microlife®

BodyGem

Indirect Calorimeter

BodyGem(200-0001-12)

Instruction Manual

EN

About the BodyGem Device by Microlife Medical Home Solutions, Inc.

The BodyGem device by Microlife Medical Home Solutions is a handheld indirect calorimeter that measures resting metabolic rate (RMR), the number of calories a person burns in a day at rest. Knowing your client's RMR and monitoring them on a regular basis is a key element in monitoring their nutritional needs and in helping them achieve their weight management goals.

The BodyGem is easy to use, delivering an RMR measurement quickly and accurately. Useful as a tool for monitoring changes in metabolism, BodyGem gives you important information to help Individuals achieve personal weight management and nutrition goals.

Before using the BodyGem device, refer to the safety information on page 12.

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

Microlife Medical Home Solutions,Inc. • 2801 Youngfield St., Suite 241 • Golden, CO 80401 USA • 1-800-968-1378 • www.MiMHS.com

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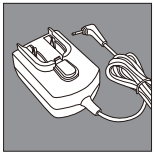
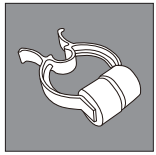
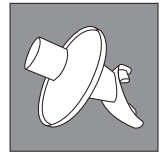


A) Power Supply

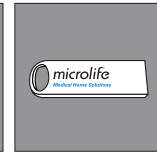


B) Nose Clip

C) BodyGem Device



D) Single-Use Mouthpiece



E) USB Flash Drive

BodyGem Device

This device measures RMR and displays the measurement results in the LCD screen at the front of the unit. The DC power supply, flow tube and mouthpiece attach to the main indirect calorimeter.

Power Supply

Plug the DC power supply into a wall outlet. Attach the DC power supply cable to the connector on the side of the BodyGem.

Single-Use Breathing Attachments*

The BodyGem indirect calorimeter uses a single-use mouthpiece and nose clip. The mouthpiece is inserted into the flow tube and is used with a nose clip 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.*

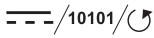
Analyzer software can be downloaded in the following website. Please use RS232 cable with power input approved by manufacturer.

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

BodyGem Symbols:

Indicator Light

Press to Start Button



DC Power In/Data/Reset

Using the BodyGem Device

When to Use the BodyGem Device

To obtain a true resting metabolic rate (RMR), it is important that your client is in a calm and relaxed state. If your client has been active or stressed, or has recently eaten or exercised, that rate of energy expenditure (metabolism) that the BodyGem measures will be accurate for that condition but not representative of actual RMR. Ideally, RMR is measured 4 hours after eating or exercise. If you are using the BodyGem in other conditions, have your client sit quietly and rest for 15 minutes.

How to Use the BodyGem Device

It is important to use the BodyGem device while quiet and relaxed in a seated or reclined position as this measurement can be affected by noise and distractions. Make sure that there is no tension on the power cord before you begin.

How Often to Use the BodyGem Device

Microlife suggests measuring RMR with the BodyGem device after ±10% weight change and at maintenance to monitor changes in metabolism as part of a nutrition, weight management or fitness program.

How to Store the BodyGem Device

To protect the sensors inside the BodyGem device, it is recommended that you leave the device standing upright between uses and store it in its case when not in use. Do not lay the BodyGem device on its side other than inside the case.

Caution: *Do not expose the device O2 sensors to direct sunlight or UV light. The O2 sensors are located behind the flow tube and are exposed if the flow tube is removed. Therefore, do not remove the flow tube.*

The BodyGem 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 BodyGem 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 BodyGem device will beep once. The BodyGem device is on and warming up.
- The indicator light on top of the unit will briefly show red and then cycle to amber when ready for calibration.
- If using a SmartGem* model (with pre loaded measurements), then the LCD screen will display the number of measurements remaining. (Fig. B - *Applies to SmartGems only)

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.*

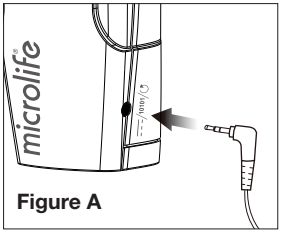


Figure A

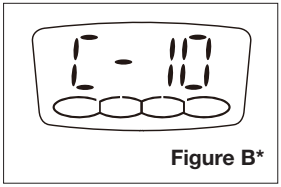


Figure B*

Single-Use Breathing Attachments:

- Insert the single-use mouthpiece into the flow tube on the BodyGem device until it fits snugly (Fig. C)
- Ensure that the flow tube fits snugly into the BodyGem device. The top of the flow tube should be flush with the BodyGem device unit (Fig. D & E).

Note: *When you receive the BodyGem device, the flow tube should already be inserted. Simply insert the single-use mouthpiece into the flow tube after ensuring that the flow tube is fitted snuggly to the device. Be careful not to touch the part of the mouthpiece that goes in the client's mouth.*

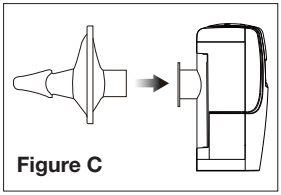


Figure C

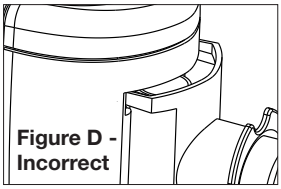


Figure D - Incorrect

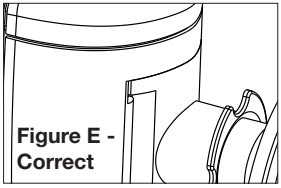


Figure E - Correct

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

Step 2 - BodyGem Self-Calibration:

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

NOTE: *It is very important to leave the BodyGem 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 BodyGem device until it beeps and the amber indicator light flashes green.*

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

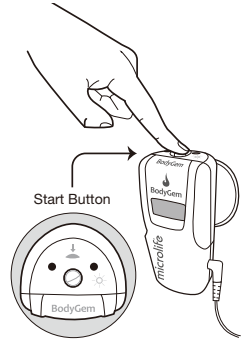


Figure F

When the BodyGem device is ready to begin a measurement, the indicator light will flash green and the BodyGem 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 stand-by mode, press the Start Button. The BodyGem 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 with nose clip on the client.
- 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 client is seated, comfortable and they have been instructed not to move during the measurement. They will need to hold the BodyGem 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 BodyGem device will buzz softly throughout the 5-10 minute measurement period.

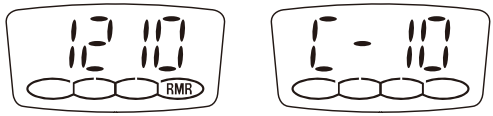
Note: *Measurement time will vary, as the time needed to reach a steady state of breathing is patient-specific.*

At the completion of the measurement, the BodyGem device will beep and the indicator light will change back to amber, signaling the end of the measurement.

Step 4 - Obtain RMR Reading from the BodyGem LCD screen

Remove the device from the client and discard the single-use mouthpiece. Do not iscard the flow tube. The RMR measurement result will be displayed in the LCD window.

If using a SmartGem model, with pre loaded measurements, the LCD screen will also display the number of measurements remaining. These readings will alternate every two seconds until another measurement is taken.



Enter the RMR reading from BodyGem into the BodyGem Analyzer[1] software program then use this information to develop a personalized nutrition and weight management plan, including a daily calorie budget, nutrient targets and an exercise target for your client.

Precautionary Measures

- To hold the BodyGem 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 BodyGem on page 8 for more details.

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

1 *The BodyGem Analyzer software by Microlife Medical Home Solutions allows professionals to create personalized calorie budgets, exercise targets and diet plans for individual clients using the real-time RMR data captured from their BodyGem measurement.*

Caring for the BodyGem Indirect Calorimeter

The BodyGem Device Cleaning Instructions

The BodyGem 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. There are components and sensors exposed when the flow tube is removed that may be damaged if exposed to water or cleaning solvents. Therefore, do not remove the flow tube from the device. **DO NOT SUBMERGE THE BODYGEM DEVICE IN WATER OR ALLOW WATER OR ANY SOLUTION TO PENETRATE THE DISPLAY WINDOW, SOCKETS, OR OPENINGS ON THE PRODUCT.**

Cleaning Limitations

To prevent damage to the flow tube, avoid the following:

- Heat should not equal or exceed 45ºC (113ºF)
- Autoclaving Pasteurization
- Ethylene Oxide (ETO)
- Solvents (Examples include Benzene, Acetone and all Hydrocarbons)

WARNING: DO NOT submerge the BodyGem device in liquid.

Protecting the BodyGem Device from Damage

Protect the BodyGem 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 eplacement parts. There are no user-serviceable parts inside the BodyGem device.

How to Store the BodyGem Device

To protect the sensors inside the BodyGem device, it is recommended that you leave the BodyGem 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 call Microlife Customer Support at 1-800-968-1378*

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

Troubleshooting

If there is a problem with the BodyGem device, the following will occur:

1. The indicator light on the top of the BodyGem 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 BodyGem LCD window.
4. Use the Error Code and Solution Table (below) to remedy the problem.
5. Once the problem has been identified, unplug the BodyGem device from the power supply to erase the error code.
6. Reconnect the power supply to turn the BodyGem 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 15).
9. Device may shut down during power failure, and will automatically reboot when electricity return to normal. Contact customer support If there's any issue.

BodyGem 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 BodyGem 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 BodyGem 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 BodyGem 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 BodyGem device. 3. Do not move the BodyGem device if it beeps once and the light flashes green. 4. If the BodyGem 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 BodyGem 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 BodyGem 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 BodyGem device. * *Contact Customer Service if this error persists (see page 15).*
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 BodyGem 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 BodyGem
Any error codes other than those listed above, may indicate an internal component error	1. Contact customer support for further assistance. (See page 16)

All About Your Metabolism

What is metabolism?

Metabolism is the body's process of converting food and stored fat into energy. This energy is used to stay warm, move around and keep vital organs functioning. Metabolism is typically measured in calories.

Total metabolic rate represents the calories needed to maintain body functions, daily activity (occupational and lifestyle) and exercise.

What is RMR?

Resting metabolic rate (RMR) represents the number of calories required by the body in 24 hours to maintain vital body functions (such as heart rate, brain functions and breathing). In simple terms, it is the number of calories a person would burn if he or she were awake but at rest all day. RMR can account for up to 75% of a person's total energy expenditure.

Why is it necessary to measure RMR?

Metabolism is impacted by unique characteristics such as gender, age, weight, body composition (amount of muscle versus fat), level of fitness, physical activity, eating, stimulants, emotional excitement, stress and gaining and losing weight. A knowledge of RMR is important in managing caloric needs. Traditionally, it has been difficult and expensive to accurately measure RMR, so people have used estimates, which are inaccurate on many people.

Because metabolism is different among individuals and is influenced by many factors, it should be measured regularly during a weight management program. Your metabolism can vary from daytoday and within the same day. That is why it is important to measure your metabolism under similar conditions to get the most accurate reading of resting metabolism.

Why is RMR unique to each individual, and why could it change?

RMR is influenced by a number of factors, including:

- **Body weight**
- **Body Composition (the amount of fat and muscle)**
- **Age**
- **Gender**
- **Hormones**
- **Stress**
- **Use of stimulants such as caffeine**

- **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 burns more calories than fat, even at rest. People with a higher percentage of muscle will usually have a higher metabolic rate. In an example from a recent weight management study, Woman A, who weighed 158 lbs with 33% body fat, had a measured RMR of 1570 calories a day, while woman B, who also weighed 158 lbs but with a body fat of 48%, had a measured RMR of 1250 calories per day. At the same wight, similar height and same age, these women have very different RMR values due, in part, to differences in body fat .[1] Exercise, especially resistance training, can increase lean tissue, and therefore positively affect 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.
- **Stimulants and Pharmaceuticals:** Caffeine and other stimulants such as ephedrine can temporarily stimulate body functions and increase RMR. Drugs may either increase or decrease RMR. These effects can cause the resting metabolism reading to be inaccurate. Try to avoid use of stimulants and nonessential pharmaceuticals for at least 12 hours before the measurement.
- **Genetics:** There are many genetic factors that may increase or decrease resting metabolic rate.

Metabolism and Weight Loss

When individuals lose weight, their metabolic rate may decrease. This should not be a cause for alarm since this decrease is part of the body's normal response to calorie restriction and may be associated with tissue loss (fat and muscle). Weight loss ideally results in proportionally more fat loss than muscle loss. Exercise during weight loss can lessen the muscle loss, but most people will experience some muscle loss.

During weight loss the body may also lower metabolism in response to a lower calorie intake. Most people experience this change in metabolism without realizing it. Weight loss may be easy for the first few pounds, then become more difficult, and may even plateau. At a lower metabolic rate, an individual must adjust dietary intake and/or exercise to lose additional weight. The good news is that after weight loss, metabolism may increase slightly once the person's weight is stable. For the most effective weight management program, it is helpful to monitor changes in metabolism following 10% weight loss.

Metabolism and High Fitness

Individuals who are highly fit and have a higher percentage of muscle mass will typically have a higher RMR. Muscle is a "metabolically active" tissue and requires more calories to maintain than fat tissue.

1 Alexander et. al, Efficacy of a Resting Metabolic Rate Based Energy Balance Prescription in a Weight Management Program. Presented at Nutrition Week, San Diego, CA. 2/02.

Important Safety Information

- The BodyGem 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 BodyGem 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 BodyGem 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 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.
- Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC standards (e.g. IEC 60950 for data processing equipment and IEC 60601-1 for medical equipment). Furthermore, all configurations shall comply with the system standard IEC 60601-1-1. Any person who connects equipment to the signal input part or signal output part configures a medical system and is therefore responsible for ensuring that the system complies with the requirements of the system standard IEC 60601-1. If in doubt, consult Microlife customer support.

Caution: This equipment is not intended for use in residential environments and may not provide adequate protection to radio reception in such environments.

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 other than domestic 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 immunity			
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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.

BodyGem Specifications

RMR Measurement Range: 500 to 5000 kilocalories per day
RMR Measurement Resolution: 10 kilocalories per day

BodyGem 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)

BodyGem Dimensions: 6.0 x 5.6 x 11.8 cm (2.4 x 2.3 x 4.6 in)
BodyGem Weight: 130 gm (4.6 oz)

There are no user serviceable parts in the BodyGem device, please return to Microlife customer support department for servicing.

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
	FCC Certification		Type B applied part

Declaration of Conformity

WHOLECARE BIOMEDICAL CORPORATION
9F., NO.439, 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 BodyGem 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 at 1-800-968-1378

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 call Customer Support at 1-800-968-1378

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 call Customer Service@ 1-800-968-1378

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 at 1-800-968-1378

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 call Customer Support at 1-800-968-1378

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 call Customer Service@ 1-800-968-1378

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.

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