ECGVue™ Holter Sub-System- User Manual

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Intended purpose

This manual describes the intended use of the ECGVue™ Holter PC App and observance of the manual is a prerequisite for proper performance, correct operation and ensures patient and user safety. The intended audience are Service Provider Operator and Clinical professionals who are expected to have a working knowledge of medical procedures, practices, and terminology to provide patient care.

Safety notices

The following safety notice formats are used in this manual. Safety notices are used at the start of sections or embedded in operating instructions. Ensure you fully understand and comply with the notices in this manual.

Warning

Indicates a potential hazardous situation which, if not avoided, could result in serious injury.

Caution

Indicates a potentially hazardous situation which, if not avoided, could result in minor or moderate injury.

Notice

Indicates an important situation which, if not avoided, may seriously impair operations.

Tip

Additional information relating to the current section.

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1 Safety information

1.1 Intended use and indications for use

The LifeSignals ECGVue™ Holter Sub-System is a wireless remote monitoring system intended for use by healthcare professionals for continuous collection of electrocardiography (ECG) and heart rate (optional) data in home and healthcare settings.

Patient physiological data is transmitted wirelessly from the LifeSignals Wearable Biosensor to a remote ECGVue™ Holter Central Server for storage and analysis.

The LifeSignals ECGVue™ Holter Sub-System is intended for non-critical, adult population, who are 18 years of age or older.

1.2 Contraindications

- The Biosensor is not intended for use on critical care patients.
- The Biosensor is not intended for use on patients with any active implantable devices, such as defibrillators or pacemakers.

1.3 Warnings

Warning

- DO NOT use if the patient has a known allergic reaction to adhesives or electrode hydrogels.
- DO NOT use if the patient has inflamed, irritated or broken skin in the Biosensor placement area.
- The patient should remove the Biosensor if skin irritation such as severe redness, itching or allergic symptoms develop, and seek medical attention if an allergic reaction persists beyond 2 – 3 days.
- The patient should not wear the Biosensor for more than the prescribed hours.
- The patient should remove Biosensor immediately if their skin feels uncomfortably warm or experience a burning sensation.

1.4 Precautions

Caution

- Advise patient to avoid sleeping on their stomach, as this may interfere with the Biosensor performance.
- DO NOT use the Biosensor if the package has been opened, appears damaged or has expired.
- Avoid use of the Biosensor less than 2 meters from any interfering wireless devices such as certain gaming devices, wireless cameras or microwave ovens.
- The Biosensor contains a battery. Dispose of the Biosensor in accordance with local laws, care facility laws or hospital laws for non-hazardous electronic waste.
- If the Biosensor becomes soiled (e.g. coffee spill), wipe clean with a damp cloth and pat dry.
- If the Biosensor becomes soiled with blood, and/or bodily fluids/matter, dispose in accordance with local laws, care facility laws or hospital laws for biohazardous waste.
- DO NOT allow the patient to wear or use the Biosensor during a magnetic resonance imaging (MRI) procedure or in a location where it will be exposed to strong electromagnetic forces.
- DO NOT reuse the Biosensor, it is for single use only.
- Keep the Biosensor out of reach of children and pets.
- Advise patient to keep showers short with their back to the flow of water while showering. Gently pat dry with a towel and minimize activity until the Biosensor is fully dry and not to use creams or soap near the Biosensor.
- DO NOT use any skin barrier agents prior to Biosensor application, as it may cause skin irritation/injury due to a reaction between the barrier agent and the hydrogel electrodes.
- DO NOT immerse the Biosensor in water.

2 Product description

2.1 LifeSignals ECGVue™ Holter Sub-System

The LifeSignals ECGVue™ Holter Sub-System contains the following components:

Wearable Biosensor	Acquires ECG signals, buffers and transmits to the ECGVue™ Holter PC App when available.
ECGVue™ Holter Central Server	Receives and stores patients ECG data from the ECGVue™ Holter PC App
ECGVue™ Holter PC App	Hereafter referred to as ECGVue™ PC App. Installed on compatible computer. Facilitates data retrieval from a batch of Biosensors and sends to the ECGVue™ Holter Central Server

2.2 LifeSignals Wearable Biosensor

The LifeSignals Wearable Biosensor acquires ECG signals from the body, pre-processes the signals as two channels of ECG data, buffers and wirelessly transmits the ECG data to the ECGVue™ PC App when available.

1	Right upper electrode.
2	Left upper electrode.
3	Right lower electrode.
4	Left lower electrode.

Figure 1 - LifeSignals Wearable Biosensor

LP1251, LP1251E & LP1251A.

- **ECG A**: Left lower electrode → Right upper electrode
- **ECG B**: Right lower electrode → Right upper electrode

To support a ECGVue™ Holter workflow, the acquired data is buffered (temporarily stored) in the Biosensor until communication with the ECGVue™ PC App is available.

The Biosensor uses standard WLAN (802.11b) secured (AES) communication protocol for wireless data transmission to the computer. The LP1251A, LP1251 and LP1251E are designed and tested for 3, 5 and 7 days respectively (actual wear duration claims may vary between countries based on regulatory clearance).

The Biosensor is a battery-operated device, and the Biosensor battery life may vary depending upon storage temperature and the WLAN environment.

2.3 ECGVue™ Holter Central Server

ECGVue™ Holter Central Server is a cloud-based server application that operates as the back end of the ECGVue™ Holter Sub-System.

The ECGVue™ Holter Central Server performs the following functions:

- Receives and stores ECG data and Holter diary events sent by the ECGVue™ PC App. The stored ECG data is identified with the Biosensor ID.
- Receives and stores Holter diary images uploaded by ECGVue™ PC App.
- Provides the necessary access to the Customer Business Logic to download the data from the ECGVue™ Holter Central Server.

2.4 ECGVue™ PC App

ECGVue™ PC App is an application installed on a dedicated laptop with customized OS. The OS and support packages are bundled with ECGVue™ PC App distribution, and their installation and customization are performed by ECGVue™ installer, in addition to installation of the ECGVue™ PC App itself.

ECGVue™ PC App is used for retrieval of data from a batch of Biosensors. The presence of an operator is required only for submitting the batch of Biosensor to the retrieval queue. Operator can then leave the ECGVue™ PC App to retrieve data from the Biosensors, one by one, and send it to ECGVue™ Holter Central Server. The operator may add one or more Biosensors to the retrieval queue at any point of time.

Additionally, ECGVue™ PC App can take images of the Patient Diary and upload them to ECGVue™ Holter Central Server, using an add-on Document Camera. Uploading of Biosensor Data and corresponding Patient Diary can be done in any order.

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3 Install ECGVue™ PC App

Please follow the steps outlined in the Installation Manual (Document ID 1000001978A) to install ECGVue™ PC App on a compatible computer. These instructions along with a list of compatible computers are available from LifeSignals, Inc..

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4 ECGVue™ clinical application

4.1 Advise patients

The following guidance is also shown in the Patient Information Leaflet found inside the Biosensor packaging:

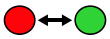
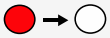
- Limit activity for one hour after the Biosensor has been applied to ensure good skin adherence.
- Carry out normal daily routine but avoid activities that cause excessive sweating.
- Press the ON button when they feel a symptom and record on the Holter Diary.
- Keep showers short with their back to the flow of water while showering.
- If the Biosensor accidentally gets wet, gently pat dry with a towel and minimize activity until the biosensor is fully dry.
- If the Biosensor becomes soiled (e.g. coffee spill), wipe clean with a damp cloth and pat dry.
- If the Biosensor loosens or starts to peel away, press down the edges with their fingers.
- Avoid sleeping on the stomach, as this may interfere with the Biosensor performance.
- Occasional skin itchiness and redness are normal around the Biosensor placement area.
- Travel is permitted when wearing the Biosensor. If you are questioned during security screening, show the Patient Information Leaflet.

4.2 LED status indicators

The Biosensor light (LED) provides information related to the functional status of the Biosensor.

Table 1 - LED status indicators on the LifeSignals Biosensor

Light	Behaviour	Status
	Slow flash	Biosensor is connected to the ECGVue™ PC App or a Holter test is ongoing.
	Fast flash	Biosensor is attempting to connect with the ECGVue™ PC App.
	Slow flash	Low Battery indication.

Light	Behaviour	Status
	Alternate flashing	Biosensor connecting to ECGVue™ PC App.
	Fast flash → Off	Biosensor turned off.

4.3 Prepare skin

Before applying the Biosensor, the skin surface must be prepared. Correct skin preparation will ensure the following:

- High patient comfort and compliance
- Reliable and robust ECG waveforms
- Artefact-free ECG reporting
- Good Biosensor adhesion for the wear duration

To prepare the skin for a Biosensor follow this procedure:

1. If required, remove excess hair from upper left chest area, preferably using hair clippers.

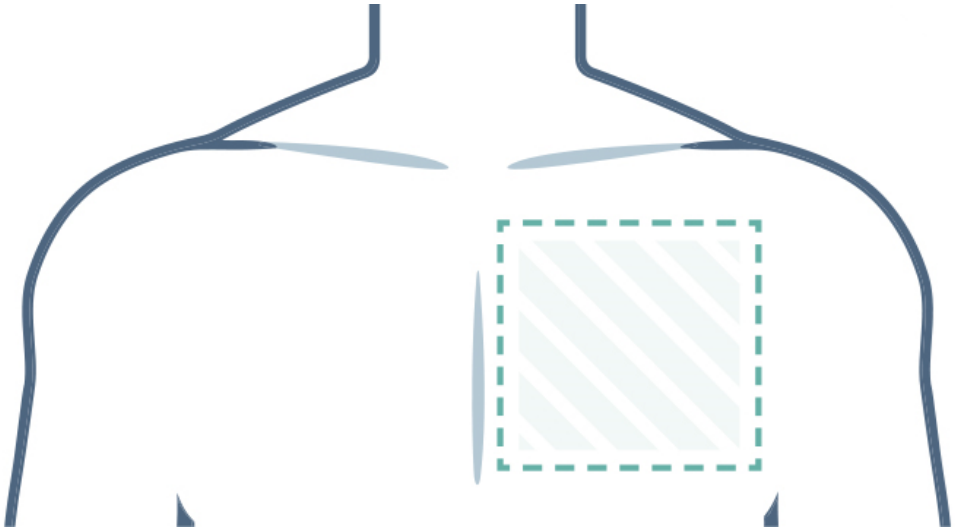


Figure 2 - Area of upper left chest to attach Biosensor

2. Clean the area with non-moisturizing soap and water.
3. Rinse the area making sure you remove all soap residue.
4. Dry the area vigorously.

Notice

Avoid the use of wipes or isopropyl alcohol to clean the skin, as alcohol dries the skin, increases the possibility of skin irritation and can reduce the electrical signal to the Biosensor.

4.4 Apply Biosensor

The Biosensor must be correctly positioned and applied to the patient.

1. Gently peel off the Biosensor protective backing film. Start with the four corners before removing the centre section.
2. Place the Biosensor on the upper left chest of the patient, below the collar bone and left of the sternum.

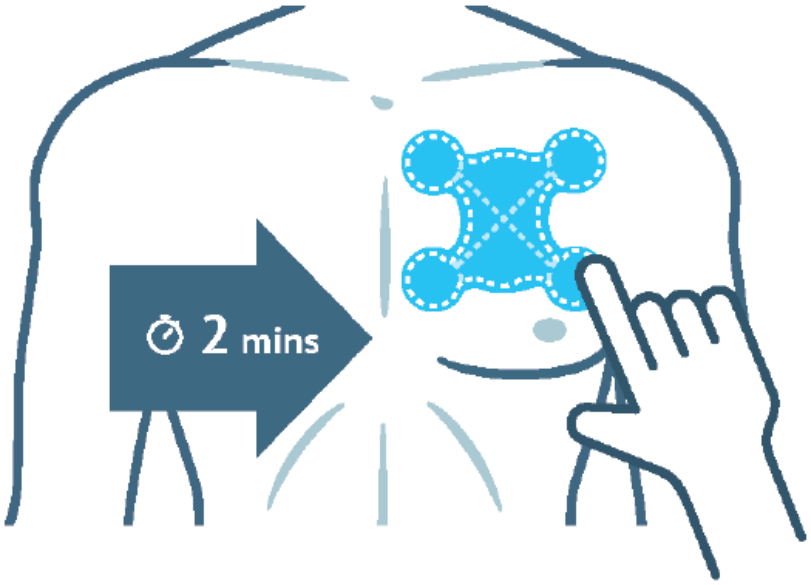


Figure 3 - Biosensor application position

3. Press the entire Biosensor firmly for 2 minutes, especially around the four circular areas.

4.5 Remove Biosensor

At the end of the Holter test, the Biosensor can be removed.

Notice

For patients with fragile or delicate skin, consider using an adhesive remover when removing the Biosensor. Silicone-based adhesive removers are preferred (instead of alcohol-based removers) as they fully remove adhesive residue from the skin, do not cause skin dehydration or an uncomfortable stinging sensation.

To avoid adhesive-related skin injury, follow these steps*:

1. Slowly peel each of the four Biosensor circular edges towards the centre of the Biosensor, keeping as close to the skin as possible.
2. With the other hand, gently press and support newly exposed skin to reduce skin stretch and avoid patient discomfort.
3. Peel off the remaining Biosensor (where relevant, in the direction of hair growth).

Figure 4 - Support newly exposed skin whilst removing the Biosensor

**Fumarola S, Allaway R, Callaghan R, Collier M, Downie F, Geraghty J, Kiernan S, Spratt F.*

Overlooked and underestimated: medical adhesive-related skin injuries. Best practice consensus document on prevention. J Wound Care 2020; 29(Suppl 3c):S1-S24.

5 Upload Biosensor data

Data from multiple Biosensor (batch of Biosensors) can be uploaded to the ECGVue™ Holter Central Server using the ECGVue™ PC App.

5.1 Login to ECGVue™ PC App

Follow these steps.

1. Select ***ADD Biosensor*** button, this opens a popup window.
2. Scan the QR/barcode or manually enter the Biosensor ID, this opens a new popup window with the patient details.
3. Enter the Start date and time from Holter Diary.
4. If there is no Holter Diary, tick the Not Available check box. (Note: Once selected, Holter Diary can NOT be added in the future) OR if you want to add Holter Diary images later, leave the Not Available check box unticked.
    a. Select ***NEXT*** to begin Biosensor data retrieval.
    b. When requested, turn on the Biosensor by pressing the Biosensor ON button once, a red light will flash followed by a flashing green light, then the Biosensor will join the retrieval queue. (Note: It will take a few seconds to connect to the Biosensor).
    c. The popup window to add another Biosensor for data upload will appear.
5. If there is a Holter Diary, select ***ADD IMAGE***, this will open a popup window with camera preview.
    d. Place the Holter Diary underneath the camera and select the camera button (camera preview popup window) to capture an image.
    e. Select ***ADD IMAGE*** to capture another image ***OR*** select ***REPLACE IMAGE*** if the image is unclear (Note: minimum of two images – front & back of Holter Diary– maximum of 10 images)
    f. When image capture is complete, select ***BACK***.
    g. Select ***NEXT*** to begin Biosensor data retrieval.
    h. When requested, turn on the Biosensor by pressing the Biosensor ON button once, a red light will flash followed by a flashing green light, then the Biosensor will join the retrieval queue.
    i. The popup window to add another Biosensor will appear to begin another Biosensor upload.

5.2 Add Holter Diary images later (if applicable)

1. Select the red Holter Diary icon in the Queue or History tab to open the popup window with the patient details and select ***ADD IMAGE***.

2. Follow the “If there is a Holter Diary” steps to add images in *Login to ECGVue™ PC App* section.

5.3 Search for Biosensor or Facility

1. Select the ***History*** tab.
2. Select Biosensor or Facility in the dropdown menu.
3. Enter Biosensor ID or Facility name (partial or complete text) in the search field.
4. Select a ***From date*** and ***To date*** in the calendar dropdown menu.
5. Select ***CONFIRM***.

5.4 Check status of assigned Biosensor

1. Select the ***Query*** tab.
2. Enter Biosensor ID in the search field.
3. Select ***SEARCH***, this opens the popup window with the patient details.

Note:- Holter diary images can be added for 'data transfer ongoing' or 'completed Biosensors'.

5.5 Additional Menu features in ECGVue™ PC App

My profile

Displays user information and Reset Password button.

Settings

Opens the settings popup window

Settings tab

- Max. no. of Biosensors (1-1000) - set the maximum number of Biosensors that can be added to the retrieval queue. Note:- If the added number of Biosensors exceeds the 'Max. no. of Biosensors', the user will receive a notification.
- Max. retrieval time (1-1000 hours) - user selectable, set the maximum retrieval time for Biosensor data. Note:- ECGVue™ PC App calculates retrieval time based on quantity of Biosensor data as Biosensors are added to queue. If the calculated time exceeds the 'Max. Retrieval time', the user will receive a notification.
- Units (Metric or Imperial) - user selectable, set units for height and weight.
- Time zone - user selectable, set time zone for current location.
- Patient Identification (Patient ID or MRN) - user selectable, set according to local requirements.
- Screen lock (5-480 minutes) - default = 15 min.

Advanced tab

- Timeout for Biosensor connection (adding to queue) - set the time duration for Biosensor to establish successful connection with ECGVue™ PC App.
- Timeout for Biosensor connection (before retrieval) - set the time duration for queued Biosensor to go into retrieval mode, default = 120 sec. Note:- If the Biosensors does not go into retrieval mode, the Biosensor moves from the queue to the 'Action required' tab
- Timeout for Biosensor connection (during retrieval) - set the time duration for retrieval, if there is a delay of greater than 120 sec (default setting), then the Biosensor moves to Action required tab.
- Wi-Fi channel - there are 11 channels (frequency ranges) to transmit Biosensor data, select channels 1,6 or 11.
- Camera source - select camera to capture Holter Diary images.
- ***UPDATE ECGVue™ PC App*** - Select to remotely update ECGVue™ PC App.
- ***UPLOAD AUDIT LOG*** - select to upload audit logs to ECGVue™ Holter Central Server. Data range - user selectable.
- ***SAVE*** - select to save changes in settings.
- ***CANCEL*** - select to cancel changes in settings.

About

Provides additional information on ECGVue™ PC App.

Change user/Screen lock

Allows change of user or screen lock, retrieval of Biosensor data is not impacted.

Logout

User can logout, but only when the retrieval of Biosensor data is completed.

Shut down

Closes the ECGVue™ PC App and shuts down the computer. This action will be prevented if Biosensors are queued for retrieval.

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6 Specifications

6.1 Biosensor

Table 2 - Biosensor (LP1251, LP1251E & LP1251A) specifications

Physical	
Dimensions	105 mm x 94 mm x 12 mm
Weight	28 gm
Status LED Indicators	Amber, Red and Green
Patient Event Logging Button	Yes
Water ingress protection	IP24
Colour	White
Specifications	
Battery type	Primary Lithium Manganese dioxide Li-MnO2
Battery Life	168 hours
Charging Mode	Not rechargeable
Wear Life	LP1251, LP1251E up to 168 hours& LP1251A up to 72 hours [1]
Defib Protection	Yes
Applied Part Classification	Defibrillation-proof type CF applied part
Operations	Continuous
Usage	
Intended environment	Home, Clinical and Non-Clinical facilities
Intended Population	18 years or older
MRI safe	No
Single use / Disposable	Yes

[1]Actual wear duration claims may vary between countries based on regulatory clearance.

ECG Performance and Specifications	
ECG number of channels	Two
ECG sampling rate	244.14 and 976.56 samples per second
Frequency response	0.2 Hz to 40 Hz and 0.05 Hz to 150 Hz
Lead off detection	Yes
Common Mode rejection ratio	> 90dB
Input Impedance	> 10 Meg ohms at 10Hz
ADC Resolution	16 bits
ECG Electrode	Hydrogel
Wireless & Security	
Frequency Band (802.11b)	2.400-2.4835 GHz
Bandwidth	20MHz (WLAN)
Transmit Power	0 dBm
Modulation	Complementary Code Keying (CCK) and Direct Sequence Spread Spectrum (DSSS)
Wireless Security	WPA2-PSK / CCMP
Data Rate	1, 2, 5.5 and 11 Mbps
Quality of service–Range	5 meters (typical)
Environmental	
Operational temperature	+0 ºC to +45ºC (32ºF to 113ºF)
Operational relative humidity	10 % to 90 % (non-condensing)
Storage temperature (≤ 30 days)	+0ºC to +45ºC (32ºF to 113ºF)
Storage temperature (> 30 days)	+10ºC to +27ºC (50ºF to 81ºF)
Transportation temperature (≤ 10 days)	-5 ºC to +50 ºC (23 ºF to 122 ºF)
Storage relative humidity	10% to 90% (non-condensing)
Storage pressure	700 hPa to 1060 hPa
Shelf life	13 months

7 Regulatory

The ECGVue™ Holter Sub-System complies with the following regulations.

7.1 Standards used in design, development, labelling, and testing

Table 3 - Standards used in design, development, labelling, and testing

Standards	Rev	Description
ANSI AAMI ES 60601-1	2012	Medical electrical equipment - Part 1: General Requirements for basic Safety & Essential Performance
ANSI AAMI IEC 60601-1-2	2014	Medical Electrical Equipment -- Part 1-2: General Requirements For Basic Safety And Essential Performance -- Collateral Standard: Electromagnetic Disturbances -- Requirements And Tests
IEC 60601-1-11	2015	General Requirements For Basic Safety And Essential Performance - Collateral Standard: Requirements For Medical Electrical Equipment And Medical Electrical Systems Used In The Home Healthcare Environment
ANSI AAMI IEC 60601-2-47	2012	Particular Requirements For The Basic Safety And Essential Performance of Ambulatory Electrocardiographic Systems
IEC 60601-1-6	2013	Medical Electrical Equipment - Part 1-6: General Requirements for Basic Safety And Essential Performance - Collateral Standard: Usability
ISO 10993-1	2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
ANSI C63.27	2017	American National Standard for Evaluation of wireless coexistence
IEC 60086-4	2011	Primary batteries - Part 5: Safety of batteries with aqueous electrolyte
AAMI ANSI EC12	2012	Disposable ECG Electrodes
ASTM D4169	2014	Standard Practice for Performance Testing of Shipping Containers and Systems

ISO 15223-1	2016	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied. Part 1: General requirements.
IEC 62304	2015	Medical device software – Software life cycle processes
IEC 62366-1	2020	Medical devices – Application of usability engineering to medical Devices
ISO 14971	2019	Medical devices – Application of risk management to medical devices
FCC	2015	47 CFR 15
ETSI	2019	EN 300 328

7.2 EMC compliance and warning statement

IEC 60601-1-2: 2014

The LifeSignals Biosensor has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules and with the limits of the standard for medical devices, ANSI/AAMI/IEC 60601-1-2:2014 and ANSI/AAMI/IEC 60601-2-47:2012 202.6.1.1 & 202.6.2.3 suitable for use in all environments including domestic. The unit also complies with the requirements of EN 60601-1-2:2015, providing the presumption of compliance to the European Union's Medical Device Directive 2007/42/EC. The limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

This equipment generates, uses radio-frequency energy for its functions. Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to LifeSignals Biosensor. Otherwise, degradation of the performance of this equipment could result.

7.3 Guidance and manufacturer's declaration – electromagnetic emissions

Table 4 - Guidance and manufacturer's declaration – electromagnetic emissions

Biosensor is intended for use in the electromagnetic environment specified below. The customer or the user of the Biosensor should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11 / EN5501	Group 1	LifeSignals Biosensor uses RF energy only for its internal functions. RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.

RF emissions CISPR 11 /EN5501	Class B	LifeSignals Biosensor is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network which supplies buildings used for domestic purposes.
Harmonic emissions EN 61000-3-2	Not Applicable	
Voltage fluctuations/flicker emissions EN 61000-3-3	Not Applicable	

7.4 Guidance and manufacturer's declaration – electromagnetic immunity

Table 5 - Guidance and manufacturer's declaration – electromagnetic immunity

LifeSignals Biosensor is tested for conformance to meet the following intended for use in the electromagnetic environment specified below. The customer or the user of the Biosensor should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be of wood, concrete or ceramic tiles. If the floor is tiled with synthetic material the relative humidity should be at least 30%.
Power frequency magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be that of a typical domestic environment.
Radiated RF EN 61000-4-3	10 V/m 80 MHz to 2.7 GHz 80% AM, 1 KHz	10 V/m 80 MHz to 2.7 GHz 80% AM, 1 KHz	Home Healthcare environment.

The Biosensor is also tested for immunity to proximity to wireless communication equipment as per Table 9 of IEC 60601-1-2 using the test methods specified in IEC 61000-4-3.

The Biosensor is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Biosensor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Biosensor as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (Watts)	**Separation distance according to the frequency of transmitter (Meters)**		
	150 kHz to 80 MHz $d = 3.5/V1 * \sqrt{P}$	**80 MHz to 800 MHz** $d = 3.5/E1 * \sqrt{P}$	**800 MHz to 2.7 GHz** $d = 7/E1 * \sqrt{P}$
	10V/m	**10V/m**	**10V/m**
0.01	0.04	0.04	0.08
0.1	0.11	0.11	0.22
1	0.35	0.35	0.70
10	1.11	1.11	2.22
100	3.50	3.50	7.00

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacture.

NOTE 1: At 80 Hz and 800 MHz the separation distance for the frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorptions and reflections from structures, objects and people.

7.5 EMC guidance

In accordance with Clause 4.3 of IEC 60601-1, the Essential Performance of LifeSignals ECGVue™ Holter Sub-System is:

- Data loss between Biosensor & ECGVue™ PC App shall be less than 0.035%
- There shall not be noise exceeding 50 uV p-v on ECG signal over any 10 second period continuously

Caution

RF emitting devices such as diathermy, electrocautery, radio frequency identification (RFID), security systems (e.g., electromagnetic anti-theft systems, and metal detectors) may affect essential performance. These sources of electromagnetic energy should be avoided when using Biosensor. In case of potential exposure to this equipment, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient Biosensor away from these equipment (behind the patient body)
- Increase the separation between the Biosensor and the equipment.

7.6 Symbols

Table 6 - Symbols

Label	Identification	Description
	Caution or Warning	This symbol instructs the user to consult the instructions for warnings and safety precautions that could not be presented on the device.
	Manufacturer	Legal manufacturer.
	Product Disposal	Dispose of the Biosensor as battery/electronic waste - controlled by local regulations.
 NNNNN	GUDID (Level 0) & Serial No.	On PCBA – Level 0 – GUDID in data matrix format & Serial number in human readable format.
 XXXXX	GUDID (Level 0) & Pairing ID	On Biosensor – Level 0 – GUDID in data matrix format and Pairing ID in human readable format.
	GUDID (Level 1,2 & 3)	Device GUDID (Level 1, 2 & 3) with manufacturing information. – Level 1: Serial No., Level 2 & 3: Lot No.
	Unique Pairing ID	Unique Pairing ID.
	Catalogue Number	Device Catalogue number / Labeller Product number.

Label	Identification	Description
QTY	Quantity	Number of devices in pouch or multi-carton box.
℞ ONLY	Prescription only device	To be used under prescription supervision by a medical practitioner.
	Consult instructions for use	Refer to instruction manual.
 >PnD	Temperature range	Operating, storage and transportation temperature, short and long term, in days: • **P**: Duration • **n**: Number • **D**: Calendar days
	Atmospheric pressure limitation	Indicates the acceptable upper and lower limits of atmospheric pressure for transport and storage.
	Humidity limitation	Indicates the acceptable upper and lower limits of relative humidity for transport and storage.
	Expiry Date (YYYY-MM-DD)	Use device in packaged condition before expiry date.
	Manufacturing date and country of manufacture.	Device manufacturing date and country of manufacture.
LOT	LOT Code	Manufacturing Batch or LOT code.
	Applied part	Defibrillation-proof, Type CF Applied Part.
	Do not reuse	Do not reuse; single patient use.
IP24	Ingress Protection Rating	Protection against solid objects that are over 12.5 mm (e.g. large tools and hands) and protection against water splashing from any angle.
	Keep dry	Keep away from liquids or water or chemicals.

Label	Identification	Description
	Max Stack	Do not stack more than (n) number of boxes tall.
FCC ID	Federal Communications Commission	Federal Communications Commission ID.
	MR unsafe (black or red circle)	Standard practice for marking medical devices and other items for safety in the magnetic resonance environment.
	No pacemaker	Contraindicated for use on patients with active implantable medical devices including pacemakers, ICD and LVAD.
	Authorized representative of Country	Authorized representative of Country XX - Country code as per ISO 3166-1.
	CE marking	CE marking indicates product conformance with the applicable European Union Directives.
	Importer	Indicates entity importing the medical device into the locale.
	Distributor	Entity distributing the medical device into the locale.
	Damaged packaging	Do not use if package is damaged. Device must not be used if the package holding the device is damaged.

This manual is intended for the following catalogue numbers: LP1251A, LX1251, LX1251E and KM1251E

7.7 Declaration of conformity

(Issued according to EC directive 93/42/EEC relating to Medical Devices)

Manufacturer:	LifeSignals, Inc., 426 S Hillview Dr., Milpitas, CA 95035, USA Tel: +1 510.770.6412 info@lifesignals.com
EC Representative:	Renew Health Limited, IDA Business & Technology Park Garrycastle, Athlone, N37 F786. Ireland Tel : +353 90.646.5460 lssupport@lifesignals.com
Product Category:	Electrocardiography telemetric monitoring system
Product Name:	ECGVue™ Holter Sub-System
Model Number:	LP1251E and KM1251E
Product Description :	The ECGVue™ Holter Sub-System is a wireless remote monitoring system intended for use by healthcare professionals for continuous collection of Electrocardiography (ECG) and Heart Rate monitoring in home and healthcare settings
Quantity:	
Lot No .:	
Class:	Class IIa
Annexure No:	Annexure II
Notifying Body:	BSI, Netherlands (notified body No. 2797)
Applied Directive:	Directive 93/42/EEC on medical devices, conformity assessment according to Annexure II, excluding Section 4.

The company, LifeSignals, Inc, herewith declares that the above- mentioned product meets all applicable provisions of the Directive 93/42/EEC. The product is safe under prescribed and specified conditions of storage and use.
The company has instituted a procedure, to continually review the experience gained from devices in post-production phase & to implement appropriate measures for the necessary required improvements.
If the device is modified or used other than the Intended purpose, this declaration becomes invalid.

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Saravanan Balasubramanian
Vice President - Medical Systems & Regulatory Affairs

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