UBORA

Euro-African Open Biomedical Engineering e-Platform
for Innovation through Education

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Authors	June Madete, Caroline Ng'anga', Carmelo De Maria, Licia Di Pietro, Arti Ahluwalia, Andres Diaz Lantada
Abstract	Projects, teaching material and statistics of the UBORA design school 2018, held at Kenyatta University (Nairobi – Kenya) from 11th to 15th December 2017
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Executive Summary

UBORA's objective is to create an EU-Africa e-Infrastructure for open source co-design of innovative, useful and safe biomedical technology. Design Competitions and Design Schools have been identified as instrumental for optimising the e-infrastructure. The Design Competitions generate and nurture new ideas among young students, while the Design Schools are the means by which these ideas are turned into real and safe medical devices using the UBORA platform. They are also platforms for disseminating UBORA and its innovative approach of open-design underpinned by standards and safety regulations.

The aim of this deliverable is to show case the eight projects developed at the UBORA Design School- which was held in Nairobi in December 2018 - in the form of a compendium. All 8 projects are available on the UBORA platform which was used during the Design School to turn ideas and needs into real and safe medical devices. The contents of the Design School are also briefly described, along with the results of a post-school survey.

Aspects of the School which could be improved are underlined and will be addressed in future events.

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Part I: Design Competition and Design School

1 Design Competition

The UBORA Design Competition 2017 was focused on creating effective and affordable solutions which will contribute to improved child health outcomes. According to the World Health Organisation (WHO) all Millennium Development Goals (MDGs) influence health and health influences the MDGs. With this in mind, there are many problems that can be solved through the UBORA platform and Design Schools, from nutrition, to eradication of maternal deaths. The design competition was implemented in two stages: the first involved submission of a 1-page concept, while the second was a more detailed execution plan for an innovative medical device. A total of 113 projects were submitted at the first stage, from which 60 were selected for a second round. After the second round, 24 particularly relevant projects and their teams were awarded a travel fellowship for one team member to attend the "UBORA Design School". Among the projects and solutions presented, all of which were centered on infant and child mortality and health we can cite: medical devices for detecting or preventing malaria, portable vaccine coolers, systems for the sterilization of medical and instruments, incubators for newborns, devices for monitoring pregnancy, breast pumps with milk cooling systems, 4D printed ergonomic supports, polymeric devices for articular pathologies and CPAP devices for babies, to mention just a few examples.

2 Design school

The first UBORA Design School kicked off on 11th December 2017 at Kenyatta University and was auspiciously flagged of by Kenyatta University Vice Chancellor, Prof. Paul Wainaina amongst other dignitaries. There was a total of 39 students (24 sponsored and 15 self-sponsored) and 15 mentors from 18 nationalities. In attendance, also were 5 invited speakers, 15 Volunteers and Staff. The objectives of the 5-day (from 11th to 15th December 2017) School were to promote the ideas of safety, security, sharing, regulations, creativity and needs based design using a "**C**onceive, **D**esign, **I**mplement and **O**perate" (CDIO) approach.

2.1 Device Selection

The Design School was built around group projects. Students were divided into groups and assigned mentors, who had the role of guiding students through the CDIO process. Each group was assigned a design project, which had to be completed and ranked by all mentors on the last day of the School. Before starting the Design School, we selected 8 biomedical devices to be Conceived, Designed, Implemented and Operated during the intense one-week CDIO experience. The devices were chosen on the basis of the outcomes of a needs assessment campaign conducted by the Uganda Industrial Research Institute (UIRI), together with an analysis of the ideas presented to the Design Competition. The devices identified were:

1. Continuous airway pressure for neonate.
2. Sensorized pacifier to reduce sudden infant death syndrome.
3. Warmer for infants with hypothermia.
4. Universal splint for articular immobilization.

5. Face protecting splint for children with broken nose.
6. Phototherapy device for treating infant jaundice.
7. Portable cooler for vaccines.
8. Resuscitation device for newborns.

Group forming and mentor and group project assignment was performed some weeks before the starting of the design school. We sought to form the groups with a good balance of gender, cultural background and skills in an effort to promote multidisciplinary. None of the groups had more than one student from the same university or country, again enhancing diversity and internationalization. Moreover, mentors were allocated to the 8 selected projects on the basis of their specific technical or medical expertise (Table 1). Given that the groups had only 5 days to design and prototype innovative devices, mentors prepared supporting resources in advance so as to facilitate the students. The students did not know the group they were assigned to or the devices they would develop until the presentation pitches on the first morning of the design school.

Table 1 Working groups, projects and mentors assigned

Group 1				Innovative continuous airway pressure for neonate
Name	**Surname**	**Institution**	**Sex**	
Beatriz	López Arnedo	Universidad Politécnica de Madrid (UPM)	F	Mentors
Fethya Seid	Yimer	Jimma University	F	
Brenda	Chepng'eno	University of Eldoret	F	Akinniyi Osuntoki (LAGOS)
Emmanuel	Kamuhire	Mbarara University	M	Juan Manuel Munoz-Guijosa (UPM)
Job Wakesa	Chaka	Kenyatta University	M	Mathew Ocheng (UIRI)
Group 2				A new sensorized pacifier to reduce SIDS
Name	**Surname**	**Institution**	**Sex**	
Florinda	Coro	University of Pisa	F	Mentors
Nourhan Khaled	Shokir	Cairo University	F	
Benson Kagiri	Muriuki	University of Eldoret	M	David Malombe (Mombasa)
Patience	Bwire	Mbarara University	F	Muhammad Rushdi (CAIRO)
Brian	Matovu	Makerere University	M	Mannan Mridha (KTH)
Group 3				Appropriate warmth for infants with hypothermia
Name	**Surname**	**Institution**	**Sex**	
Sabina	Maglio	University of Pisa	F	Mentors
Yasmin Emad	Ahmed Abdela	Cairo University	F	
Rodrigo	Zapata Martinez	Universidad Politécnica de Madrid (UPM)	M	Mainen Moshi (MUHIMBILI)
Moses	Openja	Mbarara University	M	
Deogratias Blasius	Mtei	Muhimbili University	M	Miriam Wegoyer (UIRI)
Group 4				Elbow, knee, ankle, neck "universal splint for immobilation"
Name	**Surname**	**Institution**	**Sex**	
Rosa	Lotano	University of Pisa	F	Mentors
Crystal Kayaro	Emonde	Kenyatta University	F	
David Givondo	Sayia	University of Eldoret	M	Janno Torop (TARTU)
Kindie Solomon	Ferede	Addis Ababa Institute of Technology	M	Andres Diaz Lantada (UPM)
Adrian	Martinez Cendrero	Universidad Politécnica de Madrid (UPM)	M	Carmelo De Maria (UNIPI)
Group 5				Face protecting slint for children with broken nose
Name	**Surname**	**Institution**	**Sex**	
Mercy	Takuwa	Makerere University	F	Mentors
Jacopo	Zurlo	University of Pisa	M	
Nebyu Ahmed	Temam	Jimma University	M	Philip Kangogo Talam (ELDORET)
Jim	Gitonga	Technical University of Mombasa	M	Enrique Chacon (UPM)
Group 6				Phototherapy band to trat the infant jaundice
Name	**Surname**	**Institution**	**Sex**	
Elena	Crespo Domingo	Universidad Politécnica de Madrid (UPM)	F	Mentors
Martha	Mulerwa	Makerere University	F	
Gabriele	Fortunato	University of Pisa	M	Dawit Assefa Haile (ADDIS)
Rowland	Mjumira	Malawi University	M	Paul Niyitanga (UIRI
John Gichuru	Chege	Kenyatta University	M	Wasihun Alemayehu (JIMMA)
Group 7				Portable cooler for vaccines
Name	**Surname**	**Institution**	**Sex**	
Isabel	Alvarez Cespedez	Universidad Politécnica de Madrid (UPM)	F	Mentors
Tadala	Mtimuni	Malawi University of Science and	F	
Usama	Gazai	School The School of Technology and	M	Robert Ssekitoleko (MAKERERE)
Pius	Nuwabiine	Makerere University	M	Philippa Makobore (UIRI)
Gilbert	Chesoi	Technical University of Mombasa	M	Licia Di Pietro (UNIPI)
Group 8				Resuscitation device for newborns
Name	**Surname**	**Institution**	**Sex**	
Mihiret Yilma	Redi	Jimma University	F	Mentors
Oscar	Blanco Fernandez	Universidad Politécnica de Madrid (UPM)	M	
Adah Jepkoech	Limo	University of Eldoret	F	Edwin khundi (MALAWI)
Enos P.	Tupokal	Kenyatta University	M	Daniel Atwine (MBARARA)
Atish	Shah	Muhimbili University	M	Hudson Kagoda (UIRI)

2.2 Design School Format

Students went through the design process of medical devices compliant to relevant standards, by attending specific classes, workshops and lectures from outstanding speakers. Together with their peers and under the guide of expert mentors, they undertook to prototype one of the medical devices listed and assigned as a challenge at the beginning of the school (Sect. 2.1). Table 2 reports the agenda at a glance.

Table 2 UBORA Design School 2017 Timetable

<table>
<tr><th>Time</th><th>Day 1</th><th>Day 2</th><th>Day 3</th><th>Day 4</th><th>Day 5</th></tr>
<tr><td rowspan="2">8:30 – 9:30</td><td>Registration</td><td rowspan="2">Class on project development</td><td rowspan="3">Class on project development</td><td rowspan="2">Class on project development</td><td rowspan="3">Hands-on</td></tr>
<tr><td>Opening ceremony</td></tr>
<tr><td>9:30 – 10:30</td><td>Presentation of the School</td><td>Hands-on</td><td>Keynote presentations</td></tr>
<tr><td>10:30 – 11:00</td><td colspan="4">Health Break</td></tr>
<tr><td>11:00 – 11:30</td><td rowspan="2">Keynote presentations</td><td rowspan="2">Workshops</td><td rowspan="2">Hands-on</td><td rowspan="2">Hands-on</td><td rowspan="4">Hands-on</td></tr>
<tr><td>11:30 – 12:30</td></tr>
<tr><td rowspan="2">12:30 – 13:30</td><td>Student's pitch</td><td rowspan="2">Keynote presentations</td><td rowspan="2">Keynote presentations</td><td rowspan="2">Keynote presentations</td></tr>
<tr><td>Students assignment</td></tr>
<tr><td>13:30 – 14:30</td><td colspan="4">Lunch</td></tr>
<tr><td>14:30 – 15:30</td><td>Class on project development</td><td rowspan="3">Hands-on</td><td rowspan="3">Hands-on</td><td rowspan="6">Tour in Nairobi</td><td rowspan="6">Closing Ceremony</td></tr>
<tr><td>15:30 – 16:30</td><td rowspan="2">Hands-on</td></tr>
<tr><td>16:30 – 17:00</td></tr>
<tr><td>17:00 – 17:30</td><td colspan="3">Health Break</td></tr>
<tr><td>17:30 – 18:30</td><td rowspan="2">Workshops</td><td rowspan="2">Workshops</td><td rowspan="2">Workshops</td></tr>
<tr><td>18:30 – 19:30</td></tr>
<tr><td>19:30 – 21:00</td><td colspan="3">Dinner</td><td rowspan="2">Gala Dinner</td></tr>
<tr><td>21:00 – 23:00</td><td>Hands-on</td><td>Hands-on</td><td>Hands-on</td><td>Hands-on</td></tr>
</table>

Summarizing, we planned one basic lesson linked to the fundamental aspects (engineering-design methodologies, prototyping of medical devices, standards & regulations and usability of medical devices) for each of the first four days (Monday to Thursday). In addition, 15 workshops and keynote talks were distributed over the first four days, giving students the opportunity to appreciate the extensive applications of BME (Table 3). At least 3 time slots were set aside each day for hands-on group activities, in which the groups (guided by their mentors) could develop their projects applying the concepts acquired. The first morning was devoted to registration, the opening ceremony, formation of groups, and to the presentation of

the UBORA e-infrastructure, which was used as design tool during the School. The presented release of UBORA, named Kahawa from the hill where Kenyatta University is situated, allowed students to identify the risk class of medical device, the horizontal standards, to go through the process of conceptual design and the mechanical and electronic implementation of the project. The Design School in Nairobi can be considered as the first stress-test on the e-infrastructure, and feedback from users was obtained through direct interviews during the week and through an anonymous questionnaire (see sect. 5.2).

Table 3: Summary of contents: Lessons on biomedical project development, workshops or seminars and keynote presentations of the "UBORA Design School 2017".

Teaching event	**Topic**	**Date**
Lesson	CDIO Methodology for Medical Devices	Day 1
Lesson	Standards and Regulations on Medical Devices	Day 2
Lesson	Technologies for Prototyping and Manufacturing Medical Devices	Day 3
Lesson	Usability of Medical Devices	Day 4
Workshop	Creativity Promotion in Medical Devices	Day 1
Workshop	Programming in Matlab®	Day 1
Workshop	Tracking Movements	Day 2 (M)
Workshop	Electronic Rapid Prototyping	Day 2 (M)
Workshop	Electronic Measurements	Day 2 (A)
Workshop	Mass Production by Injection Molding	Day 2 (A)
Workshop	Medical Imaging Processing and Matlab®	Day 3
Workshop	Arduino and Matlab® for Prototyping Medical Devices	Day 3
Keynote talk	Economic Development and Healthcare Technology	Day 1
Keynote talk	Clinical Needs and Medical Equipment	Day 1
Keynote talk	In Vitro Models for Reducing Animal Testing	Day 2
Keynote talk	Textile Technology Biomedical Engineering	Day 3
Keynote talk	Affordable Healthcare	Day 3
Keynote talk	From Mind to Market	Day 4
Keynote talk	Soft and Smart Robotics in Bioengineering	Day 4

The last morning (Friday) was dedicated to fine-tuning the projects, while the afternoon was reserved for the final presentations, overall assessment and a short closing ceremony in which the best 3 projects were nominated. A tour of Nairobi National Park on Thursday afternoon completed the programme. As seen in Table 1, hands-on activities continued after dinner, indeed, given the intensive nature of the school, the Thursday afternoon tour and a closing dinner were the only social events organized.

2.3 Accommodation and Conferencing

The students and mentors all stayed within the campus to ease the logistics of getting to the conference hall as well as their boarding quarters. The conference halls and workshops were held at the Business Students Centre.

All Mentors stayed at Kenyatta University Conference Centre on half board basis. There were a total of 25 mentors and professors and 5 external visitors (international stakeholders such as members of UNECA and CAMTECH). The 39 students stayed at the Nyayo Hostels, which are located less than kilometre from Business Students Centre. Some machine and electronics shop specifically for their prototyping was set up in the Business Center. Most of the students worked late into the night on their projects.

2.4 Supporting Resources

Apart from prototyping facilities, an Internet connection and the support of the UBORA e-infrastructure, students were provided with additional tools and resources for developing their design, prototyping and testing tasks during the design school. Common computer-aided design and simulation software, with licenses provided by the members of UBORA or from companies offering student licenses, such as NX-10 (Siemens Lifecycle Management Solutions), Catia v.5 (Dassault Systemes), Autodesk Moldflow and Matlab (The Mathworks), enabled the teams to design and perform mechanical, thermal, fluidic and manufacturing simulations. Two fused-deposition modelling 3D printers Flashforge Creator Pro with the related free supporting slicing software helped students to materialize their designs. One Arduino starter kit for each team, including common pressure, temperature, light and vibration sensors, LEDs, micro-motors and actuators promoted the development of 'smart' systems capable of monitoring some human signals and responding to them, after adequate signal processing with the Arduino micro-controller, according to specifications of the different biodevices. Finally, some supporting oscilloscopes, kits for paper rapid prototyping and common materials from mechanical and electronic workshops helped students along the week.

3 Results of the Design School

3.1 Overview of the implementation process

Overall the design school was implemented according to the initial planning, with all 39 students and with the 25 professors and mentors arriving in Nairobi without major delays. Minor adjustments, consisting of a couple of lessons performed via Skype and two additional modifications to the topics of keynote speeches did not affect the overall teaching-learning programme and the 8 groups of students were able to complete the desired complete CDIO cycles with their biomedical projects (see the Compendium in Part 2) using the UBORA e-infrastructure as a support and working tool.

Taking into consideration the relationship between students and mentors during the design school, a great ambience of collaboration achieved, especially taking into account the international and multi-cultural audience, which was a source of inspiration for all. Gender balance was very appropriate with a 42% of

female students and mean student age was 23 years, with most students (around a 75%) in the range of 21-25. Regarding nationalities, students from the following countries (numbers in brackets) were involved: Kenya (9), Uganda (7), Spain (6), Italy (5), Ethiopia (4), Egypt (2), Tanzania (3), Malawi (2) and Sweden (1), which to our knowledge constitutes one of the most international CDIO experiences ever.

3.2 Course contents

A short description of each course is given in this section. For the sake of brevity, the complete course contents and slides are not reported here but can be downloaded from the UBORA project webpages (http://ubora-biomedical.org/first-ubora-design-school/).

3.2.1 Class: CDIO Methodologies for Medical Devices

Speaker: Andrés Diaz Lantada

This lesson introduced the engineering design process, a methodical series of steps (or methodology) that engineers use in creating functional products, processes and systems for secure and straightforward developments. The methodology was presented in a form adapted to the special challenges of the biomedical industry and with advices for better tackling medical needs. The conceive-design-implement-operate phases were detailed covering aspects including: medical needs, market analyses, product specifications, global functions, conceptual designs, basic engineering & prototyping issues, detailed engineering topics, production planning and supply chain questions and overall sustainable development concerns. The steps were illustrated using a real case of study for providing participants with an overview of the process to live along the design school with their biomedical projects.

3.2.2 Class: Standards and regulations on Medical Devices

Speaker: Alice Ravizza

The presentation described the risk-based approach to controlling the placing on the market of medical devices in Europe and the means of compliance to the essential requirements for safety and performance. The classification of medical devices based on risk were described and justified. The main standards for design, manufacturing and testing medical devices were briefly explained.

3.2.3 Class: Fabrication Technologies for prototyping and manufacturing medical devices

Speakers: Carmelo De Maria, Andrés Diaz Lantada

Speakers described the fundamentals in Computer-controlled fabrication tools, including additive manufacturing technologies, for prototyping and manufacturing medical devices. In particular, the participant went through the fabrication cycle of a personalized medical device from scanning data and the Fused Deposition Modelling (FDM) 3D printer. Slic3r (http://slic3r.org/) and Flashprint (http://www.flashforge.com.hk/downloads.html) were used as slicing software.

3.2.4 Class: Usability of medical devices

Speaker: Alice Ravizza

The presentation described: i) methods to identify user error- related risks in the use of medical devices; ii) methods for designing medical devices according to Human factors engineering principles and for identification of mitigation measures to user error- related risk; iii) methods for testing normal and abnormal use of medical devices.

3.2.5 Workshop: Electronic measurements

Speaker: Mannan Mridha

This workshop (Figure 1) had four measuring stations for students to get hands-on experience with biomedical sensors and devices:

- Study some characteristics like accuracy, linearity and response time of RTD, thermistors and thermocouples.
- Recording ECG signals by selecting the suitable amplification and filters.
- Recording heart rate using piezoelectric sensors and optical sensor.
- Measuring energy delivered from a pacemaker.

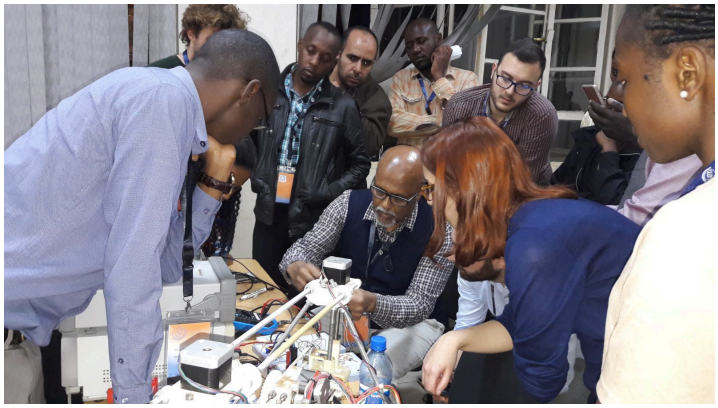


Figure 1: Students during the workshop held by Prof. Mannan Mridha

3.2.6 Workshop: Programming Matlab® and Color Medical Image Processing

Speakers: Prof. Arti Ahluwalia and Dawit Haile

The Workshop was composed of two parts: a first part on "A short introduction to Matlab®" and a second part on "Color Medical Image Processing", which was focused on:

- Representation of Color Images
- Color Image Fourier Transforms
- Color Edge Detection and Segmentation
- Applications

3.2.7 Workshop: Tracking movements

Speaker: June Madete

This workshop used Biomechanics (body as a machine) principles to analyze motion. It focused on calculating the orientation of a body in a three-dimensional space using a maker based system and showing how 3 coordinates (x, y, z), can be transformed to motion of the knee. In addition, participants were shown how to compare the marker data to CT scans and fluoroscopy and shown how engineering principles can be applied to clinical data.

3.2.8 Workshop: Electronic rapid prototyping

Speakers: Philippa Makobore, Mathew Ocheng, Paul Niyitanga, Hudson Kagoda, Miriam Wegoye

Participants were led through the phases of project development to realise an incubator with sensors.

- Proposed project for rapid prototyping: Temperature Monitoring and Control for baby incubators;
- Presentation on rapid electronics prototyping tools and rationale for selecting example project for rapid prototyping;
- Identifying/understanding clauses from the Baby Incubator medical device standards related to temperature monitoring and control;
- Adapt standards as requirements;
- Draw block diagram, schematic and connect circuit on a breadboard with guidance from facilitators;
- Draw flowchart, write sample code;
- Walk through a more comprehensive software and testing.

3.2.9 Workshop: Creativity promotion in Medical Devices

Speaker: Andrés Diaz Lantada, Juan Manuel Muñoz Guijosa

This workshop was aimed at "deconstructing" creativity and presented creativity promotion as a methodical process, which can be understood and systematically trained. A set of creativity promotion techniques, linked to the main stages of the creative process, namely generation, association and evaluation, were presented and actively employed during the workshop by teams of participants. Connections with common engineering design methodologies and with the CDIO approach were also presented, which will serve teams of students during their design tasks along their biomedical project implementation. Cases of study in relation with innovative medical devices developments were discussed to illustrate these methods and techniques.

3.2.10 Workshop: Mass production by injection molding

Speaker: Andrés Diaz Lantada

This workshop focused on mass production technologies in the biomedical field paying special attention to injection molding for the creation of large series of polymeric components. The fundamentals of injection molding were introduced and essential design for mass production recommendations provided and illustrated by means of real case studies. The capabilities of Autodesk Moldflow, the most extended simulation

software employed in the plastic part production sector, were presented and applied to real biodevices. Teams of students worked together for analyzing the potential mass production of their biomedical projects and prepared a conceptual design of the related injection molds, while also living a design for manufacturability experience.

3.2.11 Workshop: Arduino and Matlab for Prototyping Medical Devices

Speaker: Enrique Chacón

In this workshop, students learned to design and create prototypes of an electronic device with the Arduino platform. In order to reach that goal, the workshop was divided into two modules: i) Basics of hardware (Arduino, sensors, actuators, basic electronic circuits, etc.) and software (Arduino programming and control with Matlab); ii) perform design, manufacturing and testing projects.

3.2.12 Paper Rapid prototyping

Speaker: Robert Ssekitoleko

Paper prototyping is a cost effective and time saving technique that enables the designer to make prototypes from paper or otherwise very cheap and easy-to-find objects. Unlike computer-based models and simulations, paper prototypes are helpful in helping the designer easily understand the ease or difficulty in assembling the designed parts. It is also useful in the usability testing where the human interaction with the device can be studied. In the workshop, simple devices were designed and paper prototypes of the same were made to explore ways of how they can be very useful to a Design Engineer.

3.2.13 Keynote Presentations

- Relationship between economic development and healthcare technology. **Speaker: Dr. Victor Konde.** Dr. Konde gave an inspiring presentation on the state of healthcare in Africa and the potential of economic growth were the continent able to manufacture certified medical devices.
- Clinical Needs and Medical Equipment Assessment. **Speaker: Philippa Makobore.** The presentation was focused on Clinical Needs and Medical Equipment Assessment in Uganda, on the design of Portable Neonate Warmer (PNW) and on a brief Case Study of ECGF. Mrs. Makobore discussed background, methodology and results from the clinical needs and medical equipment assessment, with the final aim at giving inputs for ranking needs in the UBORA e-infrastructure.
- In vitro models for reducing animal testing in development process of medical devices. **Speaker: Prof Arti Ahluwalia.** Prof. Ahluwalia gave a talk on the history and ethics of animal models and the development of alternatives to animal experiments.
- Soft and smart robots in bioengineering. **Speaker: Prof. Danilo De Rossi.** Prof. De Rossi gave a well-documented presentation on the state of the art of robotic in biomedical engineering. Building an empathic social robotics is one of the challenges in BME, and he tried to transmit to student the impacts of this research on today's world.

- Textile Technology Biomedical Engineering. **Speaker: Prof. Danilo De Rossi.** Clothes are the closest objects every day in contact with us, and can be a valuable source of information if built with smart textile able to transduce biological signals: De Rossi outlined over 20 years of theoretical and applied research in a thought-provoking lecture on textile technology
- From Mind to Market. **Speaker Robert Karanja.** Robert, CEO of Villgro Kenya, explained the importance of innovations, social entrepreneurship and impact investment in the healthcare and life sciences industry.

4 Results

4.1 Complete development of medical devices following open-source approaches

Projects were successfully developed thanks to a tight schedule control and an adequate delimitation of boundaries for each stage of the "conceive-design-implement-operate" engineering-design process for fulfilling the tasks in just one week. In fact, Monday was devoted almost completely to introducing the school and presenting the teams, so Tuesday was dedicated to conceptual tasks, Wednesday to design issues, Thursday to implementation aspects (prototyping and testing) and Friday to the operation of the devices (final presentations and tests before the jury). The conceptual stage was limited to precisely defining the medical need, analyzing existing solutions, specifying and classifying the medical device, proposing alternative product ideas and evaluating them for selecting the adequate "concept". The design stage was devoted to obtaining basic CAD geometries of the different components, selecting materials, designing electronic circuits, defining joining forms, selecting commercial components (i.e. sensors and actuators) and briefly describing possible manufacturing processes towards production. The implementation phase included the prototyping of electronic circuits using prototyping boards and Arduino kits and the rapid manufacture of mechanical components by 3D printing, either using the real CAD geometries or resorting to scaled conceptual prototypes. Mounting and testing was also part of this phase. As for the operation stage, in our case, it was limited to preparing reports and presentations of the devices and presenting them before the jury and co-participants. The degree of completeness achieved can be compared to that of one- or even two-semester long CDIO experiences, which is extraordinary.

Figure 2: Moments from UBORA design school

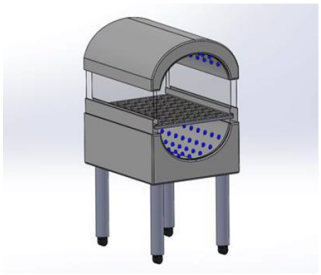
On Friday afternoon teams showcased their projects with a short pitch. During the project presentations, all the mentors and invited expert guests were given scorecards to rank the projects. During the afternoon coffee break, mentors and expert guests selected the top 3 projects.

The closing ceremony was the moment for handing out attendance certificates and announcing the winning projects.

The winning projects were: "Phototherapy band to treat the infant jaundice" (first place, group 6), "Appropriate warmth for infants with hypothermia" (second place, group 3), "Resuscitation device for newborns" (third place, group 8). Overviews of the 3 projects are presented in the figure below; more information about the technical implementation has been provided in Part 2 of this deliverable.

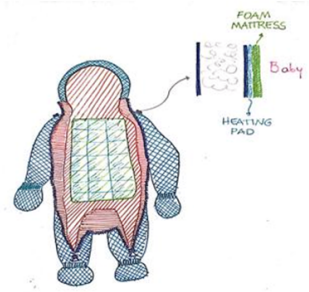
The evaluation was based on the feasibility of the conceptual design and on the technical implementation using the UBORA e-infrastructure.

The venue of the "UBORA International Design Competition 2018" was also announced to be held in Pisa from the 3rd to 7th of September 2018, following the steps of the 2017 experience.



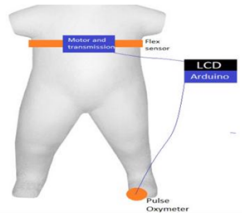
PHOTOTHERAPY BAND TO TREAT THE INFANT JAUNDICE

- Group: 6
- Clinical need: Non-surgical therapy / Administration of drugs
- Clinical area: Pediatrics
- Technology: Other supporting equipment
- Project keywords: photo-therapy band, infants, janundice
- Device classification: IIb



APPROPRIATE WARMTH FOR INFANTS WITH HYPOTHERMIA

- Group: 3
- Clinical need: Prevention of pathology or disease
- Clinical area: Pediatrics
- Technology: Other supporting equipment
- Project keywords: Premature babies,newborn, hypothermia, temperature monitoring system, Phase Change Material
- Device classification: IIb



RESUSCITATION DEVICE FOR NEWBORNS

- Group: 8
- Clinical need: Support to medical practice
- Clinical area: Pediatrics
- Technology: Other supporting equipment
- Project keywords: Neonates; Resuscitation; Chest Compressor
- Device classification: III

Figure 3: Overview of the best projects developed during the UBORA Design School 2017

4.2 Survey

On the last afternoon, just after the final presentations, students were asked to complete a survey for obtaining their impressions regarding the topics and contents for the planned teaching-learning sessions, seminars and workshops, their opinions about organizational issues, their perceptions about the medical devices developed and their feedback in connection with the promotion of professional skills during the intensive study and design week. The survey was performed using an online formulary (Google Forms) and 34 out of 39 participants provided their responses, mainly using Likert scale type questions (with values from 1 to 5), which are presented in Figures 4 to 7 and analyzed and discussed in the following sections. Additional personal impressions about the design school and about the usability of the UBORA e-infrastructure were gathered by using blank questions. Finally, informal conversations and discussions among colleagues and participants helped to analyze the implementation in more depth in order to improve next year's Design Competition and School.

4.2.1 Organization and planning

Concerning lesson contents and planned topics of workshops and seminars, the assessments presented in Figure 4show an extraordinarily positive perception from students, with typical sums of responses valued

with 4 and 5, in the 5-point Likert scale used, reaching percentages from 70% to 80%. More than an 80% of students agreed or strongly agreed that globally speaking the contents of lectures and workshops were interesting. The overall engineering-design process and the approach to prototyping, manufacturing and regulatory environment were clearly understood and especially highly appreciated according to the results.

Considering organizational issues (see Figure 5), the communication with the organizers and the information provided before the school were highly appreciated, as with the support provided by mentors, although with some minor proportions of disagreement. Accommodation and lodging received slightly lower marks, although all participant students should have borne in mind that a university residence is not a congress hotel. To summarise, it is necessary to note that more than 82% of students considered the design school a rewarding experience.

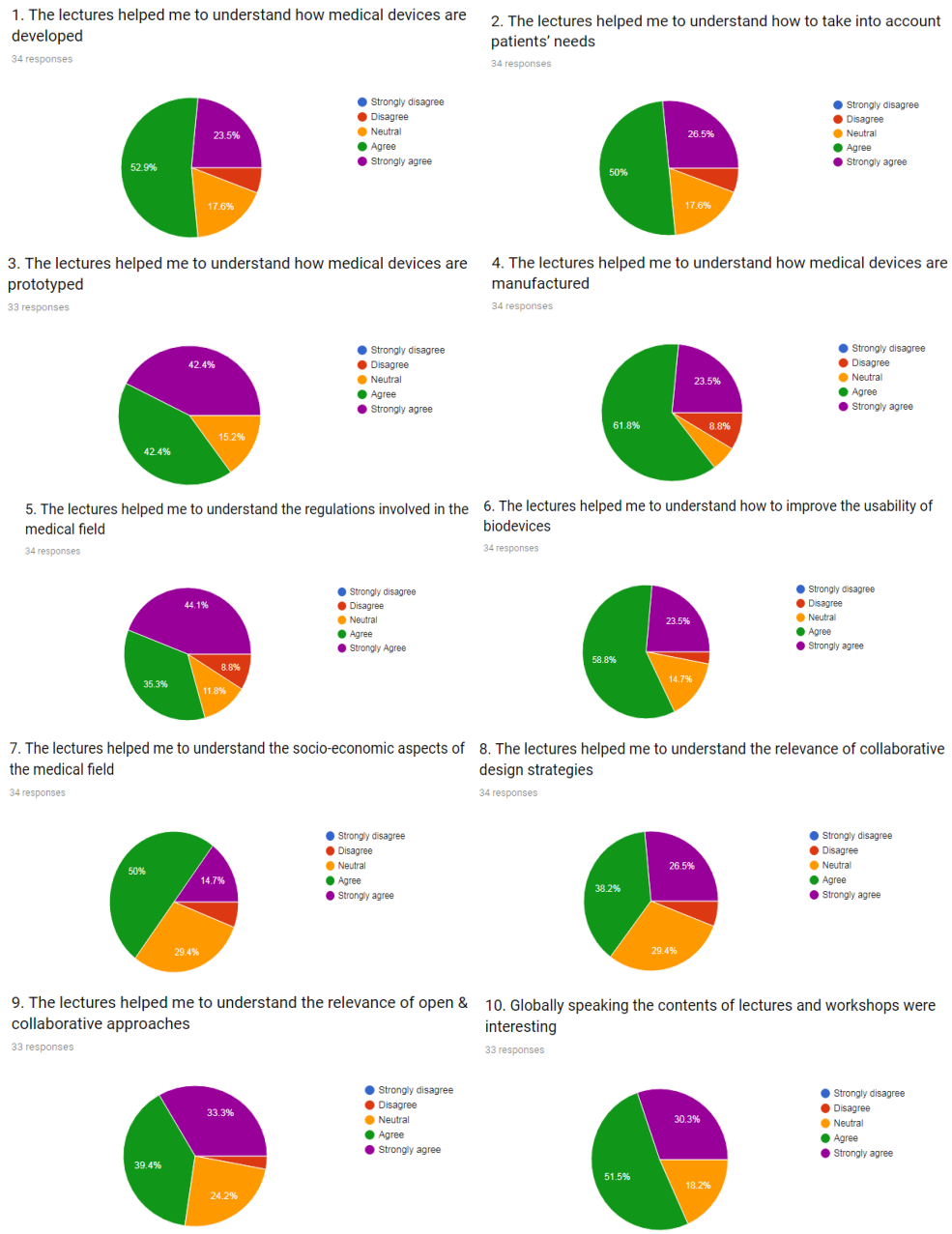


Figure 4: Summary of results regarding students' opinions about the interest of topics and contents for the planned teaching-learning sessions, seminars and workshops

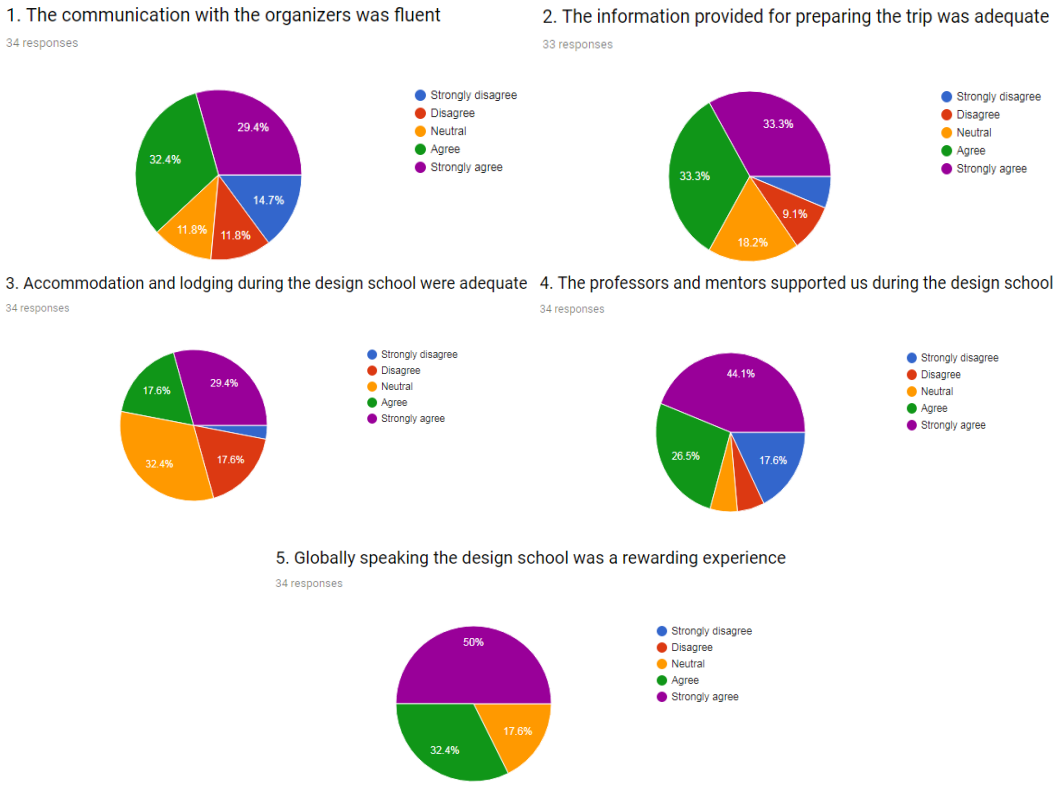


Figure 5: Summary of results regarding students' opinions about organizational issues.

4.2.2 Students' perception of their own CDIO process

Regarding the development process and the success of the CDIO stages lived through with the medical devices, students' perceptions about their progresses and results were also noteworthy. Again, more than a 70% of participants considered the project-based learning experience satisfactory according to their expectations, although in this case around a 15% were not so satisfied. In this regard, it is necessary to mention that sometimes "project-based learning experiences" are a bit frustrating for students, especially when prototyping and testing stages are involved, as they tend to focus on the product and final prototyping result (and prototypes do not always work as expected) rather than the learning experience *perse*. However, in our opinion, the final result is not as relevant as the whole teaching-learning process, which was highly gratifying both for students and teachers, as can be understood from the global analysis of the presented surveys as well as from the design and prototyping results previously shown and from all the informal discussions among teachers, mentors, students and international stakeholders.

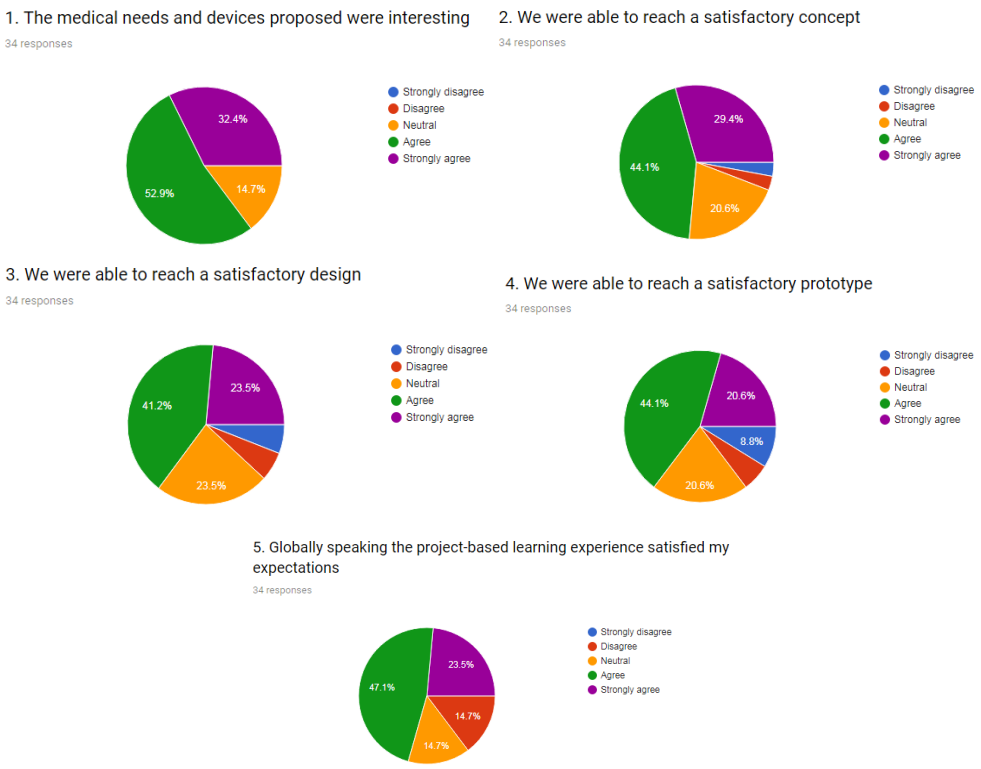


Figure 6: Summary of results regarding students' perceptions about the biodevices developed.

4.2.3 Impact on the promotion of students' professional skills

Probably the more relevant data gathered with the online surveys from the perspective of the actual impact of the teaching-learning experience, are those linked to students' perception about their promotion of professional skills thanks to the UBORA Design School. The questions were on the set of ABET professional skills, which cover most skills needed for engineering professional practice and are almost coincident with those from the CDIO standards. Results are summarized in Figure 7 and are very positive indeed. We can objectively declare that, in just one week of intensive project-based learning experience following the CDIO approach (let's call it "express CDIO" model), students performed teaching-learning activities covering the whole spectrum of ABET professional skills. To highlight just some examples, around a 90% of students considered that the experiences lived had helped them to communicate more effectively and around an 85% of students clearly confirmed that the projects helped them to apply academic knowledge to real life. The impact of engineering solutions and the need for lifelong learning were also clearly perceived by students, thanks also to the inspiring keynote speeches and to the activities performed during the school using modern engineering tools, many of which were novel for them.

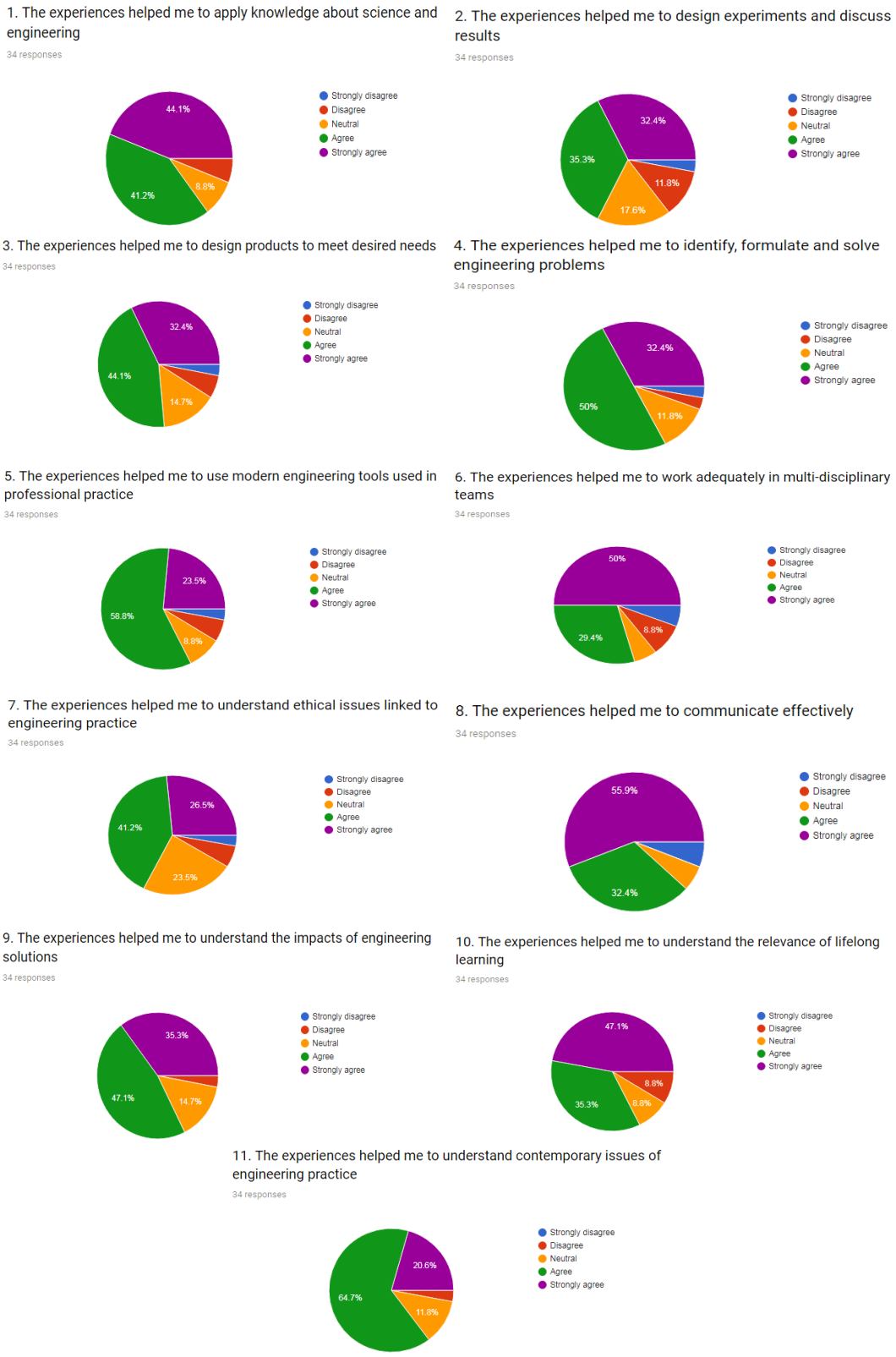


Figure 7: Summary of results regarding students' perceptions about their improvement of professional skills

5 Conclusions

5.1 UBORA as new teaching-learning paradigm in Biomedical Engineering

The purpose of the Design School and Competition in the context of UBORA was to generate new ideas and projects, nurture innovation and provide a testing ground for the first version of the new e-infrastructure. During the "UBORA Design School" (first edition, 2017), engineering students (working in teams) lived through the complete development process of innovative open-source medical devices, following the CDIO approach, during an intense week. A total of 39 students from 14 universities and 9 countries were involved in conceiving, designing, implementing and operating 8 medical devices, intrinsically safe and compliant with international regulations, for addressing relevant health concerns linked to childhood and maternity.
This integral teaching-learning experience helped to promote their professional skills and to plant the seed towards a future generation of biomedical engineers, who will collaborate as members of the "UBORA Community" by using the UBORA e-infrastructure.

5.2 Lessons learned, challenges and future proposals

Overall the Design Competition and Design School 2017 were a great success, judging from the surveys and feedback from participants. The learning experience was unique, the e-infrastructure was well received and considered extremely useful at all levels; as a learning tool, a teaching tool and also as an instrument for developers, regulators and large and small companies.

The post-school surveys were used to validate the relevance of the action and the possibility of performing highly-intense or "express" project-based CDIO learning experiences, in an international setting. An analysis of the results show that a whole CDIO cycle can be fulfilled in just one week if supported by adequate planning, relevant teaching-learning objectives, motivating sessions and continued mentoring sessions and support from devoted professors. Among the more relevant aspects for an adequate accomplishment we should highlight: the need of advanced and coordinated planning, the relevance of a methodical student selection process, the importance of a complete agenda with tight time control, the essential role of motivated mentors and the provision of complete and clear information regarding desired objectives and proposed activities, all of which proved fundamental for the success of this First UBORA Design School.

Future events, starting from the 2018 Competition and School, will be improved according to the results of the surveys and some of the objective difficulties encountered, specifically:

- use of an online platform for updating changes to the timetable;
- some students felt unprepared for the intensive week and were expecting a more relaxed school. To avoid this reaction, students will be informed on the planning of the school and its organization prior to the event;

- more rigorous follow up of projects to turn them into real and usable safe devices after the end of the school;
- involvement of mentors with more practical rather than academic skills. It may be appropriate to focus on the training of young engineering educators for generating a cohort of mentors for these express biomedical CDIO experiences;
- more involvement of industry, especially small, local ones;
- the recognition of ECTS for "UBORA Design Schools" may help to attract students and additional support from European universities. We recommend 3 ECTS for the approximately 75 hours that students devoted to the preparation of the school and to the intense week of collaboration.

The most relevant challenge we now face is the long-term sustainability of the "UBORA Design Schools". In fact, these international educational experiences require mobility of students and professors from across the World and therefore need some sort of funding or sponsorship for performing in adequate conditions. After the two first ones, funded by the UBORA EU project, we expect to have generated enough international impact, so as to make these experiences clearly sustainable. Currently plans are being drawn up to generate enough momentum and sponsorship from universities, consortia, organizations and engineering companies for being able to implement at least one in Kampala in 2019 and one in Madrid in 2020. As for the longer term, the role of already created consortia (i.e. ABEC and UBORA), the continued support of UNECA and of the EU Commission and the impact of innovative mobility schemes and projects (i.e. ABEM: https://www.africanbmemobility.org) will be crucial for transforming BME and its education towards open-source approaches linked to equitable access to healthcare technology. The UBORA e-infrastructure will be fundamental for supporting this process.

Part II: Compendium

BLosSoM - Innovative
continuous airway pressure for neonate

Device Classification: Class IIb

Globally, more than 10 million babies are born prematurely each year, and pre-term birth complications are the leading cause of neonatal death. It is estimated that over 60% of all preterm births occur in Africa, and south Asia, with the occurrence increasing almost in every country across the world. 8 in every 10 children admitted into hospital wards suffer from Respiratory Distress Syndrome (RDS), a condition that arises due to insufficient lung development. Therefore, they require continuous positive airway pressure at different stages of growth.

Due to that need, a project called "innovative continuous airway pressure for neonates" was developed, based on a previous design. This project suggested a joint solution that enables the air flow from the CPAP and administration of medicine to be supplied simultaneously. Nevertheless, the solution had some problems that we want to solve.

The most pressing challenge with existing interventions is that of: mixing air flow and medicine far away from the infant's nose which makes some of the aerosol to remain on the walls of the tube, as droplets, instead of reaching the baby's nose. Another challenge is that currently, the mask only covers the nose making dust aerosol medicine hard to be delivered since it would diffuse through the mouth.

The team worked on an innovative way to address this challenge by developing a Babies' Life Saving Mask (BLosSoM). The innovation works in such a way that it combines the two components together: Continuous positive airway pressure, and administration of aerosol simultaneously through the mask (Figure 1).

Figure 1: Baby Life Saving MAask (BlosSoM)

Medical Need and Product specification

Clinical Needs

Condition Addressed: respiratory distress syndrome in infants.

Existing solutions

The existing interventions include:

- **CPAP (Continuous positive airway pressure).** Continuous Positive airway pressure (CPAP) treatment uses a machine to pump air under pressure into the airway of the lungs. The forced air delivered by CPAP prevents episodes of airway collapse that block the breathing in people with obstructive sleep apnea and other breathing problems.
- **PumanibCPAP.** The Pumani consists of a flow source, a pressure source, and patient tubing. The flow comes from an air pump, and the pressure is provided by a water bottle.
- **MTTS CPAP.** The MTTS CPAP is designed to protect compromised airways, enhancing patient comfort and optimizing infant outcomes. Its continuous gentle pressure of air decreases the baby's work of breathing by keeping the alveoli of the lungs open, enables efficient capillary exchange of oxygen and carbon dioxide to take place, helps establish and maintain functional residual capacity, prevents collapse and upper airway obstruction, and reduces apnoea, bradycardia and cyanotic episodes.
- **KSE Bubble CPAP.** Bubble CPAP is a non-invasive ventilation strategy for newborns with infant respiratory distress syndrome (IRDS). It is one of the methods by which continuous positive airway pressure (CPAP) is delivered to a spontaneously breathing newborn to maintain lung volumes during expiration. With this method, blended and humidified oxygen is delivered via short binasal prongs or a nasal mask and pressure in the circuit is maintained by immersing the distal end of the expiratory tubing in water. The depth to which the tubing is immersed underwater determines the pressure generated in the airways of the infant. As the gas flows through the system, it "bubbles" out and prevents buildup of excess pressures.
- **Acquatherm.** Acquatherm is an innovative system which can deliver high flows of air or oxygen ranging from 1 to 15 LPM. The high flows of gases are warmed at body temperature & are humidified up to 100% relative humidity & are delivered via nasal Cannula.
- **Infant Flow SiPAP.** Infant Flow SiPAP is a device which enables the Biphasic continuous positive end-expiratory pressure (Biphasic) by addition of an intermittent "Sigh, SiPAP pressure" to the nasal DPAP. Infant Flow SiPAP has 2 basic modes, nCPAP& Biphasic. With the use of abdominal respiratory sensor enables 5 configurations including NCPAP + Apnea, BiPhasic + Apnea modes with breath rate monitoring and apnea alarm function, and BiPhasic enabling synchronized mandatory ventilation. It is expected to prevent alveolar collapse caused by lung recruitment effect, maintain FRC, reduce work of breathing, and stimulate respiratory center.

Operation of this device is all performed with the touch screen display except for the power switch at the back and oxygen concentration setup, and 2 flow meters at the front panel. The device has a two hour internal battery. The display is locked if there is no entry thorough display in 120 seconds to prevent inadvertent entry. When high priority alarm activates this display lock will be awoken.

- **F&P Bubble CPAP system.** Bubble CPAP is a unique form of CPAP. Infants on bubble CPAP have been reported to have chest wall vibrations similar to High Frequency Ventilation (HFV). With the combined effects of Optimal Humidity and natural pressure oscillations, bubble CPAP provides a protective, safe and effective method of respiratory support to spontaneously breathing neonates.
- **BabyLog VN500.** VN500 provides excellent conventional ventilation with "automatic leak compensation" and "VG". In addition to those functions, VN offers extensive neonatal ventilation therapy, including MMV (Mandatory Minute Volume Ventilation), APRV (Airway Pressure Release Ventilation), PPS (Proportional Pressure Support), Sigh, HFO VG and ATC（Automatic Tube Compensation）as options.
- **NeoPAP.** NeoPAP is a sophisticated CPAP delivery and treatment system developed to treat newborns and infants with respiratory distress syndrome (RDS) or who are recovering from RDS. The NeoPAP patient interface's small profile and ability to be used with both CPAP and flow modes, coupled with Baby-Trak leak compensation technology, gives you the freedom to accommodate the unique care needs of your smallest patients. The innovative bonnet, nasal cannula and nasal mask designs work in concert to help minimize the need for adjustments during therapy, allowing you to spend more time caring for your patient and less time tending to the device. NeoPAP allows you to create an environment where patients can rest more comfortably and focus their energy on growth and development. Watch the NeoPap video for more details.

Intended users

The innovation (BLosSoM) is meant for infants with respiratory difficulties.

Product requirements

For this innovation, we shall need the following:

- Baby mask which covers nose and mouth simultaneously
- Homogeneous mixture of airflow and aerosol medicine in three different sizes of to fit physionomies up to 30 weeks
- Incorporating means for the assembly of a Nebulizer
- Use possible with or without a Nebulizer
- Use possible with Oropharyngeal (Guedel) airway
- Able to be used with standard CPAP equipment

- Manufacturable with as much standard parts as possible
- Fulfilling the relevant medical devices standards and regulation
- Including Guedel airways in three sizes.

Regulation checklist

Standard	**Description**
EN ISO 11607-1:2009+A1:2014	This standard specifies how the devices shall be packaged to allow sterilization and ensure that they remain sterile. You may also be interested in ISO 14644-1 This standard specifies requirements for the manufacturing environments. NOTE: this standards has multiple chapters that may not be required while designing a medical device but will be mandatory during industrialization.
ISO 17665-1:2006(en)	You may also be interested in chapter -2 of this same standard
ISO 10993-1 and any of the additional chapters of this standard that may be applicable to your specific device	NOTE: This standard has 18 additional chapters, reading the chapter -1 will guide you on the choice of the applicable additional chapters.

The following standards and guidelines are applicable to all devices, regardless the kind and risk classification:

Standard	**Description**
EN ISO 13485:2016	This standard specifies requirements for all entities involved in medical devices, in all stages of the product life cycle: from design to manufacture to installation to disposal. UBORA Platform is structured to be a guideline for design activities in compliance to this standard.
EN ISO 14971:2012	This standard specifies requirements for designers and manufacturers of medical devices, in order to minimize the risk of the device itself. There is no "risk zero" device but many activities can be implemented to reduce and manage risk. This standard provides useful checklists and also guidance on the most widespread risk management techniques such as FMEA.
MEDDEV 2.7.1 rev 4 CLINICAL EVALUATION: A GUIDE FOR MANUFACTURERS AND	This guideline provides information on methods used to assess the clinical performance and the clinical benefit of a medical device. It is provided for free by the Commission at

NOTIFIED BODIES UNDER DIRECTIVES 93/42/EEC and 90/385/EEC	http://ec.europa.eu/docsroom/documents/17522/attachments/1/translations/en/renditions/native.
IEC 62366-1	This standard provides guidance on how to manage the human factors while designing a medical device (usability engineering). NOTE: chapter -2 of ths same standards will provide comments and integrations
EN ISO 15223-1:2016	This standard lists a series of symbols that may be applicable in labels of medical dev

Conceptual Design

Physical principles

The proposed design should have the following properties:

- Flexible mask with Smooth edges
- Thin Transparent walls for exact positioning
- Exhalation Holes in the mask
- One way valves with an active control
- Straps for holding device in place
    - These are the different types of straps available
    - One elastic strap type
    - Two elastic straps
    - Whole head helmet type
    - Fabric hat/cup
- Medicine and air mixing mechanism this property has the following variables namely:
    - Perpendicular connection
    - Flow promoting angle
    - Two different ducts
- CPAP connection - This is the point at which a positive pressurized pipe and mask connections are made. It only has two variables namely:
    - Male
    - Female
- Nebulizer holder - This is also the point at which the nebulizer piping is attached to the mask
    - Male
    - Female

- Airway opening - It prevents the tongue from covering the epiglottis, which could prevent the infant from breathing. The preferred option is the Guedel type.
- Condition monitoring - This parameter will deal with continuous monitoring of the state of the respiration on the patient. This can be achieved by using the following sensors:
    - Temp sensor
    - Pressure sensor
    - Optical sensor
    - Electrical conductivity
    - Humidity sensor
    - Noise sensor

Voting

Figure 2 shows the voting for all the conceptual design.

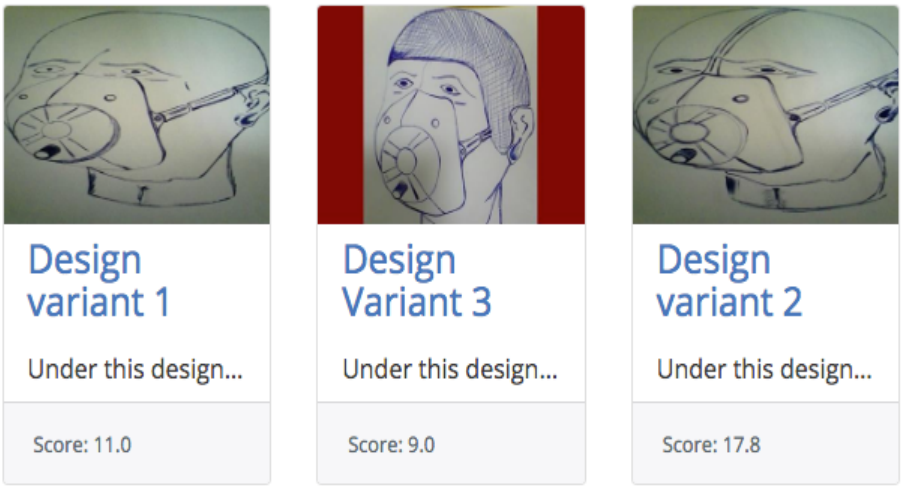


Figure 2: BLosSoM Conceptual Design

- **Design variant 1 and 2:**Under this design, the BLosSoM will have a flexible fitting mask with thin walls and holes in the mask. It will also have one elastic strap for holding the device tightly in position. For better air and medicine mixing, we intend to design the mask in an air promoting angle with male CPAP and Nebulizer connection. The air way opening will be of the Guedel type with a humidity sensor for condition monitoring.
- **Design variant 3:**Under this design, the BLosSoM will have a flexible fitting mask with thin walls and holes in the mask. It will also have an elastic strap for holding the device tightly in position. For better air and medicine mixing, we intend to attach two different ducts to the mask with male CPAP and Nebulizer connection. The air way opening will be of the Guedel type.

Concept Description

The device has a provision that connects the Nebulizer Hold and the CPAP tube allowing the positive air pressure and the aerosol to be administered to the neonate simultaneously at a flow promoting

angle. The device is flexible for proper fitting on the infant's face, smooth edges for comfort and thin transparent walls for exact positioning.

It has holes on the periphery to facilitate exhaling. Two straps will be used for holding the device at a fixed position covering both the nose and mouth of the patient. Both the Nebulizer and the positive air pressure connections will be male. The airway connection will be of Guedel type. Condition monitoring will be done using a pressure sensor.

Structured information on the device

Health technology specifications

Dimensions (mm^3)	35 mm x 34 mm x 46 mm
Weight (kg)	0.037 kg
Does it require the use of consumables? For example, disposable batteries, disposable electrodes, etc.	No
Estimated life time	
Estimated shelf life	
Can it have a telemedicine or eHealth application?	No
Does it use any kind of software?	No
Is it portable?	Mobile
Type of use	Single use
Does the technology require maintenance?	No
Energy requirements	Mechanical energy (e.g. manually powered)
Facility requirements	Sterilization (description: PASTEURISATION This is a process of hot water disinfection i.e. 70°C for 30 min which is accomplished through the use of automated pasteurisers or washer disinfectors. This method is less damaging to equipment than autoclaving, reliable, nontoxic, and less expensive.)

Design and prototyping

General product description

Hardware

- Commercial Parts
    1. CPAP device. For instance, Fisher & Paykel Healthcare.

2. A nebulizer with 20mm in diameter
3. Standard CPAP airflow tubing
4. Elastic Straps

- Purposely designed parts
  1. Mask with positive pressure air supply and nebulizer port.
  2. Adopter for mixing the Nebulizer flow and CPAP flow.
  3. End cap to close the nebulizer port when not in use
  4. System integration
- Prototypes and functional trials

  The Nebulizer and the positive air pressure tube are designed to the set standard and as a result the device can be used with all available accessories in the market.

Instruction for fabrication prototypes

Once the part is finished in the design software (NX in our case), it is necessary to create an STL file which is a triangular mesh fitting the mask geometry. This translation was done in NX software. We use a program called Meshmixer to smooth some sharp edges created during the STL conversion.

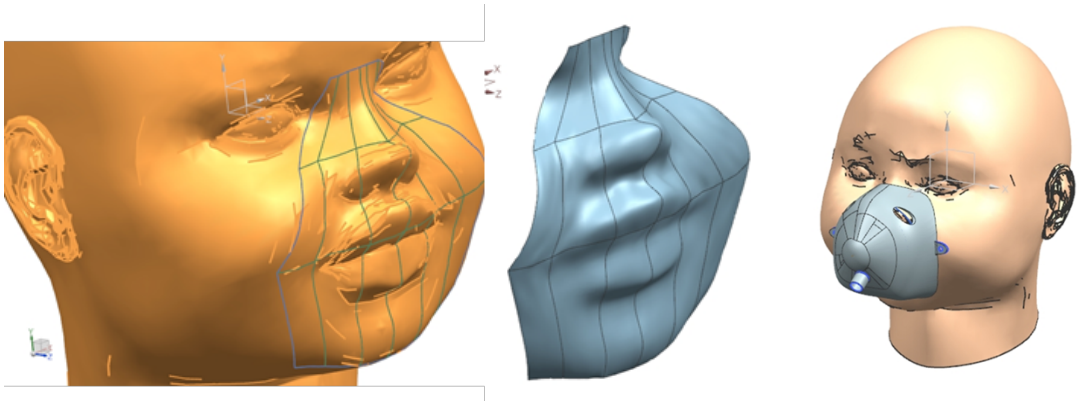


Figure 3: The geometry of the BLosSoM was based on the 3D reconstruction of the face of a doll

After STL conversion, a program called FlashPrint is used to create the code for controlling the printer. In this program, we can decide the relative position of the part to be printed. We are looking for the quickest way of print the, which is the one needing the minimum number of support. In our case this corresponds the position where the mask lays on its face edges. In the said position we did not exceed the maximum angle which additional support is needed. In the program, we can also check the time needed for the print, so that the workload of the printer can be optimized.

We used a creator pro printer to print the mask. Calibration of the printer was done by Pisa University. We used a PLA coil with 1.75mm diameter.

After printing we removed the supports, and checked that the geometry fits the with the pace of the baby. thereafter reinforced the straps hole with a soldering tip heated at 200 degrees.

PACI-SIDS
A NEW SENSORIZED PACIFIER TO REDUCE SIDS

Device Classification: Class IIb

Sudden Infant Death Syndrome, known as SIDS, is the unexplained death of children less than one year of age. SIDS is the leading cause of deaths among babies, in fact, every year, 1 out of 6 infant deaths is caused by this syndrome. It is not possible to predict SIDS, however, using a medical device that can highlight life-threatening situations allowing you to act on time, can save life. Our device is a breathing monitor system, that can be used to prevent SIDS and to diagnose night time anomalies, such as infant sleep apneas. The device is a simple system consisting of a pacifier, a flow sensor, and a case containing battery, acoustic and two visual alarms (one indicates the battery charge level, the other the sensor working). It belongs to class IIb medical devices and it is compliance to European ISO standards. Using the device has several advantages: safety for the baby, peace of mind for the parents, diagnosis of nighttime infant apneas, sudden intervention in case of accidental suffocation, decrease of child mortality percentage. The system can also be further improved, adding, for example, a thermometer that constantly measures temperature. Figure 1 shows the new sensorized pacifier.

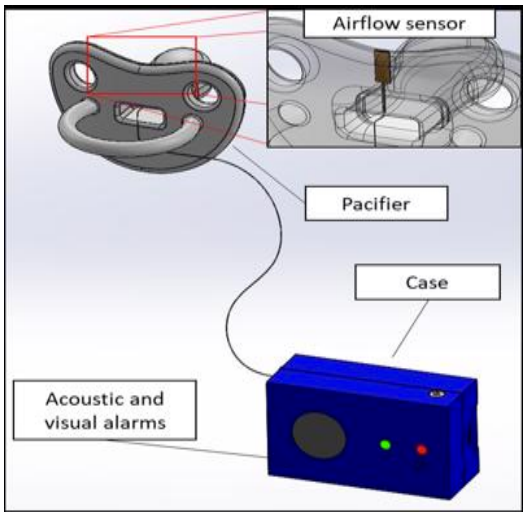


Figure 1:A new sensorized pacifier to reduce SIDS

Medical Need and Product specification

Clinical Needs

Sudden Infant Death syndrome, known as SIDS, is the unexplained death of children less than one year of age. SIDS is the leading cause of deaths among babies, in fact, every year, 1 out of 6 infant

deaths is caused by this syndrome. It is not possible to predict SIDS, however, using a medical device that can highlight life-threatening situations allowing you to act on time, can save life. Our device is a breathing monitor system, that can be used to prevent SIDS and to diagnose night time anomalies, such as infant sleep apneas.

Intended users

The device has to be used at home during sleep time.

Products requirements

The device is a simple system consisting of a pacifier, a flow sensor, and a case containing battery, acoustic and two visual alarms (one indicates the battery charge level, the other the sensor working). Acoustic alarm must be audible from at least one meter away and visual alarms must be seen from the same distance. Green light indicates the correct functioning, while red light indicates the presence of anomalies. As it should be used throughout the night, a 1200 mAh lithium battery has been selected, estimating battery life of about 8 hours. The flow-meter is a hot-wire sensor made up by two temperature-dependent platinum resistors on a single chip. One resistor is used as a reference, while the other one, crossed by the air flow, cools down. Using a calibration curve the difference of temperature between the two resistors can be correlated with the air flow velocity and, consequently, with the presence of the flow.

Regulation Checklist

Standard	**Description**
IEC 60601-1:2005+AMD1:2012 CSV (consolidated version)	This standard specifies requirements for electromedical devices; it has more than 60 related publications, that describe very specific areas of electromedical devices.
ISO 10993-1 and any of the additional chapters of this standard that may be applicable to your specific device	NOTE: This standard has 18 additional chapters, reading the chapter -1 will guide you on the choice of the applicable additional chapters.

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MEDDEV 2.7.1 rev 4 CLINICAL EVALUATION: A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES UNDER DIRECTIVES 93/42/EEC and 90/385/EEC	This guideline provides information on methods used to assess the clinical performance and the clinical benefit of a medical device. It is provided for free by the Commission at http://ec.europa.eu/docsroom/documents/17522/attachments/1/translations/en/renditions/native.
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EN ISO 15223-1:2016	This standard lists a series of symbols that may be applicable in labels of medical devices

Conceptual Design

Physical principles

- Body Temperature: We can put a sensorized belt on the baby to measure the temperature of the baby
- Respiration Rate: The device has an inbuilt sensor, the thermistor, that detects if the baby is breathing. The device has a reference resistor that reads the room temperature and the thermistor reads the temperature from the exhaled air of the baby, in this way we can understand if the child is breathing correctly.
- Heart Rate :We can add a heart rate sensor to the sensorized belt.
- Body Position: Using an additional photoresistor it is possible to understand if there are problem with baby's position or obstacles on the pacifier.
- Smoke: It's possible to put a smoke detector near the crib of the baby.
- CO: It's possible to use a similar sensor to that in the previous one.

Voting

Figure 2 shows the conceptual design. The idea is to detect baby's breathing by putting a sensor on the pacifier. Using visual and acoustic alarms it is possible to underline life-threatening situations. An

additional photoresistor can be used to verify the correct position of the baby and if there are obstacles on the pacifier. It's possible to supplement the system by adding smoke detector, CO detector and a heart rate detector.

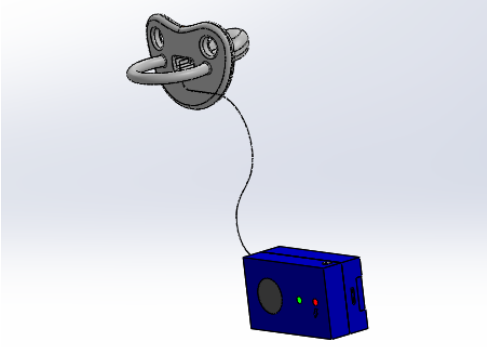

Figure 2: Conceptual design of Paci-SIDS

Concept Description

The device is composed of:

- Pacifier
- case with battery, alarms, and all circuital parts
- thermistor to detect air flow
- photoresistor to verify the position of the baby and if there are obstacles on the pacifier
- CO detector
- Heart rate detector
- Smoke detector

Structured information on the device

User and environment

Who is the intended user?	Family member
Is training required in addition to the expected skill level of the intended user?	No
Is any maintenance or calibration required by the user at the time of use?	No
Where will the technology be used?	at home

Health technology specifications

Dimensions (mm^3)	60mm x 30mm x 35mm
Weight (kg)	0.2 kg
Does it require the use of consumables? For example, disposable batteries, disposable electrodes, etc.	Yes. Lithium battery
Estimated life time	1 Years
Estimated shelf life	6 Months
Can it have a telemedicine or eHealth application?	Yes

Does it use any kind of software?	Yes
If yes, please describe the software, whether it is open source or proprietary, its use and/or license fee, etc. (10-70 words).	Arduino is an open source platform.
If yes, can the software be customized for local use? Please explain (10-70 words). Include languages available.	No
Is it portable?	Portable
Type of use	Long term use
Does the technology require maintenance?	Yes Type: preventive maintenance Frequency: 1 year Can it be done on-site / home / community?: Yes
If yes, who should provide maintenance?	Technician
Energy requirements	Batteries
Facility requirements	Access to the Internet

APPROPRIATE WARMTH FOR INFANTS WITH HYPOTHERMIA

Device Classification: Class IIb

This project is a monitored warming suit. It keeps baby temperature constant in the range 36.5-37.5°C fighting the hypothermia and preventing the complications that would derive from it. It is made by a stratified structure that holds the internal heat. It is heat insulating, breathable to allow the baby's skin to breath, and waterproof for a very easy cleaning. The heating element consists of a phase change material. It reaches the temperature of 58°C and it releases heat to the baby through a foam mattress to avoid burns. In addition, a monitoring system allows to check the core temperature of the baby and the temperature of the mattress for the security of the device. In the end, but not less important, special belts enable the mother to practice the Kangaroo Mother Care (KMC), skin to skin method to take care of premature babies and newborns (Figure 1).

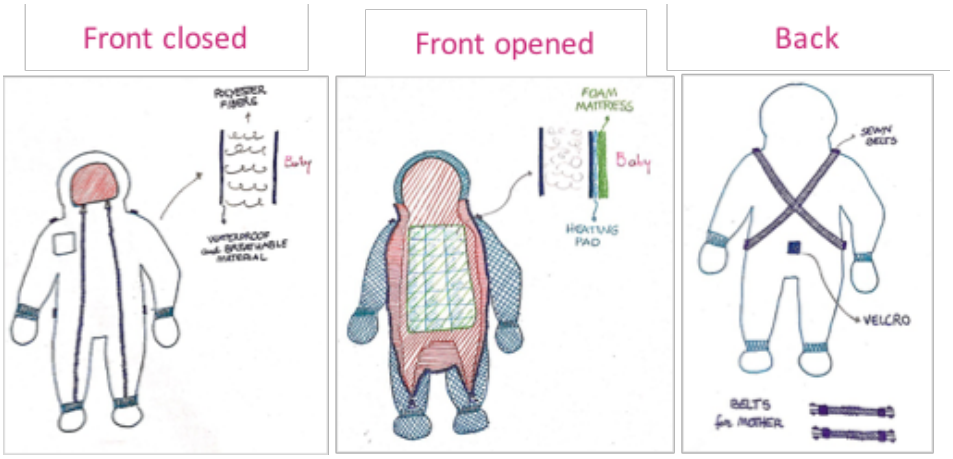

Figure 1:Warm Hug showing functionality with the from closed, open and at eth back

Medical Need and Product specifications

Clinical needs

Over 1.1 million neonatal deaths comprising 28% of the global burden occur in sub-Saharan Africa with Nigeria, Ethiopia, Democratic Republic of the Congo and Tanzania contributing 6%, 4%, 3% and 2% of the global burden of the neonatal deaths respectively. It is estimated that 17 million newborns develop hypothermia annually in the developing countries and in some parts of the sub-Saharan Africa incidence of 60% to 85% have been documented.

Existing solutions

- Radiant warmer.
- Incubator.
  (both solutions are compact, expensive and require high power supply about 100-240 volt)
- 'Embrace' : baby warmer.

Intended user

Intended users are the nurses, midwives and immediate caretakers to the child at risk of hypothermia. The suit would be applicable to a health facility setting and also to a home setting.

Product requirements

The device has to keep the temperature constant in the range of 36.5-37.5°C. The device need different electric components to monitor the temperature (Arduino, 9V battery, 2 thermistors, led monitor, sound alarm, red led and a switch).

Regulation Checklist

Standard	**Description**
IEC 60601-1:2005+AMD1:2012 CSV (consolidated version)	This standard specifies requirements for electromedical devices; it has more than 60 related publications, that describe very specific areas of electromedical devices.
EN 62304:2006+A1:2015	This standard specifies how to design and code software for medical devices and sets requirements for SW change control.

The following standards and guidelines are applicable to all devices, regardless the kind and risk classification:

Standard	**Description**
EN ISO 13485:2016	This standard specifies requirements for all entities involved in medical devices, in all stages of the product life cycle: from design to manufacture to installation to disposal. Ubora Platform is structured to be a guideline for design activities in compliance to this standard.
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MEDDEV 2.7.1 rev 4 CLINICAL	This guideline provides information on methods used to assess

EVALUATION: A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES UNDER DIRECTIVES 93/42/EEC and 90/385/EEC	the clinical performance and the clinical benefit of a medical device. It is provided for free by the Commission at http://ec.europa.eu/docsroom/documents/17522/attachments/1/translations/en/renditions/native.
IEC 62366-1	This standard provides guidance on how to manage the human factors while designing a medical device (usability engineering). NOTE: chapter -2 of the same standards will provide comments and integrations
EN ISO 15223-1:2016	This standard lists a series of symbols that may be applicable in labels of medical devices

Conceptual design

Physical principles

The heater is made with a supersaturated solution of hydrated sodium acetate. At room temperature, the solution is liquid though it is under its solidification point. After a violent movement of the molecules, caused by a small curved metallic plate, the reaction of solidification starts and all liquid crystallizes releasing heat. The solution in few seconds reaches the temperature of 58°C.

The solution has a latent heat of fusion of 264-289 kJ/kg. With a baby of 2.5 kg and a human body specific heat of 3.6 kJ/(kg°C), we need 9 kJ to heat the baby of 1°C and assuming no heat losses, we need 35 g of solution.

The insulation is provided by the polyester fibers with a thermal conductivity of about 0,038 W/m,K and the waterproof and breathable effects are provided by a material like GoreTex or NanoPro (about impermeability of 40 PSI and breathability of 4-6 RET).

Voting

The chosen design received a score of 16.5.

Concept description

Warm Hug is intended to combat hypothermia using the combination of KMC (Kangaroo Mother Care) and the heat input which supplies a Heating Pad that can raise the temperature gradually to reach 58 degrees. Which is delivered progressively and without reaching temperatures that damage the baby's skin thanks to the Foam Matress that it has.

KMC involves placing the baby in the mother's bare chest favoring skin contact between them. This contact allows to obtain a temperature control similar to that of an incubator and gives the baby safety and tranquility. What allows it to better regulate stress and improve response to external stimuli.

Pediatric studies show that KMC also promotes psychomotor development, reduces apneas and improves the baby's immune system protecting it from infections.

The benefits of KMC supports along with the action of Heating Pad allow the device to be a suitable solution to treat the hypothermia problem in premature babies as well as in older babies. Being a valid solution and applicable in any part of the world.

Design and prototyping

General product description

Hardware

- Commercial parts:

  Suit parts: polyester fibers, coating material, hinges, heating elements, belts, hooks, foam mattress.

- Purposely designed parts

  Figure2 shows the box for the electrical parts.

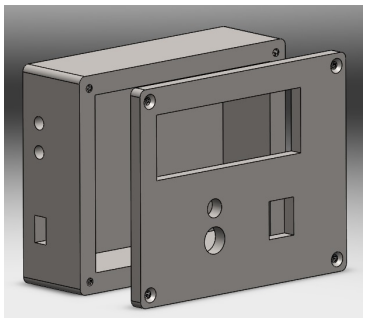

Figure 2Box Designed for the Electrical Circuit.

- Prototypes and functional trials

  The BOX has been designed with the Siemens NX CAD program.

  - Box: The first sketch is a rectangle of dimensions 100x80 mm. Once finished, we made an extrusion of the geometry with a height of 30mm. In the second sketch we introduce the geometries corresponding to the recesses that allow to house the inner circuit, the outputs for the battery cable and the outputs for both sensors. Finally round the edges of the box to get a better finish.
  - Top: It is only necessary to make a sketch that has the same dimensions (100x80) and include the necessary holes to place the LCD display, the buzzer, the LED, the switch and finally the threaded holes for the fixing screws. We finish the cover giving thickness to the geometry and rounding the edges.
  - The Heating Pad and the Foam Mattress are then introduced into the suit through a linear hole made by cutting its back.

- The suit also has two small holes through which the wires from the sensors to the box are introduced.
- The suit is made of two layers, the inner side is polyester while the outer layer is a textile finding the optimum between breathable and waterproof.

Electronic and Firmware

- Commercial parts

  Electrical parts: thermistors, wires, battery, lcd, led, buzzer, arduino.

- Purposely designed parts, Prototypes and functional trials

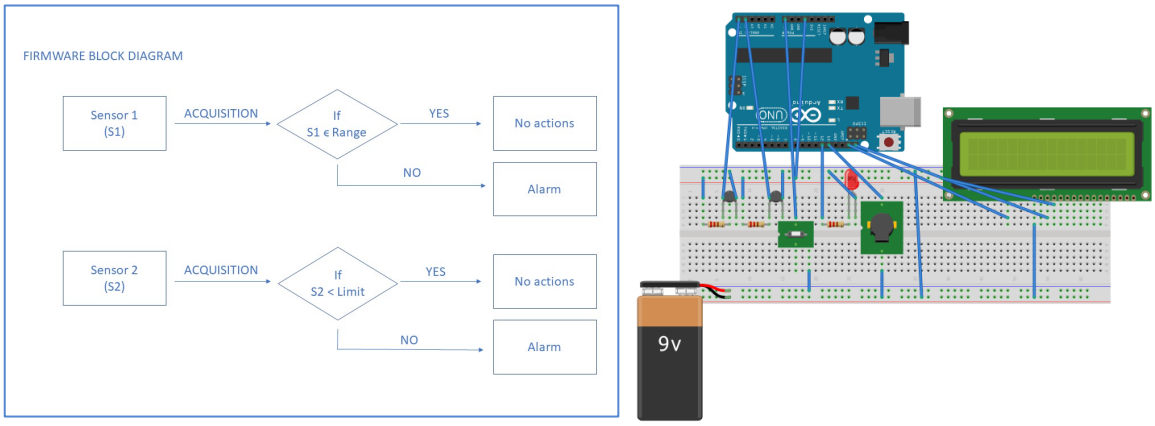

Figure 3: Block diagram of the designed firmware, and schematic of electrical circuit (designed using Fritzing)

Software

- Existing solutions (open source)

  Used libraries:

  #include <Wire.h>

  #include <LiquidCrystal_PCF8574.h>

  #include <DHT11.h>

  https://www.arduino.cc/en/Reference/Libraries

- Prototypes and functional trials

  Our software is already integrated inside the box of the electrical part, so the user needs just to turn on the monitoring system.

System integration

The mother has to insert the baby in the suit, to attach the sensor under the armpit of the baby and to close the suit. After that she has to connect the wires to the monitoring block, to insert the battery in the special space and turn on the monitoring block.

UNIVERSAL SPLINT FOR IMMOBILIZATION

Device Classification: Class I

The splint is a rehabilitation device used to immobilize and support broken or dislocated limbs as they heal. The project idea is to design a 3D printed universal splint that will be used instead of the normal plasters which have numerous disadvantages such as water absorption, causing numbness and soreness among others. Our device is an improved version that can be made to custom fit anyone hence the term 'universal splint'.

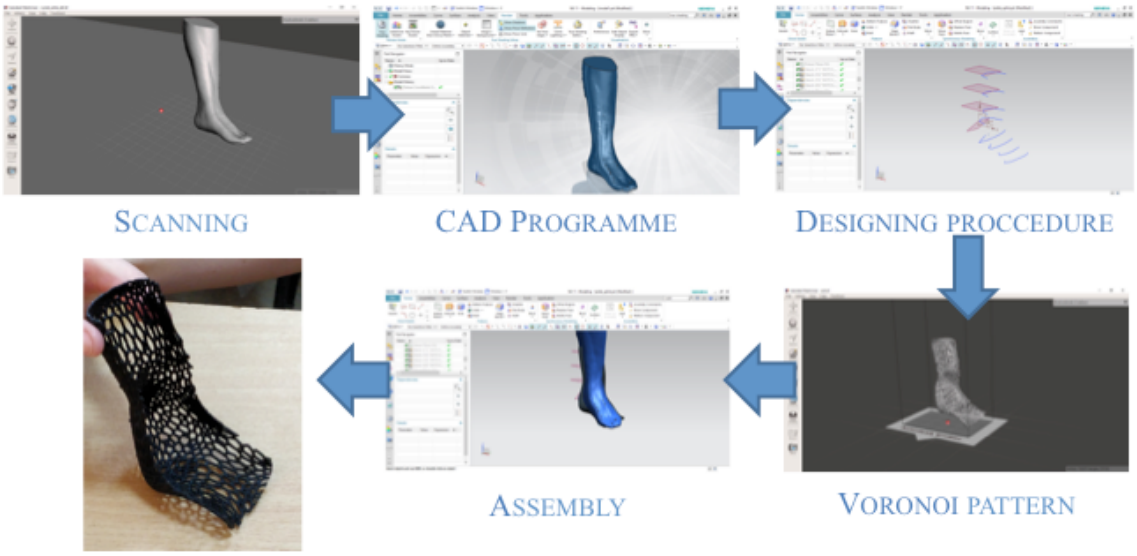

Figure 1: Design steps for universal splint for immobilization

Medical Need and Product specifications

Clinical needs

Patients with broken and dislocated limbs sometimes benefit from immobilization. Our device is aimed at immobilizing different limbs for providing a universal approach to articular problems. It can be personalized to correct problems in ankle, knee, wrist, elbow, neck and fingers.

Existing solutions

Common solutions for articular immobilization include: plasters, materials that can be thermoformed and personally adapted, polymeric-ceramic pastes, among others. Common problems of existing solutions include:

- Plasters are too rigid sometimes, promote local skin irritation and overall uncomfortable.
- Available thermoformed materials protected by patents are too expensive even if their production costs are low.

So we claim that our solution may be more personalized and comfortable, while produced where the patients are solving supply chain problems.

Intended user

Children and adults with articular pathologies all over the World.

Product requirements

- It should withstand mechanical demands to be defined depending on the articulation we focus.
- It should allow for deformations up 10-20% for improved adaptation and healing.
- It should be washable for allowing daily activities and normal lifestyle.
- It should allow the skin to breathe.

Regulation checklist

Standard	Description
ISO 10993-1 and any of the additional chapters of this standard that may be applicable to your specific device	NOTE: This standard has 18 additional chapters, reading the chapter -1 will guide you on the choice of the applicable additional chapters.

The following standards and guidelines are applicable to all devices, regardless the kind and risk classification:

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EN ISO 15223-1:2016	This standard lists a series of symbols that may be applicable in labels of medical devices

Conceptual design

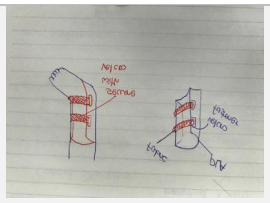
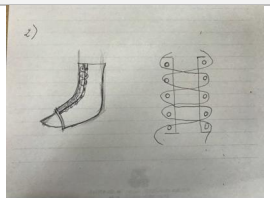
Physical principles

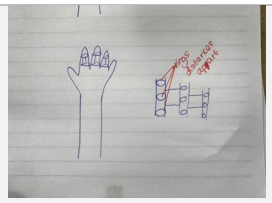
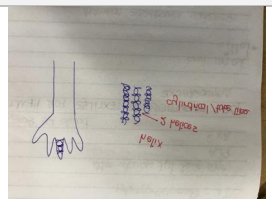
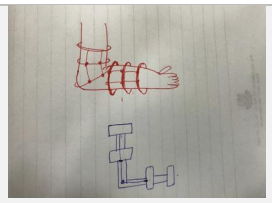
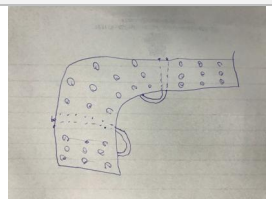
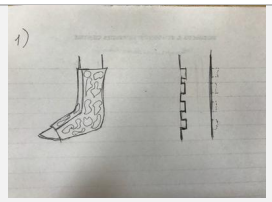
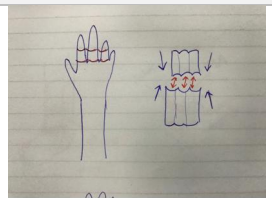
A splint is a mechanical device that is used to immobilize a fractured, broken or dislocated limb or body part. The basic design of this universal splint consists of a splint structure to support the broken/dislocated area and a method of securing the structure to ensure the area is immobilised. For the design we have considered the following product requirements:

- It should withstand mechanical demands to be defined depending on the articulation we focus.
- It should allow for deformations up 10-20% for improved adaptation and healing.
- It should be washable for allowing daily activities and normal lifestyle. The material should be waterproof to avoid water absorption.
- It should be breathable i.e. allow the skin to breathe freely and be comfortable.

Basic physical principle is having a material enough resistant to immobilize the damaged articulation, while allowing some extent of deformation for improved healing and comfort. Main subfunction is structural, but interaction with the skin is also considered and improved via controlled porosity. The attachment to the articulation is another subfunction to be solved by alternative principles, including the use of straps, velcro and mechanical joints among the components of the splints.

Voting

Design	**Image**	**Score**
ANKLE 1 Consists of PLA and securing band with velcro		16.3
ANKLE 2 Consists of two separate parts of PLA that are tied together with a string		16

FINGER 1 This design consists of rings at distances apart from each other held together		17
FINGER 2 This design consists of two helices joined together to form a cylindrical splint		18
ELBOW 1 This design consists of ring like structures that surround the hand at different distances and are held together		14.3
ELBOW 2 this design consists of PLA and belts that fasten the splint together on the elbow		13.8
ANKLE Consists of two separate part of PLA that interlock		14.8
FINGER this design consists of two halves that join together by interlocking		12

Concept description

Universality means in our case being able to adapt the basic design to any kind of articulation and articular problem and being able to promote mass-customization approaches, which can be manufactured in the point of care, hence simplifying supply chain issues.

The knee, elbow and neck splints will comprise two parts for allowing mounting (i.e. a 3D printed splint made of thermoplastic polymer and a velcro band, strip or mechanical connection for securing them in place for maintaining their structure).

However, the finger splint can be constructed as a single part, directly by 3D printing the complex geometry using normally thermoplastic materials.

They are universal because we perform parametric CAD design operations, which can be tuned in a personalized way to the patient, either by resorting to digitalization employing optical or laser-based scanners or by using more conventional measuring systems. Once the key geometrical features of the patient are known, the design is updated in "just three clicks".

The splints are waterproof, lightweight and slightly flexible to allow it to easily be placed on the affected body part and to provide comfort to the patient.

Structured information on device

User and environment

Who is the intended user?	Physician
Is training required in addition to the expected skill level of the intended user?	No
Is any maintenance or calibration required by the user at the time of use?	No
Where will the technology be used?	rural settings, urban settings, outdoors, indoors, at home, primary level (health post, health center), secondary level (general hospital), tertiary level (specialist hospital)

Health technology specifications

Dimensions (mm^3)	300 mm x 300 mm x 300 mm
Weight (kg)	0.2 kg
Does it require the use of consumables? For example, disposable batteries, disposable electrodes, etc.	No
Estimated life time	1 Months
Estimated shelf life	3 Months
Can it have a telemedicine or eHealth application?	No
Does it use any kind of software?	No
Is it portable?	Portable
Type of use	Long term use
Does the technology require maintenance?	No
Energy requirements	none
Facility requirements	none

Design and Prototyping

General product description

Hardware

- Commercial parts

  In principle, there are no commercial parts because the device is custom made or uses geometries that, after mass-production, can be mass-customized by taking advantage of the flexibility of the material and its easy adaptation to corporal geometries. This may be connected to 4D printing strategies.

  In some special cases we may need to buy medical straps that secure the splint for a better performance, especially for splints that cannot be coupled to the patient as a single part (i.e. typically in the case of neck, elbow and ankle).

- Purposely designed parts

  External geometries of the human body, especially articulations for the purpose of the project, can be digitalized with the help of optical scanning (i.e. using low-cost solutions available, such as combination of Kynect hardware and Skanect software) or even by directly measuring in more traditional ways upon the patient. This information is then used to create a phantom or digital replica of the articulation needing support.

  Afterwards, following the surfaces and geometries of the measured body structure, conventional CAD modelling operations help to achieve the personalized design.

  By means of example, in the case of a personalized splint for a damaged finger, the design process may start by a 3D spline curve or by using an spiral with controlled pitch surrounding the surface of the finger. Then, a datum plane may be used, placed normal to the curve in its extreme, in which a circumference used as section for a sweep along the spline curve is drafted. The sweep along guide operation creates a solid object, which can be further processed towards manufacture.

  Taking another example, in the case of designing a splint for an elbow, datum planes can be used to create curves surrounding the patient's elbow. These curves are used further on for defining a connected surface, which can further on be thickened to create a solid object.

Software

- Existing solutions (open source)

  To scan the body parts we used Scanned software from Microsoft Kinect

  For the computer aided design we used NX a PLM software by Siemens, which is not open source but was available for the project. There are existing alternative software that are open source.

  After the CAD we used Autodesk Meshmixer to create the triangular meshes on the splints

Finally we used FlashPrint a slice software by FlashForge, which prepares the design for the 3D printer by adding supporting materials

System integration

- Prototypes and functional trials

The splint is designed according to the size of the individual patient's limb/body part. Then it is held together using a strap to enable immobilization.

The first prototypes obtained within the First UBORA Design school have helped us to validate the concept of the "universal splint", as we have reached functional prototypes of splints for ankle, elbow and fingers. We have validated them by means of in vitro (using a baby model) and in vivo (using one of the mentors) trials.

Functionality is according to expectations, although additional research in terms of potential materials used and final tests regarding ISO compliance are still needed.

The following images provide some insight about the results of first prototyping trials (Figure 2):

Figure 2:Prototype of the universal splint for immobilization

Design for ISO testing compliance

Once the devices are manufactured, typically by using 3D printed PLA, compliance with standard ISO 10993-1 will be analyzed, so as to check the device biocompatibility.

We need still to perform the biocompatibility matrix of our device, so as to check the types of tests to perform. In principle we envision the need for testing potential skin irritability due to contact with the material used for constructing the prototypes.

Depending on the type of articular pathology and on the period the device is needed, additional tests may be needed, as duration of treatment affects the biocompatibility matrix of ISO 10993-1.

Instructions for fabrication of prototypes

The overall digitalization, design and manufacture process for reaching viable prototypes is schematically presented in Figure 3. Regarding prototyping, in short, after CAD modeling and conversion to .stl file format, topological optimizations can be performed by using software such as

MeshMixer to generate the desired lattice or porous structures, which are beneficial for letting skin breathe, for improved mechanical performance and for overall weight reduction.

After optimization, the resulting .stl file is passed forward to an slicing software (i.e. open-access options such as Cura or Flash Print) to generate the slices and trajectories for the additive manufacturing or 3D printing of the desired splints. Final tuning or personalization by including color bands or strips can be added for the pleasure of the patient.

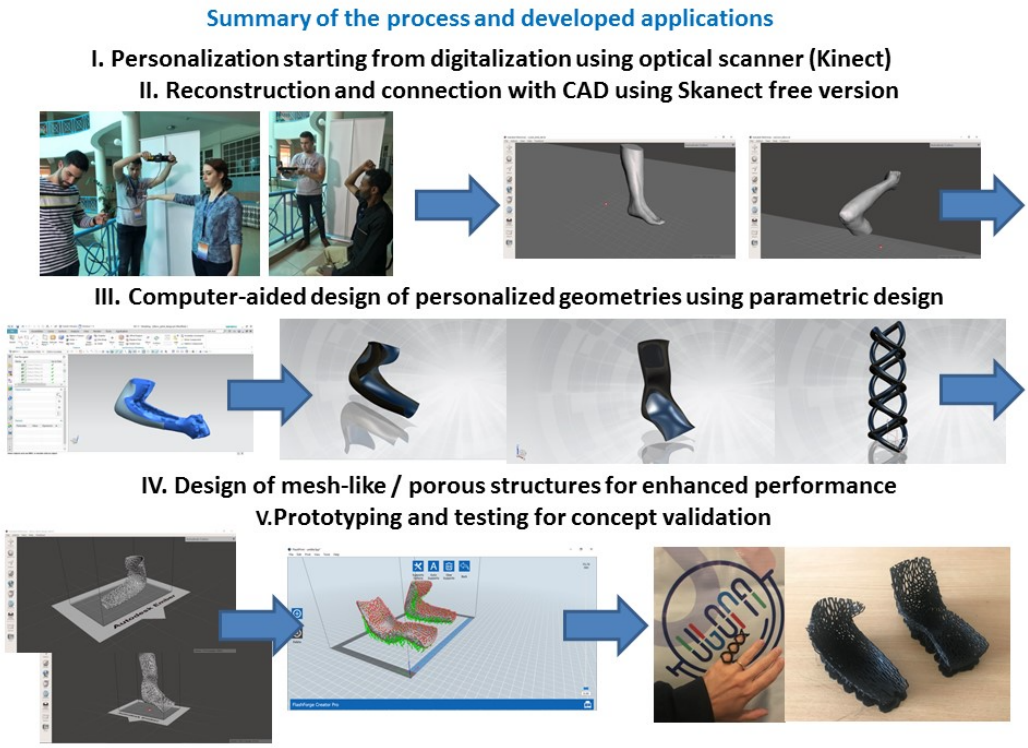


Figure 3:The overall digitalization, design and manufacture process for reaching viable prototypes

FACE PROTECTING SPLINT FOR CHILDREN WITH BROKEN NOSE

Device Classification: Class I

Nasal fractures being the most common types of facial fractures are often unrecognized and untreated at the time of injury. Different masks have been designed to help patients with broken nose however, they are not rehabilitative and are expensive. It is on this note that the team designed a modular multi-purpose face mask, Figure 1, for aligning and protecting broken nose. In addition, the mask will cover faces with burns and landmine injury from solar radiation and exterior agents. It's apparel is aesthetically pleasing in order to give children more confidence to plays with their friends.

Figure 1:Modular multi-purpose face mask

Medical Need and Product specifications

Clinical needs

The device will be used for correct broken nasal regeneration. If not treated this condition can lead to other serious problem. It can also be used for protection from external factors e.g., sun radiations, physical contact, pathogenic infection. The design can also be implemented as a cosmetic feature.

Existing solutions

Clyde's custom face masks

The mask in Figure 2on the right does not combine cosmetics function with a rehabilitative one. They are also expensive costing about $250. They are custom products.

Figure 1:Modular multi-purpose face mask

Intended user

These are those patients with broken nose and facial disfiguration.

Product requirements

- It has to be modular.
- It has a cosmetic part that can attached with a rehabilitative one.
- It has to be comfortable.
- It has to be cost effective costing about $10.
- Easy to assemble.
- Easy to clean.
- It has to be flexible.

Regulation checklist

Standard	**Description**
ISO 10993-1 and any of the additional chapters of this standard that may be applicable to your specific device	NOTE: This standard has 18 additional chapters, reading the chapter -1 will guide you on the choice of the applicable additional chapters.

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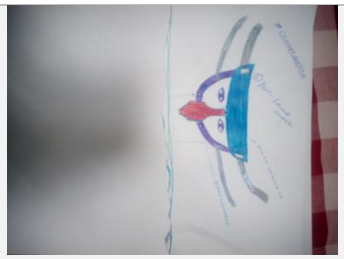
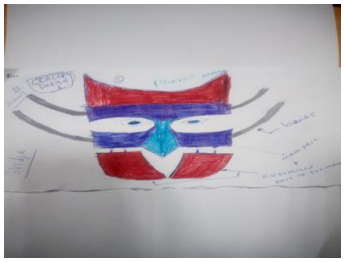
DIRECTIVES 93/42/EEC and 90/385/EEC	
IEC 62366-1	This standard provides guidance on how to manage the human factors while designing a medical device (usability engineering). NOTE: chapter -2 of the same standards will provide comments and integrations
EN ISO 15223-1:2016	This standard lists a series of symbols that may be applicable in labels of medical devices

Conceptual design

Physical principles

- Material between the mask and face: Cotton, Memory foam (polyurethane)
- Material Used to Make the Mask: PLA, ABS, Silicon for injection molding approach
- Connections: Adjustable Head Cradle, Normal Elastic head Band, Nylon fibers

Voting

Concept	Sketch	Description	Vote
Bull faced		Bull faced mask has an appearance of a bull face with pair of straps. The strength of the design is it has a low weight so it can be build with low cost. The weakness of the model is the design is weak in terms of strength and ascetically unpleasant.	**10**
Pharao Mask		Pharaoh mask has two pairs of strap one goes on the cheek and the other one on the forehead going to the back of the head, it can be adjusted to fit in. For this model the strength is it has additional part which can added to cover other parts. Simpler to produce and replicate. Large surface area which make it stable. The part above and below the eye makes it weak in terms of mechanical strength. it is also aesthetically unpleasant and Pharaoh is not popular on this time.	9.5

Modular Multiple Mask		This mask incorporate a design which is suitable for children. Since it is based on the popular figure of Batman with addition of the protection given to the broken nose. It also has parts which can be added to cover additional parts of the face for injuries protection.	17.3

Concept description

We have realised a modular mask design. It can be used for a rehabilitative and/or for cosmetic purpose. With the modular design, we can reduce the cost of making the mask because it can be assembled accordingly to the person needs. Also in this way, we can use an injection moulding approach that will reduce the overall cost.

Structured information on device

User and environment

Who is the intended user?	Self-user/patient
Is training required in addition to the expected skill level of the intended user?	No
Is any maintenance or calibration required by the user at the time of use?	Yes
Where will the technology be used?	rural settings, urban settings, outdoors, indoors, at home

Health technology specifications

Dimensions (mm^3)	200 mm x 2 mm x 300 mm
Weight (kg)	0.1 kg
Does it require the use of consumables? For example, disposable batteries, disposable electrodes, etc.	No
Estimated life time	3 Years
Estimated shelf life	3 Years
Can it have a telemedicine or eHealth application?	No
Does it use any kind of software?	No
Is it portable?	Portable
Type of use	Reusable
Does the technology require maintenance?	Yes Type: Disinfection and cleaning

	Frequency: Daily Can it be done on-site / home / community?: Yes
If yes, who should provide maintenance?	Parents
Energy requirements	
Facility requirements	

Design and Prototyping

General product description

Hardware

- Commercial parts

  Elastic ribbon to fix the mask to the face

- Purposely designed parts

  The mask is custom designed, so every part is personalized. The overall mask, the cheeks, and the esthetical add-on.

- Prototypes and functional trials

  The team has managed to print out the 3D design as shown in the figure below.

Figure 3: Face protecting splint for a "big" children with broken nose

Software

- Existing solutions (open source)
  - Skannect: scan 3D objects as faces.
  - FaceGen3D: software that can generate faces and made a model of an human face withAfrican traits and with the age of 20 years.
  - Meshmixer: repair face geometries.
  - Flashprint: 3D printer (Flashprint created pro) software.

Design for ISO testing compliance

ISO 4007. This was prepared by Technical Committee ISO/TC 94, Personal safety — Protective clothing and equipment, Subcommittee SC 6, Eye and face protection.

Instructions for fabrication of prototypes

With the use of a software that can generate faces (FaceGen3D) we have made a model of an human face with African traits and with the age of 20 years. Then with the Siemens XN cad software we have created an initial modular prototype. This version is a simplified design. Afterwards we have printed the design.

PHOTOTHERAPY BAND TO TREAT THE INFANT JAUNDICE

Device Classification: Class IIb

This device is intended for the treatment of infant jaundice. Neonatal jaundice is a yellowish discoloration of the white part of the eyes and skin in a newborn baby due to high bilirubin levels and occurs in over half of newborns in the first week following birth. The therapeutic device proposed can treat this disease using phototherapy.

Phototherapy refers to the use of light to convert bilirubin molecules in the body into water soluble isomers that can be excreted by the body. In our device blue light from LEDs (460-490 nm) is used to irradiate the baby both from the top and from the bottom at the same time, having a more rapid and efficient treatment. Meanwhile also a temperature control is provided, that allows certain LED arrays to be turned in case of increased temperatures, this lowers the heat production while continuing with the therapy. The temperature is measured near the abdomen and must be between 36.5-37.5 °C to ensure a safe treatment. Figure 1 shows the idea of the device.

Figure 1:Phototherapy device

Medical Need and Product specification

Clinical Needs

Neonatal jaundice is a yellowish discoloration of the white part of the eyes and skin in a newborn baby due to high bilirubin levels. Other symptoms may include excess sleepiness or poor feeding. Complications may include seizures, cerebral palsy, or kernicterus (a type of brain damage).

Infant jaundice is a common condition, particularly in babies born before 38 weeks gestation (preterm babies) and some breast-fed babies.

Infant jaundice usually occurs because a baby's liver isn't mature enough to get rid of bilirubin in the bloodstream. In some cases, an underlying disease may cause jaundice. In other cases it results from red blood cell breakdown, liver disease, infection, hypothyroidism, or metabolic disorders (pathologic).50% of term and 80% of preterm infants develop jaundice.

Existing solutions

Jaundice is mainly treated using phototherapy. There are two main types of phototherapy: conventional phototherapy – where the baby is laid under a halogen or fluorescent lamp with their eyes covered and fiber-optic phototherapy – where the baby lies on a blanket that incorporates fiber-optic cables; light travels through the fiber-optic cables and shines on to the baby's back. These methods however have several challenges including; noise produced by the fan in the light source, decrease in delivered energy with increase in time over heat production.

Convention phototherapy lamp using quartz bulbs were used, but in recent years, devices using LEDs have been on the rise. These present several advantages including low heat production, lower power consumption and longer life spans hence much lower prices. Figure 23 shows the idea of the device.

Figure 1:LED powered phototherapy unit

Intended users

Newborns, infants and children suffering from Jaundice

Product Requirements

Phototherapy refers to the use of light to convert bilirubin molecules in the body into water soluble isomers that can be excreted by the body. The absorptions of light by bilirubin also results in the generation of excited-state bilirubin molecules that react with oxygen to produce colorless oxidation products, or photooxidation products. This process occurs more slowly than configurational or structural isomerization. Photooxidation products are primarily excreted in the urine. Figure 3 show the effect of the blue light in the bilirubin.

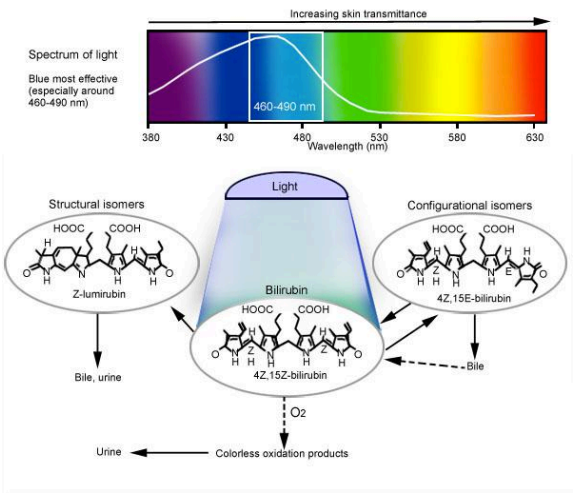


Figure 3: Effect of blue light Bilirubin

- The device should emit blue light (Frequency 460-490 nm).
- The amount of the irradiation level has to be between 6-40 µW/cm2/nm.
- The distance should not be greater than 50 cm (20 in) and can be less (down to 10 cm) provided the infant's temperature is monitored. To have a better efficiency the distance should be 10 cm.
- The device should irradiate the hole body to have a better efficiency. The device must have a temperature control (36.5-37.5 °C)

Regulation Checklist

Standard	Description
IEC 60601-1:2005+AMD1:2012 CSV (consolidated version)	This standard specifies requirements for electromedical devices; it has more than 60 related publications, that describe very specific areas of electromedical devices.
EN 62304:2006+A1:2015	This standard specifies how to design and code software for medical devices and sets requirements for SW change control.
ISO 10993-1 and any of the additional chapters of this standard that may be applicable to your specific device	NOTE: This standard has 18 additional chapters, reading the chapter -1 will guide you on the choice of the applicable additional chapters.

The following standards and guidelines are applicable to all devices, regardless the kind and risk classification:

Standard	Description
EN ISO 13485:2016	This standard specifies requirements for all entities involved in medical devices, in all stages of the product life cycle: from

	design to manufacture to installation to disposal. UBORA Platform is structured to be a guideline for design activities in compliance to this standard.
EN ISO 14971:2012	This standard specifies requirements for designers and manufacturers of medical devices, in order to minimize the risk of the device itself. There is no "risk zero" device but many activities can be implemented to reduce and manage risk. This standard provides useful checklists and also guidance on the most widespread risk management techniques such as FMEA.
MEDDEV 2.7.1 rev 4 CLINICAL EVALUATION: A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES UNDER DIRECTIVES 93/42/EEC and 90/385/EEC	This guideline provides information on methods used to assess the clinical performance and the clinical benefit of a medical device. It is provided for free by the Commission at http://ec.europa.eu/docsroom/documents/17522/attachments/1/translations/en/renditions/native.
IEC 62366-1	This standard provides guidance on how to manage the human factors while designing a medical device (usability engineering). NOTE: chapter -2 of the same standards will provide comments and integrations
EN ISO 15223-1:2016	This standard lists a series of symbols that may be applicable in labels of medical devices

Conceptual Design

Physical principles

Phototherapy refers to the use of light to convert bilirubin molecules in the body into water soluble isomers that can be excreted by the body. The absorptions of light by bilirubin also results in the generation of excited-state bilirubin molecules that react with oxygen to produce colorless oxidation products, or photooxidation products. This process occurs more slowly than configurational or structural isomerization. Photooxidation products are primarily excreted in the urine.

Voting

Figure 4 shows the voting for all of the conceptual design.

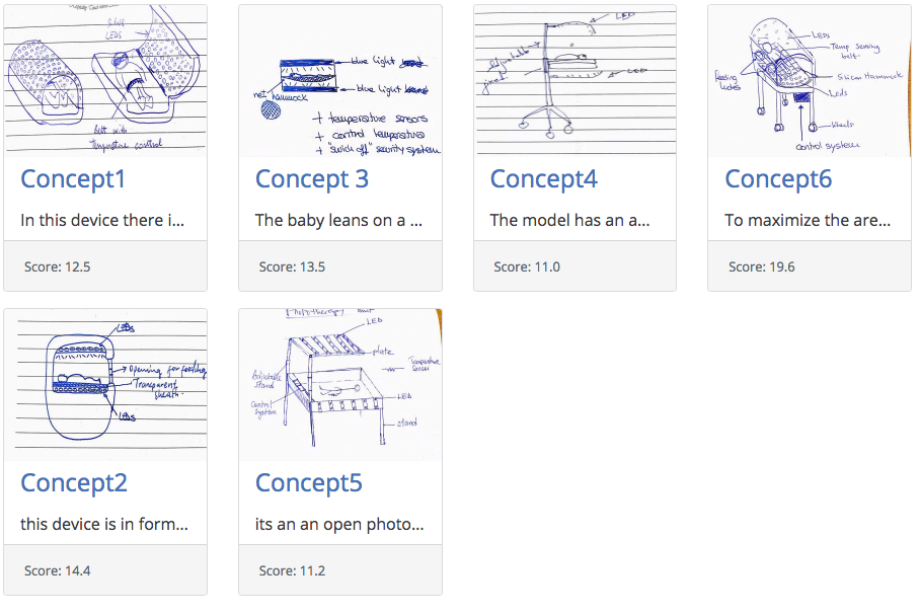


Figure 4:Phototherapy device. Conceptual Design Voting

1.1.1 Concept Description

Blue/green light at a wave length of 460-490nm converts bilirubin molecules in the body into water soluble isomers that can be excreted by the body.

The device contains LEDs both at the top and bottom with a control knob for adjusting intensity to maximize the area irradiated, a bio-compatible hammock lies on top of the bottom LEDS. A temperature control system is also implemented. The top shield is both concave for efficiency and transparent for continuous monitoring of the baby. The device has 2 openings to allow for air circulation, feeding and provision of care. it also four stands with castors making it mobile (Figure 5 on the right).

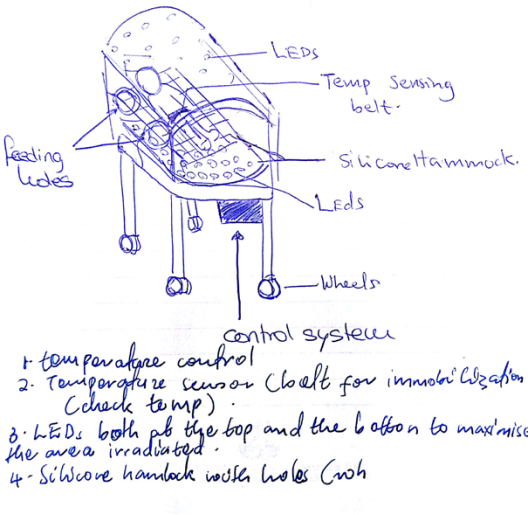


Figure 5: Sketch of device

Structured information on the device

User and environment

Who is the intended user?	Nurse
Is training required in addition to the expected skill level of the intended user?	No
Is any maintenance or calibration required by the user at the time of use?	No

Where will the technology be used?	rural settings, urban settings, indoors, primary level (health post, health center), secondary level (general hospital), tertiary level (specialist hospital)

Health technology specifications

Dimensions (mm^3)	350 mm x 1500 mm x 800 mm
Weight (kg)	9 kg
Does it require the use of consumables? For example, disposable batteries, disposable electrodes, etc.	Yes. Our device is fed by a lithium battery that needs to be recharged after a certain period of time. As well, the LEDs implemented have to be replaced if they get damaged or do not work properly. After a long period of time the cloth hammock can wear away, in that case it would need to be replaced for a new one.
Estimated life time	5 Years
Estimated shelf life	5 Years
Can it have a telemedicine or eHealth application?	No
Does it use any kind of software?	Yes
If yes, please describe the software, whether it is open source or proprietary, its use and/or license fee, etc. (10-70 words).	Arduino is an open-source platform used for building electronics projects. Arduino consists of both a physical programmable circuit board and a piece of software used to write and upload computer code to the physical board. From an economic point of view Arduino is a good option due the fact that the software is free and, what is more, the circuit boards are pretty cheap.
If yes, can the software be customized for local use? Please explain (10-70 words). Include languages available.	Arduino uses C++ language and allows a wide range of functionalities because of the possibility of customize the code depending on our needs.
Is it portable?	Mobile
Type of use	Long term use
Does the technology require maintenance?	Yes Type: check LEDs operation Frequency: once a year Can it be done on-site / home / community?: Yes
If yes, who should provide	Technician

maintenance?	
Energy requirements	Batteries Power supply for recharging Voltage required: 6 V Time required to recharge: 2 hours 30 minutes Battery life with full charge: 48 hours 0 minutes Continuous power supply Voltage required: 6 V
Facility requirements	Sterilization (description: The device must be disinfected using ethanol and 5% hypochlorite in order to avoid infections.)

Design and prototyping

General product description

Hardware

- Commercial Parts

  We need to buy the following components:

  - Silicone hammock: Lies a few centimeters above the bottom LEDs to provide support for the baby
  - Adjusting knob: To adjust the intensity of the blue LEDs;
  - Aluminum profiles: Four aluminum stands provide support for the main structure;
  - Plastic material (HDPE): This will be used to build the external body.
  - Transparent material (Acrylic, PMMA) for continuous monitoring of the baby.
  - Casters: To ease movement of the device (mobility).
  - Cotton cloth: To be put on top of the silicone hammock for baby comfort.

- Purposely designed parts

  Figure 6 shows the designed parts of the device.

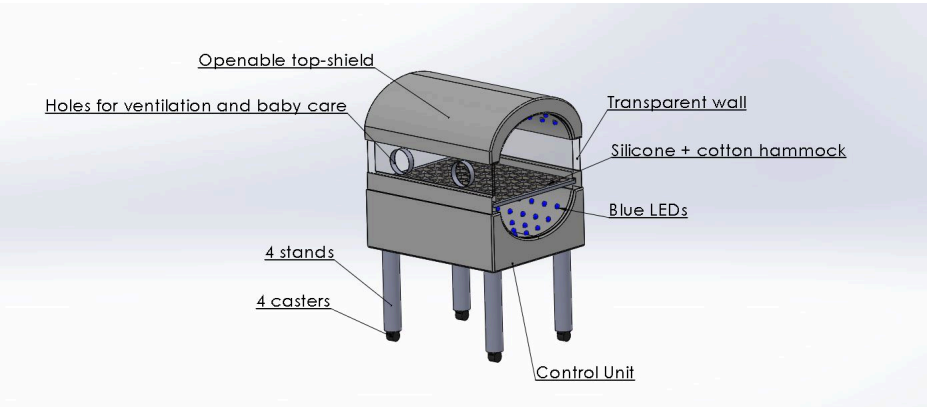


Figure 6: Purposely designed parts for the phototherapy device

- Prototypes and functional trials

  Prototype printed using Flashprint software for Flashforge Creator Pro 3D printer

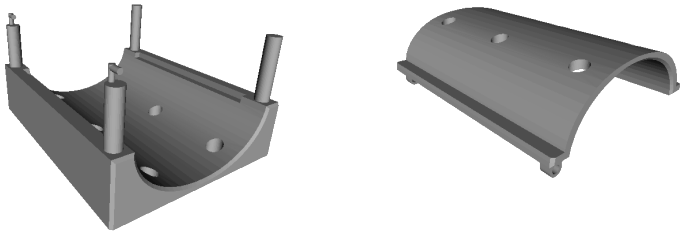


Figure 7: STL files of the components fabricated via 3D printing

Electronic & firmware

- Commercial Parts
  - LEDs: Blue light LEDs with a wave length of 460-490 nm and a forward current of 10mA.
  - Temperature sensors: Sensing temperatures.
  - Arduino, microcontrollers and LCD display: for auto control of the baby temperature.
  - Indicators: To show alert the care taker/nurse of the changes in baby temperature
  - Lithium batteries: 30AH, 12v battery for backup in case of power shortages.
  - Wires and plug: For electrical connections.
- Purposely designed parts
  - The electronic parts of our device include: A circuit board composed of: LEDs, an Arduino, resistors, temperature sensors and transistors. The device will be fed by a 30Ah 6V lithium battery.
- Prototypes and functional trials

  In the prototype, they implemented an electric circuit which is connected to Arduino UNO. The configuration design is show in Figure 8. Flowchart is available on UBORA repository

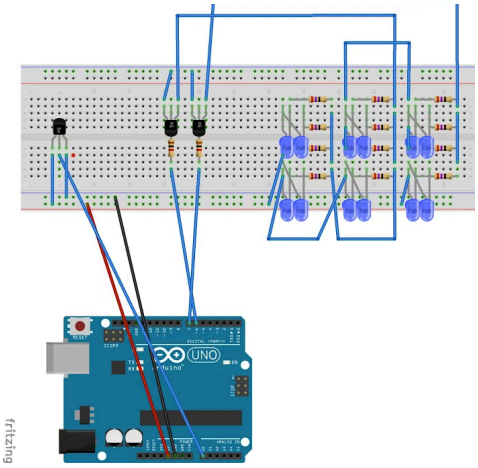


Figure 2:Configuration design of the prototype, designed using Fritzing

On the prototype, there are 6 LEDs at the base and 6 more on the top part. If the temperature is higher than 37.5 C, two LEDs on the base and two on the top will be switched off. If the temperature is still higher than 37.5 C, four LEDs on the base an four on the top will switch off automatically. Finally, if the temperature is still too high, all the LEDs will be switched off.

Software

- Existing solutions (open source)

  The team has not used any source code from other authors.

- Purposely designed parts

  The final device measures baby temperatures, turns off 30% of the LEDs if temperature is higher than 37.5 C, turns off further to 60% if high temperatures persist and finally turns off the entire device if no change is observed. This way the baby maintains its temperatures while continuously being irradiated.

- Prototypes and functional trials

  The software is coded in the Arduino IDE and installed into an Arduino microprocessor using a USB cable from a computer. The microcontroller is typically programmed using a dialect of features from the programming languages C++.

  Specs

  - Uses SRAM memory
  - CPU is AVR (8-bit)
  - Has static RAM(SRAM) memory
  - Storage is on EEPROM

  Arduino implemented code is available in the UBORA repository.

Design for ISO testing compliance

We will test biocompatibility according to ISO 10993-1, which describes the general principles governing the biological evaluation of medical devices within a risk management process.

Electrical leakage, EM interference and earthing tests will be test according to IEC 60601-1:2005+AMD1:2012 CSV (consolidated version).

Validation and verification of the software implemented will be carried out according to EN 62304:2006+A1:2015.

We will carry out safety tests according to EN ISO 14971:2012.

Design for ISO testing compliance

Firstly, we have designed our prototype in CAD software, in particular, we have used Solid Works.

After that, we have transferred our design in a stl file to the software used by the 3D printer we have used for fabricating our prototype.

Finally, the model has been printed correctly. We have removed support parts and the raft.The material used is PLA because it has optimal properties for being used for 3D printing.

The prototype has 3 different parts: base part, top part and the hammock. We have replaced the PMMA transparent walls for four columns that join base and top parts, in order to simplify the fabrication process of the prototype. As well, we have not printed the structural inferior part of the real design due to the fact it does not affect to the functionality of the device.

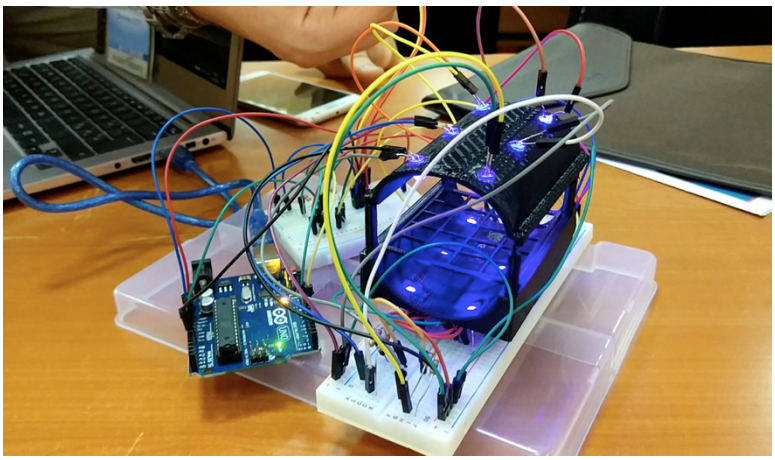


Figure 9: Functional prototype of the device

PORTABLE COOLER FOR VACCINES

Device Classification: Class I

Every year, almost 24 million of newborns are not vaccinated and 50% of the vaccines fabricated are discarded due to inadequate maintenance of cold chain. But just with the vaccines that are currently available it would be possible to save 2 million of children more every year. The device (**Errore. L'origine riferimento non è stata trovata.** aims to reduce child mortality caused by diseases that can be avoid by vaccination.

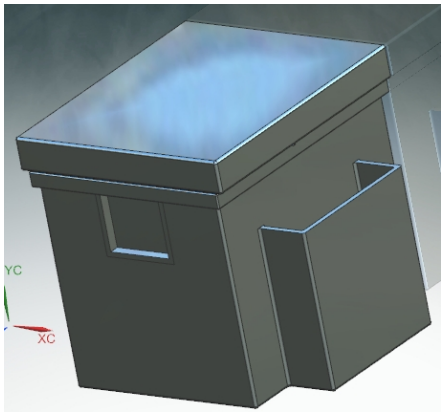


Figure 1: Portable cooler for vaccines

Medical Need and Product specification

Clinical Needs

Vaccination is essential for reaching a reduction in new-born mortality. According to OMS recommendations, children under the age of five years old must be vaccinated against eight diseases: tuberculosis, diphtheria, tetanus, pertussis, poliomyelitis, measles, hepatitis B and HIB. Unfortunately, 20% of the children born every year are not vaccinated according to UNICEF.

In addition, in 2015, an estimated 19.4 million children worldwide failed to receive routine immunization services, with more than 60% of these living in developing countries. Figures suggest that an additional 1.5 million deaths could be avoided if global vaccination system improve.

Due to the difficulties that vaccines storage and logistic entail, the loss rate is up to 50% in some cases. A reduction of this amount will lead to a decrease in infant mortality.

Existing solutions

Figure 2 shows the existing solution the vaccine cooler.

	Product	Comments	Energy supply	Costs	Existing products
Mechanical compression / steam with photovoltaic modules		26 Litres of capacity wich makes it a little heavy. It doesn't have battery.	Uses compressor, mechanical problems can occure.	710.00$	Summit SPRF26 Portable medical freezer coolers.
Adsorption with biomass		Technology in the development phase, low cost, large size.	Any available local source, such as agricultural remains.	Medium-high cost, average operational cost.	Just investigation
Ice		Doesn't get a battery. The ice gets melt. It's small (only 8 Litters).	Ice cubes	132.99$	VCA8F – Vaccine carrier
Soft gel		Doesn't have battery. Doesn't have a temperature regulator.	Soft gel (18 h of temperature maintenance)	78.3 £	The nomad portable coolers SKU: MD8L-S
Hard gel		Doesn't have battery. Doesn't have a temperature regulator.	Hard gel (37h of temperature maintenance)	81.7£	The nomad portable coolers SKU: MD8L-H

Figure 2:Existing solution for portable cooler for vaccines

Intended users

This appliance has been created with the drive of being use by NGOs, governments and armies that provide deprived children with necessary vaccines in local health centers.

Product requirements

Functional requirements

- The device should have a cooler system that holds the temperature between 2 - 8 C.
- It should be able to hold the temperature at least for 4 hours.
- It uses a battery as a source of power.
- Temperature should be monitored.

Usability requirements

- It should be portable with 3 kg of empty weight.

Safety requirements

- Electricity should be well insulated.
- The box should be lockable.
- The inside should be well designed so the content does not break

Interaction requirements

Product should be able to keep the vaccines at acceptable temperature until the vaccines is being used. It should have an ergonomic design (does not harm the user while carrying it).

Regulation Checklist

Standard	Description
IEC 60601-1:2005+AMD1:2012 CSV (consolidated version)	This standard specifies requirements for electromedical devices; it has more than 60 related publications, that describe very specific areas of electromedical devices.
EN 62304:2006+A1:2015	This standard specifies how to design and code software for medical devices and sets requirements for SW change control.

The following standards and guidelines are applicable to all devices, regardless the kind and risk classification:

Standard	Description
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MEDDEV 2.7.1 rev 4 CLINICAL EVALUATION: A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES UNDER DIRECTIVES 93/42/EEC and 90/385/EEC	This guideline provides information on methods used to assess the clinical performance and the clinical benefit of a medical device. It is provided for free by the Commission at http://ec.europa.eu/docsroom/documents/17522/attachments/1/translations/en/renditions/native.
IEC 62366-1	This standard provides guidance on how to manage the human factors while designing a medical device (usability engineering). NOTE: chapter -2 of the same standards will provide comments and integrations
EN ISO 15223-1:2016	This standard lists a series of symbols that may be applicable in labels of medical devices

Conceptual Design

Physical principles

The principles we are using is Thermoelectric cooling: using the Peltier effect create a heat flux between the junction of two different types of materials. The device has two sides, and when a DC electric current flows through the device, it brings heat from one side to the other, so that one side gets cooler while the other gets hotter.

Voting

Figure 3 shows the voting for all of the conceptual design.

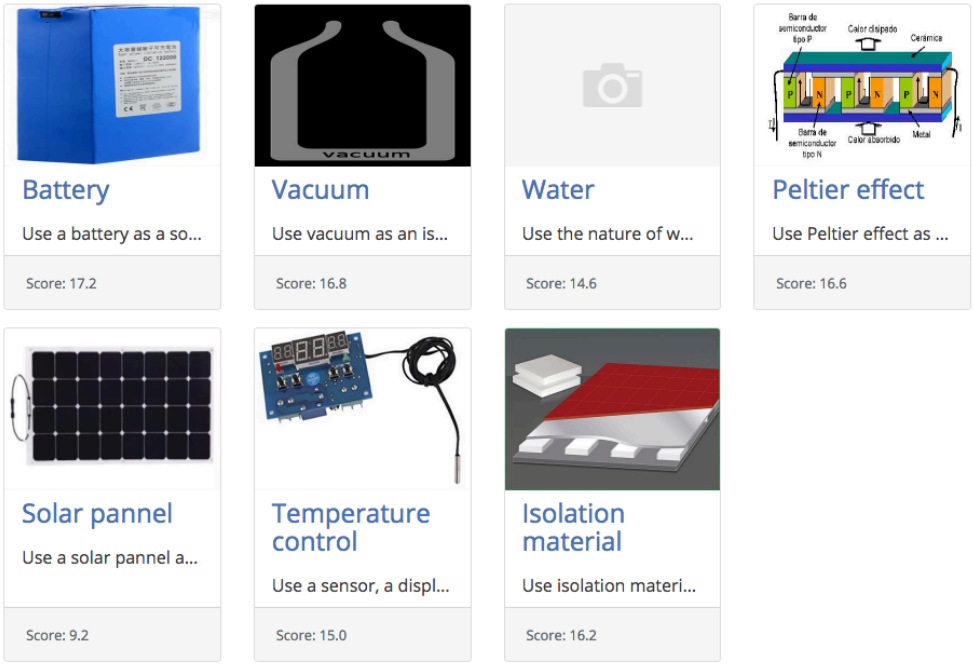

Figure 1:Conceptual design voting

Concept Description

The device is a portable vaccine cooler. It is based on three principles for functionality; It has a vacuum which will prevent the external temperature from affecting the inner temperature of the vaccine cooler. There is a water layer which utilizes the property of water (At 4 degrees, water obtains its maximum density) which means we can provide this temperature to the upper part of the cooler (Just before the cover) and this will cause the water at 4 degrees to move down and cause the water exchange hence temperature distribution.

The Peltier effect is the third principle which uses the Peltier cells powered by a battery to bring about a temperature difference in the immediate environments. These cells will be attached to the layer that is in contact with the water, hence causing the water temperature reduction to the required magnitude. In otherwords, the vacuum will be in the outer shell, and the water layer will be in the inner shell next to the storage compartment. These two will bring out temperature stability in the cooler compartment with the aid of the Peltier cells that will cause the temperature shift inside the cooler.

The cover of the vaccine cooler will be made of a double layered plastic which will have only a vacuum in it. and it will have rubber at the intact point with the lower base. This is to prevent any air penetration when the system is closed.

The system will be controlled by the Arduino majorly for the temperature monitoring and turning on and off the Peltier cells. The Arduino system and battery will be put on the external as an attachment to the vaccine cooler system.

It will have an LCD screen for displaying the temperature changes. This LCD screen will be attached on one outside wall of the system and a sensor on the inside wall.

Structured information on the device

User and environment

Who is the intended user?	**medical professionals**
Is training required in addition to the expected skill level of the intended user?	No
Is any maintenance or calibration required by the user at the time of use?	No
Where will the technology be used?	rural settings, outdoors

Health technology specifications

Dimensions (mm^3)	120 mm x 140 mm x 140 mm
Weight (kg)	3 kg
Does it require the use of consumables? For example, disposable batteries, disposable electrodes, etc.	No
Estimated life time	10 Years
Estimated shelf life	10 Years
Can it have a telemedicine or eHealth application?	No
Does it use any kind of software?	Yes
If yes, please describe the software, whether it is open source or proprietary, its use and/or license fee, etc. (10-70 words).	It's a programme that controls the temperature inside the cooler automatically. It's an open source.
If yes, can the software be customized for local use? Please explain (10-70 words). Include languages available.	No.
Is it portable?	Portable
Type of use	Long term use

Does the technology require maintenance?	No
Energy requirements	Batteries
Facility requirements	Specific temperature/humidity range (vaccines needs to be at 2-8 °C)

Design and prototyping

General product description

Hardware

- Commercial Parts

  These include the parts which we did not design by ourselves and were bought on the market:
  - Arduino Uno board
  - Temperature sensor LM35DZ
  - Peltier cells TEC-12706B
  - Battery 9V
  - LCD Screen
  - USB Cable
  - Connecting wires and breadboard
  - Heat sink
- Purposely designed parts

  These are models we designed using software and they include:
  - The vaccine cooler lid
  - The vacuum and water compartments
  - The main vaccine cooler shell
  - The external case for the battery, Arduino Uno and LCD screen.

Electronic & firmware

- Commercial parts

  This include the parts which we did not design ourselves
  - Arduino Uno board
  - Temperature sensor LM35DZ
  - Peltier cells TEC-12706B
  - Battery 9V
  - LCD Screen
  - USB Cable
  - Connecting wires and breadboard
  - Heat sink

- Purposely designed parts

  The flow chart of the firmware is here described: it is powered on either through AC or DC battery. The temperature sensor inserted in the vaccine cooler measures the temperature of its surrounding and displays it on the LCD screen. If the temperature is within the range of 2 to 8 degrees, the system is operating at its optimum, however if the temperature goes below or above the above mentioned temperature, the Peltier cells which are in contact with the water layer will turn on or off to regain the optimum temperature. The changes are all displayed on the LCD screen in real time.

- Prototypes and functional trials

  The figure below shows the schematic diagram of the Electronic assembly (circuitry) that should be able to give us the required settings. The firmware is uploaded on the Arduino Uno processor using the Arduino programming interface.

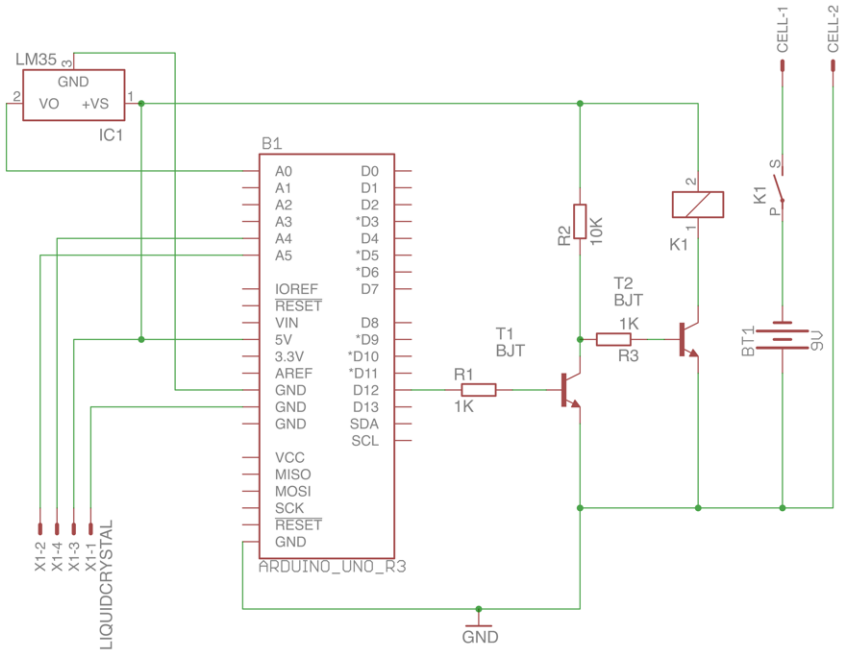

Figure 4: schematic of the driving circuit of the portable vaccines cooler

Software

- Existing solutions (open source)

  As our device requires a function that controls the internal temperature of the cooler in order to ensure the perfect conditions for it's conservation, we have decided to use the Arduino Software. It allows us to program a code that controls the interior temperature where the vaccines will be, it also will regulate that temperature by turning on and off the cooler system as necessary.

- Purposely designed parts

  We developed the program for temperature regulation with Arduino, connecting it with the temperature sensor, the LCD displaying and with the battery; Figure 5 shows the flowcharts and maps that we are going to use.

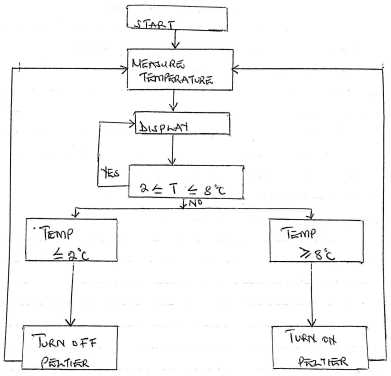

Figure 5:Flowchart of the program

Design for ISO testing compliance

This includes test conditions and procedures.

- Environmental testing:
- Include testing equipment.
- Electrical and electronic testing:
- Include testing equipment and Measurement of electrical devices. For example we used the IEC 60601-1:2005+A1:2012(E) that contains requirements concerning basic safety and essential performance that are generally applicable to medical electrical equipment. We also used the BS EN 62304:2006+A1:2015 for software testing.

Instruction for fabrication of prototypes

Our prototype is designed to regulate the temperature when transporting vaccines from the urban area to the rural area.

Our hardware has three layers with the outer layer being filled with vacuum, the middle layer has the water which is to maintain the internal temperature of the inner layer. This inner layer is where the vaccines are stored at a stable temperature awaiting usage. The above three layers form the base of this design. The cover of this design has a double layer in which there is a vacuum and it makes contact with the base using rubber membrane that prevent any air exchange to the inner chamber of the vaccine cooler. In the vaccine cooler inner compartment, there is a temperature sensor to monitor the inner temperatures while the system is running and its displayed on an LCD screen on the external of the vaccine casing. The LCD display is placed in an external casing which contains the battery and circuitry as well.

The device is being controlled by Arduino Uno. The Arduino has three important tasks:

- Measure the temperature in the cooler.
- Turn the cooling system on and off dependent on the temperature.
- Display the temperature on an LCD for the user.

To reach those two tasks a temperature sensor are being used together with other components.

RESUSCITATION DEVICE FOR NEWBORNS

Device Classification: Class III

Many rural areas in Africa do not posses the skilled personnel when delivering a baby. Thus, a device that could simplify the process would be of great help to the health care workers available. During resuscitation, the worker performs a series of chest compressions coupled with pumping by means of an ambu-bag. However, the compressions can be risky if not done properly. The right pressure has to be exerted and with the right timing for an effective cycle. The neonatal resuscitation device (Figure1) is used to tackle this problem by automating the procedure. The device does the compressions using a motor and a transmission mechanism. It also coordinates the procedure with the use of the ambu-bag while ate the same time, monitors the vitals of the neonate.

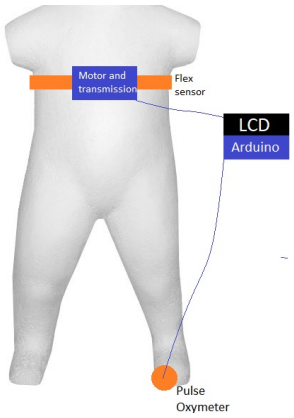

Figure1:Neonatal resuscitation device

Medical Needs and Product Specifications

Clinical Needs

An intervention of skilled personnel is needed at least in 10% of the deliveries. Moreover, this number is even larger in developing areas since risk factors increase this number. The procedure can be complicated for someone without the proper training as the compressions that are applied have to be precise, with an appropriate pressure that does not harm the new-born and the right frequency and coordination with the air pumping into the newborn.

Existing solutions

Existing solution is based on manually pressing on the chest by a trained person. Research on existing solutions has not showed any specific device for this task. However, there are devices designed for chest compression for adults, these cannot be applied to neonates, since the dimensions largely differ.

Intended users

The focused segment consists on areas where medical personnel do not possess the proper training to do the procedure of resuscitation of neonates. This could be rural areas with scarcity of resources like in some regions in Africa, where the responsible person when giving birth could be a mid-wife with reduced medical knowledge.

Product requirements

The product requires a way to exert the compressions on the neonate with an accurate pressure. Moreover, the device should be able to coordinate with the user in charge of pumping the air through an ambu bag to the neonate.

Regulation checklist

Standard	**Description**
IEC 60601-1:2005+AMD1:2012 CSV (consolidated version)	This standard specifies requirements for electromedical devices; it has more than 60 related publications, that describe very specific areas of electromedical devices.
EN 62304:2006+A1:2015	This standard specifies how to design and code software for medical devices and sets requirements for SW change control.
ISO 10993-1 and any of the additional chapters of this standard that may be applicable to your specific device	NOTE: This standard has 18 additional chapters, reading the chapter -1 will guide you on the choice of the applicable additional chapters.

The following standards and guidelines are applicable to all devices, regardless the kind and risk classification:

Standard	**Description**
EN ISO 13485:2016	This standard specifies requirements for all entities involved in medical devices, in all stages of the product life cycle: from design to manufacture to installation to disposal. UBORA Platform is structured to be a guideline for design activities in compliance to this standard.
EN ISO 14971:2012	This standard specifies requirements for designers and manufacturers of medical devices, in order to minimize the risk of the device itself. There is no “risk zero” device but many activities can be implemented to reduce and manage risk. This standard provides useful checklists and also

	guidance on the most widespread risk management techniques such as FMEA.
MEDDEV 2.7.1 rev 4 CLINICAL EVALUATION: A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES UNDER DIRECTIVES 93/42/EEC and 90/385/EEC	This guideline provides information on methods used to assess the clinical performance and the clinical benefit of a medical device. It is provided for free by the Commission at http://ec.europa.eu/docsroom/documents/17522/attachments/1/translations/en/renditions/native.
IEC 62366-1	This standard provides guidance on how to manage the human factors while designing a medical device (usability engineering). NOTE: chapter -2 of the same standards will provide comments and integrations
EN ISO 15223-1:2016	This standard lists a series of symbols that may be applicable in labels of medical devices

Conceptual design

1.1.1 Physical Principles

The compressions are needed to resuscitate a newborn in order to start the pumping of blood and air in the body of the neonate. Series of three rapid and precise compressions (three compressions in around 1.2 seconds) and respiratory air pumping are combined to complete the cycle. These series are performed for a minute, then, the vitals are monitored in order to assess the state of the neonate. If needed, the series are continued for another minute.

Voting

Motor that exerts the pressure through a rotatory to linear movement converter. The system is fixed to the babies chest through a textile wrapped around the neonate's chest. An LCD screen helps for the monitoring and coordination with the whole procedure.

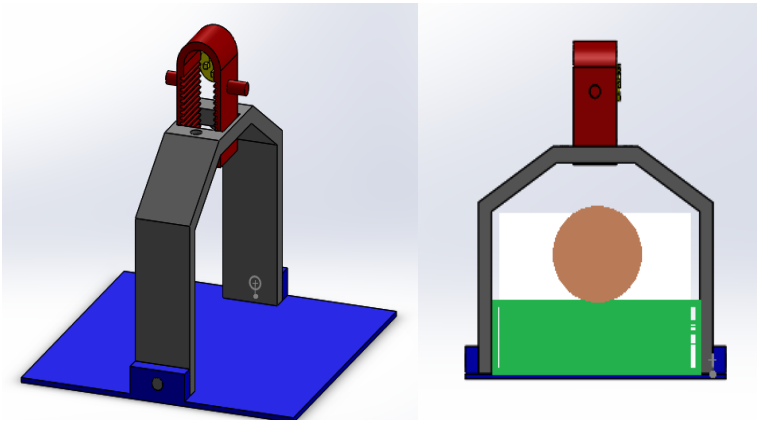

Figure 2: Concept of the resuscitation devices of newborns

Concept Description

In our design, a motor would be in charge of performing the pressure in the chest of the neonate. A normal DC motor could be used, with a rack and pinion reciprocate mechanisms to transform the rotatory movement into a linear movement. One of the extremes of this transmission mechanism would be attached to a surface in contact with the neonate, and which would be putting the pressure in the sternum of the neonate.

A strap wrapped around the neonate chest would be connected to the motor so it stays fixed in the position and it exerts the pressure when the surfaces pushes into the sternum.

Also, the device should serve as a coordination and monitoring instrument. Thus, an LCD screen will display the heart rate and respiratory rate. Furthermore, it will signal the responsible person to compress the air bag after the three chest compressions, so both procedures are coordinated.

The heart rate would be measured with a pulse oxymeter and the respiratory rate would be measured with the flex sensor that wraps around the chest.

Structured information on the device

User and environment

Who is the intended user?	Midwife
Is training required in addition to the expected skill level of the intended user?	No
Is any maintenance or calibration required by the user at the time of use?	No
Where will the technology be used?	rural settings, indoors, at home, primary level (health post, health center)

Health technology specifications

Dimensions (mm^3)	10 mm x 10 mm x 15 mm
Weight (kg)	1 kg
Does it require the use of consumables? For example, disposable batteries, disposable electrodes, etc.	No
Estimated life time	5 Years
Estimated shelf life	25 Years
Can it have a telemedicine or eHealth application?	No
Does it use any kind of software?	Yes
If yes, please describe the software,	Open source. An IDE could be used as a controller for

whether it is open source or proprietary, its use and/or license fee, etc. (10-70 words).	the device, the code would be available open source in case anyone wants to build a similar device.
If yes, can the software be customized for local use? Please explain (10-70 words). Include languages available.	If someone has the skills to program the Arduino, there could be a guidance on how to change the displayed language in the LCD screen to their preferred language.
Is it portable?	Portable
Type of use	Long term use
Does the technology require maintenance?	Yes Type: Battery recharge Frequency: After each use Can it be done on-site / home / community?: Yes
If yes, who should provide maintenance?	Nurse/Physician
Energy requirements	Batteries Continuous power supply Voltage required: 12 V
Facility requirements	

Design and Prototyping

General Product Descriptions

Hardware

- Commercial parts

  These include the parts which we did not design by ourselves and were bought on the market:

  - DC motor
  - IDE controller (such as Arduino)
  - Flex sensor
  - pulse oxymeter
  - electronic components (cables, resistances, switches, potentiometer...)
  - LCD screen
  - LEDs

- Purposely designed parts

  These are models we designed using software and they include:

  - Rack and pinion transmission for linear movement (3D printed)
  - Surface in contact to the neonate exerting the pressure (attached to the transmission mechanism and 3D printed)
  - strap that wraps around the neonate (textile)
  - Casing for electronics and motor (3D printed)

- Prototypes and functional trials

The intended prototype involves a rack and pinion mechanism that exerts the compressions in the neonate's chest, another part with the controller and the LCD screen to coordinate with the responsible person, and sensors for monitoring hear rate and respiratory rate.

The strap has not been used for the prototype and instead the aim is to 3D print the mechanism together with the base for the neonate. As a controller, an Arduino has been used and loaded with the program.

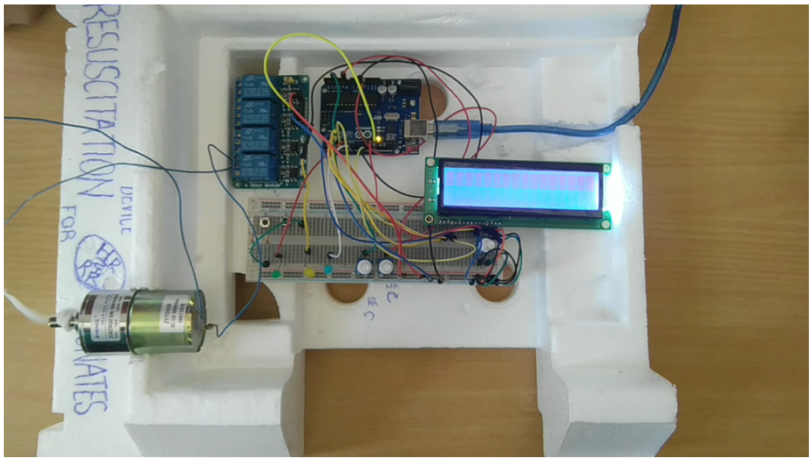

Figure 3: Prototype of the electromechanical parts of the resuscitation device of newb