Open Source Biomedical Engineering for Sustainability in African Healthcare: Combining Academic Excellence with Innovation

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Abstract—**Accessible quality healthcare is one of the biggest problems in Africa and other developing countries. This is not only due to the unavailability of resources, but also to the absence of a structured formative process for the design and management of healthcare facilities. Biomedical engineers are known to be the link between technology and medical practice, which is a pillar of healthcare systems in developed countries. In this paper, the Open Source for BioMedical Engineering (OS4BME) project and its kick off summer school are presented. The OS4BME project aims to develop a new generation of biomedical engineers, able to exploit emerging technologies generated by the recent "Makers" revolution. During the one week summer school, students from various sub-Saharan countries have been introduced to these new design, development and sharing paradigms. Students worked together identifying new possible simple biomedical devices, which could help in daily clinical practice. A cheap and easy-to-use neonatal monitoring device was chosen as a Crowd design project. The OS4BME Baby Monitor was designed and assembled by the students during the one week summer school, demonstrating the creative potential of the new generation of biomedical engineers empowered with the paradigms of crowdsourcing and rapid prototyping.**

Keywords-Biomedical Engineering; Open Source; Open Hardware; Crowdsourcing; Africa.

I. Introduction

While the pillars of healthcare are certainly doctors, clinicians and nurses, at least in the developed world, biomedical engineers are widely recognised as being the cornerstone of any medical facility with high technology diagnostic and therapeutic equipment and devices. The scarcity of accessible quality healthcare in Africa is inextricably linked not only with the lack of resources, but also with the lack of adequately trained biomedical engineers [2]. Excluding South Africa, apart from few singular initiatives (in Nigeria and Ghana), no university in sub-Saharan Africa offers a fully-fledged Biomedical Engineering graduate and post-graduate programme [3]. While several reasons can be identified, certainly the most important is the absence of a clear common understanding of BioMedical Engineering (BME) as a field of study both in higher education as well as in the medical sector. While there are a number of technical level clinical and biomedical engineering courses scattered through sub-Saharan Africa, their quality and content are often questionable [4]. Moreover, medical equipment does not have common standards or operating protocols; indeed in most developed countries, hospitals and clinics have very expensive maintenance contracts with manufacturers who train their own specialized technicians [3]. As a result, the medical device industry in Africa is largely absent and there is an over reliance on foreign companies to repair and design biomedical instrumentation, and resolve technical problems. Very often developed countries donate machines to African hospitals and clinics. While this is an honourable act, the machines usually end up being abandoned when they stop working due to lack of maintenance [5], [6].

The experience of one of the authors in the *ASIALINK* project, "Development of Core Competencies in the areas of Biomedical and Clinical Engineering in the Philippines and Indonesia 2005-2008" [7], [8] has shown us that long term and sustainable improvements can only come through i) recognition on the part of policy makers, of the importance of on loco trained experts capable of managing and repairing biomedical equipment and ii) development of expert skills through individualized programmes that cater to the specific social, cultural and technological needs of a region. These are the two keys to a sustainable and efficient health care system.

However, the world has completely changed with respect to 2006, when the *ASIALINK* project was considered a landmark in South East Asia. The continuous connectivity with tablets, mobile phones, the rapid dissemination of social networks, and the access to free e-learning [9], makes teaching easier and harder at the same time, because of the huge amount of available information.

The world of BME is also changing, here again thanks to various communities that live and discuss on the web. While, a couple of years ago, the development of biomedical devices was essentially linked to companies and universities, now the first examples of open source biomedical devices, such as the Gammasoft Open electrocardiogram and the Smartpulse oximeter are beginning to appear [10], [11]. Although these instruments are not accurate or safe enough to be inserted in the clinical routine, their use can probably save a life more than a damaged, unused (e.g., for high cost) or useless (e.g., because no one knows how to operate) Magnetic Resonance Imaging machine.

Indeed, as The Economist [12] points out in an insightful laymans overview of this burgeoning field, software-reliant devices have also brought on new types of potential risks for patients. The article underlines the difficulty of exposing spe-

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cific problems with these products, given that medical software (and hardware) is proprietary and patent-protected, thus veiled in secrecy [13]. The open-source approach could, in theory, make it easier to fix, or even avoid, dangerous flaws before they hurt or kill hundreds or thousands of patients. Despite this virtual revolution the mainstream academic community in most countries, developed or not, remains largely ignorant of the potential of open source software, hardware and prototyping. This is particularly evident in Africa - we refer in this paper to sub-Saharan Africa excluding South Africa - where tradition and hierarchy play a strong role at all levels, more so in academia. The authors are of the opinion that academia, and specifically biomedical engineers in higher education, must embrace these new tools, and pass on the message that an Open Source product, developed by a community, without a multinational brand is not equal to un-reliable.

Indeed, today, thanks to crowdthinking and crowdsourcing, the design of several products has an intrinsic revision process, thanks to the community, which has become an active player, and no longer a passive element. The community is the best analyst in terms of quality, reliability and feasibility. While this philosophy is now well accepted in the "software" world, there is still an unjustified unbelief in open "hardware", because many people are anchored to the consolidated production process, in which product development is affected by high costs due to the inflexibility of fabrication processes (e.g., injection molding). As described in the seminal work of Chris Anderson *"In the next industrial revolution, atoms are the new bits"* [14], [15] 3D printing (later described in the text) is giving everyone, companies, makers, and inventors, the tools that were the exclusive prerogative of a few companies less than ten years ago.

A note of caution however; the freedom given by the Web, and by the possibility to share, fork and re-implement projects, which characterises the Open Source Software, Electronic, and Hardware world, has one major drawback: organizing information (schematics, blueprints) is the boring part that is not always pursued in a passion-driven and self assembled community. In the context of BME however, this latter aspect is critical for ensuring safety and efficacy of biomedical devices, and must go hand in hand with the adoption of open resources for medical applications.

We present here a **position paper** on the benefits and use of Open Source tools and platforms in BME specifically in Africa, which needs to jump on the fastest, cheapest and greenest wagon to growth and self-sufficiency in healthcare. The adoption of these new methods of creating and thinking needs to be coupled with open standards and regulations for medical device safety. We thus argue that the new virtual sharing mentality should be wholeheartedly embraced, valorised and overseen by African universities through a common Open Source for Biomedical Engineering platform (OS4BME) rendering the development, and maintenance of medical equipment accessible to the African continent.

After a discussion on the potential of Crowdthinking (II) and BME in an African context (III), we describe the OS4BME project and its kick-start initiative in Nairobi in 2013 (IV).

II. Crowdsourcing and Crowdthinking Platforms

Currently, there are several resource sharing platforms available on the internet. Their use is spreading throughout the developed World, starting from Europe and the US. The growing accessibility of these platforms, like any shared common resource, has resulted in the generation of huge amounts of garbage. Sifting the useless from the useful is a monumental task and requires experience in design and engineering as well as some skills in negotiating the now cluttered internet of things. More importantly, at present, there are no specific engines or platforms focused on the sharing of biomedical instrumentation and devices. This is because, by their very nature, biomedical devices possess stringent performance requirements to comply with regulatory standards to ensure patient safety.

In the past few years, various studies on social epistemology and group judgment aggregation have been published [16], [17] demonstrating both theoretically and practically the superior heuristic value of collective, non expert, knowledge compared to individual or small group assessment, based on consolidated rules and expectations. In 2006, Jeff Howe coined the Crowdsourcing Neologism in a futuristic article in Wired magazine [18]. Publishing of a neologism related to society cooperation in a magazine instead of in a traditional journal paper is a clear indication of how this new field is driven by a sort of creative talent of the community leading to tangible products for business and non-profit purposes [19].

Crowdthinking platforms are becoming important tools for design and development of new products. Platforms like Wikipedia, Thingiverse, Instructables allow the generation of information that spans from text documents to complex designs and blueprints. Nowadays, various web based communities [20] have an active role in crowd-development and crowd-thinking and also various FabLabs (Fabrication Laboratories) [1] are being born with the aim of bring technology to the people, empowering the creative process with the possibility of building real, physical objects.

In the BME context, we still need a level of supervision, to control the quality and to guarantee the respect of safety standards. By virtue of their access to the brains of the future, universities are the right (and perhaps the only) institutions to properly teach instruments for crowd-"doing", while giving due importance to concepts, such as ethics, standards and regulations. However, although the latter is at least briefly outlined in university courses, the former sometimes is unknown even to the most brilliant professors.

We define the Crowd, with a capital "C", as groups of individuals trained and assisted by institutions of technical and higher education, to design, innovate and build together through sharing. As such, the Crowd can and should consist of healthcare providers as well as engineers and technicians. If properly guided by standards and regulations, guaranteed by universities as the organ for control, certification, knowledge and learning, the Crowd is an enabling system for the design and development of medical devices. In addition, the Crowd philosophy can be extended to production processes so fostering local economic growth. In fact, the new methods of production now accessible to all do not require the delocalization of manufacture somewhere else.

III. Contextualization

A. Biomedical Engineering for Africa Today

As Nkuma-Udah et al. point out [3], there are few African universities which offer BME courses. The few that do are based on curricula which were designed for Western universities over 20 years ago and which place undue emphasis on niche subjects like MicroElectroMechanical Systems (MEMs) and cell engineering and less on the learning of new, hard technology and equipment management, maintenance and repair [21]. Evidence from the *ASIALINK* project has demonstrated the value of developing expert skills through individualized programmes that cater to the specific social, cultural and technological needs of a region. While we are not advocating a revolution in BME teaching here, we are strongly in favour of the upgrading of curricula based on solid engineering principles (as outlined by Linsenmeier [22]) with new courses, new technology and new ways of thinking and problem solving, specifically adapted to the needs of countries with few resources. This approach is similar to that proposed by Tzavaras et al. [23] on computer enhanced education laboratories. Fusing the crowd design philosophy with the Biomedical Engineer's objective of improving human healthcare requires that patient safety and efficacy be the paramount concern and also the motivating force behind Crowd driven innovative biomedical device design. Biomedical devices must be designed with safety and efficacy in mind, and they should adhere to regulatory standards (albeit most of the countries in the region of interest have no regulatory authority for biomedical devices). Thus, the Crowd not only needs to be empowered with the technological know-how, but also be given the means to intelligently scan and filter the internet for useful open source materials without being overwhelmed by the choice available. To do so requires fundamental knowledge on biomedical devices, ergonomics, engineering and human physiology: this multidisciplinarity cries out for Crowd. Leaving aside large diagnostic and imaging equipment and prosthetic implants, the vast majority of biomedical devices have a large turnover and no one company monopolizes the market. They are also extremely diverse: examples are plasters, thermometers, hospital beds, sphygomanometers, etc. In this arena, there is huge scope for Crowd driven improvements and innovation.

B. Social Context

We are fully aware that although professors, students and technicians maybe very enthusiastic with the idea of open source and Crowd driven biomedical device design, some Ministries of Health, or some powerful economic and other interest groups in developing countries could to be linked to major device manufacturers and therefore can block or hinder our initiative because their interests are threatened. For this reason, part of our project is also focused on creating awareness-raising activities and workshops targeting policy-makers, e.g., representatives of the Ministries of Health and Education. Through the help of our funders we will develop advocacy campaigns for the recognition of the importance and relevance of biomedical and clinical engineering in the health care system for creating and managing a sustainable high technology health care system which does not rely on foreign economic aid. Indeed, our aim is to give the universities the tools, guide them through the platform and then let them research the best social conditions (at state level, society level, and so on) to turn the implementation of the project into a success. In fact, we are extremely sensitive about the issue of not imposing our ideas and cultural values on the People of Africa.

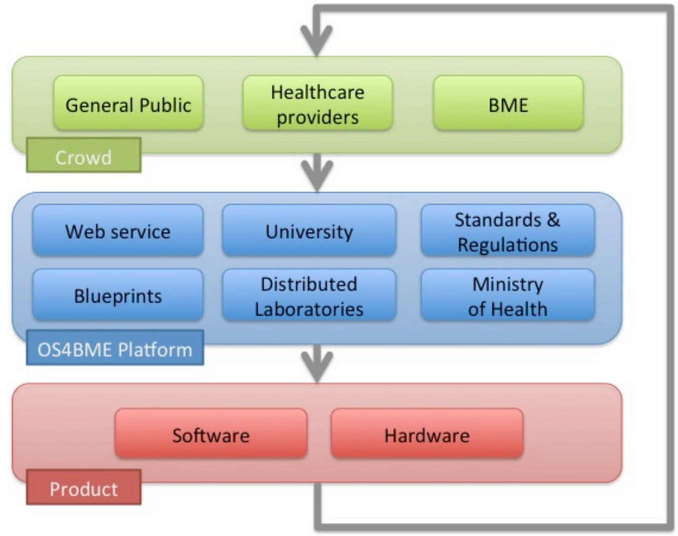

Figure 1. Schematic of the OS4BME work flow.

IV. Teaching the Crowd Philosophy in the BME Context

What we advocate therefore is giving biomedical engineers in sub-Saharan Africa, through their universities, the tools and knowhow in order to design, develop and maintain their own equipment based on the new open hardware and open source revolution, which is happening before our eyes. To achieve this ambitious goal, we outline three main objectives:

- the development of human resources in higher education in Biomedical Engineering in Africa,
- the creation of the OS4BME infrastructure, a sharing, making and repository platform based on the customization and integration of already available web tools,
- the making of a new genre of Biomedical Engineer in Africa equipped with the capacity to exploit and develop innovative designs on the OS4BME platform and of discriminate use of web based and open source resources.

Setting up the OS4BME platform requires the creation of a professional BME working group, versed in the regulatory aspects of biomedical safety and standards, which is able to assess, vet and categorize projects, designs or blueprints and then make them available through the platform open repository. The philosophy is summarised in Figure 1.

A. Identification of Tools for Crowd Design

The identification of the most suitable instruments and classroom management and organization is the first step to demonstrate the potential of open source in the BME context. We targeted three main areas of teaching, necessary to give a shape, a brain and to share the ideas:

1) Rapid prototyping: The term Rapid Prototyping (RP) indicates a group of technologies that allows the automatic realization of physical models based on design data using a computer. RP processes belong to the generative (or additive) production processes. In contrast to abrasive (or subtractive) processes, such as lathing, milling, drilling, grinding, eroding, and so forth in which the form is shaped by removing material, in rapid prototyping the component is formed by joining volume elements. In general, RP techniques follow a Computer Aided Design/Computer Aided Manufacturing (CAD/CAM) approach. The object is designed using a computer (CAD) which then sends the instructions to the machine to obtain the desired shape (CAM), fabricated layer by layer. For the implementation of the RP principle several fundamentally different physical processes are suitable, as photopolymerisation, conglutination of granules or powders by additional binders, extrusion of incipiently or completely melted solid materials [24], [25].

RP was originally conceived as a way to make one-off prototypes, but as the technology spreads more things will printed as finished goods [26].

Although 3D printing is not competitive for mass production (millions of parts), it is perfect in fields where the customization of products is important: because the expense of making tools no longer figures in the equation, the economics of mass production will give way to mass customisation. Parts will then be made in production runs not of a million or even of a few thousand, but of one. Thus, 3D-printed products will continue to creep into the medical, dental and aerospace industries where customers are willing to pay a premium for custom products. In industries that are not built on "markets of one", 3D printing will help product designers accelerate the design process. 3D printers would also be invaluable in remote areas [27]. Thanks to the various Do-It-Yourself (DIY) communities, several models of Open 3D printers are now available on the Web. One of the most famous is the RepRap community [28] built around the ideas of Adrian Bowyer. He imagined a printer that can print its own parts, and hence through a process of self replication is able to spread this technology throughout the population. All the parts of this type of printer (there are several versions) are open source. The electronics is based on Arduino (see the next section), the software is open source and produces standard G-code files. Designs can be shared and any unprinted parts of the machine are easy to find in any DIY shop. Although, the quality of 3D printed parts made by a RepRap is not high, we believe it is the right starting point to teach the potential of 3D printing to newcomers. The design and printing process is completely transparent so that each step of the complex procedure is easy to follow and replicate.

2) Electronic Prototyping Systems: Until about ten years ago, electronic system design and development was a field accessible only to skilled users, such as engineers, technicians, physicists, etc. Each time an electronic control system was required in a project, the design process had to necessarily include the choice of microcontroller, of a communication system, of a power source, etc. This choice was then binding for the selection of further components, interfaces and programming software. In 2005, in Ivrea (Italy) a team of designers created Arduino [29], a tiny board onto which a microcontroller was mounted together with all the necessary circuits and peripherals required for powering, communication and expansion. A revolution had begun: electronic control systems were not the bottleneck of prototyping anymore. With Arduino, even users without electronics and programming skills could integrate and electronic control system in their own project pushing the limits of complex system design and prototyping. The key factor of the Arduino platform is not only the board but also the easy-to-use programming environment, which allows unskilled users to program through a very intuitive C like programming language. These two factors allowed the birth of a huge user community which empowered the Arduino world through the sharing of code, libraries and projects with open source license. The availability of a pre-made piece of code allowed people to focus their designs on the development of functional and challenging parts using other projects and codes as inputs for their own designs.

Figure 2. Group photo from OS4BME class, hosted by the innovator Summer School, in the Kenyatta University conference center.

3) Content Management and Sharing platforms: As highlighted previously, the fast growing DIY community leaves several interesting projects to languish without documentation or with missing parts because a new, more interesting idea was released. Indeed, one of the most challenging aspects of cooperation in design and development is the organization and sharing of information and content. However, thanks to the revolution introduced by the blogging phenomenon, nowadays there are various free and open source Content Management Systems (CMS), which allow an easy and intuitive co-production of documents. These systems have been demonstrated to be useful even for the documentation of engineering and technical projects. MediaWiki [30] in particular is the core engine of the most famous web based encyclopedia Wikipedia. With MediaWiki or similar engines it is possible to create hypertexts made of a huge number of cross-linked pages allowing the creation of very detailed documentations and designs. MediaWiki is designed for the creation of text based documents with embedded pictures and table. Graphics and templates are very minimal allowing users to focus on the real content, which is a core feature of a concurrent design.

B. OS4BME Class

To kick start the initiative and to demonstrate the potential of a regulated open source design and prototyping platform to academics and regulators/decision makers, we proposed a short term intensive course. The course was implemented in August 2013 in Nairobi, Kenya. Our aim was to introduce the OS4BME concept to the African Engineering community and thus create a small working group who will be involved in the set-up of the new platform. To fulfil this objective, the course was focused on the design of a biomedical device from first principles, its assembly and testing and discussion of regulatory issues in device development. The OS4BME course was hosted by the Innovators Summer School held at the Kenyatta University Conference Center, Kenya and took place from the 12th – 16th of August 2013. The Innovators Summer School is an initiative of United Nation Economic Commission for

Africa (UNECA [31]), and is aimed at fostering the economic development of Africa by powering the higher education of the African students. The key player in the initiative is the African Biomedical Engineering Consortium (ABEC [32]), a consortium of African universities with the common mission of bringing excellence to BME in Africa. Over 48 students, technicians and lecturers from the ABEC universities: Kenyatta University (Kenya), University of Nairobi (Kenya), University of Eldoret (Kenya), Addis Ababa University (Ethiopia), Makerere University (Uganda), Kyambogo University (Uganda), Mbarara University (Uganda), University of Malawi (Malawi), Muhimbili University of Health and Allied Sciences (Tanzania), and University of PISA (Italy) attended the course (Figure 2).

After introductory lessons to explain the aim of the course, and some preliminary basics on RP Hardware, software, electronics, and safety regulations; hands-on sessions were provided, giving the students the opportunity to learn by doing. Following the spirit of the course, the free and open CAD/CAM software programs (FreeCAD [33], Slic3r [34], and Pronterface [35]) were adopted to introduce the design approach for 3D printing. For the electronics part, the Arduino platform was selected, for both price, ease of use and flexibility. All documentation was reported using Mediawiki. The keystone of the course was represented by the brainstorming coordinated by the authors with the help of Dr. Molyneux, a pediatrician from the University of Malawi, to understand the problems of a pediatric department in an African hospital context.

The discussion was centred on the respiratory problems of new born premature babies and the monitoring of breathing and body temperature. The aim was to design and build a low cost device, for monitoring respiratory movements and temperature, able to shake the cot to resuscitate the normal breathing of the baby when it stops, and equipped with a sound and light alarm to call a nurse to the cot. The implementation of these features was established together with students, after the brainstorming session. The discussion was focused not only on the functional aspects of the devices, but also on their cost, feasibility safety and reliability, giving the right direction to the project from its start.

After the definition of design specifications, students and attendees were divided into four thematic groups, on the basis of their previously indicated preferences: 1) mechanical design; 2) electronic design; 3) Software design; 4) Standard and regulation identification, and documentation. The subdivision in groups was fundamental in order to keep everyone involved in something they enjoyed: creativity is fed by passion and enthusiasm, boredom kills innovation.

The proposed approach led to the design and fabrication of an open source and low cost baby monitor (Figure 3) in the space of 3 days. The monitor was composed of three modules:

- the elastic band, to monitor the temperature and the breath of the baby;
- a vibrating box, activated when the baby stops breathing for more than 15 seconds;
- a control unit, with a LCD display, 3 LEDs, sound alarms and all the control boards.

Students were encouraged to refer to ISO standards, such as IEC ISO 80601-2-56, with the aim of using these documents to help their work rather than a constraint.

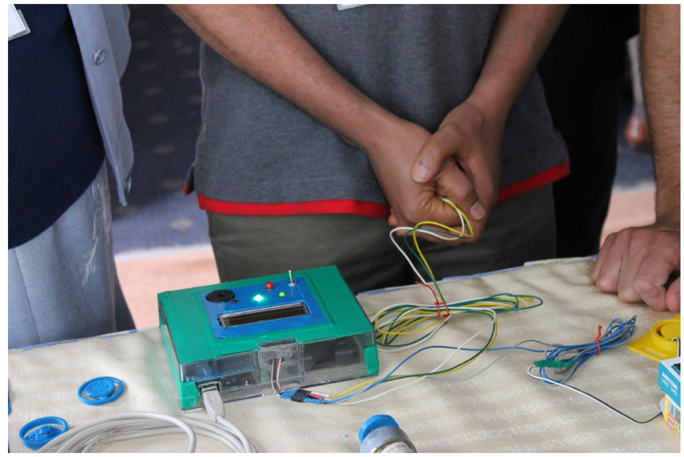

Figure 3. Some moments during the OS4BME class: preliminary test of the device.

At the end of the course an evaluation survey was conducted by the funders. Over 81% of participants expressed extreme satisfaction in the course, although a good proportion (46%) of them could have benefited from more time and previous knowledge on electronics, CAD and programming. In fact, only one participant had previously been exposed to open source technology. There was also interest in the regulatory aspects and standards in medical devices. As the participants were from different backgrounds, many had very little idea what medical devices are and the critical importance of safety issues in such devices. The action thus served to bring home the importance of this aspect during the design of instruments for BME.

V. Conclusion and Future Work

The objective was to develop and nurture resource sharing and technological self-competency through the establishment of a virtual platform containing ideas, blueprints, FAQs and safety regulations for creating new, competitively priced and innovative biomedical devices. We envisage an OS4BME platform managed, regulated and monitored through an academic led pan-African organization, assigned with the task of collecting, classifying, vetting and disseminating information and know-how on the design and development of biomedical devices and instrumentation. In the long term, the sharing of ideas and designs should become the norm, allowing continuous user-driven improvements in healthcare.

A summer school was organized to kick off these ideas, with the aim to create a cohesive working group on which built the platform. The response from students, professors and technicians involved in the school was enthusiastic. It was crucial for participants to play an active role in the identification of the problem, selection of components, design, assembling and testing of the device and in the discussion of regulatory issues in the development of the device. Participants were able to gain a hands-on introduction to electronic system design and programming. All teaching materials, including course documentation, the baby monitor design blueprints are available online for the community to take on and develop further. The 3D printer and all components are now hosted at Kenyatta University's Faculty of Engineering.

Accordingly to the funders' survey the course was an undoubted success. Most students and staff were unaware of the existence of tools, such as Arduino, FreeCad, Slic3r, Media Wiki, etc., let alone the power and implications of open source design and prototyping. The experience was instrumental in bringing this knowledge to the participants, and their keen interest throughout, particularly on 3D printing was apparent.

Although there are several resource sharing platforms available as well as several courses on RP, digital design and embedded electronics, none of these is dedicated to biomedical devices. This is because biomedical devices must be designed first and foremost with patient safety and efficacy in mind. The OS4BME infrastructure, managed by the new genre of biomedical engineers, can be the tool to address this challenge, and its implementation is our objective in the next few years. The first cornerstone of this project was an intensive course, the first of its kind, held in Nairobi addressed safety, ergonomics, biomedical device design, and RP in an integrated manner.

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