

1 - Executive Summary BREATH U

1.1 Relazione tra Business Idea, contenuto tecnologico e Università

This idea was born as a thesis project in Biomedical Engineering by one of the team members, Alessandro Pellegrino. The scientific feasibility of the project was extensively discussed and demonstrated in this thesis.

The idea was selected to participate in the Contamination Lab of Trieste 2019, where it was fully understood, expanded, discussed and finally realized in a first prototype. With the help received in such a various and professional context is the Contamination Lab, it was possible to study, evaluate and finally develop the economic feasibility.

This project, as well as being supervised by university professors from the University of Catanzaro and the University of Trieste, was presented to some doctors at the Burlo pediatric hospital in Trieste (IRCSS), where a possible collaboration is being negotiated.

1.2 Sintesi del progetto imprenditoriale

Problem: The monitoring and analysis of bio-signals play a fundamental role in the medical-diagnostic field. Indeed, it is precisely with this basis operations that it is possible to arrive at the diagnosis and therefore be able to schedule a therapy. Also, monitoring and analysis are very important especially for the prevention of patient health.

Product: The project consists in a CE certified portable medical device, capable of monitoring various vital parameters related to breathing through a smartphone application. The device is a clip that is inserted on the trousers and through the movements that take place in the abdominal region, and it's able to extrapolate and analyze the values related to breathing. Breath-U provides fundamental data for a thorough medical analysis, such as: respiratory rate, duration of breath, duration of the inspiratory phase, duration of the expiratory phase.

Market: According to the "WEARABLE MEDICAL DEVICES MARKET - GROWTH, TRENDS, AND FORECAST (2019 - 2024)" Report of 2019, the key to the growth of the global market for wearable medical devices is the improvement of the lifestyle of patients, and of the population in general. Currently, these devices are gaining enormous popularity, thanks to the improved technologies that are introduced every day by the main companies in the market.

State of development: a first version of the prototype has already been completed; the construction of the second version is currently in progress. As already mentioned above, the idea has already been presented to specialist doctors who have highlighted its usefulness and potential.

Competitors and competitive advantage: The main competitors are AngelCare, BabySense and Nanni products (CE certified medical device). The key value driver of the start-up is also its main advantage for the end consumer; functionality, once again, the software inside the device can process the data that the competitors ignore.

Team management:

1. **Alessandro Pellegrino (Founder and CEO): (25 years)** Provides the guidelines for management and appears to be an essential figure being the one who designed and distributed the product in question. Bachelor's Degree in Biomedical Engineering, nearing the completion of the master's degree in Clinical Engineering. Experience as a Java programmer.
2. **Marco Martire (CFO - Financial Director): (29 years)** He takes care of all the responsibilities related to the flow of money and other activities, using the deep understanding of the laws, regulations and procedures concerning finance. Master's Degree in Economics and Management, Master's Degree in Business Administration (MBA) from the Real Madrid football club. He is fluent in English, Spanish and Portuguese. He has had several experiences abroad. He currently works at a trading company located in Prague.
3. **Valeria Bortoletto (Sales and Marketing Director): (23 years)** It's the figure who, within the company that coordinates the team of experts and technicians who regulate all the promotion operations for development and maintenance on the market of a product or service, being a small company, it also deals with sales. Bachelor's degree in economics and management from the University of Trieste. He is currently attending a master's degree in Copenhagen.

Risks and protections /legal defenses: The main risks are those related to the use of a first-class medical device, which by definition is low-risk. However, once the CE certification is obtained, the risks (mainly due to malfunctions or false positives / negatives) will still be very low, and producing a good user manual and specifying the intended use well will produce solid legal defenses.

Milestones: **1)** obtain the CE certification of the device within one year. **2)** set up the company and start selling the device. **3)** development of a device that is useful for athletes aimed at improving sports performance

Summary of economic plan of the company: The initial investment amount is, related to start-up costs and production costs in the year 2020, € 50.440.

The change in Ltd company and the consequent capital increase is expected at the end of 2021.

In the two-year period 2022-2023, it intends to launch a wider marketing operation both device, outsourced product, and of intellectual property.

Once the first stock of products has been produced, which should amount to around 600 pieces with an investment of € 50,000 to be sold at a cost of between € 120-180, the financial coverage will be guaranteed by the proceeds from sales and consultations offered to others. companies. The main object of the consultancy that Breath-U intends to offer concerns the CE certification of first-class medical devices.