

Zephyr BioHarness™ 3

PRODUCT DESCRIPTION

The BioHarness™ 3 is a compact physiological monitoring module. It is attached to a lightweight Smart Fabric strap or garment which incorporates ECG and Breathing detection sensors.

The BioHarness™ module can transmit physiological data or record it to internal memory.



Company Information

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Data subject to change

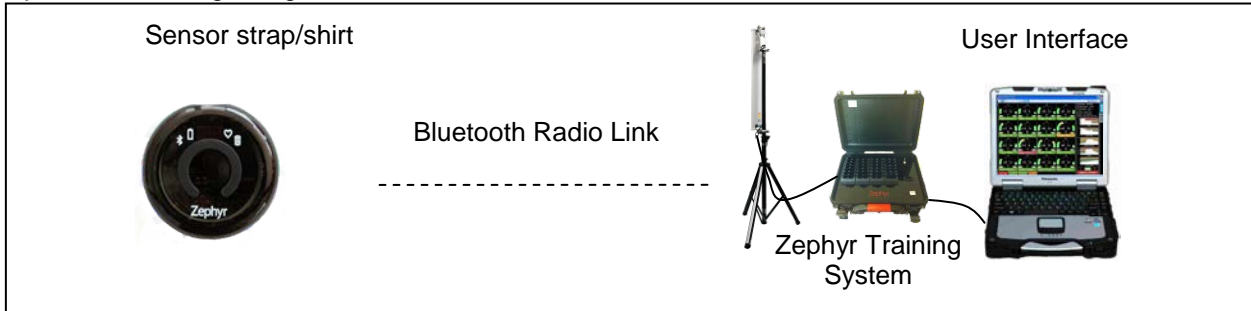
FEATURES

- Bluetooth Connectivity to receiver or external sensors
- Heart Rate 25 – 240 BPM (± 1 BPM)
- Breathing Rate 3 – 70 BPM (± 1 BPM)
- Device Temperature 10 – 60°C (± 2 °C)
- Position/posture $\pm 180^\circ$ (Laying, standing)
- Activity in VMU (Stationary, walk, run)
- 3 axis Acceleration to 16g
- Red / Orange / Green subject status indication
- Transmit and/or Logging Modes
- EC38 Type 3
- 250Hz ECG Transmission & Logging
- 100Hz Accelerometer Logging
- USB connectivity for data download & charging
- Up to 500+ hours data storage
- Internal algorithms for
 - Estimated core temperature
 - Jump Test
 - Dash Test
 - Fall detection
 - Heart Rate Variability
 - Human Real Data

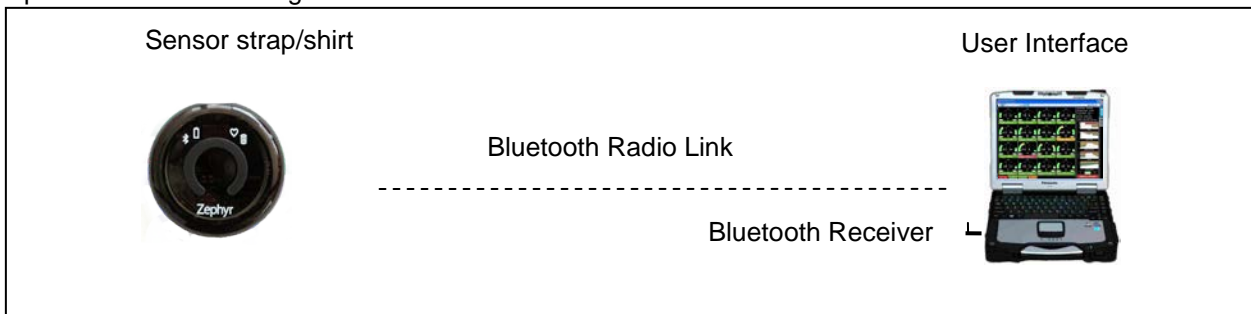
APPLICATIONS

- Biomechanical and physiological research
- Remote Patient Monitoring
- Physical status monitoring in real world situations

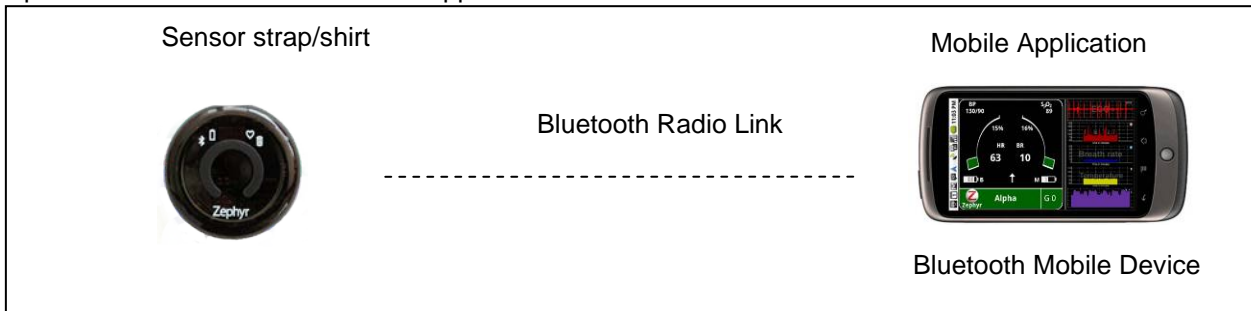
Optional Live Long-Range Data Transmission



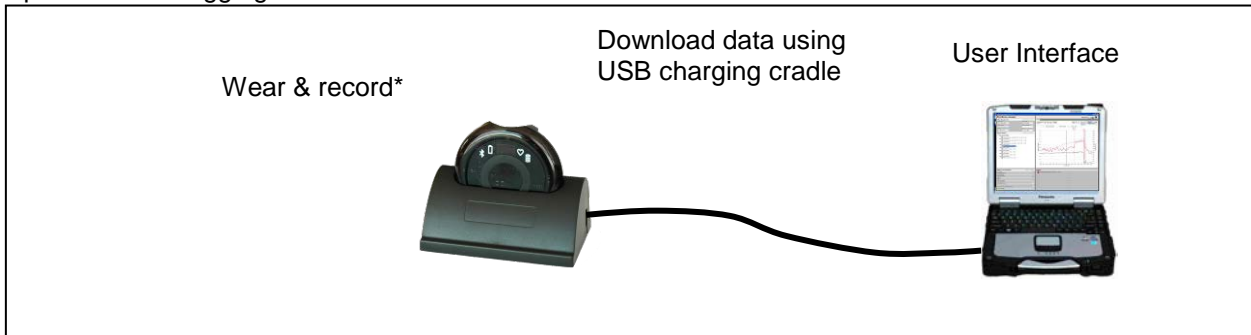
Optional Live Short-Range Data Transmission



Optional Transmit to Mobile Device Application



Optional Data Logging



*Device must be configured to log. Software needed for data import.

Specifications (Unless otherwise stated: Temperature = 25 °C, Pressure = 1 ATM, Fresh battery, g = gravity units)

Power Supply: Internal Lithium cell, rechargeable via USB charging cradle or USB wall charger.

Parameter	Notes	Values			resolution	Unit
		Min	Typ.	Max		
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
Log Download Time	4	1		6		Min per hr of log
Charging Time			3			hrs
Storage	Between charges		6			months
Charging Cycles	5		300			Cycles
ECG Digital resolution	6	10		12		bits
Heart Rate						
ECG sensor sampling frequency			1000			Hz
Range	7	25		240	±1	BPM
R-R		250		1500		ms
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	8	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. Min: General Log only. Max: Summary + Waveform
5. After 300 deep discharge/charge cycles the battery will retain a minimum of 80% of its original capacity.
6. 12 bit sampling. Transmit 10 bit, Log 12 bit.
7. Heart Rate Accuracy for defined activity levels: based on USARIEM* guidelines

Accuracy (bpm)	Activity Level	VMU	USARIEM % of time	Zephyr % of time	Max Deviation (bpm)
±1	Laboratory – ECG simulator		100	99	1
±2	Low activity (static)	< 0.2	99	99	5
±3	Moderate activity (walk/jog)	< 0.8	95	96	5
±3	High activity (run)	> 0.8	90	95	10

8. Accuracy greater of 100 µV or 10%

*United States Army Research Institute of Environmental Medicine

Parameter	Notes	Values			Acc'y	Unit
		Min.	Typ.	Max.		
Breathing Rate						
Sampling frequency			25			Hz
Range	9	3		70	±1	BPM
No signal response time			15			s
Step change response time			15			s
Device Temperature						
Sampling frequency	10		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)	11			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	12	-180		+180		Degrees
Epoch			1			s
Sensitivity		8		1		Degrees

Recommended storage temperature 20°C

Notes:

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

Accuracy (Bpm)	Condition (average every 15 seconds)	VMU	USARIEM % of time	Zephyr % of time	Max Deviation (bpm)
±2	Laboratory – breathing emulator		100		2
±3	Low activity (static)	< 0.2	95	75	5
±3	Moderate activity (walk/jog)	< 0.8	95	65	5
±5	High activity (run)	> 0.8	90	75	12
±5	Talking & breathing rate in range 6 – 25 bpm		100		

10. Min = device transmitting, Max = device logging

11. Vector Magnitude Units, 3 axis, sampled at 100 Hz, averaged to 1 second epoch.

12. 0° = vertical, 90° = horizontal. 180° = inverted. Subject anterior inclination is a positive value, posterior is negative. Mediolateral inclination does not affect sign of posture value (i.e. sideways tilt).

Data Output – Transmitted Data

Data output is in the form of a number of messages, each of which can be enabled or disabled.

Parameter	Reporting Frequency (Hz)	Range	Units	Description
General Data Packet				
Heart Rate	1	25 – 240	BPM	Beats per Minute
Breathing Rate	1	3 – 70	BPM	Breaths per Minute
Skin Temperature	1		°C	Invalid (-3276.8) always returned. Not supported.
Posture	1	±180	Degrees	Vertical = 0°, Inverted = 180°
Activity Level	1	16	VMU (g)	
Peak Acceleration	1	±16	g	
Battery Voltage	1	3.5 – 4.2	V	
Breathing Wave Amplitude	1	0 - 65534	bits	Indicative only
ECG Amplitude	1	0 – 0.05	V	Indicative only
ECG Noise	1		V	Indicative only
X Acceleration Min	1	±16	g	Vertical axis, output 1/10 g's
X Acceleration Peak	1	±16	g	
Y Acceleration Min	1	±16	g	Lateral axis
Y Acceleration Peak	1	±16	g	
Z Acceleration Min	1	±16	g	Sagittal axis
Z Acceleration Peak	1	±16	g	
ROG Status	1	R,O,G		See section 3.4.2
Strap Worn Status	1	0,1		0 = not worn.
Device Button pressed status	1	0,1		0 = not pressed
Battery Percentage of Full Charge	1	0 – 100	%	% of full capacity
Breathing Data Packet				
Breathing sensor output	18	0 – 4095	bits	Does not indicate breathing depth
ECG Packet				
ECG Sensor output	250	0 – 1023	bits	For debugging purposes only 1 bit = 0.013405 mV Reference generated at 60bpm
Heart Rate R-R Packet				
HR RR value	18	Minimum 250	ms	Alternating ± sign at new detection
Accelerometer Data packet				
X axis acceleration	50	±16		Scaled 0 – 4095, 2131 = 0g 83 = 1g (16g accelerometer)
Y axis acceleration	50	±16	bits	
Z axis acceleration	50	±16	bits	

1. All data packets are time stamped in milliseconds.

Parameter	Reporting Frequency (Hz)	Range	Units	Description	Invalid Value
Summary Data Packet					
Heart Rate	See 1. below	25 – 240	BPM	Beats per Minute	65535
Breathing Rate		3 – 70	BPM	Breaths per Minute	6553.5
Skin Temperature	2.		°C	Invalid always returned – not supported.	-3276.8
Posture		±180	Degrees	Vertical = 0°, Inverted = 180°	-32768
Activity Level		16	VMU (g)		655.35
Peak Acceleration		±16	g		655.35
Battery Voltage		3.5 – 4.2	V	3904 = 3.904V	65.535
Battery Level		0 – 100	%		255
Breathing Wave Amplitude		0-65534	LSB	Indicative only	65535
Breathing Wave Noise		N/A	V		65535
Breathing Rate Confidence		N/A	%		255
ECG Amplitude		0 – 0.05	V	Indicative only. 0.000001 resolution. 2376=0.002376V	0.065535
ECG Noise		0 – 0.05	V	Indicative only. . 0.000001 resolution. 1245 = 0.001245V	0.065535
Heart Rate Confidence		0 – 100	%		255
HR Variability		0 - 280	ms		65535
System Confidence		0 – 100	%	Physiological data validity	255
Galvanic Skin Response		N/A			
ROG Status		R,O,G		See section 3.4.2	0
Vertical Acceleration Min		±16	g	-83 = -0.83g	-327.68
Vertical Acceleration Peak		±16	g	1225 = 12.25g	-327.68
Lateral Acceleration Min		±16	g		-327.68
Lateral Acceleration Peak		±16	g		-327.68
Sagittal Acceleration Min		±16	g		-327.68
Sagittal Acceleration Peak		±16	g		-327.68
Device Internal Temperature		0 – 100	°C	612 = 61.2	-3276.8
Status Info				16 bit number. See 3. below	0
Link Quality		0 - 254		High number = high quality	255
RSSI		-127 – 127	dB	-5 = -5dB	-128

Tx Power		-30 – 20	dBm	10 = +10dBm	-128
Estimated Subject Core Temperature		33 – 41	°C	386=38.6	6553.5
Aux ADC Channel 1		0 - 65534		Implementation specific	65535
Aux ADC Channel 2		0 - 65534		Implementation specific	65535
Aux ADC Channel 3		0 - 65534		Implementation specific	65535
Reserved					

1. The Summary data packet has a configurable reporting frequency, in the range 1 sec ~ 18 hrs. Data reported is the latest value for each parameter at time of transmission, other than Activity, Peak, Max & Min accelerations, which use the reporting interval as the epoch over which they are calculated.
2. Invalid Values may be reported if the data is not available at the time of transmission, or the device does not support that parameter. The BioHarness 3 Medical does not support Skin Temperature.
3. Status Info is a 16 bit number which flags the following parameters. Full descriptions and values can be found in the *Bluetooth Comms Link Specification*.
 - DWDL Device Worn Detection Level
 - BPDF Button Press Detection Flag
 - NFTG Not Fitted To Garment
 - HRUF Heart Rate Unreliable Flag
 - RRUF Respiration Rate Unreliable Flag
 - STUF Skin Temperature Unreliable Flag
 - POUF Posture Unreliable Flag
 - ACUF Activity Unreliable Flag
 - HRVUF Heart Rate Variability Unreliable Flag
 - ECTUF Estimated Core Temperature Unreliable Flag

Data Output – Logged Data

Logging Modes

- General (default)
- General + ECG
- General + Acceleration
- Summary
- Summary + Waveform

Where used, “Bits” refers to raw ADC output throughout. Note that some parameters are logged with greater resolution than is possible for transmitted data.

General Log

Parameter	Reporting Frequency (Hz)	Range	Units	Description
Heart Rate	1	25 – 240	BPM	
Breathing Rate	1	3 – 70	BPM	
Skin Temperature	1	N/A	°C	Not supported.
Posture	1	±180	Degrees	Vertical = 0° Inverted =180°
Activity Level	1	16	VMU(g)	
Peak Acceleration	1	±16	g	
Battery Voltage	1	3.5 – 4.2	V	
Breathing Wave Amp	1	0 – 65534	bits	Indicative
GSR Level	N/A	N/A	nS	Indicative
ECG Amplitude	1	0 – 0.05	V	Indicative
ECG Noise	1	0 – 0.05	V	Indicative
X Acceleration Min	1	±16	g	
X Acceleration Peak	1	±16	g	
Y Acceleration Min	1	±16	g	
Y Acceleration Peak	1	±16	g	
Z Acceleration Min	1	±16	g	
Z Acceleration Peak	1	±16	g	
Breathing Sensor output	18	0 - 4095	bits	
HR RR Value	18	250 – 1500	ms	Alternating ± sign on new detection

ECG Log

Parameter	Reporting Frequency (Hz)	Range	Units	Description
ECG	250	0 – 4095	Bits	Indicative

Accelerometer Log

Parameter	Reporting Frequency (Hz)	Range	Units	Description
Acceleration Magnitude	100	±160	g x 10	$\sqrt{(X^2 + Y^2 + Z^2)}$

Summary Log

Parameter	Reporting Frequency (Hz)	Range	Units	Description
Heart Rate	1	25 – 240	BPM	
Breathing Rate	1	3 – 70	BPM	
Skin Temperature	1	N/A	°C	Invalid returned -3276.8
Posture	1	±180	Degrees	Vertical = 0°
Activity Level	1	16	VMU(g)	
Peak Acceleration	1	±16	g	
Battery Voltage	1	3.5 – 4.2	V	
Breathing Wave Amp	1	0 – 65534	bits	Indicative
Breathing Wave Noise	1	N/A		
Breathing Rate Confidence	1	N/A	%	
ECG Amplitude	1	0 – 0.05	V	Indicative
ECG Noise	1	0 – 0.05	V	Indicative
Heart Rate Confidence	1	0 – 100	%	
Heart Rate Variability	1	0 – 65534	ms	
System Confidence	1	0 – 100	%	
GSR	1	N/A	nS	nano Siemens
ROG	1	R, O, G		0 = invalid
Vertical Acceleration Min	1	±16	g	
Vertical Acceleration Peak	1	±16	g	
Lateral Acceleration Min	1	±16	g	
Lateral Acceleration Peak	1	±16	g	
Sagittal Acceleration Min	1	±16	g	
Sagittal Acceleration Peak	1	±16	g	
Internal Device Temperature	1	-40 – 80	°C	
Status Info	1			
Link Quality	1	0 – 254		0=Lowest quality
RSSI	1	-127 – 128	dB	Received Signal Strength Indication
Tx Power	1	-128 – 128	dBm	
Estimated Core Temperature	1	33 – 41	°C	Under Development
Auxiliary ADC Channel 1	1	0 – 4095	Bits	
Auxiliary ADC Channel 2	1	0 – 4095	Bits	
Auxiliary ADC Channel 3	1	0 – 4095	Bits	

Summary and Waveform Log

Parameter	Reporting Frequency (Hz)	Range	Units	Description
All summary parameters	1			As Summary Log Format
Breathing Sensor Waveform	25		*	
Vertical Axis Accelerometer	100	0 – 4095	Bits	Centered on 2048 1g = 83
Lateral Axis Accelerometer	100	0 – 4095	Bits	Centered on 2048 1g = 83
Sagittal Axis Accelerometer	100	0 – 4095	Bits	Centered on 2048 1g = 83
ECG	250	0 – 4095	Bits	Indicative
Heart Rate RR intervals	Per R detection	250 – 1500	ms	40 – 240bpm equivalent
Breathing BB intervals	Per B detection	850 - 15000	ms	4 – 70Bpm equivalent
Event	Per event			See Event Descriptions

*Raw breathing sensor output.

Event Log

Parameter	Reporting Frequency (Hz)	Description
Event	Per event	See event descriptions

Event Descriptions

Timestamp	Event Code	Type	Source	EventID	Event Data
YYYY/mm/dd/ms	See 1	System	Bluetooth	See 2	Event description e.g. 'Worn status changed from 100% to 0%'
			Button Press		
			Emergency Press		
			Battery Low		
			Diagnostics		
	See 1	Physiological	ROG Change		
			Worn Detection		
			HR Reliability Change		
			Fall Detection (see 3.)		
			Jump Detection		
			Dash Detection		

1. 16 bit Event Code= Event Type + Event Source + Event ID
2. 6 bit Event ID
3. Available on demand. Tested using young subjects on a crash mat.

RF Characteristics

Bluetooth

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

Red / Orange / Green Subject Status Indication

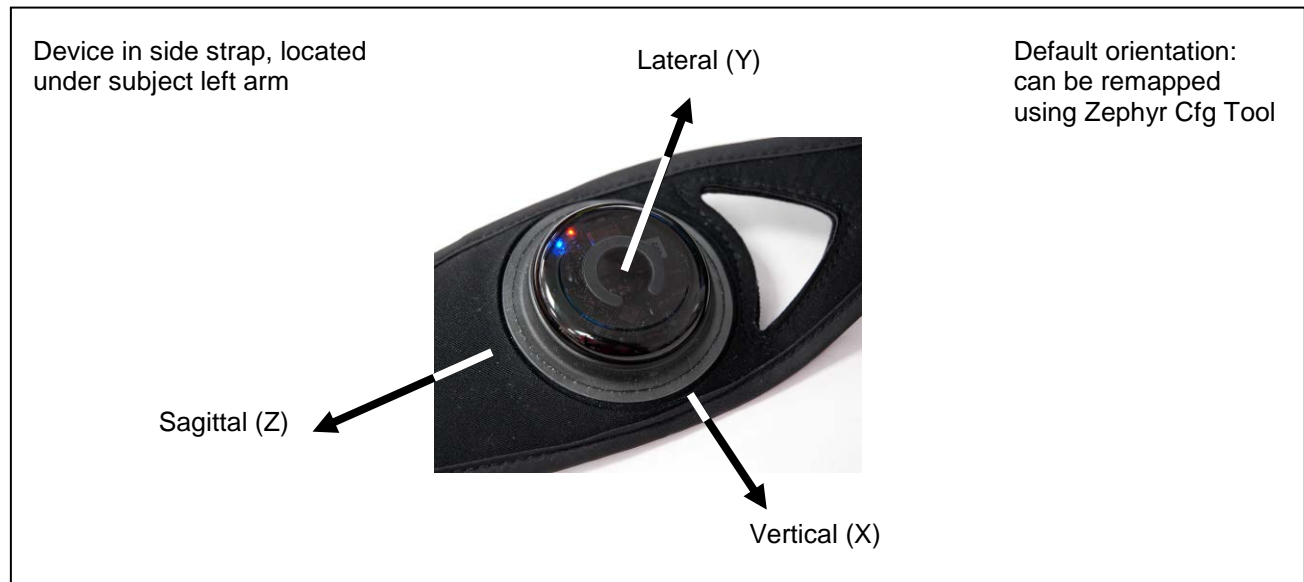
This is a value which is calculated in the device. It is dependent upon a number of thresholds for:

- Heart Rate
- Breathing Rate
- Activity level

Current and previous Heart Rate and Breathing Rate values are used in conjunction with activity level to establish a subject's status, using Zephyr proprietary algorithms.

Threshold levels are stored within the device and are configurable by USB.

Accelerometer Axis Orientation

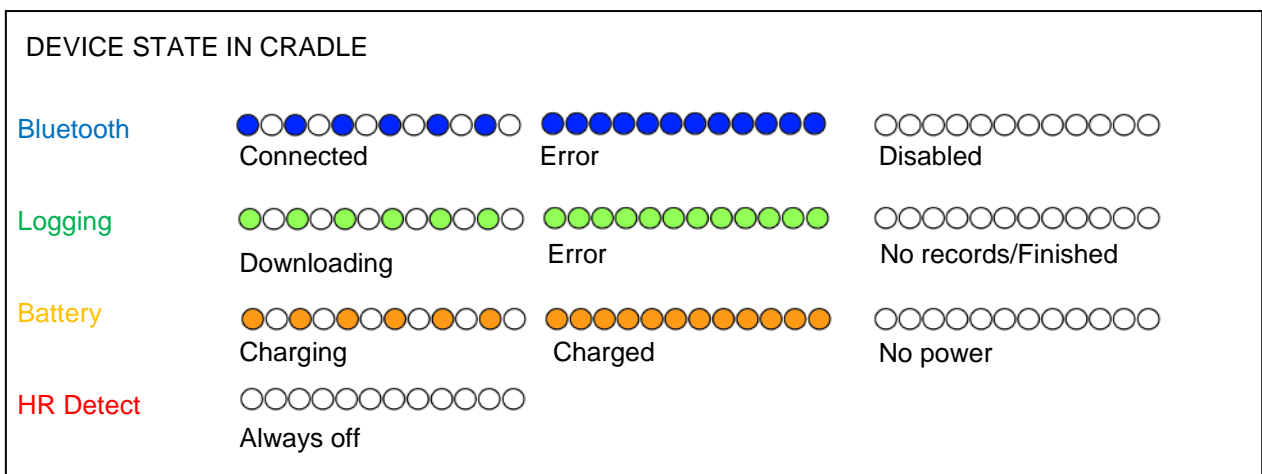
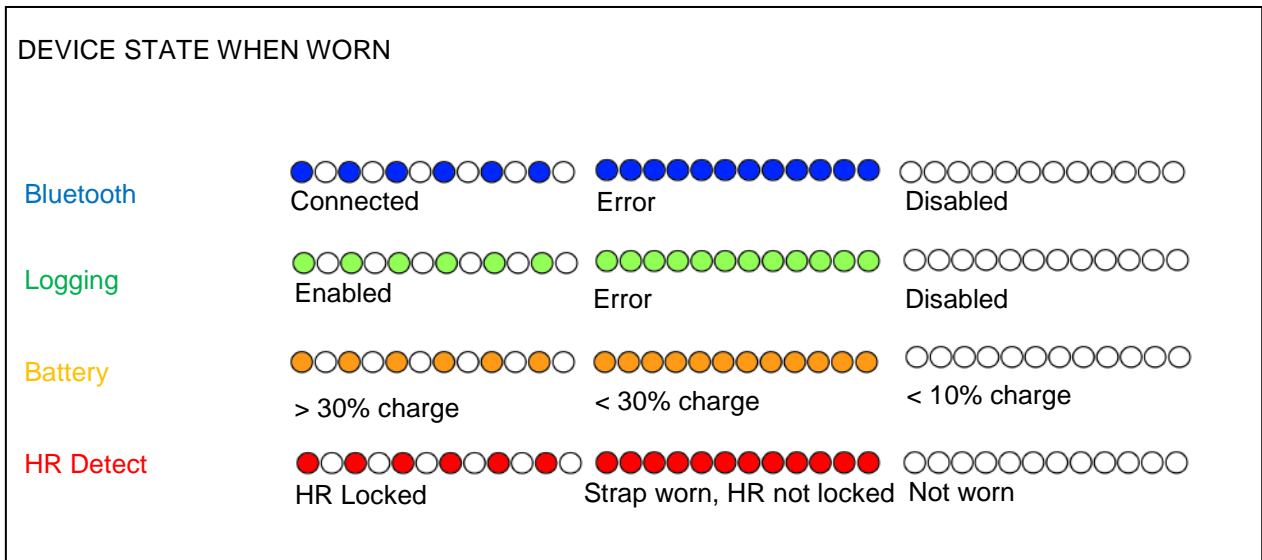


LED Behaviour

The BioHarness module can operate in four modes:

- Transmit data by Bluetooth
- Log data to internal memory (no transmit)
- Transmit and log the same data simultaneously
- Sample data, but not transmit or log until requested by BT

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



Standards/Compliance/Certification

The BioHarness has been designed to conform to the following:

EC38 Type: Type 3
RTTE: Directive 1999/5/EC
Contains Transmitter Module:
FCC ID: T7V1315



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

Portable Military Standards 810F Pending

High Temperature: 501.4
Low Temperature: 502.4
Temperature Shock: 503.4
Low Pressure: 500.4
Solar Radiation: 505.4
Ran & Blowing Rain: 506.4
Humidity: 507.4
Salt Fog: 509.4
Dust: 510.4
Vibration: 514.5
Shock: 516.5

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.

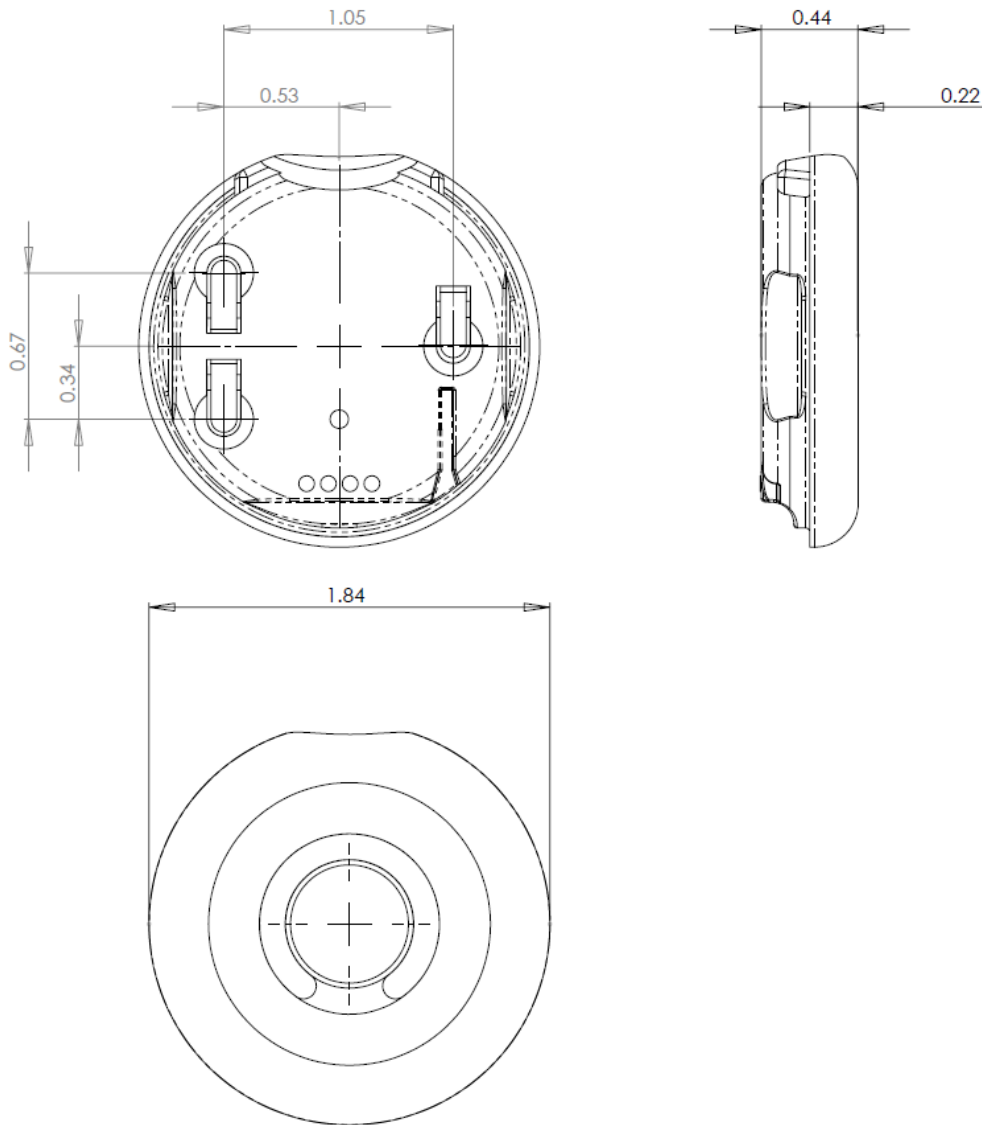
Any computer used in conjunction with this device must be covered by a Declaration of Conformity or must be FCC certified in its own right.

Mechanical Characteristics

Dimensions	BioHarness module	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
	BioHarness module	18 grams
Case Material	PC	Polycarbonate

BioHarness

All dimensions in inches



Accessories

Part Numbers for the Zephyr BioHarness™ BT and associated components:

Component	ZPN
BioHarness™ 3 Module	9600.0254
BioHarness™ Smart Fabric Strap Side fitting XS to M adjustable	9600.0262
BioHarness™ Smart Fabric Strap Side Fitting M to XL adjustable	9600.0265
BioHarness™ Smart Fabric Strap Side Fitting L to XXL adjustable	Pending
BioHarness™ Single Unit Charging Cradle	9600.0257

Cleaning & Sterilisation

- TBD

Hazards

- Subjects fitted with a heart pacemaker should not use this device
- Device should not be worn in explosive atmospheres (such as gas stations)
- Device should not be worn near blasting areas where radio detonation methods may be used
- Charging at high temperatures has risk of fire or explosion (> 45 °C).
- Unit should not be disposed of in fire

Notes

- Should not be used for swimming or similar water-based activities
- No user-serviceable components
- Warranty void if opened

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