EQUIVITAL™ EQ-01 VITAL SIGNS MONITOR
HEALTH CARE PRACTIONER GUIDE

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For Support or further information on this product contact:

Customer Support
Hidalgo Limited
Stable Block at The Grange
20 Market Street
Cambridge
CB4 5QG
United Kingdom

www.hidalgo.co.uk

Tel: +441954 233430

email: equivitalsupport@hidalgo.co.uk

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Explanation of Symbols

Within this manual the following symbols are used to indicate warnings and precautions a user or operator should take when using this device:

A warning is shown within a highlighted box and includes a symbol 

Failure to follow the warning may comprise the safe operation of the device and can lead to a risk of injury.

A precaution is noted in a highlighted text. Failure to follow a precaution may lead to a reduction in performance of the device when in use.

Purpose of this guide

This guide is intended for use by trained Health Care Practitioners using the Equivital™ physiological monitoring device to monitor individuals vitals signs and who are familiar with cardio respiratory monitoring terminology and practise.

It also provides information for system integrators who wish to use Equivital™ as element of a broader healthcare monitoring system.

A separate user guide is available for use by patients and users of the device. Consult this manual to find information on:

- Warnings and Cautions a user/patient should know before wearing the device
- How to fit the device to the body
- How to switch on the device
- How to change batteries and recharge the device

Before using Equivital™

Please observe the following warnings and precautions:

Warnings

- **THE EQUIVITAL™ DEVICE MAY BE USED TO MONITOR INDIVIDUALS IN THE WORKPLACE. WHEN USED IN THIS MANNER THE DEVICE MUST BE INTEGRATED INTO THE OPERATING ORGANISATIONS SAFETY AND RISK MANAGEMENT PROCEDURES. USERS SHOULD RECEIVE APPROPRIATE TRAINING FROM YOUR ORGANISATION BEFORE USING THIS DEVICE**
- **USE OF THE DEVICE DOES NOT JUSTIFY THE USER OR ORGANISATION TO TAKE ADDITIONAL SAFETY RISKS OR TO REDUCE LEVEL OF CARE.**
- **THIS DEVICE DOES NOT AUTOMATICALLY CALL EMERGENCY SERVICE ASSISTANCE.**
- **THE DEPLOYING ORGANISATION IS RESPONSIBLE TO ENSURE THAT THESE WARNINGS ARE UNDERSTOOD AND FOLLOWED.**

- **THE EQUIVITAL DEVICE SHOULD NOT BE USED FOR SURGICAL PROCEDURES, TO PERFORM SYNCRONISED CARDIOVERSION OR INTRACARDIAC MONITORING, OR WHEN PERFORMING EXTERNAL PACING.**

- **THE DEVICE SHOULD NOT BE APPLIED TO USERS WHO HAVE EXISTING SIGNS OF SKIN IRRITATION AND DAMAGE AT THE SITES THE DEVICE IS LOCATED ON.**
- **USERS WHO EXPERIENCE IRRITATION AND RASHING SHOULD BE ADVISED TO DISCONTINUE USE IMMEDIATELY.**

- **THE DEVICE SHOULD NOT BE USED ON PATIENTS WITH IMPLANTED DEFIBRILLATORS OR PACEMAKERS.**

- **DO NOT ATTEMPT TO CONNECT ANY CABLES TO THE EQUIVITAL DEVICE WHEN WORN ON BODY- THIS INCLUDES HIDALGO SUPPLIED BATTERY CHARGING DEVICE. ALWAYS REMOVE THE DEVICE BEFORE CHARGING.**
- **USE ONLY THE HIDALGO PROVIDED BATTERY CHARGER AND BELT ASSEMBLIES WITH THE DEVICE. THE SAFE USE OF THE DEVICE IS ONLY GUARANTEED WITH THESE ACCESSORIES. A FULL LIST OF ACCESSORIES IS PROVIDED AT THE REAR OF THIS DOCUMENT**

Precautions

- **ADVISE THE USER NOT TO USE LOTIONS, OILS, PERFUMES, DEODORANT OR POWDER ON THE AREA WHERE THE SENSOR BELT IS BEING APPLIED**
- **EACH TIME YOU ISSUE THE SENSOR INSPECT THE BELT AND CASE UNIT FOR SIGNS OF DAMAGE (TEARS/ CRACKS ETC). IF ANY DAMAGE IS IDENTIFIED DO NOT USE THE SENSOR UNTIL THE DAMAGED PART HAS BEEN REPLACED**
- **TO GET MAXIMUM PERFORMANCE FROM THE SYSTEM YOU SHOULD REPLACE THE BELT HARNESS AFTER 25 WASHES.**

Equivital Monitor Intended Use:

The Equivital™ Vital Signs Physiological Monitor is a non-invasive ambulatory wireless telemetry device intended to allow monitoring of a users vital signs physiology in environment's where access to traditional clinical care facilities may be limited or impractical (for example in the workplace or outdoors) and justification exists for such monitoring.

The device maybe used by persons operating in circumstances where an increased risk of physical trauma exists due to the environment in which the user is placed. Typically, these environments may be found within personnel working in the military, public safety and hazardous plant workplaces.

The device may also be used as a general cardio respiratory monitor, in particular, where the compact and ambulatory characteristics of the device are advantageous. In addition, the device may also be used for the collection of ambulatory physiology for general research purposes in application such as sports or human performance medicine and research.

The device offers continuous monitoring of two views of the user's heart electrical activity (ECG) and respiratory breathing frequency inferred from thoracic cavity movement and uses this data to derive a Heart and Breathing Effort Rate.

The sensor also provides additional information:

- Physiological waveforms.
- an indication of the users activity level (none, low or high) derived from a movement detection sensor.
- body orientation.
- chest skin surface temperature.
- alternate secondary measurement of heart rate based on the detection of the users R wave using a separate hardware processing function.
- alternate secondary measurement of respiration effort using thoracic impedance pneumography.
- indications and alerts if physiology exceeds predefined boundaries.

The wireless data provided by the sensor may be viewed using a standalone PC based viewing application, or integrated into a broader care monitoring application. In the later application the system integrator is responsible for the end to end performance of the system and appropriate regulatory compliance.

It use within occupational welfare monitoring is intended as an addition to the deploying organisations established risk assement and welfare management procedures. The device is not intended to replace the need for such assessments to have occurred and appropriate procedures to be put in place.

Contraindications

The device is not intended to replace the need for appropriate medical supervision and safe practise to be provided to users by an operating organisation.

The device is not intended for use by children less than 16 years or adults over 65 years.

The device is not intended for use as apnea monitor within a clinical context.

The device is not intended for surgical use or as part of life support systems within a clinical context.

Technical Description :

System Overview

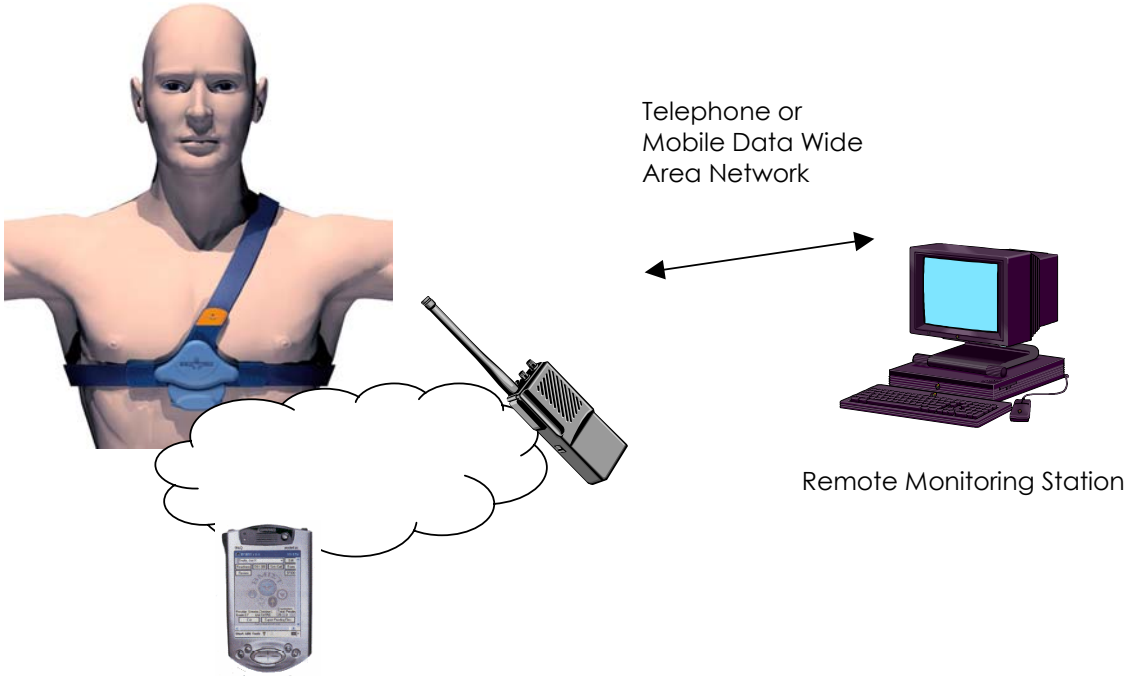


Figure 1 - Sensor Application Diagram

Figure 1 shows an application diagram for the Equivital™ sensor. The sensor is worn by a user and records the user's physiology in real time.

The Equivital™ sensor comprises of two main elements:

- A passive chest belt containing three conductive sensor electrodes and a expansion strain gauge.
- A sensor electronics module (or "SEM") which contains power, processing electronics and a wireless transmitter.

The sensor transmits this data on its personal area network radio to a wireless receiving device. The choice of radio technology used by the device is selectable at the point of manufacture and currently the following options can be supplied:

- Type 0 radio interface – A low power packet radio interface designed for use in applications within the United States Military.

- Type 1 radio interface – Bluetooth™ Transceiver supporting the Bluetooth™ defined Serial Port Profile (SPP).

The sensor can communicate with a wireless receiving device which may either record and display the data locally (e.g. on a PC which contains an integral wireless transceiver) or may relay the data over further wide area communications networks before it is displayed on a remote monitoring station.

The wireless receiving device used is dependant on the type of radio interface ordered. For the Type 0 interface, the sensor is designed to use a protocol suitable to send data to a US Department of Defense developed receiver/data logger know as a Hub. The same interface is also supported by the MiniMitter/Respironics Vitalsense® monitor.

The Type 1 interface is designed to allow flexibility in choice of receiving device and hence uses the open communications standard Bluetooth™ to provide the data communications path. Hence the device may be used with any Bluetooth™ compliant receiver.

The system is provided with a Window s based viewing application "Equivital Viewer" which enables the data from a sensor to be displayed and recorded. It is expected that some deploying organisations will wish to develop specific applications which integrate the sensor into a larger scale monitoring system (eg: including location and mapping functions).

- **ORGANISATIONS INTEGRATING THE EQUIVITAL SENSOR INTO LARGER SCALE SYSTEM APPLICATIONS ARE RESPONSIBLE FOR ENSURING AND VALIDATING THE SAFETY, EFFICACY AND REGULATORY COMPLIANCE OF THE RESULTING SYSTEM**

A system integrators toolkit is available which provides information on the wireless protocol and a test application to assist development of such applications.

System Components

Hardware:

The following sections provide an overview of each of the main elements needed to use the Equivital sensor:

Chest Belt

The chest belt comprises a horizontal band which goes around the users chest beneath the pectorals. Within this band three fabric based silver coated electrodes are located which connect to the body in order to capture ECG signals and also measure thoracic cavity impedance changes from the user. In addition a strain gauge is also contained to measure the expansion of the thoracic cavity, associated with breathing effort.

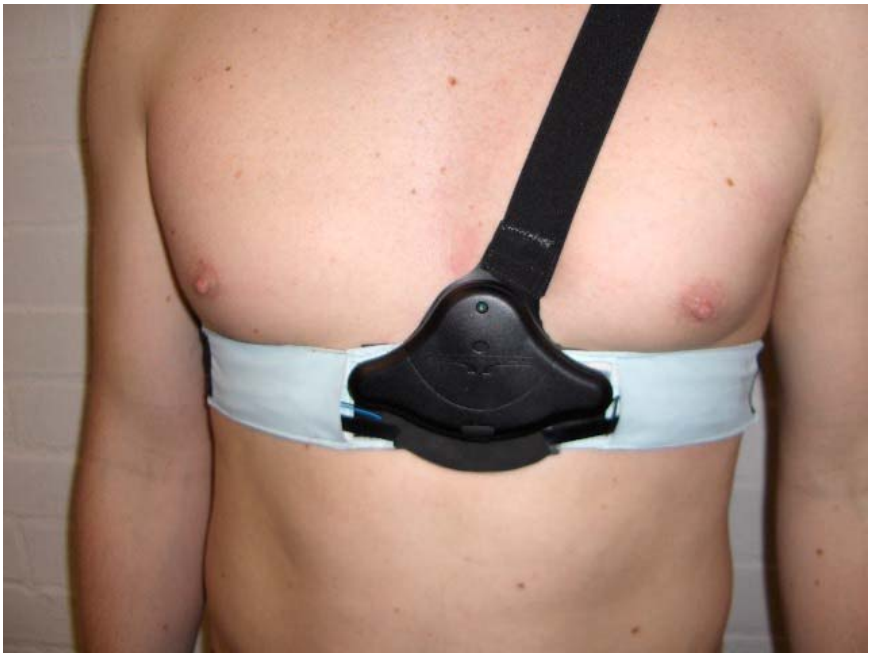


Figure 2 - VSDS Chest Belt

The horizontal strap is tensioned by a belt adjuster provided at the rear of the belt. Details on how to fit the belt correctly are provided in the Equivital User Application Guide.

A elasticated shoulder strap is provided which acts to minimise the belt slipping down the torso during exercise.

The chest belt contains a center piece which sits beneath the sternum and provides five snap connectors which are used to connect the electronics module ("SEM") to the belt.

The chest belt is available in a variety of sizes to match differing users – See for details

The materials selection used to make the belt is provided in Section tbd.

The Sensor Electronics Module "SEM"

The Sensor Electronics Module "SEM" device contains all of the processing electronics , software and communications circuits needed to operate the sensor.

The SEM may be ordered from the factory in two power supply variants;

- 2 x AAA/LR03 primary (non rechargeable) cells
- Rechargeable Li-ION battery

Figure 3 - Sensor Electronics Module Front and Rear

The rear of the SEM unit provides the mating connectors needed to attach the device to the chest belt. In addition, a battery door is also provided to allow batteries to be changed.

On the front of the unit is an external interface connector which normally has a protective bung connected.

This interface is used to:

- Recharge the Li-ION Cell
- Customise the SEM with specific information
- Perform system maintenance functions (by the factory)

NOTE THE DEVICE WILL NOT FUNCTION IF THE BUNG IS NOT FITTED

Battery Charger

The battery charger is a medically approved recharging device and needs to be connected to the SEM to recharge the SEM.

The battery charger will charge a flat battery in 2.5 hours.

- **USE ONLY PRIMARY NON-RECHARGABLE (LR03 AAA) ALKALINE CELLS. RECHARGEABLE AAA CELLS SHOULD NOT BE USED.**

- **DO NOT ATTEMPT TO CONNECT ANY CABLES TO THE EQUIVITAL DEVICE WHEN WORN ON BODY- THIS INCLUDES HIDALGO SUPPLIED BATTERY CHARGING DEVICE. ALWAYS REMOVE THE DEVICE BEFORE CHARGING.**
- **USE ONLY THE HIDALGO PROVIDED BATTERY CHARGER AND BELT ASSEMBLIES WITH THE DEVICE. THE SAFE USE OF THE DEVICE IS ONLY GUARANTEED WITH THESE ACCESSORIES. A FULL LIST OF ACCESSORIES IS PROVIDED AT THE REAR OF THIS DOCUMENT**

Software :

SEM Customisation Utility

This is a Windows ™ based application which allows health care professional to configure certain thresholds and features within the Sensor Electronics Module.

Minimum system and operating system requirements are provided with distribution discs containing this application.

SEM Viewer

The SEM Viewer is a Windows™ application which allows a remote user to display

- Heart Rate
- Heart Rate Indications
- Respiration Effort Rate
- Skin Temperature
- Body Position
- Motion
- Sensor information and diagnostics

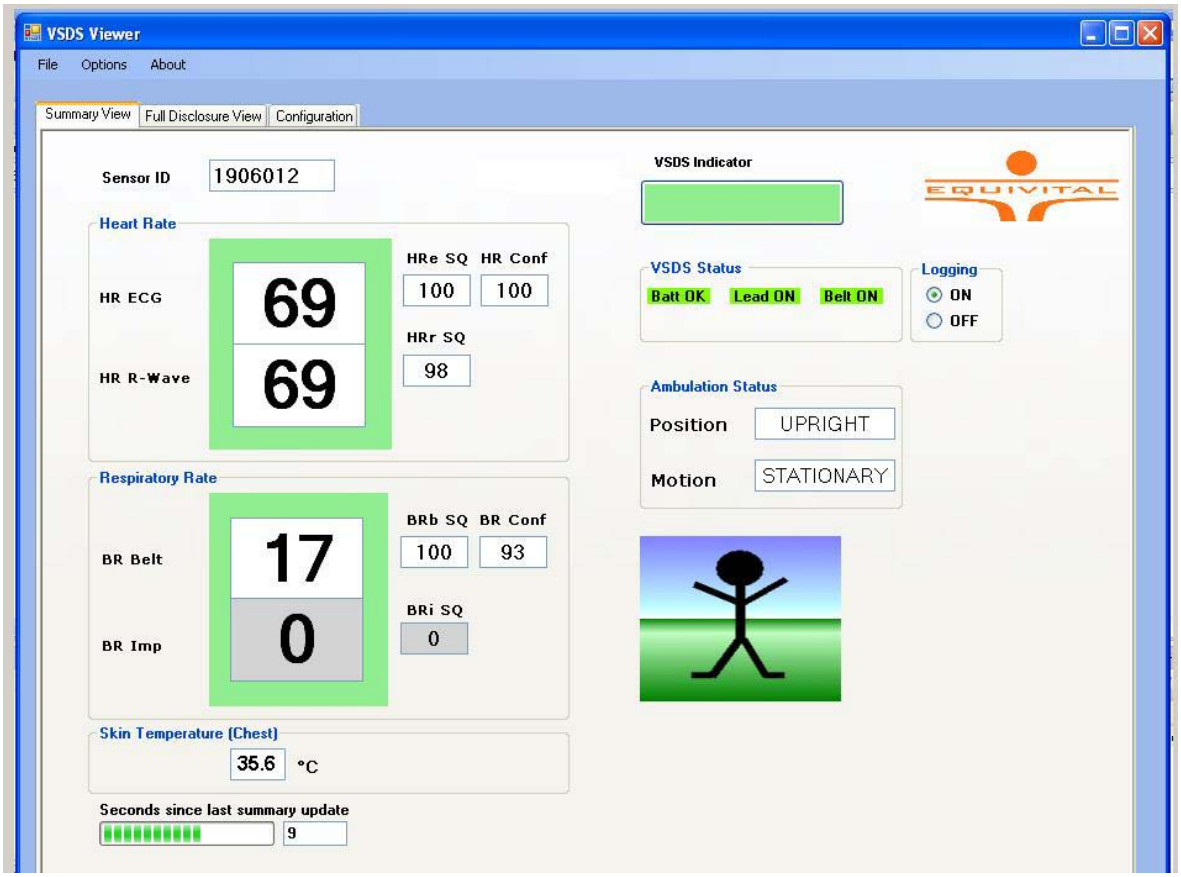


Figure 4 - SEM Viewer Application

System Integration Kit

For system integrators a special development kit is available which includes protocol interfacing information and test applications to ease integration and application development. Contact Hidalgo for further details.

Sensor Overview

Block Diagram

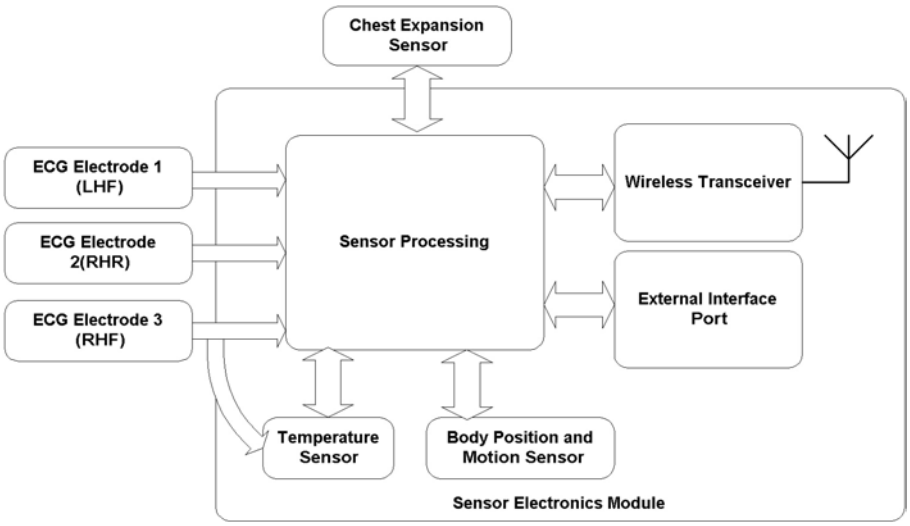


Figure 5 - Sensor Electronics Module Block Diagram

Figure 5 shows the outline block diagram of the sensor.

Three ECG electrodes from the belt provide the on-body electrical connection to the sensor providing two alternate views of the users ECG. Two of the ECG electrodes are also used to measure thoracic impedance variations of the user associated with respiration effort. The primary chest expansion sensor, contained in the belt, is also connected to the SEM unit.

The core of the sensor electronics module comprises signal filtering and conditioning circuitry for each of the sensor parameters and also for internally contained sensors to measure skin surface temperature (sensed by a probe connected to the right hand front ECG electrode) , motion and body position sensor. The signal conditioning circuitry also contains a software controller which digitises the sensor data waveforms, processes the data to derive measures such as rates , and transfers the data periodically to the wireless transceiver for onward transmission from the sensor.

An external interface port is also provided which can be used to configure operational information the SEM uses, to charge the unit and also to connect external sensors.

ECG and Heart Rate Derivation

The sensor provides two leads of ECG sharing a common reference electrode (Left Hand Front location).

The electrode locations within the sensor belt are shown in Figure 6 . These provide two non-standard views of the hearts electrical activity.

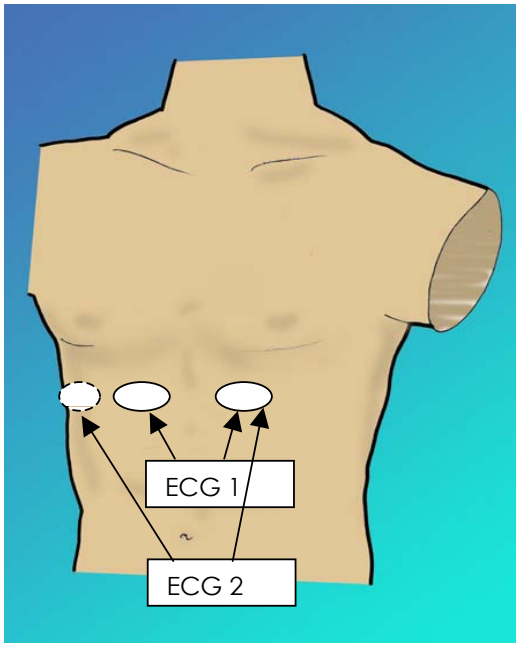


Figure 6 - ECG Electrode Locations

The ECG is samples at 256Hz with a 10 bit resolution. The signal bandwidth is switchable between ambulatory monitoring mode (5Hz – 85Hz) and diagnostic quality (0.05Hz – 85Hz) settings under software control. The sensor defaults to ambulatory monitoring mode unless a command is sent to switch it into diagnostic mode. The ambulatory filtering chosen for the device is designed to optimise detection reliability under high activity and removes significant amounts of the low frequency elements of the ECG waveform not needed to achieve this.

Figure 7 provides an example of the same ECG views in both filtering modes for comparison.

The sensor also contains an alternate means to measure heart rate using an analogue heart-beat detector circuit (commonly known as an "R Wave Detector) using the same view as the ECG 1 electrode. This measure is provided for redundancy purposes and also can be used to increase battery life in circumstances where the HCP does not require digitised ECG.

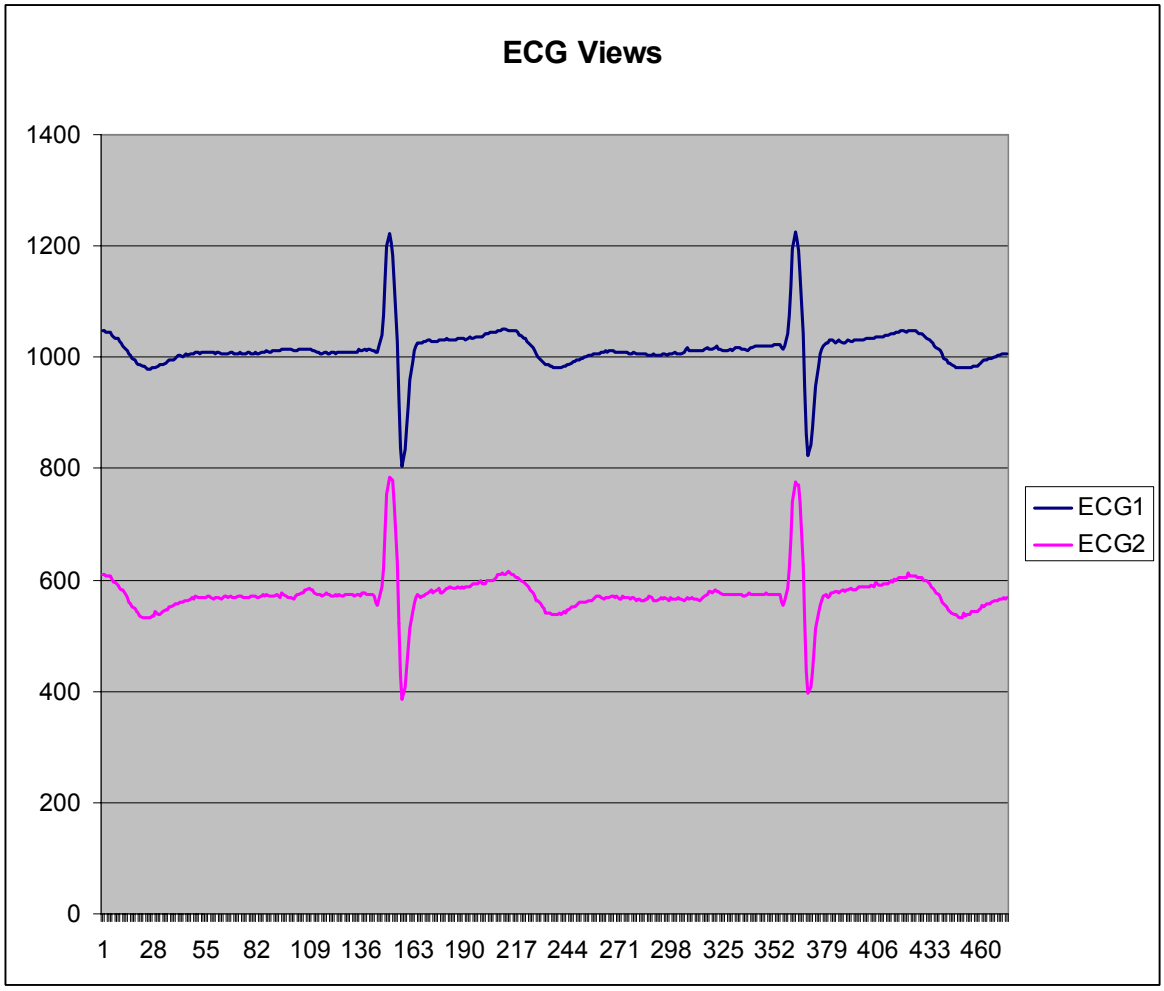


Figure 7 - ECG Waveform examples

Heart rate is calculated as a 60 second rolling average reported every 15 seconds. The rates are identified as HRe (Heart Rate – ECG derived) and HRr (Heart Rate – R wave(hardware) derived)

A signal quality indicator is also provided with each rate in the range 0-100 (100 = best).

The **HRe** signal quality is calculated as follows:

(No of confirmed beats/No of candidate beats) * 100

This provides an indicator which will reduce when noise peaks occur within the ECG trace.

The **HRr** signal quality is calculated as follows:

(Mean IBI/ Mean IBI of lowest 8 inter beat intervals) * 100

This provides an indicator which will reduce if extra or missed hardware pulse are decoded by the R wave detection circuit.

Note: Irregular rhythms will also act to reduce the signal quality indicator for HRr.

An overall HR confidence figure is also provided in the range 0-100 (100=best)

This indicator is meant to assist a HCP viewing remotely to a potentially noisy trace and hence the increased risk of inaccuracy (See Confidence Derivation :)

- **THE EQUIVITAL DEVICE SHOULD NOT BE USED FOR SURGICAL PROCEDURES, TO PERFORM SYNCRONISED CARDIOVERSION OR INTRACARDIAC MONITORING, OR WHEN PERFORMING EXTERNAL PACING.**

The radio system used by the sensors offers a variable delay (in the order of milliseconds) in the transmission of the ECG and hence the device waveforms cannot be assumed to be truly real time synchronised to the users ECG.

Breathing Frequency

The primary means of deriving breathing frequency is via a resistive expansion sensor contained within the belt as shown in Figure 8;

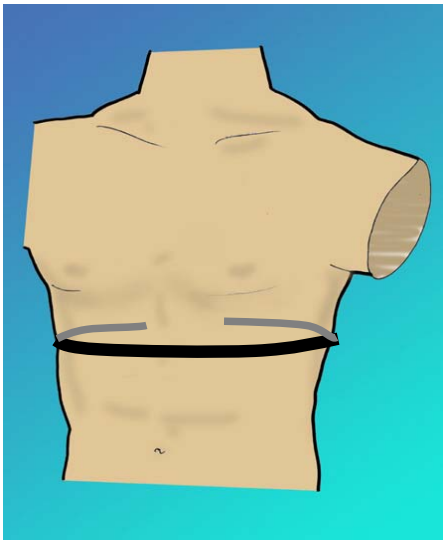


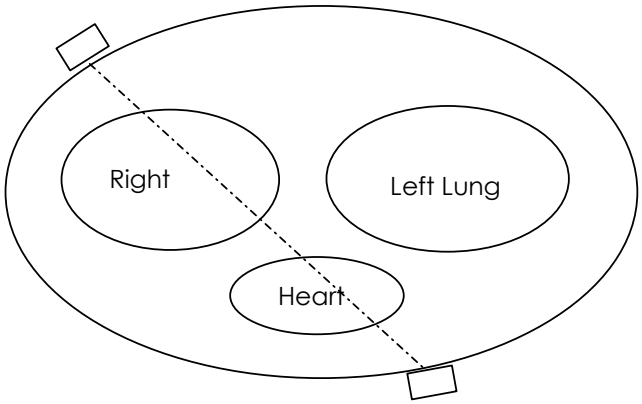
Figure 8 - Respiration Sensor Location

As the users thoracic cavity expands and contracts with respiration effort the sensors resistance decreases and increases respectively and when fed into appropriate circuitry can be converted into a respiration effort rate waveform. The belt sensor is sampled at 25.6Hz at a resolution of 10bits. The signal is filtered to reject noise and then digitised. The overall gain in the circuit is switched between ambulatory mode and high sensitivity mode. The later mode is used

on static, non – upright users to increase breathing sensitivity to shallow breathing patterns as may be found on resting or sleeping individuals.

In addition respiration effort may also be measure using a thoracic impedance pnuemography technique. In this technique a high frequency (50kHz) constant current signal is passed through the body. This signal is modulated by the varying impedance of the thoracic cavity due to breathing effort and the resultant signal may be processed to provide a breathing frequency.

Thoracic impedance pneumography is known to suffer from significant motion artefact and should only be used on static patients.



The Respiration effort frequency is calculated as a 60 second rolling average reported every 15 seconds. The rates are identified as BRb (Breathing Rate Belt) and BRi (Breathing Rate Impedance)

A signal quality indicator is also provided with each indicator in the range 0-100. The signal quality is calculated as follows:

(No of sensor peaks meeting peak threshold/No of sensor peaks) * 100

This indicator is meant to assist a HCP viewing remotely to a potentially noisy trace and hence reducing accuracy.

An overall BR confidence figure is also provided in the range 0-100 (100=best)

This indicator is meant to assist a HCP viewing remotely to a potentially noisy trace and hence the increased risk of inaccuracy (See Confidence Derivation :)

Skin Temperature

Skin temperature is measured by a thermistor contained in the sensor module adjacent to the right hand front ECG electrode. Skin temperature is calculated to a resolution of 0.1°C every 15 seconds.

Because of the mass of the sensor, an initial settling time is needed from when the device is placed on body. This is typically 15 minutes.

Body Position and Motion

Body Position and motion are calculated using orthogonal three accelerometer channels and are reported as follows:

- Prone (lying down - face down)
- Supine (lying down -face up)
- Upright
- Side (lying down – right or left side)
- Inverted (upside down)

Motion is reported as:

- None (stationary)
- Low (ie: walking)
- High (ie: running)

- **MOTION DETECTION CAN ERROR DUE TO EXTERNAL INFLUENCES. FOR EXAMPLE: CERTAIN VEHICLES AND TERRAINS MAY PRODUCE PATTERNS SIMILAR TO AMBULATORY ACTIVITY. FOR THIS REASON THE PRESENCE OF MOTION SHOULD BE USED AS A SUPPLEMENTAL INDICATION AND NOT AS A SOLE MEANS TO DETERMINE THE WELFARE OF A USER.**

In addition the raw accelerometer waveforms may also be transmitted from the sensor.

Indications and Alerts

Indications are sent by the sensor once is determines certain conditions have been exceeded within the measured physiology:

ECG Indications

Three indications are provided:

Heart Rate High (Tachycardia) Indication:

The measured heart rate exceeds the customised tachycardia threshold in the sensor (See Sensor Configuration Data)

Heart Rate Low (Bradycardia) Indication:

The measured heart rate exceeds the customised bradycardia threshold in the sensor (See Sensor Configuration Data)

Short Term Heart Rate Alert (Cardiac Standstill)

The sensor has not detected a heart beat for a defined time window. This window is normally set to be shorter than the normal heart rate window in order to provide early indication of possible cardiac standstill. The time window may be customised in the SEM (See Sensor Configuration Data)

Respiration Effort Indications

Three indications are provided:

Breathing Rate High Indication:

The measured heart rate exceeds the customised high breathing rate threshold in the sensor (See Sensor Configuration Data)

Breathing Rate Low Indication:

The measured heart rate exceeds the customised low breathing rate threshold in the sensor (See Sensor Configuration Data)

Short Term Breathing Rate Alert

The sensor has not detected a breath for a defined time window. This window is normally set to be shorter than the normal breathing rate window in order to provide early indication of possible respiratory distress. The time window may be customised in the SEM (See Sensor Configuration Data)

Combined Indication

Because the device may be used remotely to monitor users, an additional alert/indication is provided which is an aggregation of the earlier thresholds measured by the device.

This may assist the HCP in more rapid detection of users displaying unexpected physiology or multiple threshold exceptions.

The combined indication uses a colour coded scheme:

- Red = Alarm - high risk physiology requiring immediate review
- Yellow = Indication that physiology is outside expected boundaries and requires closer scrutiny.
- Grey = Absence of detectable physiological signals for a sustained time period.
- Green = Normal – Physiology is within expected boundaries.
- Blue = Device in an inoperative or inconclusive state.

The boundaries are also defined by configurable levels within the VSDS (See Sensor Configuration Data).

These shall be set by the managing health care professional and will be occupationally/activity dependent. A set of default setting are provided to assist the HCP with a defined starting point.

The setting of the indication output is defined as per the state transition diagram shown in Figure 9 overleaf.

As well as using the current physiology values to determine the output value of this indicator the sensor also uses the confidence values associated with these measures (See Technical Description :) to determine the signal quality being measured by the sensor in order to assess if the noise level are likely to be within a range where reliable indication can be generated. This allows the sensor to reduce false indications by avoiding raising indications and alerts if the underlying cardio respiratory data may be noisy due to external influences. Note that in this case the sensor state output indicates this is the case and does not indicate a normal (none alerting) state so the monitoring personnel can take appropriate action to investigate the cause.

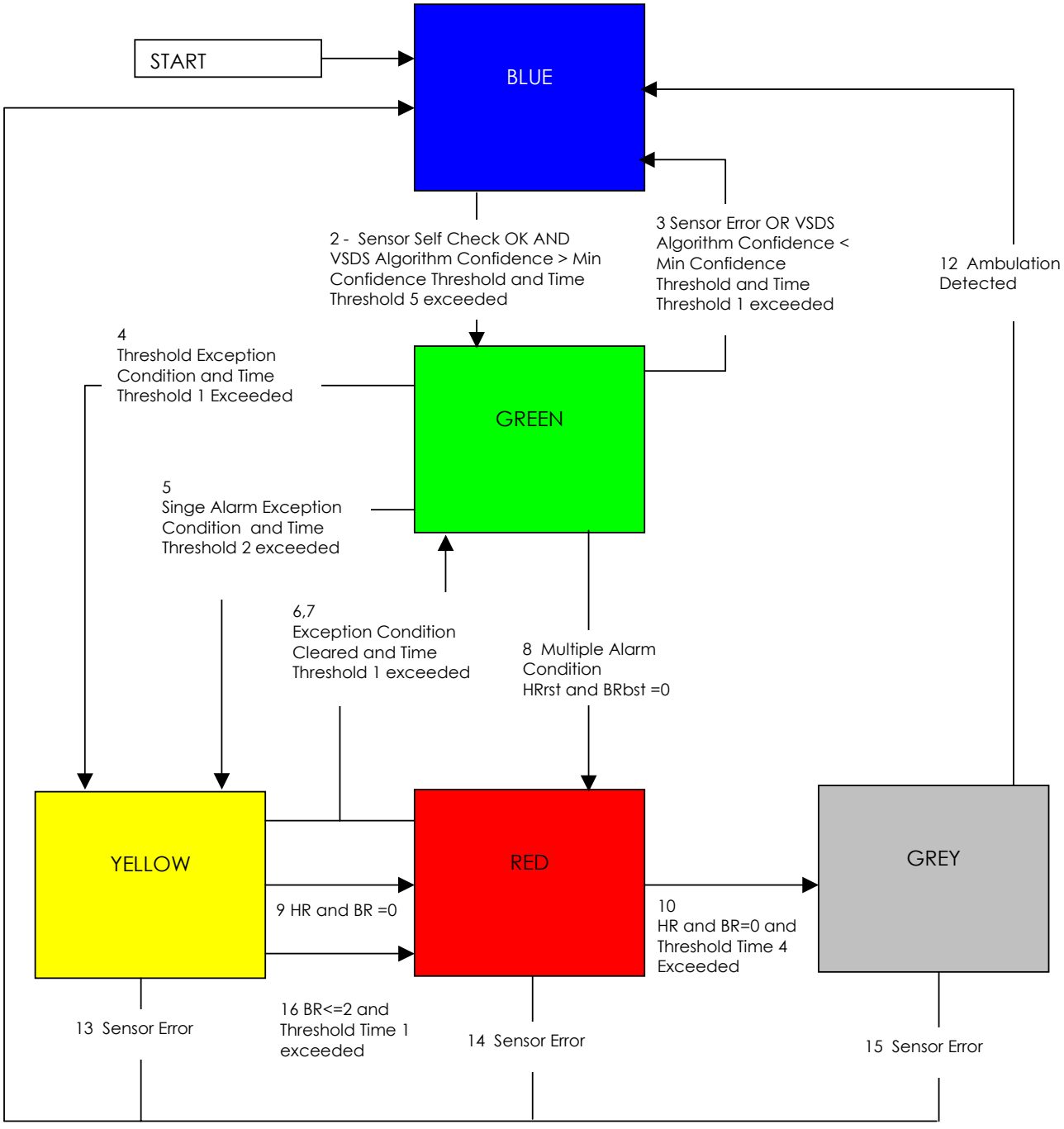


Figure 9 - Combined Indication States

Threshold Exception Condition:

The threshold exception condition is intended to identify vital signs cardio respiratory physiology which is outside expected values (but is not for example absent all together).

The condition is present if either of the following criteria are met for Time Threshold 1:

Heart Rate
R Wave derived Heart Rate (HRr) is > HR Hi Threshold (Tachycardia) AND Heart Rate confidence HR Conf is > HR Confidence Threshold

OR

ECG derived Heart Rate (HRe) is is > HR Hi Threshold (Tachycardia) AND Heart Rate confidence HR Conf is > HR Confidence Threshold

OR

R Wave derived Heart Rate (HRr) is < HR Lo Threshold (Bradycardia) AND Heart Rate confidence HR Conf is > HR Confidence Threshold.

OR

ECG derived Heart Rate (HRe) is is < HR Lo Threshold (Bradycardia) AND Heart Rate confidence HR Conf is > HR Confidence Threshold

Breathing Frequency Rate

Chest expansion derived Breathing Rate (BRb) is > BR Hi Threshold AND Breathing Rate confidence BR Conf is > BR Confidence Threshold

OR

Belt derived Breathing Rate (BRb) is < BR Lo Threshold AND Breathing Rate confidence BR Conf is > BR Confidence Threshold.

Single Alarm Exception Condition:

The single alarm exception condition is intended to identify the absence of detectable vital signs cardio respiratory physiology:

The condition is present if the following criteria is met for Time Threshold 2:

Heart Rate

R Wave derived short term Heart Rate (HRrst) is = 0 AND Heart Rate confidence HR Conf is > HR Confidence Threshold

OR

ECG derived short term Heart Rate (HRest) is = 0 AND Heart Rate confidence HR Conf is > HR Confidence Threshold

Breathing Frequency Rate
Belt derived Short Term Breathing Rate (BRbst) is = 0 AND Breathing Rate confidence BR Conf is > BR Confidence Threshold.

Multiple Alarm Exception Condition

The multiple alarm exception condition is intended to identify the cessation of all measured vital signs cardio respiratory physiology.

The condition is present if the following criteria is met:

Heart Rate

R Wave derived short term Heart Rate (HRrst) is = 0 AND Heart Rate confidence HR Conf is > HR Confidence Threshold

OR

ECG derived short term Heart Rate (HRest) is = 0 AND Heart Rate confidence HR Conf is > HR Confidence Threshold

AND

Belt derived Short Term Breathing Rate (BRbst) is = 0 AND Breathing Rate confidence BR Conf is >
BR Confidence Threshold.

Sensor Error Condition:

A sensor error condition is detected if the following criteria is met:

Failure of power on self checks (the SEM unit or belt is faulty)

OR

Failure of in operation self checks (the SEM or belt has developed a fault)

OR
ECG Lead Off detection

OR
Respiration expansion belt off detection

OR
VSDS Algorithm Confidence is < VSDS Min Operational Confidence

Sensor Self Check Okay:

A sensor self check okay condition is detected if the following criteria is met:

Successful power on self checks

AND

ECG Lead On Detection

AND

Respiration expansion belt On detection

AND
VSDS Algorithm Confidence is > VSDS Min Operational Confidence for Time Threshold 1.

Exception Cleared Condition:

The exception cleared condition is intended to identify vital signs cardio respiratory physiology which is inside expected values :

The condition is present if the following criteria is met for Time Threshold 1:

Heart Rate

R Wave derived Heart Rate (HRr) is < HR Hi Threshold (Tachycardia) AND Heart Rate confidence HR Conf is > HR Confidence Threshold

AND

ECG derived Heart Rate (HRe) is < HR Hi Threshold (Tachycardia) AND Heart Rate confidence HR Conf is > HR Confidence Threshold

AND

R Wave derived Heart Rate (HRr) is > HR Lo Threshold (Bradycardia) AND Heart Rate confidence HR Conf is > HR Confidence Threshold.

AND

ECG derived Heart Rate (HRe) is is > HR Lo Threshold (Bradycardia) AND Heart Rate confidence HR Conf is > HR Confidence Threshold

Breathing Frequency Rate

Belt derived Breathing Rate (BRb) is < BR Hi Threshold AND Breathing Rate confidence BR Conf is > BR Confidence Threshold

AND

Belt derived Breathing Rate (BRb) is > BR Lo Threshold AND Breathing Rate confidence BR Conf is > BR Confidence Threshold.

Confidence Derivation :

Heart Rate

The methods to derive Heart Rate signal quality are specified in Sensor Overview.

An overall Heart Rate confidence is provided by the following rule:

A comparison of the two Heart Rates (HRe and HRr) is defined as the percentage error (unsigned) between the primary measure (HR ECG) and R waved derived Heart Rate (HRr)

Heart rate confidence is then computed as a weighted average as follows:

HR Conf = ((w*HRe Signal Quality)+(x* HRr Signal Quality)+(y*HR Correlation))/3

The weighting factors are defined to bias the confidence to be higher if the two measures are enabled and reporting values

If at the point of computation only a single measure is enabled then confidence will be simply be:

Weighting factor * HRx Signal Quality

The weighting factors are w, x = 0.9 , y = 1.2. The weighting factors are defined to bias the confidence to be higher if the two measures are enabled and reporting values.

Breathing Rate

The methods to derive Breathing Rate signal quality are specified in Sensor Overview.

BR Correlation is defined as the percentage error (unsigned) between the primary measure (BRb) and Impedance derived Heart Rate (BRi)

Breathing rate confidence is computed as a weighted average as follows:

BR Conf = ((w*BRb Signal Quality)+(x* BRi Signal Quality)+(y*BR Correlation))/3

The weighting factors are defined to bias the confidence to be higher if the two measures are enabled and reporting values.

If at the point of computation only a single measure is enabled then confidence will be simply:

Weighting factor * BRx Signal Quality

The weighting factors are w, x = 0.9 , y = 1.2

VSDS Confidence Rate

The VSDS confidence value is derived as follows:

VSDS Confidence = ((w*HR Conf)+(x* BR Conf))/2)

The weighting factors are defined to bias the confidence measure towards higher respiration confidence considering its primary importance in vital signs assement compared to heart rate variation (excluding the cardiac arrest case)

The weighting factors are w= 0.5 , x =1.5.

Secondary Confirmation:

Secondary confirmation is used to improve the confidence in a vital sign parameter by comparing it to an alternate measure of the same parameter and measuring the error between the two. If the error is close then confidence can be increased that the sensor is operating correctly. This is then included in the confidence measure which is used to determine the state transition validity.

The following rules are used to determine when a state change dependent secondary confirmation is undertaken:

Heart Rate

- By Customisation:

If by customisation the device is configured to enable both means of Heart Rate measurement all the time then by default secondary confirmation is used as part of the confidence computation.

- Dependent on the Current Active Measure Signal Quality

If the current heart rate derivation has a high signal quality (> HR Signal Quality Threshold)then the device will not need the secondary confirmation before making a transition. The secondary measure however will be enabled for future measurements however.

Respiration Rate

- By Customisation

If by customisation the device is configured to enable both means of Respiration Rate measurement then by default secondary confirmation is used as part of the confidence computation only when the subject is static. This reflects that the secondary respiration means can only be considered reliable when the subject is not moving.

- Dependent on the Current Active Measure Signal Quality

If the current respiration rate derivation has a high signal quality (> BR Signal Quality Threshold)then the device will not need the secondary confirmation before making a transition. The secondary measure however will be enabled for future measurements

however. If the signal quality is less than the signal quality threshold then the device will perform a secondary confirmation if the subject is not moving.

Connecting and Using the Sensor – Model Number EQ01-002/012 (Type 0 Low Power PAN Interface)

The Type 0 radio interface is intended for use by the following defined receiver modules:

1. Mini Mitter/Respironics Vital Sense (K)
2. A US DoD re-packaged variant of the above monitor (restricted to the US Military)

Consult the user instructions for the receiver module for more details on how to operate the receiver unit and recover the sensor data.

Sensor Activation

The protocol used requires sensors to be optically activated by receiver module before use. This is achieved by operating the activation command on the receiver, and holding the activation sensor on the receiver close to the SEM activation window shown below:

Sensor Range

The sensor range is intentionally low and the device should be kept within 1 meter of the receiver unit to guarantee reliable data transmission.

Protocol Overview

The protocol employed by the system uses repeated transmissions of a data packet sent approximately every 15 seconds. The transmission rate has been chosen to provide some redundancy if a packet is not received due to noise on the radio channel. The sensor will continue to transmit data once activated and hence a sensor which is not operational, has stopped working , or has gone out of range, can be detected rapidly by the absence of a valid data packet over a fixed time window (eg: 1 minute)

The data packet contains:

- Sensor Transmitter Serial Number
- Heart Rate and Confidence Value
- Respiration Effort Rate and Value
- Skin Temperature (Chest)
- Motion
- Body Position

The packet is protected by a cyclic redundancy code to detect transmission errors and reject corrupted data.

The data is transferred in a binary formatted, non-text format and hence is not directly readable without the packet data specification.

Sensor Diagnostics

The Sensor also provides the following diagnostics

1. Low Battery – The batteries should be changed as soon as possible.

2. Sensor INOP – The sensor has detected an internal problem and has become inoperative. If this message is seen persistently (more than 3 sucessive transmissions) the device should be returned for service

3. Sensor Lead Off – The ECG or Belt Sensor have become detached from the SEM. Check the belt location and that the SEM is clipped to the belt correctly. Other causes may be excessive skin impedance (dirt , dead skin) or a damaged belt.

Connecting to and Using the Sensor– Model Number EQ01-001

(Type 1 Bluetooth™)

Bluetooth™ Connection Information

The Type 1 version of the sensor complies with the Bluetooth™ protocol specification V1.1 and can be used with a Bluetooth™ certified transceiver which supports the serial port profile. This profile allows serial data to be passed over the Bluetooth™ radio and to be presented at the receiver end as a serial data stream communications port.

The SEM sensor appears as a "discoverable slave" device which means it can be located and connected to by the receiving unit. Consult the manual for your Bluetooth™ receiver for instruction on how to do initate the connection.

Sensor Data Security

The Bluetooth™ protocol implements both encryption and a pass key access.

The pass key for the sensor should be programmed into the unit by the SEM customise utility (See Sensor Configuration Data)

- **Failure to set a unique Bluetooth™ pass key may compromise the security of the device and may make it easier for other persons to connect to the sensor.**

Application Protocol Overview

Summary Disclosure

Summary disclosure is transferred every 15 seconds. The transfer of data is defined in [4].

The data sent is as follows:

- Respiration Band Rate (if configured)
- Respiration Band Signal Quality (if configured)
- Impedance Rate (if configured)
- Respiration Rate Confidence
- EDR Rate (if configured)
- EDR Quality (if configured)
- Skin Temperature
- Body Orientation
- Motion Classification
- Combined Vital Signs Indication and Confidence (if configured)
- ECG Heart Rate (if configured)

- ECG Signal Quality (if configured)
- R Wave Heart Rate (if configured)
- R Wave Signal Quality (if configured)
- Heart Rate Confidence

The following indications are sent every 5 seconds:

- ECG Indications:
    - Low Heart Rate
    - High Heart Rate
- Respiration Indications
    - Low Breathing Rate
    - High Breathing Rate
- Sensor Fault Codes

Full Disclosure

When full disclosure is selected, then in addition to the Summary disclosure, the following data are transmitted:

- Raw Waveform Data
    - ECG1 and 2
    - Impedance Trace
    - Respiration Belt Trace
    - Accelerometer Traces
    - Battery voltage sensor value

A four bit sequence number is transmitted with the ECG1 and 2 waveform data. The lower two bits of the sequence number are transmitted in the most significant two bits of the 12 bit message data of ECG1. The upper two bits are transmitted in the most significant two bits of the 12 bit message data of ECG2. The sequence number is incremented every time both messages have been transmitted. The sequence number will cycle every 16 transmissions, allowing the detection of dropouts of up to 16/256 s or 62.5 ms.

The protocol uses a non human readable tag based method to transfer the data

All application layer messages are 3 characters long and consist of a single character message type followed by two characters of data, regardless of the need for this amount of data. This is illustrated in Figure 10.

Message Type	Data 1	Data 2

Figure 10 - Message Structure

When the data is carrying a single unsigned integer value (the normal case) the data is encoded as follows:

The maximum size of unsigned integer value is taken to be 12 bits (the A/D converter has a maximum resolution of 10 bits so this allows some flexibility).

The first transmitted data character is formed by taking the least significant 6 bits of the 12 bits and adding 32 decimal (20 Hex) to avoid non-printing characters. Similarly the second transmitted data character is formed by taking the most significant 6 bits of the 12 bits and adding 32 decimal.

A copy of the interface protocol is available as part of the system integrators kit provided by Hidalgo.

Sensor Configuration Data

Indication Rate Limits and Time Thresholds

Parameter	Parameter Name	Description	Range	Default
Tachycardia limit	HR High Threshold	Tachycardia limit for heart rate	0: No Limit 1-255 bpm	200 bpm
Bradycardia limit	HR Low Threshold	Bradycardia limit for heart rate	0: No Limit 1-255 bpm	30 bpm
Upper Respiration Limit	BR High Threshold	Upper respiration limit for respiration rate	0: No Limit 1-255 bpm	0 (i.e. no limit)
Lower Respiration Limit	BR Low Threshold	Lower respiration limit for respiration rate	0: No Limit 1-255 bpm	5 bpm
Threshold Exception Time	Time Threshold 1	Time required for an out of threshold rate to exist before an indication is raised	0: Infinite 1 – 255 minutes	2 minutes
Short term Heart Rate Window	HR(st)TimeWindow	Time period over which a short term heart rate is measured in order to provide an early indication of failure to detect heart	0: None 1-255	10 seconds

Parameter	Parameter Name	Description	Range	Default
		beats	seconds	
Short term Breathing Rate window	BR(st)TimeWindow	Time period over which a short term breathing rate is measured in order to provide an early indication of failure to detect respiration effort	0: None 1-255 seconds	20 Seconds
Time to alert – cardiac alarm	Time Threshold 2	Time period when HR(st) = 0 before an indication is raised	0-255 seconds	0 seconds
Time to alert – breathing alarm	Time Threshold 3	Time period that BR(st) = 0 before an indication is raised	0-255 seconds	0 seconds
Heart Rate Confidence Threshold	HR Confidence Threshold	Minimum confidence in Heart Rate signal needed to make a alarm or alert condition	0-100%	80%
Breathing Rate Confidence Threshold	BR Confidence Threshold	Minimum confidence in Breathing Rate signal needed to make a alarm or alert condition	0-100%	80%
Breathing Rate Secondary Confirmation Threshold	BR Signal Quality Threshold	Minimum signal quality threshold needed to allow a state change to be made without a secondary confirmation measurement being made	0-100%	85%
Heart Rate Secondary Confirmation Threshold	HR Signal Quality Threshold	Minimum signal quality threshold needed to allow a state change to be made without a secondary confirmation measurement being made	0-100%	85%
Combined indication operational confidence threshold	VSDS Minimum Operational Confidence	Minimum VSDS combined algorithm confidence below which the output is considered unreliable and should be set to unknown or inoperative	0-100%	65%

Parameter	Parameter Name	Description	Range	Default
		unknown or inoperative		
Time Threshold – Sustained absence of cardio respiratory signals	Time Threshold 4	Time period to transition from red to grey state when no vital sign signals are being measured.	0-255mins	5 mins
Time Threshold – Sensor Initialisation	Time Threshold 5	Time period to transition from BLUE state to GREEN state once VSDS algorithm confidence is above minimum threshold.	0-255mins	3 mins

Power On Defaults

Parameter	Parameter Name	Description	Range	Default
Power on disclosure control	Full Disclosure	Whether the sensor will power up and send physiological waveforms as well as summary data (applies to the Type 1 radio interface only)	On Off	On
Heart Rate and ECG Control		Whether the sensor will power up with its ECG derived heart rate (HRe) enabled	On Off	On
Heart Rate – R Wave Control		Whether the sensor will power up with its hardware derived heart rate (HRr) enabled	On Off	On
Breathing Rate – Chest Expansion Belt Control		Whether the sensor will power up with its thoracic expansion belt derived respiration rate (BRb) enabled	On Off	On

Parameter	Parameter Name	Description	Range	Default
Breathing Rate – Thoracic Impedance Control		Whether the sensor will power up with its thoracic impedance derived respiration rate (BRi) enabled	On Off	Off
Combined Indication Control		Whether the sensor will power up with its combined indication algorithm enabled	On Off	On

Bluetooth Link Parameter

Parameter	Parameter Name	Description	Range	Default
Bluetooth Access Code		Pass key used to allow connection to the sensor	4 digit numeric	1111

Belt Construction

The chest belt is made of the following materials:

4% Polyurethane
36% Polyamide
9% Lycra
15% Neoprene
21% Polyester

The following sizing chart provides a guideline on how to select the correct belt size to use

Belt Size	Shirt Size	Chest Circumference
S	S	33-37
M	M	37-41
L	L	41-45
XL	XL	45-49

Some variation may exist for uses at the size boundaries in which case it is recommended to go for the larger sized belt.

Accessories

- **USE ONLY THE FOLLOWING ACCESSORIES.**

Battery Charger

Hidalgo Part Number:

EQ-ACC-01 - Mascot 2240 LI(UK Plug)

EQ-ACC-02 - Mascot 2240 LI (US Plug)

EQ-ACC-03 - Mascot 2240 LI (EU Plug)

Chest Belt

Hidalgo Part Number:

EQ01-020 (/S/M/L/XL)

Repair and Service

- **THERE ARE NO USER SERVICEABLE PARTS IN THE DEVICE. SHOULD YOU REQUIRE SERVICE OR REPAIR PLEASE CONTACT HIDALGO**

Technical Specifications

Device Classification

Shock Protection : Type BF Applied Part , Internally Powered Equipment

Enviromental Protection: IPx0 (unprotected)

Flammable Gas Protection: Unprotected

Mode of Operation: Continuous

FDA Device Classification: Class II

EU Device Classification: Class IIb

Chest Harness /Belt

Size (circumference):

Small:	40mm x	108mm
Medium:	40mm x	116mm
Large:	40mm x	124mm
Extra Large:	40mm x	131mm

Weight: 80g

Operating temperature: -10°C to +55°C
Operating Humidity: 10% to 75% RH Non-Condensing
Storage Temperature: -20°C to +65°C
Storage Humidity: 5% to 90% RH Non-Condensing
Air Pressure: 570hPA – 1060hPA

Sensor Electronics Module

- **General**

Size (overall dimensions): 123mm x 75mm x 14mm

Weight: 75g

Power: 2 x 1.5v AAA LR03 Alkaline cells or
3.7V 740mA Li-ION rechargeable cell

Operating temperature: -10°C to +55°C
Operating Humidity: 0% to 95% RH Non-Condensing
Storage Temperature: -20°C to +65°C
Storage Humidity: 0% to 95% RH Non-Condensing

- **ECG**

No of leads: 2
Sampling frequency: 256 Hz
Resolution: 10 bits
Voltage range: +/- 5mV
CMRR: >85 dB
Frequency Range: Diagnostic Setting : 0.05 – 85 Hz (3dB points)
Monitor/Ambulation Setting : 5Hz – 85Hz (3dB points)
Heart Rate Calculation Frequency: 15 seconds

- **Impedance Respiration Effort**

Measurement type: Bipolar
Sampling frequency: 25.6 Hz
Resolution: 10 bits
Modulation: 50 KHz
Drive Current: 200 µA
Frequency Range: 0.05 – 7 Hz

Respiration Rate Reporting
Frequency: 15 seconds

- **Chest Expansion Respiration Effort**

Measurement type: Resistive strain gauge
Sampling frequency: 25.6 Hz
Resolution: 10 bits
Frequency Range: 0.05 – 7 Hz
Respiration Rate Reporting
Frequency: 15 seconds

- **Temperature**

Sampling frequency: 0.25Hz
Resolution: 10 bits
Range: 10°C - 45°C
Sensor Accuracy: <35.8C and > 41C +/- 0.3 C
35.8C to 37C +/-0.2C
37 to 39 C +/- 0.1C
39C to 41 C +/- 0.2 C

Measurement type: Thermistor
Temperature Reporting
Frequency: 15 seconds

Electromagnetic Compatibility

This device has been designed to meet the relevant radio and electromagnetic interference standards for the countries it is used in.

A risk remains however, as for all radio based devices, that interference may occur either from or to the device.

If you experience unwanted interference increase the physical separation between the devices.

We recommend a separation of 0.5 meter or greater between the SEM device and other wireless devices.

If you have specific concerns about the devices compatibility or experience problems which cannot be resolved by increasing separation of the devices, please contact Hidalgo.

- **IF YOU ARE ENTERING A FACILITY WHERE INTERFERENCE MAY BE A PARTICULAR CONCERN (EG: A HOSPITAL OR HAZARDOUS PLANT ENVIROMENT) CONTACT THE PERSON IN CHARGE OF THE FACILITY TO CHECK IF ANY SPECIAL PRECAUTIONS NEED TO BE TAKEN.**

FCC Compliance and Advisory Notice (US Markets)

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 for use, 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 the receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/television technician for help.

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) these devices must accept any interference received, including interference that may cause undesired operation.

Type 0 Radio Interface:
FCC ID:

Type 1 Radio Interface:
FCC ID: