

SenseWear® body monitoring system

Instructions For Use



SenseWear® software
SenseWear® Professional software
SenseWear® armband
and data collection

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NOTE:

Read these instructions and the *Warnings and Cautions* on pages 2-6 before using the Body Monitoring System.

Introduction

This manual will instruct you in the use of the SenseWear® Body Monitoring System™. It covers the routine operations and frequently-used features of the SenseWear® software, SenseWear® Professional software and the SenseWear® armband.

If you have not done so already, please refer to the Getting Started Guide included in the System box to install the SenseWear software or SenseWear Professional software and configure the armband. After completing the initial set-up (Step 3), you may proceed with this manual.

IMPORTANT

To run the SenseWear software or SenseWear Professional software, the minimum requirements for your PC are Pentium III or higher, with at least 256 MB of RAM, Windows 2000 SP3 or later/XP/Vista and a USB port for the armband connection. For the SenseWear Professional you will need an additional USB port to accommodate the license key.

Important Information About the SenseWear® armband

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.

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. Clinicians should not make drastic changes to a user's lifestyle based solely on data from the armband. The Body Monitoring System 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) out-

Important Information About the SenseWear® armband

WARNINGS

side 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.

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

Please 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 7-10. 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.

Important Information About the SenseWear® armband

WARNINGS

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 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. 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.

Important Information About the SenseWear® armband

WARNINGS

Water resistance

DO NOT IMMERSE THE ARMBAND IN WATER. The monitor 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. Do not remove the battery label. Dispose of properly. For further information about the disposal of the battery, please follow manufacturer's instructions.

Batteries may present a choking hazard for small children.

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

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.

Important Information About the SenseWear® armband

CAUTIONS

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.

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 may affect the performance and lifespan of the strap.

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 Information About the SenseWear® armband

Patient Environment

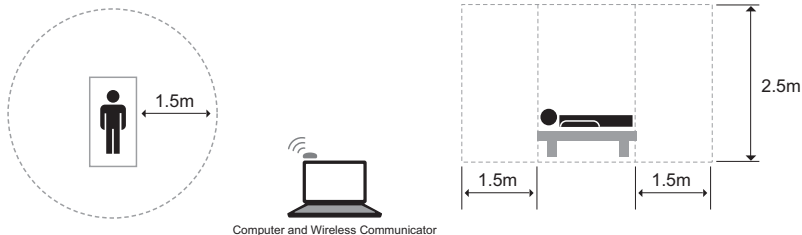


Diagram not to scale.

Guidance and Manufacturer's Declaration - Emissions

The 908901PROD2 (SenseWear® armband) is intended for use in the electromagnetic environment specified below. The customer or user of the 908901PROD2 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 908901PROD2 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 908901PROD2 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 Information About the SenseWear® armband

Guidance and Manufacturer's Declaration - Immunity

The 908901PROD2 (SenseWear® armband) is intended for use in the electromagnetic environment specified below. The customer or user of the 908901PROD2 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 908901PROD2 requires continued operation during power mains interruptions, it is recommended that 908901PROD2 be powered from an uninterruptible power supply or battery.
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.

Important Information About the SenseWear® armband

Guidance and Manufacturer's Declaration - Emissions

The 908901PROD2 (SenseWear® armband) is intended for use in the electromagnetic environment specified below. The customer or user of the 908901PROD2 should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
<p>Conducted RF IEC 61000-4-6</p> <p>Radiated RF IEC 61000-4-3</p>	<p>3 Vrms 150 kHz to 80 MHz</p> <p>3 V/m 80 MHz to 2.5 GHz</p>	<p>3 Vrms 150 kHz to 80 MHz</p> <p>3 V/m 80MHz to 2.5 GHz</p>	<p>Portable and mobile communications equipment should be separated from 908901PROD2 by no less than the distances calculated/listed below:</p> <ul style="list-style-type: none"> • $D = (3.5/V1)(\text{Sqrt } P)$ • $D = (3.5/E1)(\text{Sqrt } P)$ 80 to 800 MHz • $D = (7/E1)(\text{Sqrt } P)$ 800 MHz to 2.5 GHz <p>Where P is the max power in watts and D is the recommended separation distance in meters.</p> <p>Field strengths from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance levels (V1 and E1).</p> <p>Interference may occur in the vicinity of equipment containing a transmitter.</p>

Important Information About the SenseWear® armband

Recommended Separations Distances for the 908901PROD2

The 908901PROD2 (SenseWear® armband) is intended for use in the electromagnetic environment specified below. The customer or user of the 908901PROD2 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications Equipment and the 908901PROD2 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

Retrieving armband Data to Your Computer

To start the program, double-click on the SenseWear[®] software or SenseWear[®] Professional^{*} software icon on your desktop. The main screen (figure 1) will appear as shown. There are three buttons at the top under the menu bar: **Retrieve Armband Data**, **View & Annotate Armband Data**, and **Configure Armband**. **Retrieve Armband Data** will already be selected.

Connect the USB cable to the armband and to one of your computer's USB ports. Then click **Retrieve** to transfer data from the armband to your PC.

A window will pop up (figure 2), requesting you to enter a file name. Enter a name and click **Continue**. The data file will be saved in your default directory.

If you want to change the location of your default directory, click **Browse** and select a new destination directory.

IMPORTANT

After the armband data has been successfully retrieved and saved to a data file, the data is cleared from the armband. If you want the data to remain on the armband then unselect the **Clear armband for next use...** checkbox before clicking **Continue**.

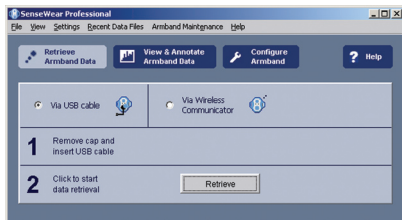


figure 1

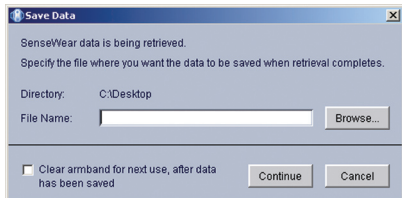


figure 2

TIP

When naming your files use numbers rather than names to protect your patients' identities. For example, Patient1234.

**SenseWear Professional software requires the License Key to be inserted into a USB port.*

Retrieving armband Data to Your Computer

My Data Properties

Subject Info Clinician Info Notes Activity Levels Timezone

In order to accurately interpret the data you are retrieving, please specify the following body parameters of the wearer.

Subject: 3124

Date of Birth: May 22, 1964

Age at Data Collection: 41 yrs

Height: 5'10" feet/inches or 178 centimeters

Weight: 147 pounds or 66.7 kilograms

BMI: 21.05

Sex: Male

BSA (m²): 1.82

Handedness: Right Handed

Smoker: Non Smoker

Note: To make these changes permanent, go to **Configure Armband** after the data retrieval completes.

Save Cancel

figure 3

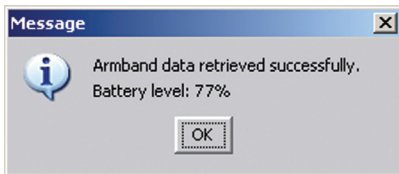


figure 4

If the armband was not configured prior to wearing, you will receive a pop up window (figure 3) after the data has been retrieved. The window will prompt you to enter the wearer's Subject Info and other important information needed to derive accurate lifestyle information. The subject information **MUST** be entered to ensure that the software can accurately analyze the raw data collected by the armband. (see *Getting Started Guide*, Step 2, Configuration).

The software lets you know that you have successfully retrieved the data by a pop up message that appears on your screen (figure 4). The newly retrieved data will be displayed automatically.

* TIP

A new AAA battery can collect up to 14 days of continuous data. Keep in mind that the battery life is reduced under colder conditions. To avoid losing data or interrupting a longer continuous data collection, pay particular attention to the battery level after retrieval (figure 4). As a rule of thumb, 50% battery life will last about 7 days and 25% battery life will last approximately 3 days. See page 32 for more information about battery life and how to check the level from the armband.

Viewing & Analyzing the Data

If you have just retrieved data from the armband, then the data file will already be displayed. If you would like to view a previously saved data file, go to **File** on your menu bar and select **Open Data File**. A window (figure 5) will open up to your default directory. Double click on the data file you wish to open.

▲ IMPORTANT

SenseWear® software and SenseWear® Professional software v. 6.0 are designed to work with SenseWear Pro2 and Pro3 armbands. The software does not support earlier armbands or data files by earlier armbands.

On the **View & Annotate Armband Data** screen (figure 6), the total duration of the file and on-body data collection times is indicated on the interactive time selector (figure 7) on the upper right of your screen. The bottom half of the screen is a summary of the Lifestyle Indicators and Health Indicators. By default, the Lifestyle Indicators tab will be selected, displaying a summary of the derived armband data for the entire duration of the collected data file. Clicking on the **Health Indicators** tab will display a graph of any available biometric data (blood glucose, blood pressure, or weight) retrieved from the armband.

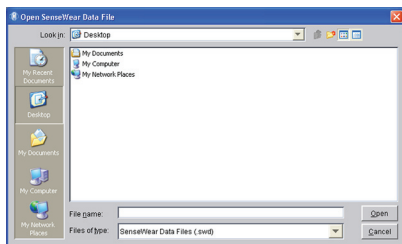


figure 5



figure 6

Viewing & Analyzing the Data

The date and time located to the left and right just above the selector indicate the total duration of the data file. Inside the rectangle itself, the beginning of each day (midnight) within this duration is marked by the date and a thin vertical white line. Solid-colored areas show periods when the armband was on-body and collecting data. Thin horizontal grey lines show periods when the armband was off-body and not collecting data. The shorter dark blue vertical lines indicate that the Timestamp/Status button was pressed.

You can highlight different time periods within the entire duration of the collected data with the time selector. To select only one day from the time selector, click anywhere on the day you wish to view. The selector will automatically select that day (midnight to midnight). To select multiple complete days click on the first day you would like to view and shift-click on the final day you want displayed.

To select start and end times, drag the time selectors below the horizontal box. You can then move the selected time period by dragging the bar between the widgets. All values for these selected times will automatically update on the right.

Click the **Show Sessions and Timestamps** checkbox under the Subject ID on the upper left of your screen for a chronological list of all on-body sessions and Timestamps. The list will appear in the window below the Subject ID. Clicking on a specific day or time on the list will also highlight that item in the interactive time selector.

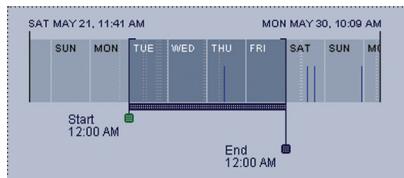


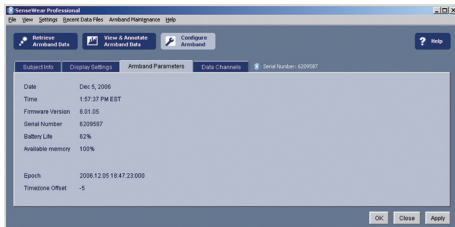
figure 7

* TIP

To select only one day from the interactive time selector (Figure 7), simply position your mouse on top of the day you wish to view and click. You can then drag the selected area to move this 24 hour time period.



Using the Software to Configure an armband and display



The armband **Parameters** tab (figure 27) allows you to verify the date and time of the armband clock. It also allows you to check the hardware version, serial number, battery level, and memory capacity.

figure 27

⚠ IMPORTANT

If the armband clock is not synchronized with your PC clock, a message may suggest that you synchronize the clocks. If your PC clock time is the correct time, we recommend doing this by clicking the **Apply** button.

⚠ IMPORTANT

If using the optional SenseWear® display, be sure to have your PC clock set with the same time zone of the location you will be wearing the display. Because data is displayed in 24 hour increments, this will ensure the accuracy of your data. Please refer the SenseWear® display Operating Manual for proper usage.

Using the Software to Configure an armband and display

The SenseWear® Professional software includes the Data Channels tab (figure 22) feature. This tab lets you configure the data channels to be collected and the sampling rates used by each channel.

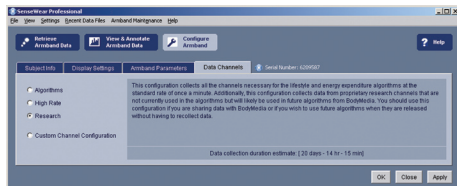


figure 28

If you are not familiar with the low-level physiological parameters the device collects, we strongly recommend not changing this section.

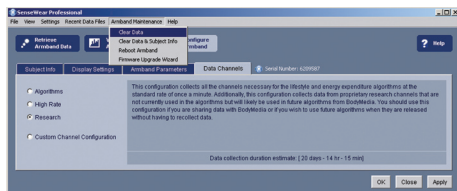


figure 29

If you need to clear memory from an armband, select **Armband Maintenance** (figure 23) from the menu bar at the top of your screen and select the appropriate command from the list.

⚠ IMPORTANT

Do not select Reboot Armband unless instructed to do so by a BodyMedia representative or Technical Support Specialist. Unnecessary reboots of the device can result in data loss.

Features of the SenseWear® armband

Battery

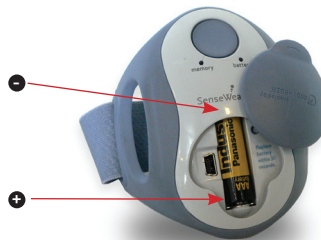
The armband is powered by one AAA battery. During continuous use (24/7), it will last approximately 14 days.

To check the status of the battery, remove the armband and press the Timestamp/Status button. The light above the word “battery” will turn on as follows:

- Green (solid) = More than 24 hours of battery life remains.
- Amber (flashing) = Less than 24 hours of battery life remains.
- Red (flashing) = Battery life is very low and the armband will not collect data. Change the battery before continuing use.

If you are wearing the armband, a subtle vibration and sound will alert you when there is less than 24 hours of battery life remaining. When the battery is too low to operate, the alert will become more urgent.

In addition to the battery status light on the armband, you can also view how much battery life is left every time you retrieve your data (Figure 4).



To replace the battery, lift and rotate the top hatch counterclockwise. Remove the drained AAA battery and replace it with a new AAA battery immediately.

⚠ WARNING

Once you remove the AAA battery, you have 30 seconds to replace it with the new one. Failure to do so may lead to loss of data.

Ensure proper disposal of batteries.

Features of the SenseWear[®] armband

Memory

Under default configurations, the armband has approximately 10 days of data collection memory. To check the memory status, remove the armband and press the Timestamp/Status button. The light above the word “memory” will turn on as follows:

- Green (solid) = More than 24 hours of memory remains.
- Amber (flashing) = Less than 24 hours of memory life remains.
- Red (flashing) = Available memory is low and the armband will not collect data. Retrieve your data before continuing use.

If you are wearing the armband, a subtle vibration and sound will alert you when there is less than 24 hours of memory life remaining. When the memory is full, the alert will become more urgent.

Wearing your armband

The SenseWear[®] armband is designed to be worn on the back of the upper right arm (the triceps), touching the skin.

1. Make sure that your upper right arm is clean and dry. You should not wear any lotion or body oil where the armband will come in contact with your skin.
2. Slide the armband onto the back of your upper right arm with the SenseWear logo facing up.
3. Adjust the strap so that it fits on your arm comfortably, then secure the oval pull-tab. Flex the arm a few times to make sure that the strap is neither too tight nor too loose. It should be snug, but comfortable. You do not need to adjust the strap again in the future; just slide it on and off.

WARNING

Be careful not to overtighten the armband. If, at any time, you feel constriction or loss of circulation, simply loosen the adjustable strap and refasten it to a more comfortable setting.

Features of the SenseWear® armband

Threading your adjustable strap

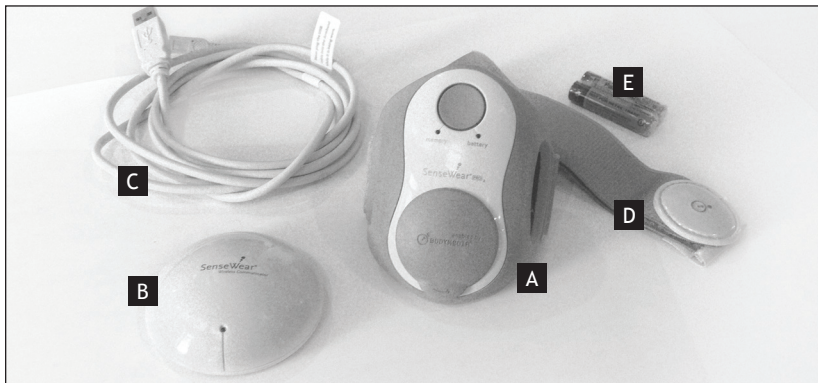
Your SenseWear® armband comes with two identical adjustable straps. One strap comes attached to the armband and the other is a spare to be used if you're cleaning the first one. See the *Cleaning* section (page 6) of this manual for information on cleaning your adjustable strap. Follow these steps to thread your adjustable strap into your armband.

1. Hold the armband upright with the sensors facing you. Take the square end of the adjustable strap with the two Velcro® pads and thread it through the narrow, vertical slot in the wing. The Velcro® pads should be facing you, with the edge of the wing in between the two pads.
2. Fold over the end of the strap and press the Velcro® pads together.
3. Take the other end of the adjustable strap with the oval pull tab and thread it through the narrow, vertical slot in the other wing. The Velcro® side of the oval pull tab should be facing you.
4. Pull the strap through the slot in the wing and press the oval pull tab against the adjustable band. Create a space that is approximately the size of the circumference of your upper arm.
5. When completed, the square end of the strap should be on the inside of the band and the oval pull tab should be on the outside of band. Use the oval pull tab to adjust the size of the strap while on your arm.

**WARNING**

Do not use unapproved accessories with the armband.

Features of the SenseWear® armband



- A** SenseWear® armband - Part No.100156 (US), 100153 (Europe-Italian), 100154 (Europe-English).
 - Wearable body monitor with multi-sensor array collects data directly off skin of the wearer's arm.
- B** SenseWear® wireless communicator - Part No.100155 (US) and 100158 (Europe)
 - Directly connects to computer to wirelessly retrieve data off of armband.
- C** USB Cable - Part No.100108 (US/Europe-English) and 100128 (Europe-Italian)
 - Connects wireless communicator or armband to computer.
- D** SenseWear® armband Strap - Part No.100114 (Sm), 100115 (Med), 100116 (L)
 - Spare strap for armband.
- E** Two AAA Batteries

Features of the SenseWear® armband

Armband features

- Gathers raw physiological data, including movement, heat flux, skin temperature, near body temperature, and galvanic skin response.
- Battery lasts approximately 14 days when worn continuously.
- Stores approximately 10 days of continuous physiological and lifestyle data with default configuration.

Product specifications

- Sensors:
 - Accelerometer (2-axis)
 - Heat Flux
 - Skin Temperature
 - Near Body Temperature
 - Galvanic Skin Response
- Materials:
 - Monitor: ABS, urethane, FDA approved co-polyester, hypo-allergenic grade stainless steel
 - Wireless Station: ABS
 - Adjustable Strap: Nylon, polyester, polyisoprene (no latex content)
- Battery type: 1 AAA battery
- Battery power: about 14 days under continuous use (24/7)
- Memory capacity: about 10 days under continuous use (24/7) with default configurations.
- Monitor size (without wings): (l) 85.3mm x (w) 53.4mm x (h) 19.5mm; [(l) 3.4 in x (w) 2.1 in x (h) 0.8 in]
- Monitor weight (with adjustable strap): 2.8 oz (79 g)
- Water resistance: splash-resistant
- Operating temperature/humidity: 0° C to +45° C (32° F to 113° F)/100% RH non-condensing
- Storage temperature/humidity: 0° C to +45° C (32° F to 113° F)/100% RH non-condensing

Design and specifications are subject to change without notice.

Features of the SenseWear® armband

Sensor Accuracy

Accelerometer (2-axis)

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

Heat Flux

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

Skin Temperature

- Range is from 20.00°C to 40.00°C
 - A minimum resolution of 0.05°C
 - A 2 standard deviation range of +/- 0.80°C across the temperature range
-

Galvanic Skin Response

- Range is from 56KW to 20MW (50.00 nSiemens - 17.00 uSiemens)
 - A two-standard-deviation range of +/- 7.00 nSiemen up to 233.34 nSiemens reading
 - A two-standard-deviation range of +/- 3.00% of expected value otherwise
-

Features of the SenseWear® armband



Follow operating instructions.



Caution



Tested to applicable safety standards.



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: 0051.

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

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. 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

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

Features of the SenseWear® armband

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