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Editor's Corner

When was the last time you thought about your next breath? Will it happen? Do I need to do something to get it going? Like you, I do not find myself thinking about it. Fortunately, the respiratory center controlling our breathing is in our upper brainstem where the medulla oblongata and the pons send signals to the muscles that control involuntary respiration and cause breathing to occur. Unfortunately, before the discovery of a safe and effective vaccine, some children were infected with the poliomyelitis virus that leads to paralysis. There is no cure for the devastating effects of polio but it can be prevented by the vaccine and the volume of global cases since 1988 have been reduced by 99.9% according to Rotary Club (<https://www.endpolio.org/>). This becomes much more personal and touching after one of our own Editorial Board members shared with me the story, from over a generation ago, about the loss of his sister at the age of 12 from polio.

In 1927 Philip Drinker and Louis Shaw (faculty members at Harvard University) invented a mechanical respirator powered by an electric motor that could temporarily maintain artificial respiration in a person. A couple of years later, calling it the tank respirator, inventor John Emerson refined the design and adopted cost-cutting engineering enabling this “contraption” to become a staple within medical facilities.

The cost of the tank respirator was, at the time, equal to the cost of a house. In the 1930s, Drinker and Harvard University took John Emerson to court, claiming he had infringed on patent rights by altering Drinker’s iron lung design. Emerson defended himself by making the case that such lifesaving devices should be freely available to all. Emerson’s tank respirator was first used in 1931 in Rhode Island, USA. Years later, when Jonas Salk (inventor of the polio vaccine) was asked whether he would patent his polio vaccine and make a fortune, he replied that the

vaccine belonged to everyone, making the comparison, “How could you patent the sun?”

The first human use of a mechanical ventilator was recorded in 1909 when George Poe, Jr. was able to revive Moses Goodman using the apparatus, he called Machine for Inducing Artificial Respiration that he patented two years earlier. (https://en.wikipedia.org/wiki/George_Poe#/media/File:Poe_patent.gif). About a century later, due to the coronavirus pandemic, once again the world is becoming concerned over the lack of availability of mechanical ventilators (<https://www.weforum.org/agenda/2020/04/covid-19-ventilator-shortage-manufacturing-solution/>).

The history of the mechanical ventilator is the story of how an engineering solution addressed critical and urgent medical needs and healthcare’s growing dependence on technology. Also highlighted was that the technology lifecycle, from innovation to use, and from upgrades to accessibility, must be professionally managed by competently trained experts like clinical engineers. To be considered competent, clinical engineering education and training must include innovation, disaster preparedness, and assets management strategies.

Unfortunately, during this COVID-19 pandemic, like the previous era of the polio virus, lives that technology could have saved, were lost. Yet, the ability to connect challenges with engineering solutions just like John Emerson did about 90 years ago is the contribution to better care that clinical engineers do every day. In the profession that creates and ensures that technological tools are patient-ready there no room for error or mistakes. The professional principals that every engineering training program must incorporate into their curriculum.

Regardless of the era humans live in, they can always find ways to collaborate and disseminate information, and there is no better time than now to appreciate and participate in the Global Clinical Engineering Journal.



Today, there are still few polio-stricken patients like Paul Alexander from Dallas, Texas, who are surviving thanks to the engineers and technicians who can keep old iron lung machines going for over six decades (<https://www.youtube.com/watch?v=gplA6pq9c0s>). Like Paul Alexander says in the linked video “I’m not crippled. I’m a human being.” So, let me ask you again: when was the last time you thought of your next breath? How fortunate we are not having to think about it. I hope you will enjoy reading the rest of this Journal and remember to send me your feedback.

Today, tomorrow, together!

Dr. Yadin David



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CONTENTS

Editor's Corner	2
Maternal-Fetal Simulator By L.R. Rodrigo, A.M. Marcelo and A.S. Anderson	5
Emerging Horizons of Clinical Engineering in Disaster Preparedness and Management: Proposal for an expanded professional identity By F. Hosea	10
Redesigning protective gear for health workers during the COVID-19 pandemic: leveling up the "aerosol box" By R. Moreno, E. Pedraza, F. Morales, R. Mijares, R. Boccardo and M.A. García	27
Submissions Style Guide for the Global Clinical Engineering Journal By J.S. Schultz and Y. David	33
Flow Analyzer for Blood Pump By R.L. Rezer, M.A. Marciano, A.A. Santos, and W.K. Souza	44

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Maternal-Fetal Simulator

By L.R. Rodrigo¹, A.M. Marcelo² and A.S. Anderson¹

¹ Moinhos de Vento Hospital/ Clinical Engineering, Porto Alegre, Brazil.

² Moinhos de Vento Hospital/ Clinical and Hospital Engineering, Porto Alegre, Brazil.

ABSTRACT

This study presents the implementation of a low-cost automated prototype, in an open code platform, that simulates the maternal-fetal signal using the Arduino platform. Several options exist for providing a basic evaluation of the maternal-fetal monitors, but the need to simulate the medical environment with a man-machine interface is needed in this age of simulation-based medicine.

Another possible application of this simulator is as a teaching tool. Using data generated by the simulator the man-machine interface can measure fetal movement, uterine activity, and fetal heart rate. The data from the interface can then be compared with those presented by the fetal monitor. This comparison makes it possible to check the correct functioning of the equipment tested.

Keywords – *Fetal Monitor, Quality Control, Biomedical Simulator, Arduino.*

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INTRODUCTION

The concern over fetal cardiac arrhythmia has increased over the last few years, creating a bigger demand in the use of fetal monitoring methods.¹ The function of the electronic fetal monitor is to detect and record both the heart rate of the fetus and the uterine activity of the mother in labor.² To verify the electronic functioning of the fetal monitor there is a need for performance testing. The tests are divided into two parts – quality evaluation (that consists of visual inspection of the structural conditions of the equipment, parts, modules, and accessories) and quantity tests (that consists of the measurement or simulation of biomedical parameters of the equipment).³

An alternative to the test is to use simulators. Simulators aim to present practical situations from everyday life.⁴ The use of simulators also allow new approaches in education and medical practices such as simulation-based medicine.

For example, the students can use anatomical and physiological simulations to predict the results of procedures and, therefore, keep up with the results of treatments in virtual patients.⁵ The improvement of simulators in the health field is largely due to the use and sophistication of Artificial Intelligence-based on microprocessors using algorithms that can change concepts and mechanisms are used.⁶

The Arduino platform is an easy to use micro-processing tool that allows the utilization of medicine-based simulation. Arduino is based on a very versatile system microcontroller that potentate its functions beyond a simple passive interface of data acquisition and can operate independently while controlling many devices.⁷ Due to the need for testing of maternal-fetal monitors, developing a strict quality process allows for the appraisal

of the level of equipment deterioration. This provides information about deficient components and verifies the quality of repairs made.⁸ In the continuous processes of improvement, the implementation of quality control aims to guarantee the safety and reliability of the results of the diagnostic testing.⁹

Another point to consider is the need to involve the assistant medical team in the performance of a hospital's medical technology. Besides understanding the technology used, the assistant team (doctors, nurses etc.) will need to get involved increasingly in the life cycle of the equipment. To help with cost reduction and maximize the clinical benefits, interaction with the clinical engineers guarantees the effectiveness of preventive maintenance through the use of simulator-based tests and allow participation in the evaluation of potentially outdated or unsafe technology.¹⁰ To address this need we developed a low-cost automated system prototype to simulate uterine contractions and fetal heartbeats. The aim was to make it easy to use in universities and hospitals that are looking for quality in fetal monitors testing.

METHOD

With the specified, calculated, modeled, and simulated data, a prototype was designed, developed, and tested according to the flow-gram demonstrated in Figure 1.¹

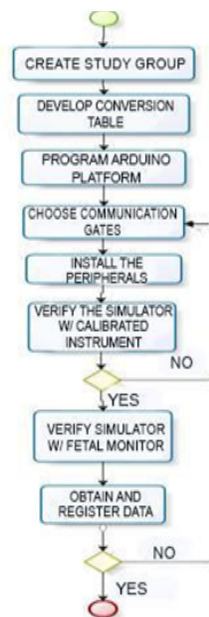


FIGURE 1. Method flow-gram.

Initially, the project was organized as a study group for evaluating the possible solutions for a low-cost prototype of a maternal-fetal simulator. Many follow-ups were made with the nursing team in the obstetric center to measure a real antenatal exam. The other steps outlined in the flow-gram in Figure 1 are described below in Equation 1 and Equation 2 as a two-step conversion calculation that was within the limits of the processor and the requirements of the maternal-fetal monitor.

$$1\text{BPM} = 1/60\text{Hz} \quad (\text{Equation 1})$$

$$T = 1/f \quad (\text{Equation 2})$$

Through these calculations Table 1 was created within the parameters of the development of the program. Time periods with whole numbers were used to facilitate the programming.

TABLE 1. Conversion – Relation between Heart Rate (BPM), Frequency (Hz) and Period (Ms)

(BPM)	(Hz)	Period (Ms)
30,0	0,5	2000,0
60,0	1,0	1000,0
90,0	1,5	666,7
120,0	2,0	500,0
180,0	3,0	333,3
240,0	4,0	250,0

PROGRAM

In this step we dealt with programming for the Arduino platform (Figure 2), with the principle of language C. Based on Table 1, the periods of each heartbeat were defined causing each one to stay for a minute. After this step, the signal of fetal movement was programmed with the stimulus of five pulses at intervals of one minute. After that, the lines of programming were implemented for the sensor responsible for controlling the pressure bomb causing a variation of pressure of 0–100 mmHg. After getting to maximum pressure, to stabilize the circuit for a minute at a 50 mmHg, the valve must open to reset the pressure of the system. Lastly, the display was programmed to show the pulses of fetal movement, uterine pressure, and heart rate/frequency of the fetus.

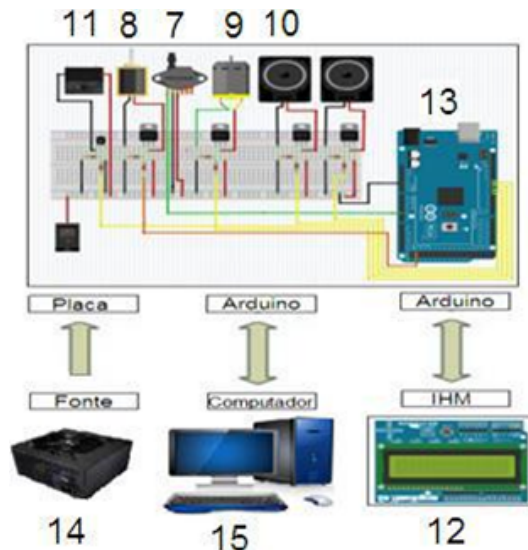


FIGURE 2. Arduino platform circuit diagram.

INSTALLING THE PERIPHERALS

The system used a selective on/off key. The power to the board and peripherals was through a computer source. For the electromechanical components (the speaker which is responsible for the sound wave emission that will stimulate the ultrasonic transducer of the fetal monitor), a TIP122 was used that received power of 12V from the switching power supply. Control of simulation of the fetal movement was via the use of a 12V relay with a NA contact. The pressure sensor used was an MPX5700DP, which controlled the pressure inside the neonatal PNI and was connected directly in the Arduino platform. The sensor was powered by the 12V source. The pressure bomb was connected with the component TIP22 and powered by 12V from the switching power supply.

The valve connected to the TIP122 received control of the main board and was also powered by the 12V power supply. The display was connected to the processor board. In this prototype, the Arduino MEGA microcontroller was used. The coding platform and free hardware that has its own compiler was developed for use by people with little programming knowledge.

The microcontroller used in the Arduino MEGA 2560 was the ATMEL ATmega2560, an 8-bit microcontroller of advanced RISC architecture. It has 256 KB of Flash (8 KB more are used for the boot-loader), 8 KB of RAM and 4 KB of EEPROM. It has 16 MIPS, operating in 16 MHz. Arduino

based in Atmel ATMEGA, among which can highlight 4 communication serial channels, 16 analog inputs, and 15 PWM outtings. It has SPI communication, 12C and 6 pins of external interruption. The MEGA 2560 board has 54 input pins and digital outputs that can be used as inputs or outputs. The pins operate with a tension of 5V and can provide or drain up to 40 mA. Each pin has a “pull-up” intern resistor that can be enabled by software. It has 16 analog inputs (A0 to A15 pins), where the conversion can be made with a resolution of 10 bits, that is, the value will be converted between 0 and 1023.

IHM

The IHM of the Arduino platform was chosen so the simulator could have mobility and easily interface between the operator and the device.

Driver

The TIP122 was used to control the electromechanical devices.

Power Source

Standard 12V, 2.3A, real potency of 500 Watts, Efficiency >70%, MTBF of 100.000 hours, 25°C, intern protection against short circuit OVP/OCP/SCP, AC input with manual switching 110/220V, low acoustic noise, cables with protection covering, cooling temperature controller system, silent ventilator of 120 mm, IEC60950 technical norms (electrical safety), IEC 61000 (electromagnetic safety), on/off switch.

Diaphragm Pump

A diaphragm pump was used to inject pressure on a plastic membrane controlled by the pressure sensor which generated pressures to the touch. Figure 3 shows the system functions of the circuit.

Relay – with a NA/NF of 12V.

Speaker – 4Ω/66W.

Neonatal Cuff – Cuff of neonatal PNI with a tube.

Valve – Valve with solenoid of 12V.

Pressure Sensor – MPX5700DP.

TIP122 – 5A, power transducers, 60 volts, 65 watts.

RESULTS

After connecting all peripherals, the program was run to verify if the simulator was within the minimum of

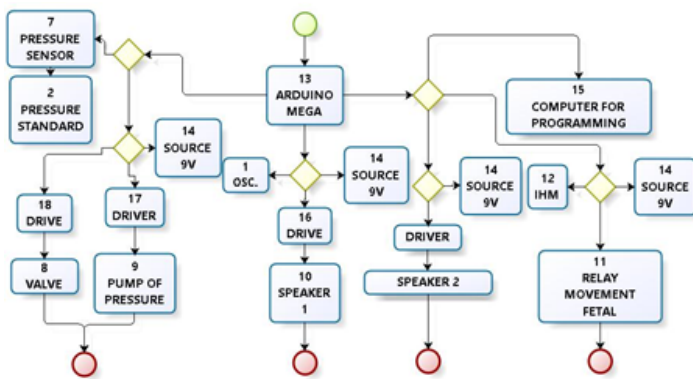


FIGURE 3. Circuit flow-gram.

uncertainty. To determine the reliability of the prototype a digital oscilloscope was connected (Figure 4) in the pressure circuit. The cycle of the program was monitored through this oscilloscope and calibrated with traceability. To obtain the final results, the fetal monitor's transducers were connected in the simulator and five tests were executed with satisfactory results as shown in the IHM,



FIGURE 4. Frequency generated by Arduino.

with the visualization of the measurement of the fetal movement (Figure 5), uterine activity (Figure 6), and fetal heart rate (Figure 7).

As a complement to the results, Figure 8 shows the system during the testing of the prototype including the



FIGURE 5. IHM fetal movement.



FIGURE 6. IHM uterine activity.



FIGURE 7. IHM fetal heart rate.

number identification for the components of the system. This is also shown in Figure 8.

DISCUSSION

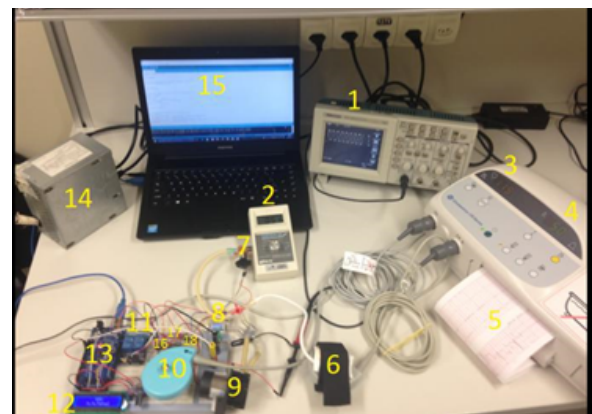


FIGURE 8. Prototype test.

It wasn't simple to reproduce the BPM with an electro-mechanical system and develop a structure that accommodates the sensors of many models, to execute a low-cost prototype. One of the difficulties was transforming the "electronic garbage" (useless components) available into the appropriate components needed in the simulator.

One of the improvements to the project could be a Wi-Fi-connected system to allow Cloud storage of data and information collected by the fetal detectors. The data could be identified as patrimony or by an identification code.

Proposed future improvement requiring further study include the development of similar devices to analyze PNI, ECG, and electrical tests, in an integrated way by

adding modules to this simulator. This would be made easier due to the simplicity of the program structure and that the Arduino platform has many tutorials available on the Internet.

CONCLUSION

The goal of simulating uterine contractions and fetal heart rate with a low-cost automated system was accomplished using quality standards in the tests of the maternal-fetal monitors and executed by the clinical engineering services. Additional improvements, developments, and new validations are also achievable.

CONFLICT OF INTEREST

The authors declare that they have no conflict of interest.

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Emerging Horizons of Clinical Engineering in Disaster Preparedness and Management: Proposal for an expanded professional identity

By F. Hosea

Yachay Tech University, Ecuador.

ABSTRACT

The COVID-19 pandemic of 2020 has exposed a wide range of systemic deficiencies in public health strategy, poor alignment of global health and economic institutions, insufficient budgeting, and the urgent need for real-time management of scientific resources, rapid-cycle clinical innovations, competent political decision-making, and supply chain logistics under disaster conditions. This article proposes that a new model of multi-disciplinary professional skills is needed globally to re-engineer existing public and private healthcare systems for both normal and disaster conditions. Clinical engineers are recommended to play a growing role in future global disaster management and systems integration activities, owing in large part to their multifunctional expertise in technology assessment, hospital operations, and as stakeholders in healthcare innovation. Twenty-six recommendations are presented as foundational strategies to create a 21st century model of globally aligned healthcare systems, centered on the growing role of clinical engineers as subject matter experts in both normal and disaster conditions.

Keywords – disaster preparedness, clinical engineering, systems engineering, alternate sites of care, health technology design, dual-use infrastructure.

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INTRODUCTION

GLOBAL DISASTER UNPREPAREDNESS

The global COVID-19 crisis of 2020 has thrown a global spotlight on the many ways in which healthcare systems,^{1,2} governments,^{3,4} medical industries,⁵ markets,⁶ and healthcare professions⁷ have been unprepared, under-resourced, tragically slow and uncoordinated in responding to the most disruptive medical disaster of our times. Despite numerous threat-analysis studies,⁸ detailed pandemic scenarios,⁹ and simulations by state and federal agencies,¹⁰ despite trillions of dollars spent on post-9/11 international disaster preparedness,¹¹ and

repeated top-levels warnings by epidemiological and public health experts, the world's governments, markets, and healthcare systems have failed to prepare and prevent a health disaster from exploding into a multidimensional catastrophe.

The fragmentation of plans and competencies across sectors – complicated by political decision-making – clearly demand mission-critical re-organization among the institutional players, with more coordinated, integrated, and *systems-oriented* professional approaches worldwide,

and active cultivation of public health intelligence. For the reasons that follow, clinical and biomedical engineers are among the best-suited health professionals to assume an expanded and more comprehensive leadership role as subject matter experts in this urgently needed transformation, “particularly following the recent adoption of the recommendations of the UN High-Level Commission on Health Employment and Economic Growth, the WHO Global Strategy on Human Resources for Health, and the establishment of national health workforce accounts.” In particular, the WHO analysis and recommendations in “Human Resources for Medical Devices” provide a transformational vision for Biomedical and Clinical Engineering worldwide that strongly harmonize with the recommendations contained in this article.¹²

WHY CLINICAL and BIOMEDICAL ENGINEERS?

Traditionally, Clinical Engineers and Biomedical Engineers are professionally prepared to perform a very broad range of overlapping clinical, technical and operational tasks – working from bench innovations to bedside care, including the design and assessment of medical devices and their internal components,¹³ to the management of complex hospital infrastructures and supply chains, encompassing possibly hundreds of device families, models, network interfaces and “care-anywhere” services via telehealth and telemedicine. For the purposes of this article, the term “Clinical Engineer” (CE) will be used to encompass both biomedical and clinical engineers, because clinical engineers (and clinical systems engineers) typically have the widest, multi-systems professional orientations and skillsets that are well-suited to the often improvisational complexities of disaster preparedness and management in healthcare systems^{14,15}

Beyond individual hospital operations, CEs may also be involved extramurally in standards development and technology assessment organizations, research and clinical trials, innovation consortia, startups, professional associations, and consultations to ministries of health and the World Health Organization. As such, they can have wide-ranging, *inter-institutional* experiences that are directly relevant to the *multi-systems challenges* of disaster preparedness and management. Although they may work with different job titles and tasks different

professional education and certifications around the world, CEs share a common mission to optimize safety, efficiency, cost controls, and healthcare quality through the application of systems-oriented engineering expertise that encompasses not only devices, but processes, human resources, procurement, risk management, and strategic planning. These integrative skillsets take on even greater importance in disaster circumstances. Compared to many other vertically-specialized professions in healthcare, the multi-disciplinary, intersectoral span of professional relationships in CE provides a unique foundation to bring a more coherent, rapid-cycle integration of science, technology, standards, regulation, institutional strategy, planning, and execution.

As science and technology have advanced with increasing velocity and scope, these life-saving engineering professions are also evolving and expanding to incorporate new tools and processes into increasingly complex healthcare systems.¹⁶ The successful incorporation of existing knowledge and urgent innovations *under disaster circumstances* requires new categories of professional expertise and institutional alignments. Because of their wide-ranging organizational knowledge and technical skills, CEs are uniquely prepared to become the next generation of multifunctional experts who can help cultivate the systemic organizational intelligence and planning that is increasingly indispensable for modern healthcare, as well as for disaster preparedness and management.

PROPOSAL FOR AN EXPANDED PROFESSIONAL IDENTITY

THE GROWING NEED FOR SYSTEMS EXPERTISE FOR BOTH NORMAL AND EMERGENT CONDITIONS

As innovators in the medical device industry, CEs may be involved in highly specialized research aimed at designing or improving diagnostic devices,¹³ monitoring,¹⁷ or therapeutic devices that are technically complex,¹⁸ multifunctional, networked,¹⁶ and designed for “precision medicine” that may disrupt traditional clinical and business practices. As managers of a clinical operations infrastructure, CEs may be responsible for the 24 × 7 hospital requirements for maintenance and repairs, for

assessing new technologies, managing installations and upgrades, project and team coordination, scheduling maintenance and repairs, coordinating IT integration, facility design consultation and new facility provisioning, cross-functional troubleshooting with IT, end-user training, vendor and supply chain management, surge capacity planning, replacement planning, service-level agreements, budgeting, technology assessment, risk management,¹⁹ hazard alerts and recalls, and emergency preparedness.

Because CEs may span such vast areas of expertise^{20–23} that are essential to the quality and reliability of day-to-day healthcare services, they are at the same time uniquely positioned to be recognized as systems-oriented, subject matter experts who can help repair and re-engineer the prevailing fragmentation in disaster preparedness and management.

AN ACTION PLAN FOR THE FUTURE

This article provides a very condensed compilation of technological, organizational, and professional recommendations that will enable CEs, clinical systems engineers, and biomedical engineers to build upon their existing system lifecycle expertise and assume wider institutional roles in disaster preparedness (DP) and disaster management (DM). Although the current global concerns are for pandemic response, the following topics will be equally relevant for all-hazards disaster conditions, as well as for improving normal strategic and operational efficiencies and resilience of clinical systems, ensuring a more robust, integrated infrastructure for future events. Because of the inherent complexities of normal healthcare operations, where it is necessary to work in a 3-to-5-year planning window to make significant changes, it is likewise necessary to begin planning now during the 2020 COVID-19 pandemic, to deliver the global systemic improvements that will be necessary to prevent, mitigate and better manage future disaster challenges 5 to 10 years from now.

These expanded CE competencies will fill critical gaps in the ways that healthcare systems plan and manage their future DP/DM programs, which often suffer from lack of functional integration, staffing, and budgets. While most of the current responses to the COVID-19 pandemic are necessarily focused on near-term endpoint devices, therapies and protections, this article will offer a wider,

panoramic, long-term *systems-of-systems* view that will strengthen the organizational, technological and professional underpinnings of both normal operations and DP that should dramatically improve the global response to future threats to public health.

These recommendations are organized in a series of highly concentrated topics and specific actions that can be executed incrementally over time to expand the professional competencies and institutional roles of CEs for DP/DM. Each topic can easily be expanded as a workshop or academic course to provide the necessary technical or operational details needed for full implementation. While some of the recommendations can be enacted at an individual level of persons and organizations, others will require scaling up through new regional, national, and international collaborations.

Ongoing programs between WHO,²⁴ the International Federation of Medical and Biological Engineering (IFMBE, through its CE Division²⁵), the ICEHTMC (International CE and Health Technology Management Congress²⁶), the American College of CE (ACCE),²⁷ the Chinese Society of CE, The Association for the Advancement of Medical Instrumentation (AAMI),²⁸ the European Alliance for Medical and Biological Engineering & Science (EAMBES),²⁹ and the *Global CE Journal*³⁰ are creating new, global frameworks for research,³¹ professional development, conference coordination, standards development, credentialing, regulatory frameworks, and consultation to establish more coherent, innovative and dynamic capabilities across healthcare systems. In many cases, the ability to ask *systemically relevant* questions will be more important than the application of known, but overly specialized answers which may risk delivering obsolete or disjointed solutions. The world is clearly in need of professional expertise that can help compress and align the scientific, technological, and operational timelines for life-critical innovations and successful implementation under extraordinary circumstances.

We cannot allow these monumental challenges to deter us from the necessity, now being proven worldwide, to forge a radically different, long-term model of public health stewardship and institutional capabilities that are suited *simultaneously* to both normal and disaster

conditions. The world is already fortunate this day to have many gifted CEs around the world who are ready for such a noble quest – highly educated, energetic, caring, creative, expert in the complex lifecycles of healthcare systems, and now, tested by the high-velocity change, logistical chaos, global uncertainty, economic disruption and human sufferings imposed in the 2020 pandemic. In the coming years, let there be no doubt how these quiet heroes rose to the occasion.

RECOMMENDATIONS

(**Note:** Additional information and links for many of the following recommendations can be found in the RE-SOURCES section at the end of this document, grouped by topic)

1. **Understand your existing local, national, and international frameworks of DP and Management.** Don't re-invent the wheel. Investigate with your Ministry of Health and Emergency Preparedness agencies, public health agencies, and local hospitals to identify existing agreements, processes, and resources.
 - a. United Nations, WHO, OCHA, CADRI, UN Clusters (UNISDR, UNHCR, IFRC, IOM, FAO, WFP, UNDP, UNICEF, Save the Children), IFRC, ICRC, Sendai Framework, GDACS, OSOCC, INSARAG (See Resources section)
 - b. Your national frameworks: National Incident Management and Emergency Operations Centers.
 - c. Your state/province and local hospital and public health frameworks.
 - d. Conduct interviews and document existing gaps at any level of preparedness or response capabilities and discuss proposals to remediate them.³³ Arrange to attend training and simulations, and become subject matter expert in one or more areas of DP/DM.^{32–35}
2. **In your organizations (hospital, professional association, standards organizations, R&D consortium, government agency, legislative and regulatory bodies), promote Clinical and Biomedical Engineers as Subject Matter Experts for System Lifecycle Management, with specific applications in DP/DM.** Develop DP/DM skillsets and experience through the following:
 - a. **Schedule specialized DP/DM coursework**, interdisciplinary and cross-functional workshops, conferences, credentialing and certification.
 - b. **Re-write job descriptions for CEs to include DP/DM as a required competency**; set aside time for dedicated assignments to organizational emergency preparedness teams and practice drills. Include readiness research, conferences, and publication in scientific and professional journals^{36,37} as CE performance evaluation criteria.
 - c. **Arrange for CEs to be permanent delegates** to organizational Emergency Preparedness Teams – local, regional, and national.
 - d. **Delegate CEs to serve on standards committees** and medical device design consortia to promote inclusion of DP/DM performance factors in design standards for medical devices and systems.³⁸
 - e. **Contribute to the design of table-top exercises** for DP/DM, with emphasis on functional inter-dependencies and risk/failure points that other stakeholders might ignore.
3. **Promote regional and national purchasing cooperatives** to maximize cost-savings over the lifecycle of devices and services, including specific disaster-related terms and conditions.
4. **Promote Health Technology Design among CEs as the front-end of the Device Lifecycle management process to integrate best disaster practices into future designs.**
 - a. **Formalize device and system design** to provide *real-time networked performance feedback* of device data to manufacturers (as feedforward into next-generation device/system design, with all necessary safeguards for patient privacy and confidentiality). Formalize consulting relations between CEs and manufacturers to conduct regular design consultations as part of the contractual relationship.
 - b. **Define, design, and enforce Universal Minimum Functionality for medical devices (UMF).** Most medical device manufacturers emphasize product differentiation from their competitors, and this produces highly specialized devices that may be perfect for normal circumstances, but be sub-optimal or dangerous under disaster conditions,

when there may be a transfer of life-support patients to other sites of care, significant rotation of staff across locations, and staff who have to use medical devices that are different from what they are accustomed to. The specialized differences in user interfaces, IT connectivity, consumables, and performance characteristics may cause significant risk to patient safety. We need to promote UMF requirements for procurement of all medical devices to ensure the lowest common denominator of safety, performance, and user interfaces as a default setting under disaster conditions, to support rapid transport and accurate continuity of patient care across locations, caregivers, and device brands. With the push of a button, the UMF functions can be invoked to provide a specific menu of minimum, universally standardized functions, and user interfaces. UMF device design and training would support patients with generic functionalities that would assure higher overall population benefits than what would result from overly specialized functions that could put patients at risk due to inappropriate use by untrained staff. Include supply chain guarantees and contingency plans to ensure technical support for diverse disaster locations, and plan for universally standardized consumables.

- c. Develop **Capability Maturity Roadmaps** to identify strategic pathways for medical technologies and services with a 5- to 10-year performance horizon. Adjust roadmaps for different economic conditions.^{39,40}
- d. Promote **formal collaborations between IT and biomedical forecasting institutions** such as Gartner and ECRI, professional and industry associations. Produce joint assessments of innovative technologies and plot on Biomed/CT/IT hype cycles and magic quadrants.
- e. **Design to Cascade** – Devices should be designed for extended use and re-use across diverse economic development zones so that UMF functions eventually become available to LDCs (less-developed countries) through redeployment, using local refurbishing and production where possible, and strictly-managed donations. This will gradually create a predictable minimum of standardized

device functionality globally that will increase the safety and efficiency of clinical efforts by clinicians who at times must work at remote and unfamiliar disaster sites.

5. **Include Smart Design requirements** for all medical devices with computing capabilities so they have extensive, built-in capabilities for universal time synchronization, self-monitoring, self-reporting, self-updating, self-diagnosis, and self-healing. Real-time location, performance readiness, configuration, and mobility of medical devices will be critical for rapid emergency deployment and redeployment conditions (e.g., patient transfer to an alternate site of care, with infusion pump and ventilator).
 - a. **Specify multicore device design**, which will segregate clinical and device lifecycle operations functions on separate computing cores, with a hypervisor bridge. This will enable highly secure, real-time asset, service, and configuration management to be executed without interfering with clinical performance. This includes device identification, location, configuration history, component provenance, performance and service history, making the device an active partner in managing its asset, and service lifecycle. Architect devices to internalize and support external service, security and *process controls* so that devices themselves become active players in managing routine monitoring, compliance, and reporting activities.
 - b. **Leverage emerging IPv6 capabilities**⁴¹ Envision devices as intelligent members of the extended IoMT (Internet of Medical Things). Device components can be independently addressed and managed via IPv6 addressing, to significantly improve security, remote patient monitoring, and cloud management of IoMT data which will become increasingly important in “care-anywhere” and behavioral health services.
 - c. **Build “developmental headroom”** into device hardware and software architecture, to extend usable life and afford built-in capacity for new functionality without burdensome replacement costs and inefficiencies.

- d. **Coordinate CE tightly with IT *asset management and service management*** to develop aligned processes, data dictionaries, configuration management, and roles that will support standardized service and performance analytics for primary, transitional and Alternate Sites of Care, including ambulance services and military locations having other network, security, and compatible consumables standards.
 - e. **Explore secured, cloud-based product development *partnerships*** for device design and prototyping. Promote interdisciplinary, intersectoral alliances, and collaboration frameworks.
6. **Adopt the ITIL *framework of service strategy and service management*.** The Information Technology Infrastructure Library (ITIL) is the global standard for business process engineering, based on IT life-cycles, for ensuring alignment and coherence of all services provided within an organization and between organizations. It is an indispensable tool to ensure that all organizational services support healthcare activities that are safe, efficient, effective, and expertly managed. Careful mapping of service processes and accountabilities during normal operations should be used to create parallel process maps that are adapted to disaster conditions.
- a. Obtain **training and certification** for CE staff in basic ITIL concepts and methods (3-day course).
 - b. Create **end-to-end service process maps** for your organization for normal and disaster conditions, working closely with all stakeholders, escalation paths, and decision points.
 - c. Where feasible, explore how **business process automation** can improve workflows during disaster conditions by guiding staff through automated, pre-defined checklists and options so staff doesn't have to improvise randomly amid stressful circumstances.
7. **Prepare Professionally for *Alternate Sites of Care (ASOCs)*.** Certain disaster situations will overwhelm existing hospital facilities and small-scale surge preparation, requiring the setup of emergency hospital capabilities at schools, warehouses, hotels, sports arenas, field tents, military bases, factories, and other sites.
- CEs should play a major role in anticipating, planning, and executing on ASOC logistics, deployment, testing, and site readiness certification.
- a. **Anticipate the need to prepare** to work rapidly and closely with local, national, and international military, National Guard, national and local police authorities to manage dynamic disaster conditions and coordinate efforts to plan and deploy ASOCs.
 - b. **Clarify in advance the *hierarchy of decision-making*** authorities, geographical jurisdictions, and processes. Use scenarios to anticipate potential decision crises.
 - c. **Evaluate facility *Surge Area design***, setup, device requirements, disinfection, patient identification, tracking, and medical record continuity, patient transfer processes, patient monitoring, surge capacity limits. Conduct periodic drills. Establish criteria for transfers from hospital or surge areas to ASOCs.
 - d. **Develop technology-mediated *patient transfer protocols*** and process maps to ensure continuity of care: patient transport, infusion pumps, medications, belongings, device tracking, ventilators, vital signs, family contacts, data interfaces with electronic medical records, wireless or cellular connectivity.
 - e. **Evaluate and acquire *Early Situation Awareness software***, pre-load critical infrastructure locations, facilities and profiles. Update annually. This will enable instantaneous activation of a regional incident tracking utility, enabling Emergency Operations Centers to know exact the GPS location of incidents, deployed responder vehicles, and dangerous conditions.
 - f. **Evaluate *facility needs*** for backup power, space management coordination, utilities, wireless access, medical gasses, waste management, security, maintenance and repair parts, disinfection, IT coordination.
 - g. **Arrange to serve** as a multifunctional Engineering expert and consultant in *Disaster Resource/ Emergency Operations Center design*, simulations, response roles.

- h. **Evaluate the need for *additional equipment*** for decontamination, generators, mobile or field operating rooms, Rapid Assembly Shelters, Containerized Clinics.
 - i. **Perform quarterly updates of ASOC status** to identify any significant changes in readiness, resources, staffing, plans.
 - j. **Evaluate the role of *portable Emergency Electronic Medical Records*** and mobile connectivity to medical devices for vital signs, medications, infusions, treatment plans, etc.
 - k. **Review *Supply Chain Management*** practices to address specific disaster conditions.
 - (i.) Use multi-professional scenarios to identify probable stress points, gaps, failures, and decision-making bottlenecks that may impede rapid ramping up of disaster response actions: vendor contracts, pre-orders, 3-D printing, open-source online design specifications, delivery, receiving, storage, distribution, security, configuration for ASOCs.
 - (ii.) Anticipate the need to coordinate with national military logistics agencies and ensure that minimum compatibility standards for devices and consumables are applied in the procurement process.
 - (iii.) Identify critical trigger points in early disaster awareness that will prepare manufacturers to shift from just-in-time production to large-scale emergency production standards.
 - l. **Pre-define equipment lists**, rapid supply chain strategies, and ASOC requirements to manage the possibility of ***multiple-hazard disasters*** and resulting health threats (e.g., simultaneous pandemic and earthquake victims).
 - m. **Identify *multiple constituencies/stakeholders*** who need to be involved in normal and ASOC capability planning: Building science professionals (air quality, negative pressure, decontamination, medical gasses), contractors and vendors, childcare providers, disaster survivors, emergency managers and personnel, fire services, community safety associations, disabled persons, language translators, time-sensitive treatments (chemotherapies, pregnancy, dialysis, etc.), livestock owners, parents and teachers, pet owners, individuals with physical access and mobility needs, media contacts, tribal representatives, university research partners, volunteer coordinators.
 - n. Consult with anthropologists, ethologists, social psychologists and historians to evaluate the impact of ***cultural, ethnic, religious, and linguistic differences*** that will significantly affect patient treatment and possible interactions with families, relatives, loved ones, ambulance services, forensic, morgue and funeral services, burial, and grieving practices.
4. **Establish Dual-Use Infrastructure** - The dual-use concept in traditional military usage refers to civilian materials or processes that can also be used or altered for terrorist purposes. But in our case, the *Dual-Use-Infrastructure* concept requires that all medical equipment that may be used under disaster conditions shall be designed for *maximum compatibility between civilian and military services*, and shall include a least-common-denominator of clinical functionality, data standards and user interfaces that enable instant usability by trained clinical staff anywhere, regardless of brand.
- a. **Build on *military alliances*** for large/complex disasters; identify and establish formal liaisons and schedule periodic meetings to keep current of developments.
 - b. For all-hazard risks, **identify relevant *medical devices needed for each risk category***, including multiple disaster situations (e.g., simultaneous earthquake, tsunami, radiation), and ensure cross-compatibility between military and civilian applications.
 - c. **Align *military and civilian procurement processes***, inventory synchronization, and decision-making for disaster procurement, especially for national stockpiles.
 - d. **Ensure *interoperability*** of electronic identity management applications and processes so that military and civilian professionals can interact without obstruction or delay.

- e. **Review and establish *trusted domain rights*** on DM networks; update credentials as needed for instant, uncontested sign-on in ASOCs.
 - f. Negotiate with government and commercial network providers to **establish *dedicated network priority bandwidth* during disaster conditions**, providing top *Quality of Service* for all medical system users and devices, and research partners.
 - g. **Require universal wireless location of medical devices** and high-value, mobile capital equipment by using built-in radio-frequency identification; use this function to support patient and device transfer to ASOCs and timely return of outgoing devices; formalize control of network credentials, login, and device recovery processes.
5. **Ensure *Cross-border credentialing database*** exists to enable rapid verification of professional skills for ASOCs.
- a. Volunteers and retirees from other regions/states/countries may arrive to assist in disaster response activities, and it is important to verify in advance their identities, relevant skills, and credentials, and issue necessary identification badges, vests, or wristbands to enable rapid access to different areas of disaster control
6. **Research and compose *Mutual Aid Agreements*** at all levels and ensure clear jurisdictional authorities at each level.
- a. Obtain Master Service Agreement templates⁴² and confer with local public health agencies to identify existing agreements.
 - b. Meet with actual and potential partners to review MSAs and adjust as needed.
7. **Research and Incorporate *Rapid Deployment Technologies*** for DM
- a. Hastily formed networks.
 - b. USHAHIDI (an online tool for aggregating information from the public for use in crisis response).
 - c. Sahana (open-source DM software).
 - d. Google Crisis Response, Google Public Alerts, and Fusion Tables.
 - e. Solar-powered wireless access points.
 - f. Failsafe communications: Bluetooth walkie talkie; ham radio.
 - g. SMS messaging.
 - h. Mobile refrigerated morgue trailers.
8. **Plan for Standard Tests and *Point-of-Care Diagnostics*** to supplement or replace centralized laboratory use
- a. Evaluate rapid turnaround, automated, and self-administered COVID-19 tests.
 - b. Evaluate conformal electronic vital signs monitors and wireless links to nursing station monitors or telemedicine monitoring stations.
 - c. Assess telemedicine/telehealth and automated monitoring technologies annually to determine the best combination of onsite clinicians, offsite monitors, and automated alerts to manage patients who may be treated at home, in ambulance, in hospital, at ASOCs, or post-discharge.
 - d. Evaluate:
 - (i.) Bluetooth proximity monitoring technologies on smartphones as early detection and contact tracking tools.
 - (ii.) Smartphone diagnostic attachments: microassays, flow cytometry.
 - (iii.) Miniaturized mass spectrometry.
 - (iv.) Lab on a Chip.
 - (v.) Electrochemical detection.
 - (vi.) Saliva test.
 - (vii.) Antibody test.
 - (viii.) Antigen test.
 - (ix.) Molecular/PCR test.
 - (x.) ELISA, IFA tests.
 - (xi.) CRISPR.
12. **Identify and track *emerging Treatment Modalities*** (COVID-19 examples)
- a. Blood purification, apheresis, and adsorption.
 - b. Convalescent plasma transfusion.
 - c. Antivirals.
 - d. Interferon.
 - e. Monoclonal antibodies.
 - f. Hydroxychloroquine.

13. **Refine Triage and Fatality Management** resources and processes
 - a. Isolation tents with diagnostic and sterilization tools.
 - b. Wireless patient identification and vital signs monitoring, location monitoring.
 - c. Backup plans for wireless infrastructure during disasters that can include cell towers and Hastily Formed Networks.
 - d. Refrigerated morgue trailer.
14. **Test DP** routinely to point of failure, to identify weak links in plans and performance.
 - a. Large-scale stress testing.
 - b. Intersectoral simulations.
15. **Include Failsafe and High-Reliability Communications** to ensure basic communication capabilities if commercial wireless or Internet services fail or are overloaded.
 - a. Ham radio.
 - b. Dedicated medical Wi-Fi spectrum.
16. **Acquire Early Situation Awareness** platform capabilities and integrate into Emergency Operations Centers⁴³
 - a. Evaluate software options; acquire and install the application in Emergency Operations Center and dedicated cellphones.
 - b. Pre-load regional database with critical infrastructure sites, profiles, contacts.
 - c. Establish criteria for distributed use of cellular reporting application by responsible staff and civilians to ensure data reliability.
 - d. Conduct training and simulations.
17. **Negotiate Trigger Criteria and Rapid Execution Timelines and Industry Workplans.** Negotiate specific terms under which Early Disaster conditions will be officially declared which will trigger initial work plans of academic, professional, government, and industry partners, to prepare for ramping up of pre-defined research activities and production of essential equipment and supplies.
18. Evaluate and **Negotiate Manufacturing Alliances for DP/DM** to establish contractual agreements that obligate manufacturers to prioritize emergency production requirements specific to the disaster type.
19. **Promote an organizational culture of Information Sharing and Tactical Flexibility** for DP/DM
 - a. Promote professional and organizational norms of informational openness to ensure that decisions are made based on evidence, not rumor or guesswork.
 - b. Promote professional and organizational norms that optimize the ability to be tactically flexible and adaptable to changing circumstances and information. Build in specific secondary role assignments and responsibilities (role-shifting) in job descriptions for all CEs and disaster-related staff.
20. **Define need for Role Shifting.** During early and mid-disaster conditions, routine clinical roles and responsibilities and reporting relationships may need to change significantly to enable proper execution of disaster protocols. Doctors, nurses, CEs, facility, and administrative staff may be shifted to other tasks that over-ride normal job descriptions.
 - a. Identify most likely disaster scenarios for your location or region, including the possibility of 2 simultaneous disasters.
 - b. Based on projected needs for equipment, staffing, and ASOC, estimate which types of activity will be de-prioritized (such as elective surgery, non-critical preventive maintenance, training), and which activities will become mission-critical.
 - c. Identify secondary roles for each job family to be invoked under disaster conditions and obtain cross-training as needed. Specialists may be re-deployed as hospitalists. Hospitalists may be re-deployed as call-center staff for telemedicine screening; CEs may be re-deployed to set up field hospitals or other ASOCs and work closely with IT staff to integrate ASOC devices into IT networks. Identify the rescheduling and re-prioritization criteria for corrective and preventive maintenance services.

21. **Form *Strategic Health Intelligence Alliances*** between academic, government, provider, and medical industry partners.
 - a. Develop comprehensive models of healthcare *ecosystems* to complement the increasing clinical specializations and technical granularity that often lack proper integration or rational cost controls.
 - b. Coordinate 5-year outlook analyses to identify, assess, and prioritize candidate technologies to provide new efficiencies and DM capabilities.
 - c. Establish routine evaluation sessions to review device and system performance data and discuss any strategic implications for next-generation device/system design.
 - d. Explore academic and professional channels for joint degree and certificate programs with medical and nursing schools, to build stronger career relationships between CEs and other clinicians.
22. **Establish or link to *Data Fusion and Monitoring Centers*** to monitor emergent, multi-hazard conditions that may require rapid changes in disaster response – flooding, landslides, biohazard dispersion, disruption of transport or supply chain plans, power outages, gas leaks, tsunamis, firestorms, etc. Establish formal membership for CE liaisons with fusion and monitoring centers.
 - a. Establish hourly conference calls to review incidents, discuss options, and coordinate decisions.
23. **Establish an *International CE Rapid-Response Network*** for rapid-response information sharing in the early stages of any disaster. Convene daily online consultation meetings.
 - a. Establish a dedicated website and teamwork tools to compile findings, promote problem-solving, and maintain, professional focus under difficult circumstances.
 - b. Compile improvised and emerging good practices for ongoing evaluation and validation, using a standardized ontology for technologies, pharmaceuticals, clinical trials, prototyping, dilemmas, and other relevant topics of concern.
24. **Establish *Inter-professional Innovation Partnership Networks*** to coordinate brainstorming, prototyping, troubleshooting, problem-solving, resource-sharing, team formation, standards promotion, process engineering, best-practice identification, and dissemination.
 - a. Form a **dedicated DP/DM** team to sustain multi-year innovation efforts and report results in all relevant professional journals and associations.
 - b. Use virtual meetings and conferences to **sponsor *Inter-professional Design Forums*** and scenarios to ensure – in advance of disasters – the alignment of cross-functional activities, data exchange, device interoperability, status updates, and prioritization criteria.
25. Work with ***Media Liaisons*** to help elevate social expectations that DP is a social priority and that political leadership will be expected to understand and incorporate preparedness recommendations into public policy and budgets.
 - a. Invite media and other clinical professionals to CE and DM conferences, simulation exercises, and disseminate proceedings of events to media outlets, including social media.

CONCLUSION

Taken together, these aspirational recommendations offer a comprehensive, but not yet exhaustive set of actions that can improve outcomes and alter the historical trajectory of the CE profession and DM capabilities worldwide. Certainly, other topics and recommendations can and must be added to the agenda, but this list does offer a plausible foundation of starting points with sufficient breadth and detail to begin the transformational work with a collective framework of efforts. Working individually and in teams and associations, the daunting magnitude of the challenge can be mastered over time, building on the global presence and growing leadership of CEs.

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AUTHOR BIOGRAPHY

Fred Hosea, PhD, has worked in different areas of health care and psychosocial development for over 30 years, conducting research on professional development in philanthropy, conducting FBI research on convicted sex offenders, and working as a mental health worker in

RESOURCES

NOTE: All commercial mentions are for illustrative purposes only and do not imply a recommendation or endorsement. Links are active as of April 2020.

TOPIC	DETAIL	URL
IFMBE/CED	Clinical Engineering Division of the International Federation of Medical and Biological Engineering	https://ced.ifmbe.org/
United Nations	The United Nations	https://www.un.org/en/
WHO	World Health Organization	https://www.who.int/
OCHA	UN Office for the Coordination of Humanitarian Affairs	https://www.unocha.org/
CADRI	Capacity for Disaster Reduction Initiative: global partnership of FAO, IOM, UNDP, UNICEF and UNFPA (executive partners), GNDR, IFRC, OCHA, UNESCO, UNOPS, WFP, WHO, WMO (technical partners) and GFDRR, OECD, ODI, RedR Australia, UNDRR, UN WOMEN	https://www.cadri.net/
UN Clusters	UNISDR, UNHCR, IFRC, IOM, FAO, WFT, UNDP, UNICEF, Save the Children	https://www.who.int/health-cluster/about/cluster-system/en/
UNDRR (formerly UNISDR)	UN Office for Disaster Risk Reduction	https://www.undrr.org/about-undrr
UNHCR	UN High Commission for Refugees	https://www.unhcr.org/
IFRC	International Federation of Red Cross and Red Crescent Societies	https://www.ifrc.org/en/--/
IOM	International Organization for Migration	https://www.iom.int/
FAO	Food and Agriculture Organization of the UN	http://www.fao.org/home/en/
WFP	UN World Food Program	https://www.wfp.org/
UNDP	UN Development Programme	https://www.undp.org/content/undp/en/home.html
UNICEF	UN International Children's Emergency Fund	https://www.unicef.org/
Save the Children	Save the Children	https://www.savethechildren.org/
IFRC	International Federation of the Red Cross	https://www.ifrc.org/en/--/
PAHO/OPS	Pan American Health Organization/Organizacion Panamericana de Salud	https://www.paho.org/en/health-emergencies/disaster-risk-reduction

TOPIC	DETAIL	URL
Sendai Framework	The Sendai Framework	https://www.undrr.org/publication/sendai-framework-disaster-risk-reduction-2015-2030
GDACS	Global Disaster Alerting Coordination System	https://www.gdacs.org/
OSOCC	On-Site Operations Coordination Center	https://www.gdacs.org/
INSARAG	International Search and Rescue Advisory Group	https://www.insarag.org/
FEMA	Emergency Planning Exercises	https://www.fema.gov/emergency-planning-exercises
Institute of Medicine	Crisis Standards of Care: A Systems Framework for Catastrophic Disaster Response	https://www.ncbi.nlm.nih.gov/pubmed/24830057
IFRC	Training in Disaster Management	https://www.ifrc.org/en/what-we-do/disaster-management/preparing-for-disaster/disaster-preparedness-tools/training-for-response/
Purchasing cooperatives	US General Services Administration State and Local Disaster Purchasing	https://www.gsa.gov/buying-selling/purchasing-programs/gsa-schedules/schedule-buyers/state-and-local-governments/state-and-local-disaster-purchasing
Multicore	Processors meet medical device design challenges	https://www.embedded.com/processors-meet-medical-device-design-challenges/
Multicore	The Impact of the Introduction of Multicore Technologies on the Computing Market and Opportunities for Europe	https://publications.europa.eu/resource/cellar/d2eeb993-5e7c-403d-b0bc-fda57388d211.0001.01/DOC_1
Multicore	Enabling embedded multicore systems with multiple OSes and critical goals	https://www.techdesignforums.com/practice/technique/enabling-embedded-multicore-systems-with-multiple-oses-and-critical-goals/
Alternate Sites of Care	Infection Prevention and Control Considerations for Alternate Care Sites	https://www.cdc.gov/coronavirus/2019-ncov/hcp/alternative-care-sites.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fhealthcare-facilities%2Falternative-care-sites.html
Alternate Sites of Care	Global Base Camp Support Services	https://www.basecampservices.com/
Alternate Sites of Care	Standards and Guidelines for Healthcare Surge During Emergencies	http://www.cidrap.umn.edu/sites/default/files/public/php/258/258_acstools.pdf
Alternate Sites of Care	Medical Surge and the Role of Health Clinics; Public Health Emergency Preparedness, and other articles	https://asprtracie.hhs.gov/technical-resources/48/alternate-care-sites-including-shelter-medical-care/47

TOPIC	DETAIL	URL
Mutual Aid Agreement	Mutual Aid Template draft text for customizing to user needs	https://emilms.fema.gov/IS706/assets/WyomingTemplate.pdf
Rapid Deployment	Blockchain Technology for Emergency Response	https://scholarspace.manoa.hawaii.edu/bitstream/10125/63814/0061.pdf
Rapid Deployment	The Evolution of Hastily Formed Networks for Disaster Response	https://www.researchgate.net/publication/221567937_
USHAHIDI	The Ushahidi Platform allows anyone to gather distributed data via SMS, email or web and visualize it on a map or timeline. Its goal is to create the simplest way of aggregating information from the public for use in crisis response.	https://www.ushahidi.com/
Sahana	Open-source disaster management software	https://sahanafoundation.org/
Google Crisis Response	Google.org supports nonprofits working alongside affected communities from the immediate aftermath of a crisis through long-tail recovery. This includes providing nonprofits with funding and connecting them to the right Google volunteers—whether they're a data scientist, a communications expert, or an engineer.	https://crisisresponse.google/
Google Public Alerts	Provides global map with data on floods, earthquakes, fires and other disaster conditions	https://google.org/publicalerts
Solar-powered Wi-Fi	Solar-powered wireless access points	https://robotechvision.com/solar-access-point/
Ham Radio	Backup radio communication technology in case normal telephone and cell services fail	https://www.youtube.com/watch?v=ILqC8cvH_Aw
Point-of-care testing	Geospatial Science and Point-of-Care Testing: Creating Solutions for Population Access, Emergencies, Outbreaks, and Disasters	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6988819/
Point-of-care testing	PATH diagnostics for low-income settings	https://www.path.org/programs/diagnostics/
Point-of-care testing	Innovations in Point-Of-Care Testing for Enhanced United States Disaster Caches – American Journal of Disaster Medicine	https://www.wmpllc.org/ojs/index.php/ajdm/article/view/2135
Point-of-care testing	Smartphone based medical Diagnostics	https://www.sciencedirect.com/book/9780128170441/smartphone-based-medical-diagnostics
Point-of-care testing	Lab on a chip	https://www.azolifesciences.com/article/Health-Applications-of-Lab-on-a-Chip.aspx
Advanced Diagnostic Lab Technology	Mass spectroscopy	https://pubs.acs.org/doi/10.1021/acsomega.9b03764#
Defense Production Act	Enables the government to commandeer national production capabilities in order to meet defense and national emergency needs.	https://www.fema.gov/defense-production-act-program
Mobile Morgue Trailer	Refrigerated body storage	https://www.mopec.com/mortuary-response-solutions/

TOPIC	DETAIL	URL
Mobile Hospital Solutions	Mobile clinics, hospitals, prefabricated hospitals, hyperbaric oxygen chambers	http://oxycare.com.tr/
Mobile Hospital Solutions	Mobile medical, dental, mammography, blood mobiles, laboratories	https://lifelinemobile.com/
Mobile Hospital Solutions	Modular disaster response solar-powered clinics in a mobile container; morgue unit; laboratory; radiology suite; maternal/infant clinic; primary care exam	http://www.clinicinacan.org/#about
3D Printing	3D printing solutions for healthcare	https://www.dynamism.com/healthcare.shtml
3D Printing	Medical devices produced by 3D printing include orthopedic and cranial implants, surgical instruments, dental restorations such as crowns, and external prosthetics	https://www.fda.gov/medical-devices/products-and-medical-procedures/3d-printing-medical-devices
Supply chain management in disasters	Prepared by US Center for Disease Control and Prevention	https://www.cdc.gov/cpr/readiness/healthcare/SupplyChainDisasterPreparednessManual.htm
Disaster credentialing	Sample guidelines for Credentialing for volunteer physicians and allied health practitioners; need for credentialing of professionals, call-center staff, and volunteers from other states, countries	https://studylib.net/doc/7359857/guidelines-for-credentialing-and-granting-disaster-privil...
Common Operating Picture	Online mapping software that combines pre-loaded data about critical infrastructure elements with real-time, location specific (GPS) data about disaster incidents and conditions that are submitted via cellphone app. Helps track deployment of first responders and visualization of regional response activities in real time.	http://comopview.org/sfc/
Pandemic Planning Checklist	US Dept. of Health and Human Services checklist for pandemic planning	https://www.phe.gov/Preparedness/COVID19/Documents/COVID-19%20Healthcare%20Planning%20Checklist.pdf
Capability Maturity Roadmapping	PAHO Information Systems for Health Maturity Assessment Tool	https://www.paho.org/ish/images/docs/about-IS4H-mm.pdf?ua=1
Capability Maturity Roadmapping	The Use of Maturity/Capability Frameworks for Healthcare Process Assessment and Improvement	https://www.semanticscholar.org/paper/The-Use-of-Maturity%2FCapability-Frameworks-for-and-S%C3%B6ylemez-Tarahan/30b0cdbcdb75b8f6a0105b59627d8d5f2c015284
Research Coordination	The WHO R&D Blueprint is a global strategy and preparedness plan that allows the rapid activation of R&D activities during epidemics.	https://www.who.int/blueprint/en/
Action Research on Disaster Response	A proposal to IFMBE/CED to document best practices, problems and recommendations about management of the COVID-19 pandemic, led by Clinical Engineers.	https://www.dropbox.com/s/9zgq5absdlno9fu/Draft%20proposal%20for%20Disaster%20Mgt%20Research%20program%20Rev3.pdf?dl=0

adolescent psychiatric wards, community-based residen-



tial care for adolescents, school-based counseling, and in a maximum security treatment center for the criminally insane. He has taught graduate-level courses in business and professional ethics, and has taught undergraduate courses in “The Art and Science of Innovation” at Yachay Tech University. He worked for 17 years with Kaiser Permanente, the largest non-profit hospital system in the US, responsible for annual clinical technology plans for Northern California, implementing a national process re-engineering, asset management and IT service management systems, and most recently was Director

of Research and Innovation in Clinical Technology. He has published articles on disaster management and the future of biomedical and clinical engineering professions. He edited Human Resources for Medical Devices in 2017 for the World Health Organization to promote biomedical and clinical engineering as essential professions for modern healthcare systems worldwide. He lives in Cotacachi, Ecuador and is active in a variety of projects to strengthen indigenous Kichwa culture, improve local health services, and promote sustainable models of development. Fred is currently a collaborating member of the Clinical Engineering Division of the International Federation of Medical and Biological Engineering, and has presented on the future of CE at international conferences in Beijing, Shenzhen, Visakhapatnam, Bangkok, Rome, Geneva, Sao Paulo, and Zagreb.

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Redesigning protective gear for health workers during the COVID-19 pandemic: leveling up the “aerosol box”

By R. Moreno¹, E. Pedraza², F. Morales, R. Mijares², R. Boccardo² and M.A. García²

¹Hospital de Clinicas Caracas (HCC) / Clinica Santa Paula (CSP), Caracas-Venezuela.

²Universidad Simon Bolivar (USB), Caracas-Venezuela.

ABSTRACT

Background and Objective: During the last decade, Venezuela has suffered several crises concerning its health, socio-economic, and political institutions. While having a minimum wage of roughly \$2.32 US dollars per month, and a precarious quality and coverage of public services (such as water, public transportation, electricity, and Internet services), the COVID-19 virus struck the nation. This pathology became a pandemic quickly since its transmission occurs mainly through contact with the secretions of infected patients or with contaminated surfaces. Health workers face a higher risk of infection than the rest of the population. For this reason, the objective of this work is to reduce the threat that medical personnel face while working with COVID-19 patients and redesigning the original “spray box,” to avoid further deterioration of the health institutions. The cooperation and support of the Universidad Simon Bolivar (USB) and the Hospital de Clinicas Caracas (HCC), as well as the job of the manufacturer companies, was exceptional for accomplishing this work.

Materials and Methods: To develop the prototype, the following phases were carried out: (a) A sketch was created; (b) A 3-D CD model was created; (c) The prototype was manufactured; (d) The prototype was improved; and (e) The effectiveness and safety tests were carried out.

Results: The research team produced protective gear for the safety and health of medical personnel when attending patients with COVID-19 to help limit the spread of the virus. This instrument was called “Cube de Vie” (CubeDV).

Conclusions: The work demonstrates that disregarding the struggling circumstances Venezuela faces daily, it was possible to solve a problem that threatened public health globally, to fight the serious COVID-19 pandemic. CubeDV was a result in a time of crisis and added another tool in the fight against the virus. This gear is just one example of our longing to win this fight and we hope it will represent significant help for people involved in fighting against this crisis.

Keywords – SARS-CoV-2, COVID-19, protection, personnel, health, CubeDV, box, aerosol, workers, protective gear, pandemic, infection risk.

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INTRODUCTION

The United Nations (UN) and international health agencies have indicated that Venezuela's health crisis is causing an increase in infectious diseases, and the resurgence of others that were once considered eradicated, such as malaria or tuberculosis. The World Health Organization (WHO) considers that the political and socio-economic

situations in Venezuela are responsible for the collapse of the healthcare system since those conditions have caused a severe scarcity of medical supplies, the closure of many clinics and hospitals, and a significant decrease of medical personnel who have emigrated from the country.

Since February 23, 2020, the closure of Wuhan in China alarmed the world population with the presence

of a new coronavirus (SARS-CoV-2), which causes the COVID-19 disease. This virus managed to spread globally in a considerably short time becoming a pandemic. Globally, public health has been facing significant challenges in consequence of this situation,¹ to this date (04-30-2020), the WHO has confirmed 3,090,445 cases and 217,769 deaths worldwide.²

The transmission of COVID-19 occurs mainly through droplets which are responsible for spreading the virus when they come in contact with healthy individuals, whether directly or indirectly through contaminated surfaces. Coughs, sneezes, and some medical airway management procedures can also produce aerosols made up of smaller airborne particles (droplets), which may contain this virus. These airborne particles can travel long distances and be inhaled, increasing the risk of transmission of COVID-19.¹⁻⁵

During the SARS-CoV outbreak in Canada (2002), half of all SARS-CoV cases were nosocomially transmitted to healthcare workers. During these high-demand times, the available human resources to attend to patients may decrease significantly, especially in countries with struggling healthcare institutions as considerable personnel have been subjected to quarantine and isolation measures to try to prevent further transmission of the virus. In healthcare institutions, the virus is widely distributed in the air and on the surfaces of objects (for example floors, garbage cans, handrails for sickbeds, and computer mouse devices). This can include general rooms, intensive care units,⁶ and cardiac laboratory rooms.⁷

In this regard, healthcare workers are threatened with an increased risk of infection, while managing COVID-19 positive patients or by performing procedures that may generate aerosolized saliva particles, such as mechanical ventilation, misting medication, non-invasive ventilation, manual ventilation, tracheal intubation and aspiration, secretion aspiration, bronchoscopy, endoscopy, bronchoalveolar lavage, surgical tracheostomy, or cardiopulmonary resuscitation. Several guidelines and recommendations have been published and introduced to reduce these risks; however, the cases of infections and deaths in health professionals due to COVID-19 are still increasing in institutions with patients with serious complications.⁸

Recently, Robert Canelli et al⁹, published a study in which they tested the effectiveness of a barrier that they

called an "aerosol box", which consisted of a transparent plastic that could cover the head of a patient, and incorporated two circular ports to perform medical airway procedures. To demonstrate the effectiveness of the box, they simulated a "strong cough" with a small latex balloon containing 10 mL of fluorescent dye in the hypopharynx of an anatomical model. The explosion of this balloon produced an expansion of dyed particles in the area. They repeated the experiment with and without the aerosol box and illuminated the scene with ultraviolet light to visualize the spread of the dye. With the use of the aerosol box, the simulated cough was only able to "contaminate" the internal surface of the box, and the covered arms and gloves of the worker performing the laryngoscopy. However, with further examination, they concluded that the simulation method was not valid enough to prove an accurate direction of the liquid, its speed, turbulence, or particle size distribution, as it would happen with real coughs. Taking this background into account, this "aerosol box" was redesigned to increase the protection of healthcare workers performing high-risk procedures on COVID-19 patients.⁹

MATERIAL AND METHODS

The following phases were carried out: (a) A sketch was created; (b) A 3-D CD model was created; (c) The prototype was manufactured; (d) The prototype was improved; and (e) The effectiveness and safety tests were carried out.

RESULTS

A Sketch was Created

Analyzing the original design of the aerosol box, with the experience of medical anesthesiologists, and with the support of the multidisciplinary team, the medical device was redesigned with two specific criteria: safety and effectiveness.

To achieve those criteria, the following improvements were made:

- An inclined front panel that limits the particles to the distal plane of the patient, and that allows a complete visualization of the procedure to be performed on the patient (Figure 1 in annexes).

- More length to cover the patient, since the redesigned box measures approximately 60 cm (23.6 inches) from the patient's head to the upper chest (Figure 1).
- The incorporation of a distal flange that reduces the possibility of particle expansion outside the box (Figure 2).
- The addition of two lateral closing holes to reduce the risk of infection of the auxiliary personnel in the following procedures: intubation, Sellick's maneuvers, BURP, cuff inflation, or endotracheal tube fixation.

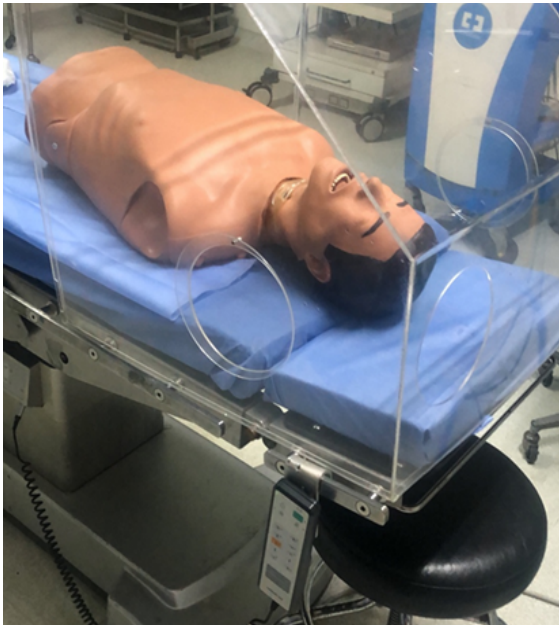


FIGURE 1. Inclined front panel and CubeDV extension.

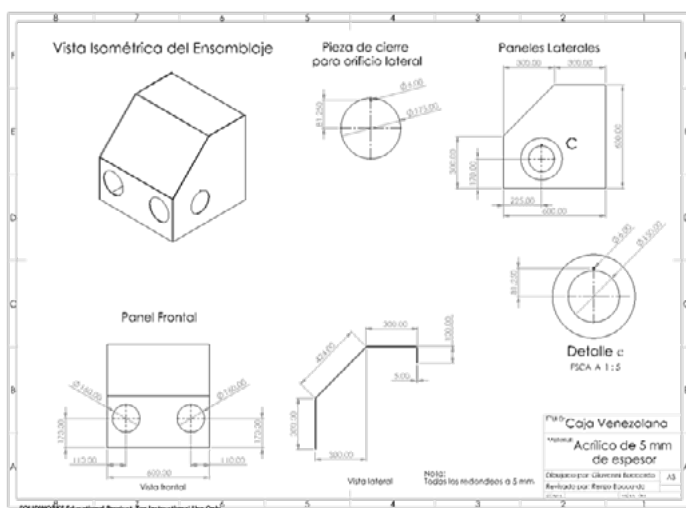


FIGURE 2. CubeDV sketches of the design.

A 3-D model Was Created

The sketch is represented in a three-dimensional shape and was analyzed by specialists. This new gear was named "Cube de Vie" (CubeDV). After some corrections, we moved on to the next step.

The Prototype Was Manufactured

CubeDV is made entirely of 3-mm polymethylmethacrylate (PMMA). In order to keep costs as low as possible, the team aimed for the use of the smallest possible caliber of sheets that could provide stability. To shape the box, the surface on which it is supported was heated. Afterwards, gutters were drilled at the joint points of the three main pieces of the box, this allowed the sheets to fit into a channel that also added support and stability to the entire system. Additionally, at these joint points, chloroform was used as a chemical weld, since it dissolves a small layer of the plastic, to allow the pieces to combine and harden.

The Prototype was Improved

After some stability tests, it was decided to make a thicker prototype, using 5-mm PMMA. The material used on the CubeDV, PMMA, is probably the most transparent plastic material and is also resistant to degradation by UV radiation. PMMA is not heavy due to its low density (1190 kg/m³), which is less than half that of glass making it is easy to transport. It is also 15 times more resistant than ordinary non-tempered glass of the same thickness. As well, PMMA is washable and not affected by detergents and commercial solutions commonly used in hospitals for cleaning and disinfecting potentially infected medical equipment.

The CubeDV is an economical, reusable, easy to transport tool, with the ideal dimensions to carry out procedures with great comfort and protection. To comply with Venezuelan national regulations, quality certification of the medical device was necessary, to demonstrate its effectiveness and safety.

The Effectiveness and Safety Tests were Carried Out

To simulate the dispersion of the virus, a test was performed in the operating room area of the Hospital de Clinicas Caracas (HCC) with a volunteer as a patient, who simulated sneezing with a fluorescent liquid aerosol device (Figure 3), which he squeezed at mouth level at the time of intubation. The test was carried out in two

stages, with and without the CubeDV. In both cases, the expansion of the aerosol particles was recorded with the addition of ultraviolet light through photographs, filming, and testimony of the medical team in the operating room. In the first step of the investigation (without CubeDV) the results showed that the distribution of the fluorescent aerosol particles from the position of the patient (where the spray was triggered), was: 1.2 meters (47.2 inches) away in both right and left sides, 1 meter (39.4 inches) in the air, the superior plane of the patient (Figure 4), 1.1 meters (43.3 inches) in the coronal plane and 1 meter (39.4 inches) in the distal plane. Moreover, there was an evident presence of particles in the facial protection masks of the operator (Figure 5). Subsequently, the second step of the investigation was carried out with the CubeDV, reporting the distribution of the aerosol particles only on the internal part of the box (Figure 6) and on the covered hands and forearms of the operator (Figure 7). The use of CubeDV was also tested in other medical procedures such as: bronchoscopy, upper digestive endoscopy, and induction of inhalation anesthesia in pediatric patients.



FIGURE 3. Inclined front panel and CubeDV extension.



FIGURE 4. Upper extension of the fluorescent ink to the surgical lamp.

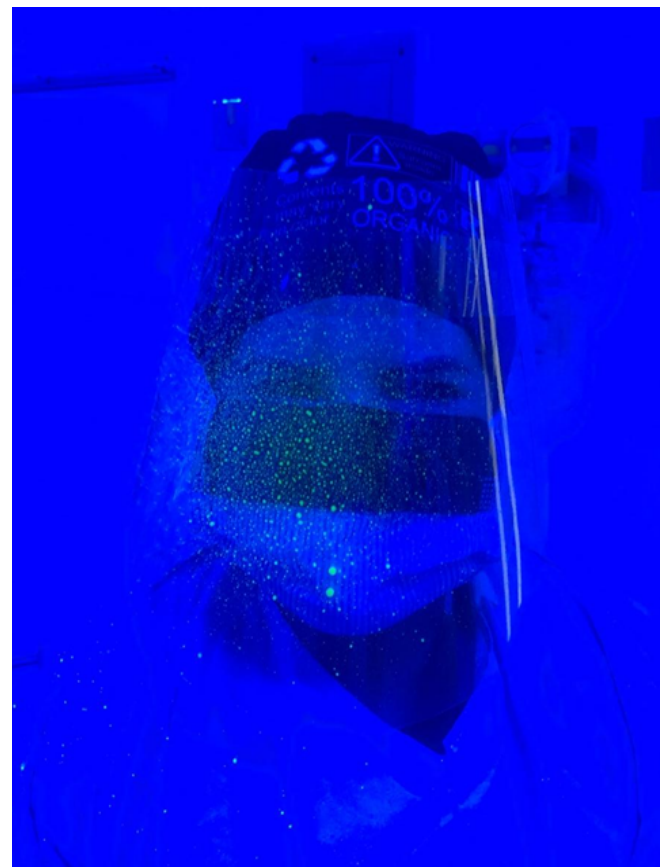


FIGURE 5. Ifluorescent ink spread to operator and assistant facial protection.

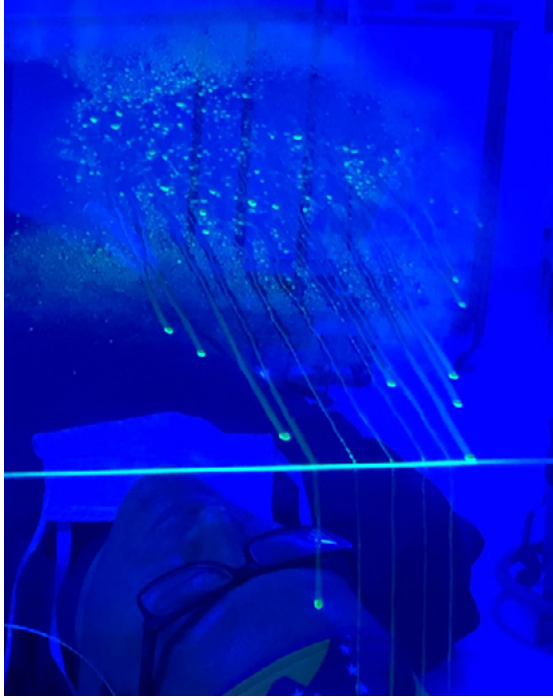


FIGURE 6. Containment of the fluorescent ink inside the CubeDV.



FIGURE 7. Fluorescent ink spread limited to operator's forearms with use of CubeDV.

The Use of the CubeDV

From the tests carried out on the CubeDV to prove its effectiveness, the following results were obtained: (a) The sloped front panel allows an important improvement of the visibility of the patient; (b) The CubeDV's improved length played an important role in protecting health workers during procedures with high risk of infection; (c) The distal flange decreases the possibility of particle expansion outside the box. The tests showed that the CubeDV contained both the droplets and the large diameter drops, thus avoiding dispersion and contamination of the area; (d) The lateral closing holes reduced the risk of exposure of assisting personnel during different procedures.

CONCLUSIONS

This work demonstrates that in spite of the the struggling circumstances Venezuela faces daily, it is possible to solve a problem that threatens global public health and to fight the serious COVID-19 pandemic.

Taking into consideration the length of the box, the improved panel, and its material, it is possible to conclude that the team of HCC and USB obtained an effective result when redesigning the aerosol box. Our analysis and tests suggested that the CubeDV may play an exceptional job protecting the health workers while attending to infected patients.

CubeDV is a result in a time of crisis and another tool in our fight against the COVID-19. This protective gear is just one materialized example of our efforts to win this fight, and we hope, and to provide significant help in this crisis.

ACKNOWLEDGMENTS

To the group of anesthesiologists of the Hospital de Clinicas Caracas, who supported the financing of the prototype and facilitated their working hours to carry the tests out.

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Submissions Style Guide for the Global Clinical Engineering Journal

By J.S. Schultz¹ and Y. David²

¹ Department of Biomedical Engineering, University of Houston, Houston, Texas, USA.

² Biomedical Engineering Consultants, LLC, Houston, Texas, USA.

ABSTRACT

This paper provides guidelines for writing an effective manuscript that complies with the general scientific writing style. In particular, these guidelines are used by the editors and reviewers of the *Global Clinical Engineering Journal* (www.GlobalCE.org) when they evaluate submitted manuscripts. Readers of this paper will gain an understanding of the preferred writing format for each of the manuscript's individual sections. Examples are provided that illustrate their purpose and presentation style for each section. We expect the guidance provided in this paper to improve the quality of writing in general but especially by young clinical engineers so that their published work will attract the interest of the general scientific community.

Keywords – Clinical engineering, Paper, Manuscript, Scientific paper, submission, journal, global ce, global, write, technical writing, abstrcat, conclusion, methodology, results, methods, review, guide, conclusions.

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INTRODUCTION

Publications and distribution of research work and of best practices in the field of clinical engineering remain highly limited. This is particularly the case for young beginning researchers in the healthcare technology management area. Yet, writing a scientific manuscript is arguably the most important step in the development and preservation of knowledge.¹ Nevertheless, few authors have been taught how to effectively communicate and to professionally write manuscripts. In addition, they struggle with selecting the most suitable writing style and the best way to present their data.² Writing styles vary according to the purpose of the paper and the intended audience. For example, the format for a newspaper article is vastly different than for a scientific journal. Even within the scientific journal domain, there are different styles for

research accounts, review papers, editorials, and letters to the editor. Because readers are accustomed to a certain style in the different domains, using the conversation-like style of a letter in a scientific paper can put off the reader. Clinical engineering authors may be challenged to identify and use the optimal visual medium to use to report on their work results and processes. For example, finding the optimal way to share data that lends itself more to a presentation using graphical or tabulated formats.³

METHODS

Aside from some minor variations, the structure and organization of most scientific manuscripts follow a simple format: Introduction, methods, results, discussion, conclusions, and references.⁴ Writing a manuscript,

especially for a peer-reviewed journal like *Global Clinical Engineering Journal* (http://www.globalce.org/downloads/Guidelines%20to%20Authors_final.pdf) demands work that may seem like a burden within the clinical engineering community. But there are good reasons to persevere. Knowledge grows and advances through sharing, supporting, and challenging information. It also contributes to the author's expertise and career advancement. Basically, authors are expected to write accurately, clearly, and succinctly. Here, we provide some guidelines for submitting research articles in this journal.

The basic format for manuscripts submitted for consideration by the reviewers for this journal is outlined below:

1. Title Section
2. Authors and their Affiliations
3. Abstract Section
4. Introduction Section
5. Methods Section
6. Results Section
7. Discussion and Conclusions Section
8. References Section

In this paper, we will provide some guidance and suggestions for successfully getting your message to your audience.

1. Title Section

The choice of words for the title of the paper is quite important. The title is the first piece of information that can catch the attention of reviewers as well as prospective readers. The title should be concise and should reflect the content and impact of your study.

Title Example 1.

"Progressing Toward the Application of Artificial Intelligence for Medical Equipment Replacement in Canadian Hospitals —An Idea from the Biomedical Engineering Department at Northern Health"⁵

This title might be better stated as:

"Artificial Intelligence Methods for Medical Equipment Replacement Decisions"

Title Example 2.

"Benchmarking Comparison Between Beijing and American Hospitals"⁶

This title might be better stated as:

"Comparison of Beijing and American Hospitals in Operations, Finance, and Staffing/Productivity"

Title Example 3.

"Pulse Spectrophotometric Determination of Plasma Bilirubin in Newborns"⁷

Might be better stated as:

"Plasma Bilirubin Determination in Newborns by Plus Spectrophotometry"

Lang¹ gives the following list of items to consider for titles of public health type articles:

- (I) the study setting, location, or both;
- (II) the patients, organism, event, or relationship studied;
- (III) the intervention, treatment, or exposure;
- (IV) the comparator or control group(s);
- (V) the outcomes or end points;
- (VI) the study design, and sometimes;
- (VII) the time period or duration of the study.

For example, suppose an investigation has the following characteristics. Any of them can impact the selection of an appropriate title:

A long title might be:

"Effectiveness of 'Smart Toilets' Using Ultraviolet Germicidal Irradiation vs. Regular Cleaning for Reducing

Study characteristics	Potential impact of title selection
the setting and location:	refugee settlements in Jordan
the patients or subjects:	residents using public toilets
the intervention:	self-disinfecting "smart toilets" using ultraviolet irradiation to kill bacteria
the control condition:	regular manual toilet cleaning
the end point:	Escherichia coli infections
the study design:	randomized trial
the time period	(probably not a factor in this study)

Escherichia coli Infections in Refugee Settlements in Jordan: A Randomized Trial”

A short title instead might be:

“Effectiveness of Self-Disinfecting Toilets for Reducing Escherichia coli Infections”

2. Authors and their Affiliations

The author’s names will be published exactly as they appear in the accepted article. It should not include titles such as Dr., or Professor, or Ph.D. One of the early considerations by readers of the published articles is reviewing the author or authors and their affiliations. Each author usually will have at least one or more affiliations. Affiliation means the association of the author with an organization or a group. Noted affiliations usually suggest a relationship between the article work and the location where the work conducted, support was provided, or the tools used were located. Affiliations will be published as they appear in the accepted manuscript. Include each component of the affiliation information in order of small to large (Department, Division, Section, Institution, City, State, Country). Do not include ZIP or Postal Codes, street addresses, or building/office numbers. There is also no need to list positions within an institution (e.g., Department Chair, Professor, etc.). Consider the designation of the corresponding author for future communications, but do not include physical addresses; only an e-mail address is required. You can list the corresponding author’s initials in parentheses following the email address. The corresponding author should be indicated with the placement of an asterisk after the name, and be written corresponding with the author’s e-mail below the first page of the manuscript. The asterisk shall be omitted if there is only one author.

You are, as an author, expected to review this carefully as names and affiliations may be automatically corrected and modified with various editing apps.

3. Abstract Section

The Abstract section is one of the most important parts of a published article. After the title, it is the section that an individual reads or scans to decide whether to look at the full paper. It is essential that authors be very careful that the abstract is consistent with the rest of the manuscript. Studies have shown that many abstracts do not

reflect the content of the report in the methods, results, or conclusions.^{8,9}

The abstract should contain the following information.¹⁰ Highlights of an abstract include:

- a. An introduction of the topic
- b. A brief mention of the important methods or techniques that were used in the report
- c. The most significant results of the report
- d. A succinct summary of the conclusions

The following is an example of an abstract with too much detail (about 425 words).⁶

“The first clinical engineering (CE) benchmarking between Chinese and American hospitals was performed in 2014. At that time, only data from Zhejiang province were available. A new comparison was completed in 2018 with data collected from 11 hospitals from the capital city of Beijing. These data were compared with those from 270 acute care hospitals in the United States. First, comparisons were made with hospital data such as patient discharges, patient days, equipment quantity and cost, and operating costs. The CE benchmarking comparison was made in 3 categories: (a) operations, (b) finance, and (c) staffing/productivity. Within the operations category, the following metrics were compared: equipment amount/operating beds, annual repairs/equipment amount, and annual scheduled maintenance/equipment amount. Within the finance category, the following metrics were compared: total CE expense/total hospital operating expense, total CE expense/operating beds, and total CE expense/equipment cost. Within the staffing/productivity category, the following metrics were compared: total CE full-time equivalent (FTE)/equipment amount, total CE FTE/operating beds, and total CE FTE/total hospital operating expense. These comparisons showed the following: (1) Although still a bit lower than the United States, Beijing hospitals have more equipment than Zhejiang but a slightly lower amount of repairs and scheduled maintenance per equipment; (2) the total CE expense/total hospital operating expense ratio is around 1% in both Beijing and the United States, but slightly greater than in Zhejiang; however, the total CE expense/operating beds and total CE expense/equipment cost are still lower in Beijing and Zhejiang

than in the United States; and (3) the CE FTE amount is lower in Beijing than in Zhejiang and closer to the United States relative to both equipment amount and total hospital operating expense, but still a bit lower than the United States relative to the number of operating beds. Some of the differences detected are likely caused by the same factors found in the previous study of Zhejiang hospitals, namely, higher length of stay in China than in the United States, lower wages and living costs in China, and different healthcare delivery methods in these countries. The differences found between Beijing and Zhejiang cannot be explained solely by inflation (~2%/year) or even higher cost of living in the capital but likely because of more equipment-intensive medical practice. Overall, these results confirm the outstanding progress and level of excellence of CE in China. The original abstract includes information concerning Zhejiang province, but the main focus of the paper is the comparison between Beijing and the United States. So, references to Zhejiang were removed from the abstract.”

The abstract should follow the journal author’s guidelines. The guidelines for the Global CE Journal can be found on the journal website (http://www.globalce.org/downloads/Guidelines%20to%20Authors_final.pdf). Using the above abstract as an example, the revised abstract shown below serves as a clear summary containing objectives, results, and a brief conclusion. It is now shorter and contains about 200 words. In this suggested revision, we deleted comments related to Zhejiang since the main point of the study was a comparison of Clinical Engineering practice between Beijing and the United States.

We report a new clinical engineering (CE) benchmarking comparison between Beijing (11 hospitals) and the United States (270 acute care hospitals) that was completed in 2018. First, comparisons were made with hospital data such as patient discharges, patient days, equipment quantity and cost, and operating costs. The CE benchmarking comparison was made in 3 categories: (a) operations, (b) finance, and (c) staffing/productivity. These comparisons showed the following: (1) Beijing hospitals have a bit lower equipment than the United States; (2) the total CE expense/total hospital operating expense ratio is around 1% in both Beijing and the United States; however, the total

CE expense/operating beds and total CE expense/equipment cost are still lower in Beijing than in the United States; and (3) the CE Full Time Equivalents amount relative to both equipment amount and total hospital operating expense is similar in Beijing and the United States. Some of the differences detected are likely caused higher length of stay in China than in the United States, lower wages and living costs in China, and different healthcare delivery methods in these countries. Overall, these results confirm the outstanding progress and level of excellence of CE in China.

The abstract should be composed at the very end of your writing since it includes a summary of the elements of your work such as the research problem and objectives, the methods, key results, and the main conclusion.

4. Introduction Section

The primary purpose of the Introduction section of a research paper or report is to provide background and place the specific context of the work from the perspective of a more general issue or problem. A common mistake in writing an introduction is to provide too much detail in reference or methods.^{1,11}

Elements of the Introduction section are:

- Background
- importance of the problem
- what the objectives of the study
- what is the existing state of knowledge of this topic – mini-review that traces the development of the problem and summarizes its current state
- how was the study conducted and why
- a preliminary indication of the outcome or conclusion of the report

Here we provide an Introduction section from two articles that discuss issues related to alarms in intensive care units. The presentation in Example A is very thorough, but perhaps over extensive in the literature review citations. The presentation in Example B is more descriptive, does not provide literature citations, and is perhaps more suitable for a magazine rather than a scientific journal.

Example A¹²

“With the development of medical technology, clinical alarms from diverse medical devices, which are explosively increasing, are becoming a new issue in intensive care units (ICUs). Medical device (clinical) alarms, which were designed to draw medical staff’s attention when a patient’s conditions goes beyond the proper range, are causing a new alarm hazard problem.¹ According to previous studies, there were no more than 6 types of alarms from one critically ill patient in 1983; however, there were at least 40 types of clinical alarms in 2011.¹

Excessive clinical alarms may cause an alarm hazard, which includes inappropriate application of alarms, alarm fatigue, and the application of a uniform alarm range to every patient.² While defects of devices threatened patient safety in the past, alarms indiscriminately generated by the explosive increase in the number of medical devices now threaten their safety. Reports on safety accidents related to the diversity of medical device alarms have raised awareness of the clinical alarm hazard. In 2002, 65% of 23 sentinel events were related to dysfunction and disuse of alarm devices and inappropriate alarm setting.³ Five-hundred sixty-six deaths related to the monitoring of device alarms⁴, severe burns due to neglect of alarms from hyperthermic machines⁵ and hypoxic brain damage⁶ were also reported. In 2012, alarm hazard was ranked first among ten types of medical technology hazards in the United States.²

Ambient noises, including clinical alarms in ICUs were estimated to be more than 80 dB, which is close to the noise level generated by a pneumatic drill in an operating room.⁷ In addition to the noise problem caused by alarms, ICU nurses may have difficulty in distinguishing alarms for urgent intervention from others since different device manufacturers use different types of alarms. For example, they need to differentiate alarms for replacing the syringe of an infusion pump from those for a life-threatening emergency when they hear both types of alarms.⁸ ICU nurses were found to have difficulty in differentiating more than 6 different alarms^{1,9} and could differentiate no more than 9–14 out of 23 alarms on average.¹⁰

In one study, medical staff members were repeatedly exposed to an average of 771 patient monitor alarms

per patient per day.¹¹ Medical staff overexposed to alarms may experience a decrease in concentration, become careless, and commit mistakes. Moreover, overexposure may make medical staff less sensitive to alarms and may cause them to cope improperly with significant alarms that can affect patients’ safety.¹² The literature suggests that excessive medical device alarms may cause nurses to feel alarm fatigue.^{7,13,14}

Alarm fatigue occurs when medical staff are overwhelmed by excessive clinical alarms²; in particular, false (positive) alarms, inappropriate alarms-setting ranges, and the overuse of patient monitors act as principal factors that cause alarm fatigue.^{7,14} Of these, the most problematic factor is false alarms: frequent false alarms may produce the ‘cry wolf’ effect and may cause nurses to regard significant alarms as false and thus fail to respond properly. It may also make an alarm system less reliable and may cause nurses not to use alarm devices.^{14,15} It is therefore essential to effectively manage medical device alarms and develop good interventions that can reduce false alarms. Since 2010, standardized prevention has been suggested on the basis of various studies on how to conceptualize and reduce alarm fatigue^{16,17,18,19} and basic research on nurses’ recognition of clinical alarms and on the obstacles to their alarm management^{16,17} in the United States. On the contrary, in Korea, little research has been conducted on medical device alarms. Medical device alarm hazard and alarm fatigue are novel concepts, and the Korean Society for Patient Safety established in 2013 has just posted a foreign article introducing the concept of clinical alarms.²⁰

This study aimed to investigate the current status of medical device alarms in ICUs, where medical devices equipped with an alarm function are most frequently used, to determine nurses’ recognition of and fatigue in relation to alarms, and to identify obstacles to alarm management. This information will provide basic data that could help create a safe hospital environment.”

Example B¹³

“More and more medical devices are being used throughout healthcare institutions with an increasing variety of alarm-related features. Alarms are used to warn of disconnected monitoring electrodes and ventilator

breathing circuits. They can alert clinical staff when important measurements like oxygen saturation exceed safe limits or when a dangerous situation occurs like air entering the IV line for an infusion pump. Most of the time, clinical alarms work well and serve, literally, as a life-saving technology. However, for many devices, alarms can be confusing or can create confusion, for example from false positive events. For some devices, alarm settings can be adjusted outside of safe limits or the alarms can be completely defeated. As a result of these and other problems, deadly and life-threatening alarm-related incidents continue to occur. While the development of broad systematic improvements for how clinical alarms are designed and used are necessary to achieve the ultimate goal of reliable clinical alarm performance, the results are years away. This article focuses on ways that clinical engineers can have a much more direct and immediate impact on minimizing clinical alarm risk in their institutions. These include establishing safety criteria for alarms during the device selection process, performing alarm-related safety audits to identify specific areas of risk with existing alarms and systems, helping to establish alarm setting and response protocols, and supporting the training of clinical staff on the proper operation and use of medical devices with clinical alarms."

5. Methods Section¹¹

The Methods section is where the procedures used in the study are described and a description of how data were collected is given. In providing information on the methods used, one doesn't need to give a detailed recipe of every detail but sufficient information for those who are "skilled in the art"¹⁴ to understand and evaluate the procedures. Where possible, a method used that was described elsewhere in the literature should also be indicated and cited by reference.

The format of a Methods section depends somewhat on the type of investigation. For an article that is primarily of a survey nature, such as the performance evaluation of a system such as "alarms in intensive care" as mentioned above, the methods section would include how survey data were obtained. For articles that are experimental in nature the methods section usually describes materials and procedures.

The example below¹⁵ illustrates a thorough description of a Methods section for an experimental research paper. It provides adequate information on describing the source and characterization of materials used in the study (MATERIALS). Then a clear description of how the data were collected and analyzed (ASSESSMENT OF AEROSOL OUTPUT and IMAGE ANALYSIS OF AEROSOL PLUMES). Then a thorough explanation of the evaluation of the reliability of the data (STATISTICAL ANALYSIS OF RESULTS).

Materials

This study was performed using the following pharmaceutical preparations:

(1) the CFC-free MDI Airomir." This preparation contains albuterol sulfate as the active ingredient and nominally releases 200 \times 100-pg doses of albuterol. It also contains the propellant HFA-134a and oleic acid and ethanol as inactive ingredients.

(2) The multidose DPI Terbasmin Turbuhaler,b which nominally contains 200 \times 500-pg doses of terbutaline sulfate.

(3) The CFC-propelled MDI Terbasmin Inhalacion,c which nominally contains 400 \times 250-pg doses of terbutaline; it also contains a mixture of three CFC propellants (1:2:1 of CFC 11:12:114 mixture) and other inactive ingredients. The two pharmaceutical preparations of terbutaline were obtained from commercial sources.

Assessment of aerosol output

Experiments were conducted in industrial thermostated (2°C) chambers" at room (22 °C), cool (0 °C), or cold (-10 °C) temperatures. Three groups of fully assembled HFA-134a inhaler devices (canister, mouthpiece) with different initial contents (full, one-half full, and one-fifth full, titrated by 0, 100, or 160 actuations, respectively) were stored in the thermostated chambers hours before the standardized set of nebulizations. The assembled containers were then shaken for approximately 30 seconds, and the valve was actuated at intervals of 10 seconds in an inverted position. DPI devices were inserted via a mouthpiece adapter into an inhalation simulation machine formed by a glass bulb and tube connected to a vacuum pump. The inhalation flow rate necessary to activate the DPI

was provided by turning the pump on for five seconds and adjusting the suction pressure to obtain a flow rate of 60 L/mhv1, which is appropriate for the Turbuhaler system. Forty actuations were performed with each pharmaceutical preparation to reduce potential minor variabilities between individual measures. To avoid the thermal influence of the operators' hands during actuation, the operators wore thick latex gloves stocked with the inhalation devices inside the chambers. The canisters were weighed at 25 °C using a Mettler precision balance (readability 10g, accuracy defined as 100 [displayed weight - true weight]/true weight ranged from 3% to 5%). Each container was weighed before and after its particular set of actuations, and the net amount of aerosol emitted was determined by subtracting final weights from the initial weights of the canisters; the results were expressed in grams or milligrams. Results are also expressed as a percentage of the amount of aerosol discharged in cool or cold conditions with respect to that expelled under control conditions (22 °C).

Image analysis of the aerosol plume

The propelled aerosols from HFA-134a and CFC-containing MDIs were visualized by a sequence of highspeed dark-field photographs taken of three actuations at 22 °C and -10 °C. Representative pictures of a fully formed aerosol plume were digitized by scanning analysis; the captured image was then improved, transferred to the appropriate format,¹ and processed using image analysis software.¹ Isodensity lines were defined with this software in the digitized image of the aerosol cloud (i.e., lines connecting points of equal gray intensities [from 0 to 220 arbitrary units]). The aerosol plume formed after activation of a DPI in the inhalation simulation machine was observed only by visual inspection, since the quality of photographs was poor due to light reflecting brightly from the glass of the apparatus.

Statistical analysis of results

Data are expressed as mean SEM. The data on experimental groups passed the Kolmogorov-Smirnov normality test; hence, statistical analysis was performed using ANOVA, followed by the Bonferroni multiple

comparison test. k Linear regression analysis was conducted using the same software. Significance was defined as p less than 0.05.

6. Results Section

Typically, the Results section provides information that was gathered during the study. Of course, not all the data would be selected for publication, but the studies that are pertinent to the thrust of the project. Some comments, explanation, or discussion should be provided with each element of the results.

The text in the Results section should act as a tour guide, leading your reader from item to item (every figure or graph must be cited in the text and in numerical order), and drawing attention to the highlights, especially to those that will be important in making conclusions.

There are several keys to writing a good results section. These include:

(1) Presentation of the results in an orderly sequence, following the sequence of the Methods section when feasible.

(2) If tables and figures will be used to summarize your data, then construct these first and use them as a basis for writing the Results sections. Make sure the main points of explanation and interpretation are given prominence in the first sentence of each paragraph.

(4) Avoid redundancy in the text and only cite representative data from the tables and figures. Do not repeat

TABLE 1. An example of Medical Equipment Management Plan (MEMP) inventory inclusion criteria using patient risks and mission criticality for planning preventive maintenance (PM) and safety and performance inspection (SPI) activities.

		Patient Risks (Listed in the EP)*		
		High	Medium	Low
Mission criticality	Critical	Include	Include	Include
	Important	Include	Optional†	Exclude
	Necessary	Include	Exclude	Exclude

*EP = Element of Performance, from the Joint Commission on Accreditation of Healthcare Organizations' published accreditation standards.

†Indicates that some of the equipment may benefit from scheduled services, depending on the failure modes and effects analyses or other studies conducted by the organization.

but summarize the information in tables and figures.

(5) Avoid vague references to tables and figures in the text.

Example:

BAD: Results of the survey of nurses are shown in Table 1.

GOOD: A high percent of alarm notifications were ignored by nurses in the ICU setting, see Table 1.¹⁵

(6) Avoid repeating a description of the methods in the Results section.

(7) Avoid discussion of conclusions in the Results section. In other words, present the facts but save interpretation of the significance of the results for the Discussion/Conclusion section.

Whenever appropriate, the results of the study should be summarized in tables and/or graphs. Readers may look at tables or graphs even before reading the text and would like to understand these without searching back and forth to the body of the text. The design of tables and graphs are quite critical to helping the reader fully understand the quality of the data and how the data supports the conclusion of the report.¹²

Some good and bad examples and suggestions for best practices for tables and graphs are given in a pdf from MIT.¹⁶ A recent article from the *British Journal of Dermatology*⁸ illustrates excellent examples of tables and graphs.

Above is an example of a well-organized Table 1. The title is a concise sentence. The column headings and sub-headings are clear enough to make the data understandable without having to look at the text. The footnote gives enough detail to make the data understandable without going into experimental detail.¹⁸

Graphs are used to present data in an organized way, not to dress it up. One should not use both graphs and tables for the same data. Line graphs are best for data that show pronounced trends, while bar and dot charts are better to show items with different values. Consider the impact from the use of colors versus black and white especially if the publication cannot accommodate the use of color. In most of the on-line publications like the *Global Clinical Engineering Journal* this is not a problem. One should provide textual context for graphs, indicating how the graph advances, summarizes your discussion, and supports and clarifies your conclusions. Graphs should be as self-explanatory as possible. This allows the reader to scan through the article and get the key messages without needing to read the text in detail.

Fig.3 (next column) is an example of a poor graph.¹⁷ The symbols AE, AV, EE, and EP are not defined in the

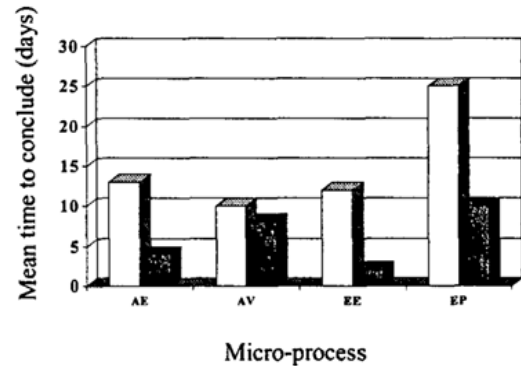


Fig. 3. Elapsed time (including non-working days) to solve micro-processes. Micro-processes are defined in Table I. Clear and shaded bars refer to 1997 and 1999 data, respectively.

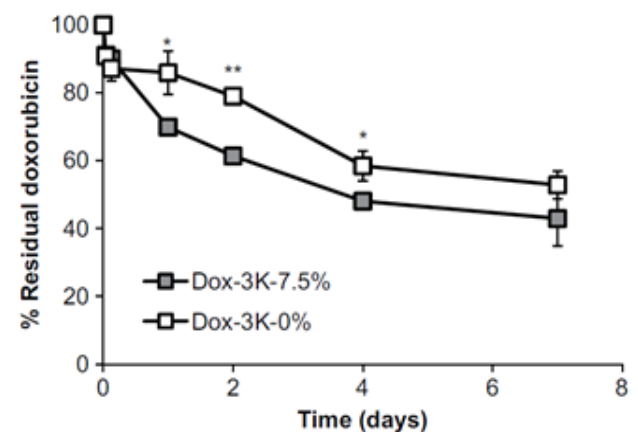


Fig. 5. In-vitro release kinetics of doxorubicin from PLGA microparticles. Doxorubicin remaining in the particles at each time point was plotted vs. incubation time. The data represent the average results of 3 independent batches. Error bars are standard deviations and not seen in some data points as they are smaller than the symbols. * ($p < 0.05$) and ** ($p < 0.01$) indicate statistical difference between Dox-3K-7.5% and Dox-3K-0% at each time point.

legend of the graph, nor is the meaning of the term Micro-process explained.

Fig.5 (next column) is an example of a good graph. The lettering is large enough to withstand photographic

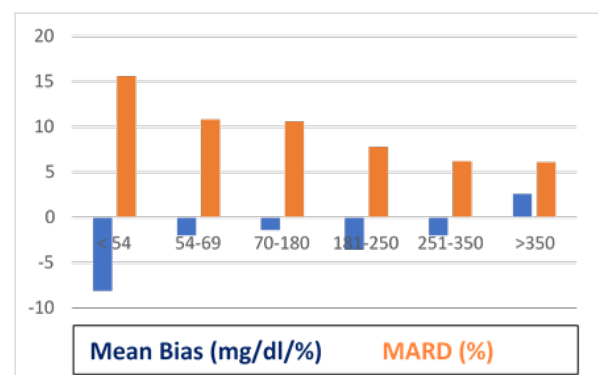
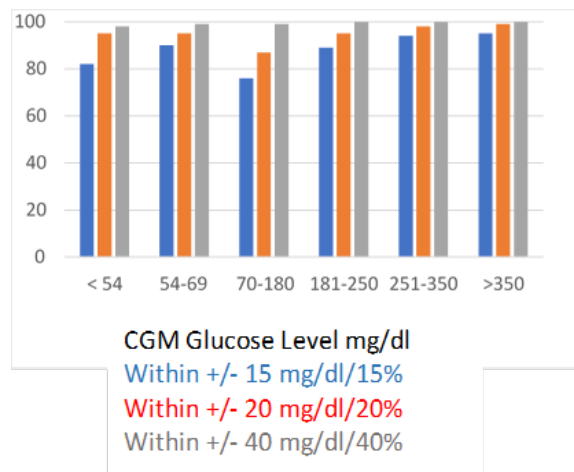


Table 1: Performance characteristics of FreeStyle Libre system with new glucose algorithm

CGM Glucose Level ¹ (mg/dL)	CGM-YSI Pairs	Within ±15 mg/dL /15%	Within ±20 mg/dL /20%	Within ±40 mg/dL /40%	Mean bias*, mg/dL /%	MARD (%)
<54	60	81.7	95.0	98.3	-8.1	15.6
54-69	3311	90.5	95.1	99.3	-2.0	10.8
70-180	7944	76.4	86.5	99.1	-1.4	10.6
181-250	3038	89.1	95.0	99.9	-3.6	7.8
251-350	3849	93.7	97.7	100.0	-2.0	6.2
>350	652	94.5	98.6	99.8	2.6	6.1
All	18856	86.0	92.8	99.6	-1.7	9.2

¹System dynamic range is 40-500 mg/dL

* Difference in mg/dL for blood glucose values < 70 mg/dL and relative difference in % for blood glucose values ≥ 70 mg/dL



reduction. The caption is concise and provides information pertinent to the discussion, tolerance of error bars are provided.²⁰

Often data can be presented in either a graph or a table. The choice depends on which better informs the reader. In the example below, data are provided for the comparison of an implanted glucose monitor (FreeStyle Libre) with blood-sample technique (YSI). Trends across different levels of blood glucose are much clearer in the bar graphs than in the published table below.¹⁹

7. Discussion and Conclusion Section

The main purpose of this section is draw conclusions from the data gathered in the study and perhaps to compare the results to previous similar studies. Here you provide an interpretation of your results and answers the study question. You can suggest further work to be done and review the literature again as it now can shed more insight on the subject of the paper.²¹ Here are some guidelines for structuring this section.

Title

Concise & descriptive

All words capitalized except articles and prepositions

Abstract

Describes problem & states objectives/hypotheses

Describes technique(s) used & avoids experimental detail

Reports most significant results

Concluding statement

Introduction

Demonstrates good clinical engineering insight, understanding, & accuracy

Reviews & interrelates relevant scientific literature

Cites literature correctly using name-year or citation-sequence convention

Flow of ideas – starts broadly, then leads to a specific topic

Ends with clearly & concisely stated 1–3 hypotheses/objectives

Methods

Written in the third person and past tense

Concise but complete

Accurately describes what was done, without giving instruction

Statistics and quantitative methods are explained

Literature cited (if appropriate)

Results

Results clearly and accurately explained

Statistical output appropriately noted

All relevant tables and figures cited appropriately

Discussion and conclusions

Clearly addresses each hypothesis/objective – supported or rejected?

Demonstrates good insight and mastery of relevant ideas

Compares results to previous studies (cite relevant literature)

Explains unexpected results (e.g., provides alternative hypotheses)

Describes or suggests future experiments

List your conclusions and possible impact from the results

Acknowledgments

Be professional (avoid being "gushy" or overly flippant)

Literature Cited

Precisely and consistently follows style of Global CE Journal
All citations noted in the manuscript are included in the Literature Cited list
Each reference listed has been cited at least once in the manuscript

Tables

Tables appear after Literature Cited section
Tables are numbered consecutively, starting with Table 1
Titles are sufficiently clear and concise
Double-spacing used throughout the table
Columns of numbers aligned by decimal point using decimal tabs

Figures

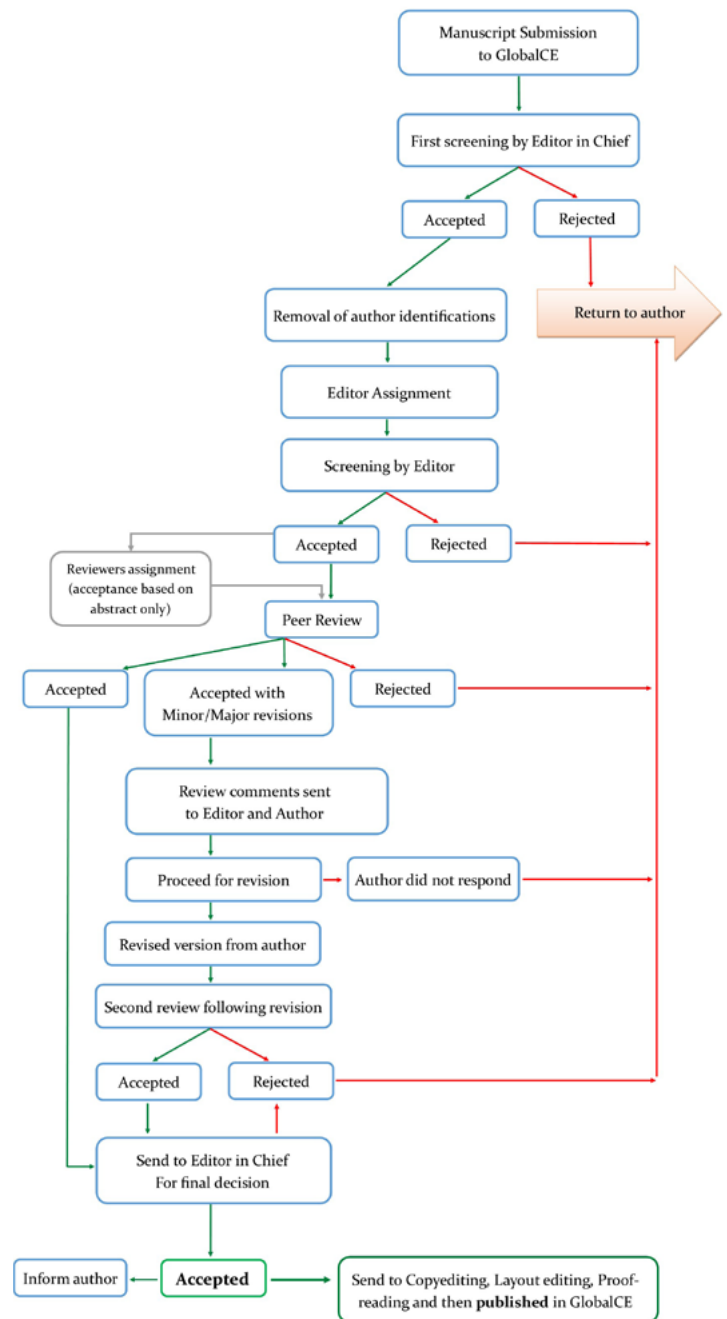
Horizontal axis = independent variable, vertical axis = dependent variable
Axes clearly labeled

1. Summarize key findings and interpret the results
2. Compare with other studies
3. Generalize results if appropriate
4. Speculate on implications of the study
5. Point out any limitations of the study
6. Suggest possible follow-up studies
7. Succinctly list your conclusions

The table below summarizes the elements and suggestions for submitting a paper to the *Global Clinical Engineering Journal*:

SUBMISSION TO GLOBAL CLINICAL ENGINEERING JOURNAL

Manuscripts submitted to the Global Clinical Engineering Journal are subjected to the initial review by the Editor-in-Chief for the purpose of identifying overlap between the manuscript and the mission of the Journal and for identifying the most appropriate editors to be assigned for the double-blind review process. The complete publication process is posted on the Journal website (http://www.globalce.org/downloads/Flowchart_GlobalCE.pdf) and is presented below.



This process provides for a quality review that is fair and timely. It helps the authors receive constructive feedback on how to improve their submission. It also facilitates the posting of individual accepted manuscripts immediately or even prior to the scheduled publishing of the next issue of the Journal. Now, we encourage you to begin working on your manuscript and gain recognition for your work.

CONFLICTS OF INTEREST STATEMENT

The authors declare that there is no conflict of interest.

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Flow Analyzer for Blood Pump

By R.L. Rezer¹, M.A. Marciano², A.A. Santos,¹ and W.K. Souza¹

¹ Moinhos de Vento Hospital/Clinical Engineering, Porto Alegre, Brasil.

² Moinhos de Vento Hospital/Clinical and Hospital Engineering, Porto Alegre, Brasil.

ABSTRACT

Medical equipment that supports life, relieves diseases, and overcomes disabilities can also cause damage and death due to operational failures, user failures, and misuse. Hemodialysis machines include roller pumps that control the flow of blood, and these pumps have to be calibrated accurately to ensure they are working properly.

This article describes the development of a low-cost, open source prototype that automates the flow analysis (measurement and recording) of the blood pumps in hemodialysis machines. Being able to accurately inspect the machine's operation improves the quality and safety of its use. Through this technology (this process automation), it is believed equipment downtime and total tests cost will be reduced.

This device has a system that collects data in real time, generated by the blood pump dialysis. Mathematical calculations are used to present flow information, including the standard deviation of the measurement, which is reported at the end of the test in an objective and simple way. Through a software and human machine interface (HMI), the test can be monitored and generate a report that contains the name and model of the equipment, the quantitative results of the flows, and the standard deviations of the measurements. The device can be used by clinical engineering teams in preventive maintenance and after corrective maintenance, as a control practice, making the calibration process easier and more cost-effective.

Keywords – Hemodialysis, Quality Control, Biomedical Analyzer, Arduino.

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INTRODUCTION

Renal insufficiency occurs when the kidneys are unable to function properly.¹ Hemodialysis is performed from a venous access allowing high blood flow. The blood is transported through an extracorporeal circulation system to a capillary filter, where it is purified and then returned to the body. It is usually performed three times a week, for an interval of three to four hours.² Hemodialysis is susceptible to adverse events (AE) since it involves several risk factors, such as complications of invasive procedures, the use of complex equipment, critical patients, high patient turnover, and the administration of potentially dangerous drugs.³

The increasing use of hemodialysis worldwide is worrying specialists, researchers, managers, and health professionals. Data from the World Health Organization indicate that, annually, tens of millions of people worldwide suffer disabling injuries or death due to AEs following hemodialysis.⁴

Medical equipment that supports life, relieves diseases, and overcomes disabilities can also cause damage and death due to operational failures, user failures, and misuse.⁵ Hemodialysis machines include roller pumps that control the flow of blood. The pumps should contain various alarms and other devices to ensure patient safety.

Specific calibration is an important step for the correct operation of the equipment because the volume infused is the main parameter of the pump. It is essential that the methodology used in calibration be adequate for the tests to be validated as failure to do so can cause complications, including phlebitis, venous spasm, and pulmonary edema.⁶ The tests involve two parts – a qualitative evaluation (consisting of visual inspection of the structural conditions of equipment, parts, modules, and accessories) and quantitative tests (consisting of measuring or simulation of the parameters and/or the biomedical magnitude of the equipment).⁷ Some trials are still done manually making the process time-consuming and decreasing the availability of dialysis equipment in a busy center. The calibration of the rollers involves adjusting the distance between the roller and the rigid bed (occlusion).⁸ At present, to perform calibration of the blood pump assembly, a precision scale, a graduated glass, and a digital timer are used, all of them traceable. Among the restrictions of this method are the uncertainties generated by the technical measurement process itself and the delay to carry out the measurements.⁹

The main objective of this work is to develop a flow measurement device for blood pumps of hemodialysis machines. Whereas flows generated by hemodialysis machines are greater than 1200 mL/h (maximum flow measured by the analyzers present in the market). The specific objectives to be achieved are (a) improving the process of inspecting the operation of the device, (b) reducing equipment downtime, (c) reducing costs related to the process of inspecting and testing quantitatively the equipment, and (d) improving the quality and safety of equipment use. For this development of the process automation, open source devices will be used, reducing the cost of the process.

METHODS

Method Flow

Figure 1 shows the flow of the steps followed for the development of this work. With the data specified, calculated, modeled, and simulated, the prototype was designed, developed, and tested.

Initially a group of studies was organized to evaluate possible solutions for a low-cost prototype for the blood pump flow analyzer. Several follow-ups were conducted at the hemodialysis center, along with the nursing group to measure the real complications of the conventional hemodialysis therapy. As shown by the flowchart if Figure 1, the other steps are described below.

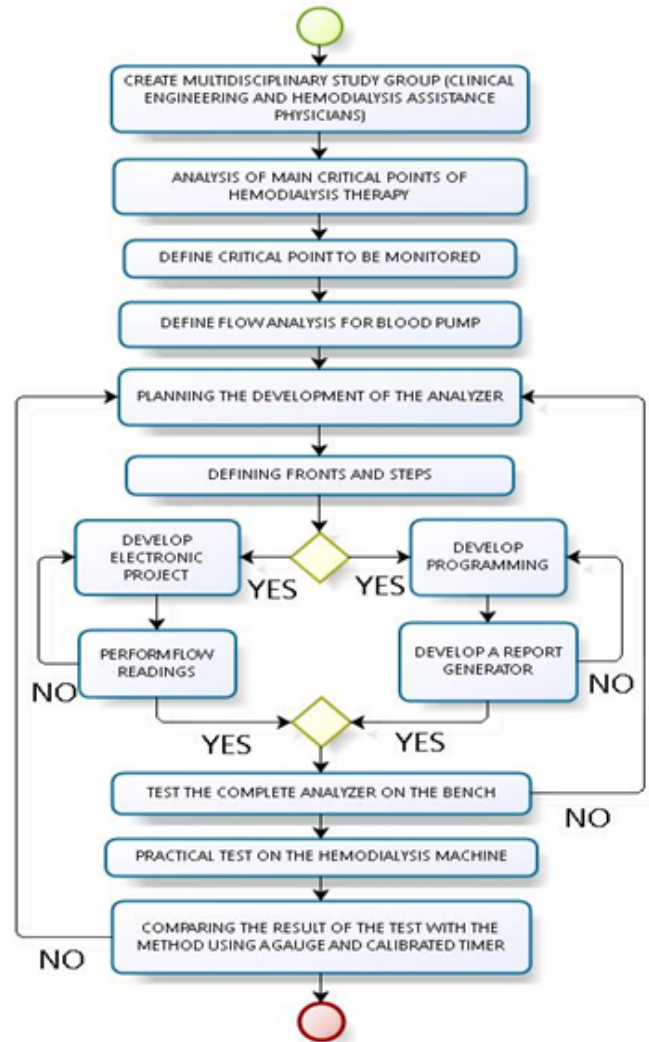


FIGURE 1. Flow of the working method.

In order to perform this stage, three calculations were used: one to generate the flow, another to generate the volume, and a third to determine the standard deviation, within the limits of the processor and the requirements to analyze the blood pump flow, according to the following equations:

Conversions

Through the equations, Tables 1, 2, and 3 were developed with parameters for program development and report generator. The largest number of variables of the circular constant or Ludolph number (called “ π ”, being $\pi = 3.14159265$) was used to obtain the most accurate number possible.

$$v = h\pi r^2 \quad (1)$$

$$Q = \frac{\text{volume}}{\text{time}} \quad (2)$$

$$S = \sqrt{\frac{\sum_{i=1}^n (x_i - \bar{x})^2}{n-1}} \quad (3)$$

TABLE 1. Conversion – Relation between Height (cm) and Volume (mL) in the Recipient

(1) $v=h\pi r^2$		
Direct Reading Container (mL)	Direct Reading Height (cm)	Calculated Volume (mL)
0	0	0
50	0.63665	50.00237407
100	1.2733	100.0047481
150	1.90995	150.0071222
200	2.5466	200.0094963
250	3.18325	250.0118704
300	3.8199	300.0142444

Considering $r = 5.0000$

TABLE 2. Conversion – Relation between Volume (mL) and the Time (minute)

(2) $Q = \text{volume/time}$		
Volume (mL)	Time (minutes)	Flow (mL/min)
50	1	50
300	6	50
600	12	50

This table represents the analysis of a flow of 50 mL/minute.

TABLE 3. Conversion – Relation between Flow Readings and the Standard Deviation of the Readings Performed in the Range of 50 mL/Minute

(3) $S = \sqrt{\frac{\sum_{i=1}^n (x_i - \bar{x})^2}{n-1}}$		
Reading numbers	Flow (mL/min)	Standard deviation (mL/min)
1	51	1
2	50	
3	49	
4	51	
5	49	

Programming

At this stage the Arduino platform was programmed (Figure 2), with a C language principle. Based on Tables 1 and 2, the volume and flow were described in the program. After this stage, the ultrasound sensor signal was programmed, making it a height meter to detect the volume of water and the valve, as a mechanism for releasing the water from the container in order to keep the blood pump always on, without overflowing the graduated container. The maximum level of volume was limited to 800 mL, and the minimum was 50 mL for the beginning of the readings.

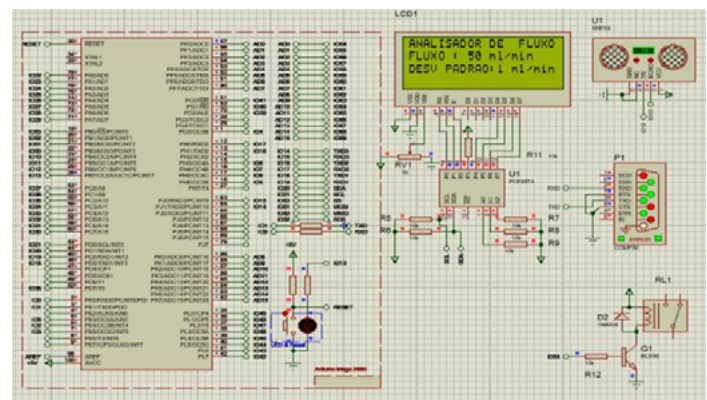


FIGURE 2. Electronic diagram of the circuit with the Arduino Platform.

Finally, the serial port was programmed where the name of the technician, the type of equipment, and the date and time of the service execution were introduced. On the display it shows only the flow values and the

standard deviation. Figure 3 shows the flow and standard deviation in the display, data transmitted by the serial port and the final report.

```
ANALISADOR DE FLUXO
DATA:13/05/2017
HORA: 14:00
TECNICO : Rodrigo
Equipamento : Maquina de Hemodialise

FLUXO (ml/min):50.00
VOLME (ml):50
DESVIO PADRAO (ml/min):0.00

FLUXO (ml/min):50.00
VOLME (ml):100
DESVIO PADRAO (ml/min):0.00

FLUXO (ml/min):50.00
VOLME (ml):150
DESVIO PADRAO (ml/min):0.00

FLUXO (ml/min):50.00
VOLME (ml):200
DESVIO PADRAO (ml/min):0.00
-
```

FIGURE 3. Data shown on the serial output.

MATERIALS

Peripherals

Peripherals installation – The system used a selector switch. The power to the board and the peripherals was through a computer source. For the control of the electromechanical device (valve), which is responsible for the release of water from the container, a normally open 5V relay was used. The ultrasound sensor (HC-SR04) was applied to read the height of the water in the container, connected directly to the Arduino's inlet. The display uses I2C communication to transmit data from the Arduino to the HMI (Human Machine Interface). We used a serial output for communication of the Arduino with the computer. We can see the circuit of the project in Figure 2.

Microcontroller

The Arduino Mega was used in this prototype, a free hardware and code platform that has its own compiler, designed to reach people who have little programming knowledge. The microcontroller used is the ATmel ATmega 2560, an 8-bit microcontroller of advanced RISC architecture. It has 256 KB Flash (plus 8 KB that are used for the bootloader), 8 KB RAM and 4 KB EEPROM. There are 16 MIPS, operating on 16 MHz. Arduino based on Atmel ATmega, among which we can highlight 3 serial communication channels, 16 analog inputs and 15 PWM outputs. It has also SPI, I2C communication and 6 pins for external interruptions. The Mega2560 board has 54 pins

of digital inputs and outputs that can be used as input or output. The pins operate at 5V voltage and can supply or drain up to 40 mA. Each pin has internal pull-up resistor which can be software-enabled. It has 16 analog inputs (pins A0 to A15), where the conversion can be made with a resolution of 10 bits, that is, the value will be converted between 0 and 1023.

Ultrasound

The HC – SR04 ultrasound module provides 2 to 400 cm without contact and measuring function, with precision of 3 mm.

HMI

In order for the simulator to have mobility and an easy interface between the operator and the device, it was decided to use the HMI system of the Arduino platform with I2C communication.

Power Supply

Standard 12V, 2.3A, real power of 500 Watts, efficiency > 70%, TBF of 100,000 hours, 25°C, internal protection against OVP / OCP / SCP short circuit, AC input with manual switching 110 / 220 V, low acoustic noise, cables with protective cover, thermal cooling control system, 120 mm silent fan, technical standards IEC60950 (electrical safety), IEC61000 (electromagnetic safety) and On / Off switch.

Relay

NA/NF of 5V.

Valve

Valve with 12V solenoid.

Mechanical Assembly

For the assembly of the device, 5 threaded rods of ½ inch with nut and washer were used, 1 50x50cm acrylic sheet, as shown in its assembly in figure 6.

Container

A cylindrical container was used as a reservoir, graduated with a total volume of 1000 mL.

Flange

A flange of ½ inch was attached to the bottom of the container for the water outlet.

Connector

A connector with the same diameter of the extender used in the conventional hemodialysis kit was installed for liquid inflow into the container.

RESULTS

To obtain the final results of the electronic part, the circuit was assembled. After the connection of the ultrasound sensor to the valve in the Arduino platform, four tests were performed and the analyzer responded satisfactorily. The final report is shown in Figure 3.

To obtain the final results of the mechanical part, the set was assembled as shown in Figure 4. After assembly of all electronic and mechanical parts, four tests were performed. With the design mounted, the set responded satisfactorily as shown in Figure 5.

After the complete assembly of the prototype in the initial verification form, bench tests were performed comparing the readings from this prototype with those from conventional manual methods. After all adjustments,

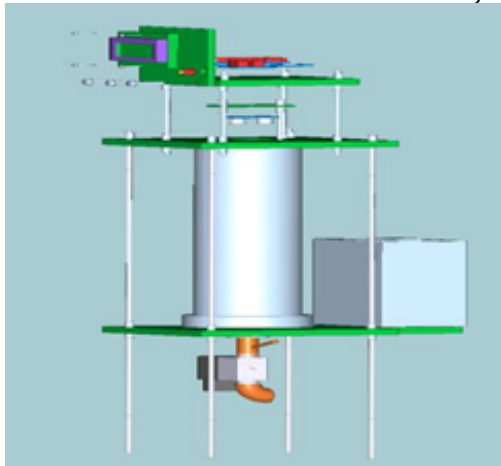


FIGURE 4. Mechanical design of the flow simulator for blood pumps.

a test with the blood pump of the hemodialysis machine was performed. At the end of the test, a detailed analysis report was generated.

CONCLUSIONS

Tools and support devices in the analysis and simulation



FIGURE 5. The final project.

of biomedical information are of great value in mitigating the risks related to the use of biomedical devices.

This article describes the development of an automated blood flow analyzer prototype to improve quality standards in the tests performed by clinical engineering services on hemodialysis machines. This prototype was found to reduce equipment downtime, reduce costs related to the testing process, and increase the safety of therapy with hospital devices that use blood pumps.

CONFLICT OF INTEREST

The authors declare that they have no conflict of interest.

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