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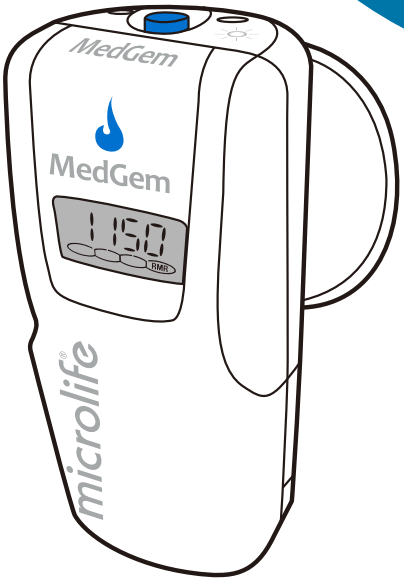
WatchWT

MedGem

Professional Indirect Calorimeter



MedGem(200-0001-22)

Instruction Manual

EN

Precautions:

Caution: Rx Only

Caution: Breathing attachments are designed for a single-use only and must be discarded after each use.

Caution: Not suitable for use in the presence of flammable anesthetics.

Service of this instrument is restricted to authorized personnel only.

Microlife Medical Home Solutions makes no claim for use of this product other than those uses specified herein and disclaims any liability resulting from other uses. Observe all warnings and cautions.

Intended use:
MedGem is a handheld, portable indirect calorimeter that measures oxygen consumption (VO_2) and determines resting metabolic rate (RMR[1]). For adult and children over than 10 years old.

Indication for use:
MedGem is for use in clinical research application for to measure the oxygen uptake and resting metabolic rate.

Contra indication
Not compatible with mechanical ventilation or patients on supplemental oxygen.
Not for exercise testing.

About the MedGem Indirect Calorimeter

Accurate measurement of oxygen consumption and energy requirements serves as an ideal basis for nutritional assessment and for administering medical nutrition therapy (MNT). Nutrition monitoring plays a vital role in the care of patients with diabetes, heart disease, high blood pressure, and obesity, as well as conditions that place patients at risk for malnutrition, such as cancer, burns, anorexia nervosa, trauma, infection, obstructive lung disease and HIV. MedGem can be used in acute care, long term care, and clinic based care settings such as physician offices, rehabilitation centers, and out patient clinical nutrition centers.

Before using the MedGem device, refer to the Important Safety Information section on page 13.

Note: *From this point forward and throughout this User Guide, the term "SmartGem" is used to define a MedGem that has a pre loaded number of measurements. This "SmartGem" version of the MedGem is only available in the United States.*

1. *RMR is calculated using the Weir Equation and a constant RQ value of 0.85, Weir, J.B., New Methods for Calculating Metabolic Rate with Special Reference to Protein Metabolism. J. Physiol, 1949. 109: pages 1-9.*

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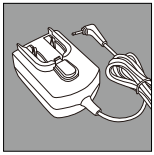
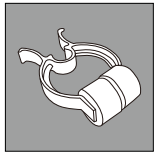
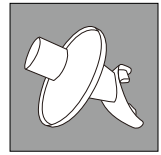


A) Power Supply

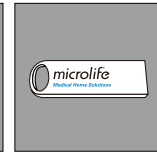


B) Nose Clip

C) MedGem Device



D) Single-Use Mouthpiece



E) USB flash drive

MedGem Indirect Calorimeter

The MedGem indirect calorimeter monitors inspired and expired air flow, oxygen levels, and environmental conditions to precisely measure oxygen consumption and determine resting metabolic rate. The MedGem device makes nutritional assessment more accurate and eliminates the need to use estimation equations and other factors.

Power Supply

(A). Insert the small plug into the DC Power In/Data/Reset jack on the side of the MedGem device and plug the power supply into any standard wall outlet.

If you are using the international power supply, attach the appropriate connector before connecting to a standard wall outlet.

Single-Use Breathing Attachments

The MedGem indirect calorimeter (C) may be used with a single-use mouthpiece (D) and nose clip (B). The mouthpiece (D) is inserted into the flow tube and is used with a nose clip (B) to prevent breathing through the nose.

Note: *The single-use mouthpiece (D) may only be used for a single measurement and should be discarded after each measurement. Subsequent measurements on the same person require the use of a new breathing attachment.*

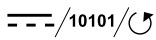
Analyzer software can be downloaded in the following website. Please use RS232 cable with power input approved by manufacturer.

https://microlife.mykajabi.com/medgem-analyzer

MedGem Symbols:

Indicator Light

Press to Start Button



DC Power In/Data/Reset

Measuring Oxygen Consumption with the MedGem

Conditions that Allow for an Accurate RMR Calculation[1]

When using the MedGem device to measure oxygen consumption and determine RMR in a spontaneously breathing patient, it is important that the patient is calm and relaxed. If the patient has been active or stressed, or has recently eaten or exercised, the rate of oxygen consumption will be accurate for that condition but may not be representative at actual rest.

- Patients should be rested in a comfortable seated or reclined position. Patients who are in a non-rested state (e.g. recent physical therapy treatment, respiratory treatments including medications, or a stressful event) should rest for approximately 10 to 15 minutes before the measurement to allow the body to stabilize.
- Measurement should be performed at least four hours after eating. Parenteral and enteral nutrients are infused at a continuous rate, thus thermic effect is stable throughout the day. Feeding does not need to be turned off.
- Supplemental oxygen (i.e., nasal cannulas or mask) should not be administered to the patient while performing a measurement. It is necessary to wait at least 5 minutes after oxygen administration before conducting a measurement.
- Measurements should be performed in a quiet, thermoneutral environment.
- Measurement should be performed at least four hours after exercise (cardiovascular or resistance training).
- Measurement should be performed at least four hours after caffeine consumption.
- Measurement should be performed at least one hour after nicotine use.

Caution: *Do not expose the device O_2 sensors to direct sunlight or UV light. The O_2 sensors are located behind the flow tube and are exposed when the flow tube is removed. It is recommended that the flow tube be kept inserted into the device at all times.*

With repeat testing, measurements should be taken at the same time of day under similar conditions.

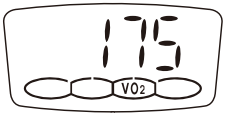


Figure A
-VO_2 Reading

Figure B
-RMR Reading

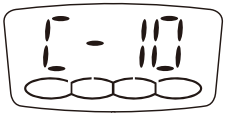


Figure B
-SmartGem only

1. *RMR is calculated using the Weir Equation and a constant RQ value of 0.85, Weir, J.B., New Methods for Calculating Metabolic Rate with Special Reference to Protein Metabolism. J. Physiol, 1949. 109: pages 1-9.*

The MedGem Device Setup

Step 1 - Warm-up:

Attach the small plug on the power supply or international power supply to the jack on the side of the MedGem device (Fig. A) and plug the power supply into a wall socket. Once it is plugged in, the device begins the warm up process:

- The MedGem device will beep once.
- The indicator light on top of the unit will briefly show red and then cycle to amber when ready for calibration.
- The MedGem device is on and warming-up.

Note: *If no measurements remain, the two-tone alert will repeat three times and the indicator light flashes red. Refer to page 9 for replenishment instructions.*

* *If using a SmartGem (with pre loaded measurements), then the LCD screen will display the number of measurements remaining.*

(Fig. B - Applies to SmartGems only)

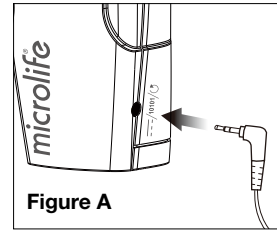


Figure A

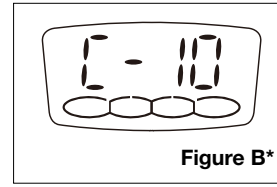


Figure B*

Single-Use Breathing Attachments:

- Insert the single-use mouthpiece into the flow tube on the back of the MedGem device until it fits snugly (Fig. C)
- Ensure that the flow tube fits snugly into the MedGem device. The top of the flow tube should be flush with the MedGem device. (Fig. D - Incorrect, Fig. E - Correct)

* *SmartGem models are only available in the United States.*

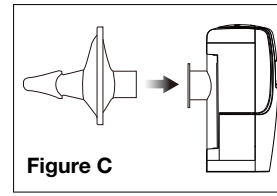


Figure C

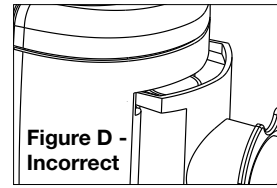


Figure D - Incorrect

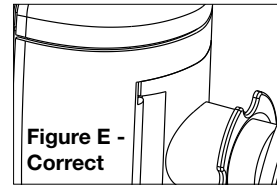


Figure E - Correct

Step 2 - MedGem Self-Calibration:

- Make sure the flow tube and breathing attachment are fully inserted into the MedGem device.
- Place the MedGem device upright on a flat surface, away from air vents or fans.
- Press the Start Button (amber indicator light on the top of the unit-Fig. F).

NOTE: *It is very important to leave the MedGem device sitting upright on a flat surface when you push the Start Button and throughout the self-calibration period (while the amber light is flashing). Do not pick up the MedGem device until it beeps and the amber indicator light flashes green.*

The amber indicator light will begin flashing and the MedGem device will buzz softly, indicating self-calibration. (Self-calibration takes up to 30 seconds.)

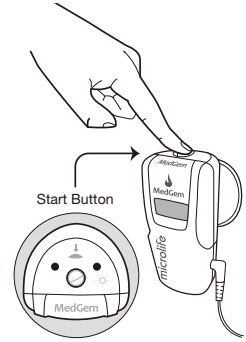


Figure F

When the MedGem device is ready to begin a measurement, the indicator light will flash green and the MedGem device will beep once.

Step 3 - Begin the Measurement:

Begin the measurement within one minute from the time the indicator light begins flashing green.

NOTE: *If the measurement is not started within a minute, the indicator light will turn amber, indicating standby mode.*

- In standby mode, press the Start Button. The MedGem device will self-calibrate and the indicator light will flash amber. The indicator light will flash green when it is ready to begin a measurement.
- Position the mouthpiece inside the patient's mouth (Figure G)
- Place the nose clip on the patient's nose to close the nostrils and make sure the patient maintains a good seal around the mouthpiece.
- Ensure patient is seated, comfortable and they have been instructed not to move during the measurement. They will need to hold the MedGem device during the measurement. To make this as easy as possible, have the patient support their arm on the armrest of the chair, a pillow or with the opposite hand.

Figure G

When the Single-Use Breathing Attachment is positioned on the patient:

- The indicator light will change to a non-flashing green during the measurement.
- The MedGem device will buzz softly throughout the 5-10 minute measurement period.

Note: *Measurement time will vary, as the time needed to reach a steady state of breathing is patient-specific.*

- At the completion of the measurement, the MedGem device will beep and the indicator light will change back to amber, signaling the end of the measurement.
- Provide the patient with a paper towel or tissue as the mouthpiece may cause increased salivation.

Step 4 - Obtain VO_2 and RMR Reading from the MedGem LCD screen:

The oxygen consumption measurement results will be displayed in the LCD window.

- Oxygen consumption, displayed in ml/min and labeled VO_2(Figure A).
- Resting metabolic rate, displayed in kcal/day and labeled RMR (Figure B).

Note: *Measurement time will vary, as the time needed to reach a steady state of breathing is patient-specific.*

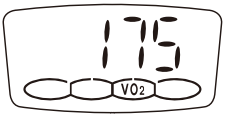


Figure A
-VO_2 Reading

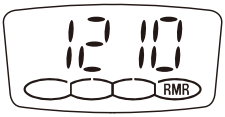


Figure B
-RMR Reading

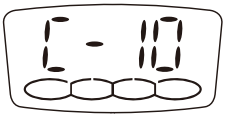


Figure B
-SmartGem only

These readings will alternate every two seconds until the MedGem device is disconnected from the power source or the Start Button on the top of the MedGem device is pushed.

Note: *The MedGem device will retain measurement results until a new measurement is begun. The device software version will display for two seconds, then the VO_2 and RMR numbers from the last completed test will display for two seconds each. Record the measurement.*

- Remove the mouthpiece from the patient and discard the single-use breathing attachment. Gently twist and pull the single-use mouthpiece to remove it from the MedGem device. Dispose of the single-use mouthpiece.
- Ensure that the flow tube remains firmly seated in the unit. Do not discard the flow tube.

The single-use mouthpiece and nose clip may only be used for a single measurement and should be discarded after each test. Subsequent measurements on the same person require the use of new breathing attachments.

Precautionary Measures

- To hold the MedGem device, place hand on the front of the unit, not on the base where gas flow will be interrupted and the measurement will be interrupted.
- Be careful not to dislodge the power cord during measurement. This will discontinue the measurement process.
- Maintain a tight seal to prevent air leaks. A leak will be indicated by a beeping sound. The indicator light will turn red and the LCD will display Er01. The measurement must be stopped and restarted beginning with Step 2. See Troubleshooting MedGem (page 10) for more details.

NOTE: *If an error occurs during a measurement the number of remaining measurements will not be affected.*

Determining RMR*- Equations and Constants

Measurement of VO_2 can be converted to resting metabolic rate with a high degree of accuracy and reliability in both healthy and pathological settings. Oxygen consumption (VO_2) is the primary basis of indirect calorimetry and the determination of resting metabolic rate. Measurement of carbon dioxide production may provide additional information regarding mixture of substrate utilization, but is not a necessary requirement for clinically accurate determination of resting metabolic rate. In clinical practice, resting metabolic rate is routinely determined from measured oxygen consumption using a respiratory quotient constant of 0.85, resulting in a clinically acceptable error of less than 2.5% in individuals consuming a standard mixed diet.

To calculate resting metabolic rate from measured oxygen consumption, the MedGem device uses the Weir equation1, which is the universal standard for the conversion of gas exchange measurements into resting metabolic rate.

Resting Metabolic Rate = [(3.941)(VO_2) + (1.106)(VCO2)]

The MedGem device does not measure CO_2 production. Instead, it uses the abbreviated version of the Weir Equation1, which calculates resting metabolic rate using only oxygen consumption.

Resting Metabolic Rate = [(3.941)(VO2) + (1.106)(VO_2)(RQ)]

Use of the abbreviated version of the Weir equation requires a constant for the respiratory quotient

(RQ), which is the ratio of an individual's CO_2 produced relative to O_2 consumed. This ratio varies depending on the energy substrates used by the body.

* *References for this section can be found on page 8*

Respiratory quotients for energy substrates*:

Energy Substrate	Respiratory Quotient
Carbohydrate	1.00
Protein	0.82
Lipid (fats)	0.71

In clinical settings, RQ typically averages 0.85. Under both normal and pathophysiologic conditions, it is extremely rare for a human subject to have a true metabolic RQ outside of the range of 0.75 to

0.95 (i.e., it would be highly unlikely for every cell in the body to be burning pure carbohydrate

(RQ = 1.0) or pure fat (RQ = 0.70). Cobean et al.2 and McClave et al.3.

The MedGem device uses the following formula to convert oxygen consumption (VO_2) to resting metabolic rate (RMR). (A constant of 0.85 is used for RQ.)

$RMR = [(3.941 \times VO_2) + (1.106 \times VO_2 \times RQ)] \times NF1$

The potential error of using a constant RQ of 0.85 versus measurement of VCO_2 for determination of the resting metabolic rate using the Weir equation is shown in the following table.

VO_2 ml/min	VCO_2 ml/min	RQ	kcal/day using measured VCO_2	Constant RQ	kcal/day using constant RQ	kcal/day	% error from constant RQ
250	187.5	0.75	1,693	0.85	1,732	39	2.3
250	200	0.8	1,713	0.85	1,732	19	1.1
250	212.5	0.85	1,732	0.85	1,732	0	0
250	225	0.9	1,752	0.85	1,732	-20	-1.1
250	237.5	0.95	1,772	0.85	1,732	-40	-2.3

Therefore, use of a constant RQ of 0.85 with VO_2 results in a minimal under/over estimation of RMR.

* *References for this section can be found on page 8*

RMR Discussion

Clinical Practice and Calculation of RMR from VO_2

Weir1 clearly states that the determination of metabolic rate requires only the measurement of the volume of air expired and its oxygen content (p. 7). A number of clinical references applying this approach are summarized below:

i. In their review article titled Indirect calorimetry in critically ill patients: clinical applications and practical advice, Brandi, et al.4 states that the main determinant of energy expenditure is VO_2 but not VCO_2 (p. 351) and recommended using the formula EE = VO_2 x 4.813 x 1.44.

ii. Kirkland5, in his article titled Effects of ventilator resetting on indirect calorimetry measurement the importance of patience, stated, Neither RQ nor VCO_2 are required to determine REE, only the accurate measurement of VO_2, at steady physiologic state and constant FiO_2 (p. 539-40). He further stated that eliminating VCO_2 from the Weir equation results in only about 2% error, and this study found excellent correlation between REE and VO_2 (r2 = .97). If substrate utilization and dead space are not desired, VCO_2 is unnecessary (p. 540).

iii. In the article Effects of ventilator resetting on indirect calorimetry measurement in the critically ill surgical patient, Brandi6 stated VO_2 is the overwhelming determinant of energy expenditure because energy is derived mainly from substrate oxidation. It should be noted that energy expenditure calculation can be obtained solely from VO_2 by neglecting VCO_2, with an error in energy expenditure of approximately 2% (p. 536).

iv. In clinical practice throughout the world, a formula commonly known as the Harris-Benedict Equation is used by dietitians and other nutritionists to estimate resting metabolic rate based on the height, weight, age, and gender of an individual. Interestingly, Harris and Benedict performed measurements of indirect calorimetry as the basis of generating their formula. In this landmark publication, A Biometric Study of Basal Metabolism in Man,7 the authors stated that the computation of heat-production is usually based upon the oxygen consumption, making allowances for the slight changes in the calorific equivalent of oxygen with varying respiratory quotients. The calorific value of oxygen is much more nearly constant, irrespective of the character of the metabolism, than is that of carbon dioxide, and hence in practically all of the cases we have used the oxygen consumption (p.30). For the purpose of determining resting metabolic rate, the authors chose to use VO_2 in the formula described above using a common respiratory quotient of 0.85 (p.31).

References

1. *Weir, J.B., New methods for calculating metabolic rate with special reference to protein metabolism. J. Physiol, 1949. 109: p. 1-9.*
2. *Cobean, R.A., et al., Nutritional assessment using a pulmonary artery catheter. Journal of Trauma-Injury Infection & Critical Care, 1992. 33(3): p. 452-6.*
3. *McClave S.A., McClain C.J., Snider, H.J. Should Indirect Calorimetry be Used as Part of Nutritional Assessment? J. Clin Gastroenterology 2001;33:14-19.*
4. *Brandi, L.S., R. Bertolini, and M. Calafa, Indirect calorimetry in critically ill patients: clinical applications and practical advice. Nutrition, 1997. 13(4): p. 349-58.*
5. *Kirkland, L., Effects of ventilator resetting on indirect calorimetry measurement — the importance of patience. Critical Care Medicine, 1999. 27(3): p. 459-60.*
6. *Brandi, L.S., et al., Effects of ventilator resetting on indirect calorimetry measurement in the critically ill surgical patient. Critical Care Medicine, 1999. 27(3): p. 531-9.*
7. *Harris, J.A. and F.G. Benedict, A Biometric Study of Basal Metabolism in Man. 1919, Washington, D.C.: Carnegie Institution. 30-31.*

Caring for the MedGem Indirect Calorimeter

The MedGem Device Cleaning Instructions
The MedGem device is designed for extended use under normal conditions. It contains electronic components that may be damaged if not cared for properly. You can wipe the device, with the flow tube still inserted, using a clean dry cloth, Clorox® Disinfecting Wipes, or a clean cloth slightly dampened with the following: isopropyl alcohol (91%), hydrogen peroxide (3%), Cidex™, Clorox® bleach or soap and water. **Do not remove the flow tube!** There are components and sensors exposed if the flow tube is removed that may be damaged if exposed to water or cleaning solvents.

WARNING: *DO NOT SUBMERGE THE MEDGEM DEVICE IN WATER OR ALLOW WATER OR ANY SOLUTION TO PENETRATE THE DISPLAY WINDOW, SOCKETS, OR OPENINGS ON THE PRODUCT.*

Protecting the MedGem device from damage
Protect the MedGem device from extreme temperatures and avoid exposure to excessive heat or moisture that can cause damage to internal components.

Use only Microlife supplied mouthpieces, accessories, power supplies, and replacement parts. There are no user-serviceable parts inside the MedGem device.

How to store the MedGem device
To protect the sensors inside the MedGem device, it is recommended that you leave the MedGem device standing upright between uses. Store it in its case overnight or when it is not in use.

Replenishment for the SmartGem model*

Low on Authorized Tests
In this mode the LED will blink between amber and green. A double, 2-tone error sequence will sound. This is a 'warning' error and pushing the top button will bypass this condition. Warning will only sound when the unit is initially powered up. At this stage new measurements should be ordered.

See replenishment instructions below.

Out of Authorized Tests
In this mode the LED will flash red and the LCD will show C-00. A triple, 2-tone error sequence will sound. This error sounds when the unit is initially powered up or when the button is pushed requesting a test. Pushing the top button to bypass this error will leave the unit in error mode.

Replenishment Instructions: *To order more measurements please Email: info@MiMHS.com*

* *SmartGems come pre loaded with a limited number of measurements and are only available in the United States.*

Troubleshooting

Clinical Practice and Calculation of RMR from VO_2

The MedGem device has advanced internal components that precisely measure oxygen consumption, temperature, pressure, and relative humidity. If the unit detects a problem with any of these measurements, an error message is displayed for easy troubleshooting. If there is a problem with the MedGem device, the following will occur:

1. The indicator light on the top of the MedGem device will turn red.
2. An error beep tone of four low frequency beeps will be heard.
3. An error code will be displayed in the MedGem LCD window.
4. Use the Error Code and Solution Table (below) to remedy the problem.
5. Once the problem has been identified, unplug the MedGem device from the power supply to erase the error code.
6. Reconnect the power supply to turn the MedGem device on.
7. Refer to Step 3 (Begin the Measurement) of the Measuring Oxygen Consumption section of this manual (page 4) to restart the measurement.
8. If an error message persists, contact customer support (see page 16).

MedGem Error Codes

Error	Solution
Er01 Detection of an air leak during the measurement	1. Make sure flow tube and single-use breathing attachment are firmly attached to the MedGem device. 2. If using a mouthpiece: • Make sure patient's mouth is sealed completely around the mouthpiece. • Ensure that the nose clip is across the patient's nose, eliminating any air passing through the nostrils. Breathing is done through the mouth. 3. Repeat the measurement.
Er04 Detection of an interruption during the measurement such as a cough or sneeze or any action that removes the MedGem device from the patient's mouth	1. Resolve the condition that caused the interruption and allow the patient time to return to a resting state. 2. Repeat the measurement.
Er05 Detection of airflow during calibration and the process was not completed	1. Internal calibration must be performed with the MedGem device placed on a stable, flat surface. 2. Make sure there are no air vents or other sources of air flow (e.g., fans) near the MedGem device. 3. Do not move the MedGem device if it beeps once and the light flashes green. 4. If the MedGem device continues to display this error code, try moving to a better location away from vents and fans.

Error	Solution
Er06 Detection of a pause in breath of greater than 30 seconds	1. Make sure the patient is breathing normally, keeping a good seal around the mouthpiece. 2. Remind the patient not to hold his/her breath. 3. Repeat the measurement.
Er07 Detection of an unusually low rate of oxygen consumption	1. Make sure the patient is breathing normally. 2. Repeat the measurement to verify the results. 3. The MedGem device will not detect oxygen consumption below 72 ml/min or an RMR of 500 kcal/day.
Er08 Detection of an unusually high rate of oxygen consumption	1. Have the patient rest a minimum of 10 minutes before measurement and have the patient avoid strenuous activity for 12 hours prior to measurement. 2. Have the patient relaxed and breathing normally while in a quiet environment for optimal measurement conditions. 3. Repeat the measurement to verify results. 4. The MedGem device will not detect oxygen consumption greater than 721 ml/min or an RMR of 5,000 kcal/day.
Er23* Improper insertion of the flow tube	1. Make sure the flow tube is inserted completely. The flow tube should be flush with the MedGem device. * *Contact Customer Service if this error persists (see page 16).*
Er27 Occurs when the start button is pressed during device power up or if the start button is defective	1. Unplug device and plug back in. Make sure you are not pressing the start button down when you apply power to the MedGem device.
Er40 Indicator light blinks, alternating between amber and green. This indicates the device exceeds operational parameters.	1. Contact customer support for further assistance. (See page 16) 2. Microlife cannot guarantee the accuracy and/or the reliability of the MedGem
Any error codes other than those listed above, may indicate an internal component error	1. Contact customer support for further assistance. (See page 16)

RMR and Nutrition Assessment

Why is it necessary to measure oxygen consumption?

Most healthcare professionals recognize that resting metabolic rate is impacted by unique characteristics such as age, obesity, body composition (muscle versus fat), recent weight changes, disease state, surgery, fever, stress, and medications. When assessing a patient's nutritional needs, knowledge of RMR is critically important for determining the patient's unique nutritional needs.

In the clinical setting, a patient's resting metabolic rate may increase or decrease significantly depending on the patient's status. For example, when a patient develops a fever, RMR may increase significantly. Monitoring these changes will allow the healthcare professional to revise nutrition recommendations to meet the patient's changing needs. In some instances, this will mean measuring RMR daily.

In outpatient settings, it is appropriate to remeasure every ± 10% weight change to ensure continued weight management success.

Factors Influencing Oxygen Consumption and RMR

- **Body weight:** A larger person will typically have a higher oxygen consumption because the body must provide energy to support the extra body mass.
- **Body composition:** Muscle requires more oxygen than fat, even at rest. People with a higher percentage of muscle will usually have a higher RMR. Exercise, especially resistance training, can increase lean tissue, and therefore increase RMR.
- **Age:** RMR declines naturally in adults at a rate of about 3% per decade after age 30. However, this decrease is primarily a result of muscle loss.
- **Gender:** Men normally have a higher oxygen consumption than women, partly because they tend to have a lower percentage of body fat than women.
- **Hormones:** Certain hormones can increase or decrease oxygen consumption. The thyroid gland has the most marked effect on metabolism.
- **Stress:** Stress, trauma, burns, infections, and sepsis promote a hypermetabolic response. The severity of the surgical procedure or the trauma influences the metabolic response.
- **Medications:** Medications can increase or decrease oxygen consumption depending on the mechanism of action.
- **Genetics:** There are many genetic factors that may increase or decrease resting metabolic rate.

Important Safety Information

- The MedGem device is provided solely to measure personal respiratory airflow and oxygen consumption. This product is in no way a substitute for medical counseling.
- Always follow basic safety precautions when using this product to reduce the risk of injury, fire, or electrical shock.
- Read and understand all instructions in the Operator's Manual.
- To protect against electrical shock, do not use this product near or in water.
- Do not use liquids or aerosol sprays for cleaning. If the product comes in contact with any liquids, unplug the power cord immediately. Do not plug the MedGem device back in until it has dried thoroughly.
- Unplug the power supply unit from the wall outlet when not in use.
- To avoid choking or strangulation, avoid entanglement of the power cable around the user's neck.
- Use this product in a protected location where no one can trip over the power cord. Protect the power cord from damage or abrasion.
- Protect the MedGem device from extreme temperatures and avoid exposure to excessive heat or moisture that can damage internal components.
- Do not attempt to disassemble or alter any part of this equipment that is not expressly described in this manual. Disassembly or alteration may result in shock or injury. All maintenance or repair must be performed by a Microlife authorized service agent.
- Stop operating the equipment immediately if it is dropped and the casing is damaged. Never touch internal components of the equipment that have become exposed as a result of damage.
- Stop operating the equipment immediately in the event that it emits smoke or noxious fumes. Immediately unplug the power supply from the electrical socket, and contact Microlife customer support, for further instructions.
- Use of power sources not expressly recommended for this equipment may lead to overheating, fire, electrical shock, or other hazards. Use only Microlife approved power supplies and accessories distributed by Microlife.
- This equipment has been tested and found to comply with the limits for the Medical Device Directive 93/42/EEC (EN 60601-1-1 and 60601-1-2). These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. The equipment generates and can radiate radio frequency energy and, if not installed and used in accordance with these instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference with other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one of the following measures:

- Reorient or relocate the receiving device.
- Increase the separation between equipment.
- Connect the equipment into an outlet on a circuit different from that to which the other device(s) is connected.
- Consult the manufacturer for help.
- This equipment should not be used adjacent or stacked with other equipment.

Guidance and manufacturer´s declaration – electromagnetic emission – for all EQUIPMENT AND SYSTEMS

1	**Guidance and manufacturer´s declaration – electromagnetic emission**		
2	The model MedGem(200-0001-22) / BodyGem(200-0001-12) is intended for use in the electromagnetic environment specified below. The customer or the user of the model MedGem(200-0001-22) / BodyGem(200-0001-12) should assure that it is used in such an environment.		
3	**Emission test**	**Compliance**	**Electromagnetic environment – guidance**
4	RF emissions CISPR 11	Group 1	The Model MedGem(200-0001-22) / BodyGem(200-0001-12) uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
5	RF emissions CISPR 11	Class A	The Model MedGem(200-0001-22) / BodyGem(200-0001-12) is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
6	Harmonic emissions IEC 61000-3-2	Class A	
7	Voltage fluctuations /flicker emissions IEC 61000-3-3	Compliance	

Guidance and manufacturer's declaration – electromagnetic immunity – for all EQUIPMENT and SYSTEMS

Guidance and manufacturer´s declaration – electromagnetic emission			
The Model MedGem(200-0001-22) / BodyGem(200-0001-12) is intended for use in the electromagnetic environment specified below. The customer or the user of the Model MedGem(200-0001-22) / BodyGem(200-0001-12) should assure that it is used in such an environment.			
Immunity test	**Emission test**	**Compliance**	**Electromagnetic environment - guidance**
Electrostatic discharge(ESD) IEC 61000-4-2	Contact:±8 kV Air±2 kV,±4 kV,±8 kV,±15 kV	Contact:±8 kV Air±2 kV,±4 kV,±8 kV,±15 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst IEC 61000-4-4	+ 2kV for power supply lines + 1kV for input/output lines	+ 2kV for power supply lines Not applicable	Mains power quality should be that of a typical professional healthcare environment.
Surge IEC 61000-4-5	+ 0.5kV, +1kV line(s) to line(s) + 0.5kV, +1kV,+ 2kV line(s) to earth	+ 0.5kV, +1kV line(s) to line(s) Not applicable	Mains power quality should be that of a typical professional healthcare environment.
Voltage Dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Voltage dips: 0 % UT; 0,5 cycle 0 % UT; 1 cycle| 70 % UT; 25/30 cycles Voltage interruptions: 0 % UT; 250/300 cycle	Voltage dips: 0 % UT; 0,5 cycle 0 % UT; 1 cycle 70 % UT; 25 cycles Voltage interruptions: 0 % UT; 250 cycle	Mains power quality should be that of a typical professional healthcare environment. If the user of the Model MedGem(200-0001-22) / BodyGem(200-0001-12) requires continued operation during power mains interruptions, it is recommended that the Model MedGem(200-0001-22) / BodyGem(200-0001-12) be powered from an uninterruptible power supply or a battery.

Power frequency(50, 60 Hz) magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz	The Model MedGem(200-0001-22) / BodyGem(200-0001-12) power frequency magnetic fields should be at levels characteristic of a typical location in a typical professional healthcare environment.
NOTE *UT is the a.c. mains voltage prior to application of the test level.*			

Guidance and MANUFACTURER'S declaration – electromagnetic IMMUNITY

Guidance and manufacturer's declaration – electromagnetic immunity

The Model MedGem(200-0001-22) / BodyGem(200-0001-12) is intended for use in the electromagnetic environment specified below. The customer or the user of the Model MedGem(200-0001-22) / BodyGem(200-0001-12) should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms 150 kHz to 80 MHz outside ISM bandsa	3 Vrms: 0,15 MHz – 80 MHz 6 Vrms: in ISM bands between 0,15 MHz and 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the 200-0001-22, 200-0001-12 including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	80 % AM at 1 kHz 3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	Recommended separation distance: d = 1,2 d = 1,2 80MHz to 800 MHz d = 2,3 800MHz to 2,7 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 *At 80 MHz and 800 MHz, the higher frequency range applies.* ***NOTE 2*** *These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.*			

Recommended separation distances between portable and mobile RF communications equipment and the model MedGem(200-0001-22) / BodyGem(200-0001-12)

The Model MedGem(200-0001-22) / BodyGem(200-0001-12) is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Model MedGem(200-0001-22) / BodyGem(200-0001-12) can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Model MedGem(200-0001-22) / BodyGem(200-0001-12) as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output of transmitter	**Separation distance according to frequency of transmitter m**		
W	150 kHz to 80 MHz d =1,2	80 MHz to 800 MHz d =1,2	800 MHz to 2,7 GHz d =2,3
0.01	0,12	0,12	0,23
0.1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters rated at a maximum output power not listed above the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 *At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.*

NOTE 2 *These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.*

Manufacturer's declaration-electromagnetic immunity
Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

The Model MedGem(200-0001-22) / BodyGem(200-0001-12) is intended for use in the electromagnetic environment (for professional healthcare) specified below.
The customer or the user of the Model MedGem(200-0001-22) / BodyGem(200-0001-12) should assure that it is used in such an environment.

Test frequency (MHz)	Band a) (MHz)	Service a)	Modulation b)	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)	Compliance LEVEL (V/m) (for professional healthcare)
385	380-390	TETRA 400	Pulse modulation b) 18 Hz	1.8	0,3	27	27
450	430-470	GMRS 460, FRS 460	FM c) ±5 kHz deviation 1 kHz sine	2	0,3	28	28
710	704-787	LTE Band 13, 17	Pulse modulation b) 217 Hz	0,2	0,3	9	9
745							
780							
810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation b) 18 Hz	2	0,3	28	28
870							
930							
1720	1700 –1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation b) 217 Hz	2	0,3	28	28
1845							
1970							
2450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation b) 217 Hz	2	0,3	28	28
5240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation b) 217 Hz	0,3	0,3	9	9
5500							
5785							

NOTE *If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.*

a) For some services, only the uplink frequencies are included.
b) The carrier shall be modulated using a 50 % duty cycle square wave signal.
c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

MedGem Specifications

VO2 Measurement Range: 72 to 721 ml/min
VO2 Measurement Resolution: 1 ml/min
RMR Measurement Range: 500 to 5000 kilocalories per day
RMR Measurement Resolution: 10 kilocalories per day

MedGem Power and Data Communications Jack:
RS232 Data output,
11-12V DC, 180 mA Power Input, typical

Operating Range:
Tidal Volume: 500 to 1500 ml

Operating Environment:
Temperature: 15° to 30° C (59° to 86° F)
Relative Humidity: 10 to 88% RH Non-condensing
Elevation: -30 to 3040 meters (-100 to 10,000 feet)

Storage and transport Environment:
Temperature: -10° to +50° C (+14° to +122° F)
Relative Humidity: 5% to 95% RH Non-condensing

Power Supply:
Note: For use only with the Microlife supplied DC power supply P/N: 307-0001-04
Input Voltage: AC 100 to 240 V (50-60 Hz)
Rated Input: 2 Watts

Data Port:
RS-232 Serial Port
Note: For use only with the optional Microlife data cable
(p/n 306-0002-01)

MedGem Dimensions: 5.5 x 5.5 x 11.5 cm (2.2 x 2.2 x 4.5 in)
MedGem Weight: 110 gm (4 oz)
There are no user serviceable parts in the MedGem, please return to Microlife for servicing.
Certifications:

Symbol information

	Manufactured by		Temperature limit
	Date of manufacture	REF	Catalogue number
	Keep dry		Comply with WEEE Directive 2012/19/EU
SN	Serial number		Refer to instruction manual or booklet
	Humidity limitation		Direct current
FC	FCC Certification		Type B applied part

Declaration of Conformity

WHOLECARE BIOMEDICAL CORPORATION
8F., NO.443, RUIGUANG RD., NEIHU DIST., TAIPEI CITY 11492, TAIWAN (R.O.C.)
service@microlife.com.tw
www.microlife.com.tw

Wholecare Biomedical declares under its sole responsibility that the product MedGem complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

1. This device may not cause harmful interference, and
2. This device must accept any interference received, including interference that may cause undesired operation.

NOTE: *This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:*

- *Reorient the receiving antenna*
- *Increase the separation between the equipment and receiver*
- *Move the computer away from the receiver*
- *Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.*

Tested to comply with FCC standards for office use.

Changes or modifications to the device not expressly approved and authorized by Microlife Medical Home Solutions, Inc. could void the FCC approval and negate the user's authority to operate the product. Disassembly or modification by other than authorized service personnel shall void any applicable warranties for this product.

Complies with IEC 60601-1, ANSI/AAMI ES60601 and CSA C22.2 NO. 60601-1

Type B Applied Part.

Class II equipment; (Double insulated, i.e. no protective earth connection in power supply).
Mode of operations: Short-Time operation.

Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

IPX0 rating (degree of protection against ingress of water)=0

Use with Microlife DC power supply (P/N 307-0001-04).

Warranty Policies

MICROLIFE MEDICAL HOME SOLUTIONS WARRANTY POLICY FOR WATCHWT MEDGEM AND BODYGEM KITS

The following conditions and terms are enclosed for your understanding and information on our return and warranty policies.

Customer Satisfaction Issues:

For assistance with these issues contact Sales Support Email: info@MiMHS.com

1. Wrong order, dis-satisfied with product.
   - 45 day return privilege from date of order.
   - Customer pays shipping and handling.
   - Restocking charge of $45.00
   - Refund processed upon review of product, product is in working order with no damages and all of product returned including mouthpieces and software.
2. Measurements have been used on the device.
   - 45 day return privilege from date of order.
   - Customer pays shipping and handling.
   - Twenty ($20) charge per mouthpiece used.
   - Restocking charge of $45
   - Refund processed upon review of product, product is in working order with no damages and all products are returned including mouthpieces and software.
3. Software return policy.
   - If package has been opened there is no refund.
   - If package is still sealed, purchase price refunded minus a Re-stocking fee of $10
4. Error 40 Code.
   - Contact Sales Support to purchase a new device, pricing determined by market value and selected products.

Customer Satisfaction Issues:

For Assistance Email: info@MiMHS.com

5. Product was defective.
   - Microlife Medical Home Solutions, Inc. to provide replacement device with return shipping label to return defective device.
6. Returned for calibration/evaluation (out of warranty).
   - There is a $99.00 evaluation charge.
   - Customer pays shipping.
7. Returned for calibration (out of warranty) and product failed.
   - Customer calibration fee will be applied to the purchase of a new device.
   - Pricing will be determined by market value and selected products.

For any other warranty issues please Email: info@MiMHS.com

Limited Warranty. Microlife Medical Home Solutions, Inc. warrants to you that this product, when used in accordance with the operator's manual, will be free from defects in material and workmanship, under normal use, for a period of two years from date of purchase. The entire liability of Microlife Medical Home Solutions, Inc. and your exclusive remedy shall be limited to, at Microlife Medical Home Solutions, Inc.'s option, the repair or replacement of the product, or any part thereof. This warranty does not cover replacement of products damaged by abuse, misuse, alteration, self-

repair, loss or theft. THE LIMITED WARRANTY SET FORTH IN THIS SECTION GIVES YOU SPECIFIC LEGAL RIGHTS. YOU MAY HAVE OTHER RIGHTS, WHICH VARY FROM STATE TO STATE OR JURISDICTION TO JURISDICTION.

This warranty does not cover replacement of products damaged by abuse, misuse, alteration, self-repair, loss or theft.

DISCLAIMER OF OTHER WARRANTIES. EXCEPT FOR THE LIMITED WARRANTY SET FORTH ABOVE, MICROLIFE MEDICAL HOME SOLUTIONS, INC. HEREBY EXPRESSLY DISCLAIMS ALL WARRANTIES WITH REGARD TO THE PRODUCT, WHETHER EXPRESS, IMPLIED, OR STATUTORY, INCLUDING BUT NOT LIMITED TO ANY IMPLIED WARRANTIES OF NON-INFRINGEMENT OF THIRD-PARTY RIGHTS, MERCHANTABILITY, OR FITNESS FOR ANY PARTICULAR PURPOSE. MICROLIFE MEDICAL HOME SOLUTIONS, INC. DOES NOT AND CANNOT WARRANT THE PERFORMANCE OR RESULTS YOU MAY OBTAIN BY USING THE PRODUCT. YOU acknowledge that YOU haVE relied on no warranties other than the express warranties in this Agreement and that no warranties are made by any of MICROLIFE MEDICAL HOME SOLUTIONS, INC. 'S suppliers. Some states or jurisdictions do not allow the exclusion of implied warranties or limitations on how long an implied warranty m ay last, so the above limitations may not apply to you.

No Medical Advice. Any information, content or results available through use of the product are made available to you for informational purposes only and should not be construed as medical advice. Use of the product or any information, content or results available through such use is not intended to be a substitute for professional medical advice, diagnosis or treatment. Always seek the advice of your physician or other qualified healthcare provider with any questions you may have regarding a medical condition. Never disregard professional medical advice or delay in seeking it because of any information, content or results you obtain from the product. Reliance on any information, content or results available through use of the product is solely at your own risk.

MICROLIFE MEDICAL HOME SOLUTIONS WARRANTY POLICY FOR MEDGEM AND BODYGEM SMART GEM KITS

The following conditions and terms are enclosed for your understanding and information on our return and warranty policies.

Customer Satisfaction Issues:

For assistance with these issues contact Sales Support Email: info@MiMHS.com

1. Wrong order, dis-satisfied with product.
   - 45 day return privilege from date of order.
   - Customer pays shipping and handling.
   - Restocking charge of $45.00
   - Refund processed upon review of product, product is in working order with no damages and all of product returned including mouthpieces and software.
2. Measurements have been used on the device.
   - 45 day return privilege from date of order.
   - Customer pays shipping and handling.
   - Twenty ($20) charge per mouthpiece used.
   - Restocking charge of $45
   - Refund processed upon review of product, product is in working order with no damages and all products are returned including mouthpieces and software.
3. Software return policy.
   - If package has been opened there is no refund.
   - If package is still sealed, purchase price refunded minus a Re-stocking fee of $10
4. Error 40 Code.
   - Contact Sales Support to purchase a new device, pricing determined by market value and selected products.

Product Warranty Issues:

For Assistance Email: info@MiMHS.com

5. Product was defective.
   - Microlife Medical Home Solutions, Inc. to provide replacement device with return shipping label to return defective device.
6. Returned for calibration/evaluation (out of warranty).
   - There is a $99.00 evaluation charge.
   - Customer pays shipping.
7. Returned for calibration (out of warranty) and product failed.
   - Customer calibration fee will be applied to the purchase of a new device.
   - Pricing will be determined by market value and selected products.

For any other warranty issues please Email: info@MiMHS.com

Limited Warranty. Microlife Medical Home Solutions, Inc. warrants to you that this product, when used in accordance with the operator's manual, will be free from defects in material and workmanship, under normal use, for a period of two years from date of purchase. The entire liability of Microlife Medical Home Solutions, Inc. and your exclusive remedy shall be limited to, at Microlife Medical Home Solutions, Inc.'s option, the repair or replacement of the product, or any part thereof. This warranty does not cover replacement of products damaged by abuse, misuse, alteration, self-

repair, loss or theft. THE LIMITED WARRANTY SET FORTH IN THIS SECTION GIVES YOU SPECIFIC LEGAL RIGHTS. YOU MAY HAVE OTHER RIGHTS, WHICH VARY FROM STATE TO STATE OR JURISDICTION TO JURISDICTION.

This warranty does not cover replacement of products damaged by abuse, misuse, alteration, self-repair, loss or theft.

DISCLAIMER OF OTHER WARRANTIES. EXCEPT FOR THE LIMITED WARRANTY SET FORTH ABOVE, MICROLIFE MEDICAL HOME SOLUTIONS, INC. HEREBY EXPRESSLY DISCLAIMS ALL WARRANTIES WITH REGARD TO THE PRODUCT, WHETHER EXPRESS, IMPLIED, OR STATUTORY, INCLUDING BUT NOT LIMITED TO ANY IMPLIED WARRANTIES OF NON-INFRINGEMENT OF THIRD-PARTY RIGHTS, MERCHANTABILITY, OR FITNESS FOR ANY PARTICULAR PURPOSE. MICROLIFE MEDICAL HOME SOLUTIONS, INC. DOES NOT AND CANNOT WARRANT THE PERFORMANCE OR RESULTS YOU MAY OBTAIN BY USING THE PRODUCT. YOU acknowledge that YOU haVE relied on no warranties other than the express warranties in this Agreement and that no warranties are made by any of MICROLIFE MEDICAL HOME SOLUTIONS, INC. 'S suppliers. Some states or jurisdictions do not allow the exclusion of implied warranties or limitations on how long an implied warranty m ay last, so the above limitations may not apply to you.

No Medical Advice. Any information, content or results available through use of the product are made available to you for informational purposes only and should not be construed as medical advice. Use of the product or any information, content or results available through such use is not intended to be a substitute for professional medical advice, diagnosis or treatment. Always seek the advice of your physician or other qualified healthcare provider with any questions you may have regarding a medical condition. Never disregard professional medical advice or delay in seeking it because of any information, content or results you obtain from the product. Reliance on any information, content or results available through use of the product is solely at your own risk.

Contact Information

Microlife Medical Home Solutions, Inc.
Email: info@MiMHS.com
www.MiMHS.com

MedGem is manufactured for MiMHS
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Taipei City 11492, Taiwan ROC