

SenseWear®
WMS

Getting Started



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INTRODUCTION

Welcome to the SenseWear® Weight Management Solution (WMS). The SenseWear® solution will allow you to easily collect, manage, and analyze physiological and lifestyle data. Please read and follow the instructions included in this guide before using the armband and WMS website.

This Getting Started Guide for SenseWear® WMS takes you step-by-step through the set up of your system. It tells you how to configure and wear the SenseWear® armband, and collect and retrieve data from your armband via the SenseWear® WMS website. It is very important that you read and follow these directions to ensure the accuracy of your data.

This product complies with the general requirements for a safe medical device. However, this product alone is not meant to substitute for proper medical diagnosis, care, or treatment.



The SenseWear® WMS package includes:

- One (1) SenseWear® armband
- One (1) standard wing/strap assembly and one (1) large size wing/strap assembly
- One (1) USB cable

IMPORTANT

Intended Use

The SenseWear® armband can be used as a monitor 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.

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. Clinicians should not make drastic changes to a user's lifestyle based solely on data from the armband. The SenseWear armband has been clinically validated for subjects between 7 and 65 years of age who are engaged in resting, ambulatory, stationary biking, motoring and weight-lifting activities, etc. Due to metabolic variations, subjects who are 1) outside this age range or 2) engaged in alternate or obscure activities may see decreased accuracy in the data. Any decisions based on the data from this device should be made only by medical or paramedic personnel and should consider the condition and lifestyle of the subject tested. The SenseWear® armband 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 get the device close to other devices that can cause electromagnetic interferences of any nature.

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

IMPORTANT

Please be sure to verify equipment is connected and used compliant to UL11950.

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 8-11. Portable and mobile RF communications equipment can affect medical electrical equipment.

The equipment or system should not be used adjacent to or stacked with other equipment and 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® wireless communicator should not be used in airplanes, hospitals or locations where cellular telephones or electronic devices are prohibited.

Keep the SenseWear® armband and wireless communicator out of reach of children. Both products contain smaller, removable parts which can become choking hazards.

Wear comfortably

Be careful not to over-tighten the armband while on your arm. If, at any time, you feel constriction or loss of circulation, simply loosen the adjustable strap and re-fasten it to a more comfortable setting.

Be sure that both your arm and the sensors on the back of the armband are cleaned daily. To clean the sensors, wipe with a soft, damp cloth. If you develop a rash where the armband comes in contact with your skin, discontinue

IMPORTANT

use and consult your physician before continuing regular use of the armband. The design of the armband involved many materials experts, physicians, and suppliers who are familiar with wearable materials and products. Each material was chosen for its precedent in other skin contact products or has been independently approved for skin contact. However, everyone's skin is different and wearers with very sensitive skin may experience irritation or redness after wearing the armband. If this occurs, discontinue use and consult your physician. If you have known metals allergies, you should consult your physician prior to wearing. Do not wear armband when open sores are present.

Check armband for sharp edges or damage before each use.

There have been reports of scratches/cuts associated with the Velcro tab of the strap. The Velcro tab should be aligned with the strap to avoid contact with the skin. Also, excessively hot armbands, such as those left in a car in the summer, may cause skin burns if they are not allowed to cool before use.

When the armband is on the arm, DO NOT connect it to the USB cable.

Users with sensitive skin should avoid wearing the armband excessively. If you have sensitive skin, remove the armband 1 hour for every 24 hours of wear time to reduce potential for skin irritation.

Water resistance

The armband is not intended for long term operation under water. The armband is IP67 water resistant to 1 meter under water for 30 minutes. Loss of data may occur if the armband is under water for a longer period of time.

Please note when submerging the armband in water:

IMPORTANT

- Data accuracy may become compromised if the sensing module is submerged in water.
- The wing seal must be in good condition and the wing must be properly attached to the sensing module to avoid damaging the unit.
- Do not get the sensing module wet while removed from the wing assemble as damage will occur.

Handling

Though the SenseWear® armband was designed for wearability and long-term use, it is a sensitive monitoring device. Rough handling can break internal components. Never drop or shock the armband and always store it in a safe place when not in use.

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

To prevent possible damage to the USB cable, grasp the plug end when disconnecting the USB cable. Replace the cable if it becomes frayed.

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

Maintenance

Do not attempt to open the armband yourself. It contains no user-serviceable parts. Refer all servicing to qualified Service Personnel. Opening the armband yourself will void the warranty.

IMPORTANT

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

Cleaning

Always clean and dry the armband after vigorous sweating activities or when it becomes noticeably moist or dirty. Failure to keep the armband clean, or improper cleaning, may irritate the skin and affect the sensor performance.

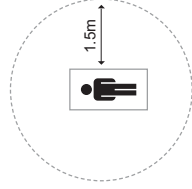
Moisten a soft cloth or towel with mild disinfectant soap and water. Wipe and dry the skin-touching side of the armband. Never use solvents to clean the armband, only for disinfecting (see below). The adjustable strap should be hand-washed with mild soap and warm water, then air-dried. Machine drying should be avoided.

Disinfecting

Wipe back of armband with soft cloth dampened with 70% isopropyl alcohol. Allow armband to dry for 5-10 minutes before wearing **DO NOT STERILIZE THIS UNIT.**

IMPORTANT

Patient Environment



Computer and Wireless Communicator

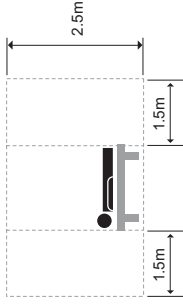


Diagram not to scale.

Guidance and Manufacturer's Declaration - Emissions

The Product MF (SenseWear® armband) is intended for use in the electromagnetic environment specified below. The customer or user of the Product MF should ensure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF Emissions CISPR 11	Class B, Group 1	The Product MF 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.
Harmonics IEC 6100-3-2	N/A	The Product MF 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.
Flicker IEC 6100-3-3	N/A	

IMPORTANT

Guidance and Manufacturer's Declaration - Immunity

The Product MF (SenseWear® armband) is intended for use in the electromagnetic environment specified below. The customer or user of the Product MF 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	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-11	±1kV Differential ±2kV Common	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	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Product MF requires continued operation during power mains interruptions, it is recommended that Product MF be powered from an uninterruptible power supply or battery.
Power Frequency 50/60Hz	3A/m	3A/m	Power frequency magnetic fields should be that of a typical commercial or hospital environment.
Magnetic Field IEC 61000-4-8			

IMPORTANT

Guidance and Manufacturer's Declaration - Emissions

The Product MF (SenseWear® armband) is intended for use in the electromagnetic environment specified below. The customer or user of the Product MF 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	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	Portable and mobile communications equipment should be separated from Product MF by no less than the distances calculated/listed below: <ul style="list-style-type: none"> • $D=(3.5/V^1)(\text{Sqrt } P)$ • $D=(3.5/E^1)(\text{Sqrt } P)$ 80 to 800 MHz • $D=(7/E^1)(\text{Sqrt } P)$ 800 MHz to 2.5 GHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m 80MHz to 2.5 GHz	Where P is the max power in watts and D is the recommended separation distance in meters. Field strengths from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance levels (V1 and E1). Interference may occur in the vicinity of equipment containing a transmitter.

IMPORTANT

Recommended Separations Distances for the Product MF

The Product MF (SenseWear® armband) is intended for use in the electromagnetic environment specified below. The customer or user of the Product MF can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications Equipment and the Product MF as recommended below, according to the maximum output power of the communications equipment.

Max Output Power (Watts)	Separation (m) 150kHz to 80MHz $D=(3.5/\sqrt{P})\sqrt{\text{Sqrt P}}$	Separation (m) 80 to 800MHz $D=(3.5/\sqrt{P})\sqrt{\text{Sqrt P}}$	Separation (m) 800MHz to 2.5GHz $D=(7/EI)\sqrt{\text{Sqrt P}}$
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

FEATURES OF THE SENSEWEAR® ARMBAND

Armband features

- Gathers raw physiological data including Movement, Heat Flux, Skin Temperature, Near Body Temperature, and Galvanic Skin Response.
- Contains approximately 7 days of battery life before needing to be recharged.
- Stores approximately 10 days of continuous physiological and lifestyle data.
- Offers sound feedback for Reminders and alerts.
- Wireless uploads available if data is sent to a PC via a wireless communicator.

Product specifications

Sensors:

- Accelerometer (3-axis)
- Heat Flux
- Skin Temperature
- Near-Body Temperature
- Galvanic Skin Response (GSR)

Materials:

- Monitor: ABS, polyurethane, co-polyester, 304 grade stainless steel
- Wireless Communicator: ABS
- Adjustable Strap: Nylon, polyester, Lycra (no latex content) or polyisoprene

Battery type: Internal lithium polymer cell battery

RF Frequency: 2.4GHz

Transmitter output power: <1mW

Battery power: about 7 days under use (18 hrs/day)

Battery capacity: about 10 days under use (18 hrs/day)

Monitor size: (l) 55mm x (w) 62mm x (h) 13mm [2.2" x 2.4" x 0.5"]

Monitor weight (with adjustable strap): TBD

FEATURES OF THE SENSEWEAR® ARMBAND

Water resistance: 1 meter for 30 minutes when properly mated to the wing assembly.

Operating temperature/humidity: 5°C to +40°C (50°F to 104°F)/100% RH non-condensing

Humidity Condensing: 5 to 95% Relative Humidity non-condensing
Design and specifications are subject to change without notice.

Sensor Accuracy

Accelerometer (3-axis)

- Calibrated range is +/- 2.00g
- The minimum resolution is 0.01g
- Two-standard-deviation accuracy of +/-0.05g, up to 1.00g on longitudinal axis
- Two-standard-deviation accuracy of +/-12.00% of expected value otherwise on the longitudinal axis
- Two-standard-deviation accuracy of +/-0.06g up to 1.00g on the transverse axis
- Two-standard-deviation accuracy of +/-12.00% of expected value otherwise on transverse axis.
- Two-standard-deviation accuracy of +/-0.06g up to 1.00g on the forward axis
- Two-standard-deviation accuracy of +/-12.00% of expected value otherwise on forward axis.

Heat Flux

- Calibrated Range is 0.00 W/m² to 300.00W/m²
- A minimum resolution of 1.00W/m²
- Two-standard-deviation of +/-10.00W/m² at heat flux less than 50W/m²
- Two-standard-deviation of +/-35.00% of expected value otherwise

Galvanic Skin Response

- Calibrated Range is 56K Ω to 20M Ω (50.00 nSiemens – 17.00 μ Siemens)
- Two-standard-deviation accuracy of +/- 7.00 nSiemens up to 233.34 nSiemens reading
- Two-standard-deviation accuracy of +/- 3.00% of expected value otherwise

Skin Temperature

- Calibrated Range is 20.00°C to 40.00°C
- A minimum resolution of 0.05°C
- Two standard deviation accuracy of +/- 0.80°C

FEATURES OF THE SENSEWEAR® ARMBAND



Caution



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TYPE B APPLIED PART



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



Identification code of Notified Body involved: XXX.

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: XXX

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

FEATURES OF THE SENSEWEAR® ARMBAND

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. 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. 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.
- CAUTION: 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.

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

FEATURES OF THE SENSEWEAR® ARMBAND

FCC 47CFR 15B CLA - 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

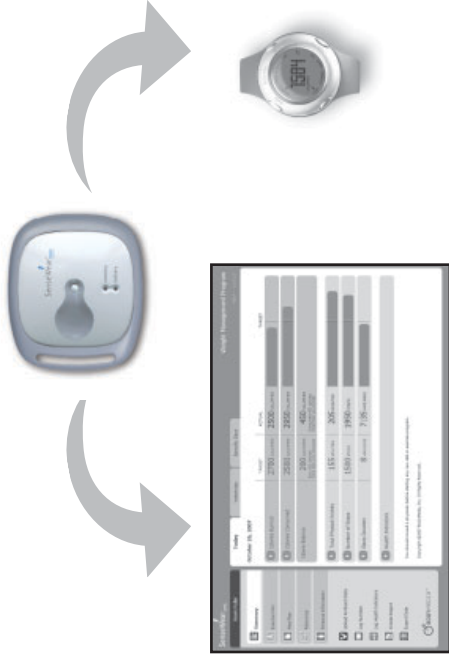
ETSI EN 301 489-3 - (Draft) Electromagnetic Compat. and Radio Spectrum Matters (ERM); Harmonized EN for ElectroMag. Compatibility (EMC) of Radio Comms. Equip. & Svcs.; Pt. 3: Specific Conditions for Short-Range Devices (SRD) Operating on Freqs Between 9 KHz and 40 GHz V1.3.1

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

YOUR SENSEWEAR® ARMBAND

The patented SenseWear® platform is a marriage of three basic components—a wearable monitor, a personal feedback device and a website. Working in concert, these three components deliver the data and insight that enable true behavior modification, guidance, and adherence.

The SenseWear® armband collects the data. The SenseWear® display shows up-to-the-minute patient feedback. The SenseWear® WMS website allows armband data uploads and manual input of nutrition intake and health indicators such as weight and blood glucose.



REGISTRATION & ACCOUNT CREATION

1. Go to www.sensewear.com and click on the link **For Health Practitioners** or **For Patients**.
2. If this is your first time entering the site, you will be directed to the “Missing Required Software” page. You must install the two support softwares to use the WMS system. Click **Next** once you have completed both installations.



Missing Required Software

We detected that your computer does not have the required software for Keystone system.

3. Use the user id and password provided to you to login.
4. You can now add facilitators. These are your health professionals that will be administering the WMS program to your patients.
5. Once the facilitators have been registered, they can log in to the system and begin entering Member (patient) accounts and setting up MBA or Weight Management Programs.
6. Once an account and program are created, there are 5 steps to complete set up:
 - Step 1.** Agree to end user license agreement. Click **Next**.
 - Step 2.** Record your patient’s basic body parameters. Click **Next**.
 - Step 3.** Enter your patient’s weight loss goals. (Weight Management Program Only). Click **Next**.
 - Step 4.** Enter their daily targets. This includes targets for total energy expenditure (TEE)/calories burned, step, physical activity duration and sleep. Click **Next**.
 - Step 5.** Click **Go** to start armband registration.

REGISTRATION & ACCOUNT CREATION



1. Plug the USB cable into a USB port on your computer.
2. Plug the opposite end of the USB cable into the armband. Windows will detect the new hardware and display the Found New Hardware Wizard.

Skip Step 3 if not using SenseWear® wireless communicator.

3. If using the SenseWear® wireless communicator, attach the wireless communicator to the USB cable. Windows will detect the new hardware and display the Found New Hardware Wizard.
4. After completing the *New Hardware Wizard*, click **Finish**.
5. Click **Register** to configure the armband. The armband is now ready to collect data.

WEARING THE ARMBAND

The SenseWear® armband is designed to be worn on the back of the upper left arm (the tricep muscle), touching the skin.

1. Slide the SenseWear® armband onto your left arm. The Status button should be closer to your shoulder.
2. Adjust the strap so that it fits on your arm comfortably, then secure the oval pull-tab. Ensure that the sensors maintain continuous contact with your skin at all times and that the armband does not slide off your arm.
3. Sync the display device with the armband by pressing the mode button and view button simultaneously on the display device and pressing the time stamp button on the armband. A Welcome message will appear on the display device when you have successfully synced the armband to the display.
4. The display device will go out-of-sync when you are not wearing the armband, to sync the display device again, press only the mode button on the display device and press the time stamp on the armband.



WEARING THE ARMBAND

Status Indicators

There is no on/off button on your SenseWear® armband. When the monitor makes secure contact with your body, it automatically performs a “turning on” sequence. This may take up to ten minutes for some people, depending on your body state. At anytime you can press and hold the timestamp button, you will hear a series of sounds as well as a which indicates the armband is working properly.

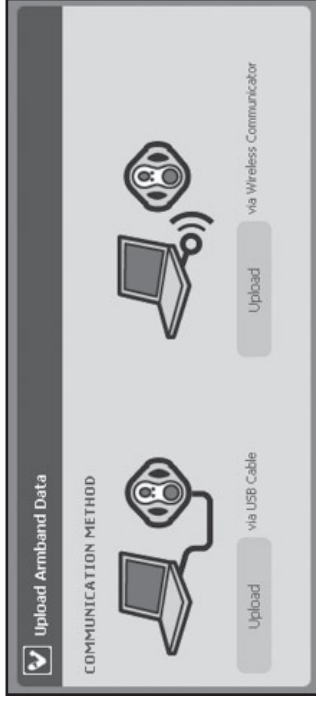
⚠ NOTE: The armband unit will collect data for at least (7) eighteen hour days on a single charge.

⚠ NOTE: Fully charge the battery before first use. the battery will arrive with a small, initial charge.

⚠ NOTE: When the armband is on the arm, DO NOT connect it to the USB cable.

UPLOADING DATA

1. Go to www.sensewear.com and click on the link **For Health Practitioners** or **For Patients**.
2. You will then be required to enter your user id and password. You will then see the summary page of the user.
3. Select the member.
4. If not using the wireless communicator, connect the armband to the USB cable.
5. Click the **Upload Armband Data** button.
6. Click **Via USB Cable** or **Via Wireless Communicator**.



7. When your data has been uploaded, you will see the summary screen showing the comparison of your targets versus your actual data.

My armband is not automatically turning on when I slide it on my arm.

If your armband has not turned on within 10 minutes of putting it on, try lightly moistening the back of your upper arm with water and slide the armband on again. It should turn on within a few minutes. If the problem persists, please contact Technical Support.

When I try to upload data from my armband, I get an error message.

1. If you are having difficulty uploading your armband data, it could be one of several reasons. Please double check the following and try again. If the problem still persists, please contact Technical Support.
2. If you are uploading wirelessly, make sure you are within 10 feet of your PC. If you wander outside of this range, the upload may not work. Also, make sure that your armband has had a chance to turn on. It can take up to 10 minutes for the armband to turn on after you have put it on your arm.
3. If you are uploading via the USB cable, make sure the cable is connected to the armband and the port on the back of your PC.
4. Make sure your battery or available memory is not too low. To make sure that the armband is powered on and the battery and memory are functioning, press the Status button while the armband is on your arm. If it produces the low sequence when you push it, the battery or memory is too low. If it produces the very low sequence, the battery is drained or the memory is full. When you plug the USB cable in while uploading, if the battery light is red, it needs to be recharged before you can upload.
5. Make sure you have the USB driver installed on the computer you are using. If you are using a computer that is different than the one you used during registration and set-up when you first received the armband, you may need to download the software that enables you to retrieve your data from the armband to the computer. This is called the USB driver.

NOTE: When installing the support software on your machine, make sure the armband or wireless communicator is NOT plugged into the USB cable! This will cause the driver to fail to install. If this happens, simply unplug the armband or Wireless Communicator from the USB cable and plug it in again. The driver will then install properly.

My armband is not responding. It seems to be off, and I cannot get it to come back on.

Press the Status button. If the battery or memory lights are flashing red, either the battery needs to be recharged or the memory is full. If after pressing the Status button you still receive no feedback (no lights or sound), try recharging the battery, it may have drained while you were not wearing the armband. If after recharging the battery you still do not receive feedback, please contact technical support and they will help solve the issue.

My armband is beeping while it is on my arm.

Solution 1: Press the Status button. If the battery lights are flashing red or amber, the battery is low and will need to be replaced.

Solution 2: Press the Status button. If the memory lights are flashing red or amber, the memory is low and you must upload the data and clear to continue collecting data.

Solution 3: You may have reminders set on your armband. Check this by clicking on the **Personal Assistance** tab and clicking **Reminders**.

TROUBLESHOOTING

When I press the armband button, the armband does not respond.

Disconnect the USB cable and hold the armband button for 15 seconds, release the button. Press the armband button again to see if it responds. Go into the software and retrieve your data (upload) to re-sync your armband before wearing again. Caution: Data loss may occur. .

Data that I thought was on my armband has been erased.

Your armband may not have turned on. If this is the case, the armband did not collect data. Or your battery may need recharged.

LEGAL INFORMATION

Patents and patents pending. The SenseWear® Weight Management Solution armband, display and wireless communicator are covered by one or more of the following patents: United States Patent Nos.: D439,981, 6,527,711, 6,595,929, 6,605,038, 7,020,508, 7,153,262; European Patent Nos.: 1,292,217, 1,292,218; and various worldwide patents pending. This notice is accurate as of August 14, 2007. For latest information please see www.bodymedia.com.

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