

EQUIVITAL[™] EQ-01 VITAL SIGNS MONITOR USER APPLICATION GUIDE

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Explanation of Symbols

Within this manual the following symbols are used to indicate warnings and precautions a user 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 box. Failure to follow a precaution may lead to a reduction in performance of the device when in use.

Before using Equivital[™]

Please observe the following warnings and precautions:

Warnings

 IF YOU ARE UNCLEAR AS TO WHY YOU ARE BEING ASKED TO WEAR THIS DEVICE PLEASE CONSULT THE HEALTH CARE PROFFESIONAL OR OCCUPATIONAL WELFARE PERSONNEL RESPONSIBLE BEFORE USE.
 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. YOU 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.



• 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.





IF YOU HAVE AN IMPLANTED DEFIBRILLATOR OR PACEMAKER DO NOT USE THIS DEVICE. IF YOU WEAR OR USE OTHER MEDICAL EQUIPMENT PLEASE CONTACT YOU HEALTH CARE PROFESSIONAL BEFORE USING THIS DEVICE.



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

- DO NOT USE LOTIONS, OILS, PERFUMES, DEODORANT OR POWDER ON THE AREA WHERE THE SENSOR BELT IS BEING APPLIED
- EACH TIME YOU USE 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.

What is the Equivital Monitor Used For:

The Equivital[™] Vital Signs Physiological Monitor is a non-invasive ambulatory monitoring 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 for the collection of ambulatory physiology for general research purposes in application such as sports or human performance medicine.

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:

• an indication of the users activity level (none, low or high) derived from a movement detection sensor.

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- body orientation.
- chest skin surface temperature.
- alternate secondary measurement of heart rat
- alternate secondary measurement of respiration effort
- indications and alerts if physiology exceeds predefined boundaries.

What does the Equivital Vital Signs Monitor Consist Of:

The device consists of two items:

A sensor electronics module (SEM) which contains a battery , electronics and software in order to measure the vitals signs signals off the body.

A belt harness which holds the SEM onto the body and contains fabric electrodes in order to contact to the user skin.



Fitting Instructions

Selecting the Correct Belt Size

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
М	М	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.

Applying the Belt



1. Pass adjuster strap through loop of shoulder strap







- 2. Place shoulder strap over left arm and then place chest strap around the waist. Then pull the adjuster band with the right hand so that it comfortable meets the buckled end (held in the left hand), on the right hand side of the torso.
- 3. Loop the adjuster band through the buckle and tighten just enough to take out excess slack.



- 4. Straighten the band so the centre section sits centrally on the chest.
- 5. Tighten strap by holding the buckle with the left hand and pulling the adjuster strap with the right hand. The belt should be a snug fit to the body
- - 6. When tensioned correctly, the strap must be comfortable and should not restrict the users chest movement. As a guide, it should be possible to easily place one finger under the strap when tightened.





7. To adjust the upper strap, remove from the shoulder and lengthen/shorten as necessary.

8. Replace strap over shoulder and adjust rear lower section such that it sits centrally on the back between the buckles.



9. To ensure that the strap is now positioned and tensioned correctly, extend arms to the side and raise and lower them a few times. Now moisten the skin under the three electrode sites with saliva or water which accelerates the electrode to skin connection and improves in the initial few minutes after application.

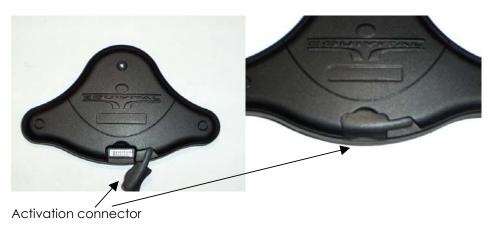
Attaching the "SEM" Electronics Unit and Final Adjustments

Take the SEM electronics module:

The rear of the SEM electronics unit has simple "snap" stud connectors which allow it to be connected to the sensor



If this is the first time you have used the SEM or you have just completed recharging the SEM. Place the activation connector into the hole on the front of the unit.





Once the device is activated, hold the device for approximately six seconds. The units internal vibration alerter will operate with three short pulses indicate that it is correctly operating.

In order to verify transmission from the sensor is being received remotely you will need to check or confirm with the receiving station or monitoring point your sensor talks to. (This will vary from system to system so ask your system operator or health care practioner if you are unsure)

Now take the unit and connect each snap in turn making sure all have been connected.

Finally adjust the location of the sensor belt for comfort and make sure the SEM unit is centrally located on the chest as shown below:



Recharging or Changing Batteries on the SEM

The sensor unit SEM comes with two options for powering the unit, a rechargeable cell, or replaceable AAA/LR03 batteries. The option you have will depend on what type of device was specified when it was purchased.

Changing the AAA Batteries

Remove the rear battery door by sliding it down and then lifting it out





Fit the batteries into the battery compartment observing the polarity marking inside the case and replace the case.





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

Recharging the SEM

Remove the activation bung and attach the charger unit cable to the connector. The charger will indicate a red light when charging and green when charged. Only connect the charger power plug to the socket after you have attached it to the SEM. Failing to do this can give false indications of charge on the charger light.



In order to maximise the rechargeable battery lifetime it is recommended to avoid leaving the unit connected to the charger once fully charged.



Switching the Sensor On and Off

If you want to stop using the sensor, or only use it intermittently – remove power by taking the activation bung out of its hole.

• REMOVE THE AAA BATTERIES FROM THE DEVICE IF IT WILL NOT BE USED FOR SOME TIME (>10DAYS). THIS IS TO REDUCE THE RISK OF THE CELLS LEAKING AND CORODING THE BATTERY CONTACTS

Washing and Cleaning

SEM

Wipe the SEM clean with a damp cloth and leave to dry normally

Belt

Wash the belt in a cold wash (40°C) using a mild non biological detergent.

• DO NOT TUMBLE DRY THE BELT – THIS WILL REDUCE THE LIFE OF THE BELT

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

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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: Operating Humidity: Storage Temperature: Storage Humidity:	-10°C to +55°C 0% to 95% RH Non-Condensing -20°C to +65°C 0% to 95% RH Non-Condensing	
• ECG		
No of leads: Sampling frequency: Resolution: Voltage range: CMRR: Frequency Range: Heart Rate Calculation	2 256 Hz 10 bits +/- 5mV >85 dB Diagnostic Setting : 0.05 – 85 Hz (3dB points) Monitor/Ambulation Setting : 5Hz – 85Hz (3dB points)	
Frequency:	15 seconds	
Impedance Respiration Measurement type: Sampling frequency: Resolution: Modulation: Drive Current: Frequency Range: Respiration Rate Reporting Frequency:	Effort Bipolar 25.6 Hz 10 bits 50 KHz 200 μA 0.05 – 7 Hz 15 seconds	
• Chest Expansion Respira Measurement type: Sampling frequency: Resolution: Frequency Range: Respiration Rate Reporting Frequency:	tion Effort Resistive strain gauge 25.6 Hz 10 bits 0.05 – 7 Hz 15 seconds	
• Temperature Sampling frequency: Resolution: Range: Sensor Accuracy:	0.25Hz 10 bits 10°C - 45°C <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

Radio – Type 0 Low Power Pan

Frequency:	40.68MHz
Modulation:	Binary FSK
Data Rate:	2400 Baud
Modulation:	+/- 4KHz

Radio – Type 1 Bluetooth

Frequency:	2401 – 2480MHz
Modulation:	TDD GFSK (BbT -0.5)
Data Rate:	1MBPS
Carrier Spacing:	1 MHz
No of Channels:	79
Tx Power:	Class 2/+4dBm Max

Electromagnetic Compatibility

This device has been designed to meet the relevant radio and electromagnetic interference standards for the countries its 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.

FCC ID: T85EQ001