BioHarness 3.0

User Manual

For support or further information on this product contact:

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This document may be subject to change without notice.

Version	Description
2011-07-27	Initial Release
2012-03-13	Various updates to specification and completion of previous omissions
2012-04-13	Add EC38 Type 3 compliance, caution on infant use
2012-06-26	Update hardware and firmware part nos. Add 802.15.4 specifications
2012-07-03	Add new FCC ID, update battery life, label
2012-07-31	Update label, intended use
2012-08-20	Correct erroneous IC ID

Contents

1. General Information

This documentation contains instructions for safe use, and a technical description of the BioHarness 3.0 device.

Operators of the device should read this manual in its entirety prior to use.

The components referred to in this manual are:

Component	Part/Product Number
BioHarness Bluetooth Module (Electronics sensor)	9800.0189
BioHarness Bluetooth Firmware Version	1.3.12.0
BioHarness Chest Strap (Sizes Small XS-M, Large M-XL)	9600.0189, 9600.0190
BioHarness Shoulder straps (optional – one size adjustable)	9600.0117
BioHarness Charge Cradle & USB Cable (single device)	9600.0257

CLASSIFICATIONS
- EC38 Type: Type 3
- The BioHarness Module is internally powered when in patient monitoring mode
- IP55 rated against ingress (should not be used for swimming or other water-based activities)
- Does not need to be sterilized as part of normal operations
- Will be used for non-continuous operation

1.1. Documentation

This device is supplied as a component of the Zephyr Bluetooth BioHarness Software Developer's Kit (SDK). The SDK contains this guide, as well as additional documentation:

Document	Description	Part Number
BioHarness BT Comms Link Specification [1]	All messages needed to communicate with the device by Bluetooth or direct serial/USB connection. All data packet descriptions.	9700.0110
BioHarness 3 Logging System Interface [2]	Description of the file structure of the device's internal memory.	9700.0158
BioHarness Bluetooth Developer Kit User Manual [3]	Overview of the software utilities supplied with the SDK.	9700.0026
BioHarness Bluetooth API Guide [4]	Overview of Data Packet structure, and protocols for communicating with the device	9700.0027
BioHarness 3 Data Sheet [5]	Specifications of device	9700.0136
BioHarness Side Strap Data Sheet [6]	Specifications of strap	9700.0024
BioHarness BT Android API User Guide [7]	Android Application Programming Interface Instructions	9700.0150
BioHarness MATLAB Script File Description [8]	Instructions for converting .csv data file output for input to MATLAB 3rd party analysis software	9700.0151
Event Messaging System [9]	Description of Msgs recorded in Event Log	6700.0157

This Guide, and the documents above, is included as a component of the BioHarness Bluetooth Developer's Kit. They are intended to provide information to integrators who wish to incorporate the BioHarness Bluetooth into a physiological monitoring product.

⚠️	These documents are *not* intended as end-user documents. Integrators must assume responsibility for documentation and software which is supplied to end-users and operators of the physiological monitoring solution which incorporates the BioHarness Bluetooth system.

⚠️	Integrators who incorporate the BioHarness Bluetooth into a proprietary physiological monitoring system assume responsibility for the validation and regulatory compliance of that system.

1.2.   Warning and Safety Notices

⚠️	The '**!**' symbol shown left indicates a warning. Failure to heed the text included beside this symbol may compromise safe operation of the device.

⚠️	The BioHarness is _not_ specified for the following uses: • As defibrillation-proof • For use in an oxygen-rich environment • As life-supporting • For use only in a shielded location • For use with heart pacemakers • For use with electrosurgical equipment

⚠️	No modification of the BioHarness Module or chest strap is allowed

ELECTROMAGNETIC COMPATIBILITY

This device has been designed and tested to comply to the relevant electrical and electromagnetic interference standards for the countries it is available in. This cannot completely eliminate the risk of interference with or from other radio transmitting or medical electrical equipment in close proximity. If such interference is suspected or experienced, interfering systems should be removed from the vicinity. Specific interference effects not resolved by this approach should be reported to Zephyr Technology.

Guidance and Manufacturer's Declaration - Electromagnetic Emissions		
The BioHarness Bluetooth is intended for use in the electromagnetic environment specified below		
Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF Emissions CISPR 11	Class B	The BioHarness Bluetooth is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes

⚠️	A Bluetooth receiving device which captures data transmitted by the BioHarness 3.0 should not be located adjacent to or on top of any electrical or medical equipment which may cause interference to data transmission or reception

⚠️	Not intended for use on infants weighing less than 22lbs (10kg)

Manufacturer's Declaration - Electromagnetic Immunity			
EMISSIONS			
Test	Requirement	Test Method	Result
AC Mains Power Input/Output Ports	ETSI EN 301 489-1 Section 8.4	EN 55022 (2006)	Compliant. Measured emissions were below applicable limits.
Harmonic Current Emissions (AC Mains Input Port	ETSI EN 301 489-1 Section 8.5	EN 61000-3-2 +A1 (2006)	Compliant. Measured emissions were below applicable limits.
Voltage Fluctuations & Flicker (AC Mains Input Port)	ETSI EN 301 489-1 Section 8.6	EN 61000-3-3 (1995)	Compliant. Measured emissions were below applicable limits.
IMMUNITY			
RF Electromagnetic Field 80 – 1000 MHz & 1400 – 2700MHz	ETSI EN 301 489-1 Section 9.2	EN 61000-4-3 (2006)	Compliant. Measured emissions were below applicable limits.
Electrostatic Discharge (ESD)	ETSI EN 301 489-1 Section 9.3	EN 61000-4-2 (2001)	Compliant. Measured emissions were below applicable limits.
Fast Transient, Common Mode	ETSI EN 301 489-1 Section 9.4	EN 61000-4-4 (2004)	Compliant. Measured emissions were below applicable limits.
Radio Frequency, Common Mode	ETSI EN 301 489-1 Section 9.5	EN 61000-4-6 (2005)	Compliant. Measured emissions were below applicable limits.
Transient & surges in the vehicular environment	ETSI EN 301 489-1 Section 9.6	ISO 7637-2 (2004) (12/24 VDC)	Compliant. Measured emissions were below applicable limits.
Voltage dips & interruptions	ETSI EN 301 489-1 Section 9.7	EN 61000-4-11 (2004)	Compliant. Measured emissions were below applicable limits.
Surges	ETSI EN 301 489-1 Section 9.8	EN 61000-4-5 (2006)	Compliant. Measured emissions were below applicable limits.

DISPOSAL AT END OF LIFE
The BioHarness Module, charge cradle and chest strap contain no hazardous components. All electrical components are lead-free.

However, where specific provision is made in a particular region for disposal and recycling of electrical goods, Zephyr advises following local guidelines for conscientious disposal of equipment.

Zephyr Technology will undertake to dispose of any end-of-life components which are returned to their facility.

Zephyr Technology is registered in Europe under the WEEE recycling scheme.

⚠	Do not dispose of the device by fire.

1.3. Intended Use

STATEMENT OF INTENDED USE

The BioHarness 3.0 is a physiological monitoring telemetry device intended for monitoring of adults in the home workplace and alternate care settings. The device consists of a chest strap and an electronics module that attaches to the strap. The device stores and transmits vital sign data including ECG, heart rate, respiration rate, body orientation and activity. The BioHarness 3.0 provides a facility to detect and transmit single lead ECG signals to be received by Bluetooth / USB qualified ECG instruments.

The BioHarness 3.0 collects and transmits measurements captured during both sedentary as well as rigorous activity for Heart Rate, Posture and Activity. Breathing rate values are accurately transmitted only during sedentary periods.

The BioHarness 3.0 is indicated for use as a general patient monitor to provide physiological information as part of an occupational welfare monitoring system, for general research and performance measurement purposes, or where prescribed by a healthcare professional.

> ⚠️ The device should not be connected to any external component, other than the chest strap, while it is being worn by the subject.

1.4. Contraindications

⚠️	The device should not be worn by any subject with prior evidence of skin irritation at any point where the chest strap will contact the subject. If a subject develops irritation or discomfort while the chest strap is being worn, then use should be discontinued.

⚠️	Users who have a surgically fitted heart pacemaker or automatic defibrillator should not use a BioHarness

⚠️	Not intended for use on infants weighing less than 22lbs (10kg)

1.5. Table of Symbols

Shall include explanation of all symbols marked on the device

🗑️	Rear label of BioHarness Module. Indicates WEEE compliance – all end-of-life BioHarness Modules should be returned to agent or distributor or recognised local channel for disposal.
C Z747	Rear label of BioHarness Module. Indicates C-tick compliance for ECM standards for Australia and New Zealand
FC	Rear label of BioHarness Module. Indicates FCC Part 15 compliance for radio emission regulation
CE	Rear label of BioHarness module. Indicates Declaration of Conformity to European health, safety and environmental regulations

2. Technical Description

2.1. Model Identification

The information in this document refers to:

Name:	Zephyr BioHarness 3
Model:	9800.0189
Firmware Version:	1.3.12.0
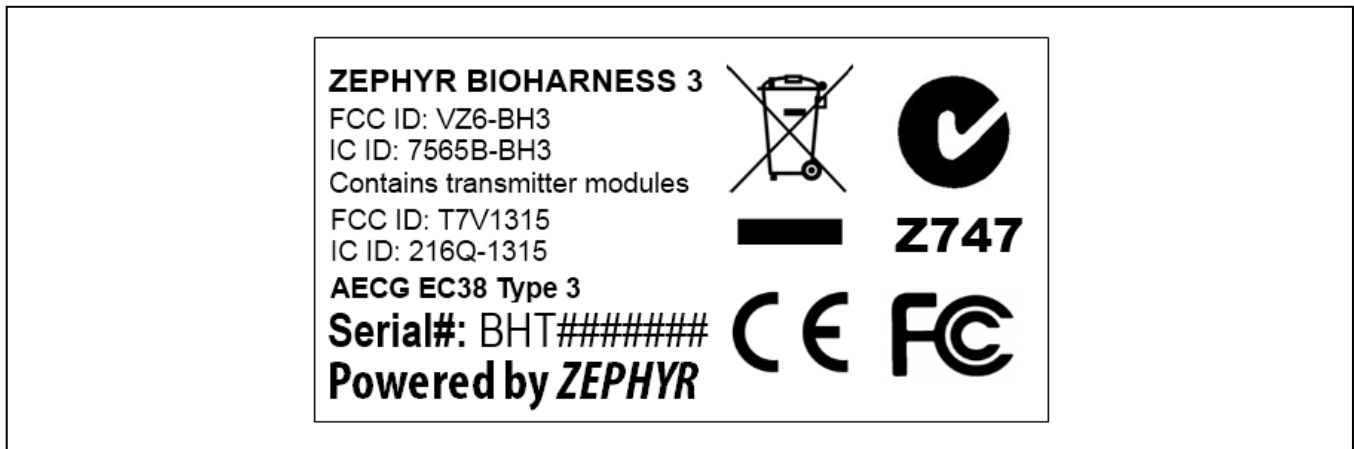
The Model number is marked on the identifying label on the rear of the device

Firmware and hardware versions can be identified using the Zephyr Configuration Tool included in the BioHarness Software Developer's Kit:
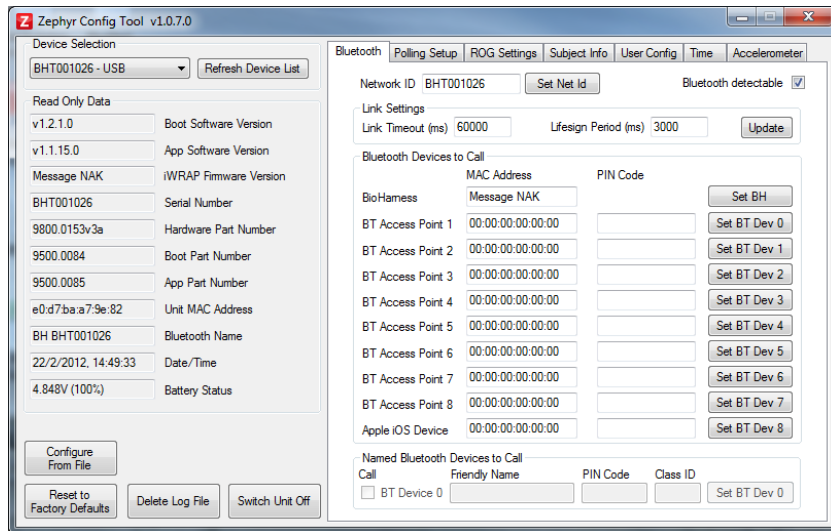
2.2.   System Overview

The BioHarness Bluetooth operates in two modes:

2.2.1.   Monitoring Mode

| BioHarness Module, attached to chest strap with optional shoulder straps | Physiological data sent by Bluetooth radio protocol or 802.15.4 protocol | Data displayed on PC |
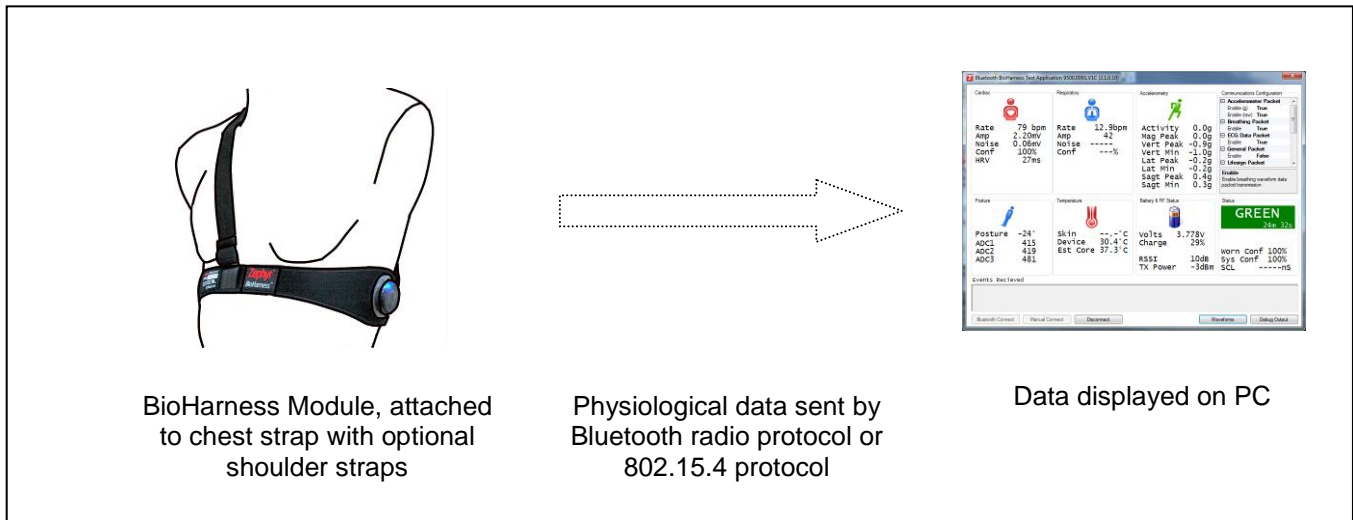
- Power Supply: the BioHarness module is powered only by an internal rechargeable lithium polymer cell
- The BioHarness Module is secured in a receptacle attached to the chest strap and worn by the subject as shown (shoulder straps are optional for additional security and do not affect the performance of the chest strap).
- It is powered on and off by depressing the front of the device.
- A series of flashing LEDs on the front of the device indicates its status
- It is powered by an internal battery.
- Passive sensors in the strap detect heart ECG signals through conductive pads
- A pressure sensor pad in the strap on the subject's left hand side detects expansion of the rib cage due to breathing action.
- A thermistor measures the device internal temperature.
- An internal 3-axis accelerometer in the BioHarness module measures subject activity level and orientation of the device (subject standing, supine, prone, inverted).
- All sensor data is processed within the BioHarness Module.
- An indication of subject physiological status (Green/Orange/Red) is calculated based on sensor input and subject threshold values stored within the device when it is configured.
- It sends physiological data wirelessly by Bluetooth or 802.15.4 to an appropriate receiving device with graphical interface
- The device can transmit over Bluetooth and 802.15.4 frequencies simultaneously

2.2.2.   Charging and Configuration Mode

CHARGING & CONFIGURATION MODE

BioHarness Module in
Charge/Configuration Cradle

USB Charge/Configuration Lead
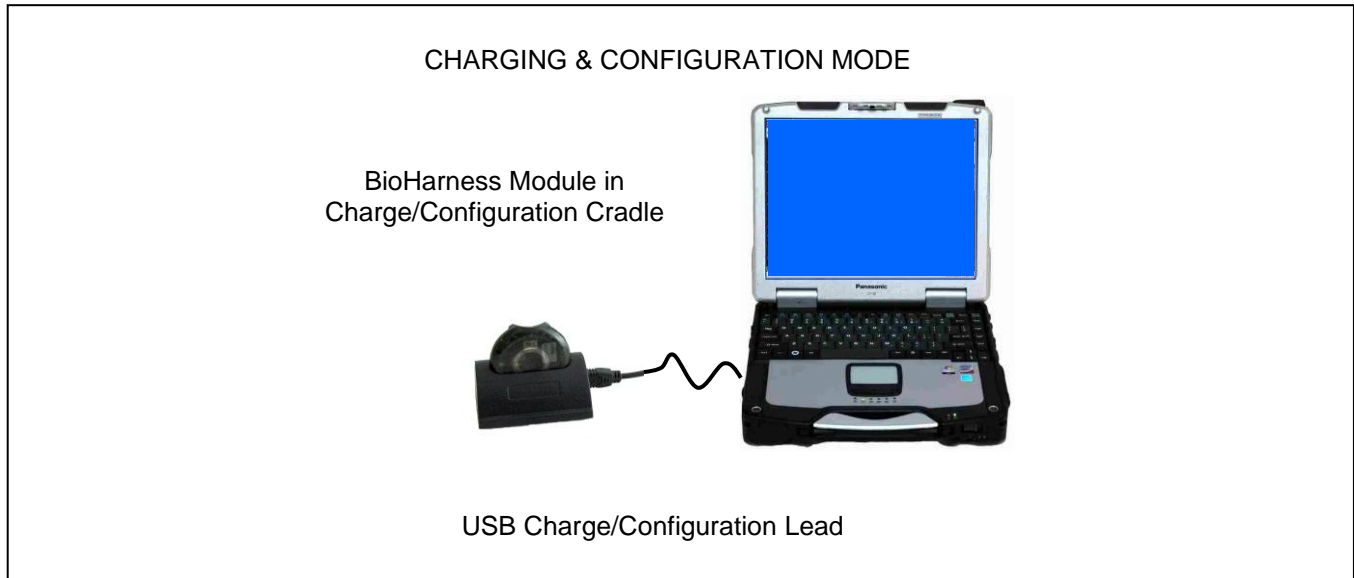
CHARGING MODE
- Power Supply: the BioHarness module receives a PC USB input of 5V DC
- The BioHarness Module is located in a charging/configuration cradle
- It cannot be fitted to a strap/worn by a subject in this mode
- An orange LED on the front of the flashes when the device is charging
- The orange LED is constantly illuminated when the device is fully charged
- The device cannot be over-charged
- Charging times: 1 hour to 90% capacity, 3 hours to 100% capacity

CONFIGURATION MODE
- Power Supply: PC USB input 5V DC
- The BioHarness Module is located in a charging/configuration cradle
- It cannot be fitted to a strap/worn by a subject in this mode
- It is connected to a USB Port of a PC for configuration
- Configuration Parameters are:
  - Transmit and/or logging mode
  - Bluetooth discoverability
  - Device Network ID
  - Bluetooth link configuration settings
  - Internal Date/Time reset
  - Disable button power off while worn by subject
- The device battery is also charged while in this mode
- The LED on the front of the device illuminates flashing orange when in configuration mode

All of these parameters are described in detail in the *BioHarness BT Comms Link Specification* [1] and *BioHarness Bluetooth API Guide* [4] documents.

2.3. System Components

2.3.1. BioHarness Module

FRONT   REAR
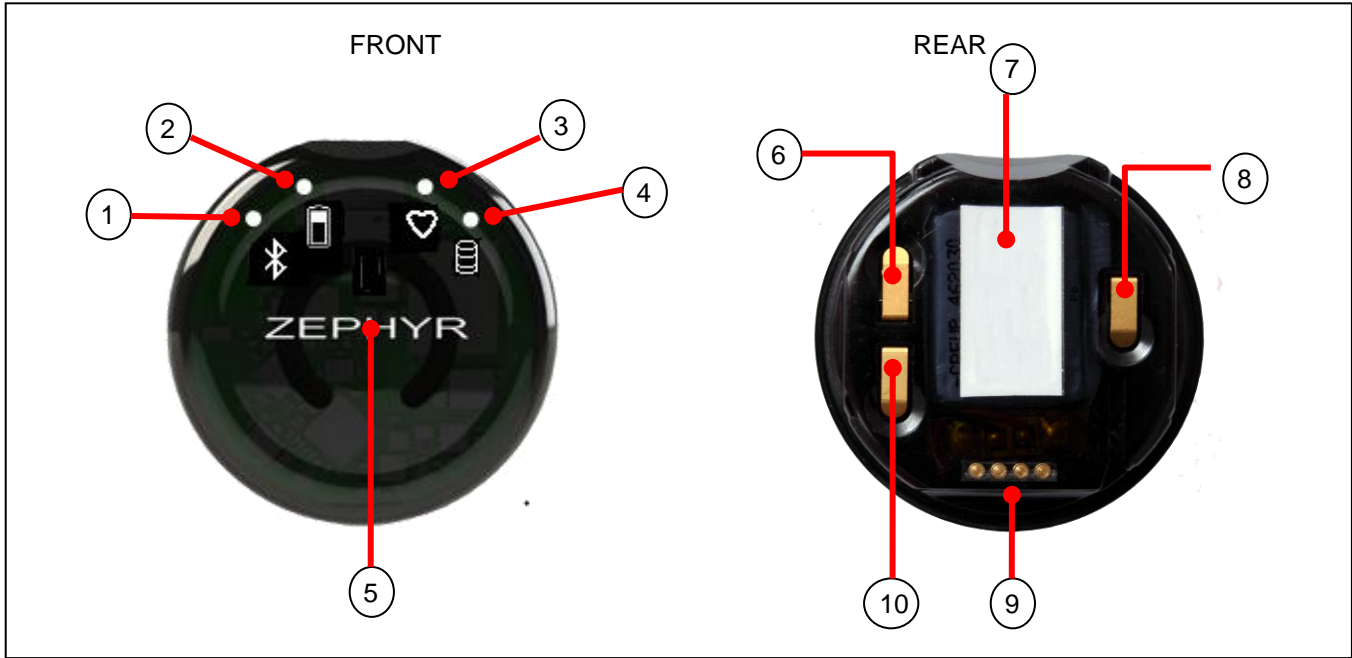
1. Blue Bluetooth indicator LED
2. Orange battery indicator LED
3. Red HR detection status LED
4. Green logging indicator LED
5. ON/OFF button

6. Ground spring contact
7. Rear label location
8. ECG signal spring contact
9. USB charging/configuration contacts
10. Breathing signal spring contact

REAR LABEL DETAIL

ZEPHYR BIOHARNESS 3
FCC ID: VZ6-BH3
IC ID: 7565B-BH3
Contains transmitter modules
FCC ID: T7V1315
IC ID: 216Q-1315
AECG EC38 Type 3
Serial#: BHT#######
Powered by ZEPHYR

Z747
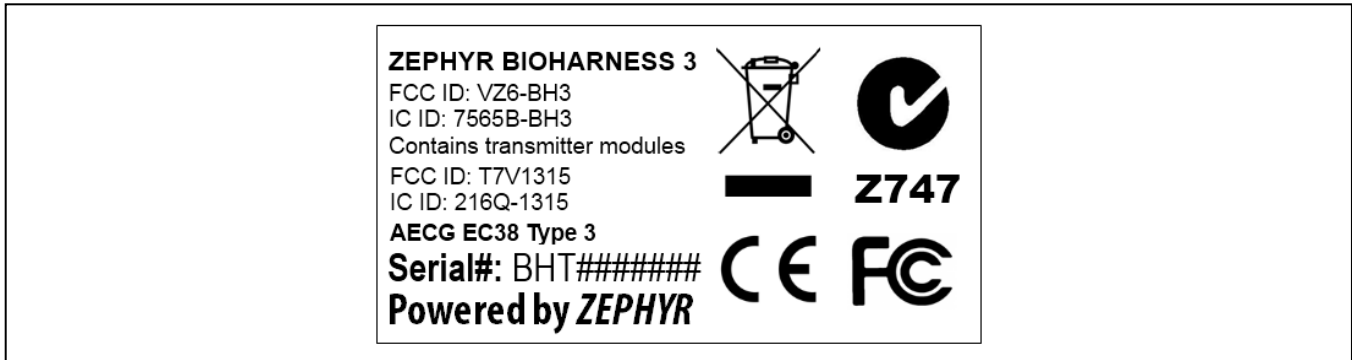
2.3.2. BioHarness Chest Strap
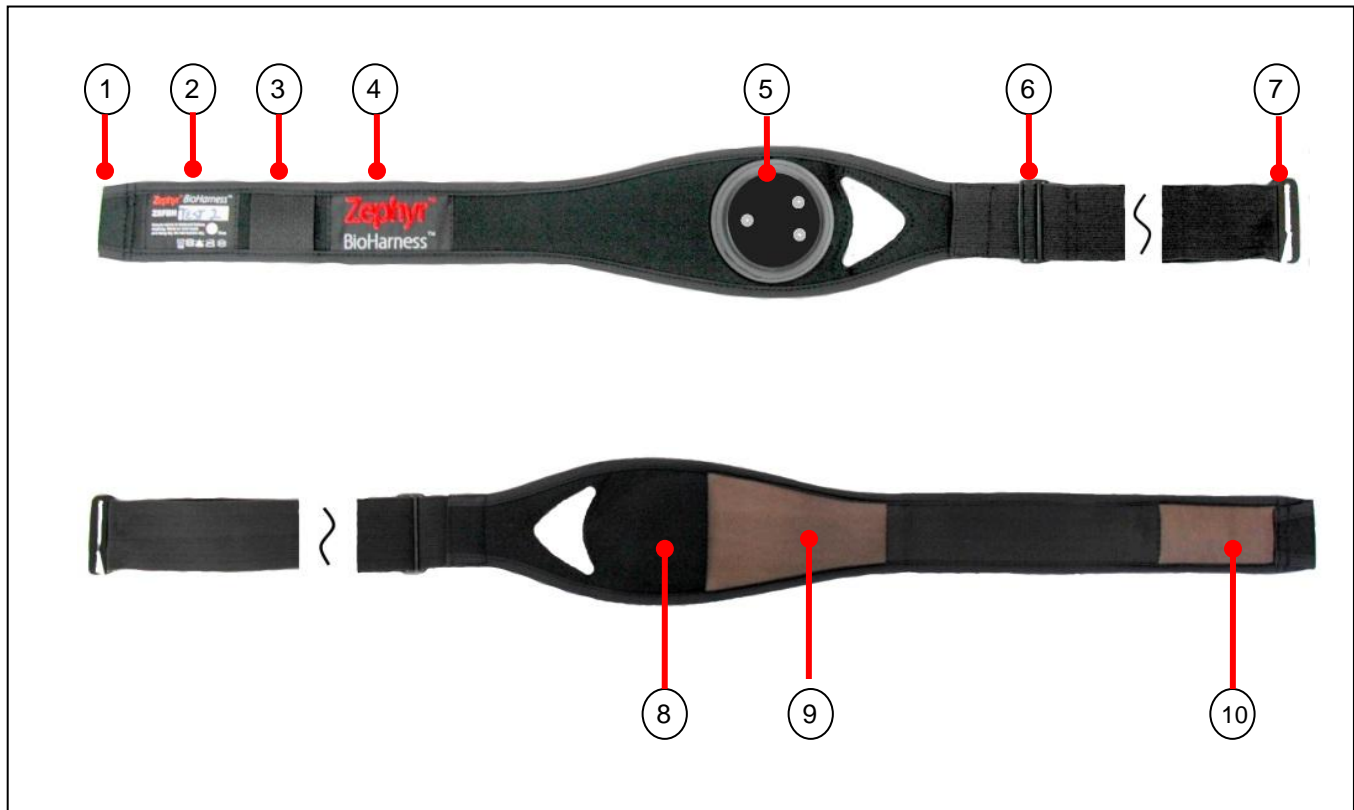
1. Main fastener sleeve
2. Wash, size and serial # label
3. Loop for optional shoulder strap
4. Zephyr brand label
5. BioHarness module receptacle and sensor contacts
6. Size adjustment slider buckle

7. Main fastener hook
8. Internal breathing sensor location
9. Conductive ECG sensor pad
10. Conductive ECG sensor pad

STRAP WASH LABEL DETAIL

Serial **ZSFBH**001019   Size **M**edium

STRAP SIZES

Size	To fit (cm)	To fit (Inches)	ZPN
Small (XS – M)	69 – 84	27 – 33	9600.0262
Large (M – XL)	84 – 104	33 – 41	9600.0265
XLarge (L – XXL)	Up to 129	Up to 51	Pending

SHOULDER STRAP SIZE

Size	To fit (cm)	To fit (Inches)	ZPN
Shoulder strap	adjustable	adjustable	9600.0117

2.3.3. BioHarness Charging and Configuration Cradle

1. USB Mini-B socket 5V 2A input
2. USB Charge & Configuration pins

2.3.4. BioHarness Charge/Configuration Lead

The charging/configuring lead is a standard USB-A plug to USB-mini plug. Zephyr Part No: 0015.0003

2.4.   Software Utilities

The BioHarness Bluetooth product is normally supplied as a software developer's kit (SDK). Included the SDK, along with the documentation described in Section 1.1, are a number of software utilities. Their installation and operation is described in the BioHarness Bluetooth Developer Kit User Manual [3].

2.4.1.   Bluetooth Test Application
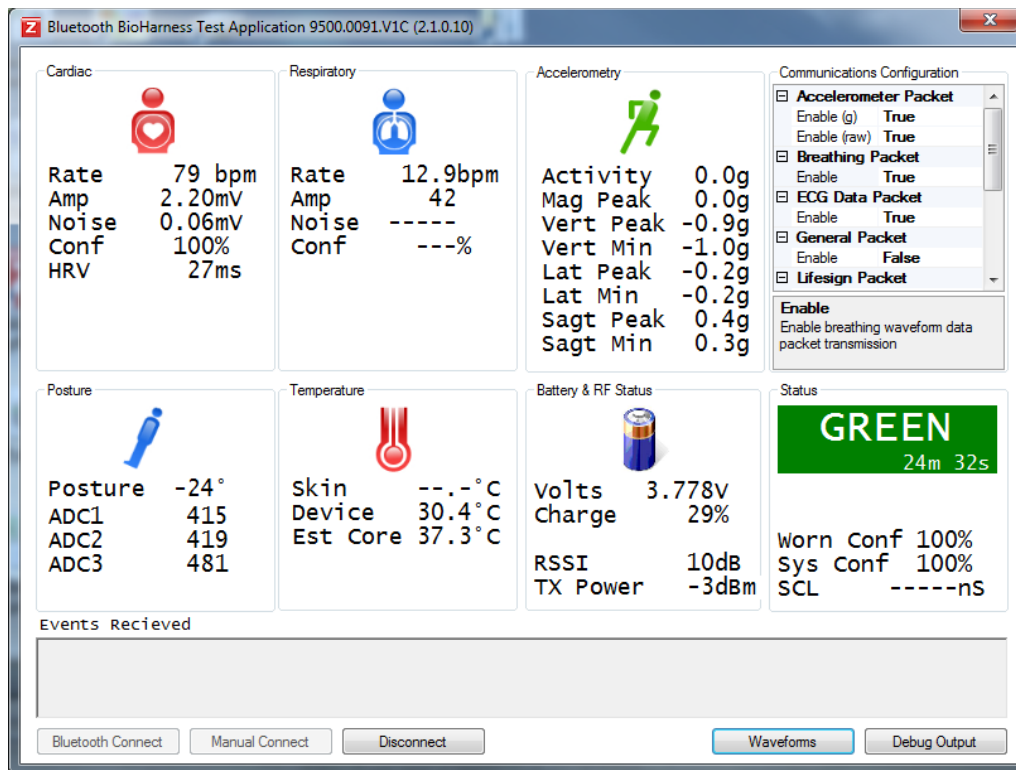
- Displays all summary physiological parameters – Heart Rate, Breathing Rate, Temperature, Posture, Activity Level, Subject Status as well as the battery level of the device
- Displays summary communication data as seen in the *General Status* window above
- Establishes a Bluetooth connection with the device
- Enables or disables the data packets being transmitted by the device
- Generates CSV files of streaming data when the application is closed – see the Data Output section 3.10 for more information.

> ⚠️ The utilities provided by Zephyr as part of the software developer's kit are intended for use by developers to confirm device performance. They are not intended as end-user utilities. Developers who produce end-user software for use with the Zephyr Bluetooth BioHarness are themselves responsible for any compliance requirements of any end-user software they have created.

2.4.2.   Zephyr Config Tool
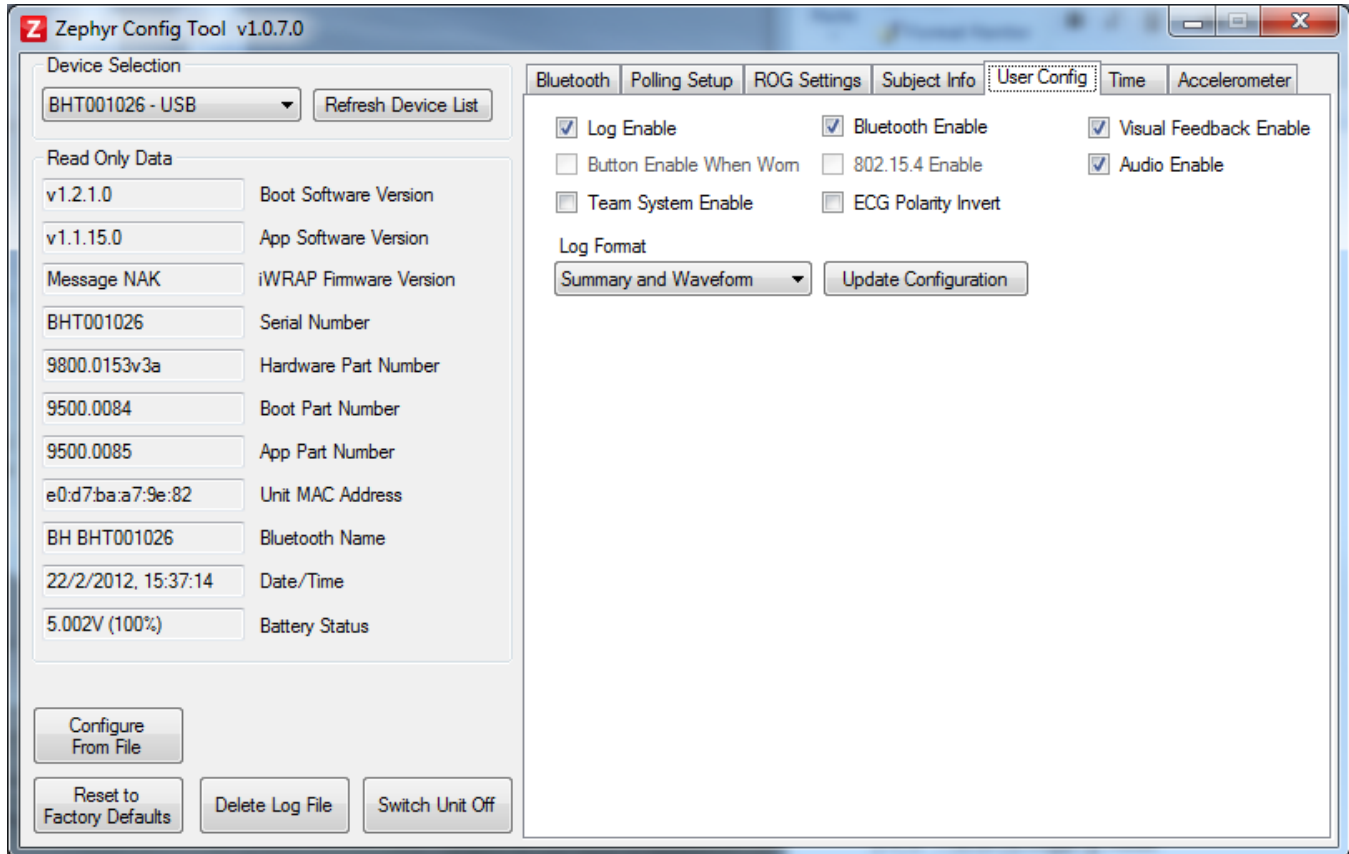
- Reads all software and hardware properties of the device
- Displays and configures Bluetooth connection parameters
- Displays and configures data transmit and/or logging mode
- Sets device internal clock date and time

2.4.3.   BioHarness Log Downloader

This utility can be used to import log data which has been recorded on the BioHarness Module's internal memory when logging mode has been enabled.

This Application generates external .csv files, and/or `.hed` / `.dat` data files, which can be interpreted using third party data analysis software.

3. Operation

3.1. Overview

The following tasks should be checked off before fitting the device to a subject:
- Check the device internal battery is sufficiently charged
- Visually inspect BioHarness Module & chest strap for signs of damage or wear
- Configure the device to transmit/log mode, or both
- Confirm that the subject ROG thresholds stored internally in the device are correct for the wearer
- Confirm the subject is not fitted with a heart pacemaker or defibrillator
- Confirm the chest strap is the correct size for comfortable fitting on the subject

Actual Operation of the device consists of the following steps:
- Fit the device to the chest strap
- Moisten the heart rate sensor pads with water to improve skin conductivity
- Fit the chest strap (and optional shoulders straps if used) to the subject and adjust for fit and comfort
- Power on the device using the front button
- Confirm operation using the LED indicators
- Confirm data reception using suitable software

3.2.   Initial Inspection

Before operation of the BioHarness and strap, check the following:

BIOHARNESS MODULE
- Damage to casing e.g. cracks, scuffing or distortion due to heat. Severe physical impact to the device may compromise subsequent accelerometer performance
- Removal or peeling of labels
- Loose contact springs
- Shake the device and listen for any loose or detached internal components
- Grease or dust contamination of contact springs or USB contact pins. Contamination may affect conductivity – clean with water and a mild detergent. Dry effectively.

BIOHARNESS CHEST STRAP
- Contamination of the strap by perspiration or external factors. Perspiration buildup may show as faint salt deposits if the strap is not rinsed in water after heavy use. Salt contamination on the conductive sensor surfaces may compromise performance of the system. Full washing instructions are included in the Maintenance Section 5.1
- Excessive scuffing or any tearing of the sensor surfaces
- Failed or loose stitching

3.3.   Charge Battery

BioHarness Module in
Charge/Configuration
Cradle

Orange LED flashes while device is charging
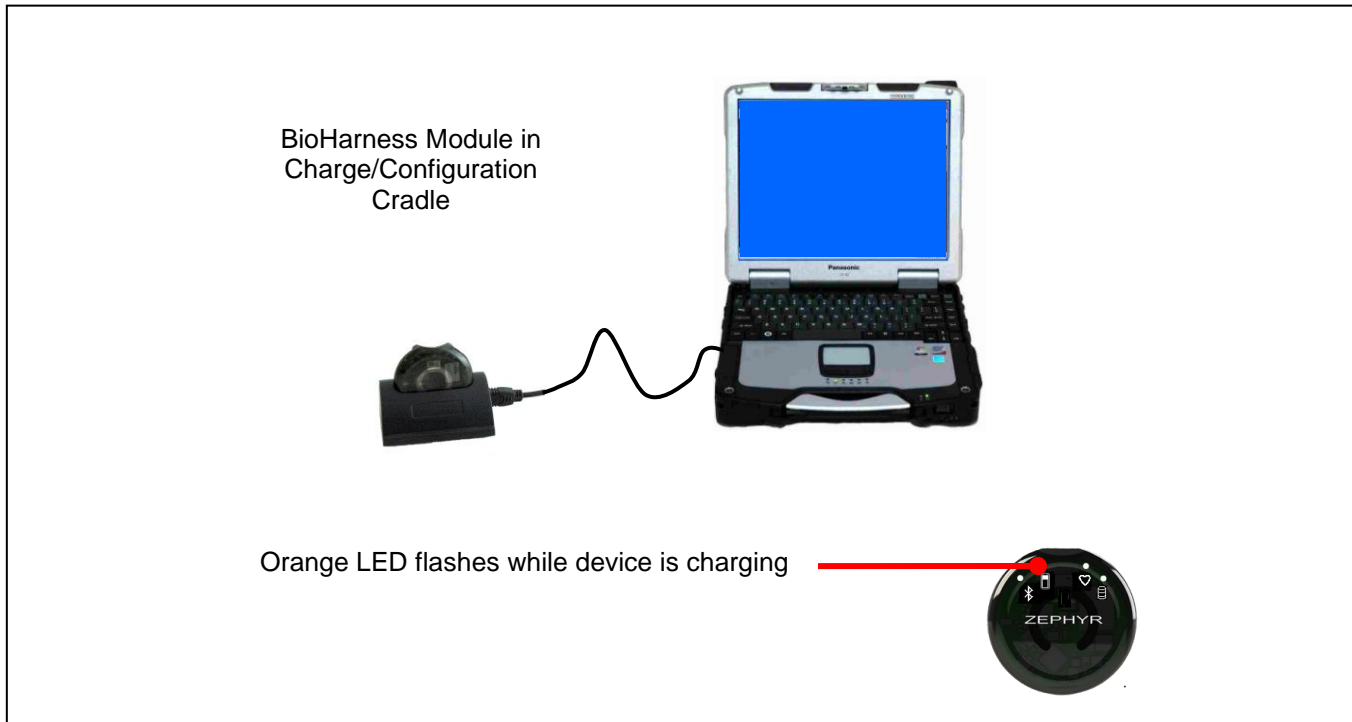
- Charge by placing the BioHarness Module in the charging cradle, and connecting to a PC USB Port.
- An orange (amber) LED will flash on the front of the device when charging
- The LED will stay illuminated when fully charged
- Charge times
  - o   1 hour to 90% capacity
  - o   3 hrs to 100% capacity
- When in operation, the orange LED will flash when battery level is greater than 30% of a full charge. When constantly illuminated, charge is less than 30%. When the orange LED extinguishes, charge is below 10%

- Use only the wall charge unit supplied with the system to charge the device from a domestic power supply.
- Charging at high temperatures (>45°C, 113°F) has risk of fire or explosion

3.4.   Check BioHarness Module Configuration

The BioHarness Module stores previous configurations. To confirm or change a previous configuration, connect the BioHarness module in its cradle to a PC hosting appropriate software, such as the Zephyr Config Tool supplied with the SDK.

The device can be configured to transmit data by Bluetooth and or 802.15.4, anjd/or log data to internal memory. Powering on the device will initiate either or both modes.

BioHarness Module in
Charge/Configuration Cradle
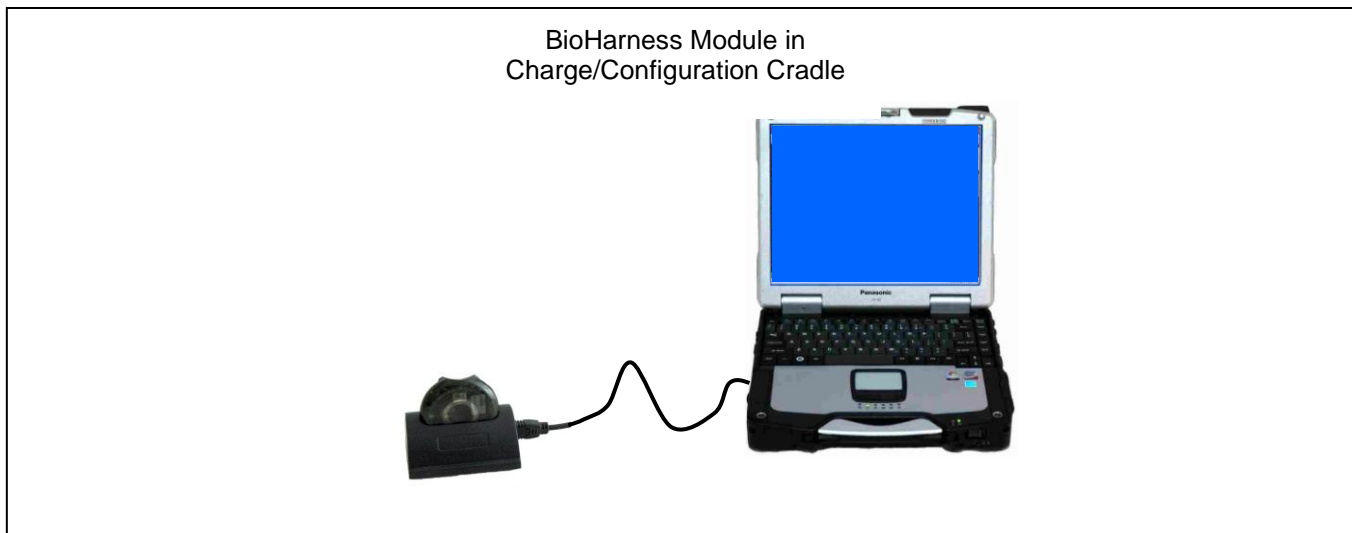
3.4.1.   Set Transmit Mode

Using the Zephyr Config Tool:

1.   Open the Application
2.   Click the *Select Device* button and use the pulldown to select the BioHarness Module, identified by its serial number. This list will automatically populate with the serial number of any device connected to the PC.
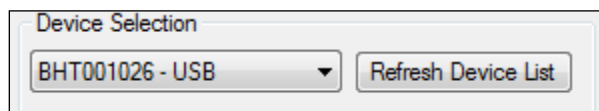
3. To activate transmitting modes, go to the User Config tab of the ConfigTool and check the *Bluetooth Enable* and/or *ECHO Enable.* ECHO is the Zephyr proprietary name for the 802.15.4 transmitting mode.
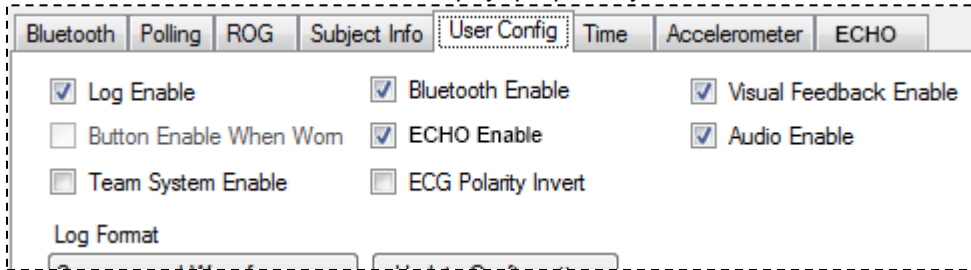
3.4.2.   Bluetooth

1. The *Bluetooth* tab in the Zephyr Cfg Tool allows the following to be configured
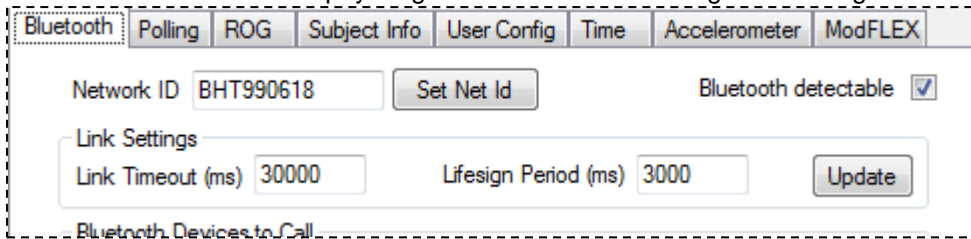
2. Network ID – the label by which the device will be identified when scanned for. Default is device serial number.
3. Bluetooth detectable – the device can be set to be non-detectable if necessary. Default is detectable.
4. Link Timeout and Lifesign period settings. Defaults are shown, for use with Zephyr OmniSense software. When both are set to), no lifesign message need be sent, and the device will never unilaterally time out the Bluetooth link.
5. Other Bluetooth Devices to Call settings are for configuring the BioHarness to connect to auxiliary Bluetooth sensor for use in Zephyr PSM monitoring systems. These will be set automatically for use when the device is used as a component of one of these systems.

3.4.3. 802.15.4 (ECHO)

ECHO is Zephyr's proprietary name for systems which are based on the 802.15.4 protocol.

1. The *Bluetooth* tab in the Zephyr Cfg Tool allows the following to be configured

2. Short transceiver Address – set for use as a polling address in conjunction with Zephyr's PSM Training system. Factory configured. Must be unique within a system (0 – 254)

Channel	Frequency
11	2.405 GHz
12	2.410 GHz
Increment by 1 up to 25	Increment by 5 MHz
25	2.475 GHz

3. RF Power Level. Factory configured at 19dB
4. Max Repeaters – defines the maximum number of Zephyr ECHO receiver units which can be used within a PSM system.
5. The maximum number of repeater hops allowed within a PSM system.
6. Beacon Interval – factory configured.

3.4.4. Set Logging Mode

In the Zephyr Config Tool User Cfg tab:
1. Set the Logging Format from the list available

2. The Summary Logging formats are only available on BioHarness 3.0 versions.

3.4.5. Subject ROG Thresholds

The BioHarness module outputs a subject status indication which has the values:

- Green – subject's physiological parameters are within thresholds as configured
- Orange – one or more of the subject's parameters have crossed the configured threshold values. The subject's data should be monitored more closely.
- Red – one or more of the subject's parameters have exceeded threshold values for a sustained period (configurable). The subject's physiological parameters should be monitored closely, and confirmation sought if there is an indication of stress, fatigue or trauma.

ROG THRESHOLD AND ALERT STATE LOGIC

Subject Status is determined by analyzing Heart Rate, Breathing Rate and Activity level values, calculated over a 5 second rolling average. Activity level is measured by an accelerometer within the BioHarness Device. Parameters are determined to be LOW or HIGH according to the following thresholds:
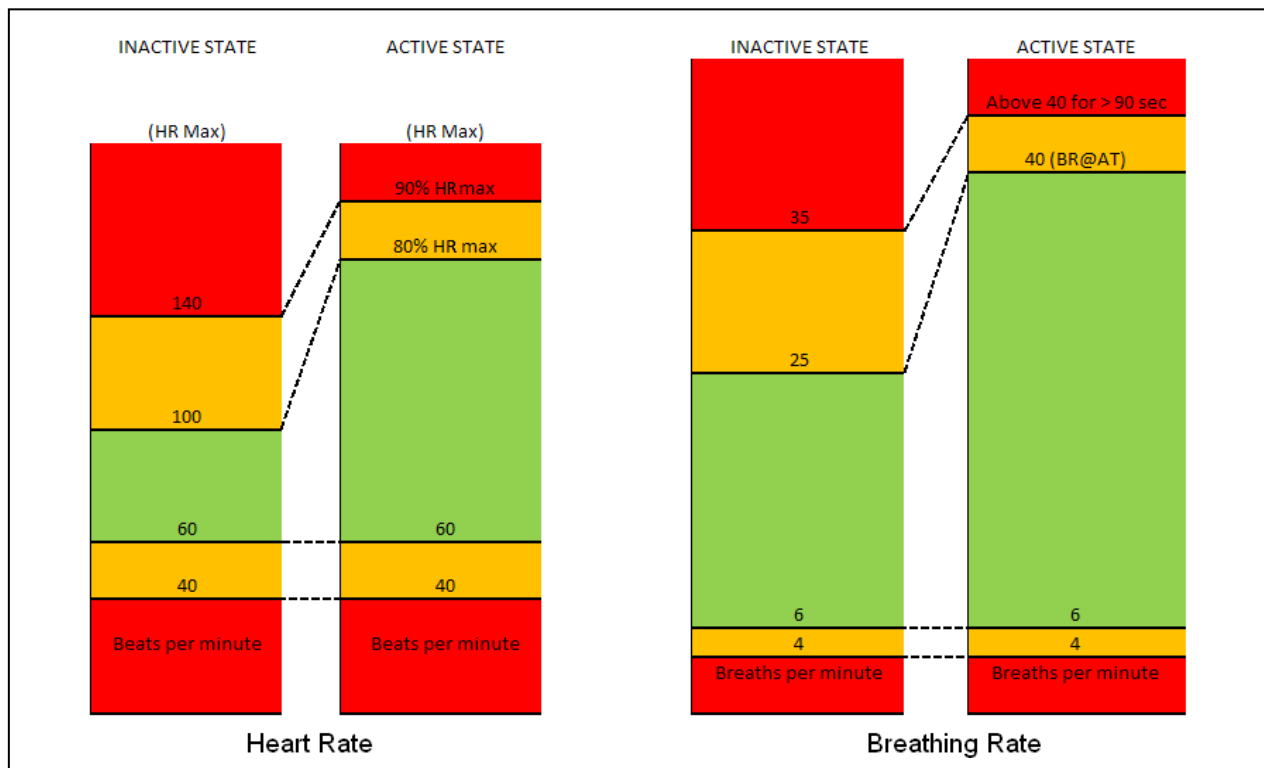
If any of the subject's parameter's above cross from the NORMAL (Green) zone to LOW or HIGH values (Orange/amber or Red), then the subject's state may be raised from Normal to Alert, according to the logic table following.

The default numerical values for the thresholds are set automatically and need not be changed for normal operation.

Any other states are Normal. Each line in the table represents one permutation of parameters which generate an Alert state.

ROG Alert Logic Table

Heart Rate	Breathing Rate	Activity Level	State
NORMAL	NORMAL	NORMAL	No Alert
LOW			Alert
	LOW		Alert
HIGH		NOT HIGH	Alert
	HIGH	NOT HIGH	Alert

The following logic is then applied:

Status Green   +   Alert for 5 seconds   =   Status Orange
Status Orange +   Alert for 55 seconds   =   Status Red

Status Red   +   No Alert for 5 seconds =   Status Orange
Status Orange +   No Alert for 5 seconds =   Status Green

A No Alert State for 5 seconds will reduce State from Red to Orange, or Orange to Green.
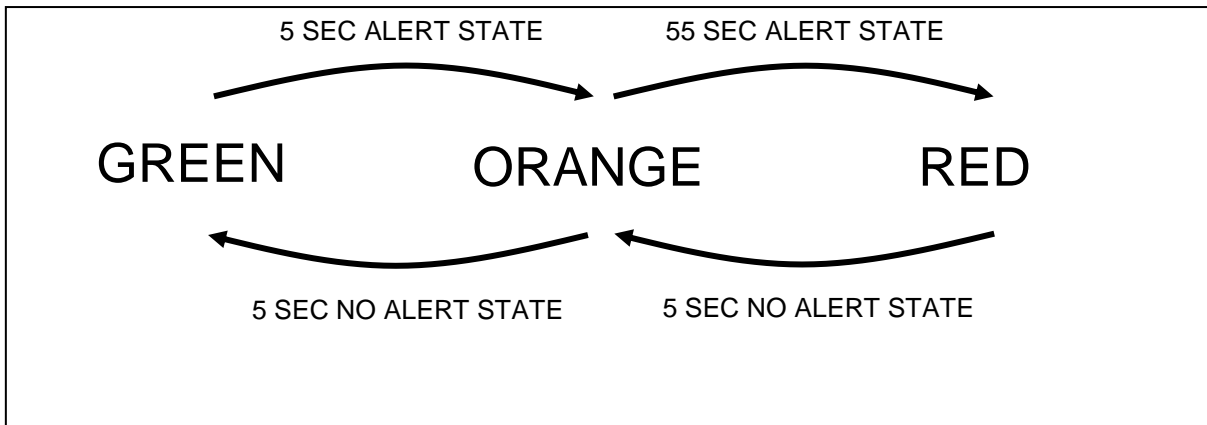
The time intervals shown above are also configurable. The values indicated are the default values:

Green + 5 seconds Alert = Orange > Green to Orange Time
Orange + 55 seconds Alert = Red > Orange to Red Time.

3.4.6. ROG Threshold Default Values

Subject ROG thresholds can be configured and stored inside the device, so that it can transmit an indication of ROG status as determined by the logic in the previous sections. Information on configuring the device ROG thresholds is described for developers in [1] *General Comms Link Specification*.

3.5. Confirm Subject State

Before fitting the chest strap to the subject, confirm the following:

- Subject is not fitted with a heart pacemaker or automatic defibrillator
- Subject has no pre-existing skin irritation or trauma on the area where the strap will be located
- Subject has not applied any lotion, cream or oil to the skin area where the ECG sensors will be located

.
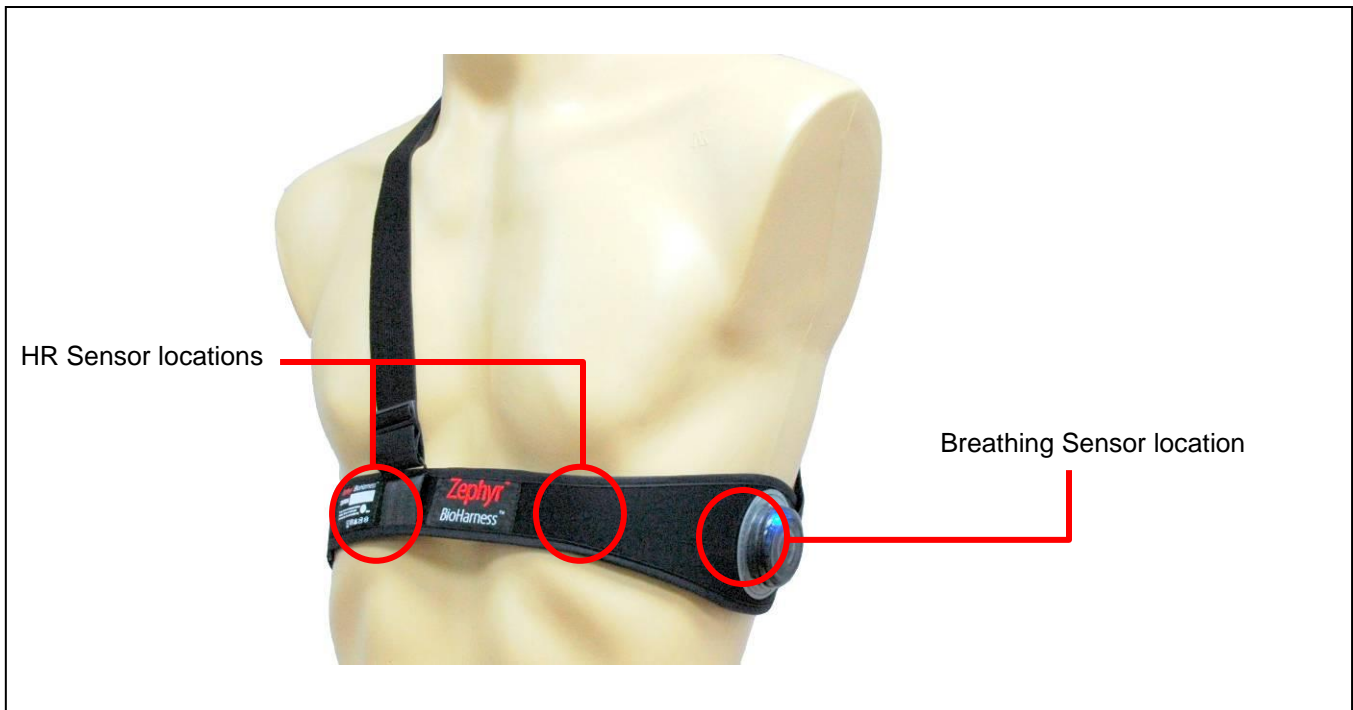
3.6. Fit BioHarness Module to Strap

The BioHarness Module attaches to the chest strap by insertion into a custom receptacle. A cutout on the top edge of the device allows for finger leverage to remove from the receptacle, and a ridge in the receptacle and matching groove in the device itself prevent improper insertion.

Three metal rivets locate through the receptacle and form conductive paths to the ECG and breathing sensors. These rivets make contact with alloy spring contacts on the rear of the BioHarness module.

Check the springs for contamination before attaching the module.

3.7.   Fit Strap to Subject

In order that the BioHarness Module may perform as it was designed, the chest strap must be fitted in the correct location, with an appropriate level of tension around the subject's torso.

1. For optimum performance, lightly moisten the sensor pad surfaces with water to aid conductivity. Press the water into the pad if beading on the surface occurs.
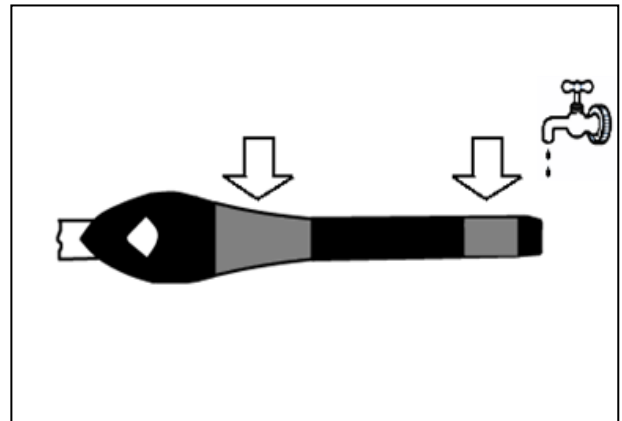
2. To adjust tension, wear the strap with the main attachment hook and tension slider adjuster *initially* at the front.

3. The strap should be a snug fit, so as not to move when the subject is active. A tension loop is sewn at the rear of the strap. When the subject has inhaled and the chest fully expanded, the tension loop should be flush with the main strap – it is shown un-tensioned in the image.

4. When size is adjusted, rotate the strap so that the device is located under the subject's left armpit, with Zephyr brand label at the front – the brand label *may not be exact centre.*

5. When correctly located, a line through the centre of the device should be directly beneath the subject's arm pit, or slightly (~1/2") to the rear
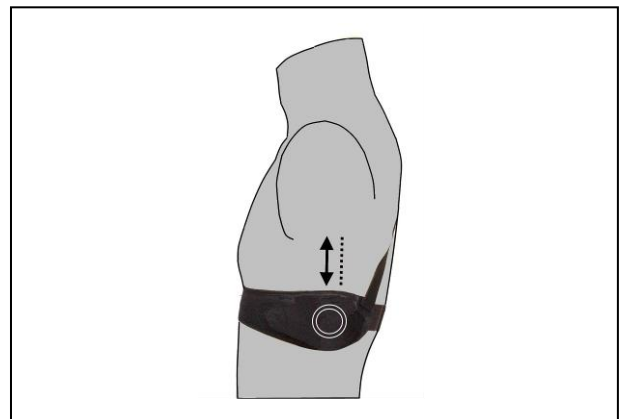
3.8. *Power On/Off BioHarness Module*

- Power On the BioHarness Module by depressing the center front of the device. The button has a tactile click to indicate switching. Hold the button depressed until the all four LEDs flash.
- The device may be powered on before or after attachment to the strap. However, attaching the device while it is recording and/or transmitting data produces an electrical noise spike as contact is made. It may not be desirable for this noise spike to be present in any recorded data. If this is the case, attach the device to strap before powering on.
- To power off the device, depress and *hold* the control button until the LED stops flashing.

3.8.1. Data Stabilisation Times

Parameter	Time to stable data output (Device ON, worn by subject)
Heart Rate	15 seconds
Breathing Rate	45 seconds
Device Temperature	Immediate
Activity Level	5 seconds
Posture	5 seconds
Subject Status Indication (Red/Orange/Green)	45 seconds

3.8.2. Device LED Behaviour

The BioHarness module can operate in three modes:

- Transmit data by Bluetooth
- Log data to internal memory (no transmit)
- Both Transmit and log the same data simultaneously

The device can be configured to these modes using the BT Config Tool.

DEVICE STATE WHEN WORN

Transmit	Connected	Error	Disabled
Logging	Enabled	Error	Disabled
Battery	> 30% charge	< 30% charge	< 10% charge
HR Detect	HR Locked	Strap worn, HR not locked	Not worn

DEVICE STATE IN CRADLE

Transmit	Connected	Error	Disabled
Logging	Downloading	Error	No records/Finished
Battery	Charging	Charged	No power
HR Detect	Always off		
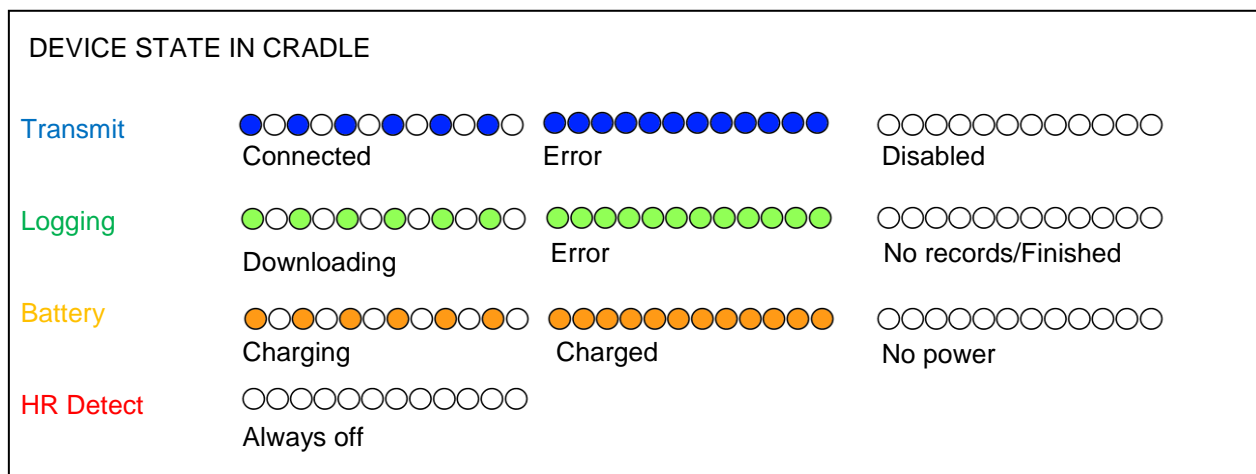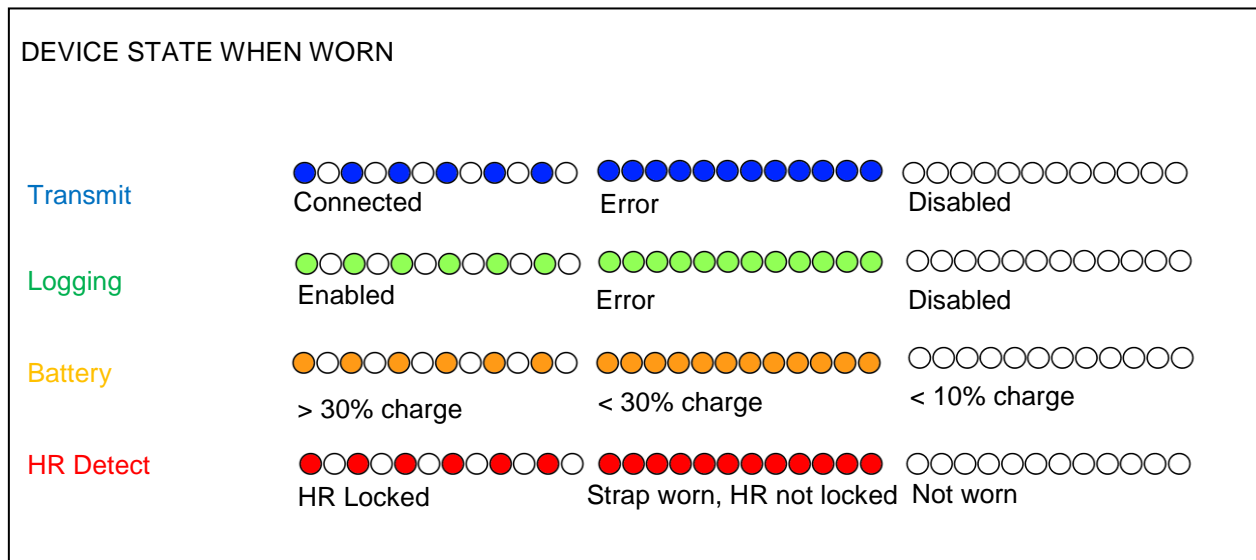
3.9. Transmitted Data

Data output from the device is described fully in the General Comms Link Specification [1]. Data output is in the form of a number of messages, each of which can be enabled or disabled. Details on how to do this are included in the above document.

For a full description of all transmitted parameters and data packet options, refer to the BioHarness 3.0 Data Sheet.

3.10. Logged Data

Logging modes can be configured using the Zephyr Configuration tool. Available modes are:
- General data (default)
- General + ECG
- General + Accelerometer
- Summary data
- Summary + Waveform

When device memory is full, older logs are overwritten automatically. Alternatively, all logs can be deleted using the Zephyr Configuration Tool.

For a full description of all logged parameters and log format options, refer to the BioHarness 3.0 Data Sheet.

4. Interpretation of Data

The BioHarness Bluetooth device intended use is to provide contextual remote physiological information. It should be used as an aid in the diagnostic process.

The device may indicate that a subject parameter is outside an acceptable range of values. Interpretation of such indication should be informed by one or more of the following:

- Knowledge of the subject's underlying physiological condition e.g. level of fitness, abnormal blood pressure etc
- Pre-existing medical or physiological conditions e.g. fatigue, dehydration, infection, trauma
- Environmental Factors such as heat, humidity etc, or mechanical or motion factors which may affect activity data
- Subject level of activity and any other circumstance which may lead to stress or fatigue such as fear, lack of sleep, etc.

Departure of heart rate, breathing rate or activity level from an acceptable range of values *may or may not* cause the subject's Red / Orange / Green Status indication to alter. This will depend on the values which have been assigned to the subject's ROG thresholds stored in the device. These values may be occupational or activity-dependent.

In addition, the following factors may affect individual physiological parameter readings:

4.1. Heart Rate

Indication	Possible Cause
Low Heart Rate	Excessive noise caused by sensor/skin relative movement and/or poor conductivity between the skin surface and the sensor. Adjustment of the chest strap tension for the correct fit, and moistening of the sensor surfaces with water will address this issue in most cases.
High Heart Rate	As above.

4.2. Breathing Rate

Indication	Possible Cause
Low Breathing Rate	Incorrect tension on the chest strap may prevent adequate sensor response to chest expansion and contraction. If the strap is too loose, it may not respond the chest expansion – if too tight, it may not respond to chest contraction. Individual subject breathing characteristics which are predominantly diaphragmatic, as opposed to apical breathing.
High Breathing Rate	Direct palpitation of the breathing sensor location from an external source which mimics the cyclical breathing action. This may be due to the regular movement of any object which can apply direct external pressure to the sensor such as equipment components or webbing.

4.3.   Skin Temperature

Indication	Possible Cause
Minus 3276.8°C	A skin temperature channel in the general transmitted packet and log format exists in order to maintain reverse compatibility with earlier versions of Zephyr application software. However the BioHarness 3.0 always returns an 'Invalid' value of -3276.8 °C for this parameter. The BioHarness 3 does not support the Skin Temperature channel.

4.4.   Activity Level

Indication	Possible Cause
Erroneous high activity level	Internal accelerometers measure absolute movement of the device. If a subject is inactive, but in an environment which exerts forces on the device e.g. almost any mode of transport, then indicated activity level will reflect the motion of the vehicle rather than the subject

5. Maintenance & Cleaning

> ⚠️ The BioHarness Module and Chest Strap contain no user serviceable parts. Return the components to your distributor, or the manufacturer, in the event of failure or need for battery replacement.

5.1.   BioHarness Module

- Visually inspect the device before use, to check for signs of damage or contamination to the casing and spring contacts
- Check that the spring contacts on the rear of the case have not been prised proud of the case surface, which may cause them to catch on the USB charge/configuration cradle when the device is inserted.
- Clean with a damp cloth when needed
- Use mild detergent if necessary
- Avoid leaving in direct sunlight for long periods
- The device does not require calibration

> ⚠️ The BioHarness Module does not require sterilisation or disinfection for normal use. Do not autoclave, or use sterilising tablets.

5.1.1.   Battery Lifetime and Replacement

The BioHarness Module is powered by an internal rechargeable Lithium Polymer cell.

> ⚠️ Battery is not user replaceable. Return to your distributor for replacement. Only trained personnel should change a battery.

Expected battery charge cycles: battery should retain 80% of new capacity after 300 charge cycles

BATTERY MAINTENANCE TIPS

- Store the device at 20 – 25 °C to prolong battery life.
- Avoid storing in an uncharged state for prolonged periods
- A top-up charge of the battery is recommended once a month if the device is not used regularly, to maintain optimum battery condition

5.2.   BioHarness Strap

WASH INSTRUCTIONS

- Detach the BioHarness™ module
- Rinse strap in fresh water after use to prevent salt buildup from perspiration
- Hand Wash, or
- Machine-wash on a Cold, Delicate setting after 30 days of use.
  - Firmly attach the Velcro® fastenings together and do not wash with other garments which may be damaged by these fastenings.
  - Use a washing pouch if possible.
  - Use soap or mild detergent, but NOT sterilizing tablets
  - Maximum recommended wash temperature: 40°C / 104°F
  - Do Not spin or tumble dry
  - Hang to dry, out of direct sunlight.
  - Do not bleach.
  - Do not iron.
- Zephyr guarantees performance for a minimum of 80 machine washes of the chest strap.

6. Accessories and Replacement Components

The following are Zephyr replacement component and accessory parts:

Component	Part/Product Number
BioHarness Bluetooth Developer Kit (includes 3 chest straps)	9700.0019
BioHarness Bluetooth Module (Electronics sensor)	9800.0189
BioHarness Chest Strap Small (XS-M)	9600.0262
BioHarness Chest Strap Large (M-XL)	9600.0265
BioHarness Shoulder straps (optional – one size adjustable)	9600.0117
BioHarness Charge Cradle & USB Cable (for single device)	9600.0257

Further component combinations, such as BioHarness Module/Strap additional units, and 5 or 50 packs of chest straps are also available. Consult a Distributor for more information.

7. Technical Specifications

Unless otherwise stated: Temperature = 25 °C, Pressure = 1 ATM

7.1. *Electrical*

Power Supply:
Type: Rechargeable Lithium Polymer
No. of cells: 1
Nominal Voltage: 3.7V
Charge Source: PC USB or USB wall charger

7.2. *General & Physiological*

Parameter	Notes		Values				
		Min	Typ.	Max	Acc'y	Unit
General						
Logging capacity	1		500+			hours
Power supply voltage	USB	4.5	5	5.5		V
Battery Life – Radio transmitting	2	12		24		hrs
Battery Life - Logging	3		35			hrs
Charging Time			3			hrs
Storage	Between charges		6			
Charging Cycles	4		300			Cycles
Digital resolution			12			bits
Heart Rate						
ECG sensor sampling frequency			250			Hz
Range	5	25		240	±1	BPM
Time to first lock	At 60 bpm		15	25		s
No Signal Response time	60 to 0 bpm		10			s
Input dynamic range		0.1		10		mV$_{pp}$
ECG Amplitude	6	0.25		15		mV

Operating Modes:
Active   – device transmitting data + logging, if configured
Standby   – device not transmitting but connectable + logging, if configured
Notes:
1. General Logging (Gen + ECG = 140hrs, Gen + Acceleration = 280hrs)
2. Min Period – after 180 charge cycles. Max Period – new battery
3. Software required for data download.
4. After 300 deep discharge/charge cycles the battery will retain a minimum of 80% of its original capacity.

5. Heart Rate Accuracy for defined activity levels: based on USARIEM* guidelines

Accuracy (bpm)	Activity Level	VMU	% of time	Max Deviation (bpm)
±1	Laboratory – ECG emulator		100	1
±2	Low activity (static)	< 0.2	99	5
±3	Moderate activity (walk/jog)	< 0.8	95	5
±3	High activity (run)	> 0.8	95	10

6. Accuracy greater of 100 µV or 10%

*United States Army Research Institute of Environmental Medicine

Parameter	Notes		Values			
		Min.	Typ.	Max.	Acc'y	Unit
Breathing Rate						
Sampling frequency			25			Hz
Range	7	3		70	±1	BPM
No signal response time			15			s
Step change response time			15			s
Device Temperature						
Sampling frequency	8		1			s
Range		10		60	±2	°C
Stabilization Time			20			minutes
Acceleration						
Sampling Frequency			100			Hz
Range (any axis)		-16		+16		g
Bandwidth			50			Hz
Sensitivity			12			mg
Activity						
VMU (vector magnitude units)	9			16		g
Epoch			1			s
Bandwidth		0.06		9		Hz
Dynamic Range (any axis)		−16		16		g
Sensitivity			10			mg
Noise			7.2			mg
Posture						
Reporting frequency			1			Hz
Dynamic Range	10	-180		+180		Degrees
Epoch			1			s
Sensitivity		8		1		Degrees

Recommended storage temperature 20°C

Notes:

7. Breathing Rate Accuracy for defined conditions: based on USARIEM* guidelines

Accuracy (Bpm)	Condition (average every 15 seconds)	VMU	% of time	Max Deviation (bpm)
±2	Laboratory – breathing emulator		100	2
±3	Low activity (static)	< 0.2	95	5
±3	Moderate activity (walk/jog)	< 0.8	95	5
±5	High activity (run)	> 0.8	90	12
±5	Talking & breathing rate in range 6 – 25 bpm		100	

8. Min = device transmitting, Max = device logging
9. Vector Magnitude Units, 3 axis, sampled at 125 Hz, averaged to 1 second epoch.
10. 0° = vertical, 90° = horizontal. 180° = inverted. Subject anterior inclination is a positive value, posterior is negative. Medio-lateral inclination does not affect sign of posture value.

7.3. RF

7.3.1. Bluetooth

Compliance	Version 2.1 + EDR
Supported Profile	Serial Port
Discoverability	Configurable
Frequency	2.4 to 2.835 GHz
Output Power	10 dBm
Operating Range	Up to 300ft / 100m
	Up to 300yds with long range receiver antenna
	(Dependent on Bluetooth receiver components)
Sensitivity	-91 dBm
Antenna Type	Internal

7.3.2. 802.15.4

Compliance	IEEE 802.15.4
Frequency	2.405 – 2.480 GHz
Output Power	100mW
Operating Range	Up to 300 yds / 275m
Sensitivity	-89 dBm
Max Data Rate	250 kbps
Modulation Type	OQPSK
Spread Spectrum	DSSS

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7.4. Compliance

The BioHarness has been designed to conform to the following:

EC38 Type:	Type 3
RTTE:	Directive 1999/5/EC
FCC ID:	VZ6-BH3
IC ID:	7565B-BH3
Contains Transmitter Module:	
FCC ID:	T7V1315
IC ID:	216Q-1315

FCC Declaration

NOTE: THE MANUFACTURER IS NOT RESPONSIBLE FOR ANY RADIO OR TV INTERFERENCE CAUSED BY UNAUTHORIZED MODIFICATIONS TO THIS EQUIPMENT. SUCH MODIFICATIONS COULD VOID THE USER'S AUTHORITY TO OPERATE THE EQUIPMENT.

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.

Any computer used in conjunction with this device must be covered by a Declaration of Conformity or must be FCC certified in its own right.
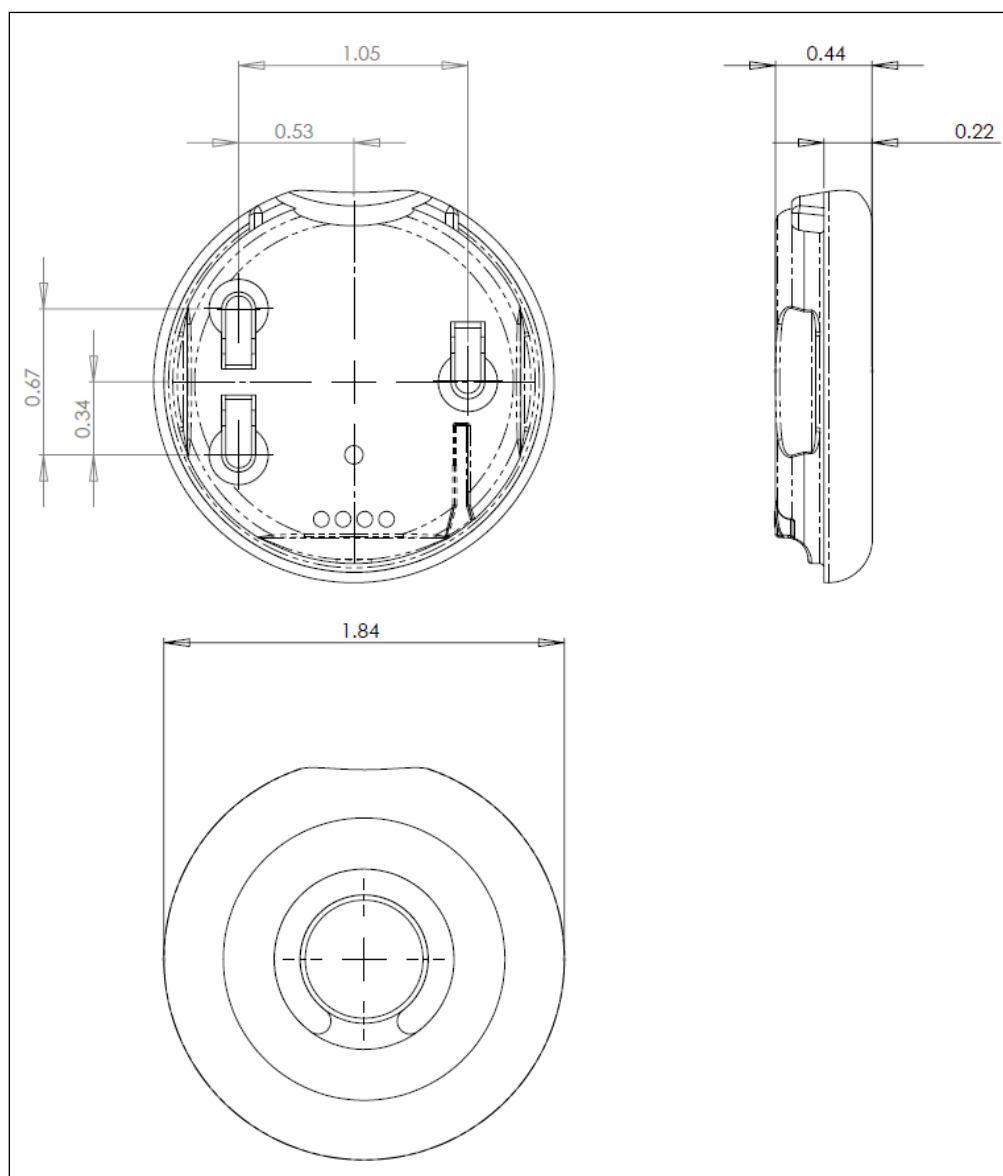

7.5. Environmental

Operating Temperature	-30°C / +60°C
Storage Temperature	-40°C / +85°C
Charging Temperature	0°C / +45°C
ESD	IEC 801-2KV
IP Rating:	IP55

7.6. Mechanical

Dimensions	Transmitter/recorder	28 (Diam) x 7 mm (1.84 x 0.44 inches)
	Charging Cradle (Single device)	80w x 24d x 37h mm (2.5 x 1.6 x 1.1 inches)
Weight	Strap (Large)	71 grams
	Transmitter/recorder	18 grams
Case Material	PC	Polycarbonate

All dimensions in inches.

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