PROJECT ACRONYM

CUPIDO

PROJECT TITLE

Cardio Ultraefficient nanoParticles for Inhalation of Drug prOducts

Deliverable 2.6

Wearable devices for usage on mini-pigs (M36)

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Table of Revisions

REVISION NO.	DATE	WORK PERFORMED	CONTRIBUTOR(S)
1	02/12/2019	First release	Alessandra Leonardi
2	03/12/2019	Revision	Daniele Catalucci
3	07/01/2020	Revision	Ethics Board
4	13/01/2020	Revision	CCG
5	20/01/2020	Revision	IPR Team
6	28/01/2020	Formatting	Paulina Piotrowicz

Table of Contents

1. Executive summary

D2.6 reports on the activities carried out within the WP2 to test and improve dedicated wearable devices described in D2.5. The effectiveness of the new treatment developed by the CUPIDO Consortium can be evaluated quantitatively via continuous cardio-respiratory monitoring, enabled by these wearable devices.

The prototype described in D2.5 was tested on mini-pigs with implanted pacemakers (PM). The mini-pigs were then paced for a period of at least 4 weeks to induce a heart failure. Each test was supposed to last 24h, but mini-pigs could not bear to wear the wearable device for such a long time. As suggested by CHA staff, we heavily modified the design, obtaining a new version of the prototype that is now well tolerated by mini-pigs. Little optimizations are still ongoing.

Concerning device realization: 6 old version prototypes have been realized and delivered, but they are no longer usable; 6 new version prototypes are almost ready to be delivered by the end of M36. The agenda for further future delivery to Charité will be discussed and decided in collaboration with the other partners and according to the development stages reached in the relevant WPs.

The current version of the Deliverable D2.6 is public and contains only a few details. 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.

Key deliverable achievements:

1. On field test and evolution in prototype design
2. Realization and delivery of device based on new design
3. Software implementation

2. Cooperation between participants

The results obtained – and described hereafter – required the collaboration between L.I.F.E. Italia S.r.l. and Charitè Universitätsmedizin Berlin.

3. D2.6 Wearable devices for usage on mini-pigs (M36)

3.1. New prototype design and testing

Poor results were obtained in long term testing (24h). With the aim to facilitate wearing procedure the layout of the prototype has been heavily modified by minimizing the surface area in contact with the body of the animal and maintaining the number and the position of the sensors. Prototypes have been realized in two sizes: 20 kg and 25 kg. A third size (30 kg) will be realized.

Long term tests on live animals have been performed at Charitè Universitätsmedizin Berlin (Berlin) on two mini-pigs with a weight and size compatible with the prototypes (20-25 kg). Operators were able to wear the device both on sedated and conscious animals. Tests confirmed that a skin shaving procedure, in correspondence of the electrodes, and electrolytic gel use (once a day) is fundamental for the acquisition of a good ECG signal.

Minimal changes of the prototype are ongoing on the basis of feedback received from our clinician colleagues. The design will be finalized by the end of M36.

3.2. Software implementation

The device includes software components with two main objectives: 1) Real time data visualization to assess quality of the signal before starting the 24h recording; 2) Automated analysis and data export in EDF format.

Real time data visualization software is a standalone proprietary software, available for Microsoft Windows platform (32bit, 64 bit). The graphical user interface (GUI) of the software allows to visualize the signal recorded by the wearable device and to manage the start of a new acquisition.

The tool for the execution of automated analysis is implemented in Python, available for Microsoft Windows platform (64 bit). Automated analysis provides the estimated trends of heart rate and respiratory rate based on ECG and respiratory signals collected by the device. The possibility to estimate the trend of activity based on accelerometer data is under study.

The export function in EDF format is included in the above described tool. The European Data Format (EDF) was chosen because is a simple and flexible format for exchange and storage of multichannel biological and physical signals and it is compatible with many visualization software available on the market. EDF file can be opened with LabChart software, currently used by many research centers.