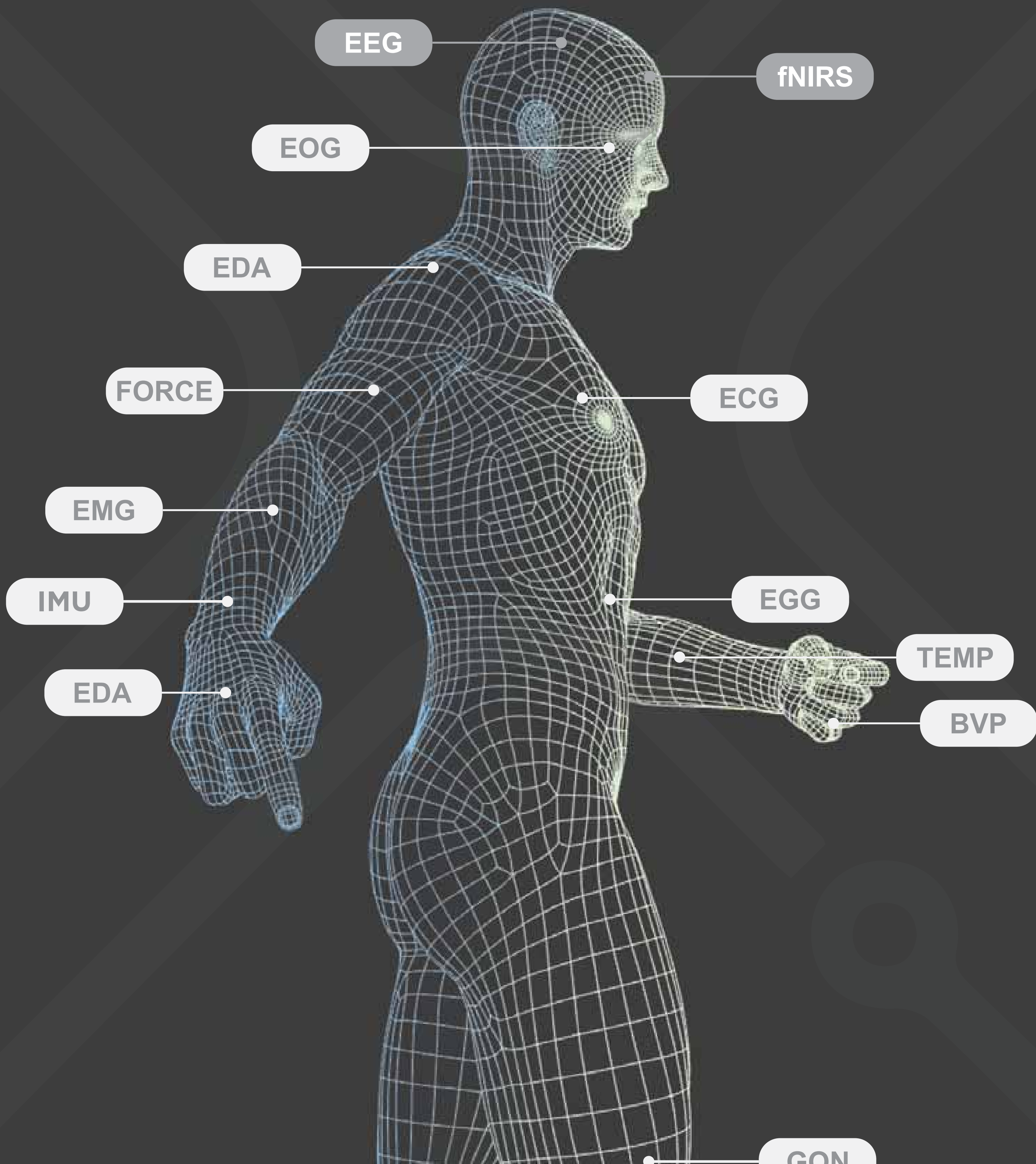
How to develop new biosignals based products

PLUX approach to design new products based on human biosignals



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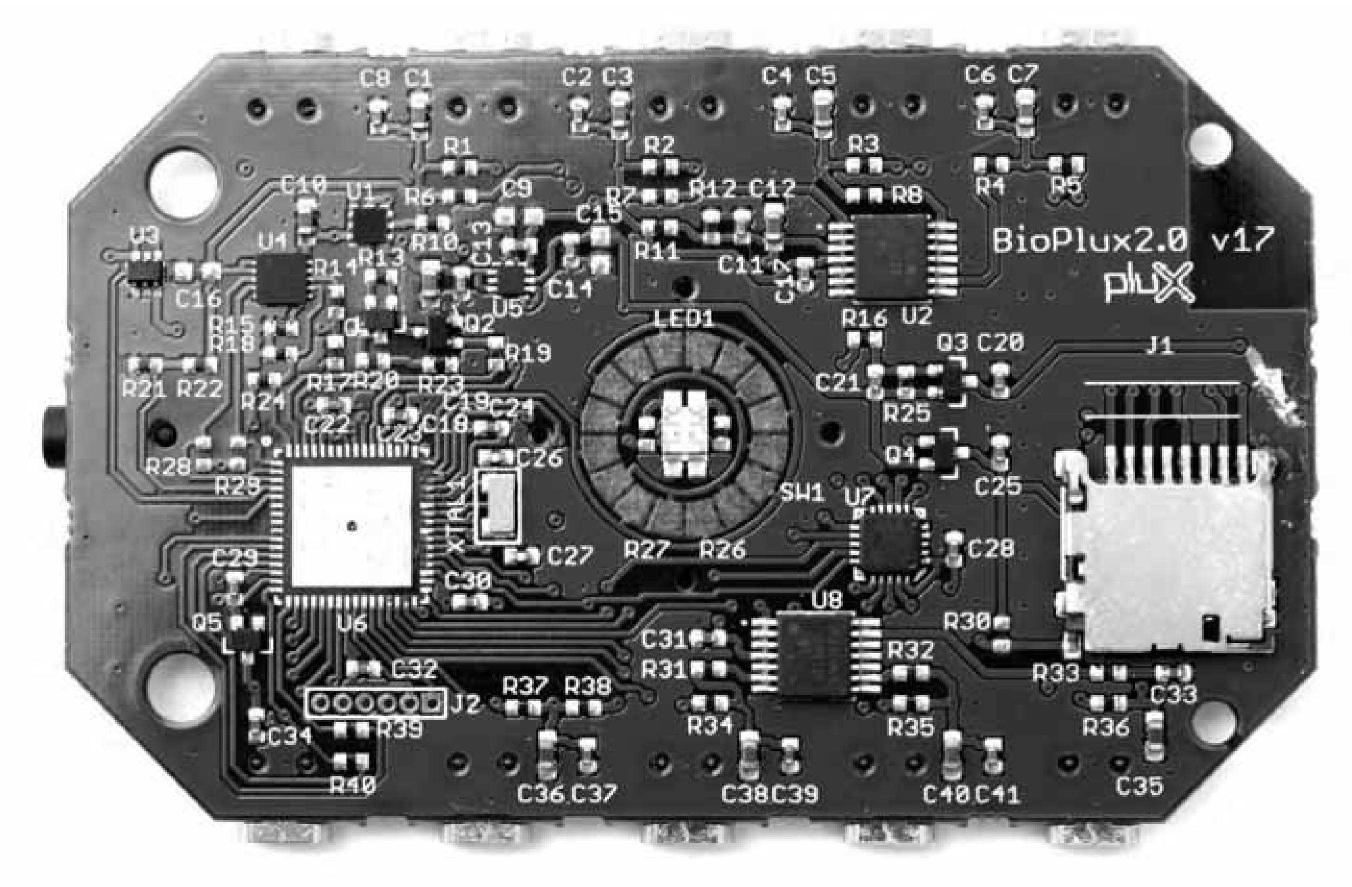
plux charles river analytics

Abstract

Access to human physiological, neurophysiological, and behavioral signals (biosignals) can revolutionize health solutions, scientific research across multiple fields, and everyday interaction between the digital and human worlds (e.g., through the internet of things, “smart” technologies, smartphone apps). One of the earliest capabilities to extract biosignals from humans were ECG recordings [1]. Since then technology has been constantly evolving into a growing list of sensors capable of enabling a deeper understanding of the human physiological and cognitive state. Still there are a great number of challenges, both technical and methodological, that need to be tackled.



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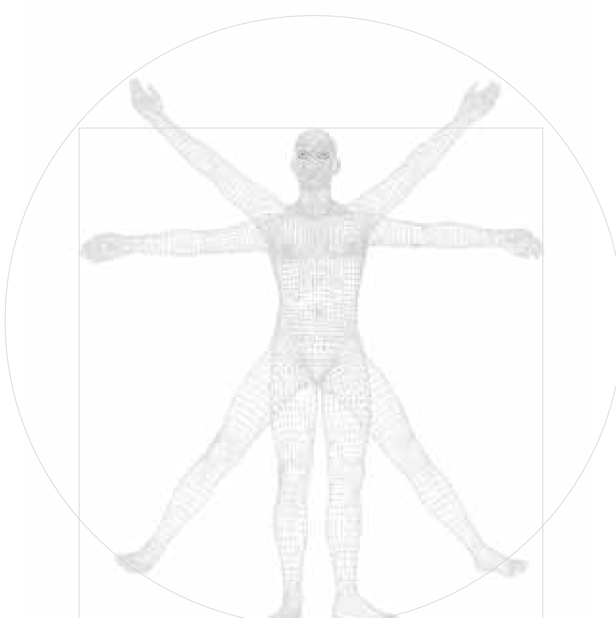
PLUX, a biomedical engineering company focused on biosignals solutions development, has been addressing these challenges for over a decade, and in the process, has developed technical toolkits and methodologies that can help other organizations, public and private, more effectively and efficiently carry out research and development in the biosignals space. These technological advances allow our partners to benefit from our scientific knowledge and experience in acquiring reliable and trustworthy data from human biosignals. This reduces the time to market for new biosignals based products built by our research and technology company customers.

This document summarizes how these assets can be leveraged in private or public projects, presenting PLUX as a key partner to support other institutions in their research and productization process involving human biosignals.



plux

we develop **biosignals acquisition systems**
applied in **hundreds of R&D facilities worldwide**
to boost their work

1 Introduction

Working with biosignals is still challenging. There are a number of key concerns that are shared by most of the researchers and developers in this field including:

The need to easily test diverse hypotheses using multiple sensors to support an investigation (sensor fusion);

The need to access raw data to make sense of their investigation, as closed platforms provide black box solutions that are difficult to fully understand or don't allow access to the raw data from the sensor;

The need to maintain control over data, so third party cloud platforms need to be well structured or avoided for this large community;

The need to avoid wasting time reinventing standards used in analogue conditions used for data transmission;

The need to collect data during longer sessions, preferably in real world environments while individuals carry out typical activities, or at least not requiring the individual to be tethered to a desk;

The need for expertise in of data preprocessing and during feature extraction (making sense of acquired data) particularly for novices to biosignals research;

The need to develop machine learning algorithms necessitating structured data acquisition.

PLUX's mission is to fill these gaps and make research and productization in the biosignals environment easier for individuals interested in this space ranging from hackers and hobbyists to scientists and researchers to biotech companies. To support and empower all types of researchers and developers PLUX created two distinct product lines, BITalino and biosignalsplux, that together address the key aspects of mature and open scientific research, education, and early stage prototyping.

This document presents details on how to use BITalino and biosignalsplux as support tools for reference projects in research and productization based in biosignals. The document is broken down into the following sections. Section 2 documents how to use our modular platforms to access biosignals in your own work. Section 3 details our systematic approach to designing and developing an end-product. Finally, Section 4 includes a project example that use this method in order to achieve a set of desired outputs.

By sharing this knowledge PLUX aims at supporting researchers and developers in the inclusion of biosignals in scientific tools and end-customer products

- thus fulfilling its Mission -

2 ACCESSING BIOSIGNALS

Biosignals are time representations of changes in energy produced in the body. These changes correspond to energy variations of different origin, including electrical, chemical, mechanical and thermal. Table 1 shows an example of each of these origin types, associated parameter changes, and examples of how to measure each.

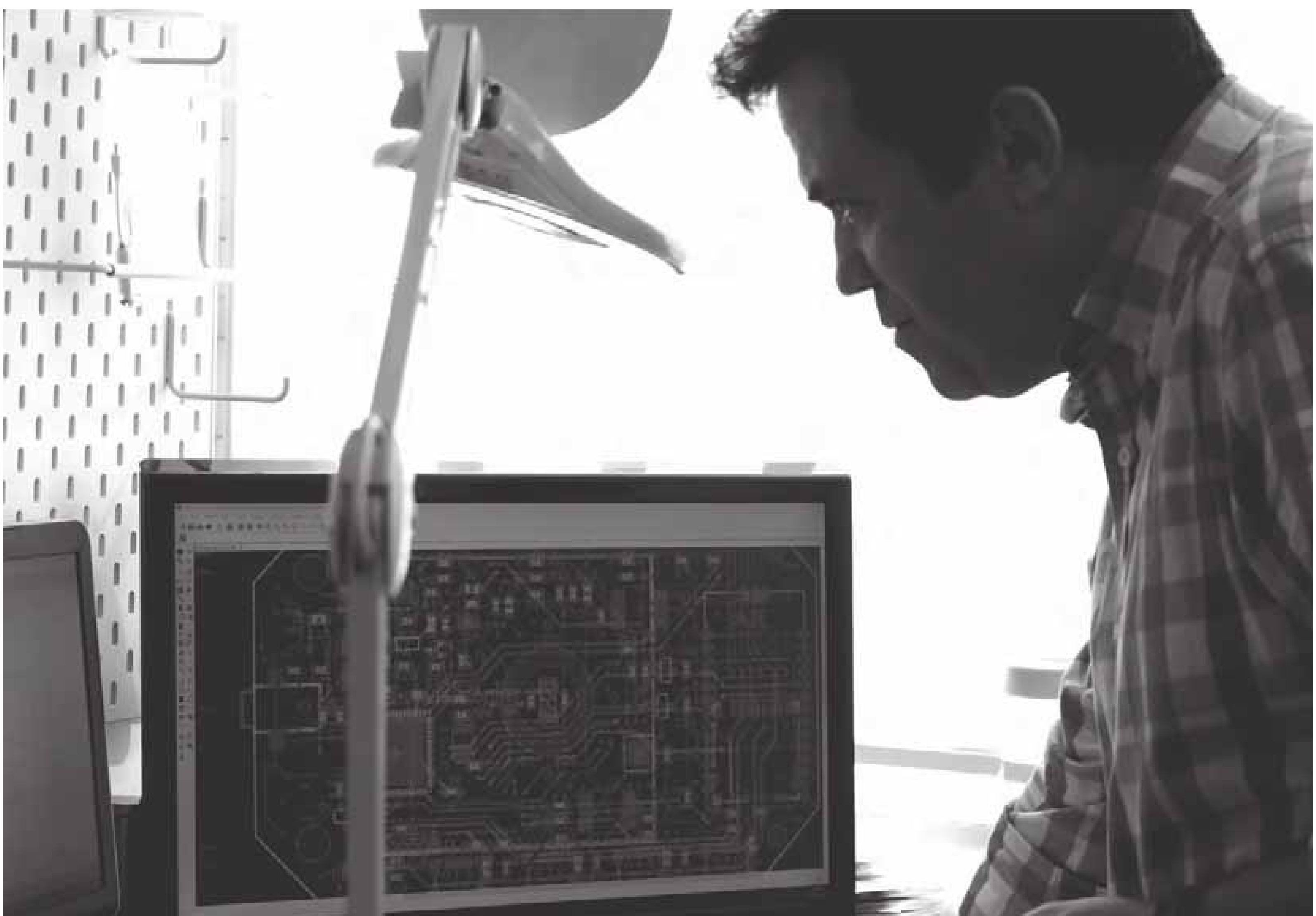
ENERGY	CHANGING PARAMETER	MEASUREMENT EXAMPLES
Mechanical	Position, force, torque, pressure	Muscle contractions, cardiac pressure, muscle movement
Electrical	Voltage, current and resistance	EMG, ECG, EEG, EDA, EOG
Thermal	Temperature	Surface body temperature
Chemical	Concentrations, exchanged energy	pH, oxygen, hormonal concentration

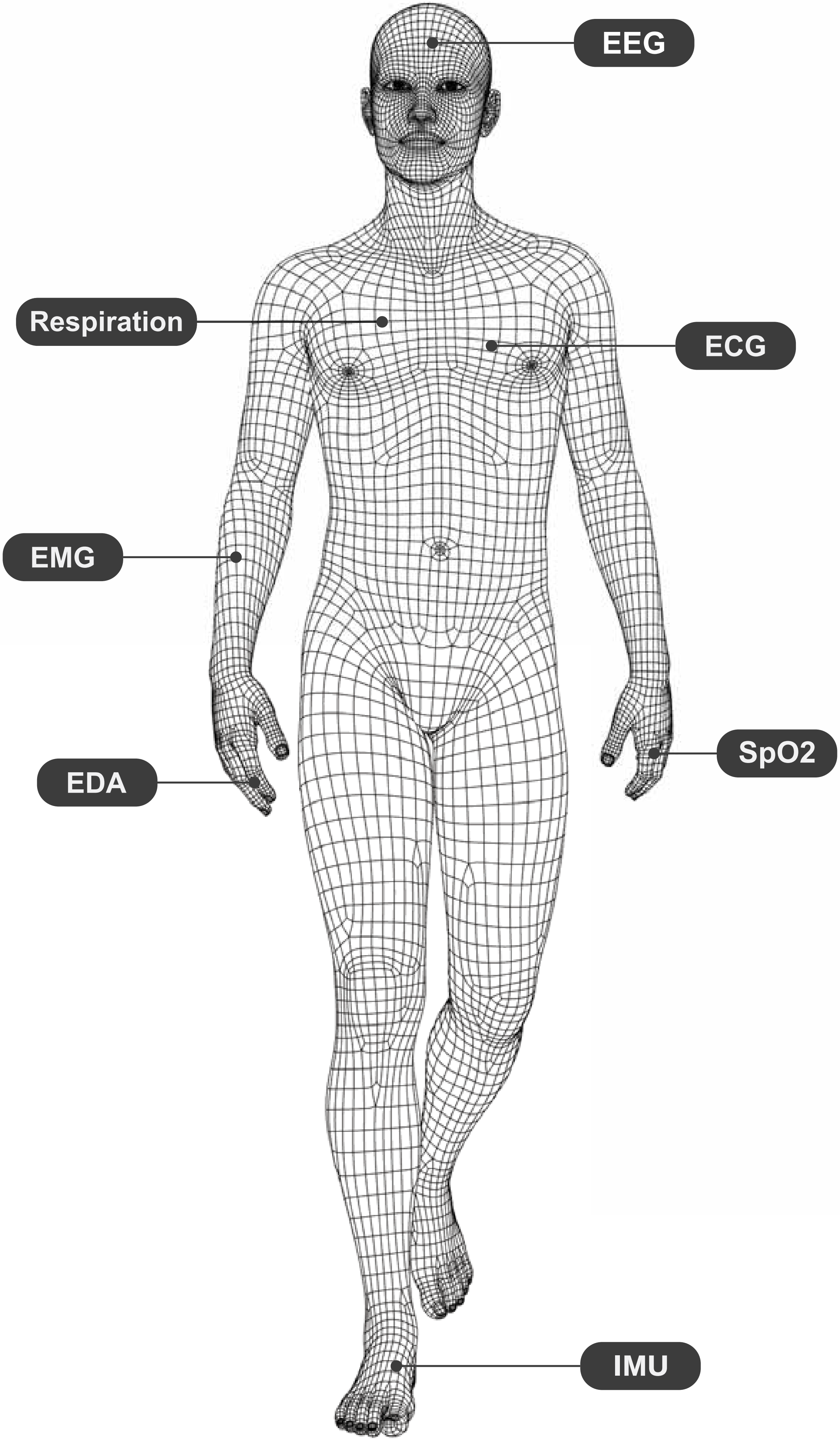
Table 1 *Adapted from Semmlow-Griffel [2]*

Until recently, biosignals were mainly used in clinical settings for health monitoring, or in specialized research labs focused in fields such as the study of heart, muscle or the brain activity as addressed in classical texts of physiology [3][4][5].

As technology continued to develop enabling reduced size, weight, power, and cost, there has been a fast-paced growth in the number and type of biosensing technologies beyond the clinical and research lab settings. A direct consequence of this rapid expansion was the creation of an ever-expanding number of sports and health monitoring apps available in our smartphones that interact with biosignals captured from smartphones, smartwatches or other sensor devices. Biosignals are now accessible in multiple contexts through wearable technologies. Moreover, the fact that biosensing platforms are being used outside clinical context is contributing to the adaptation of typical research techniques into new products and services.

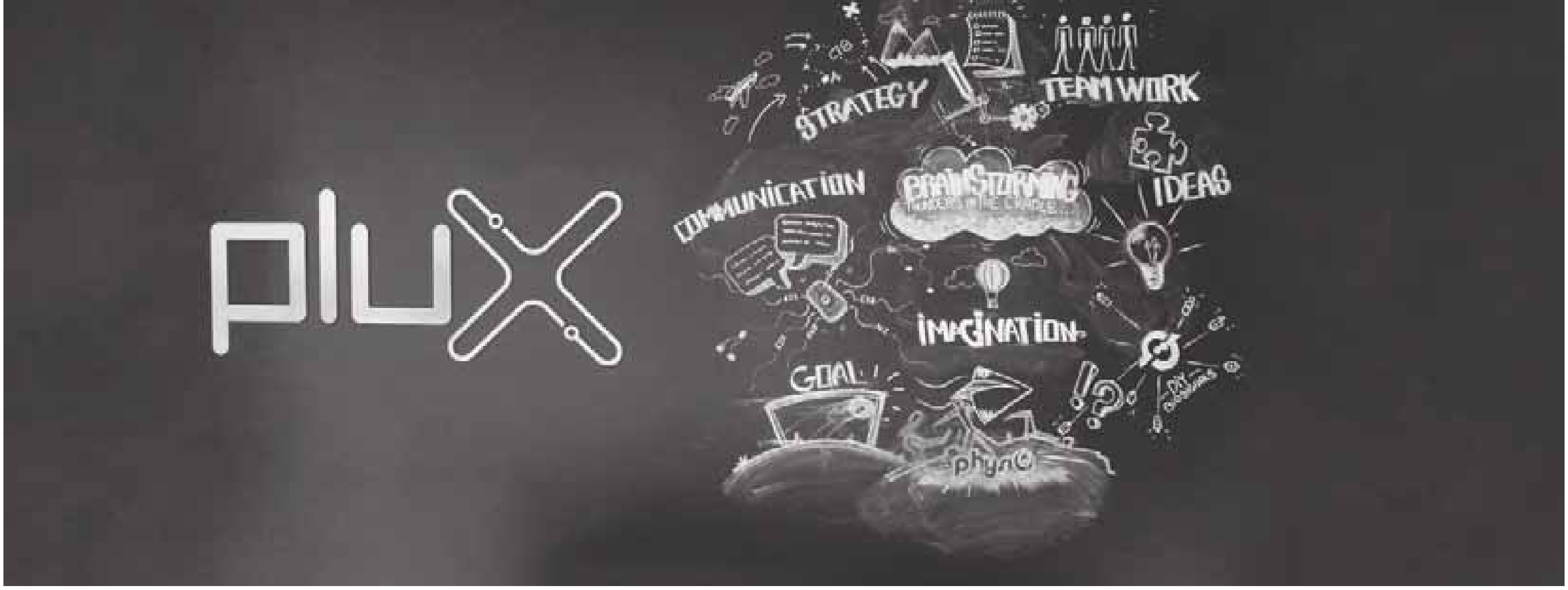
PLUX has been working at the forefront of this frontier that requires knowledge of the scientific principles associated with biosignals and signal processing, allowing us to understand the specific user requirements for the new solutions empowered by smart sensing of biosignals in a unique way.




EEG
Respiration
ECG
EMG
SpO2
EDA
IMU

BIOSIGNAL	HOW IT WORKS	WHAT IS EXTRACTED	WHERE IT IS COLLECTED	HOW TO SAMPLE IT	KNOWN LIMITATIONS
EEG	Measurement of brain electrical activity, voltages corresponding to ionic currents correlated with the activation of neurons	Most studies focus on changes in neural activity observed at the onset of certain stimuli, through changes in the different frequency bands (alpha, beta, gamma, delta, theta, mu) linked to different brain functionalities	Several electrodes placed directly on standard locations on the scalp surface, with EEG caps, EEG headsets and meshes, or single EEG electrodes	The easiest signals to discern are those in the highest frequencies (e.g., gamma band) in event-related potentials. The user must choose a signal that avoids frequency aliasing, and a recommended sampling rate is a frequency of 250Hz	Requires direct contact with the scalp, involves assessment and integration of several channels concurrently and is highly susceptible to noise
Respiration	Monitors the inhalation-exhalation cycles of breathing, as well as supporting sound and speech production	Features include breathing rates, maximum relative amplitude of the cycle, inhale-exhale volume estimation, inhale-exhale duration, and inspiration depth	A piezoelectric breathing sensor or inductance plethysmography belt is usually positioned on the thoracic cavity or on the belly	Relatively slow biosignal, with breathing rates often below 20 inhale/exhales per minute; an applicable sampling rate frequency can be as low as 50Hz	Movement artifacts are prevalent during physical activity. A respiratory inductance plethysmography sensor compensates due to it's localized piezoelectric nature
ECG	Measurement of the electrical activity of the heart	Cyclical activity of the heart, with a well-studied pattern of peaks and troughs, that provides information about the heart functionality	Based on the assessment of electrical potential differences between two locations with a common reference point (lead), with a gold standard of 12 multilead systems	Cycle that comprises the electrical activation of different regions of the heart; a sampling rate of 250Hz is recommended	Needs direct contact to the skin, and is susceptible to motion artifacts and EMG-related interference
EMG	Measurement of electrical activity produced by surface muscles	Time presentation of rapid voltage oscillations with an amplitude range of approximately 5mV	Skin that lies on top of the muscle of interest, along the longest axis of the muscle fiber	A base maximum frequency of EMG is ~450Hz requiring a sampling rate of 1000Hz guarantees integral recording of the signal	Limited non-superficial muscles, and is susceptible to motion artifacts, muscular crosstalk, and power supply noise contamination
SpO2	Local blood oxygenation captured through an optical sensor	Red and Infrared reflection or transmission in capillaries	In a location with large numbers of capillaries such as a finger or ear lobe	Slow physiological variation that can be extracted with frequencies of 50 Hz	Light pollution due to positioning or bad light isolation. On non-capillary locations advanced signal processing is required
EDA	Electrodermal activity (EDA), also known as galvanic skin response (GSR), measures the electrical properties of the skin, linked to the activation of the autonomic nervous system	Activity of the sympathetic (autonomic) nervous system. Given its electrolyte composition, sweat impacts the electrical properties (electrical impedance) of the skin	Two electrodes to monitor changes in electric potential between two locations on the skin; palms of the hand or soles of the feet are typical locations (needs to be in locations with sweat glands)	EDA is a slow physiological signal, and sampling frequencies as low as 10Hz are applicable. Activity peaks usually occur after a few seconds after stimulus exposure (1 to 5)	Since sweating is not only triggered by arousal but also the human thermoregulation system, ambient heat and physical activity monitoring areaspects that limit the applicability of EDA studies
IMU	An inertial measurement unit (IMU) combines accelerometers, gyroscope and magnetometer sensors to measure acceleration, rotation and magnetic field in the three spatial directions	Can access characteristics such as tilt (orientation), changes of direction or number of repetitions in a given movement pattern (e.g. steps)	IMUs as body movement sensors work by means of the different sensors placed on the body part that is subject to study	May vary depending on the objective, ranging from less than 50 Hz for some activity tracking up to 1 KHz for fast vibrations or change in rotation	Signals can be relatively complex to integrate, as magnetometer measurements are prone to disturbances caused from the environment

Table 2 *Biosignal key features*



3 Design and development process

Design methodologies are core components to deliver effective products to the market, that integrate customer needs including scalable production with controlled costs.

Product design and feedback management

Design thinking is a core method for effective product design, evolving from human-centered design perspectives and the rise of design-centered business management in the ‘80s. Tim Brown, CEO of IDEO, the most famous product design consultancy, defines Design Thinking as “a human-centered approach to innovation that draws from the designer's toolkit to integrate the needs of people, the possibilities of technology, and the requirements for business success”[6].

Typical design thinking pipelines include five stages: empathy, definition, ideation, prototype and testing:

1. **Empathy** - The first step consists of learning about the final users and the people who the design is meant to help.
2. **Definition** - The definition step is when the designers develop and evaluate the point of view of the users’ needs and insights.
3. **Ideation** - This is a brainstorming step, which entails proposal of various solutions in order to come up with something new. Then, a filter is applied in order to identify the solutions that meet some predefined requirements.
4. **Prototyping** - The solutions that have been defined as the best alternatives in during the previous steps are prototyped to allow the designer to visualize and evaluate the solutions in the real world.
5. **Testing** - The final stage is to test the solutions by evaluating users’ feedback in the new product.

Each of these steps may involve various techniques and are not fixed. The process iterate through the steps until a final solution is reached and, even then, the process may continue. In cases such as websites and products that allow continued collection of user feedback, designers are challenged to take that feedback into consideration in order to improve the current product, future versions of the current product, or future new products.

So, a critical part in every model is ensuring that feedback by the product owners and/or customers is included into the design and development process. There are different approaches for when and how this feedback is captured.

The following list of models introduces different models for feedback capture, arranged in ascending order relative to feedback loops:

- **Serial models** - these models, as the name indicates, start at one end and finish on the other end without communication. In other words, the project only moves forward and there is no feedback.

- **Ad hoc feedback** - in these models, the project starts at one end, but there is feedback. However, in some cases it may be too expensive to change anything by the time the feedback is received.

- **Concurrent design** - in these models, there is a division of jobs after the detailed design phase, allowing for highly specific teams to focus on each part of the design. In the end all parts are integrated into the solution. These models require a strong component of project management to ensure that all teams are working according to each other and to the detailed design.

- **Holistic models** - in these models all teams collaborate from project initiation instead of only after the detailed design phase. Thus, the lead design team works more to ensure the proper collaboration between teams than on the project itself. As opposed to the other models, this team is responsible for the development of the design through the technical design phase.

While serial and ad hoc feedback models seem too simple, there are cases in which the overhead needed for feedback loops does not pay off in terms of investment. There is no perfect model. Instead, all projects should be evaluated individually to define the best model to use in each case. In short, there is a trade-off between feedback loops of interaction and the costs associated with delivering a project.

PLUX ‘s methodological approach and toolkits

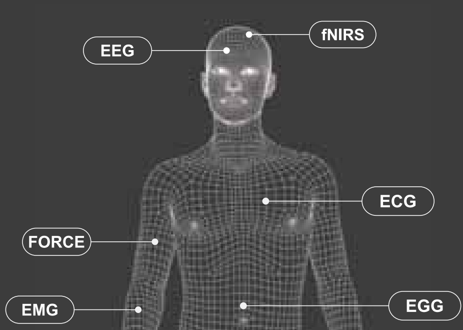
PLUX’s proprietary design and development methodology integrates key design thinking and concurrent engineering design components. These components are aligned with the overall steps needed to specifically generate an end product based on biosignals that include the form factor, hardware, signal processing algorithms, and user-interface software components.

The key aspects are the following:

- From early stages, an emphasis is placed on the intended use case discussion and in defining what sensors to integrate and in how this wearable should look in the end product.

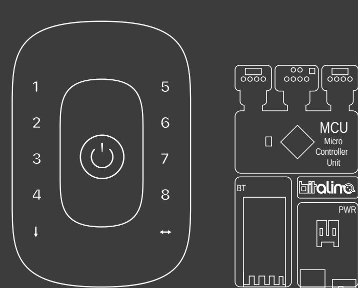
- PLUX then uses its existing toolkits (BITalino and biosignalsplux) to speed up the development process reusing and facilitating the integration between the multiple project components.

- PLUX IP assets can be introduced in real-life product market integration tests, reducing initial investment needs. If tests are successful, a second development loop, with investment focused on cost reduction, can ensure unit costs will meet the product needs.



A long list of available sensors and actuators

PLUX has integrated more than 30 different biosignals to its award-winning acquisition system



Efficient firmware handling data acquisition and wireless transmission

PLUX native devices support highly efficient acquisition processes, of up to 4.000 Hz, and already solve your memory scheduling and wireless transmission needs

Multiple API to integrate in your own software

If you are looking for a highly specialized hardware manufacturer, PLUX can be your partner letting you focus on the SW side of the project

The PLUX five step approach works in the following order:

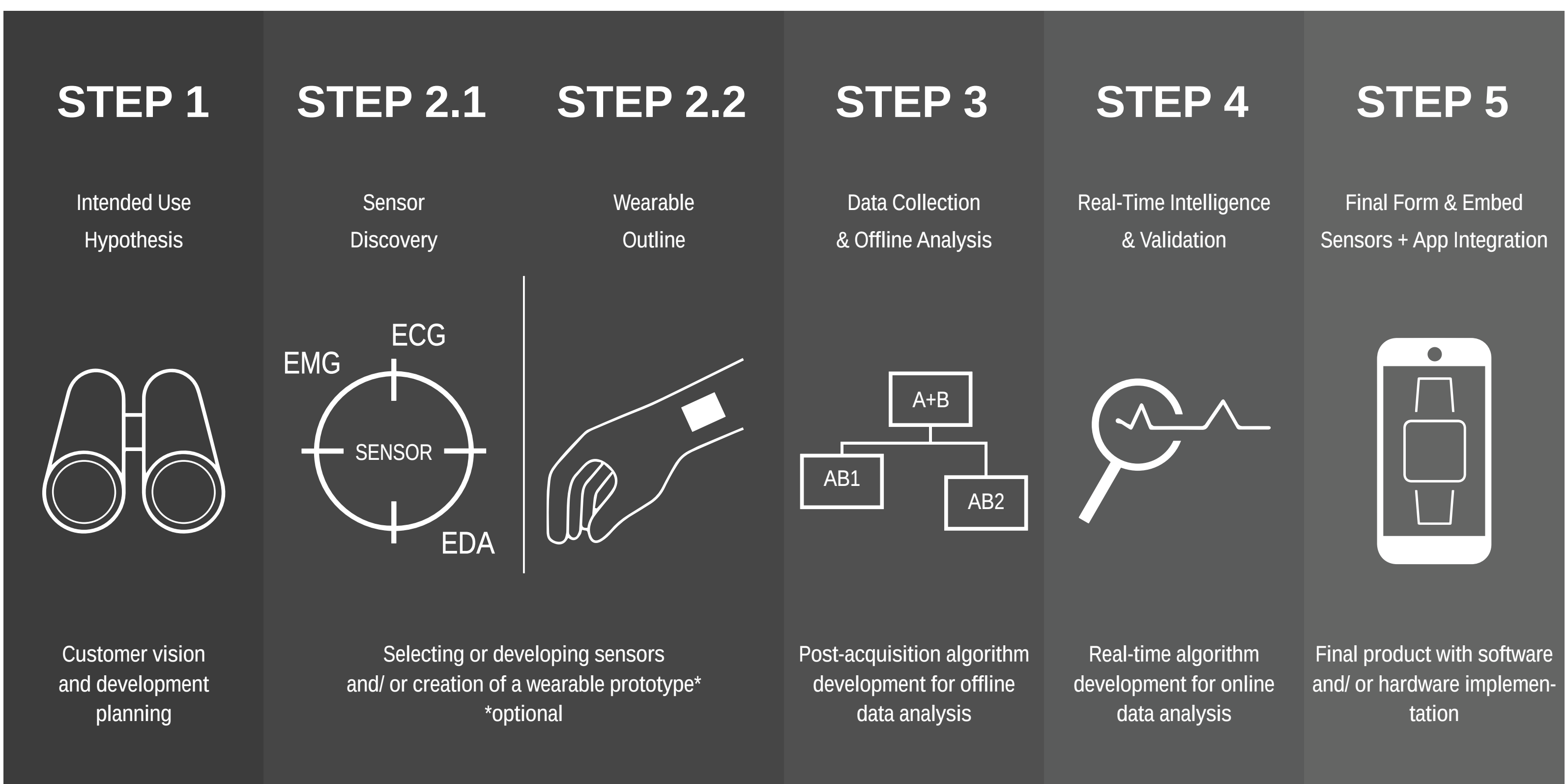
- STEP 1 - In the first step the customer requirements and use cases are captured, with a focus on the intended use and on providing a clear view of the needs that design will need to address.

- STEP 2 - The second step is an ideation step on the biosignals that can be used to address the use case, and the impacts that the use case will have on the wearable technology (e.g., correct location for body placement in order to access the intended biosignals and the impacts of the real-life utilization of the product).

- STEP 3 - In step three the design phase moves into a more technical stage where the objective is to clean and extract data off-line in order to design the feature extraction algorithms that will enable a live product. For developing these intelligent algorithms, a thorough scientific review is needed, with machine learning techniques used to facilitate signal filtering and feature extraction.

- STEP 4 - On step four, these intelligent algorithms are used in real-time situations, so that the final product can be adjusted for day-to-day living, and not be limited to post-hoc investigations.

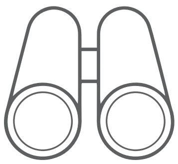
- STEP 5 - Finally, step five is a first early productization stage, where a first real-life prototype emerges, that addresses the intended use that was captured in step 1 with the full solution that was prepared for the design project.




fNIRS

4 Use case example

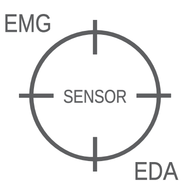
An example of the application of PLUX methodology and assets was the joint development, with Charles River Analytics (CRA), of a new fNIRS sensor that resulted in a patent submission for a portable, durable, rugged, functional near-infrared spectroscopy (fNIRS) sensor [7].



STEP 1 - Intended use case

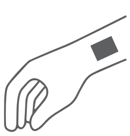
PLUX and Charles River initially iterated on how to improve training effectiveness based on biosignals. The end customer was trainers of US Army medics. Medical personnel may be deployed to operational environments where their success in saving lives depends on their ability to act quickly and effectively. Therefore, it is imperative that medics are trained to the point at which skills transfer to these chaotic and stressful environments. The US military uses high fidelity training simulations (e.g., simulated mass casualty situations) to allow medics to practice skills in realistic situations.

Currently, trainers must infer competence of trainees by observation alone—a challenging task. The goal of this project was to create objective tools to understand student mental effort (i.e., cognitive workload) during training, as a way to develop alternative teaching methods that could ensure that skills were trained to automaticity, no longer requiring high mental effort.

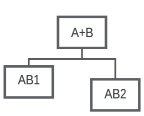


STEP 2 - Sensor discovery and wearables outline

Different sensors could be used to monitor trainees. Charles River's objective was to identify potential sensors to study cognitive awareness, but there was a need to do this without using traditional methods for brain sensing, such as large, obtrusive, and expensive multi-channel laboratory-grade EEG or fNIRS sensors.



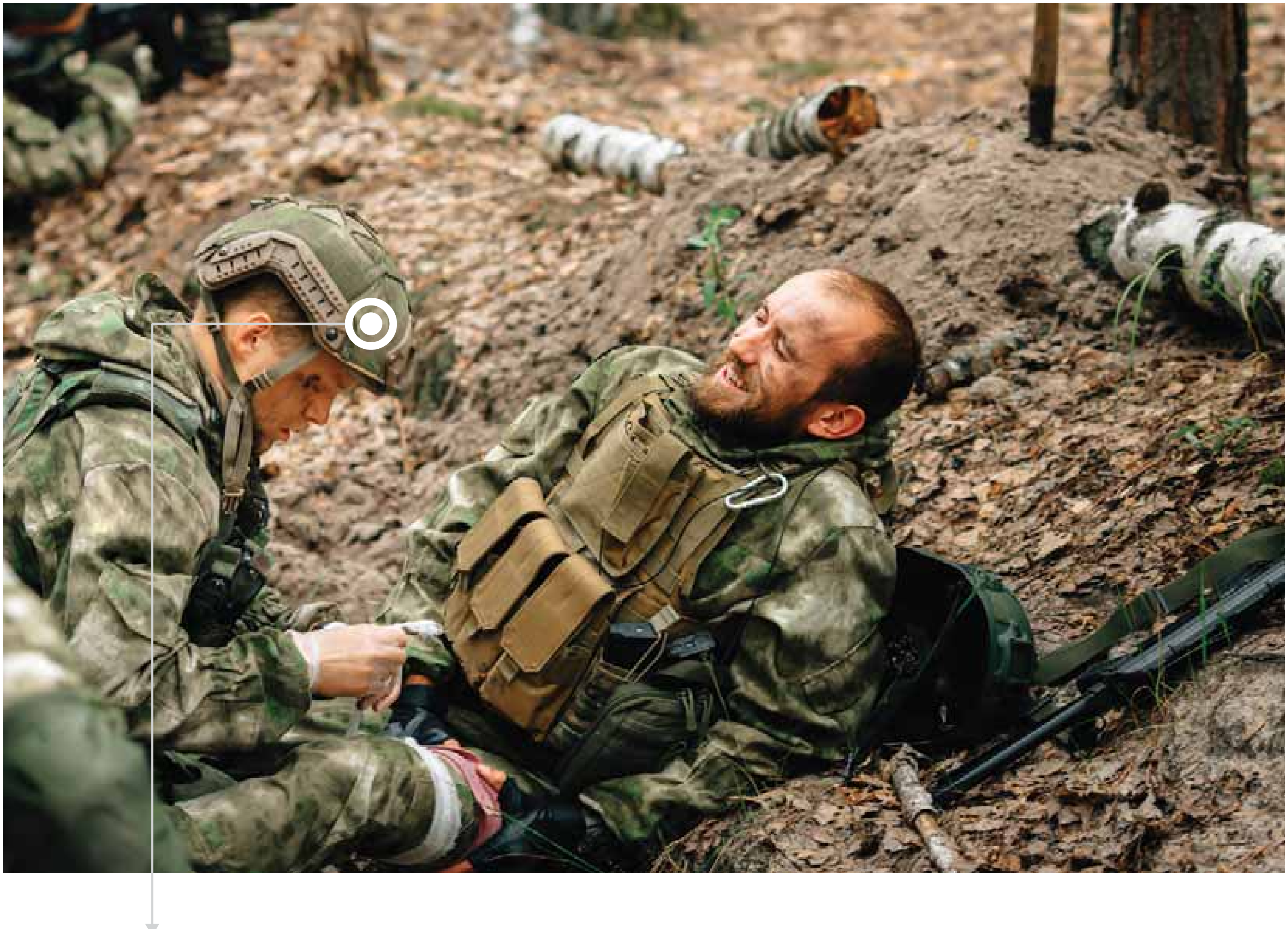
PLUX and Charles River iterated on the design of a single channel fNIRS that could be easily attachable to the head under a heat, surgeon's cap, or helmet. The objective was to produce a sensor that does not require the subject preparation, vis-a-vis an EEG for example, and that its electronics would be small enough to be unobtrusive, portable and ruggedized [8].

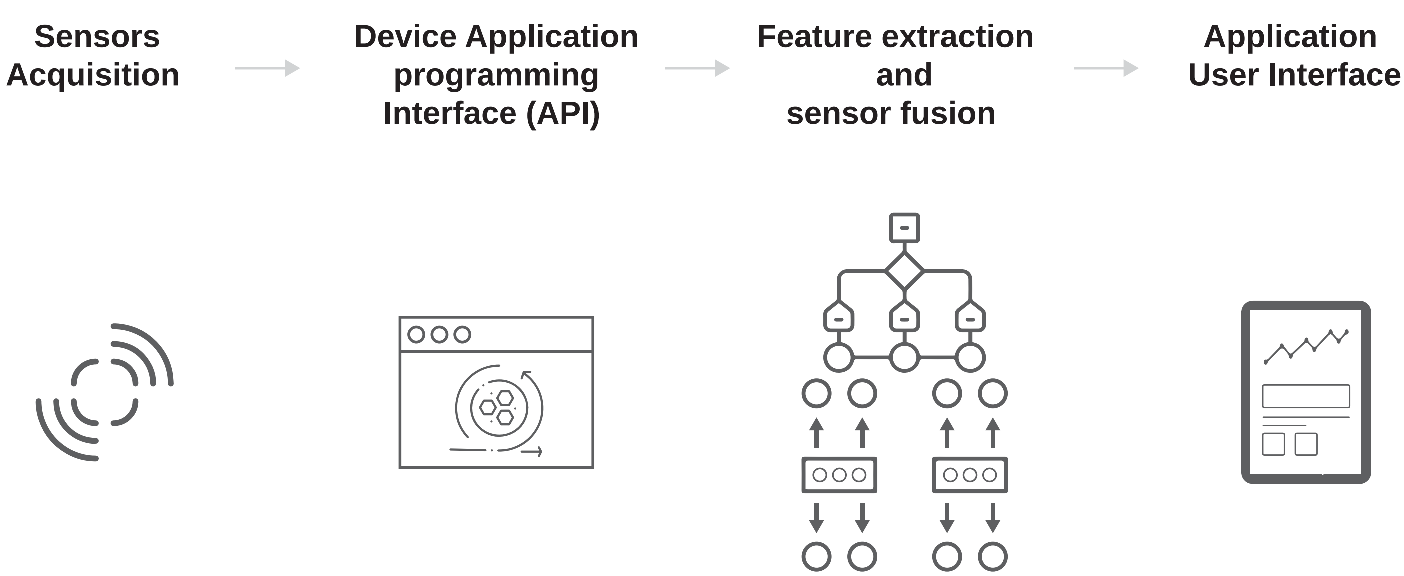


STEP 3 - Data collection and off-line analysis

CRA then was able to use both PLUX's existing Opensignals platform and develop a custom set of API's for signal acquisition and development of the key algorithms for feature extraction. In this collaboration PLUX's main role was to ensure that raw data was being successfully acquired and processed - with feedback loops on sensor design issues that increased data capture accuracy.

MEDIC +





Sensors Acquisition
Device Application programming Interface (API)
Feature extraction and sensor fusion
Application User Interface

STEP 4 - Real time intelligence variation

After studying the best techniques for signal noise removal and feature extraction, Charles River was then able to develop real-time algorithms for feature extraction based on the initial sensors prototypes.

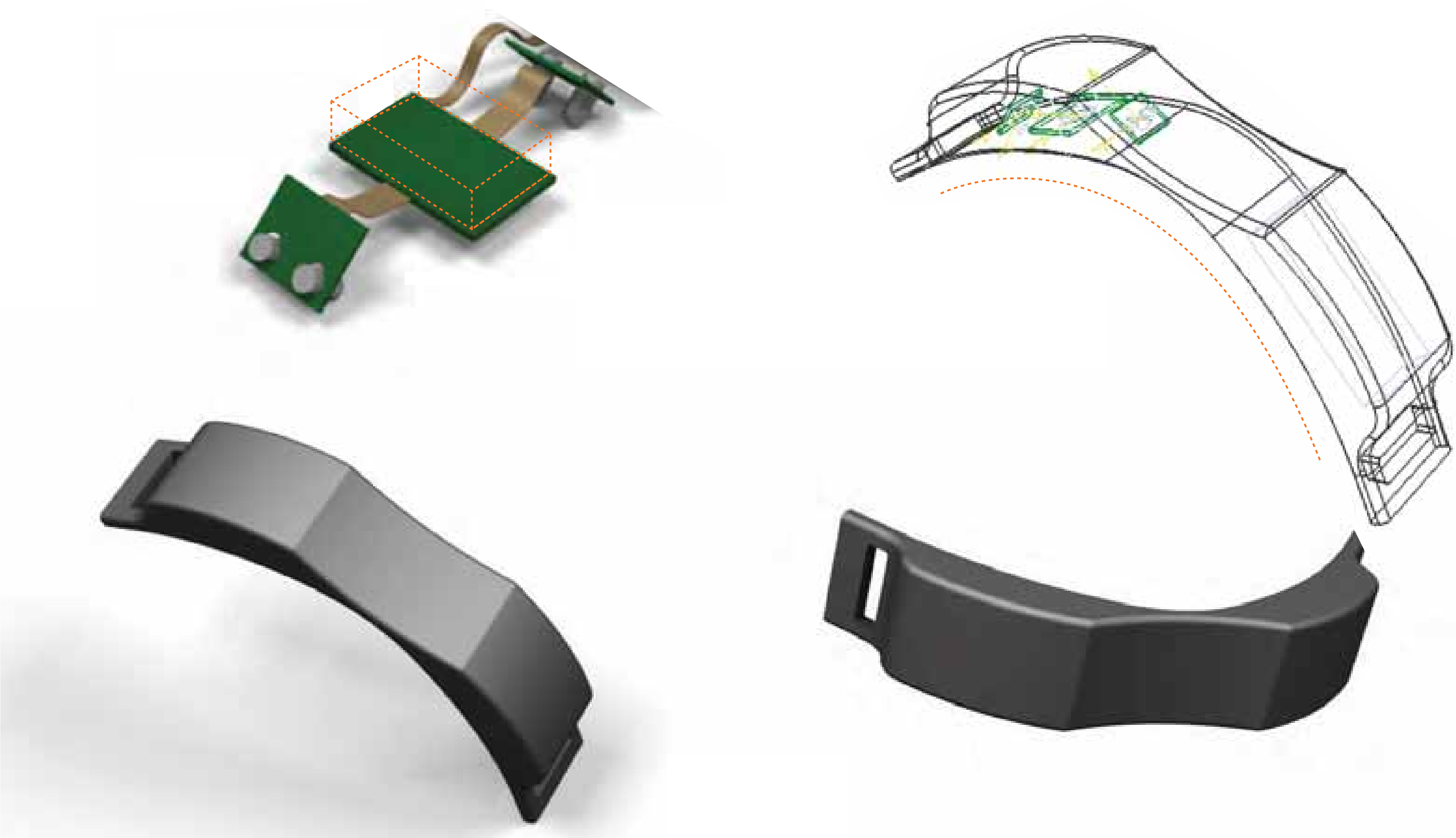
Scientists and software engineers at Charles River Analytics developed Sherlock™, an open and extensible platform that can perform real-time monitoring of performance-relevant constructs, such as cognitive workload, using techniques as data-driven probabilistic models and deep learning architectures and techniques (e.g., convolutional neural networks) [9].

STEP 5 - Final product

This combined effort between Charles River and PLUX generated a jointly owned solution, the fNIRS Pioneer™ [10], that has been commercially deployed to 18 public and private research groups, in 10 different countries.

Additionally Charles River was able to explore its Sherlock™ software in other human sensing projects, such as CAPT PICARD, where it has supported the North American Space Agency (NASA) into developing solution to measure, assess, and predict cognitive workload to assist astronauts or mission control in responding more effectively [11].

PLUX and Charles River iterated on the design of a single channel fNIRS that could be easily attachable to the head under a heat, surgeon's cap, or helmet. The objective was to produce a sensor that does not require the subject preparation, vis-a-vis an EEG for example, and that its electronics would be small enough to be unobtrusive, portable and ruggedized [8].



5 Conclusions

The methodologies and toolkits developed by PLUX provide public and private R&D teams with strong bases to develop their biosignals related projects.

These same toolkits and knowledge have already received significant market recognition, as PLUX deployed systems to hundreds of R&D facilities worldwide, including over 40 of the world's top 100 universities in the Times Higher Education ranking [12].

In the described use case PLUX helped Charles River develop an innovative asset to assess cognitive workload, with reduced project risk, producing a solution that was market oriented and able to scale for further growth.

PLUX believes that, by developing additional R&D collaborations with new, public and private, organizations it will fulfil its mission to support the world learn and use biosignals in everyday solutions.

About PLUX

PLUX was created in 2007 with the ambition of helping the world access human biosignals to improve solutions for health, research and, overall, simplify human-computer interaction scenarios.

During its journey PLUX has been able to collaborate in multiple innovative research projects in a growing number of science fields that use biosignals as key data to improve human health, performance or to expand the frontiers of knowledge on biosignals.

Today PLUX develops biosignals acquisition systems applied in hundreds of R&D facilities worldwide to boost their work. Among our staff we hold competencies in electronic design, biomedical engineering, signal processing, cloud development and machine learning.

Benefit from our award-winning wireless and modular multi-sensor platforms by developing custom solutions based on our experienced team and field-proven solutions.

About Charles River Analytics, Inc.

Since 1983, Charles River Analytics has been delivering intelligent systems that transform our customers' data into mission-relevant tools and solutions to support critical assessment and decision-making.

Charles River continues to grow its technology, customer base, and strategic alliances through research and development programs for the DoD, DHS, NASA, and the Intelligence Community.

We address a broad spectrum of mission areas and functional domains, including sensor and image processing, situation assessment and decision aiding, human systems integration, cyber security, human-robot interaction, and robot localization and automation.

These efforts have resulted in a series of successful products that support continued growth in our core R&D contracting business, as well as the commercial sector.

About Authors

Hugo Gamboa founded PLUX in 2007 together with 4 other partners and has grown the company from an individual research project to product medical device company with growing international sales. PhD in Electrical and Computer Engineering from Instituto Superior Técnico, University of Lisbon.His thesis entitled "Multi-Modal Behavioral Biometrics Based on HCI and Electrophysiology" presents new behavioral biometrics modalities which are an important contribute for the state-of-the-art in the field).
From 2000 to 2007 he was a Professor at Escola Superior de Tecnologia de Setúbal, where he taught in the field of Artificial Intelligence. In recognition of his work by the European Biometric Forum, he was among the three finalists of the EBF Biometric Research Award 2007. In 2008 he was the winner of the Portuguese National Award “Futuras Promessas” ISA/Millennium BCP, granted to the best PhD thesis on Physics, Electronics, Informatics or Biomedical Engineering fields. He is currently an Assistant Professor at Universidade Nova de Lisboa, collaborating as a researcher at LIBPhys, Laboratório de Instrumentação, Engenharia Biomédica e Física das Radiações and in the Fraunhofer Institute in Lisbon as a Senior Scientist.

Manuel Pacheco is the CEO of PLUX, responsible for corporate strategy and business development. He previously worked as a Principal, Project Leader and Consultant in the Boston Consulting Group, and prior to this role he was a consultant for IT and process engineering at Accenture. He holds an MBA from the Lisbon MBA program, in collaboration with MIT, and is a BSc in Economics from Nova School of Business and Economics.

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Rui Varandas is a Research Biomedical Engineer enrolled in the support of R&D projects at PLUX. He is an Msc in Biomedical Engineering from Faculdade de Ciências e Tecnologia, Universidade Nova de Lisboa and a PhD student at the same faculty in collaboration with PLUX and LIBPhys, Laboratório de Instrumentação, Engenharia Biomédica e Física das Radiações.

Bethany Bracken is a Senior Scientist at Charles River Analytics. Throughout her career, Dr. Bracken has used a variety of behavioral, physiological, cognitive, molecular, and neuroimaging methodologies to answer questions about the neurobiology of human and animal behavior. At Charles River, she currently leads multiple research and development efforts involving neurophysiological and physiological sensing methods to assess human states such as stress, focused attention, and cognitive workload and to predict upcoming performance deficits. Dr. Bracken has a B.S. in Psychology from Clarion University of Pennsylvania, and a Ph.D. in Neuroscience from Brandeis University in Boston Massachusetts. Before joining Charles River Analytics, Dr. Bracken completed a postdoctoral fellowship, quickly followed with a promotion to the faculty level, in the department of Psychiatry at McLean Hospital and Harvard Medical School.

Abbreviations and acronyms

API - Application Program Interface

DHS – Department of Homeland Security

DoD – Department of Defense

ECG - Electrocardiography

EDA - Electrodermal Activity

EEG - Electroencephalography

EMG - Electromyography

EOG - Electrooculography

fNIRS - Functional Near Infra-Red Spectrography

HCI - Human Computer Interaction

IMU - Inertial Measurement Unit

IP - Intellectual Property

NASA – National Aeronautics and Space Administration

R&D - Research and Development

SpO2 - Peripheral capillary oxygen saturation

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[10] **fNIRS Pioneer product** (https://plux.info/kits/438-fnirs-pioneer.html)

[11] **NASA Awards Charles River Analytics Additional Funding to Improve Astronaut Mission Readiness** (https://www.cra.com/company/news/nasa-awards-charles-rier-analytics-additional-funding-improve-astronaut-mission)

[12] **PLUX** university customers list matching the Times Higher Education top 100 universities in the World University Ranking of 2018