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SAM – Simulation Airways Models.

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Abstract: SAM is a digital and material tool for advanced training in interventional pneumology. This idea combines the design culture to the specialized disciplines of pulmonology. The research aims at achieving three major design goals such as interactivity, performance and traceability of educational processes. SAM consists in a navigable 3D model of the human airways. The process facilitates the pulmonary physicians in their didactic training course and in their skills' acquisition through realistic simulation. These skills are traced and then evaluated in different simulations such as clinical case histories. SAM includes video animation, application of augmented reality to the model, a design model for dummies and a mediastinal and bronchial plastic model with support base. All these systems are managed by a specific App. SAM can be applied to each apparatus and pathology and it's a modular and modifiable tool that could be applied for any training needs and situation.

Keywords: health design, simulation, product design, pneumology, interaction design, smart materials.

1. Introduction

Thanks to the innovative opportunities offered by design, there is now the opportunity of collecting lots of data and to process them to supply some feedback that will lead to the realization of a new, better, relationship, with the patient. In the current landscape the rapid technological progress offered by design has reached unprecedented achievements in scientific knowledge, recording a multiplicity of very different images which interlace two-dimensional and three-dimensional. The real body is compared with its digital clone and lends itself to animated introspection of endoscopic

analysis that medicine realizes on a living body, showing through the videos what generally we can't see (Ciammaichella, 2015). The medical imaging allows us to see our body's organs and systems in four dimensions (three spatial and one temporal). Now for the first time in the history of medical clinic, we're able to observe by dynamic-interactive monitoring in a three-dimensional space, the structures and functions of the human body (Combi, 2000). In this way the most advanced methods of digital representation manifest themselves in different modern design practices and do not respond solely to document the medical and scientific discovery, but they are addressed toward the definition of aesthetic and formal solutions induced by digital technologies, which cohabit and at the same time shape a figure in constant transformation. (Ciammaichella, 2015). Therefore, "It no longer makes sense considering the body like a social or psyche place, but rather a structure to control and modify. The body not as a subject but as an object, not as an object of desire, but as the subject of redesign. It is no longer of any benefit to remain human or to evolve as a species, the evolution ends when the technology invades the body "(Sterlac, 1994).

Currently the majority of learning in medicine is structured through two poorly effective ways, consisting in a program of frontal lessons and learning 'see one, do one, teach one', with little theory and little practical experience. The Practice Centre or Boot Camp, where training takes place through a gradual process from theory to practice -using the Live Sessions and simulation- can provide an effective training, according to the current needs of the competence improvement and the professional upgrade.

The concept of 'learning by doing' is no longer acceptable, especially when we consider invasive and risky procedures for the patient. Recently, the learning processes switched to a more complex and detailed model - but also more effective - centered on 'See one, simulated many, do one competently' and possibly 'teach everyone'. This change has led to the development of simulation tools, able to increase and facilitate hands-on learning as well as to expand the educational growth of students. (Epstein, Hundert 2002)

The training in Interventional Pulmonology should therefore be organized in four phases:

1. The theory phase, which still involves the use of new teaching methods, more interactive, such as simulation of pathological case studies, the use of video animations, material and interactive 3D printed device, all provided from Sam;
2. The practice phase with simulators Low & High Fidelity (artificial models, animals, virtual reality exercises on the corpse). This phase could also provide traceability of educational processes and procedures carried out by the learner, very important references to assess learning specialist and as a tool for a self-evaluation;
3. The practice phase on the patient with the supervision of a tutor, on the basis of the learning curve of each specific procedure and individual performance;
4. Assessment quantity and quality of the acquired competence, and final certification. (Fielding., Maldonado, Murgu 2014).

2. SAM, the project

SAM - Simulation Models Airways is a 'digital and material' tool aiming at training scientific researchers and professionals in the field of interventional pulmonology. This experimental project, created by a process of cross-fertilization between the scientific area of the design and that of

Interventional Pulmonology, combines the design culture and the specialized know-how of the experienced interventional pulmonologist.

SAM is built has three main design goals such as interactivity, performance and traceability.

Interactivity in SAM is outlined by the fact that the real model of the trachea, bronchi and mediastinum covered with E-skin interacts with the App on smartphone or tablet. In fact, going to select the anatomical terms subject of interest on the device, these will light up together on the real model too, allowing the user to learn the anatomy in a clear and direct way with a simple click. In addition, the interactivity between the E-skin and the device is useful in indicating the placement of the various lymph node stations, located outside of the trachea and bronchi. These lymph nodes are very numerous and they're very important for doctors who have to do a bronchoscopy because they must be identified with certainty and without hesitation to proceed with the removal of organic material. In the simulation of a bronchoscopy, the E-skin is placed as an aid to indicate, by lighting, the area where is externally located a lymph node that needs to be biopsied. E-skin also gives out a corrective feedback in the case of, simulating a biopsy or a needle aspiration, We are erroneously going to sting, for example, the aorta instead of a lymph node, a circumstance which would produce internal bleeding in the patient.

The idea of the interface of the App is not based on the contortion of those present on the market, but rather on the correction of some of their characteristics and on adding new, essential elements with the aim to improve and extend the overall performance, by providing a user-friendly and greatly simplified graphical interface.

Regarding traceability, the E-skin allows to list, in connection to the App on device, vital parameters and to report a map of the various carried out procedures, both those exact and incorrect ones, a sort of "electronic notebook", of diary, so that we can constantly recheck our growth path in the formation of our skills. In this way, the teacher himself can control, through the App, the progress and the most common mistakes committed by its learners.

The device involves the production of a three-dimensional parametric model of the respiratory system, a simulation tool aim at effectively facilitating the pulmonologist doctor/researcher in his training on the anatomy of the trachea, bronchi and mediastinum. The path of competences acquisition is then developed through simulation processes.

One of SAM main usage regards the training on the execution of bronchoscopy and eco-bronchoscopy. Both of these medical tests are essential in minimally invasive diagnostic process about respiratory diseases with extremely complex instruments, especially in the case of bronchoscopy with ultrasound (EBUS EndoBronchialUltraSound) (VanderLaan, Wang, Majid, Folch 2014).

In fact, SAM includes video animations for teaching, the application of augmented reality to the model, a project of three devices and finally the design of an application for smartphones and tablets.

1. The video animations have been created for educational purposes, aiming at showing from different points of view the multiple body parts, their morphology and the relationships established between them. These animations are extremely useful to the respiratory specialist, because the process gives a complete overview on the interested body's part. Otherwise, it would be very difficult to focus on specific sections through traditional study, based on texts and two-dimensional images. In the

absence of this innovative methodology, the specialist could have a clear and complete overview on the interventional topics only after several years of study and practice.

2. The reproduction of body sections through an augmented reality model is aiming at facilitating the understanding of the anatomy and chest storage, preparatory phase to the procedural training.

3. The project also includes three devices, two active and one passive:
The passive device is the realization of a disposable dummy that can be engraved to allow medical professionals to practice in drilling operations in the tracheal tract. The shapes of the active devices are covered by E-coated skin, an electronic skin that mimics human skin, able to light up. These dynamic devices are two, one is a model trachea, bronchi and mediastinum on a suitable support base, and in which the E-skin supports the learning process and the innovative procedural training. The third and last device is also active, it consists in a dummy internally coated with E-skins. By equipping phibro-bronchoscopy (Casalini 2007), beyond that of their usual functions, also of a probe capable of interacting with the E-skin, this is able to send both auditory and visual feedback corrective procedures performed incorrectly. A red light and a sound s show the error or errors committed by providing traceability of the training process. As part of the training on a dummy, through the self-illumination of which it is capable, the E-skin is useful in indicating the positioning of the different lymph node stations, located externally to the model trachea, bronchi and mediastinum. These lymph nodes must be identified with certainty and without hesitation to proceed with the removal of organic material and so as not to cause injury to the patient. In the simulation of bronchoscopy, the E-skin is therefore at as an aid to indicate, by lighting, the level of the area which is located externally to the trachea a lymph node that needs to be biopsied.

4. The Active Device talks through an App that presents attractive graphics and greatly simplified compared to the existing ones. The design idea of the app is not based on the distortion of those on the market, but rather on the correction of some of their features and adding new ones, essential elements with the aim to improve and broaden the overall performance.

For example, going to click on the button E-skin of the App, a menu appears allowing, by simply selecting the anatomical terms of the object of interest of organs tablet or smartphone, to do enlighten those bodies in the real model. As mentioned above, in fact, the electronic skin is able to light up in different colors. Then, associating each term of the device to the corresponding part of the body in the real model of the mediastinum and bronchi, the user would be able to learn anatomy in a much more clear, rapid and direct than current learning methods. E-skin is also suitable for listing, also on the tablet device or smartphone, vital signs and signaling map out the various procedures carried out, both those exact that the wrong ones, a kind of 'digital notebook', diary, so that we can constantly rechecking its growth path in the formation of its powers.

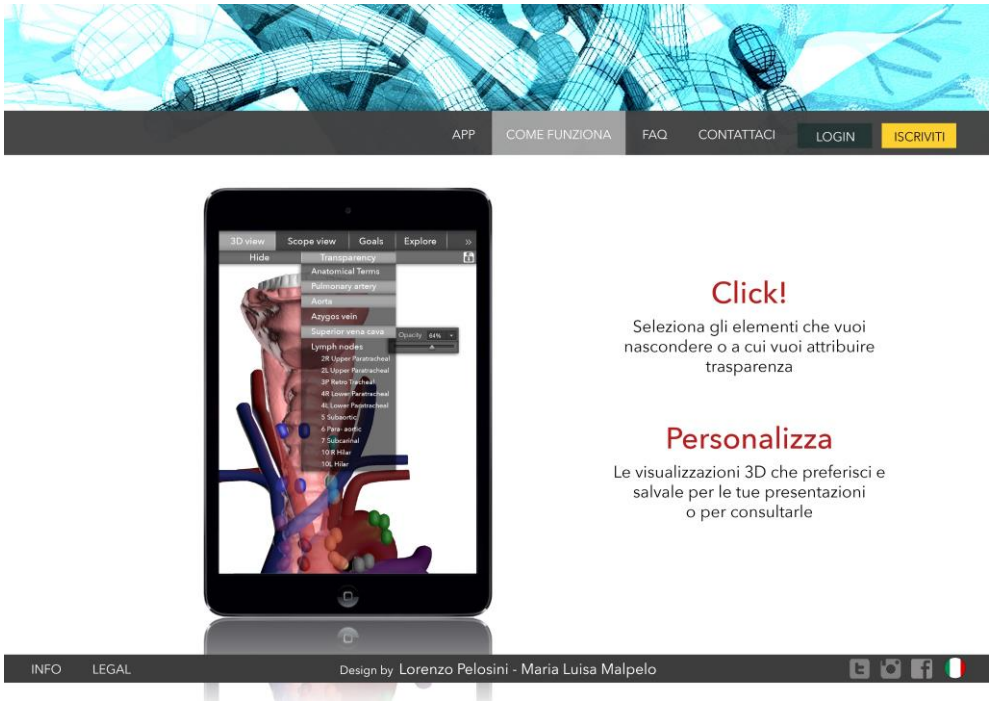

Figure 1. The attractive and greatly simplified graphics of Sam App. You can select the items to which you want to attribute transparency or hide and you can also customize the three-dimensional views which you prefer and save them for your presentations or to consult them.

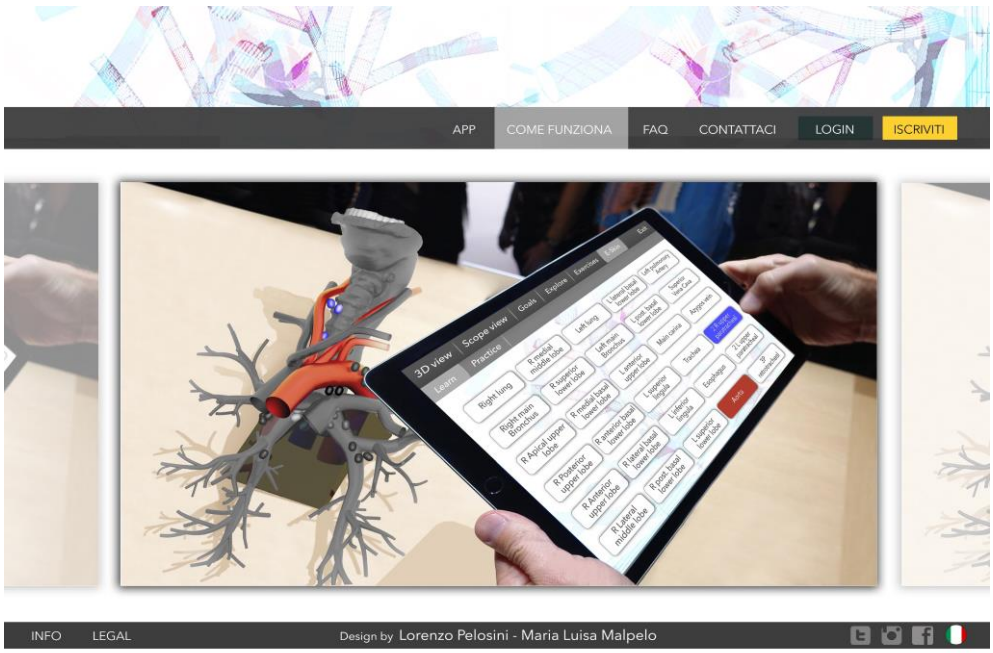

Figure 2. Going to click on the button E-skin of the App, a menu appears allowing, by simply selecting the anatomical terms of interest on tablet or smartphone, to do enlighten those body parts in the real model. As mentioned above, in fact, the electronic skin is able to light up in different colors. Then, associating each terms of the device to the corresponding part of the body in the real model of the mediastinum and bronchi, the user would be able to learn anatomy in a much more clear, rapid and direct way than current learning methods.

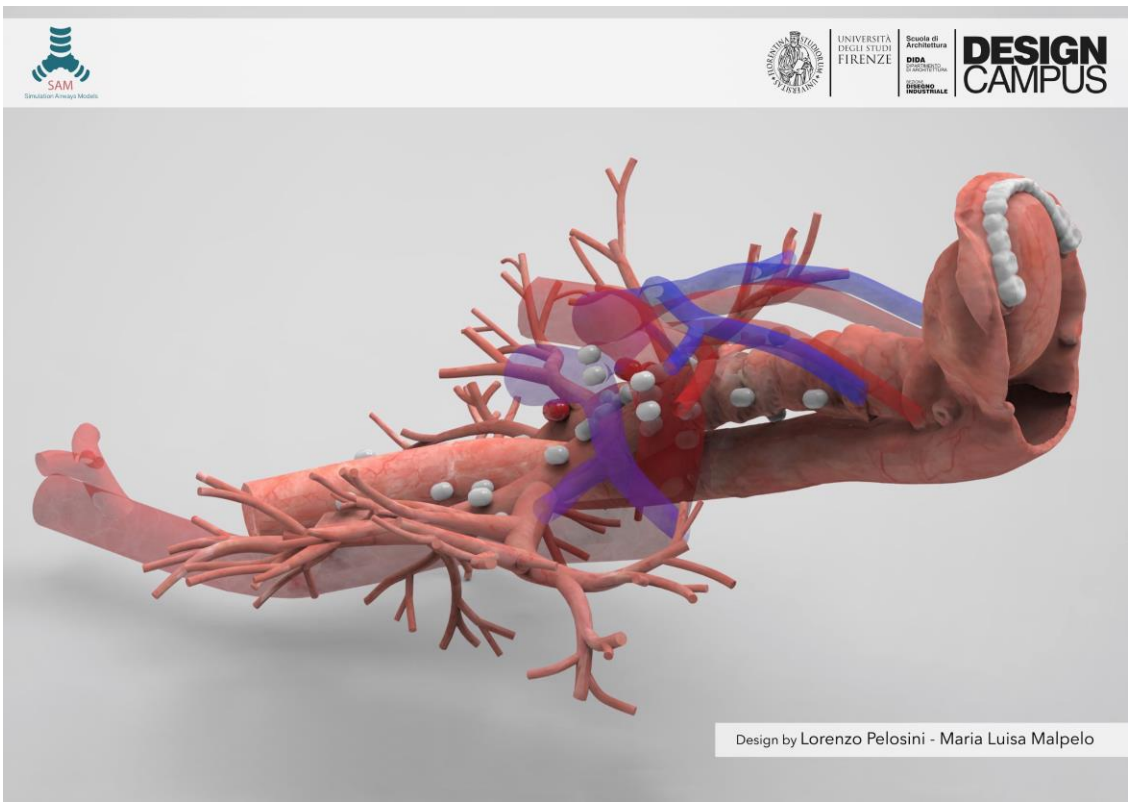

Figure 3. The Three Dimensional Model of Trachea, bronchi and mediastinum created for educational purposes, aiming at showing from different points of view the multiple body parts, their morphology and the relationships established between them.

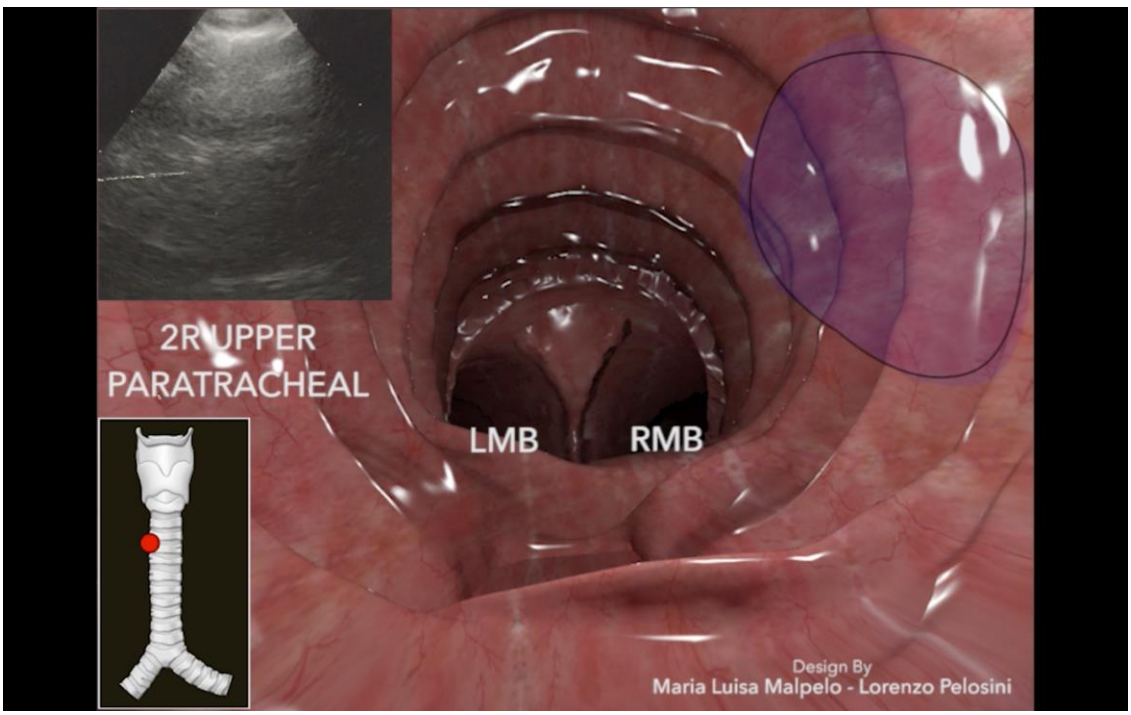

Figure 4. The view inside the trachea, indicating ultrasound view and the area in which 2R upper paratracheal lymph nodes are externally located.

2. The Research Process

The first phase of the research took place mainly through the consultation of books, web sites and through the realization of interviews to industry professionals. (One of these, Dr. Antonio Tavano, emergency room physician at the hospital company of Catanzaro). The research team also contacted and visited a company that works in the biomedical sector, the 'Rand' in Medolla (MO), as a case history.

A second research phase was then structured by collaborating with the Master in Pneumology second level held by prof. Lorenzo Corbetta at University Hospital of Careggi – Florence (Italy). The attendance of lectures on anatomy and on the Master medicine practices was flanked on number of practical lessons on simulation in interventional pulmonology. The goal was to develop a knowledge base and in-depth experiences on the subject.

The respiratory specialist must to acquire theoretical and practical skills in interventional pulmonology through a post-graduate studies targeted the acquisition of the main manual skills of their discipline. The first part of the master was focusing on teaching the theory and practice of endoscopic procedures, while the second part was dedicated to the analysis of processes and diagnostic and therapeutic pathways which included the execution of the endoscopic procedures. Within the master other specializations were also proposed such Thoracic Surgery, ENT, Radiology, Anesthesia and Intensive Care, Internal Medicine, Oncology. The teaching, entrusted to experts of the University of Florence and the main Italian centers of Interventional Pulmonology, was directed primarily to medical specialists in Respiratory Diseases and other specialists. The Master made use of traditional teaching methods Frontal and seminars and innovative methodologies that have planned to be used in conjunction mannequins with Storz, virtual reality simulators in collaboration with Simbionix, links in 'real time' with endoscopic rooms, e-learning sessions, video conferences and internships in various centers of Italy.

Master participation framework:

- February 29th 2016 – Lesson “From Bronchoscopy to the Interventional Pneumology” Prof. F. Paternostro, Prof. M. Patelli.
- March 1st 2016 – Dissertation of Prof. L. Corbetta about “PLB - Problem Based Learning”.
- March 2nd 2016– lesson Prof. L. Corbetta and prof. I. Lazzeri “About operational Bronchoscopy / EBUS in anesthesia deep sedation”.
- March 14th 2016- lesson prof. Bezzi “Pulmonary Navigation”.
- March 15th 2016- Practical exercises of the participants in the Master of High Fidelity Simbionix simulators and low fidelity simulators with ORSIM simulator.
- April 5th 2016 – lesson Prof. P. Vivoli about practice on mannequins and virtual reality.
- May 3rd 2016 - lesson Prof. L. Michieletto, L. Corbetta, M. Bezzi, S. Orsi supported by video streaming of endosopic room and practice on mannequin of Prof. Lotti.
- May 23rd 2016 - Presentation of SAM project referring to technology transfer in Interventional Pulmonology, attended the lecture of Prof. S. Scarlet, P. Candoli, L. Lazarus on exercises on Simbionix simulator.

4. Conclusions and Scientific Feedbacks

SAM is a project involving many professionals and is the result of the contribution of trans-disciplinary studies. The SAM's main purpose is to facilitate the learning and exercising medical practice before to operate on the patient. SAM offers a range of pathological cases providing to medical specialists in Interventional Pulmonology, students in Medicine and enthusiasts of Science, a broad framework of study and research analysis. SAM stands as an innovative learning method for interventional medicine. The research had interesting feedbacks from private companies and research institutions:

1. 1. Several Italian companies are interested in the project of SAM, particularly companies Var Group of Empoli (FI), and the company Pharma Consulting SRL of Florence, with which we are still working (We have signed a confidentiality agreement).
2. 2. The professor Lorenzo Corbetta presented on several occasions, during conferences held in America, England and China the SAM project, arousing public interest. On 21/22 October 2016, in particular, he presented at SAM Guangzhou Medical University, China.

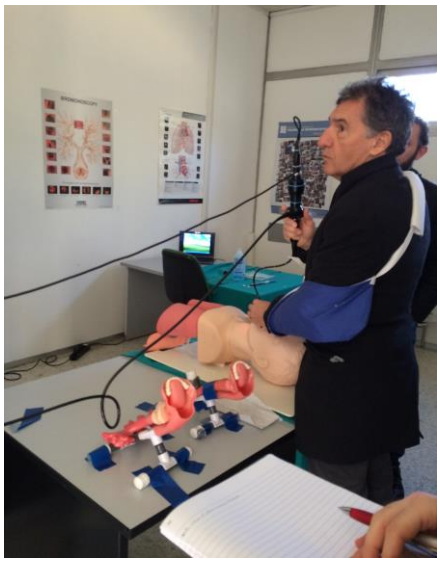

Figure 5. The collaboration with the Master in Pneumology second level held by prof. Lorenzo Corbetta at Training Center in Careggi, Florence.The attendance of lectures on anatomy and on the Master medicine practices was flanked on number of practical lessons on simulation in interventional pulmonology.

3. On the occasion of the 'Italy-China Science, Technology Innovation Week' 25-27 October 2016, held in Naples, Professor Gabriele Goretti took part in three tables with Zhukangkeqiao Medical Technology (Beijing) Limited Company, to introduce the technology and products of medical health, Hunan Jiuhua Pharmaceutical Health Industry Co. Ltd BMSTC To seek international cooperation in the new materials, bio-medicine and other fields ed infine Peking University Health Science Center BMSTC for the Embolic agents - medical device for interventional therapy

4. Encouraging feedback emerged from the students of Medicine and Interventional Pulmonology by specialists of the sector, during the presentation of the SAM project held in the week of 'Simulator Ebus Day' (May 23, 2016) at the Careggi NIC during Master in Pneumology of II ° level.

These promising aspects are equally surfaced following the presentation of the SAM project at the Design Campus of Calenzano (FI), during the presentation of the Advanced Product Design course of Corso di Laurea Magistrale in Design (master in design) of University of Florence (Italy).
5. SAM has laid the foundation of the laboratory HSD - Health Simulation Design at Design Campus of University of Florence. HSD is a research and development laboratory which has its operational core in the design innovation for health. The laboratory will carry out its research activities on two main areas. The first area is dedicated to the development and practical application of platforms and educational processes, tracing and certifying procedures including the use of virtual simulation models and / or three-dimensional real augmented reality and interactive. An other area is dedicated to the design of interacting medical devices. In this section, the design is focusing on devices for healthcare professionals and for the final user.

The design areas that characterize the HSD work are the Interaction Design and Advanced Product Design research. HSD lab works in partnership with medical specialist – selected by different skills and specializations - to design and test prototypes and products or to develop specific training courses.

In order to respond adequately to the contemporary needs of the health sector, the research team structured a “flexible and inclusive” research lab including all the professional and scientific skills aiming at giving a specific and rapid response.

HSD Lab is aiming at defining a 'good' communication addressed both inside and outside the health sector, as a strategic tool of relationship and comparison within the healthcare environment. This network mission results as a very important value in order to create a network among the best practices in health and good practices within the advanced design research. Focusing on these topics, HSD aims at generating products such as models and simulation processes for the competence-oriented training in healthcare and ever more efficient devices supporting medical practices.

Following this mission, the laboratory intends to carry on its research as part of a continuous applied research process in interdisciplinary model, structuring consultancy and training services for the different professionals in healthcare.

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