# **University of Sussex**



# **General Risk Assessment Template**

For Guidance & examples on how to complete this form please refer to <u>HS FG 069 Risk assessment guidance</u> on the <u>Health & Safety Website</u>.

This form should only be used for general hazards that are not covered by a specific risk assessment template.

A list of templates can be found on the Health & Safety Website

	Section 1 General Information								
Α	School / Department:	School of Psychology							
	Brief description of the activity: Start to finish, step by step	Three Ag/AgCl electrodes will be placed (on the collar bones and above the hip bone) for each participant to collect their ECG (from which the heart rate and the number of heartbeats that occurred during a specific period will be extracted).							
В		NA CA							
С	Location(s) covered by this risk assessment: Include building and room number if applicable	Testing room offered by the university in Pevensey building							
D	Equipment and materials used:	Electrocardiography (ECG) electrode https://www.pluxbiosignals.com/coagcl-electrodes-pack-of-200		trodes/products/gelled-sel	f-adhesive-c	disposable-ag-			
E	Name(s) / Group(s) involved in the activity: Consider Staff, Students, Visitors, Contractors and members of the public	Jingxiong Xu (researcher), Dominiqu	e Makowski (	supervisor), and participan	s in the stu	dy			
F	Name of person completing this risk assessment: Students and PhD students should only complete risk assessments for their projects. Sign off for all student projects should be by the student's supervisor.	Jingxiong Xu	Signature	jingxiong Xu	Date:	23/06/2023			
G	Risk assessment approved by:  The individual approving the risk assessment should be familiar with the work being undertaken. This should in most cases be the assessor's supervisor, line manager or the principle investigator.	Dominique Makowski	Signature	Dom	Date:	23/06/2023			

Document Control							
H&S Document No	HS F001	Version	6.1	Date Issued	September 2022		
Author	Seimon Barton-Jones	Reviewed by	Angelina Janus	Department ID code			

Н	Send a copy to School/Department Safety Coordinator			

	Section 2 Hazards & Controls  See the accompanying guidance document on the safety section website for further information on how to complete this form.											
		Risk with current control measures				Risk after additional con	Risk after additional control measures					
Potential hazards	Who might be harmed and how?	What current controls are in place to avoid harm?	Likelihood 1-5	Severity 1-5	Risk (LX R)	What further control measures are required to reduce risk?	Likelihood 1-5	Severity 1-5	Risk (LX R)	Who will do this?	When must this be done?	Completed on:
Allergic to electrodes	Participants  Dermatitis caused by the allergic reaction from the electrodes	Participants will be asked before the placement of the electrodes if they had negative experience in the past with similar equipment. Additionally, the researcher will monitor potential discomfort or skin redness after the placement of the first electrode and remove everything if any suspicion arises.	1	1	1		1	1	1	Researcher And participants	During the study	

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Author	Seimon Barton-Jones	Reviewed by	Angelina Janus	Department ID code			

#### **Section 3 Risk Matrix**

# Risk Matrix - Likelihood x Severity (L x S)

Almost

certain

Likely

Possible

Rare

>50%

10-50%

1-10%

<0.1%

	Not expected to occur for 10 years					
Risk Rating	Score	Action				
Low	1 to 4	Low risk identified - Control measures to be adopted and monitored				
Medium	5 to 10	Medium risk identified - Ensure that the risk assessment is reviewed, further controls may be necessary				
High	12 to 16	High risk identified - Re-evaluate risk assessment and develop/determine greater controls				
Extreme	20 to 25	Extreme risk identified - Stop work immediately - Re-evaluate risk assessment and develop/determine greater controls				

Will undoubtedly happen/recur, possibly frequently

Will probably happen/recur but it is not a persisting issue

Do not expect it to happen/recur but it is possible it may do so 0.1-1.0% Unlikely 2

Expected to occur at least weekly

Expected to occur at least monthly

Might happen or recur occasionally

Expected to occur at least yearly

Expected to occur once in 5 years
This will probably never happen/recur

LIKELIHOOD

	Minor	Moderate	Significant	Major	Severe
Injury to person(s)	Minimal injury requiring no/minimal first aid. No time off required	Minor injury. First aid required. Less than 3 days off	Moderate injuries. First aid. Attend A&E. Over 7 days off. RIDDOR	Major injury. Professional medical aid. Long- term incapacity. RIDDOR	Death or multiple permanent injuries. RIDDOR
III health to person(s)	Minimal/ Transitory effects requiring no/minimal intervention	Short-term irritation or effects. Occupational health. Less than 3 days off	Occupational Health. Over 7 days off. RIDDOR	Long-term incapacity but with recovery. RIDDOR	Permanent iII health & incapacity. RIDDOR
Environment al effect(s)	Minimal or no impact on the environment	Minor impact on the local environment	Moderate impact on the local environment	Major impact on the wider environment	Severe impact on the wider environment

SEVERITY

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#### **Section 4 Communication of Risk Assessment to Users**

This assessment can either be communicated to groups or Individuals as part of a School or Divisional process or signed off by individual users.

#### **School or Divisional Process**

The contents of this risk assessment will be communicated to builder users in the University training programmes.

# Sign off by users

All individuals carrying out activities covered under this risk assessment should sign below after reading it.

By signing this document you confirm that; you have read and understood this risk assessment and that it is an accurate representation of work practice

Name	Signature	Date	Name	Signature	Date

# Section 5 Record of Risk Assessment reviews Risk assessments should be reviewed every three years or earlier if there is a significant change in the process or after an incident/near miss Date of review: Comments / date of next review: Comments / date Comments / date

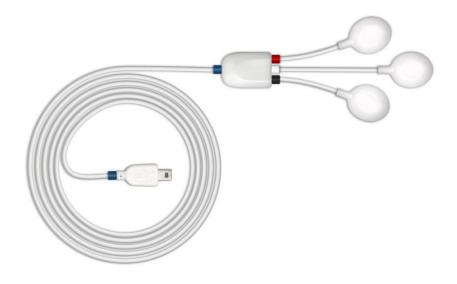
Date of review:	Reviewed by:	of next review:	
Date of review:	Reviewed by:	Comments / date of next review:	

Document Control							
H&S Document No	HS F001	Version	6.1	Date Issued	September 2022		
Author	Seimon Barton-Jones	Reviewed by	Angelina Janus	Department ID code			



biosignal acquisition tool-kit for advanced research applications

Electrocardiography (ECG) Sensor User Manual



#### **ATTENTION**

Please read this datasheet before using your biosignalsplux sensor

The information contained in this document has been carefully checked and were made every effort to ensure its quality. PLUX reserves the right to make changes and improvements to this manual and products referenced at any time without notice.

The word Bluetooth and its logo are trademarks of Bluetooth SIG Inc. and any use of such marks is under license. Other trademarks are the property of their respective own.

Please check your systems and sensors after receiving and before using it the first time to confirm if it contains all the ordered sensors, accessories and other components. Contact our support via e-mail at <a href="mailto:support@plux.info">support@plux.info</a> if there are any variations from your original order.

For regulatory information, please see the Regulatory Disclaimer at the end of this document.



PLUX – Wireless Biosignals, S.A. Av. 5 de Outubro, n. 70 – 2. 1050-059 Lisbon, Portugal plux@plux.info http://biosignalsplux.com/

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# 1. General Information

# 1.1. General Description

Our low-noise ECG local differential triode configuration enables fast application and unobtrusive single-lead ECG data acquisition (although custom electrode cable configurations are available). The state-of-the-art design of the analog frontend on this sensor is specifically targeted at analyzing minutiae in the data and provides medical-grade raw sensor data.

This sensor can be used to extract heart rate data and other ECG features, enabling its application in research fields such as biomedical, biofeedback, psychophysiology, and sports, among many others.

Together with the <u>Heart Rate Variability (HRV) add-on</u> for our OpenSignals (r)evolution software, one can easily record and extract meaningful temporal, spectral, and nonlinear signal parameters for further analysis of the acquired sensor data.

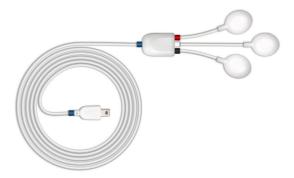


Figure 1: biosignalsplux Electrocardiography (ECG) sensor (standard version).

# 1.2. Typical Unfiltered Sensor Output

Figure 2 shows a typical unfiltered ECG sensor output acquired while at rest. The raw digital sensor values received from the **biosignalsplux** device ranged between 0 and 2<sup>n</sup> - 1 (**n**=sampling resolution) were converted into the original unit of measurement of this sensor (mV) using the transfer function found in section Transfer Function (Conversion Formula).

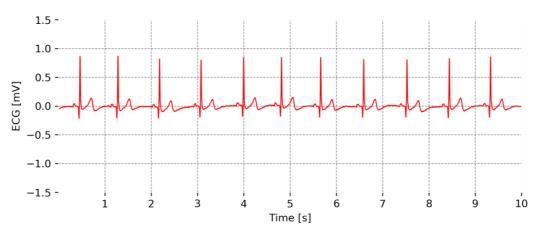


Figure 2: Typical unfiltered ECG sensor output (signal acquired while at rest).

# 1.3. Sensor Specifications

> Gain:  $\pm 1.47 \text{mV} (@ \text{VCC} = 3\text{V})$ 

> Bandwidth: 0.5-100Hz > Consumption:  $^{\circ}$ 0.5mA > Input Impedance[Typical]:  $\geq$  100GOhm > CMRR: 100dB

#### 1.4. Features

> Bipolar differential measurement
 > Pre-conditioned analog output
 > High signal-to-noise ratio
 > Unobtrusive & lightweight sensor
 > Pre-conditioned analog output
 > Ready-to-use form factor

> Medical-grade raw data output

# 1.5. Applications

Life sciences studiesHeart rate & Heart rate variabilityBiomedical device prototypingHuman-Computer Interaction

> Biometrics > Affective Computing > Physiology Studies > Psychophysiology

> Biofeedback

# 1.6. Transfer Function (Conversion Formula)

The analog sensor signals acquired with **biosignalsplux** devices are converted into digital values ranged between 0 and 2<sup>n</sup> - 1 (**n**=sampling resolution, usually 8-bit or 16-bit) and streamed in the raw digital format.

In most applications, the original physical unit of the acquired ECG signal is preferred or required. The raw digital sensor samples can be converted back into millivolt (mV) using the following formulas:

$$ECG(V) = \frac{\left(\frac{ADC}{2^n} - \frac{1}{2}\right) \times VCC}{G_{ECG}} \tag{1}$$

$$ECG(mV) = ECG(V) \times 1000 \tag{2}$$

Valid sensor range: [-1.47mV, 1.47mV]

with: ECG(V) ECG signal in Volt (V) ECG(mV) ECG signal in milli-Volt (mV)

ADC Value samples from the sensor/channel (raw digital value)

n Sampling resolution (**default:** 16-bit resolution (n=16), although 12-bit

and 8-bit may also be found in older versions)

VCC Operating voltage (3V when used with biosignalsplux)

 $G_{ECG}$  Sensor gain (1019)

# 1.7. Electrode Connections & Sleeve Color Meanings

Sleeve Color	Red	Black	White
Electrode Cable	+	-	reference

See section 2 for more information on where to place the electrodes and to connect electrodes cables for ECG acquisitions.

# 1.8. Physical Characteristics

> W1 x L1 x H1: 1.5cm x 2.1cm x 0.4cm > W2 x L2 x H2: 1.4cm x 1.7cm x 0.5cm

Sensor also available with A2 and A3 with 30cm cable lengths. Custom cable lengths for A1, A2, and A3 are possible. For custom lengths, please contact our operations team via <a href="mailto:orders@plux.info">orders@plux.info</a>.

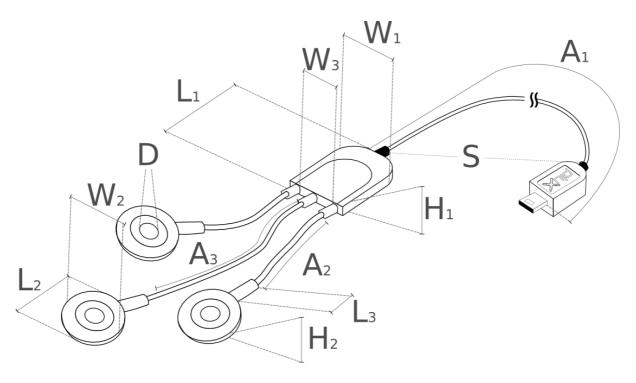


Figure 3: Physical characteristics of the standard Electrocardiography (ECG) sensor.

# 2. Sensor Application Notes

The **biosignalsplux** ECG is primarily designed for single-lead ECG acquisitions in the Einthoven configurations. The Einthoven triangle allows you to acquire 3 different ECG leads which only depend on the positioning of your electrode cables:

Lead I: measures from RA (right arm) to LA (left arm)

• Lead II: measures from RA to LF (left foot)

Lead III: measures from LA to LF

The illustrations shown in Figure 4 and Figure 5 show the recommended electrode placement for the acquisition of ECG signals in Einthoven configurations depending on the different standard ECG sensors with difference electrode cable lengths.

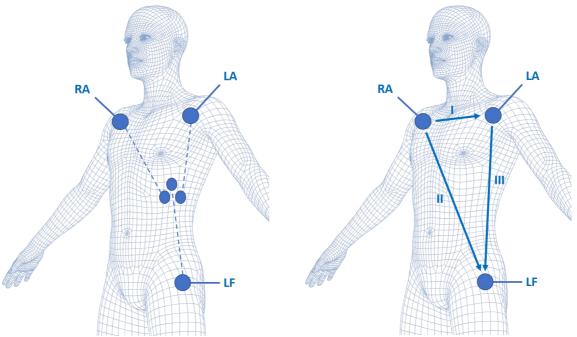


Figure 4: Electrode placements for ECG acquisitions in Einthoven configurations using the standard ECG sensor with electrode cable lenghts of 1.5cm (+ & -) and 3 cm (reference).

Figure 5: Electrode placements for ECG acquisitions in Einthoven configurations using the standard ECG sensor B with electrode cable lengths of 30cm (+, - & reference).

After placing the ECG electrodes correctly on the body, connect the electrode cables of the ECG sensor according to one of the following configurations:

Table 1: ECG sensor electrode and electrode placement connection.

	Positive Electrode (+) (red sleeve)	Negative Electrode (-) (black sleeve)	Reference Electrode (white sleeve)
Lead I	LA	RA	LF
Lead II	LF	RA	LA
Lead III	LF	LA	RA

It is also possible to use a sensor with only the + and – electrodes (must be custom ordered) without the use of an additional reference electrodes. Such sensors can lead to an increase in baseline noise due to the lack of a reference electrode but can be an alternative to the 3-electrode sensor for

applications in which a simplified ECG sensor can be useful (e.g. for the extraction of heart rate data only).

# 3. Using the Electrocardiography (ECG) Sensor with biosignalsplux & OpenSignals

# 3.1. Connecting the sensor to biosignalsplux Systems

#### 3.1.1. biosignalsplux 4-Channel Hubs

The **biosignalsplux** ECG sensor is compatible with all 4 analog input channels of the 4-channel **biosignalsplux** hub, but incompatible with the reference/ground port. Connect the sensor to an analog input to use it with this device.



Figure 6: ECG compatible biosignalsplux channels (green checkmarks).

#### 3.1.2. biosignalsplux 8-Channel Hubs

The **biosignalsplux** ECG sensor is compatible with all 8 analog input channels of the 8-channel **biosignalsplux** hub, but incompatible with the reference/ground and digital I/O ports. Connect the sensor to an analog input to use it with this device.



Figure 7: ECG compatible biosignalsplux channels (green checkmarks).



# 3.1.3. biosignalsplux Solo & Single-Channel openBAN Devices

The **biosignalsplux** ECG sensor is compatible with the analog input channel of the **biosignalsplux Solo** (openBAN) device. Connect the sensor to the analog input channel to use it with this device.



Figure 8: Connect the ECG to the analog input channel of the biosignalsplux Solo (openBAN).

# 3.2. Configuring the Sensor in OpenSignals (r)evolution

#### Note

Download OpenSignals (r)evolution here: <a href="https://biosignalsplux.com/index.php/software">https://biosignalsplux.com/index.php/software</a>

Open the **OpenSignals (r)evolution** device manager to access and configure your **biosignalsplux** device.

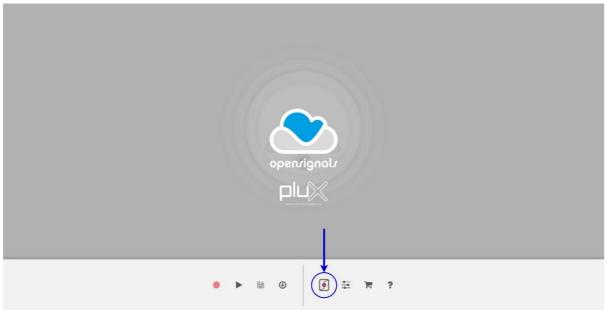


Figure 9: Access the OpenSignals (r)evolution device manager.

Select the device you intend to use for acquisition by clicking on *ENABLE button on* the device panel in the **OpenSignals** device manager. The device is activated for acquisition if the *ENABLE* button is blue.

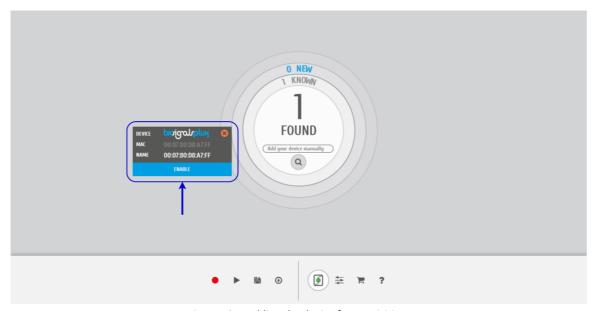


Figure 10: Enabling the device for acquisition.

Click on the **biosignalsplux** logo to access the available settings. Select the channel your sensor is connected to and select the *ECG* from the dropdown menu highlighted in the next screenshot.



Figure 11: Set the channel type of the channel you have your ECG sensor connected to, to  $\it ECG$ .

Activate the channel for acquisition by clicking on the circle next to the channel type (must be blue). If not done before, follow the instruction available in section 2 Sensor Application Notes to learn how to apply the sensors and 3.1 Connecting the sensor to biosignalsplux Systems to learn how to connect your device to your biosignalsplux device. Click on the record button in the OpenSignals main interface whenever you're ready for your acquisition.



Figure 12: Start the acquisition whenever you're ready.

# 4. Technical Notes

The **biosignalsplux** technical notes aim to provide technical in-depth information about the different applications in which the ECG sensor can be applied. Find below more information about the available technical notes which you can download from the biosignalsplux website.



**Download** 

biosignalsplux Technical Notes - ECG

# 4.1. ECG Acquisitions While at Rest

The purpose of this technical note is to show a typical acquisition of an electrocardiogram. For this application, an ECG with 6m39s was recorded with a subject in an upright standing position. To assess the quality of the signal, the Signal-to-Noise (SNR) was calculated.

# 4.2. ECG Acquisitions During Physical Activity

One of the applications of the ECG sensor is to measure cardiac activity during physical activity. In this experiment, the subject performed an intensive exercise on an ergometer during a 10min acquisition.

During the first minute, the subject was in a resting state. After this period, the subject has progressively increased his effort until he reached the maximum effort between minutes 4 and 5, resting during the last 2m30s.

# 4.3. ECG Acquisitions During Mental Activity

The purpose of this technical note is to show how a mental task can influence the heartbeat of a subject. To that effect, a 5min paced visual serial addition test was performed by a test subject.

In this test, the subject is asked to sum two numbers that are shown on a screen, which is used to assess capacity, rate of information processing, and sustained/divided attention.



# 5. Scientific Publications Using the Electrocardiography (ECG) Sensor

The following scientific resource elements is only a small selection extracted from the list of available publications using **biosignalsplux**. Please visit the following website to access the entire up-to-date list.



biosignalsplux Publications

**List of Publications** 

#### **Publications Short List**

C. Gerritsen, J. de Man, J. van der Meij, "Physiological and subjective response to injustice: The Effects of Unjust Evaluations on Physiological Responses and Subjective Experiences", in Proc. of the IEE/WIC/ACM Int. Joint Conf. on Web Intelligence (WI) and Intelligent Agent Technologies (IAT), vol. 3, pp. 179-182, 2013

A. Reiss, I. Indlekofer, P. Schmidt, K. van Laerhoven, "<u>Deep PPG: Large-Scale Heart Rate Estimation with Convolutional Neural Networks</u>", in *Sensors*, vol. 19, no. 14:3079, pp. 1-27, 2019

A. Kamenz, V. Bibaeva, A. Bernin, S. Ghose, K. von Luck, F. Vogt, L. Müller, "<u>Classification of Physiological Data in Affective Exergames</u>", in *Proc. of the IEEE Symposium Series on Computational Intelligence (SSCI)*, pp. 2076-2081, 2018

G. Ramos, M. Alfaras, H. Gamboa, "Real-Time Approach to HRV Analysis", in *Proc. Of the 11th Joint Int. Conf. On Biomedical Engineering Systems and Technologies (BIOSTEC2018)*, vol. 4, pp. 208-215, 2018

M. Knierim, J. Dominik, V. Dorner, "<u>Desgining Live Biofeedback for Groups to Support Emotion Managment in Digital Collaboration</u>", in *Lecture Notes in Computer Science*, vol. 10243, pp. 479-484, 2017

A. Bernardino, C. Vismara, F. Baptista, F. Carnide, S. Oom, S. Bermudez i Badia, E. Gouveia, H. Gamboa, "A dataset for the automatic assessment of functional senior fitness tests using kinect and physiological sensors", in *Proc. of the 1st Int. Conf. on Technology and Innovation in Sports, Health and Wellbeing (TISHW)*, pp. 1-6, 2016

- J. Pagán, J. L. Risco-Martín, J. M. Moya, J. L. Ayala, "<u>Modeling methodology for the accurate and prompt prediction of symptomatic events in chronic diseases.</u>", in *Journal of Biomedical Informatics*, vol. 62, pp. 136-147, 2016
- M. Cheetham, C. Cepeda, H. Gamboa, "<u>Automated Detection of Mind Wandering: A Mobile Application</u>", in *Proc. of the 9th Int. Joint Conf. on Biomedical Engineering Systems and Technologies (BIOSTEC)*, vol. 4: BIOSIGNALS, pp. 198-205, 2016
- J. Cusveller, C. Gerritsen, J. de Man, "Evoking and Measuring Arousal in Game Settings", in *Proc. of the Int. Conf. on Serious Games*, vol. 8395, pp. 165-174, 2014



# 6. Safety & Maintenance

# 6.1. Safety Instructions

Please read the following safety instructions **before** using your **biosignalsplux** system with the ECG sensor to prevent any damages or problems with the user, test persons and/or **biosignalsplux** devices. Violations of these instructions can lead to inferior signal quality and/or damages to the **biosignalsplux** system and user.

- ! The user should always keep the device and its accessories dry.
- ! The user must turn off the **biosignalsplux** device and contact Technical Support if the system or accessories reach uncomfortable temperatures.
- ! The user should not use the **biosignalsplux** device in noisy environments (environments with microwaves and other similar equipment). Doing so will lead to noise increase in the acquired signals and Bluetooth connectivity issues.
- ! The user must not use the device near the fire or in potentially explosive atmospheres, such as atmospheres with flammable gas.
- ! The user should only use the detection surfaces or other approved accessories purchased from PLUX or by a PLUX agent.
- ! The user should inspect the sensors on a regular basis to ensure that they remain in good working order.
- ! The user should stop using the **biosignalsplux** device if experience any kind of discomfort or skin irritation.
- ! Do not use the system on persons with allergies to silver.
- In the user should dispose detection surfaces after using the **biosignalsplux** device. Detection surfaces are single-user and disposable. Reusable electrodes should be reused by the same user. Do not use reusable electrodes on several users.
- ! The user must not place the device in the microwave.
- ! The user must not insert objects into the holes of the device.
- ! The user should not open the **biosignalsplux** device or its accessories. The repair of the same should be only done by properly authorized PLUX personnel.
- ! The user should make sure the cables do not obstruct the passage of people.
- ! The user should use the sensor cables with extreme caution to avoid risk of strangulation.
- ! The user should keep a safe distance between the **biosignalsplux** device and other devices to ensure their proper functioning.
- ! The user should only send the device to repair to qualified PLUX personnel.



- ! The user should not immerse the sensors or the **biosignalsplux** device, nor clean with liquid or abrasives.
- ! The user should handle the **biosignalsplux** device with caution and not expose the device or accessories to high accelerations and vibrations.
- ! biosignalsplux devices should not be used in patients with implanted electronic devices of any kind, including pace-makers, electronic infusion pumps, stimulators, defibrillators or similar.
- ! Do not apply electrodes over damaged or irritated skin.
- ! Do not use your device while charging its internal battery.

# **6.2. Transportation and Storage**

Please follow these recommendations to ensure safe transportation and storage of your biosignalsplux equipment and sensors to prevent any damaging of your system.

The **biosignalsplux** equipment and sensors should be stored in the original box in a dry place when those are not being used.

- Relative humidity: up to 95% with no condensation
- Ambient temperature: 10°C to 30°C
- Atmospheric pressure between 500hPa and 1060hPa

Whenever the equipment needs to be transported, it should be placed in the original box, since this was designed and tested to ensure the equipment and accessories are securely stored.

Take care while handling the transportation of the system and avoid dropping it, since the device is not shock-proof and should not be placed under stress or sudden acceleration.

#### 6.3. Cleaning

Please follow these cleaning instructions to prevent any damage of the system or the user because of conducting cleaning methods that may cause any damage.

- The **biosignalsplux** and sensors should be visually checked before each use and cleaning process to ensure that no mechanical damage occurred.
- The biosignalsplux equipment and sensors (including the cables) should be cleaned with a slightly damp cloth or suitable absorbent paper, ensuring no liquid enters the equipment of sensors. Do not use detergent or any type of cleaning liquid as these may damage your equipment and/or sensor.
- Do not clean or re-use detection surfaces (electrodes). They are only suitable for single use and should be disposed of after usage except indicated otherwise.

# 7. Ordering Guides, Regulatory & Legal Information

# 7.1. Ordering Guide

Please follow the following ordering guide when submitting orders of ECG sensors to <u>orders@plux.info</u>. If no specification is provided, the standard version of the sensor will be delivered.

### **Electrocardiography (ECG) Sensor**

SKU Reference	PLUX Code	UPC		
SENSPRO-ECG1	820201203	642554231266		
Description				
Electrocardiography (ECG) sensor with standard physical characteristics and a random cable sleeve				
color				

#### **Electrodes & Accessories**

For a full list of available and compatible electrodes, please visit the biosignalsplux store.

#### 7.2. Guarantee of Quality & Warranty

**biosignalsplux** sensors have three months quality guarantee from the date of purchase. PLUX guarantees that the system, sensors and accessories will be free from material or manufacturing defects for the mentioned time periods following date of purchase.

If PLUX receives notification of any such defects within the guarantee period, it will repair or substitute with the same unit/model, any products with proven defects at no cost to the client. During the repair period PLUX promises to provide a temporary replacement under the same specification. Repairs will be carried out at PLUX's premises after the equipment has been received.

# 7.3. Warranty Voidance

Usage of the device that is not in accordance with the handling instructions indicated in the manual, or use with accessories other than those manufactured by PLUX will invalidate the warranty of your devices.

Be careful when connecting your biosignalsplux devices, sensors and/or accessories to any third party device including the usage of the 3rd party connection components that are available for biosignalsplux systems as the usage of these components will void the electrical warranty of your biosignalsplux device and sensors and, if not indicated otherwise, the warranty of the 3rd party system you're connecting to the device. Check the electrical specifications of both systems you want to connect to prevent any damage of the user(s) or the systems.

In the case of warranty voidance, the same applies that we expressly disclaim any liability whatsoever for any direct, indirect, consequential, incidental or special damages, including, without limitation, lost revenues, lost profits, losses resulting from business interruption or loss of data, regardless of the form of action or legal theory under which the liability may be asserted, even if advised of the possibility of such damages.

#### 7.4. Contact & Support

Contact us if you are experiencing any problems that cannot be solved with the information given in the <u>biosignalsplux documentation</u>.

Please send us an e-mail with precise information about the error occurrence, device configuration, and, if possible, screenshots of the problem to <a href="mailto:support@plux.info">support@plux.info</a>.



# 7.5. Regulatory Disclaimer

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