
2020 IEEE HAC & SIGHT Projects - Response to COVID-19

IEEE Corporate - Corporate Development

Administrative Information

Primary Applicant Name:*

Character Limit: 100

Roberto Asano Junior

Primary Applicant Email:*

Character Limit: 254

roberto.asano@yahoo.com

Primary Applicant is affiliated with which IEEE OU:*

Character Limit: 100

*Jt.Chap. Energy Industry Connections, IEEE R9 South Brazil Jt Chap E25/PE31/MAG33/IA34/PEL35
CH09335*

Primary Applicant IEEE Member Number:*

Character Limit: 8

40310748

Primary Applicant IEEE Member Grade:*

Please note that a student member may not be the primary applicant.

Choices

Senior
Member

Co-Applicant Name:

Character Limit: 100

Ivan Correia Lima Coqueiro

Co-Applicant Email:

Character Limit: 254

correia.ivan@ieee.org

Co-Applicant is affiliated with which IEEE OU:

Character Limit: 100

IEEE UFABC EMBS Student Chapter - Brazil

Co-Applicant IEEE Member Number:

Character Limit: 8

95384631

Co-Applicant IEEE Member Grade:

Choices

Student
Member

Project Name*

Character Limit: 100

Low-Cost Ventilator Ara Plus: emergency response against COVID-19

In which IEEE Region will your project take place?*

Choices

Region 9

In what country will your project take place?*

If more than one country, please select the primary country, or country where you will begin implementation.

Choices

Bra
zil

Funding requested from HAC in USD*

Character Limit: 20

USD 5,000.

IEEE Organizational Unit*

Which IEEE OU is acting as fiscal agent to receive approved funding?

Character Limit: 250

Jt. Chap. Energy Industry Connections

IEEE R9 South Brazil Jt Chap, E25/PE31/MAG33/IA34/PEL35 – CH09335

<https://r9.ieee.org/br-eic/>

OU Contact Name:*

i.e. name of Section Chair or Treasurer

Character Limit: 100

Roberto Asano Junior

OU Contact Position:

i.e. Section Treasurer

Character Limit: 100.

Chapter Chair

OU Contact Email*

Character Limit: 254

roberto.asano@yahoo.com

SECTION 1: Project Overview and Background

Executive summary of project, including location, needs, and intended solution.*

Character Limit: 2000

This project is a contribution to alleviate the consequences of COVID-19 pandemic, since the treatment of critical patients requires hospitalization and intensive use of mechanical ventilation. It is observed in most regions of Brazil the saturation of public and private health systems. In the region of ABC Paulista, Southeast of São Paulo City comprehending about 3 million habitants (over 20 million habitants in the great São Paulo), 70% of the hospital beds are already occupied due to the excess of patients affected by COVID-19.

Mechanical ventilators are among the most demanded equipment and in various countries it is noticed efforts to the acquisition of new equipment, the recuperation of damaged or obsolete ones, as well as low-cost emergency alternative equipment with fast production such as the one pursued by this project. Within the current scenario of logistic restrictions and big demand worldwide, a local alternative, with industrialized and local materials is shown as indispensable in order to save lives. Thus, the group of students and researchers from Federal University of ABC (UFABC) that are enrolled in this project are developing an automated ventilator based on manual resuscitators (AMBU bag), in an open platform, easy to assemble, with minimal cost of production. We are using components there are easy to find at the local market and that comply with minimum requirements of local guidelines presented by the regulations and standards.

The concept has been under development since the end of March. It is based on Pressure Support Ventilation (PSV) mode and the functional prototype is almost completed with financial support of the volunteers, favours from local workshops and a small budget from the University.

IEEE HAC funding will be welcome to support the conclusion of the tests and the production of copies of the prototypes to be handled to the hospitals of the region of ABC Paulista, beginning with the Field Hospital situated at UFABC gymnasium.

SECTION 2: Stakeholder Mapping and End-User Engagement

Who are the stakeholders and how will they be engaged in the project?*

Stakeholder: An individual, group of people or organization that affects or is affected by an intervention. The stakeholders should include the project team, the beneficiary community, and any others that will experience relevant and significant outcomes (intended or unintended, positive or negative). Examples include local governments, non-governmental organizations, service providers, institutions such as schools or hospitals, and so on.

Character Limit: 2000

Project Team - The interdisciplinary team is composed of students, researchers and professors from UFABC and are the main responsible for the development and test of this ventilator. The team is also responsible to bridge the gap between other stakeholders for the success of this project.

UFABC (Federal University of ABC) - The university is supporting this project institutionally since it was approved under the University's initiatives against COVID-19. It is also providing the infrastructure such as laboratories for the functional tests.

FMABC - Is the private Medicine College of ABC. It is represented by one teacher who is providing the knowhow about the needs and use of the ventilator system as well as the support for the tests and clinical application. We have not yet established a formal cooperation between UFABC and FMABC

City halls - ABC region is composed of seven counties and each city hall is responsible for the local public health system (including field hospitals) and they are integrated by SUS (Unified Health System ruled by Ministry of Health). Connection of this group and city halls is by means of the UFABC COVID-19 Committee.

Local industry - Some local workshops and industries supported the construction of the mechanical parts of the prototype donating labor and raw materials so far. They are natural partners to the production of the final ventilator. Bridging the gap between local industry and university is a side benefit of the project.

IEEE South Brazil Section - Resource transfer, reimburses and eventual acquisitions/ payment.

IEEE Jt. Chapter Energy Industry Connections - controlling and reporting on the use of IEEE HAC fundings

SECTION 3: Theory of Change

This link [to a succinct explanation](#) of the differences between inputs, activities, outputs, and outcomes is provided for your reference.

Activities*

Character Limit: 2000

Within this project the team expects to donate as many ventilators as possible to the public hospitals in the local community. One of these field hospitals is being assembled in the University's gymnasium (<http://www.ufabc.edu.br/noticias/instalacao-do-hospital-de-campanha-tem-inicio-na-ufabc>) and it will be the first candidate to make clinical tests and use the ventilator we are developing.

We have started with a simple concept with minimal moving parts and a low cost DC motor gear to automate a manual resuscitator (AMBU) controlled by Arduino. At first a 3D printed concept model was built and it demonstrated the potential of the idea. Now a robust prototype, built with the aid of local industries is almost finished for performance tests. Controlled and assisted respiration mode with adjusted cycle time has been programmed in the parametric software with an easy to use interface that monitors inspiration and exhalation times and pressure.

With the support of IEEE HAC we expect to be able to conclude the certification and clinical tests that will allow the use of our equipment in hospitals, as well as, to build and donate additional ventilators.

Outputs*

Please include how these will be measured.

Character Limit: 2000

At the end of this project we expect to have an open design, hardware and software of a low cost emergency ventilator based on AMBU bag automation. To achieve this objective we plan to construct two testing prototypes and four final ventilators to be donated to public health local authority. Performance tests will be made for the early prototype. Their results will be documented and considered in the design of the improved prototype. All the documentation will be publicly available at Github.

In the late stage of the project, we will do electrical test certification based on local guidelines of Mechanical Ventilation done by a certificated organization. Then perform clinical certification testing with animal and human participants, in order to ensure the reliability of the end-product. We expect to produce four final ventilators to donate to UFABC field hospital and to the local health authority.

Outcomes*

Please include indicators and how these will be measured, in addition to opportunities for replication and scaling.

Character Limit: 2000

Due to the particularities of the COVID-19 pandemic, it would be desirable that, at the end of this project, the equipment proposed here is saving lives in hospitals.

With the development of a reliable structure and mechanism, committed to the industrial process, we seek to make a design that enables agile production and a large number of ventilators to meet the immediate needs caused by the COVID-19 pandemic. The project team is also designing an open hardware and software platform to allow basic respirator controls to adapt to the needs of less complex patients.

Throughout the development of the project, the group is establishing contacts with industrial partners, especially from the ABC region. For the moment our goal is to produce ventilators at the order of a dozens. One possible outcome is large-scale manufacturing depending on the interest of the local industry.

In addition, the participation in the project is aimed to build capacity and train students and researchers in the production of medical equipment for current and future challenges. It is also an opportunity to engage the university with local society, government and companies.

Assumptions*

Character Limit: 2000

It is an open source project and will not be made comercial by the research group. All equipment made with the project resource will be donated. It is desirable that any industrial facility benefit from the design to build copies and eventually donate or commercialize it.

The device will only perform PSV mode with cycle control and pressure limits controlled by mechanical valves. It will be useful for low to mid complexity patients requiring mechanical ventilation, reserving the more complete commercial ventilators to complex cases..

Please describe any similar projects being implemented in the region where you will be working.*

Are there any similar projects being implemented by other IEEE volunteers, institutions, organizations, or the government in the region where you will be working? If so, what are they?

Character Limit: 2000

Similar projects of open emergency mechanical ventilators appeared all over the world since COVID-19 pandemic broke out. Some of them were consulted such as the one proposed by MIT. A concept developed in parallel in Spain is named OyxGEN ventilator, and we have re-used their cam-shaft design (www.oxygen.protofy.xyz/post/cam-shaft-design).

We are aware of at least three ventilator initiatives at the region of São Paulo. The first is called Inspire and was designed by teachers and students of University of São Paulo (github.com/Inspire-Poli-USP/Inspire-OpenLung) to be an open design AMBU based ventilator operating with linear actuator and step motor. Their site is well documented but due to legal issues, control software, will remain closed until the end of the test phase. The second was developed by Instituto Mauá de Tecnologia, a private engineering school at ABC region. Apparently they have licensed their AMBU based technology to a company called Protec (www.protec.com.br). We also have news that a commercial pneumatic ventilator is under development by a local company called JHP Automação (www.jhpautomacao.com.br).

SECTION 4: Project Implementation Plan

Project work plan and milestones*

Please outline the proposed project work plan, expected timelines, and milestones associated with successful implementation of the proposed objectives.

Do not duplicate what is in the executive summary or theory of change.

Character Limit: 2000

The project is planning the following milestones until its conclusion:

- 1) Conclusion of 1st prototype experimental assembly with sensors and electronics (1 week)
- 2) Operational and performance tests (1 week)
- 3) Design review and improvements (1 week)
- 4) Construction of 2nd prototype with design improvements (2 weeks)
- 5) Certification tests (1 week)
- 6) Tests with animals (1 week)
- 7) Clinical (human) tests (1 week)
- 8) Construction of four final ventilators for donation (2 weeks)
- 9) User manual and documentation (1 week)
- 10) Training of users (1 day)

Are there any restrictions in place that would impact the execution of your project?*

For example, mobility restrictions due to COVID-19, shelter in place, etc. Please share details of mitigation plan.

Character Limit: 2000

Until the day this project was written social distancing is recommended, but not enforced by local authorities. Most of the time the team is cooperating online. A few times a week small part of the group meet at the university lab to test the equipment. If a lockdown is declared it would impact the execution of the project. A possible workaround would be to require an authorization for members of the team.

Since we are planning to make tests with animals and humans, our progress depends on the approval of the respective Ethics Committees Boards. One member of the team already performed tests with pigs for another experimental ventilator and we might rely on the experimental protocol that has already been approved. We have not yet designed the protocol for human experiments. However, University of São Paulo's (USP) has already tested an emergency ventilator in humans and we can adopt a protocol based on theirs.

Implementing Team*

Please state how many IEEE volunteers and how many non-IEEE volunteers are projected to take part in this project, including the IEEE Member Numbers if possible. Indicate if the team is an IEEE SIGHT group. (Please note, it is not required to be part of a SIGHT group.)

If readily accessible, provide short profiles for each member of the proposed implementation team (IEEE and non-IEEE) that justifies how their participation will support achieving the objectives of the proposal. The profiles should explain the relevance of their expertise and previous field work experience (particularly in the beneficiary country). Please describe any previous relevant team collaborations.

Character Limit: 2000

IEEE members (4):

Harki Tanaka, PhD, (#92593066, IEEE Member), Professor Biomedical Engineering - UFABC and Medical Professional [respiratory system research]

Felipe Augusto Massari, (#92619213, IEEE Student Member - UFABC RAS Student Chapter), Student Instrumentation Engineering - UFABC [electronics]

Ivan Correia Lima Coqueiro, (#95384631, IEEE Student Member - UFABC EMBS Student Chapter), Student Biomedical Engineering - UFABC [electronics and software design]

Roberto Asano, PhD, (#40310748, IEEE Senior Member - Jt. Chap. Energy Industry Connections), Researcher Power and Energy Engineering - UFABC [electronics and software design]

Non-IEEE members (11):

Ana Tércia Lacerda de Araújo, Student Biomedical Engineering - UFABC [tests for certification and documentation]

Danilo Buchdid, Student Biomedical Engineering - UFABC [sensors]

Danilo Luna Campos, Student Biomedical Engineering - UFABC [pneumatic design and tests]

Erick Dario Leon Bueno de Camargo, PhD, Professor Biomedical Engineering - UFABC [electronics and sensors]

Hermann Windisch Neto, MSc, PhD Student Biotechnological Science - UFABC [mechanical design and project management]

Jaqueline Badanai, MSc Student Biomedical Engineering - UFABC [tests for certification and documentation]

Olavo Luppi Silva, PhD, Professor Biomedical Engineering - UFABC [electronics and sensors]

Patricia Teixeira Leite, PhD, Professor Power and Energy - UFABC Engineering [software and tests]

Paulo Rodrigues, MSc Student Biomedical Engineering - UFABC [mechanical design]

Rodrigo Daminello Raimundo, PhD, Professor Medicine - Medicine College of ABC [respiratory system and intensive care medical research]

Victor Allisson da Silva, Student Biomedical Engineering - UFABC [sensors and application tests]

Describe the potential risks and unintended consequences associated with this project.*

This should include, but not be limited to, risk to people, property, and IEEE reputation. How will these be mitigated? Make sure to explain what measures will be taken to prevent safety hazards. Please be as detailed as possible. Highlight any political or economic risk associated with the country in which the project is located. The IEEE Office of Risk and

Insurance Management Services (ORIMS) may review proposals to assess risk and provide guidance.

Character Limit: 2000

There are risks for our team to be contaminated by coronavirus during the activities at the lab. This risk can be mitigated by using masks, maintaining doors and windows open and keeping a minimum distance of 1.5m between team members.

There are risks for the patient of unexpected operational faults. These risks might be addressed by functional, animal and human testing before it is released as well as certification. The matter of regulation and certification is certainly an issue. The Brazilian Health Regulatory Agency (ANVISA) is the organ responsible for the certification of medical equipment in Brazil. Their regular workflow usually takes several months to certify a medical product. There is a federal regulation currently in discussion at the Brazilian Senate (<https://www25.senado.leg.br/web/atividade/materias/-/materia/142132>) to simplify the approval of this type of automated AMBU system by the Brazilian Health Regulatory Agency (ANVISA).

According to this regulation our equipment is expected to be classified as "equipamento de uso em caráter experimental para enfrentamento à Covid-19" (equipment for experimental use in COVID-19 treatment) and we would need to comply with all items of this regulation.

Another alternative would be to protocol an authorization at Human Ethics Committee to make a clinical research with our ventilator with COVID-19 patients. In this case we should perform and document all certification tests within the group and train medical staff to operate the equipment safely.

Are any approvals needed to undertake this project?*

Please list the entities who would need to approve this project, such as the government, community entity, Institutional Review Board, and so on. If you already have the approvals, please include as attachments. If these approvals have not yet been secured, explain your plan to do so.

Character Limit: 2000

Yes, at this point we are finishing the laboratory tests. Once they are successfully concluded we will request the authorization from university's ethical committees to start tests with animals and afterwards clinical tests with patients. We are committed to comply with all the regulations and, therefore, we are not expecting to face problems.

Please upload any approvals you already have here.

File Size Limit: 4 MB

SECTION 5: External Collaboration

Please note: legal agreements between IEEE and external entities need to be vetted by IEEE Legal prior to signing.

What external organizations (NGOs, government organizations, companies, etc.) are you working with?*

For each please provide the name and URL of the collaborating organization.

Character Limit: 2000

This project started as an organic initiative from students and researchers from the Federal University of ABC (UFABC), in which some participants are also IEEE members and volunteers. We have institutional support of UFABC for our project. One member of the team belongs to another educational institution (FM ABC) but his collaboration is individual and not institutional.

Up to now we count with the collaboration of two companies/ workshops that donate mechanical parts. One of them is Ventisilva (www.ventisilva.com.br), a medium sized metal fan industry and the other is a Prefer Automação (www.prefer.com.br), a small sized production line automation industry.

What are the roles and responsibilities of the external organizations and IEEE?*

If there is the need for a legal agreement, note that here. Please upload any documentation.

Character Limit: 2000 | File Size Limit: 5 MB

Not applicable

SECTION 6: Requested Funding

The HAC Projects Committee prioritizes support of direct project costs, including necessary equipment, materials, supplies, and travel. Travel expenses must comply [with IEEE Travel and Expense Reimbursement Guidelines](#). Given current circumstances, travel expenses should be minimal to zero.

No reimbursement of volunteer salaries will be provided. Reimbursing the salary of anyone contributing to the project must be carefully justified. Associated salary costs should be clearly explained and not constitute any more than a minor part of the overall budget proposed.

No indirect costs will be considered for funding, including but not limited to overhead expenses, Facilities & Administrative (F&A) costs, tuition, etc. Administrative, management, and project management costs may be considered, but they must be clearly justified.

Budget Justification*

Provide a brief explanation of all proposed project implementation costs presented in the **IEEE HAC Projects Budget Application Form**. Please highlight those expenses for which funding is requested from HAC and the level of certainty of availability of any funding or resources required from third parties.

Character Limit: 2000

Part of the budget is going to be used to buy electrical, mechanical and medical parts to build two testing prototypes and eventually some necessary testing apparatus. Part of these prototypes will be funded by a UFABC grant. We will use IEEE grant to fund functional, animal, human and certification tests. The remaining will be used to fund the four final working versions of the ventilators. These final ventilators will be donated to a health authority of one of the counties of ABC region.

Completed IEEE HAC Projects Budget Application*

Please complete and submit IEEE HAC Projects Application Budget Template, which can be [downloaded here](#). Please save and rename file to Name of Proposal (or abbreviation) to avoid potential confusion.

File Size Limit: 5 MB

What, if any, mandatory bank fees would be incurred with a transfer of funds from HAC to the OU?*

Please discuss in advance with the IEEE OU that will be your fiscal intermediary (generally the local Section) if there are any mandatory bank fees that are incurred with a transfer of funds from HAC to the OU. These fees may be included in the project budget; however, the OU must confirm to HAC that these are mandatory.

If none, please state "Does Not Apply."

Character Limit: 500

USD to BRL exchange rate is quite volatile and may impact the budget. In addition to that, Section's treasury requests a 5% fee to cover bank and administrative costs from any financial movement (Checked with South Brazil Section's Treasurer). Section's Officers were consulted and they have agreed with the current application and to process eventual fund transfers via CB account 911700 - IEEE South Brazil Section Project Code: R9012.

SECTION 7: Additional Information

Have you submitted, or do you plan to submit, this proposal to another funding source?*

All proposals must disclose if an identical or similar proposal is currently under evaluation for funding elsewhere. Please state any entity(ies), including both IEEE and external funding sources.

Character Limit: 500

We have an approved university funding in the value of US\$ 1874.45

Disclose any potential conflicts of interest regarding this proposal.*

Please note: project teams must abide by [the IEEE Principles of Business Conduct](#). Project leads and any other members of project teams with decision-making authority must complete

the [Principles of Business Conduct/Conflict of Interest](#) disclosure prior to receiving funding.

Character Limit: 500

The members of the team have no conflict of interest.

Is any member of the project team also a member of any HAC or SIGHT Committee?*

If anyone on the project team or involved with the project is a member of any of the HAC or SIGHT Committees, please provide the name of the member(s).

Character Limit: 250

No

Videos and/or Photos

HAC encourages the submission of videos and/or photos that introduce the project team, demonstrate the need identified, or explain the technological solution to be implemented. (Video submission of answers to certain questions is permitted - please label video files with the question number).

Allowed file types: mp3,mp4,avi,mov

File Size Limit: 8 MB

Any supplementary materials that further demonstrate worthiness of the project

Could include publications, letters of community support, etc.

Allowed File Types: doc, docx, pdf

Character Limit: 250 | File Size Limit: 3 MB

Proposal Submission

By signing this application, I confirm that:

1. all team members named in this proposal consent to this application being signed on their behalf;
2. all individuals and organizations named in this proposal have consented to either participate in or cooperate with this proposal as presented should it be selected for support;
3. to the best of the proposers' knowledge, this proposal is aligned with national policy in the country or countries where project activities will take place, and the proposers will ensure that any necessary ethical approval will have been secured before HAC funds are released;
4. I understand that any proposal which (i) is incomplete, (ii) does not have active local community involvement and active "local" IEEE Volunteer involvement or (iii) for which a completed IEEE HAC Projects Budget Application Form is not submitted will not be reviewed.
5. the proposers individually and collectively indemnify IEEE, IEEE staff, the IEEE Humanitarian Activities Committee and IEEE HAC Projects Committee members from any liability associated with review of this proposal or subsequent implementation of their project;

6. the proposers individually and collectively acknowledge that any decision by HAC Projects as final;

7. I acknowledge that the information provided on this form will be processed according to the [IEEE Privacy Policy](#).

* Active “Local” IEEE Volunteer involvement means that key IEEE members responsible for implementing the project are **currently living** in the country/countries where the project is to take place.

SIGNATURE*

(On behalf of all named proposers – please sign by typing your full name and IEEE Member number)

Character Limit: 100

DATE OF SIGNATURE*

Character Limit: 10

06.01.2020