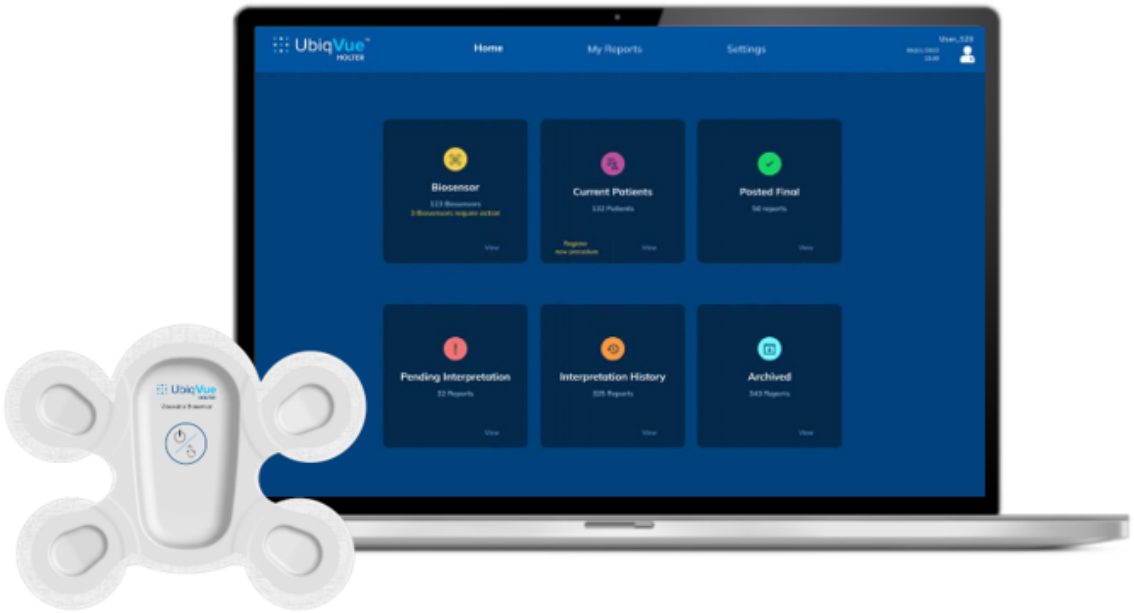

UbiqVue™
HOLTER

UX2251
UbiqVue™ 2AYe Holter System
Instructions For Use

LifeSignals™

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℞ ONLY MD

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Intended Purpose

This manual describes the intended use of the UbiqVue™ 2AYe Holter System and observance of the manual is a prerequisite for proper performance, correct operation and ensures patient and user safety. The intended audience are clinical professionals who are expected to have a working knowledge of medical procedures, practices, and terminology to provide patient care.

References

1. UbiqVue Holter System Operational Guide, 1000002125A
2. UbiqVue Biosensor Application and Removal Instructions Kit (2AYe), UC2251-PK
3. UbiqVue 2AYe Holter System Patient Information, 1000002106A

Safety Notices

The following safety notice formats are used in this manual. Safety notices are used at the start of sections or embedded in the 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.

Instructions For Use Access

Electronic IFU copies are available at: www.lifesignals.com/ifu.

Printed IFU copies are available upon request. To request a printed copy, please email LifeSignals Customer Support at: lssupport@lifesignals.com.

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Contents

1 Safety Information

1.1 Intended use statement

The UbiqVue Holter System is intended to capture, record, analyze and report both symptomatic and asymptomatic cardiac events, along with continuous electrocardiogram (ECG) information, for long-term monitoring. Following patient monitoring using the UbiqVue Wearable Biosensor, a comprehensive final report is generated from the entire ECG recording. Optionally, intended users may choose to generate an interim report from periodically or intermittently transferred ECG recording wirelessly from the UbiqVue Wearable Biosensor. The final and interim reporting is based on the beat-to-beat information extracted from the ECG recording.

The UbiqVue Holter system is intended for non-critical, adult population, who are 18 years of age or older, at home and in healthcare settings, who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light-headedness, pre-syncope, syncope, fatigue, or anxiety and patients who are asymptomatic. The reports are provided for review by the intended user to render a diagnosis based on their clinical judgment and experience.

1.2 Warnings

Warning

- DO NOT use the Biosensor if the patient has known allergic reaction to adhesives or electrode hydrogels.
- DO NOT use the Biosensor if the patient has inflamed, irritated or broken skin in the Biosensor placement area.
- Remove the Biosensor, if skin irritation such as severe redness, itching or allergic symptoms develop. Seek medical attention if an allergic reaction persists.
- DO NOT allow the patient to wear the Biosensor for more than the prescribed hours.
- Remove the Biosensor immediately if the patient reports of uncomfortably warm skin or experiences a burning sensation.
- Biosensor should not be used as an apnea monitor and has not been validated for use in the pediatric population.

1.3 Precautions

Caution

- Excessive motion or activity may adversely affect the Biosensor performance and adhesion.
- Press down the Biosensor edges and upper area with fingers at least twice a day, to maintain adhesion.
- Avoid sleeping on 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.
- The Biosensor contains a battery. Dispose of the Biosensor in accordance with the local laws, for routine non-hazardous electronic waste.
- Using certain skin barrier agents before applying the Biosensor may cause skin irritation or injury due to interaction with the hydrogel electrodes.
- DO NOT immerse the Biosensor in water.
- Keep showers short with the patient's back to the flow of water. Gently pat dry with a towel and minimize activity until the Biosensor is fully dry.
- DO NOT use creams or soap near the Biosensor.
- If 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 the local laws, care facility laws or hospital laws for bio-hazardous waste.
- DO NOT wear or use the Biosensor during a magnetic resonance imaging (MRI) procedure or in a location where it can be exposed to strong electromagnetic fields.
- DO NOT reuse the Biosensor, it is for single use only.
- DO NOT use on patients with active implantable medical devices including pacemakers, ICD and LVAD
- Keep the Biosensor out of reach of children and pets.

1.4 Cybersecurity controls

Notice

- Enable all access control systems on mobile devices, password protection to protect against unauthorized use and cybersecurity threats.
- Keep the mobile device operating system, either Android or iOS, version up-to-date as updates enhance existing features, patch security flaws, add new security features, fix bug issues and improve performance for devices.
- Limit access to authorized users.

2 Patient Advice

The following guidance should be given to the patient to ensure comfort while wearing the Biosensor and optimal Biosensor performance. The information is also provided in the Patient Information Leaflet found inside individual Biosensor packaging.

- Limit physical activity after the Biosensor has been applied to ensure good adherence.
- Keep showers short with back to the flow of water.
- If the Biosensor accidentally gets wet, gently pat dry with a towel and minimize activity until fully dry.
- 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 questioned during security screening, show the Patient Information Leaflet.
- Follow the instructions in the **"Biosensor Application and Removal Instructions Kit"** provided with the Biosensor.

Tip

Following the Biosensor Application and Removal Instructions provided with the Biosensor will ensure:

- High patient comfort
- Reliable and robust ECG waveforms
- Superior Biosensor adhesion for the wear duration

Tip

Avoid the use of isopropyl alcohol to clean the skin, as alcohol dries the skin, increases the possibility of skin irritation and can reduce the electrical conductivity to the Biosensor, thereby diminishing ECG waveforms.

3 Components and Accessories

3.1 UbiqVue Holter System

The UbiqVue 2AYe Holter System (UX2251) consists of the following components:

- UbiqVue 2AYe Wearable Biosensor (UB2251, UB2251A)
- UbiqVue Holter Web Server (UA2251-W)
- UbiqVue Holter Web Portal (UA2251 -C)
- UbiqVue Holter Analyzer (Server and Desktop) (UA2251-SA and UA2251-DA)
- UbiqVue Holter Mobile App (UA2251-R)
- UbiqVue Relay Bridge (UA2550-RB)
- UbiqVue Holter Central Server (UA2251-S)

3.2 UbiqVue 2AYe Wearable Biosensor

The UbiqVue 2AYe Biosensor is placed on the upper left chest of the patient, below the collar bone and left of the sternum (Figure 1).

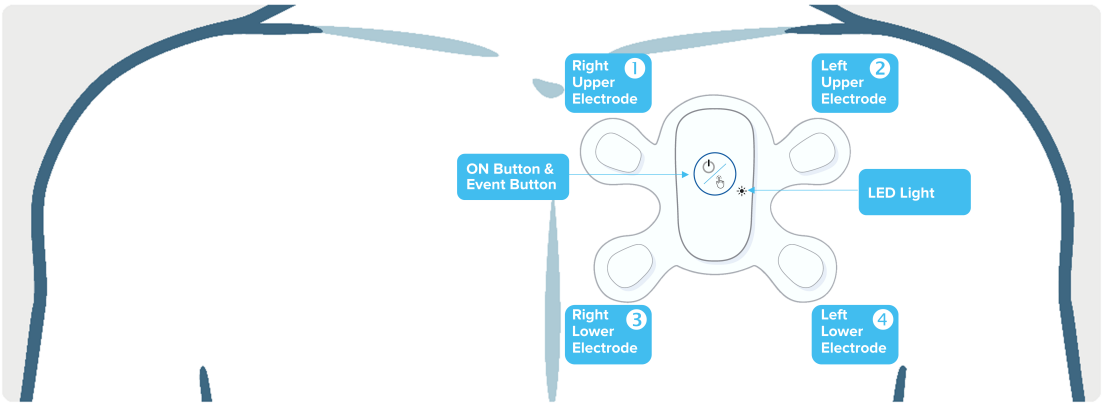


Figure 1 - UbiqVue 2AYe Wearable Biosensor

The Biosensor utilizes four integrated hydrogel-based electrodes to measure two distinct ECG channels. Channel A produces a diagonal vector of the heart and is acquired using the Right Upper Electrode and the Left Lower Electrode. Channel B produces a vertical vector of the heart and is acquired using the Right Upper Electrode and Right Lower Electrode. The Left Upper Electrode is used for biasing and not used for any ECG channel calculation.

The Biosensor wirelessly transmits the two channels of ECG data to the UbiqVue Central Server via any of the UbiqVue relay devices (UbiqVue Holter Mobile App or UbiqVue Relay Bridge). If the receiver device is not available or is not communicating, the data is buffered locally in the Biosensor until the wireless connection is reestablished and resumes communication. The Biosensor uses secured standard WLAN 802.11b or BLE 5.2.

The UbiqVue 2AYe Wearable Biosensor is a battery-operated device with on-board storage memory. The UB2251 model has the battery life and storage memory intended for up to 8 days while the UB2251A model has a battery life and storage memory intended for up to 2 days. The Biosensor battery life may vary depending upon the storage temperature, wireless data transmission environment and the parameter settings selected.

The ON Button and Event Button

The ON Button and Event Button is used to both turn the Biosensor on for use and for symptom reporting during the procedure. Refer Figure: 2

Figure 2 - ON Button and Event Button

LED Status Indicators

The Biosensor's LED light provides information related to the functional status of the Biosensor.

Table 1 - LED Light Description - 2AYe Wearable Biosensor

LED Light	Behavior	Status
	Fast flash 2 flashes per second	Connecting to Relay Bridge via Wi-Fi.
	Fast flash 1 flash per second	Connecting to Mobile Device via BLE.
	Slow flash 1 flash every 3 seconds	Connected to Relay Bridge or Mobile Device either: - before initiating procedure - during procedure - during data recovery after completion of procedure
	Very slow flash 1 flash every 5 seconds	Procedure is ongoing and there is no connection to either Relay Bridge or Mobile Device.
	Slow flash 1 flash every 2 seconds	The Biosensor has a low-battery
 OR	Solid red or No LED light	Faulty Biosensor
	No LED light	Biosensor is off or procedure is completed, however ECG data may not be retrieved.

3.3 UbiqVue Holter Web Server

The UbiqVue Holter Web Server is a multi-tenant cloud based Holter business logic system that allows Channel Partners and healthcare delivery organizations access to UbiqVue System services. It interacts with UbiqVue Central Server, UbiqVue Holter Server Analyzer and UbiqVue Holter Desktop Analyzer.

3.4 UbiqVue Holter Mobile App

The UbiqVue Holter Mobile App is intended to be used by patients using their phone to optionally retrieve the data from Biosensor and uploading to the UbiqVue Holter Central Server. This can be done periodically (e.g, every 10 minutes or every hour or every day), intermittently and/or after the completion of the Holter procedure. Patients can also mark events, enter their symptoms and activities electronically through the UbiqVue Holter Mobile App.

UbiqVue Holter Mobile App can also be used by Clinician / Nurse for initiating the Holter procedure by connecting to Biosensor.

3.5 UbiqVue Holter Web Portal

The UbiqVue Holter Web Portal provides browser-based access to a variety of users (e.g., Admin, Nurse, Physician, ECG Technician), enabling management of user roles and permissions. The portal facilitates the recovery of Biosensor data, streamlines the reporting workflow, and supports the generation, approval, and e-signing of ECG reports. Additionally, it offers access to system settings, allowing users to customize and optimize system operations according to specific clinical and administrative needs.

3.6 UbiqVue Holter Analyzer (Server and Desktop)

The UbiqVue Holter Analysis Software includes two components.

1. Cloud based Batch Processor that generates initial draft report - without any patient identifiable information.
2. PC based software that enables the ECG Technician to over-read the draft report generated by the cloud batch processor and re-generate the report based on the changes. This overread report shall be re-processed by the cloud-based batch processor for final Holter report for interpretation by adding the necessary patient information. The PC based software could also be hosted in the cloud as a virtual machine.

3.7 UbiqVue Relay Bridge

The UbiqVue Relay Bridge is an Open WRT based Access Point, with LifeSignals Relay Bridge software installed. The relay bridge wirelessly connects multiple Biosensors at a time (either Holter Procedure Completed, Procedure On-going or Unused) and allows the UbiqVue Holter Central server to retrieve the data, initiate the procedure or stop the procedure.

3.8 UbiqVue Holter Central Server

UbiqVue Holter Central Server receives, stores and provides access to ECG data retrieved by the Biosensors after the Holter procedure (or during the Holter procedure). The stored ECG data is identified with the Biosensor ID and no patient specific information is stored in the UbiqVue Holter Central Server, except the patient diary events. However, the patient demographic information is provided. The UbiqVue Holter Central Server allows the UbiqVue Web Server or any third-party Server (with Holter business logic) to access the stored ECG data with appropriate authentication via a suitable Application Programming Interface (API).

4 UbiqVue 2AYe Holter System Specifications

Table 2 - Technical Specification

Physical (Biosensor)	
Dimensions	116 mm x 91 mm x 15.5mm
Weight	32g
Status LED indicators	Green, Red
Patient event logging Button	Yes
Ingress protection	IP24 (1EC 60529:2013)
Color	White
Manufactured with natural rubber latex	No
Electrical Specifications (Biosensor)	
Memory capacity, and cache	192 hours (8 days)
Recording format	Continually sampled
Battery type	Primary Lithium Manganese dioxide (Li-MnO_2)
Battery life	up to 192 hours (8 days) of normal operation under normal wireless environment.
Wear life	up to 192 hours (8 days)
Applied part	Biosensor
Defib protection	Yes
Applied part classification	Defibrillation-proof type CF
Usage (Biosensor)	
MRI safe	No
Single use	Yes
Disposable	Yes
Rechargable	No
Serviceable	No
Intended population	18 years of age or older.

ECG Specifications (Biosensor)		
ECG number of channels	Two	
Channel to Channel skew	< 5ms	
ECG sampling rate	244.140625 samples per second (sps).	
Frequency response	Monitoring mode: 0.2 Hz to 40 Hz (with 244.14 sps)	
Lead off detection	Yes	
Common mode rejection ratio	> 90 dB	
Input impedance	> 10 Mega ohms at 10 Hz	
ADC resolution	16 bits, 5uV/ LSB	
ECG electrode	Hydrogel	
Beat and Rhythm Performance [1]		
	Sensitivity	Positive Predictive Value
Overall QRS Duration	99	100
Ventricular (V.) Beats:		
Overall V. beats	93	99
V. couplets	82	97
V. short runs	89	96
V. long runs	56	100
Supraventricular Ectopic (SVE) Beats:		
Overall SVE beats	48	82
SVE couplets	83	84
SVE short runs	92	87
SVE long runs	93	83
Atrial Fibrillation / Flutter Duration (Burden)	96[2]	97

[1] Performance assessed following the guidelines provided by ANSI/AAMI EC57: 2012

[2] Atrial Fibrillation sensitivity declines for episodes less than 20 seconds in duration

Wireless and Security - WLAN (Biosensor)	
Frequency band (IEEE 802.11b)	2.400 - 2.4835 GHz
Bandwidth	20 MHz (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
Wireless range	5 meters (typical)
Wireless and Security - BLE 5.2 (Biosensor)	
Frequency band (IEEE 802.11B)	2.400 - 2.4835 GHz
Bandwidth	1/2 MHz, 80/40 channels, frequency hopping
Transmit power	0 dBm
Modulation	Frequency Shift Key (FSK)
Wireless security	Advanced Encryption Standard – CCM Mode (AES-CCM 128-bit Encryption).
BLE range	5 meters (typical)
Environmental (Biosensor)	
Transportation temperature (≤ 7 days)	-30°C to +60°C (-22°F to 140 °F)
Operational temperature	+0°C to +45°C (32°F to 113°F) Maximum applied part measured temperature may vary by ±1°C.
Operational relative humidity	10 % to 90 % (non-condensing)
Operational altitude	up to 3000 m (10000 ft)
Storage temperature (≤ 30 days)	+0°C to +45°C (32 °F to 113°F)
Storage temperature (> 30 days)	+10°C to +27°C (50°F to 80°F)
Storage relative humidity	10% to 90% (non-condensing)
Storage pressure	700 hPa to 1060 hPa
Shelf life	13 months

5 Regulatory

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

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

Description
ANSI AAMI ES 60601-1:2005 (R) (Cons. Text) [Incl. AMD2:2021] /2012, EN 60601-1 2006 /A1:2013, IEC 60601-1 :2005 /A1 2012 +AMD2:2020, IS 13450: Part 1:2018
ANSI AAMI IEC 60601-1-2: 2014, EN 60601-1-2: 2015, IEC 60601-1-2: 2014+AMD1:2020, IS 13450: Part 1: SEC 2:2018
ANSI AAMI HA 60601-1-11:2015, EN 60601-1-11:2010, IEC 6061-1-11: 2015+AMD1:2020, IS 13450: Part 1: SEC 11 :2020
IEC 60601-1-6:2013 (ed 3.1) +AMD2:2020, EN 60601-1- 6: 2010 or ANSI AAMI IEC 62366-1: 2015+AMD1:2020, IEC 62366:2008, IEC 62366-1:2015+AMD1:2020, IS 13450: Part 1: Sec 6: 2020
ANSI AAMI IEC 60601-2-47:2012 (R2016), EN 60601- 2-47:2001, IEC 60601-2-47:2012, IS 13450: Part 2: Sec 47: 2018
AAMI ANSI EC12 2000 (R) / 2012
ANSI AAMI EC57:2012
ISO 10993-1:2018; ISO 10993-5:2009; ISO 10993-10:2021
FCC CFR47 Part 15 subpart C
ETSI EN 300 328 V2.2.2
ETSI EN 301 489-17 V2.2.3 and 489-1: V2.2.3:2019
IEC 62304:2015
ANSI AAMI ISO 14971:2019 / EN ISO 14971:2019/A11:2021
USFDA Guidance for Radio Frequency Wireless Technology in Medical Devices
USFDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
USFDA Guidance for Off-The-Shelf Software Use in Medical Devices
USFDA Guidance for Content of Premarket Submissions for Management of Cybersecurity in Medical Devices
USFDA Guidance for Applying Human Factors and Usability Engineering to Medical Devices

USFDA Guidance for Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically Powered Medical Devices
ANSI C63.27: 2017 American National Standard for Evaluation of Wireless Coexistence
IEC 60086-4:2019 Primary batteries - Part 4: Safety of lithium batteries
ASTM D4169 - Standard Practice for Performance Testing of Shipping Containers and Systems
IEEE ISO 11073-10404, 10406, 10408, 10441, 40101, 40102
IEC 81001-5-1: Health software and health IT systems safety, effectiveness and security – Part 5-1: Security – Activities in the product life cycle
ISO 15223-1: 2021 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
IEC 82304-1:2016 Health Software – Product requirements for Safety
MIL-STD-810H-CHG-1 (Temperature & Humidity Cycling, Thermal Shock & Vibration)
ANSI/CAN/UL 2900-1:2020
ANSI/CAN/UL 2900-2-1:2020
IEC 80001-1:2021; BS EN IEC 80001-1:2021; ANSI/AAMI/IEC 80001-1:2010
IEC TR 80001-2-2:2012; ANSI/AAMI/IEC TIR80001-2- 2:2012
IEC TR 80001-2-5:2014; ANSI/AAMI/IEC TIR80001-2- 5:2014
ISO 20417:2021; EN ISO 20417:2021
Restriction of Hazardous Substances Directive 2011/65/EU AMD 2015/863
Registration, Evaluation, Authorisation and Restriction of Chemicals

5.2 EMC compliance and warning statement

IEC 60601-1-2: 2014

UbiqVue 2AYe Wearable Biosensors have 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 environment including domestic. The unit also complies with the requirements of EN 60601-1-2:2015, providing the presumption of compliance to the European Union 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 (RF) energy for its functions. Use of this equipment adjacent to or stacked with other equipment should be avoided asit 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 the UbiqVue 2AYe Wearable Biosensor. Otherwise, it could result in degradation in the performance of the equipment.

FCC Statement (FCC ID : 2AHV9-UB2251)

This device complies with Part 15 of the FCC rules. Operation is subject to the following conditions:

- This device may not cause harmful interference.
- This device must accept any interference received including interference that may cause undesired operation of this device.

Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment. Biosensor radiator (Antenna) is at 12.8mm away from the body and hence, exempted from SAR measurement. Affix the Biosensor on the body as instructed in this manual for maintaining the separation distance.

5.3 Guidance and manufacturer's declaration – electromagnetic emissions

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

The 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	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	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	

5.4 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.

Table 6 - Immunity to RF Wireless Communication Equipment [Frequency]

LifeSignals Biosensor is 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.				
Test frequency (MHz)	**Band [a] (MHz)**	**Service [a]**	**Modulation**	**IMMUNITY Test Level (V/m)**
385	380 TO 390	TETRA 400	Pulse modulation [b] 18 Hz	27
450	430 to 479	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	28
710	704 to 787	LTE Band 13, 17	Pulse modulation [b]	9
745				
780				
810	800 to 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	28
870				
930				
1 720	1 700 to 1 990	GSM 1800, CDMA 1900; GSM 1900; DECT; LTE Band 1,3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	28
1 845				
1 970				
2 450	2 400 to 2 570	Bluetooth WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	28

5 240 5 500 5 785	5 100 to 5 800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	9
If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIMENT OR ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.				
a) For some services, only the uplink frequencies are included.				
b) The carrier shall be modulated using a 50% duty cycle square wave signal.				
c) As an alternative to FM modulation, the carrier may be pulse modulated using a 50% duty cycle square wave signal at 18 Hz. While it does not represent actual modulation, it would be worst case.				

Table 7 - Immunity to RF Wireless Communication Equipment [Power]

The Biosensor is intended for use in an electromagnetic environment in which radiated RF disturbances are are controlled. The customer or the user of the Biosensor can help prevent electromagnetic interference by maintaining a minimum distance between the portable and the mobile RF communications equipment (transmitters) and the Biosensor as recommended below, according to the maximum output power of the communications equipment. Refer to Table 9 & Table 11 of IEC 60601-1-2 and test methods specified in IEC 61000-4-3 and IEC 61000-4-39.			
Rated maximum output power oftransmitter (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. NOTE 3: All recommended standard 3rd party hardware equipment shall comply with the applicable IEC for ISO standards.			

5.5 EMC guidance

In accordance with Clause 4.3 of IEC 60601-1, the Essential Performance of UbiqVue 2AYe Holter System is:

- There shall not be noise exceeding 50 uV p-v on ECG signal over any 10 second period continuously

- Within 5 seconds after exposure to the defibrillation voltage, the Biosensor shall resume normal operation.
- The event marker shall be present in the data capture (if event button is pressed manually) and the captured time must be within 10 seconds of actual manual pressed time.

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 the Biosensor. In case of potential exposure to such equipments, the user is recommended to correct the interference by one or more of the following measures:

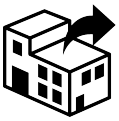
- Reorient the Biosensor away from these equipments (behind the patient body).
- Increase the separation between the Biosensor and the equipment.

5.6 Symbols

Table 8 - 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 the Biosensor as a battery/electronic waste - controlled by the local regulations.
 NNNNN	GUDID (Level 0) and Serial No.	On the PCBA – Level 0 – GUDID in data matrix format and Serial number in human readable format.
 XXXXX	GUDID (Level 0) and Pairing ID	On the Biosensor – Level 0 – GUDID in data matrix format and Pairing ID in human readable format.
	GUDID (Level 1,2 and 3)	Device GUDID (Level 1, 2 & 3) with manufacturing information. – Level 1: Serial No., Level 2 & 3: Lot No.

Label	Identification	Description
	Unique Pairing ID	Unique Pairing ID.
REF	Catalogue Number	Device Catalogue number / Labeler Product number.
QTY	Quantity	Number of devices in a pouch or in a multi-carton box.
℞ ONLY	Prescription only device	To be used under prescription supervision by a medical practitioner.
	Electronic instructions for use	Indicated on a product or product packaging that relevant information for use of the product is available in electronic form rather than, or in addition to printed form. Available at: www.lifesignals.com/ifu.
	Consult instructions for use	Refer to the 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 the device in packaged condition before the expiry date.
KR	Manufacturing date and country of manufacture.	Device manufacturing date and country of manufacture.
LOT	LOT Code	Manufacturing Batch or LOT code.

Label	Identification	Description
	Applied part	Defibrillation-proof, Type CF Applied Part.
	Do not reuse	Do not reuse; single patient use.
	Medical Device	Indicates the item is a medical device.
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.
	Max Stack	Do not stack more than (n) number of boxes. "n" indicates the number of boxes.
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	Do not 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.
	Importer	Indicates the entity importing the medical device into the locale.
	Distributor	Entity distributing the medical device into the locale.
	Damaged packaging	Do not use if the package is damaged. The Device must also not be used if the package holding the device is damaged.