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RIGHTTEST
Continuous Glucose Monitoring System



User's Manual
For use with mobile App

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READ THIS FIRST :

It is important to read the entire contents of this manual before using the RIGHTEST Continuous Glucose Monitoring System. The instructions, warnings, precautions, safety information and tips contained within this manual are intended to ensure proper use and optimal results. Discuss the best way to use your Rightest CGMs with your healthcare professional. Failure to operate the system according to the guidelines and safeguards specified in this manual may present risks. If your glucose readings do not match your symptoms or how you are feeling, check your blood glucose level with a blood glucose meter and consult a healthcare professional if necessary.

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INDICATIONS FOR USE & STATEMENT AND ADVISORY

INDICATIONS FOR USE

The RIGHTEST Continuous Glucose Monitoring System (hereafter referred to as the "RIGHTEST CGMs") is indicated for detecting glycemic trends and for the management of diabetes in persons aged 4 to 80. It is an applied device designed to replace fingerstick blood glucose testing for diabetes treatment decisions. Interpretation of the RIGHTEST CGMs results is based on the glucose trends and several sequential readings over time. It also aids in detecting episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments.

This system can be use with the dedicated mobile App or the receiver as display device.

STATEMENT AND ADVISORY

This manual is designed to instruct all personnel responsible on the proper use and care of the RIGHTEST CGMs in non-professional environments. All users are encouraged to read this manual carefully before using the system.

SAFETY INFORMATION

The following is a summary of safety information which must be observed before using the RIGHTEST CGMs. WARNING indicates potential danger to the user. PRECAUTION indicates potential injury to the user or damage to the system. To minimize risks, read the following safety information before using the system. Improper use and maintenance may damage the system resulting in failure or injury to the user. It is important to understand that this safety information is not exhaustive. It is intended to ensure the safety of the user when using the system.



CONTRAINDICATION :



No MRI/CT/Diathermy: The RIGHTEST CGMs (sensor, transmitter, receiver and/or other display devices) must be removed prior to Magnetic Resonance Imaging (MRI), Computed Tomography (CT), or high frequency electrical heat (diathermy) treatment. People who are unable or unwilling to contact with their healthcare professional are not recommended to use the RIGHTEST CGMs. Sufficient vision or hearing is critical for successful use of the system including effective recognition of the alerts.

WHEN NOT TO USE: DO NOT Use If You Are Pregnant, on Dialysis or Critically Ill. Do not use the RIGHTEST CGMs if you are pregnant, on dialysis or critically ill; or on users with other implanted medical devices (e.g. a pacemaker). The system has not been evaluated for use in these populations.

If you experience serious incidents caused by the use of the RIGHTEST CGMS, contact your local emergency services for help. Please report the incident to Bionime Corporation and the local competent authority.

**WARNINGS :****Use a Blood Glucose (BG) Meter To Make Treatment Decisions Under The Following Conditions:**

- During the first 1-hour warmup period when you start a new sensor. You will not receive any sensor readings, alarms or alerts until your system begins to transmit data.
- If you suspect that your sensor readings may be inaccurate for any reason.
- If your sensor readings do not match what you are feeling.
- If you are experiencing symptoms that may be due to low or high blood glucose.
- If your system does not include your current glucose concentration or a glucose trend arrow.
- If you wish to confirm hypoglycemia or impending hypoglycemia as reported by the system.
- If you are experiencing rapid glucose changes (greater than 2 mg/dL per minute), the sensor readings displayed may be less accurate and less timely.
- When you see  on your display device, you must check your BG value with a BG meter before making any treatment decisions. Sensor readings may be less accurate and may not reflect your current glucose levels.

Not receiving Urgent Alarms: The display device lets you know when your sensor readings drop to 54 mg/dL or below regardless your alert settings.

- When either your display device or transmitter battery is dead.
- When your display device is turned off.
- When there is a system error (e.g. no glucose readings, sensor error, signal loss, etc.) or damage to the system.
- During the 1-hour sensor warm-up period.
- If your sensor readings do not match what you are feeling.
- When the display device is out of range (6 meters/20 feet) from your transmitter; or obstacles (metal, walls, water, etc.) are between them.

Modification of the System is Not Permitted: Do not modify or tamper with any components or accessories of the RIGHTEST CGMs. Do not use any component of the RIGHTEST CGMS with any product not included in this system. Otherwise, you may damage the integrity of the system and put yourself at risk especially when you have a severe low or high glucose event.

Children or pets without adult supervision: Do not allow children or pets to play with any parts of RIGHTEST CGMs without adult supervision.

Choking Hazard: The RIGHTEST CGMs contains small components that may be dangerous if swallowed.

**PRECAUTIONS :**

Calibration Safety: Calibration is not required if users scan the sensor and transmitter codes. Otherwise, only use fingerstick blood glucose values to calibrate your system for accurate readings. Entering incorrect fingerstick blood glucose values or blood glucose values taken from testing at other places can result in inaccurate glucose readings, which may result in missing a high or low glucose event.

Skin Irritation Reaction Caused by the Sensor Adhesive: Some individuals may be sensitive to the medical adhesive that keeps the sensor attached to the skin. If you develop a rash around or under your sensor, remove the sensor and stop using the RIGHTEST CGMs. If necessary, consult your healthcare professional.

Avoid Skin Care Products: Do not apply skin care products such as sunscreen, moisturizer, perfume or insect repellent over the sensor insertion site or any components of the RIGHTEST CGMs. Failure to comply may lead to damage of the plastic used in the RIGHTEST CGMs or reduction in the stickiness of the sensor adhesive.

Do NOT Attempt to Reinsert a Sensor: If the adhesive patch is loose or if the sensor tip is pulled out from your skin, remove the sensor and replace it with a new sensor. Sensor readings may be unreliable until a new sensor is inserted.

Store the Sensor in a Cool and Dry Place: Store the sensor in a cool, dry place between 5°C to 30°C (41°F to 86°F) and 10-90% non-condensing humidity.

If the temperature may exceed 30°C (86°F), you may store a sensor in a refrigerator. Do not freeze sensors. Avoid direct sunlight, extreme temperatures, and high humidity. These conditions may damage the sensor and cause inaccurate sensor readings.

DO NOT Reuse Your Sensor or Inserter: The entire Sensor Kit package is sterilized and designed for single use. It is not suitable for re-sterilization. Re-sterilization of these components may result in no glucose readings and infections.

Use as Directed: The charging accessories provided with RIGHTEST CGMs comply with safety regulations for medical devices. Use only these components when charging your receiver and transmitter. Otherwise, the system may be damaged or a fire hazard may be presented. Make sure access to the power adapter is not blocked and it can be easily unplugged due to the potential risk of electrical shock.

Do NOT Put the Receiver In Contact with Water: Do not spill liquids on the receiver or submerge it in water or other liquids. If the receiver has fallen into water, do not touch it until you unplug it from any electrical outlet. Touching the receiver while it is wet may result in electric shock or no glucose results.

DO NOT Use If Any Component Appears to be Damaged: A damaged or cracked inserter, sensor, transmitter, or receiver may compromise the integrity of the system and contribute to infection risk.

Traveling by Air: Always check and follow flight rules and regulations before departure.

Notify the security personnel of the presence of the RIGHTEST CGMs and comply with requirements for pat-downs, visual inspection and metal detectors. You must comply with any requests by airline personnel (e.g. turning off the system). Do not pass through an advanced imaging technology (AIT) body scanner (e.g. millimeter wave scanners) or put RIGHTEST CGMs components through x-ray machines since the effect of this equipment on RIGHTEST CGMs has not been evaluated.

Changing Time Zone Is Not Permitted: You are not allowed to change time zone during the 14-day monitoring period. Changing the time or date settings during monitoring may result in gaps in the graph or hidden glucose readings.

Keep an Emergency Kit with You: Make sure necessary supplies are always available. Let your family, co-workers, or friends know where the emergency kit is.

The emergency kit should contain:

- Fast-acting glucose tablets.
- Blood glucose monitoring supplies.
- Insulin syringe and rapid-acting insulin (with dosage instructions from your healthcare professional).
- Adhesive dressing.
- Glucagon™ emergency kit.

Troubleshooting: If any situation not mentioned in this user manual occurs, please

contact your healthcare professional or Customer Service.

Be Careful of Electromagnetic Disturbance: Stacking equipment, or using AC power adapters, USB cables and USB chargers not provided with RIGHTEST CGMs may negatively influence on electromagnetic compatibility. Stay a distance greater than 30 cm (12 inches) from any part of any portable RF communications equipment and at least 1 meter from sensitive equipment. If abnormal behavior is observed due to EM disturbances, please relocate the device accordingly.

SYMBOL DEFINITIONS

The following symbols apply to the RIGHTEST CGMs:

	Date of Manufacture		Do not use if the package is damaged
	Manufacturer		Biological risks
Rx Only	Prescription Required		For single use only
LOT	Batch / Lot Number		Type BF applied part device
	Expiry date		Direct current
	Temperature limitation		Alternating current

	Humidity limitation	MD	Medical Device
STERILE R	Method of sterilization using irradiation		Keep Dry
SN	Serial Number		MR Unsafe
	Near-field communication (NFC) scan area		Importer
	Bluetooth		Refer to Instruction Manual / Booklet
	Class II Equipment		Warning / Precaution
	Input		Operating Instructions; consult manual for further instructions

	Keep away from heat		Discard this product according to local regulations
	Electrical Equipment Designed Primarily for Indoor Use (Chargers Only)		
IP21	Protected from touch by fingers and objects greater than 12.5 millimeters. Protected from vertical dripping water for 10 minutes		
IP22	Protected from touch by fingers and objects greater than 12.5 millimeters. Protected from dripping water when tilted at 15° for 10 minutes		
IP47	Protected from tools and small wires greater than 1 millimeter. Protected from immersion between 15 centimeters and 1 meter in depth.		

GETTING TO KNOW YOUR RIGHTEST CGMS
PERFORMANCE FEATURES

The RIGHTEST CGMs is an integrated continuous glucose monitoring system (iCGM) that provides glucose readings, trends, and levels every minute.

The RIGHTEST CGMs has user-friendly features and benefits including:

- Ergonomic design of sensor inserter allows users to insert the sensor safely with just one hand.
- Easy-to-read visual glucose values and trends.
- Powerful transmitter storage holds 14 days of glucose readings with zero data loss.
- Visual and audio alerts for to hypoglycemia and hyperglycemia.
- Lightweight sensor and transmitter for maximum comfort.