SenseWear® **biotransceiver**

for use with Accu-Chek® Advantage® Blood Glucose Monitor

Operating Manual

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BT-2.4-BG-LIT Rev.1

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NOTE:
Read these instructions and the ***Warnings and Cautions*** on pages 2-4 before using the Body Monitoring System.

Important Information About the SenseWear® biotransceiver

Intended Use
The SenseWear® biotransceiver can be used to collect data from OEM biometric monitors and upload it to the SenseWear® PRO_3 armbands or SenseWear® wireless gateway for applications such as: nutritional diagnostics, metabolic diseases, pediatrics, pulmonary and cardiac studies, geriatrics, internal medicine, occupational medicine, neurology, psychiatrics, sleep screening, and in general anywhere it is necessary to monitor caloric and energy consumption, movement, physical activity, quality of life, lifestyle, behavior and/or stress.

⚠ WARNINGS

This product complies with the general requirements for a safe medical device under applicable directives. However, this product alone is not meant to substitute for proper medical diagnosis, care, or treatment. Any decisions based on the data from this device should be made only by medical personnel and should consider the condition and lifestyle of the subject tested. The SenseWear® biotransceiver should not be used for life critical applications; improper usage may result in harm or even death to the wearer.

This product is non-defibrillation proof.

Do not place the device close to other devices that can cause electromagnetic interferences of any nature.

EQUIPMENT not suitable for use in the presence of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR or WITH OXYGEN OR NITROUS OXIDE.

Be sure to verify equipment is connected and used compliant to UL1950.

Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided on pages 5-8. Portable and mobile RF communications equipment can affect medical electrical equipment.

Important Information About the SenseWear® biotransceiver

⚠ WARNINGS

The equipment or system should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the equipment or system should be observed to verify normal operation in the configuration in which it will be used.

The SenseWear® biotransceiver should not be used in airplanes, hospitals or locations where cellular telephones or electronic devices are prohibited.

Keep the SenseWear® biotransceiver out of reach of children. The product contains smaller, removable parts which can become chocking hazards.

Water resistance
DO NOT IMMERSE THE BIOTRANSCEIVER IN WATER. The biotransceiver is not designed to be used underwater or to come in continuous contact with water. To prevent a shock hazard, never use the armband in water environments (e.g., in the shower, swimming pool, or rain). IPX0 classified.

Ordinary Protection, not protected against ingress to moisture.

⚠ CAUTIONS

Batteries
Batteries may explode or leak and can cause burn injury if recharged, disposed of in fire, or disassembled. Dispose of properly. For further information about the disposal battery, please following manufacturer's instructions.

Batteries may present a choking hazard for small children.

Remove battery if biotransceiver will not be used for over 30 days.

Important Information About the SenseWear® biotransceiver

⚠ CAUTIONS

Handling
Avoid exposing the biotransceiver to extreme temperatures, direct sunlight, moisture, sand, dust, or mechanical shock.

Dispose of device in accordance with local, state, federal, or country specific regulations.

Maintenance
Changes or modifications to this equipment not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

If the biotransceiver is dropped, ensure that it is working properly and not physically damaged before relying on readings.

Cleaning
Moisten a soft cloth or towel with mild disinfectant soap and water. Wipe and dry the biotransceiver. Never use solvents to clean the biotransceiver, only for disinfecting (see below).

Disinfecting
Wipe biotransceiver with soft cloth dampened with 70% isopropyl alcohol. Allow biotransceiver to dry for 5-10 minutes before using DO NOT STERILIZE THIS UNIT.

Important Information About the SenseWear® biotransceiver

Patient Environment

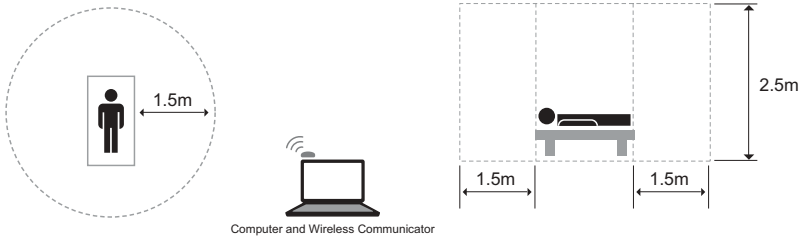

Diagram not to scale.

Guidance and Manufacturer's Declaration - Emissions		
The BT-2.4-BG (SenseWear® biotransceiver) is intended for use in the electromagnetic environment specified below. The customer or user of the BT-2.4-BG should ensure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF Emissions CISPR 11	Group 1	The BT-2.4-BG uses RF energy only for its inernal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The BT-2.4-BG is suitable for use in all establishments, including domestic, and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonics IEC 6100-3-2	Class A	
Flicker IEC 6100-3-3	Complies	

Important Information About the SenseWear® biotransceiver

Guidance and Manufacturer's Declaration - Immunity			
The BT-2.4-BG (SenseWear® biotransceiver) is intended for use in the electromagnetic environment specified below. The customer or user of the BT-2.4-BG should ensure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
ESD IEC 61000-4-2	±6kV Contact ±8kV Air	±6kV Contact ±8kV Air	Floors should be wood, concrete, or ceramic tile. If floors are synthetic, the r/h should be at least 30%.
EFT IEC 61000-4-4	±2kV Mains ±1kV I/Os	N/A	N/A
Surge IEC 61000-4-5	±1kV Differential ±2kV Common	N/A	N/A
Voltage Dips/ Dropout IEC 61000-4-11	>95% Dip for 0.5 Cycles 60% Dip for 5 Cycles 30% Dip for 25 Cycles >95% Dip for 5 Seconds	N/A	N/A
Power Frequency 50/60Hz Magnetic Field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be that of a typical commercial or hospital environment.

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Guidance and Manufacturer's Declaration - Emissions			
The BT-2.4-BG (SenseWear® biotransceiver) is intended for use in the electromagnetic environment specified below. The customer or user of the BT-2.4-BG should ensure 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 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	N/A 3 V/m	Portable and mobile communications equipment should be separated from BT-2.4-BG by no less than the distances calculated/listed below: • D=(3.5/V1)(Sqrt P) • D=(3.5/E1)(Sqrt P) 80 to 800 MHz • D=(7/EI)(Sqrt P) 800 MHz to 2.5 GHz where P is the max power in watts and D is the recommended separation distance in meters. Fleld strengths from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment containing a transmitter 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

Important Information About the SenseWear® biotransceiver

Field strenghts from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, and electromagnetic site survey should be considered. If the measured field strength in the location in which the BT-2.4-BG is used exceeds the applicable RF compliance level above, the BT-2.4-BG should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocationg the BT-2.4-BG.

Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended Separations Distances for the BT-2.4-BG			
The BT-2.4-BG (SenseWear® biotransceiver) is intended for use in the electromagnetic environment in which radiated disturbances are controlled. The customer or user of the BT-2.4-BG can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications Equipment and the BT-2.4-BG as recommended below, according to the maximum output power of the communications equipment.			
Max Output Power (Watts)	**Separation (m) 150kHz to 80MHz D=(3.5/V1)(Sqrt P)**	**Separation (m) 80 to 800MHz D=(3.5/V1)(Sqrt P)**	**Separation (m) 800MHz to 2.5GHz D=(7/E1)(Sqrt P)**
0.01	0.1166	0.1166	0.2333
0.1	0.3689	0.3689	0.7378
1	1.1666	1.1666	2.3333
10	3.6893	3.6893	7.3786
100	11.6666	11.6666	23.3333

For transmitters rated at a maximum output power not listed above, the recommended seperation distance d in meters (m) can be determined 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 seperation distance for the higher frequency range applies.
NOTE 2 These guideleines may not apply in all situations. Electromagnetic propogation is affected by absorption and reflection from structures, objects and people.

Important Information About the SenseWear® biotransceiver

Follow operating instructions.

Caution

3011299

Tested to applicable safety standards.

The Waste Electrical and Electronic Equipment Regulations indicates separate collection for electrical and electronic equipment.

0051

Identification code of Notified Body involved: 0051.

EMC Alert Mark for non-ionizing radiation .

Classification of the device, as per 93/42 directives : IIa (rule 10)
Certification procedure : 93/42/EEC, Annex VI, VII.
Identification code of Notified Body involved: 0051

2.400 - 2.483 GHz
Transmit Power Class 8 - Less than 10mW output power
Duty Cycle Class 4 - permitted to operate at 100% duty cycle
Receiver Class 3 - Standard reliable SRD communication media

Conforms to UL STD 60950
Certified to CSA C22.2 No. 950

Taking a Reading

The following instructions will tell you how to take a reading.

1. Unplug the SenseWear® biotransceiver from the blood glucose meter.
2. Insert a test strip and perform a blood glucose meter reading.
3. When your reading is displayed, remove the strip.

For more information about your blood glucose meter, please consult the Accu-Check® Advantage® First Time Guide and Accu-Chek® Advantage® Owner's Booklet included in the Accu-Chek® Blood Glucose meter box.

Sending a Reading to SenseWear® armband

1. Place the blood glucose meter and SenseWear® biotransceiver within 2 meters (6 feet) of the SenseWear® PRO_3 armband.
2. Press the armband button (**figure 1**). Note: the armband must be on-body at time of button press (indicated by a short vibration by the armband).

figure 1

figure 2

Sending a Reading to SenseWear® armband

3. Plug the biotransceiver into the blood glucose meter (**figure 2**). The biotransceiver will immediately retrieve data off the meter. As soon as retrieval is complete, the biotransceiver will send data to the armband. The Status LED on the biotransceiver will blink green when successful and red if the transfer failed.
4. The armband will also beep and vibrate once the transfer is successfully completed.

Sending a Reading to SenseWear® wireless gateway

1. Place the blood glucose meter and SenseWear® biotransceiver within 5 meters (15 feet) of the SenseWear® wireless gateway.
2. Plug the biotransceiver into the blood glucose meter (**figure 2**).
3. Please consult the SenseWear® wireless gateway Operating Manual for further details.

Copyright, Patent and Trademark Notices

FCC Statement

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, uses, 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 or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit separate from the receiver.
- Consult the dealer or an experienced radio/TV technician for help.

This device 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.

FCC 47CFR 15C TCB - 47 CFR Part 15 Subpart C Intentional Radiator
Certification Test

FCC 47CFR 15B cIA - 47 CFR Part 15 Subpart B Unintentional Radiators Class A Verification

UL 60601-1 - UL Standard for Safety Medical Electrical Equipment, Part 1:
General Requirements for Safety First Edition

CENELEC EN 60601-1-2 - 2001 - Medical Electrical Equipment Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests IEC 60601-1-2: 2001

CENELEC EN 60601-1-1 - Medical Electrical Equipment - Part 1: General Requirements for Safety - Collateral Standard: Safety Requirements for Medical Electrical Systems.

CAN/CSA-C22.2 No.606.1-M90

ETSI EN 301 489-1 - Electromagnetic Compatibility and Radio Spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) Standard for Radio Equipment and Services; Part 1: Common Technical Requirements V1.3.1

ETSI EN 301 489-3 - (Draft) Electromagnetic Compat. and Radio Spectrum Matters (ERM); Harmonized EN for ElectroMag. Compatibility (EMC) of Radio Comms. Equip. & Srvs.; Pt. 3: Specific Conditions for Short-Range Devices (SRD) Operating on Freqs Between 9 KHz and 40 GHz V1.3.1

ETSI EN 300 440-1 V1.3.1 (2001-07) Electromagnetic compatibility and Radio spectrum Matters (ERM);Short range devices; Radio equipment to be used in the 1 GHz to 40 GHz frequency range