PROJECT ACRONYM

CUPIDO

PROJECT TITLE

Cardio Ultraefficient nanoParticles for Inhalation of Drug prOducts

Deliverable 2.5

Wearable devices for usage on mini-pigs (M24)

CALL ID			H2020-NMBP-2016-2017
GA No.			720834
MAIN CONTACT			**Matteo Santoro** Email: matteo.santoro@x10y.com
NATURE	Report (R)	DISSEMINATION LEVEL	PU
DUE DATE	31/01/2019	ACTUAL DELIVERY DATE	20/02/2019
AUTHOR(S)			Matteo Santoro and Alessandra Leonardi

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 720834.

Table of Revisions

REVISION NO.	DATE	WORK PERFORMED	CONTRIBUTOR(S)
1	16/01/2019	First Version Released	Matteo Santoro, Alessandra Leonardi Alessandro Faragli
2	16/01/2019	Revision	Daniele Catalucci
3	28/01/2019	Revision	Consortium
4	31/01/2019	Revision & Approval	IPR Team
5	07/02/2019	Approval	Ethics Board
6	19/02/2019	Approval	CCG

Table of Contents

Index of Figures and Tables

1. Executive summary

D2.5 reports on the activities carried out within the WP2 to design and develop dedicated wearable devices required to measure physiological parameters on mini-pigs. These wearable devices are crucial to obtain quantitative evaluations of the effectiveness of the new treatment developed by the CUPIDO Consortium. The results obtained – and described hereafter – required the collaboration between L.I.F.E. Italia and Charité – University Medicine Berlin.

We performed the early tests and the official evaluation of the measurements on healthy, untreated mini-pigs. The quality of the data acquired is good and we are confident to be able to detect all the events occurring during the daily activities of the mini-pigs, and thus we are ready to start the trials in line with the official schedule.

The first prototypes are ready to be delivered by the end of M24 as planned at the beginning of the project. A more accurate agenda of the provisioning to Charité will be discussed and decided in collaboration with other partners according to the development stages reached in the relevant WPs.

The current version of the Deliverable D2.5 is public and contains only a few details. A more complete description of the system is present in the confidential version of the same document. Hereafter, we provide a short description of the work in order to prevent the dissemination of reserved information useful to patent part of the work.

2. Initial Input Requirements

LIF collaborated with CHA in order to define the specifications of a wearable device for non-invasive cardiopulmonary monitoring in mini-pigs. A joint meeting has been organized in Berlin – followed by a number of subsequent conf-calls – in order to better understand the scenario and the functional requirements for the device. The key high-level features of the systems have been defined accordingly and a first sketch of the overall architecture and single modules comprising the wearable systems has been designed.

A second version of requirements has been finalized in collaboration with the clinicians, from which we collected insightful inputs. Initially, a further important input from the clinicians was related to the duration of the battery in order to have 3 full days of continuous data acquisition. However, that is very challenging from a technical viewpoint, mainly because of the size of the case to contain both the logger and a high-capacity battery that can last for more than one full day of acquisition. The number of signals to be collected is high and some technological constraints that we have on our devices do not allow to guarantee more than one full day of acquisition. Therefore, we decided to discard this from the necessary features.

The design and production of the device shall also consider that the pigs tend to remove everything they have on.

3. Product Requirements and Specifications

After the initial gathering of the input requirements to the design phase, we moved on to create the first formal version of the functional requirements for the prototypes. Specifics are not detailed due to IP protection.

4. Garments and Sensors Design

The design of the garment has ben split in two different phases. First, we produced a prototype with the key functional requirements and tested the actual feasibility of using it on real pigs. The layout has been modified after some initial tests on real animals. Some changes are due to a further feedback from our colleagues clinicians, after they performed initial testing acquiring ECHO images.

The final design and specifications have been used to manufacture a first prototype to assess the usability requirements. The device is easy to put on conscious.

In order to further assess the usability of the system, dedicated tests on live animals have been performed in June at Ellegaard Göttingen Minipigs (Danemark) on two mini-pigs with a weight and size compatible with the prototype (25-30 kg).

The animals wore the device and were free to sit or walk around the laboratory for some minutes. The first tests confirmed that a skin shaving procedure, in correspondence of the electrodes, is fundamental for the acquisition of a good signal.

Figure 1. Shaving procedure.

5. Data Logger

The core part of the system is represented by a battery-powered electronic data device equipped with a suitable version of a general-purpose Operating System. As stated above, the details of the logger have been removed from this document due to IPR strategy.

6. Prototype Testing

In order to keep the design and development constantly tied to the final user requirements, we decided to create a simulated environment to create ECG signals on the initial prototype and assess the effectiveness of the sensor network. A suitable setup has been prepared for the bench tests with the support of an ECG simulator.

The following batch of tests has been organized to understand if our sensors are adequate to acquire signals on healthy and conscious animals.

As mentioned above, tests have been performed at Ellegaard Göttingen Minipigs (Danemark). The acquired data are high quality both when the animal was standing or walking around. The visit to Ellegaard facilities has been useful to collect information on mini-pigs and their habits, and better understand if and how to improve the usability of the garments and the possibility to develop different sizes for the garment.