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EQ02+ SERIES LIFEMONITOR

User Guide

eq02+ Series LifeMonitor and Health Care Practitioner's Guide

equivital.com

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Table of Contents

List of Figures

List of Tables

List of Abbreviations

AC	Alternating current
AM	Amplitude modulation
BPM	Beats per minute
BR	Breathing Rate
CMRR	Common mode rejection ratio
DC	Direct current
ECG	Electrocardiogram
EDR	ECG derived respiration
EMC	Electromagnetic compatibility
FDA	Food and Drug Administration
GSR	Galvanic Skin Response
HCP	Health Care Practitioner
HR	Heart Rate
IBI	Inter-beat interval (See R-R interval)
IR	Infra-red
POST	Power-on self-test
PWI	Physiological Welfare Index
QRS-T	Notation to identify key features of an ECG beat waveform
RH	Relative humidity
RPM	Respirations per minute
R-R	Interval time between the R wave peaks of the recorded QRS complex
SD	Secure Digital
SEM	Sensor Electronics Module

1 Introduction

This Guide provides key information pertaining to the use of the Equivital™ LifeMonitor and a general guide to the fitting and operation of the monitoring system. It provides an overview of all products available to use with the Equivital™ LifeMonitor so that you can maximise the use of the system.

This guide also contains the EQ02+ Healthcare Practitioner's (HCP) Guide - A reference section, specifically for use by healthcare practitioners, providing key information relating to the methodology of physiological data measurement.

1.1 User Guide - latest version

Please note that this Equivital™ LifeMonitor User Guide is updated on a regular basis.

Please register on the Equivital Helpdesk for access to the latest version of this User Guide and other customer support:

https://support.equivital.com

1.2 Getting Help

If at any point during the installation, configuration and use of Equivital LifeMonitor you encounter problems that you cannot resolve and that are not addressed in this Installation and User Guide, please contact your local Equivital Sales Representative or contact us directly via one of the contact methods below:

Tel: +44 (0) 1954 233430

Fax: +44 (0) 1954 233431

Email: support@equivital.com

Monday to Friday 9am to 5pm (United Kingdom). If you require support outside of these hours, we can arrange a support call by appointment.

1.3 Warning, Cautions and Information

The following symbols will appear throughout this Installation and User Guide to advise of any particular dangers or to provide information that may prove useful.

Warnings are provided where there is an immediate danger to Subjects (those wearing the Equivital LifeMonitor) and/or Users (those configuring, and using the data obtained from, the Equivital LifeMonitor).

Cautions are provided where there is danger of damaging equipment or associated devices.

Information Messages are provided to assist the User in the installation and use of the products.

1.4 Intended Use Summary

The Equivital™ LifeMonitor is an ambulatory multi-parameter vital signs telemetry device intended for monitoring of adults (16 years onwards) in hospital care facilities, the home, workplace and alternate care settings.

The device consists of a body worn sensor electronics module (SEM) connected to a fabric chest belt.

The device collects and transmits ECG data and heart rate, respiration data and rate, skin temperature, body orientation, motion and activity. Additionally, the device provides alerts and indications if physiology exceeds pre-defined boundaries.

The monitor is indicated for use as a human physiological monitor, to provide physiological and biomechanical information as part of an occupational welfare monitoring system, and for general research and performance measurement purposes.

1.5 Contraindications

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

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

The device is not intended for surgical use.

The device is not intended for use on Subjects who have implanted defibrillators or pacemakers.

The device should be removed before attempting defibrillation.

The device is not intended as a diagnostic ECG monitor.

1.6 Warnings

Please observe the following warnings when using the Equivital™ EQ02+ LifeMonitor.

The Equivital™ EQ02+ LifeMonitor may be used to monitor individuals in the workplace. When used in this manner the device must be integrated into the operating organisation's safety and risk management procedures. Subjects and Users should receive appropriate training from their organisation before using this device.

Use of the device does not justify the Subject, Users or organisation to take additional safety risks or to reduce level of care.

The deploying organisation is responsible to ensure that all warnings in this document are understood and followed.

This device does not automatically call emergency service assistance.

The Equivital™ EQ02+ LifeMonitor should not be used for surgical procedures, to perform synchronised cardioversion, intracardiac monitoring, or when performing external pacing.

The device should not be applied to Subjects who have existing signs of skin irritation and damage at the sites the device is to be located.

Subjects who experience irritation or a rash should be advised to discontinue use immediately. Do not allow Subjects to wear the LifeMonitor for longer than 24 hours at one time.

Only Equivital™ approved accessories are to be used with the Equivital™ EQ02+ LifeMonitor. The safe use of the device is only guaranteed with these accessories.

The Equivital™ EQ02+ SEM must not be re-charged or connected to the programming lead while being worn.

Do not dispose of the device using incineration.

1.7 General Precautions

Please observe the following precautions when using the Equivital™ EQ02+ LifeMonitor.

Lotions, oils, perfumes, deodorant or powder should not be used on the area of the body where the Sensor Belt is being fitted.

Each time an Equivital™ EQ02+ LifeMonitor is issued for use it is important to inspect the SEM and Sensor Belt for signs of damage (tears/cracks etc). If any damage is identified, do not use the equipment until the damaged part has been replaced.

To get maximum performance from the system you should replace the Sensor Belt after 6 months of regular use, or if a failure is indicated by a Belt Tester unit. The Sensor Belt should be washed, using the guidelines provided, after each use.

Refer to the environmental specifications in this document to see the environmental conditions (e.g., ambient temperature) within which the Equivital™ EQ02+ LifeMonitor should be operated.

When initially worn the Equivital™ EQ02+ LifeMonitor should be given time for the data signals to stabilise.

When using your EQ02+ SEM for the first time please remove the protective film cover from the display LEDs on the front of the SEM.

The SEM shall not be charged at temperatures below 10°C, as this will significantly reduce the charge retained by the SEM and hence the available operating time. It is recommended to charge the SEM above 20°C.

The EQ02+ SEM should be re-charged a minimum of once every 6 months

2 Overview of Equivital EQ02+ LifeMonitor and Related Products

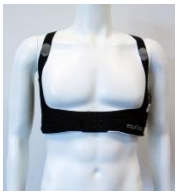
This section describes all the Equivital™ EQ02+ LifeMonitor products as well as the additional accessories available to extend the use of the system.

The Equivital™ EQ02+ LifeMonitor is a flexible and powerful physiological monitoring device that can be used in many scenarios. The components of the system include the following elements.

2.1 EQ02+ LifeMonitor

- **Sensor Electronic Module (SEM)** – The EQ02+ SEM measures physiological and biomechanical data from the Subject. It collects ECG, Breathing Rate, Skin Temperature, Tri-axis accelerometer and can derive other measures within the device. It can store up to 8 GB worth of data and it can transmit it to the Equivital™ suite of software via in-built Bluetooth capability.

- **Sensor Belt** – The EQ02+ Sensor Belt holds the SEM onto the Subject's body. It contains fabric electrodes that make contact with the Subject's skin to provide physiological and biomechanical data, incorporates a band to measure breathing and on the B3 model also allows additional sensors to be connected into the SEM.



2.2 LifeMonitor Accessories

- **SEM Lead** – Allows a single SEM to be charged and configured via a standard USB connection from a Windows laptop or PC. It also enables the SEM to be configured or for data from it to be downloaded.

- **M Dock** – Allows up to six SEMs to be docked. The M Docks can be linked together to form a chain of up to 4 M Docks/24 SEMs. The M Dock has its own power supply to charge the SEMs that are docked but it also has a USB connection to allow the SEMs to be configured and for data from the SEMs to be downloaded.

- **Belt Extender –** A belt extender can be used to extend the belt by one size. This adds extra flexibility for different body shapes and also allows a smaller distribution of belts to be held

- **Equivital™ Bluetooth Dongle** - The Class I Bluetooth dongle allows up to 6 SEMs in partial disclosure, and 3 in full disclosure, to communicate with a laptop or PC running the Equivital™ suite of software.

  The dongle is a plug-and-play USB device that does not require any additional drivers to be installed on your laptop or PC, simply plug into any available USB socket.

  For technical information please refer to *Equivital™ Bluetooth Dongle Specification* in the Appendix of this document.

The Equivital™ Bluetooth Dongle is not approved for use closer than within 25cm of the body. If your application requires closer contact to the body, additional approvals will be required.

Information on connecting the dongle to the Equivital™ Distributed Network (EDN), can be found in the Equivital™ Manager User Guide.

The LED indications on the Equivital™ Bluetooth Dongle are as follows:

- Solid Green LED – Power on
- Slow Flashing Blue LED – Device Ready
- Solid Blue LED – Searching for devices
- Fast Flashing Blue LED – Sending or Receiving Data

The Equivital™ Bluetooth Dongle will not give you access to third party Bluetooth devices. Inserting your dongle will not enable Bluetooth services on your PC or laptop.

2.3 LifeMonitor Wired and Wireless Ancillary Sensors

- **Core Temperature Capsule**[1] (Optional accessory) – The Core Temperature Capsule is used to measure core body temperature. The data is transmitted to the SEM using a proprietary wireless protocol.

- **Dermal Temperature Patch**[1] (Optional accessory) – The Dermal Temperature Patch is used to measure external skin temperature. The data is transmitted to the SEM using a proprietary wireless protocol.

- **Galvanic Skin Response (GSR) Sensor** – The GSR Sensor is connected directly to the ancillary connector on the B3 Sensor Belt and provides GSR data.

- **SpO_2 Probe** – The SpO_2 Saturation Probe is connected directly to the ancillary connector on the B3 Sensor Belt and provides oxygen saturation data. In addition, it can also provide photoplethysmography (PPG) waveforms.

- **EQ02+ External Battery Pack** – This compact pack is specifically for use with the EQ02+ B3 Sensor Belt. It is attached directly to the ancillary connector of the B3 Sensor Belt and is retained on-body by placing within a pocket on the Sensor Belt. The pack extends the EQ02+ SEM operational life and is hot-swappable. The battery pack uses 2 non-rechargeable AAA batteries.

[1] *Subject to geographical region*

2.4 Equivital Software Products

Software products that can be used with the Equivital™ LifeMonitor include:

- **Equivital™ Manager** – A PC application used for EQ02+ SEM configuration and Equivital™ data management. It enables SEMs to be configured for specific studies or trials and for the data to be downloaded and exported in different formats. Also allows SEMs and Access Servers to be configured via the Equivital™ Distributed Network (EDN), for ease of sharing data over the Equivital Suite of software.

Figure 1 Equivital™ Manager screenshots showing SEM status and saved files

- **Equivital™ Qiosk** – is a turnkey solution that allows configuration, data download and export as well as charging of multiple SEMs with minimal User interaction. This is particularly suited to studies and deployments with large numbers of Subjects, volumes of data, multiple sites or multiple site data management staff.

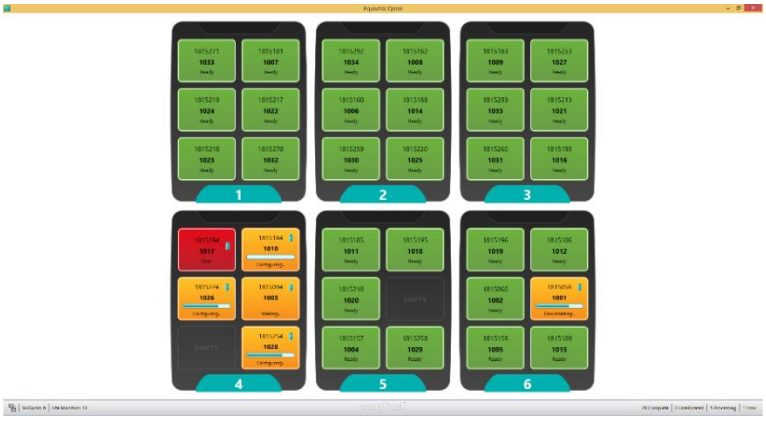


Figure 2 Example of a Qiosk view, showing 6 M Docks populated with a total of 34 SEMs

- **eqView Professional (Non-Diagnostic)** – Allows multi-Subject data to be viewed. This can be (i) Live, where SEMs are connected by Bluetooth, transmitting their data for immediate viewing or (ii) Replay, where previously recorded files, downloaded from a SEM, are replayed using the application.

Figure 3 eqView Professional screenshots showing trending and waveforms

- **eqView Mobile** – The eqView Mobile application allows you to connect a SEM to a mobile device using built-in Bluetooth. The real-time physiological data is displayed locally as summary or waveform data on the device. eqView Mobile can also forward data using Wi-Fi, 3G/4G etc.

  The current version is for Android enabled devices.

Figure 4 eqView Mobile for Android showing the home screen and waveforms

- **Equivital™ Black Ghost** – This is a real-time physiological and location Subject monitoring system, which forms the basis of a personnel welfare monitoring system. Black Ghost will provide individual Subject alarms and alerts based on physiological parameters and geo-position. It can be deployed locally or web-hosted depending on the customer requirements.

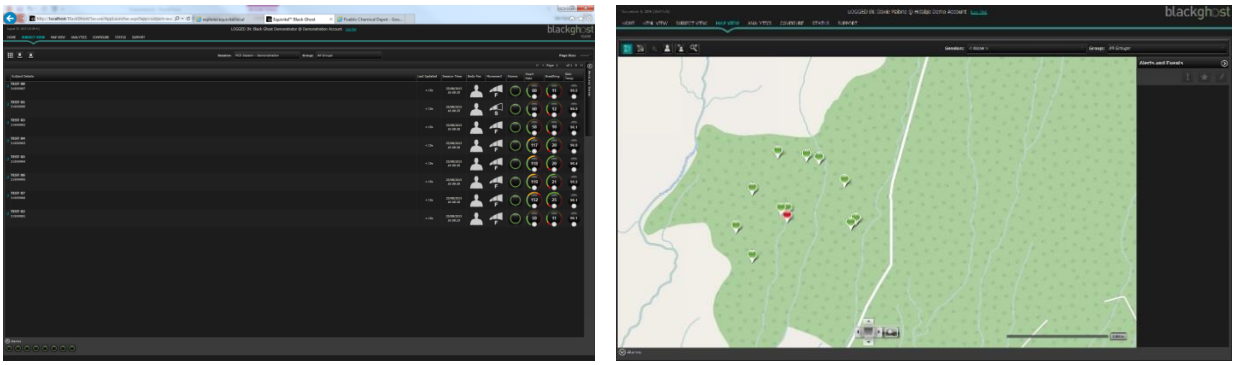


Figure 5 Equivital™ Black Ghost screenshots showing Subject overview and Map view, respectively

3 Equivital™ EQ02+ LifeMonitor

The EQ02+ LifeMonitor comprises the Sensor Electronics Module (SEM) and the Sensor Belt.

3.1 EQ02+ Sensor Electronics Module (SEM)

Figure 6 SEM view showing the buttons and indicators

When using your EQ02+ SEM for the first time please remove the protective film cover from the display LEDs on the front of the SEM.

3.1.1 Switching the SEM ON & OFF

Switching the SEM On

- Press and hold the SEM on/off button until the Power LED illuminates GREEN and the Event LED illuminates RED
- Release the button.
- The Power LED will continue to flash GREEN for approximately 30 seconds
- To check the SEM is on at any time, short press the on/off button. At minimum, the Power LED will flash GREEN 5 times (see important LED indications).

Switching the SEM Off

- Press and hold the SEM on/off button until the ! AMBER LED flashes and then turns to RED !
- Release the button and the SEM will turn off.

For certain uses you may wish to completely disable the off functionality of the power button. This ensures the SEM cannot be manually switched off using the power button. For more information on power options please see Equivital™ Manager User Guide

3.1.2 Additional On/Off Button Features

As well as simply switching the SEM on or off, the on/off button can also be used to signal an event or alert. The precise function and use of these features will vary depending upon the nature of the application.

Event Marker/Alert

- Press and hold the SEM on/off button for 0.5 second until the ! AMBER LED flashes. An event marker will be placed into the SEM file.

Charged Indicator

- When the SEM is connected to a charging unit, either a SEM Lead or M Dock, and has reached a good charge level the on/off will illuminate SOLID GREEN .

3.1.3 SEM LED Definition

Icon	LED	Indicates a function
	POWER GREEN	• When the SEM is turned on by pressing the front button for at least 3 seconds the Power LED lights up GREEN, and flashes for approximately 30 seconds. • If the SEM is on when the front button is pressed, the Power LED is immediately illuminated and flashes GREEN a minimum of five times. • Lights up GREEN when the SEM is fully charged, or the SEM has a good charge level.
	CHARGING GREEN/AMBER	• Illuminates briefly during start up.

Icon	LED	Indicates a function
		• Flashes GREEN to indicate charging. • Flashes AMBER LED to indicate a low battery condition.
	EVENT RED/AMBER	• Illuminates briefly during start up. If a POST failure occurs the LED flashes RED until the SEM is turned off • If the front button is held for more than 0.5 seconds, the AMBER LED starts to flash, indicating that the SEM has been primed to create an event marker message. • If the front button is pressed for more than 3 seconds the RED LED turns on, and the SEM is set to turn off. The SEM turns off when the front button is released.
	DATA BLUE	• The BLUE Data LED is flashed briefly when a core pill or dermal patch transmission is received. • The BLUE Data LED is flashed 3 times when the SEM is paired over Bluetooth or if it receives a Bluetooth ancillary reading.

Table 1 SEM LED Definitions

3.1.4 Other Important LED Indications

With the SEM switched on, press the on/off button for less than 0.5 seconds. The SEM will enter an indication period indicated by a flashing green power light. The status of the SEM will be shown as follows:

- When SD card logging is active. The LED flashes slow, AMBER.
- When SD card logging is active, but data cannot be written to the SD card. The  LED flashes slow RED.
- When SD card logging is inactive, the Event LED (!) is OFF.
- When SD card logging is active, but has stopped unexpectedly, the  LED is solid RED.
- When Bluetooth is connected, the  LED flashes slowly.
- When Bluetooth is enabled, but not connected, the  LED flashes quickly.
- When Bluetooth is disabled, the Data LED is off ().
- When Core Pill detection is enabled and a core pill is detected, the  LED charging light flashes slowly GREEN.

3.1.5 SEM Recharging

When the battery level is low the LED will flash continuously AMBER.

From the time at which the LED starts to flash AMBER; the SEM will function normally for a minimum period of 20 minutes (the actual time will depend on SEM settings and any ancillary sensors connected).

A single SEM USB lead and Multi Dock (MDock) are available for charging EQ02+ SEMs.

If the SEM is charging, the LED on the SEM will flash GREEN.

When the SEM has reached a good charge level the On/Off will illuminate SOLID GREEN .

When the SEM is charged, which takes around 1 hour from flat, simply remove the SEM from the charger unit. The SEM is then ready for use. If you wish to check precisely how much charge is in the SEM open Equivital™ Manager and check on the SEM Status screen.

The SEM shall not be charged at temperatures below 10°C, as this will significantly reduce the charge retained by the SEM and hence the available operating time. It is recommended to charge the SEM above 20°C.

The SEM should be re-charged a minimum of once every 6 months

Keeping the SEM on charge after on/off has illuminated SOLID GREEN will further increase the charge level. Charge level can be checked in Equivital™ Manager.

Docking a SEM to the M Dock

- Push the SEM into M Dock with the top side facing forward.
- Once the SEM is pushed firmly into the M Dock the SEM will begin charging

Attaching a SEM to the Single Lead

- Push the Single Lead into the SEM, ensuring the Connector Lead is the correct way up. The Connecter is marked 'TOP', and this should be facing upward.
- Connect the other end into a USB slot on your PC and the SEM will begin charging.

Never connect the Equivital™ supplied mains connected battery charger or programming lead to the Equivital™ SEM or Sensor Belt when the system is on-body.

Ensure that you have checked with your system operator or health care practitioner on how to reconnect your sensor to the appropriate receiving station or monitoring point.

When you connect the first SEM to your PC, Windows will automatically load drivers, which will take a few seconds. For subsequent connection of this, or other, SEMs drivers will automatically be loaded in the background.

3.2 EQ02+ Sensor Belt

The EQ02+ Sensor Belt is shown in Figure 7. The Sensor Belt contains fabric electrodes that measure vital signs when in good contact with the Subject's skin. The Sensor Belt also holds the SEM securely on-body.

The Sensor Belt is made from a breathable, lightweight fabric to ensure that it is comfortable for long-term use. The two-shoulder strap unisex design provides a secure and comfortable fit for both male and female Subjects.

The Sensor Belt should be worn as shown in Figure 7, with the two straps over the shoulders and the torso clasp placed centrally on the front of the body.

Figure 7 Wearing the sensor belt

3.2.1 Sensor Belt Fitting Instructions

A well fitted Sensor Belt is essential for collecting good quality data from the EQ02+ LifeMonitor; it is recommended that a Sensor Belt should be as tight a fit to the body as is comfortable and positioned in line with the bottom of the pectoral muscles.

When positioned correctly the belt connection clasp should be central to the chest and the shoulder straps should provide gentle support without being tightly strained, as shown in Figure 7.

Data quality verification, for example using eqView Mobile, is useful to ascertain the correct positioning and fit. It is important that the user feels comfortable wearing the sensor belt.

Measuring for the Correct Sensor Belt Size

Male Subjects: Measurement should be taken at the xiphisternum in line with the bottom of the pectoral muscles (Figure 8).

Female Subjects: The measurement is made as for the male. Positioning of the belt may be dependent on whether the belt is worn with a bra/sports bra (Figure 8).

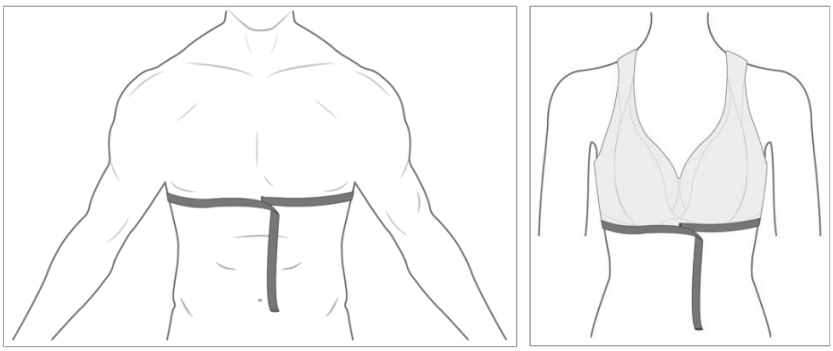


Figure 8 Measuring males and females for the correct sensor belt size

Note, as can be seen in Figure 8, that the measurement point is NOT the same as chest size.

Selecting the Correct Sensor Belt Size

The following sizing chart provides a guideline on how to select the correct belt size to use. It shows the size distribution for both narrow and broad physiques.

Belt Size	Chest Circumference Measurement User Physique: Narrow build	Chest Circumference Measurement User Physique: Broad build
Size 1	74 - 79 cm	74 - 76 cm
Size 2	79 - 84 cm	76 - 81 cm
Size 3	84 - 89 cm	81 - 86 cm
Size 4	89 - 94 cm	86 - 91 cm
Size 5	94 - 99 cm	91 - 96 cm
Size 6	99 - 104 cm	96 - 101 cm
Size 7	104 - 109 cm	101 - 106 cm
Size 8	109 - 114 cm	106 - 111 cm
Size 9	114 - 119 cm	111 - 119 cm

Table 2 Belt Sizing Chart

Identifying your Body Shape

Body shape will impact the correct sizing of the sensor belt. The belt should always fit comfortably and never cause any pain or very tight sensations around the torso.

Chest Shapes: Figure 9 show narrow chest shapes while Figure 10 show broad chest shapes.

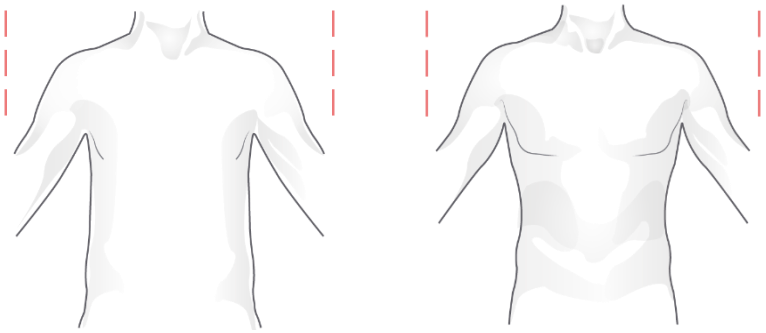


Figure 9 Examples of Narrow chest shapes

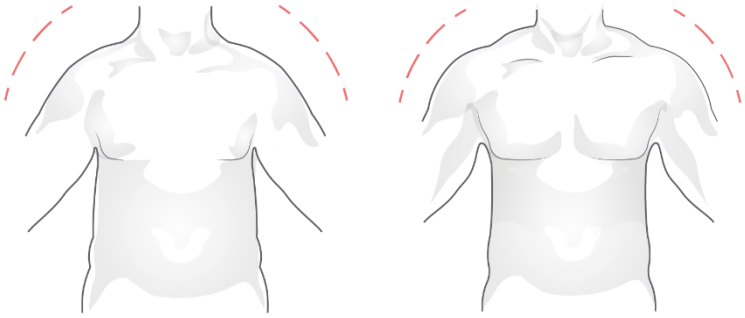


Figure 10 Examples of Broad chest shapes

A larger size should be chosen if measurements border between two sizes.

The best way to verify belt fit with regard to data quality is by using the live view from eqView Pro or eqView Mobile and watching for a stable ECG trace while still and during ambulation.

3.2.2 Wearing the Sensor Belt

1. Moisten the three silver patches on the inside of the belt (two at the front left and right and one on the right side of the back) using clean water. This helps the sensor make contact with the skin to record its signals. Do not use de-ionised water or any other gel or liquid.
2. Hold the Sensor Belt by its ends with the silver-coloured patches facing inward towards the body. Place the belt around the body with the fastener facing the front and both shoulder straps comfortably placed on each shoulder. There should be an approximate 5 cm separation, between the fastener as shown in Figure 11.

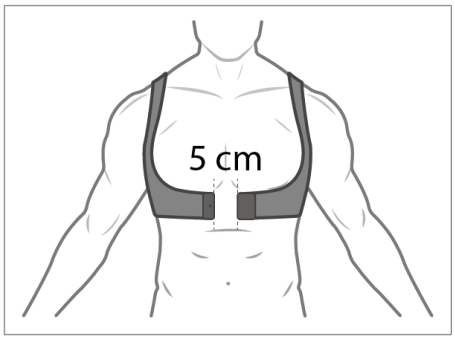


Figure 11 Fitting the Sensor Belt

3. Connect the hook and eye connections at each end of the main belt, selecting the setting which is most comfortable for you. The belt should be firmly contacting the body all around but not uncomfortable. You should be able to push your finger down between the belt and the body.
4. Gently rotate the belt so the plastic centre section is now at the front of the body near the centre of the chest.

Figure 12 Sensor Belt worn by male Subjects

Figure 13 Sensor Belt worn by female Subjects (over or below bra)

Figure 12 and Figure 13 depict the Sensor Belt worn by male and female subjects, respectively.

How to identify a Correctly or Incorrectly fitted Sensor Belt

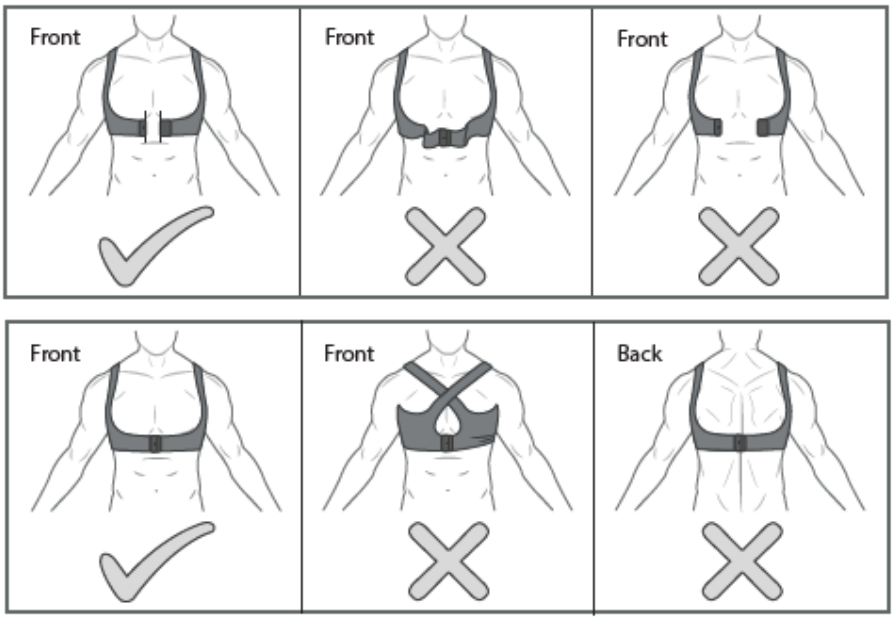


Figure 14 Sensor Belt – correct and incorrect fit

Figure 14 shows examples of a correctly and incorrectly fitted Sensor Belt.

It is essential for data quality that all three ECG electrodes of the Sensor Belt are touching bare skin at all times

Male Subjects: The Sensor Belt should be worn under all garments and equipment

Female Subjects: The Sensor Belt can be worn over or under a bra or sports bra. This is up to the Subjects personal comfort preference.

Do NOT overstretch the Sensor Belt as this can damage it.

Do NOT fit the belt by joining the connection and then pulling over the head and arms.

Lotions, oils, perfumes, deodorant or powder should not be used on the area of the body where the Sensor Belt is being fitted.

Before each use check the Sensor Belt for signs of damage (tears/cracks etc). If any damage is identified, do not use the equipment until the damaged part has been replaced.

3.2.3 Attaching the EQ02+ SEM

1. Switch the EQ02+ SEM on.
2. Insert the EQ02+ SEM into the cradle pocket inside the Sensor Belt making sure the SEM LED face down and are clearly visible through the cut-out in the Sensor Belt when fully connected.
3. A positive 'click' sound indicates a good connection.
4. Make sure the SEM Is switched on before wearing the LifeMonitor system. This can be checked by pushing the power button through the belt fabric and checking the EQ02+ SEM LED window in the belt, where the LEDs should flash.
5. To remove the SEM, hold the top sides of the cradle to compress slightly with one hand and simply pull the SEM out with the other hand.

Ensure that the EQ02+ SEM is fully inserted into the cradle pocket. There should be an audible click and the SEM LEDs shall be clearly visible in the opening of the Sensor Belt cradle.

3.2.4 Ancillary Sensor Connection (EQ02+ B3 Sensor Belt)

The Equivital™ EQ02+ B3 Belt is supplied with a permanently attached ancillary connection cable to which a variety of external sensor devices can be connected, in addition to the EQ02+ External Battery Pack. These are as described earlier in this document.

Figure 15 Sensor Belt ancillary connector mated to external sensor

Only approved Equivital™ ancillary sensors should be connected to the Equivital™ B3 Sensor Belt

Only the Equivital™ EQ02+ External Battery Pack should be connected to the Equivital™ B3 Sensor Belt

It will be necessary to configure the SEM to recognise the wired ancillary sensors. Refer to the Equivital™ Manager User Guide for further information.

3.3 Washing & Cleaning

3.3.1 Equivital™ EQ02+ SEM

Wipe the EQ02+ SEM clean with a damp cloth or sterile wipe and leave to dry normally.

3.3.2 Equivital™ EQ02+ Sensor Belt

To wash the EQ02+ Sensor Belt

1. Fold the belt carefully and insert into a delicates wash bag.
2. Hand or Machine Wash at a low temperature (30°C) using a mild non-biological detergent with no bleaching agents.
3. Re-shape while wet and allow to drip dry.

The Sensor Belt should be washed, using the guidelines provided, before each use.

The Sensor Belt should be washed with items of similar colour

Do NOT leave the Sensor Belt to soak.

Do NOT use fabric softeners, optical brighteners, or any bleaching agents

Do NOT spin or tumble dry

To maximise performance from the system you should replace the Sensor Belt after 6 months of regular use, or if a fail is indicated by a Belt Tester unit.

4 Healthcare Practitioner's (HCP) Guide

4.1 ECG and Heart Rate Derivation

The Equivital™ EQ02+ LifeMonitor 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 16.

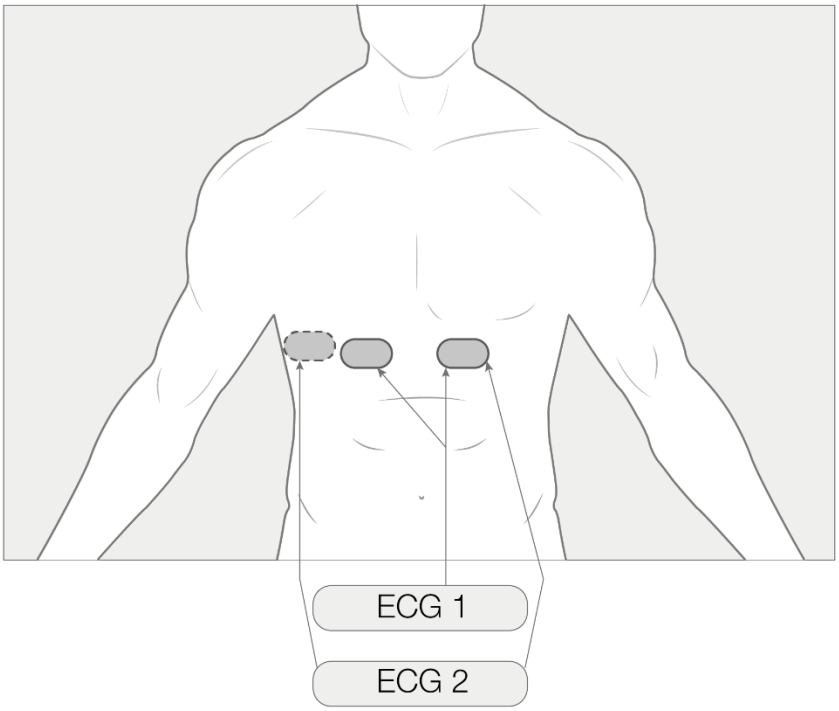


Figure 16 ECG Electrode Locations

The signal bandwidth is switchable between an ambulatory monitoring mode and a clinical/diagnostic mode.

The ambulatory filtering has been chosen to optimise R wave detection reliability under high activity (e.g., running) and removes significant amounts of the low frequency elements of the ECG waveform that are not needed.

4.1.1 ECG Waveforms

Figure 17 provide an example of the same ECG views in both filtering modes for comparison.

The ECG views shown in Figure 17 show that in diagnostic mode the ECG view resembles a traditional view. However, as the views are non-standard, they are not intended to be used for diagnostic ECG screening/monitoring.

The radio system used by the EQ02+ SEM has a variable delay in the transmission of the ECG. Hence the device waveforms displayed cannot be regarded as being exactly real-time, synchronised to the Subjects ECG.

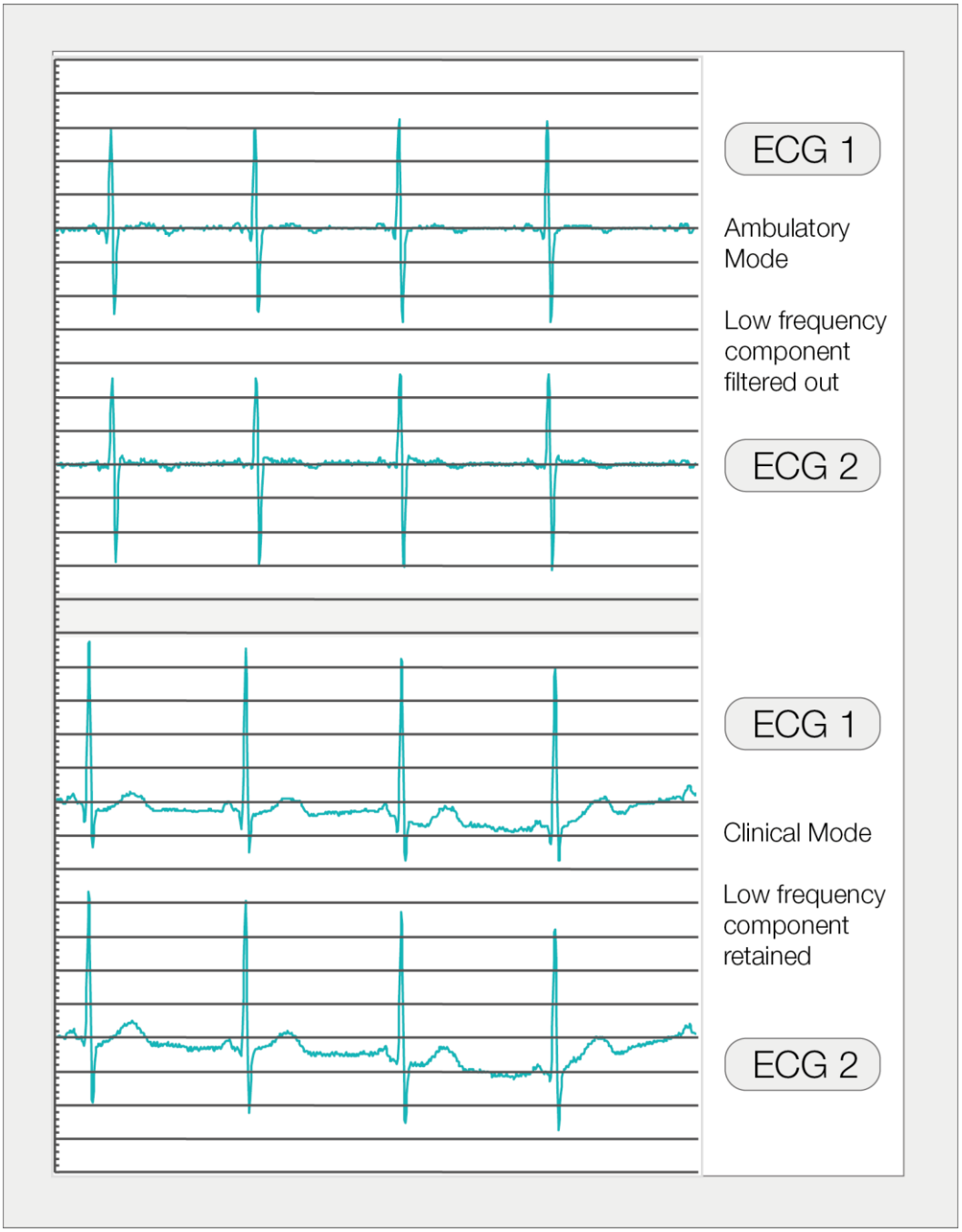


Figure 17 ECG Waveform Examples

4.1.2 Heart Rate Calculation

Heart Rate is calculated as a 30-second rolling average, by default, reported every 15 seconds. The Equivital™ Manager application can be used to modify the reporting time.

The sensor ECG operation has been performance tested to the American National Standard – ANSI/AAMI EC13:2002. The performance results for this testing are disclosed in the technical section at the rear of this document.

4.1.3 Signal Confidence and Quality Measures

A measure of signal quality is provided to assist the HCP in determining if the traces being used to compute the Heart Rates are suffering from noise/artefacts and hence that the Heart Rate accuracy may be degraded. This is particularly useful if the data is being viewed remotely from the patient/Subject.

An overall HR confidence figure is provided in the range 0-100 (100=best). This confidence measure is based on the two measures of signal quality, the amount of noise on the ECG signals and measure of large-scale variation in the inter-beat interval (a clean normal sinus rhythm ECG trace will produce a high value of confidence).

The Equivital™ EQ02+ LifeMonitor should not be used for surgical procedures, to perform synchronised cardioversion or intracardiac monitoring, or when performing external pacing.

Note: Irregular rhythms will also act to reduce the HR confidence figure.

4.2 Breathing Frequency

The primary means of deriving breathing frequency is via an expansion sensor contained within the Sensor Belt, namely Expansion Derived Breathing.

As the Subject's thoracic cavity contracts and expands with respiration effort the sensor's resistance decreases and increases, respectively. Using appropriate circuitry, this can be converted into a respiration effort rate waveform.

The overall sensitivity of the breathing detection switches between a normal mode and a higher sensitivity mode. Theb latter mode is used on static, non–upright Subjects to increase breathing sensitivity to shallow breathing patterns as may be found on resting or sleeping individuals.

As with any indirect measure of breathing frequency, in this case from the measurement of chest expansion, excessive upper body motion and activity can cause artefact that will reduce the accuracy of the rate measured.

Note, the presence of breathing effort does not guarantee adequate ventilation is taking place as this is a single belt derived waveform and therefore open to inaccuracy when used to derive information on ventilation.

4.2.1 Breathing Rate Calculation

The Breathing Rate frequency is calculated as a 60 second rolling average reported every 15 seconds.

4.2.2 Breathing Rate Signal Quality and Confidence Measure

An overall BR confidence (BR Conf) is also provided in the range 0-100 (100=best). This is provided to assist the HCP in determining if the traces being used to compute the Breathing Rates are suffering from noise/artefact and hence that the Breathing Rate accuracy may be degraded. This is particularly useful if the data is being viewed remotely from the patient/Subject.

4.3 Skin Temperature

Skin temperature is measured by an IR thermometer contained in the sensor module. Skin temperature is measured to a resolution of 0.1°C every 15 seconds. An initial settling time, of approximately 15-minutes, is required from when the device is on body**.**

4.4 Body Position and Motion

Body Position and motion are calculated using three orthogonal 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 (i.e., walking)
- High (i.e., running)

Motion detection can create an 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 Subject.

In addition, the raw accelerometer waveforms (gravitational load versus time) may also be transmitted from the EQ02+ SEM. These waveforms may be used to derive additional motion and activity measures by third party or bespoke software programmes.

4.5 Alerts and Alarms

The Equivital™ Manager application enables the configuration of an EQ02+ SEM. For further details, refer to the Equivital™ Manager User Guide.

SEM Alerts and Alarms are set in Equivital Manager and sent by the EQ02+ SEM once it determines that certain conditions have been breached.

Alert and Alarm threshold level information can be found in the *EQ02+ SEM Configuration Data* section.

4.5.1 ECG Alerts

Heart Rate High (Tachycardia) Indication:

The measured Heart Rate exceeds the customised tachycardia threshold in the EQ02+ SEM.

Heart Rate Low (Bradycardia) Indication:

The measured Heart Rate falls below the customised bradycardia threshold in the EQ02+ SEM.

Irregular Rhythm/Noise Alert

The measured ECG inter beat interval variation exceeds the customised threshold in the EQ02+ SEM. This may be due to an irregular rhythm or high degree of noise on the ECG due to motion or incorrectly fitted belt.

4.5.2 Breathing Rate Alert

Breathing Rate High Indication

The measured Breathing Rate exceeds the customised high Breathing Rate threshold in the EQ02+ SEM.

Breathing Rate Low Indication

The measured Breathing Rate falls below the customised low Breathing Rate threshold in the EQ02+ SEM.

Short-Term Breathing Rate Alert

The SEM 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 EQ02+ SEM.

4.5.3 Physiological Welfare Indicator (PWI)

Because the EQ02+ LifeMonitor may be used remotely to monitor Subjects, an additional Vital Signs alert/indication is provided which is an aggregation of the earlier alerts and alarms measured by the device. This may assist the HCP in more rapid detection of Subjects displaying unexpected physiology or multiple alerts/alarms.

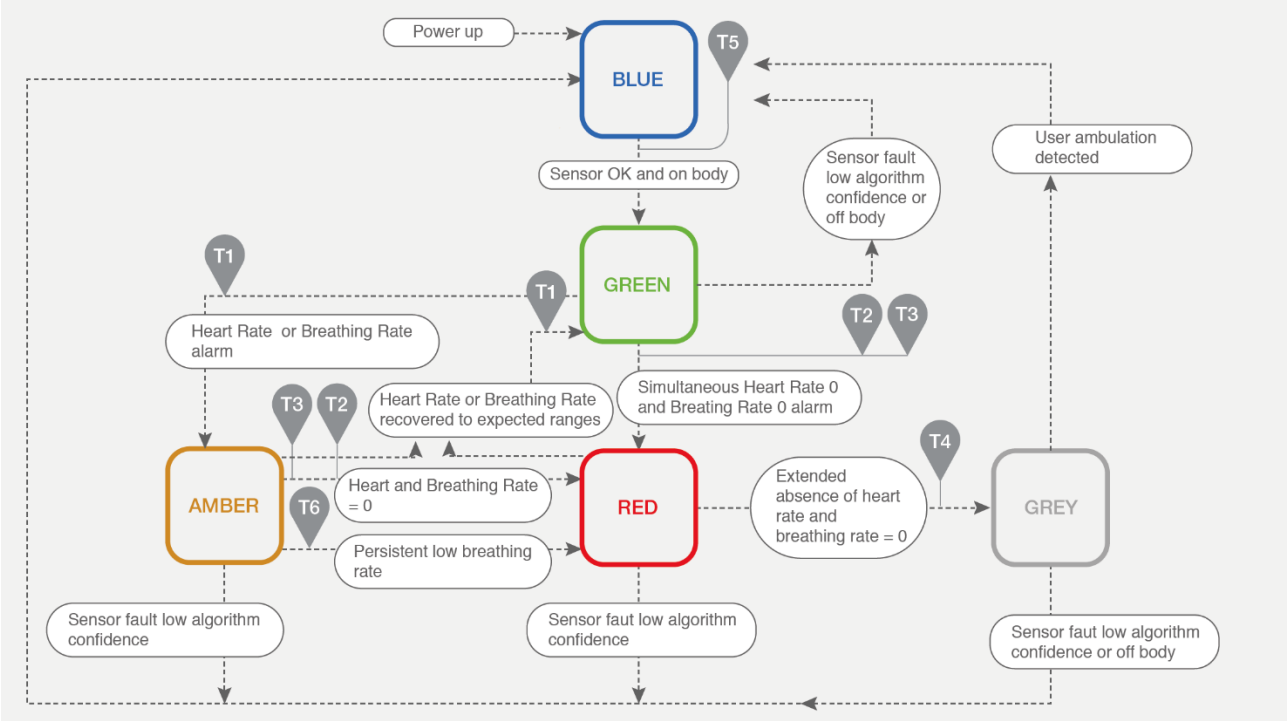


Figure 18 PWI Indication Outputs, (see Table 6 for transition times T1-T6 above)

This combined indicator uses a colour-coded scheme related to the vital signs physiology measured:

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

The colour designations of the PWI indicator should not be assumed to denote clinical priority or urgency. The health care professional is responsible for making this decision on a case-by-case basis.

The boundaries and settings are defined within the SEM (see *EQ02+ SEM Configuration Data*). The setting of the indication output is defined as per the state transition diagram shown in Figure 18.

As well as using the current physiological values to determine the output value of this indicator the SEM also uses an overall Vital Signs confidence value associated with the Heart and Breathing Rate measures. This value is based on the confidence measures for Heart and Breathing Rates discussed earlier. It is intentionally biased towards Breathing Rate Confidence, reflecting its primary triage importance.

This allows the SEM to reduce false indications by avoiding raising the combined Physiological Welfare Indicator if the underlying cardio-respiratory data is noisy due to external influences as the overall confidence measure will be lower in this case. Note that in this case the device state output indicates BLUE and does not assume a normal (non-alerting) state. This is so that monitoring personnel can take appropriate action to investigate and rectify the cause.

The PWI indicator is reported every 15 seconds and is permanently enabled.

4.5.4 Fall Alarm

The EQ02+ SEM can use its built-in accelerometers to monitor upright to non-upright transitions that may be indicative of a fall event. If the correct combination of rapid changes of accelerometer data and change to a non-upright position are detected the SEM will indicate a Fall Suspected.

After the SEM has registered a Fall Suspected it can also progress to issuing a Fall Confirmed alarm.

In order for the SEM to send a Fall Confirmed alarm there needs to be a period of no movement following a Fall Suspected. The period of 'No Movement' can be set by the User (see *EQ02+ SEM Configuration Data*).

5 EQ02+ SEM Configuration Data

5.1 Default Settings

The following list covers the parameters that are intended for configuration by the system's User. Other parameters exist in the device but are not configurable by the User as standard.

Data is logged and stored locally on the EQ02+ SEM, irrespective of other parameters, e.g., Partial and Full disclosure

It is advisable to check the factory default settings using Equivital™ Manager to ensure that the EQ02+ SEM defaults have not changed.

Parameter	Description	Default
Bluetooth Connectivity	This enables the connectivity to the radio interface in the SEM. If this parameter is ENABLED, power will be applied to the radio and hence the SEM can communicate wirelessly. DISABLING this parameter will save battery power and hence increase the SEMs ON time, for Subjects who do not need to communicate wirelessly.	ENABLED
Bluetooth PIN	PIN used to allow connection to the SEM via Bluetooth. It is recommended that the User modify this PIN from the factory default at first use. The range that can be used is 4-15 digit numeric	1111
Live Data Transmission	This parameter can be set to FULL or PARTIAL DISCLOSURE. If set to the former the Live data output from the SEM will include Live Waveforms in addition to Summary data. The use of PARTIAL DISCLOSURE during Live transmission will improve SEM battery life and may also be preferred if data bandwidth limitations are present. It should be noted that irrespective of this setting Full Disclosure data is stored internally on the SEM	FULL DISCOSURE
Heart Rate Reporting	The HR can be reported every 5-seconds or every 15-seconds	15s
Expansion Derived Breathing	Sets the SEM to output Breathing Rates calculated from the belt respiration sensor	ENABLED

Parameter	Description	Default
ECG Derived Breathing	Sets the SEM to output Breathing Rates derived from the ECG signal	DISABLED
Body Temperature Sensors	This will allow Core Pill and Dermal Patch data to be received and output by the SEM if ENABLED. DISABLING this parameter will save battery power and hence increase the SEMs ON time, for Users who do not need this feature.	ENABLED
Usage Mode	This allows the filtering method for the ECG signal for to be set for the patient anticipated use case of AMBULATORY or CLINICAL (sedentary).	AMBULATORY
ECG Processing	Specifies whether the SEM should use both leads (STANDARD) or only the ECG1 lead (USE ECG 1 ONLY) for Heart Rate data	STANDARD
Accelerometer	This specifies whether the SEM should log high-resolution (256Hz) accelerometer data to the SD card. This is in addition to STANDARD resolution data, which is always logged.	STANDARD
Fall Detection	The SEM can be configured such that Fall Detection is ENABLED or DISABLED	ENABLED
Lead Off Alarm	The Lead Off alarm indicates that the ECG electrode signal quality is poor. It can be ENABLED or DISABLED by the User.	ENABLED
Real Time Clock	The Real Time Clock of the SEM can be set to UTC or to the Computer's local time. It is recommended that the SEM be set to UTC.	UTC
Wake Up Settings	This specifies if the SEM is ENABLED to sleep periodically. If ENABLED after the SEM is turned on, it will remain awake for the Duration specified and then will turn off. The SEM will then turn on at the specified Interval.	DISABLED
Sensor Power Button	The SEM can be configured such that the ability to turn it off manually by pressing the power button is ENABLED or DISABLED.	ENABLED
USB Connection Removed	The SEM can be configured to turn OFF or remain ON when the USB connection is removed	ON

Table 3 EQ02+ SEM Default Configuration Settings

5.2 Alerts, Alarm Limits & Time Thresholds

5.2.1 User Configurable

Parameter	Parameter name	Description	Range	Default
Tachycardia limit	HR High Threshold	Tachycardia limit for Heart Rate	1-255 bpm	220 bpm
Bradycardia limit	HR Low Threshold	Bradycardia limit for Heart Rate	1-255 bpm	45 bpm
Upper Respiration Limit	BR High Threshold	Upper respiration limit for Breathing Rate	1-70 rpm	60 rpm
Lower Respiration Limit	BR Low Threshold	Lower respiration limit for Breathing Rate	1-70 rpm	4 rpm
Sp02 Alarm Threshold	Oxygen Saturation Low Alarm setting	Lower limit for oxygen saturation percentage	0-100%	95%
No Breath Time Limit	No Breath Alarm	Specifies the time in seconds of No Breath detected after which the SEM sends an alarm	0-255 sec	45 sec
No Movement Threshold	Post-Fall no movement threshold	Specifies how long, in seconds, the Subject must remain motionless following a Fall Suspected before a Fall Confirmed alarm is sent by the SEM	0-160 sec	15 sec

Table 4 EQ02+ SEM Alerts, Alarm Limits & Time Thresholds

For the HR and BR high/low threshold levels a value of '0' corresponds to no threshold having been set

5.2.2 Set Configuration

The following parameters are NOT User configurable.

Confidence Thresholds

Parameter	Parameter name	Description	Default
Heart Rate Confidence Threshold	HR Confidence Threshold	Minimum confidence in Heart Rate signal needed to make an alarm or alert condition	80%
Breathing Rate Confidence Threshold	BR Confidence Threshold	Minimum confidence in Breathing Rate signal needed to make an alarm or alert condition	80%

Table 5 EQ02+ SEM Confidence Thresholds Configurations – not User configurable

PWI Specific

Please refer to Figure 18 for the transitions related to the Time Thresholds in Table 6.

Parameter	Parameter name	Description	Default
Combined indication operational confidence threshold	Minimum Operational Confidence	Minimum PWI algorithm confidence below which the output is considered unreliable and should be set to unknown or inoperative (BLUE)	45%
Threshold Exception Time	Time Threshold 1 (T1)	Time required for an out of threshold rate to exist before an indication is raised. A setting of 0 minutes corresponds to an effective update time of 15-seconds.	0 minutes
Time to alert – cardiac alarm	Time Threshold 2 (T2)	Period when HR = 0 before an indication is raised.	15 seconds
Time to alert – breathing alarm	Time Threshold 3 (T3)	Period when BR = 0 before an indication is raised	15 seconds
Time Threshold – Sustained absence of cardiorespiratory signals	Time Threshold 4 (T4)	Period to transition from RED to GREY state when no vital sign signals are being measured.	2 mins
Time Threshold – Sensor Initialisation	Time Threshold 5 (T5)	Period to transition from BLUE to GREEN state once the sensor PWI algorithm confidence is above minimum threshold.	1 min
Time Threshold – Low Breathing Rate alarm whilst alert active	Time Threshold 6 (T6)	Period to transition from AMBER to RED state if very low Breathing Rate (< 2 rpm) is observed	2 seconds

Table 6 EQ02+ SEM PWI Specific Configurations – not User configurable

6 Appendices

6.1 EQ02+ LifeMonitor Technical Specifications

6.1.1 Device Classification

Parameter	Specification
FDA Medical Device Classification	Class II
EU Medical Device Classification	Class IIb (EQ02+ SEM) Class I (EQ02+ Sensor Belt)
Electrical Shock Protection	Type BF Applied Part, Internally Powered Equipment *IEC 60601-1*
Mode of Operation	Continuous
Water Ingress Protection	IPx7
Flammable Gas Protection	Unprotected

Table 7 EQ02+ LifeMonitor Device Classification

IPx7 is only applicable when the EQ02+ SEM and Sensor Belt are connected together as described in this guide

During immersion in water the EQ02+ LifeMonitor is not guaranteed to provide accurate physiological data

After immersion in water the EQ02+ LifeMonitor (SEM and Sensor Belt) will need to dry out in order to provide accurate physiological data

6.1.2 EQ02+ Sensor Belt

Parameter	Specification
Duration of Continuous Use	24-hours
Operating temperature	-10°C to +50°C *BS EN 60068-2-1: Cold* *BS EN 60068-2-78: Damp Heat Steady State*

Parameter	Specification
Storage Temperature	-20°C to +55°C *BS EN 60068-2-1: Cold* *BS EN 60068-2-78: Damp Heat Steady State*
Operating & Storage Humidity	0% to 95%, Relative Humidity, Non-Condensing *BS EN 60068-2-78: Damp Heat Steady State*
Altitude	-300 to 30,000 feet BS EN 60068-2-13: Low Air Pressure

Table 8 EQ02+ Sensor Belt environmental specification

6.1.3 EQ02+ Sensor Electronics Module (SEM)

General

Parameter	Specification
Size (overall dimensions)	78mm x 55mm x 11mm
Weight	38g
Operating temperature	-10°C to +50°C *BS EN 60068-2-1: Cold* *BS EN 60068-2-78: Damp Heat Steady State*
Storage Temperature	-20°C to +55°C *BS EN 60068-2-1: Cold* *BS EN 60068-2-78: Damp Heat Steady State*
Operating and Storage Humidity	0% to 95% Relative Humidity, Non-Condensing *BS EN 60068-2-78: Damp Heat Steady State*
Altitude	-300 to 30,000 feet *BS EN 60068-2-13: Low Air Pressure*
Power	3.7V 300mA Lithium-Polymer rechargeable cell
Operating Time	Full Disclosure – 36 hours, typical (Bluetooth Disabled and no accessories)
Li Polymer Recharge Time	From Flat ~1hr
Charging Temperature	10°C to +40°C

Table 9 EQ02+ SEM - environmental and general specification

The SEM should not be charged at temperatures below 10°C, as this will significantly reduce the charge retained by the SEM and hence the available operating time. It is recommended to charge the SEM above 20°C.

ECG

Parameter	Specification	
Number of leads	2	
Sampling frequency	256 Hz	
Resolution	10 bits	
Voltage range	+/- 5mV	
Frequency Range	Clinical/Diagnostic Setting:	0.3 – 50 Hz (3dB points)
	Motion/Ambulation Setting:	7Hz – 50Hz (3dB points)
Heart Rate Range	0 – 300 bpm	
Heart Rate Calculation Frequency	5 or 15 seconds (User selectable in Equivital™ Manager)	
Heart Rate Accuracy	<+/-5bpm/10%	

Table 10 EQ02+ SEM - ECG Parameters

Chest Expansion Respiration Effort

Parameter	Specification
Measurement type:	Resistive strain gauge
Sampling frequency:	25.6 Hz
Resolution:	10 bits
Frequency Range:	0.05 – 7 Hz
Breathing Rate Range:	0 – 70 rpm
Breathing Rate Accuracy:	+/- 2 rpm Static Use +/- 3 rpm Moderate Ambulation Activity (e.g., walking) +/- 6 rpm High Ambulation Activities (e.g., running/heavy carrying)
Breathing Rate Reporting Frequency:	15 seconds

Table 11 EQ02+ SEM - Respiration Parameters

Skin Temperature

Parameter	Specification
Sampling frequency	0.25Hz
Resolution	10 bits
Range	–10°C to +50°C
Sensor Accuracy	32°C to 42°C = ±0.3 °C 0°C to 50 °C = ±0.5°C -10°C to 50°C = ±1.5°C
Measurement Type	IR Skin Temperature
Temperature Reporting Frequency	15 seconds

Table 12 EQ02+ SEM - Skin Temperature Parameters

For accurate skin temperature measurements an initial settling time, of approximately 15-minutes, is required from when the device is on body

Core Temperature Capsule

Parameter	Specification
Temperature Sensing Range:	32°C to 42°C
Temperature Accuracy:	-10°C to 0°C = +/- 0.3°C 0°C to 25°C = +/-0.25°C 25°C to 50°C = +/-0.1°C 50°C to 60°C = +/- 0.25°C
Measurement type:	Thermistor
Temperature Reporting Frequency:	15 -30 seconds measurement update – reported every 15 seconds

Table 13 EQ02+ SEM - Core Temperature Parameters

6.1.4 ANSI/AMEE EC 13 Performance Disclosure

The following section covers disclosure of performance requirements against tests specified in EC13 Cardiac Monitors, heart rate meters and alarms.

These settings apply when the EQ02+ SEM is set to its clinical/diagnostic filter setting and has 5 second reporting rate for Heart Rate enabled.

For details of the tests, refer to the ANSI/AMEE Standard:

- 4.1.2.1 (a) – Electrosurgery - See Contraindications
- 4.1.2.1 (b) – Lead Off Sensing – See Technical Specifications
- 4.1.2.1 (c) - Tall T Wave Rejection: The maximum T wave amplitude supported before the Heart Rate exceeds the rated 10% tolerance, relative to a 1mV QRS deflection is 0.8mV
- 4.1.2.1 (d) – Heart Rate Averaging – See Heart Rate Calculation
- 4.1.2.1 (e) - Heart Rate Meter Accuracy and response to irregular waveforms (as specified in the EC13 standard):

  3a) Ventricular Bigeminy: Recorded result = 40bpm

  3b) Slow Alternating Ventricular Bigeminy: Recorded result = 30bpm

  3c) Rapid Alternating Ventricular Bigeminy: Recorded result = 60bpm

  3d) Bidirectional Systoles: Recorded result = 90bpm

- 4.1.2.1 (f) Response time of heart rate meter to change in heart rate.

  80bpm – 120 bpm: 6s – 8s; mean 7s

  80bpm – 40 bpm: 7s – 11s; mean 9s

- 4.1.2.1 (g) Time to Alarm for Tachycardia:

  Waveform 4a): 3s – 6s; mean 5s

  Waveform 4a) halved: 3s – 9s; mean 5s

  Waveform 4a) doubled: 1s – 6s; mean 4s

  Waveform 4b): 1s – 6s; mean 4s

  Waveform 4b) halved: 3s – 7s; mean 6s

  Waveform 4b) doubled: 2s – 6s; mean 4s

- 4.1.2.1 (h) – Pacemaker rejection – The device is contraindicated for pacemaker equipped patients
- 4.1.2.1 (i), (j) – Not applicable – The device is a telemetry module intended to provide data for a separate viewer product. The alerts provided by the Hidalgo supplied viewer are documented in its user manual
- 4.1.2.1 (k) Battery power information – See Technical Specifications
- 4.1.2.1 (l) Telemetry: - See Technical Specifications – General and EMC
- 4.1.2.1 (m) Not applicable
- 4.1.2.1 (n) Not applicable – the device does not contain its own integral ECG viewing function
- 4.1.2.1(o) Not applicable – device uses specific electrode

- 4.1.2.1(p) Auxiliary output - Not applicable
- 4.1.2.1(q) See Instructions for Use
- 4.1.2.1(r) Battery disposal – See Technical Specifications
- 4.1.2.2 Application Notes – See Instructions for Use
- 4.1.3 Service – See Instructions for use
- 4.1.4 Pacemaker additional information - contraindicated

6.1.5 Electro Magnetic Compatibility (EMC)

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

Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this document.

The Equivital™EQ02+ LifeMonitor is intended for use in the electromagnetic environment specified below. The customer or the User of the EQ02+ LifeMonitor should assure that it is used in such an environment.

The EQ02+ LifeMonitor is not suitable for interconnection with other equipment.

The EQ02+ LifeMonitor is suitable for use in all establishments including those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.

Guidance and Manufacturers Declaration – Electromagnetic Emissions

EN60601-1-2			
Test	Method	Limit	Pass/Fail
Conducted Emissions	EN55011	Table 2b = CISPR22(B)	PASS
Radiated Emissions	EN55011	Table 3 = CISPR22(B)	PASS
Harmonic Currents	EN61000-3-2	EN61000-3-2	Not applicable
Flicker	EN61000-3-3	EN61000-3-3	Not applicable

Table 14 EN60601-1-2 – Electromagnetic Emissions

EN301 489-1 V1.8.1 Class B			
Test	Method	Limit	Pass/Fail
Conducted Emissions	EN55022	Table 6 & 8 = CISPR22(B)	PASS
Radiated Emissions	EN55022	Table 4 = CISPR22(B)	PASS
Harmonic Currents	EN61000-3-2	EN61000-3-2	Not applicable
Flicker	EN61000-3-3	EN61000-3-3	Not applicable

Table 15 EN301 489-1 V1.8.1 Class B – Electromagnetic Emissions

Guidance and Manufacturers Declaration – Electromagnetic Immunity

EN60601-1-2			
Test	Method	Severity	Criterion Achieved
Electrostatic Discharge (ESD)	IEC61000-4-2	Air - 2, 4, 8kV	PASS
		Contact – 2, 4, 6kV	PASS
Radiated Field Immunity	IEC61000-4-3	3V/m 80-2500MHz 1kHz 80% am	PASS
		3V/m 80-2500MHz 2Hz 80% am	PASS
Electrical Fast Transients	IEC61000-4-4	1kV	Not Applicable
		2kV	
Surge	IEC61000-4-5	1: 0kV Line - Line	Not Applicable
		2: 0kV Line - Earth	
Conducted Field Immunity	IEC61000-4-6	3Vrms 0.15-80MHz 1kHz 80% am	PASS
		3Vrms 0.15-80MHz 2Hz 80% am	Not Applicable
Power Frequency Magnetic Field	IEC61000-4-8	50Hz/60Hz, 3A/m	PASS
Voltage Dips and Interruptions	IEC61000-4-11	> 95% reduction, 10msec	Not applicable
		60% reduction, 100msec	
		30% reduction, 500msec	
		> 95% reduction, 5s	

Table 16 EN60601-1-2 – Electromagnetic Immunity

EN301 489-1 V1.8.1 Class B			
Test	Method	Severity	Criterion Achieved
Electrostatic Discharge (ESD)	EN61000-4-2	Air - 8kV	TRANSIENT
		Contact – 4kV	TRANSIENT
Radiated Field Immunity	EN61000-4-3	3V/m 80-2700MHz 80% 1kHz am mod	CONTINUOUS
Electrical Fast Transients	EN61000-4-4	0.5kV	Not Applicable
		1kV	
Surge	EN61000-4-5	1: 0kV Line - Line 2: 0kV Line - Earth	Not Applicable
Conducted Field Immunity	EN61000-4-6	3Vrms 0.15-80MHz 80% 1kHz am mod	CONTINUOUS
Voltage Dips and Interruptions	EN61000-4-11	100% reduction, 10msec 100% reduction, 20msec 30% reduction, 500msec 100% reduction, 5s	Not applicable
Vehicle Transients	ISO 7637-2:2004	Pulse 3a, 3b; Test Level III	Not applicable
Vehicle Surge	ISO 7637-2:2004	Pulse 1, 2a, 2b; Test Level III	Not applicable
Vehicle Dips	ISO 7637-2:2004	Pulse 4; Test Level III	Not applicable

Table 17 EN301 489-1 V1.8.1 Class B – Electromagnetic Immunity

The Equivital™ EQ02+ LifeMonitor is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled.

The customer or User of the EQ02+ LifeMonitor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the EQ02+ SEM as recommended in Table 18 based on the maximum output power of the communications equipment.

Recommended Separation distances between portable and mobile RF communications equipment and the EQ02 SEM			
Rated Max Output Power of Transmitter Watts (W)	Separation distance according to frequency of transmitter (m)		
	150kHz to 80MHz	80MHz to 800MHz	800MHz to 2.5GHz
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33

Recommended Separation distances between portable and mobile RF communications equipment and the EQ02 SEM			
Rated Max Output Power of Transmitter Watts (W)	Separation distance according to frequency of transmitter (m)		
	150kHz to 80MHz	80MHz to 800MHz	800MHz to 2.5GHz
10	3.69	3.69	7.38
100	11.67	11.67	23.33

NOTES

- At 80 MHz and 800MHz, the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Table 18 Recommended Separation distances between RF comms and the EQ02+ SEM

For transmitters rated at a maximum output power not listed, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, based on its output power, P, in Watts (W) as stated by the transmitter manufacturer. The equations are:

- For Frequency between 150kHz and 80Mhz: d = [3.5/3] x P
- For Frequency between 80Mhz and 800MHz: d = [3.5/3] x P
- For Frequency between 800Mhz and 2.5Ghz: d = [7/3] x P

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey should be less than the compliance level within each frequency range.

The calculations herein are for guidance only.

Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM, FM broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength exceeds the applicable RF compliance level above, the EQ02+ SEM should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary such as re-orienting or relocating the EQ02+ SEM

If you are entering a facility where interference may be a particular concern (e.g. a hospital or hazardous plant environment) contact the person in charge of the facility to check if any special precautions need to be taken.

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

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

6.1.6 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 that 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:

- Re-orientate or relocate the receiving radio or television antenna.
- Increase the separation between the equipment and the radio or television receiver.
- Connect the equipment into an outlet on a circuit different from that to which the radio or television 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: T85EQ001
Type 1 Radio Interface:	FCC ID: QOQWT11

6.2 Connecting to and Using the EQ02+ SEM

6.2.1 Bluetooth™ Connection Information

The EQ02+ SEM complies with the Bluetooth™ protocol specification V2.1 and can be used with a Bluetooth™ certified transceiver that 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 EQ02+ SEM appears as a “discoverable slave” device that means it can be located and connected to by the receiving unit. See Equivital™ Manager User Guide for instructions on how to initiate the connection.

6.2.2 Sensor Data Security

The Bluetooth™ protocol implements both encryption and authentication using a pass key (PIN) to allow access.

The PIN for the EQ02+ SEM should be programmed into the unit by the Equivital Manager Application (See Sensor Configuration Data).

Failure to set a unique Bluetooth™ PIN may compromise the security of the device and may make it easier for other persons to connect to the EQ02+ SEM.

6.2.3 Application Protocol Overview

The following information provides a summary list of data disclosed by the EQ02+ SEM in Partial (Summary) and Full Disclosure modes.

Summary Disclosure

The following data is transferred every 15 seconds:

- ECG Heart Rate
- Heart Rate Confidence
- Respiration Band Rate (if configured)
- Respiration Rate Confidence
- EDR Rate (if configured)
- EDR Quality (if configured)
- IR Skin Temperature
- Physiological Welfare Index state
- Fall state (if a Fall is Suspected or Confirmed this is sent immediately)
- Respiration Indications

- Low Breathing Rate
- High Breathing Rate

The following are sent every 5 seconds:

- ECG Indications:
  - Low Heart Rate
  - High Heart Rate
- Body Position (update also sent immediately if state changes)
- Motion Classification (update also sent immediately if state changes)
- Sensor Fault Codes

Data from the following sensors is sent whenever a value is received:

- Core Pill Temperature
- Dermal Temperature Patch
- Galvanic Skin Response
- Oxygen Saturation (SpO2)

Full Disclosure

When full disclosure is selected, then in addition to the Summary disclosure, the following data can be transmitted, depending upon the configuration:

- Raw Waveform Data
  - ECG1 and ECG2
  - Respiration Belt Trace
  - Accelerometer Traces (all axes)
  - Photo Plethysmography, PPG (if available)

6.2.4 Software Development Kit

Hidalgo provides .NET and JAVA SDKs which allow a systems integrator or developer to integrate Equivital EQ02+ SEM data into their applications.

6.3 Equivital™ Bluetooth Dongle Specification

Equivital™ provides a dedicated Bluetooth dongle that allows up to 6 SEMs in partial disclosure, and 3 in full disclosure, to communicate with a laptop or PC running the Equivital™ suite of software.

Parameter	Specification
Dimensions (excluding USB connector)	Length = 58-mm Width = 22-mm Height = 13-mm
Operating Environment	For indoor use only
Operating Temperature	0°C to +40°C
Storage Temperature	-40°C to +85°C
Operating Humidity	20% to 95%, Relative Humidity, Non-Condensing
Storage Humidity	0% to 95%, Relative Humidity, Non-Condensing
Regulatory Information	CE The unit complies with all relevant safety standards FC FCC Part 15 approval, FCC ID: QOQWT41 This symbol indicates that the unit cannot be treated as normal domestic trash at disposal but must be handed in at a collection point for recycling electrical and electronic appliances.
Bluetooth	Class 1

Table 19: Equivital™ Bluetooth Dongle Specification

The Equivital™ Bluetooth Dongle is not approved for use closer than within 25cm of the body. If your application requires closer proximity to the body, additional approvals will be required.

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Please register on the Equivital Helpdesk for access to the latest version of this User Guide and other customer support:
https://support.equivital.com

If you have any suggestions or feedback for us concerning this guide, please contact us on

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