEVUE Indirect Calorimeter
Regulation Number: 21 CFR 868.1730
Regulation Name: Oxygen-Uptake Computer
Regulatory Class: II
Product Code: BZL
Dated: October 3, 2002
Received: October 4, 2002

Dear Dr. Kofoed:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number (if known): K021490

Device Name: .....REEVUE Indirect Calorimeter

Indications for Use:.....The REEVUE is intended for use in clinical and research applications to measure oxygen uptake.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use_____

(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices