

Towards Open Source Medical Devices

Current Situation, Inspiring Advances and Challenges

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Abstract: Open Source Medical Devices may be part of the solution towards the democratization of medical technologies pursuing Universal Health Coverage as part of the Sustainable Development Goals for United Nations. Recent technological advances, especially in information and communication technologies, combined with innovative collaborative design methodologies and manufacturing techniques allow for the mass-personalization of biodevices and help to optimize the related development times and costs, while keeping safety in the foreground through the whole life cycle of medical products. These advantages can be further promoted by adequately fostering collaboration, communication, high value information exchange, and sustainable partnerships and by extending the employment of open source strategies. To this end, within the UBORA project, we are developing a framework for training the biomedical engineers of the future in open-source collaborative design strategies and for supporting the sharing of information and the assessment of safety and efficacy in novel biodevices. An essential part of this open-source collaborative framework is the UBORA e-infrastructure, which is presented in this study, together with some initial success cases. Main future challenges, connected with regulatory harmonization, with educational issues and with accessible and open design and manufacturing resources, among others, are also presented and discussed.

1 INTRODUCTION

Universal Health Care (UHC) is still a dream, even if all United Nations Member States have agreed to pursue the achievement of universal health coverage by 2030 (UN General Assembly, 2012), as part of the Sustainable Development Goals. Currently, around 60 countries offer health care to all their citizens, but vast regions of North and South America, Africa and Asia, accounting for more than the 80% of the World's population, still live without the desired coverage. In the case of Africa, the scarcity of quality healthcare is linked, not only to

the lack of resources, but also to the shortage of adequately trained biomedical engineers.

Capacity building in this sector is needed for progress and for the establishment of a sustainable healthcare system. Excluding South Africa, apart from a few singular initiatives (i.e. in Nigeria and Ghana), no university in sub-Saharan Africa offers a complete Biomedical Engineering (BME) graduate & post-graduate programme (Nkuma-Udah and Mazi, 2007). Considering that Africa has one of the youngest demographics, targeting students may be a key to rapidly and efficiently promote healthcare improvements. One way of reaching this goal is to

use the immediacy and high information content offered by the internet combined with the open source approach to teach design and fabrication of biomedical devices at university level, hence focusing on the biomedical engineers of the future.

Creating open source medical devices (OSMD) means developing these devices by sharing ideas and concepts, design files, documentation, source-code, blueprints and prototypes, testing results and all collected data, with other professional medical device designers. These interactions should benefit the whole life cycle of the devices or products under development and, in the context of BME, there is a need for a high level of supervision, to control the final quality and to guarantee the respect to standards and regulations, hence promoting the final safety of OSMD (De Maria et al., 2015).

Therefore, the core curriculum for biomedical engineering should also include courses on biomedical device regulations and standards and focus on the promotion of collaborative design strategies and on the potentials and challenges of OSMD, as we discuss further on. This approach may prove beneficial, not only in developing countries, but also in countries, in which UHC is already implemented. Taking account of the current situation of our World, in which new healthcare challenges are appearing due to shifting demographics and changing lifestyles, new strategies are needed.

In fact, the relevance of OSMD has been already put forward by inspiring projects and achieved very interesting results showing their transformative potentials. Among these influential proposals, we can cite the 3D printed hand prostheses developed in a personalized way (and for free) by the e-NABLE Community, the sharing of good practices within the Patient Innovation forum (Oliveira et al., 2017), pioneering projects for promoting open-source bioengineering (De Maria et al., 2014; 2015, Ravizza et al., 2017) and educational experiences searching for more democratic paradigms, as summarized previously (Díaz Lantada, 2016).

However, additional and systematic efforts are needed for achieving global impacts and for making OSMD a key turning point for the future of a more socially oriented medical industry. In the following sections we describe the concept and approach of the UBORA project and some recent advances achieved during its preparation and along its first year of endeavor.

Fundamental issues including: i) the promotion of collaborative biomedical design methodologies oriented to global health concerns, ii) the development of open-access e-infrastructures for

global action, iii) Education for all approaches, iv) harmonization of medical regulations and v) international partnerships are part of the strategy deployed within UBORA. Preliminary success stories and current challenges are analyzed.

2 CONCEPT AND APPROACH OF THE UBORA PROJECT

To encourage the shift towards OSMD and the democratization of medical technology, the EU funded “**UBORA: Euro-African Open Biomedical Engineering e-Platform for Innovation through Education**” project (H2020 research and innovation programme GA 731053) aims at implementing an e-infrastructure, UBORA, for open source co-design of new solutions to face the current and future healthcare challenges of Europe and Africa. UBORA (“excellence” in Swahili) brings together European and African universities and their technological hubs (supporting biomedical design and prototyping laboratories and incubators) to develop and establish a new methodology for designing biomedical devices in a collaborative and open source way.

The UBORA e-infrastructure is aimed at taking engineers and engineering students through a process of needs identification, device classification and regulation, computer-aided modeling, rapid prototyping and final preparation of production, in which each stage is vetted and monitored by experts to ensure that safety criteria are met during the design process.

Throughout the project, we are exploiting and reinforcing networking, disseminating knowledge on rapid prototyping of new ideas and sharing information about the performance and the gathered quality data, in order to maximize innovation and minimize waste along the life cycle of the biodevices being collaboratively developed, which are also providing open-access content to the UBORA e-infrastructure. The UBORA project is supported by policymakers and stakeholders covering the whole life cycle of biomedical product development, as well as propelled by a series of design schools and design competitions connected with the aforementioned formative efforts.

The UBORA design schools are inspired by the pioneering UNECA (United Nations Economic Commission for Africa) funded Innovator Summer Schools (ISS). Since 2013 the themes of these ISS have focused on the co-development of biomedical

devices based on local needs and materials. Table 1 lists the Summer Schools held so far on different topics related to Biomedical Engineering.

Thanks to UNECA the ISS bring together a community of African universities committed to developing a joint and well balanced curriculum in Biomedical Engineering and to achieving reliable results in this field from an academic point of view.

Underlying this ambition is the awareness that quality healthcare is the key to well-being and importantly helps to promote wealth as well. With UNECA's support, 13 universities in Africa have joined to form "ABEC" the African Biomedical Engineering Consortium. UBORA was born out of these initiatives, and seeks to extend the ISS through the creation of an OSMD co-creation platform: the mentioned UBORA e-infrastructure. The results from its first implementation and cases of success are detailed in the next section.

Table 1: ISS (Innovator Summer Schools) held since 2013. All ISS were funded by UNECA.

Innovator Summer School	Hosting Institution	Period	Topic
Nairobi, Kenya	Kenyatta University,	2013 August 12 th - 16 th	Introduction to BME regulations and rapid prototyping
Dar Es Salaam, Tanzania	Muhimbili University of Health and Allied Science	2014 December 8 th - 12 th	From making to marketing
Addis Ababa, Ethiopia	Addis Ababa Institute of Technology	2016 January 11 th - 15 th	Application of mobile phones in healthcare product development
Cairo, Egypt	Cairo University	2017 January 23 rd - 27 th	Biomedical and clinical data and informatics for development in Africa

3 IMPLEMENTATION OF THE UBORA e-INFRASTRUCTURE

The UBORA e-infrastructure, developed for the collaborative design of open-source medical devices, is the key tool for making our project's data available, promoting impacts and helping to support OSMD. Once completely ready, the platform will incorporate developed projects, publications, teaching materials and will be made open to the

public for being used as reference collaborative design resource in the biomedical industry.

At present, a first preliminary version is already working and is being used by UBORA project's partners and by the students taking part in the UBORA design competitions, whose research and development results are being also incorporated to the platform for generating relevant content before public disclosure. The main features of this online platform for OSMD are described further on.

3.1 Overall Structure of UBORA

The UBORA e-infrastructure is implemented in a user-friendly way and clearly oriented to biomedical engineers and designers, medical professionals, patients and patients' associations, medical device manufacturers and potential collaborators, as main stakeholders. The access to the e-infrastructure is obtained after free registration and the homepage gives the following basic possibilities: i) registration or entrance for registered users; ii) search for a medical solution; iii) proposal of ideas or solutions for relevant medical needs; and iv) consultation of existing public projects (see Figure 1).

Regarding UBORA as tool for the collaborative development of medical devices, it is necessary to highlight that the lifecycle of a medical device has numerous phases, which go from needs assessment to the manufacture, sales and disposal. UBORA will specially focus on and support the first stages of the process (up to pre-production), which include: identification of needs, specification, conceptual design and creativity promotion, geometrical design, materials selection and virtual and rapid prototyping, which are the most relevant phases for encouraging the generation of novel solutions. Conception and development are channeled following European biomedical device directives and each step of the process takes account of European regulations, as a first step towards global harmonization.

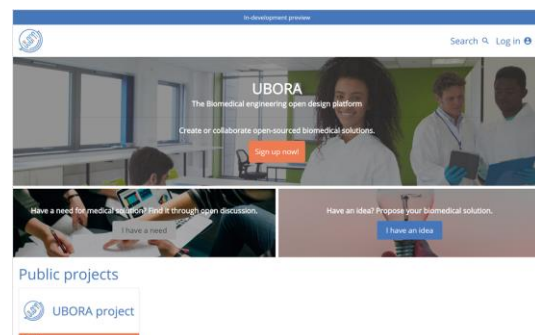


Figure 1: Structure of the UBORA e-infrastructure. The projects are structured according to the phases of systematic product development methodologies.

As a collaborative design resource, the UBORA e-infrastructure has been implemented considering the mentioned lifecycle of medical devices and the related relevant steps. Users of this online platform can create and manage biodevice development projects, whose relevant information is uploaded, organized according to the systematic development phases (see Figure 1) and made accessible to the users of UBORA.

3.2 Data Management within UBORA

The UBORA e-infrastructure is implemented following “FAIR” (findable, accessible, interoperable and re-usable) data management principles, according to current recommendations from the EU and the Horizon 2020 Programme.

Once the UBORA e-infrastructure is loaded with hundreds of projects, towards the end of the project by 2019, it will be necessary to count with adequately implemented search mechanisms for easily reaching the medical solutions and, hence, promoting its friendly usability and popularization, as a tool medical professionals, for medical device innovators, for policy makers and for patients and patient associations.

In order to make such data findable, the UBORA e-infrastructure is designed with interactive tabs, which help to organize the generated projects and the uploaded information and data. The projects are being currently created and organized answering the following questions:

- A) Which clinical area does your solution belong to?
- B) What kind of technology do you propose?
- C) Which clinical needs do you address?

Once the fields from previous questions A, B & C are ordered and numbered, such numbers may be used as identification coordinates for classifying the different projects according to the type of medical device being developed, to the medical area involved and to the clinical need being addressed. At present we are also considering the use of the Global Medical Device Nomenclature (GMDN) or the Universal Medical Device Nomenclature System™, although the use of these privately developed taxonomies requires the payment of fees, which is controversial with the open-source and free-

available developments we are pursuing, so additional reflections are needed.

Considering that UBORA will turn out to be, using a metaphor, a sort of “collaborative Wikipedia of medical devices”, the contents uploaded will be made available to the community, in principle resorting to different types of Creative Commons Licenses (<https://creativecommons.org>). In all cases, attribution to the designer or to the developing team has to be granted (CC BY).

We will analyse other possible additions to the basic mentioned CC BY license, including “share-alike”, “non-derivatives”, “non-commercial”, among others, although this may well be a final decision of the designer or developer, as happens in collaborative environments for sharing documents and blueprints such as: Wikimedia Commons, Thingiverse, Grabcad, among others.

Accessibility to the UBORA e-infrastructure requires registration, which the users achieve by introducing basic personal and contact data. Users accept the terms of usability expressed in the “terms and conditions” section of the e-infrastructure for registration. Once registered, users have access to the projects of innovative medical devices uploaded to UBORA and to their data and metadata. Search of desired data is supported by keywords and by the classifications of clinical areas, medical technologies and clinical needs previously detailed. Users are responsible for the veracity of the information uploaded to UBORA (or modified within UBORA by them) and the managers of the UBORA e-infrastructure retain the right to expel users that do not adequately use the information shared.

Interoperability will be achieved by using standard file formats and by taking account of the existing compatibilities among design programmes and files. A support document for users of the UBORA is included within the e-infrastructure. It is important to note that each project within UBORA is collaboratively developed by a different team of international designers and collaborators, which will probably choose among the existing options of computer-aided design, modeling and manufacturing software, so the file types used are varied.

It is also necessary to highlight that the final version of the UBORA e-infrastructure will count on a group of mentors or managers, i.e. partners from the UBORA project motivated about the long-term viability of the e-infrastructure and colleagues with international impact in bioengineering, who will advise users of the e-infrastructure about the preferred file formats for improved interoperation.

Regarding re-usability of the generated data, the biodevice development projects validated in the e-infrastructure by the UBORA mentors or managers and reviewed as potentially beneficial for solving global healthcare concerns, once completed, will be archived in the protected servers of the UBORA e-infrastructure and will be made available to users during the whole life of the e-infrastructure or until the developer, together with the team of mentors and managers of UBORA, decide to replace it by a better solution or to eliminate it due to existing alternatives performing better.

3.3 Ethical Issues and Security Concerns within UBORA

During the UBORA project's lifespan (2017-2019), the medical devices developed rely solely on healthy volunteers for being tested *in vitro* and in laboratory environments, hence being "prototypes for the assessment of functionality".

These devices are in most cases consequence of partners' dedication to the UBORA project or the result of students' developments within the design competitions and the design schools. No device potentially harmful for users will be tested in humans during the project. In any case, ethical approval from local ethical committees will be obtained prior to commencing any assessments.

Regarding privacy, it is UBORA's policy to respect users' privacy regarding any information that the e-infrastructure may collect. Accordingly, the privacy policy, which affects all data collected and shared through UBORA e-infrastructure, is outlined in a clear way in a specific section of the website.

3.4 Some Initial Development Cases within UBORA

The First UBORA Design Competition counted with a total of 113 submitted projects, from which 60 were selected for a second round. After the second round, 40 projects and their teams have been assessed and chosen as finalists. The best 24 teams of finalists receive travel and full-board sponsorship (for one team member) to attend the First UBORA Design School, to be held in Kenyatta University (Nairobi, Kenya) from the 11th to the 15th of December 2017, whose main topic is the systematic and collaborative development of innovative biomedical engineering solutions to reduce child mortality, which was the topic for the competition.

Among presented projects and solutions we can cite: biodevices for detecting malaria, coolers for

vaccines, systems for the sterilization of surgical instruments, incubators for premature babies, devices for monitoring pregnancy, breast pumps with cooling and preservation systems, 4D printed splints (3D printed and then personally modified to suit patients), polymeric devices for treating clubfoot, CPAP devices or preventive methods for malaria, to mention just a few examples. Such projects are already being incorporated to the UBORA e-infrastructure, as complete examples.

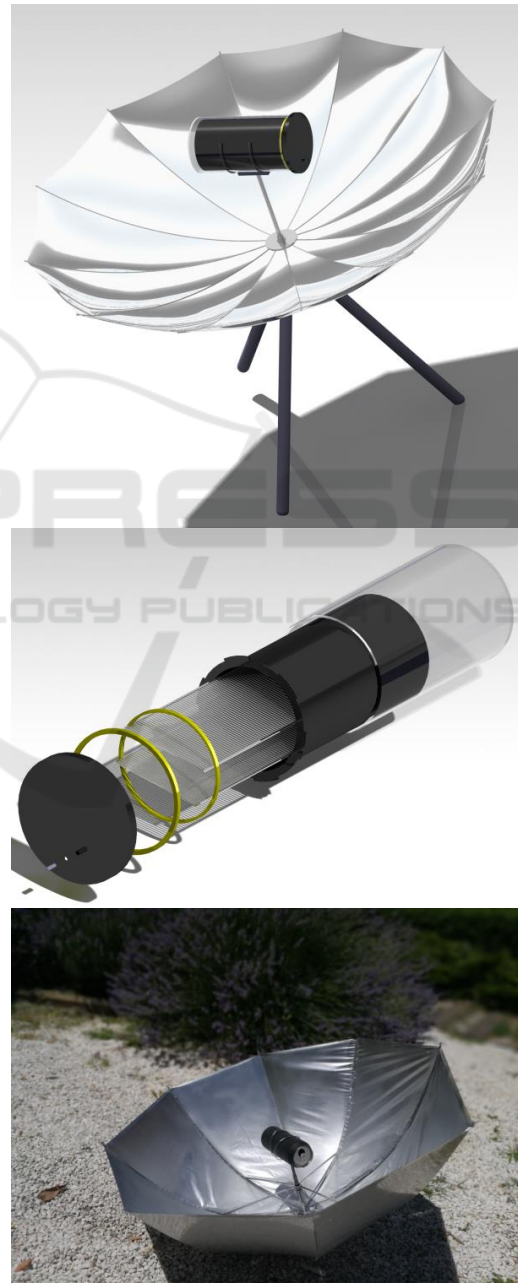


Figure 2: Open-source solar autoclave. Computer-aided design of final solution and low-cost prototype. Designed by: O. Blanco, A. García, L. Martín, L. Jiménez, D. Pérez-Urruti & P. Isla. Mentors: A. Díaz, J. Jiménez & A. Ros.

It is important to highlight that these examples, in their current state, are just helping to test the developed e-infrastructure and to provide cases of study for teaching-learning tasks, towards active education paradigms linked to OSMD, which is a fundamental issue for transforming the medical field in developing countries. Successful OSMD would probably be manufactured with alternative methods, for instance taking benefit of distributed *fab-labs* and rapid prototyping techniques nearer to the end users and searching for personalization.

By means of example, Figure 2 includes the computer-aided design and the low-cost prototype of an open-source solar autoclave and Figure 3 includes the final design of a premature baby incubator with autonomous temperature regulation and the related functional prototype.



Figure 3: Open-source premature baby incubator. Computer-aided design and functional prototype. Designed by: E. Efer, A. García, C. Hervás, S. Moreno & A. Tomás. Mentors: A. Díaz, J. Jiménez & A. Ros.

Figure 4 shows the conceptual computer-aided design of a system for cooling and preservation of breast milk, based on the thermodynamic of water evaporation. Inspired by pot-in-pot refrigerators, students selected appropriate materials and device size, with the final aim of promoting the use of breastmilk, as means for reinforcing the immune system of newborns (WHO, 2016).

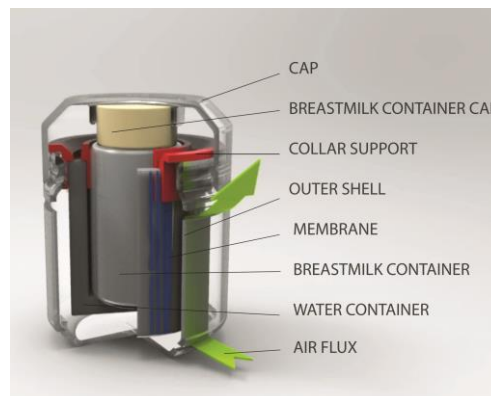


Figure 4: Cooling and preservation system for breast milk. Designed by: S. Maglio and Toncelli Giacomo.

3.5 UBORA Design School Structure

With the aim at providing students with a clear overview of the whole life cycle of a medical device, from the conceptual and planning stages, through the design and implementation, towards the operation and life, the UBORA design school will provide a combination of experts' lessons, cases of study and Conceived – Design – Implement – Operate (CDIO) teamwork activities (Crawley et al., 2007).

Lessons will cover aspects such as: introduction to the medical industry, methodologies for the development of biodevices, safety issues and standardization, creativity promotion, conceptual design, materials selection strategies, advanced design and manufacturing resources. Inspiring keynote presentation by outstanding speakers will present global healthcare issues as well as future trends in biomedical engineering. Practical workshops on electronics, software and physical rapid prototyping, on signal acquisition and data analysis complete the programme of the school.

4 CURRENT CHALLENGES AND FUTURE RESEARCH

The UBORA project is EU funded and developed among a group of European and African partners and the already implemented first version of the UBORA e-infrastructure for OSMD is now open to the project partners, to colleagues from the ABEC consortium and to participants from the First UBORA. However our approach is truly global and the second release of the e-infrastructure will be opened to collaborators worldwide along the first half of 2018. In order to obtain the desired impact and to enable OSMD to truly make a change for the better, in the path towards universal health coverage, there are some current challenges, which still require additional efforts.

The UBORA e-infrastructure itself may relevantly contribute to finding satisfactory answers to these issues, which will in any case require the support of well-established long-term partnerships, as detailed in the following subsections.

4.1 Sustainability Issues of OSMD

Open-source and collaborative developments of biodevices are aimed at reaching every single patient potentially benefiting from the novel technology, regardless of their social-economical status.

However successful open-source and freely available (for the patients) solutions rely also on their potential of generating wealth, of involving the local populations for more efficient supply chains and of sustainably growing, both environmentally and socioeconomically, while benefiting both the patients and all stakeholders involved in the lifecycle of the biodevice. To this end, educators, researchers, medical professionals, patients and associations, device manufacturers, policy makers, experts in regulation, fundraisers, patrons and sponsoring bodies have to interact (and the UBORA e-infrastructure constitutes a powerful resource for such collaboration) and work together for the sustainability of OSMD.

Regarding these issues, after the project's life, in the long-term life of the UBORA e-infrastructure, UBORA mentors or managers will not be responsible for the use given to the open-access online resources of the e-infrastructure and it will be the responsibility of the potential manufacturers, taking inspiration on the projects available in the e-infrastructure, to fulfil pre-market approvals and to respond to potential failures of the products they decide to produce and commercialize.

Our model implies manufacturers perceiving the access to UBORA's developments as a support to their reaching more rapidly the users (hence

minimizing their R&D costs by using open-designs developed following safe design procedures and supervised by a team of experts) and, subsequently, wishing to reinvest in the e-infrastructure. We also pursue that the educational aspects of UBORA will be understood by institutions and used as massive-open-online resources, which will also serve to support the sustainability of the e-infrastructure.

Inspiring cases of success, such as Wikipedia, Firefox, Linux and other open-source initiatives from the software industry provide clear examples about the feasibility of open-source strategies.

Let's apply similar development principles to the Biomedical Engineering field.

4.2 Towards Regulatory Harmonization

Continued and systematic work aimed at the global harmonization of regulations, which should also take account of the particular aspects present in collaboratively developed devices, constitute additional keys for the success of OSMD. In fact collaboratively developed projects may well result in safer devices if the correct design principles are followed (Ravizza et al., 2017).

Ideally, the standards used by the biomedical designers during their development processes should be also generated and shared using collaborative and open-source strategies, if the impact of OSMD is to be promoted in a methodic way. Considering the current costs of accessing standards, unbearable for many designers worldwide, the designers of richer countries and multinationals "play with loaded dice", and this should be corrected.

4.3 Biomedical Engineering Education for All

Biomedical Engineering Education for all should be promoted and access to validated and reliable teaching-learning resources and materials should be made widely available. Connection of potential students to networks of educators with a background in this field should be also encouraged. We consider that the UBORA e-infrastructure can again constitute a relevant tool for sharing educational resources, as the First UBORA Design School will demonstrate. All this gathering of genius, hopefully unaffected by reasons linked to social status, race, religion, political opinions, sex or sexual orientation, may prove to be transformative for the Biomedical Engineering field and its industry.

5 CONCLUSIONS

OSMD may be part of the global solution towards the democratization of medical technologies, pursuing Universal Health Coverage, as part of the Sustainable Development Goals for United Nations.

Recent technological advances, especially in information and communication technologies, combined with innovative collaborative design methodologies and manufacturing techniques allow for the mass-personalization of biodevices and help to optimize the related development times and costs, while keeping safety in the foreground through the whole life cycle of medical products, as has been discussed in this study.

Main future challenges, linked to regulatory harmonization, to educational issues and to accessible and open design and manufacturing resources, among others, have been also presented and analyzed. We propose the use of EU standards, as they are currently recognized in many African countries, at least as a starting point towards commercialization, but harmonization is a key yet unsolved issue, as mentioned before.

It is important to highlight that the advantages of OSMD can be further promoted by adequately fostering collaboration, communication, high value information exchange, and sustainable partnerships and by extending the employment of open source strategies. To this end, within the UBORA project, we are developing a framework for training the biomedical engineers of the future in open-source collaborative design strategies and for supporting the sharing of information and the assessment of safety and efficacy in novel biodevices.

An essential part of this open-source and collaborative design framework is the UBORA e-infrastructure, which has been also presented in this study, together with some initial success cases.

In short, the UBORA e-Infrastructure is a new and powerful tool for biomedical engineers to drive medical innovation forward, in the quest to a better world with Universal Health Coverage, where access to the most advanced medical technologies may not just be for the privileged few. With this UBORA e-infrastructure the worldwide biomedical community can generate and share data and blueprints of biomedical devices, accompanied by the required procedures for respecting quality assurance, and assess performance and safety. When properly implemented, and guaranteed by authorized competent authorities, these biomedical devices may safely be used in hospitals and on patients throughout the World.

Being the UBORA project focused on the establishment of international partnerships, we welcome all comments and support. Please contact us or visit: <http://ubora-biomedical.org> for updated information about progress on OSMD.

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UBORA: Euro-African Open
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