

Collaborative experience between INTI and a consortium of SMEs (Small and Medium Enterprises) related to the design of a medical equipment for ventilation of COVID-19 critical patients

December 4, 2020



Instituto
Nacional
de Tecnología
Industrial



Ministerio de
Desarrollo Productivo
Argentina

Self-inflating bag cyclor (AMBU® type)

Argentine Ventilation Equipment EVA O2

Self-inflating bag UVA O2 (AMBU® type)

Assisted Ventilation Unit O2

Proyct data

2

Devices

5

Months

30

INTI
professionals

5

SMEs

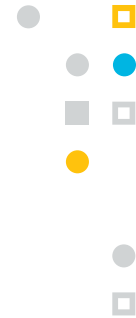
1

FONTAR*
Proyct

*Argentine Technological Fund



Self-inflating bag cycler



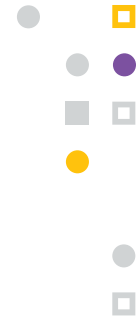
Self-inflating bag



INTI sectors
involved

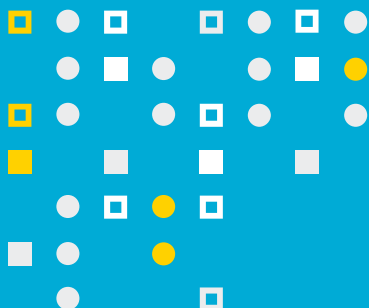
Multidisciplinary project

- Mechanics and Logistics
- Electronics and Energy
- Management Technologies
- Industrial design
- Containers and packaging
- Strategic Intelligence in Projects
- Lighting technology





SMEs Consortium



- MW Solutions Argentina: metalworking, mechanics
- Aeromedical: plastic medical devices
- Metalcrafter: mechanics, electronics
- Microlux: electronics
- Fia Implantes: implantable medical devices





Proyecto FONTAR

Aporte FONTAR:

- \$ 4.730.000 bienes

Contraparte INTI:

- \$ 1.303.000 RRHH
- \$ 180.000 bienes

Bienes en proceso de compra:

- Pulmón de prueba
para simulación de
cualquier condición
respiratoria
- Celda de carga biaxial
de baja carga (+/- 1 kN / +/-
25 Nm)



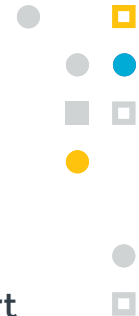
ANMAT product
registration

Standards for approval of EVA 02



Safety Standards

- ISO 80601-2-12. Medical electrical equipment - Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators.
- IEC 60601-1. Medical electrical equipment Part 1: General requirements for basic safety and essential performance.
- ISO 14971. Medical devices – Application of risk management to medical devices.
- IEC 60601-1-6. Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability.
- IEC 60601-1-8. Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems.



Standards for approval of EVA 02

Electromagnetic Compatibility Standards

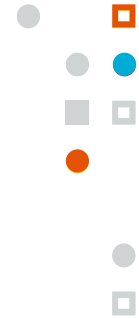
- IEC 60601-1-2. Collateral Standard: Electromagnetic disturbances - Requirements and tests.
- CISPR 11 Industrial, scientific and medical equipment - Radio-frequency disturbance characteristics - Limits and methods of measurement.
- IEC 61000-4-2 Electrostatic discharge immunity test.
- IEC 61000-4-3 Radiated, radio-frequency, electromagnetic field immunity test.
- IEC 61000-4-4 Electrical fast transient/burst immunity test.
- IEC 61000-4-5 Surge immunity test.
- IEC 61000-4-6 Immunity to conducted disturbances, induced by radio-frequency fields.
- IEC 61000-4-8 Power frequency magnetic field immunity test.
- IEC 61000-4-11 Voltage dips, short interruptions and voltage variations immunity tests.

Standards for approval of EVA 02



Other standards

- IEC 62304. Medical device software - Software life cycle processes.
- IEC 62366. Medical devices - Part 1: Application of usability engineering to medical devices.
- IEC 60068-2-27. Environmental testing - Part 2-27: Tests - Test Ea and guidance: Shock.
- EC 60068-2-31. Environmental testing - Part 2-31: Tests - Test Ec: Rough handling shocks, primarily for equipment-type specimens.
- IEC 60068-2-64. Environmental testing - Part 2-64: Tests - Test Fh: Vibration, broadband random and guidance.



Approval Process of EVA 02

1

3 Thecnical Assistance Cycles

Product safety tests
Electromagnetic compatibility tests
Risk management
Software

2

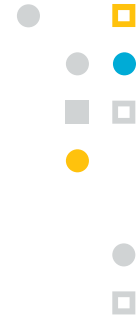
1 Final Tests Cycle

With intermediate modifications

3

3 ANMAT Presentations

Initial
With tests protocols
Minor modifications requested

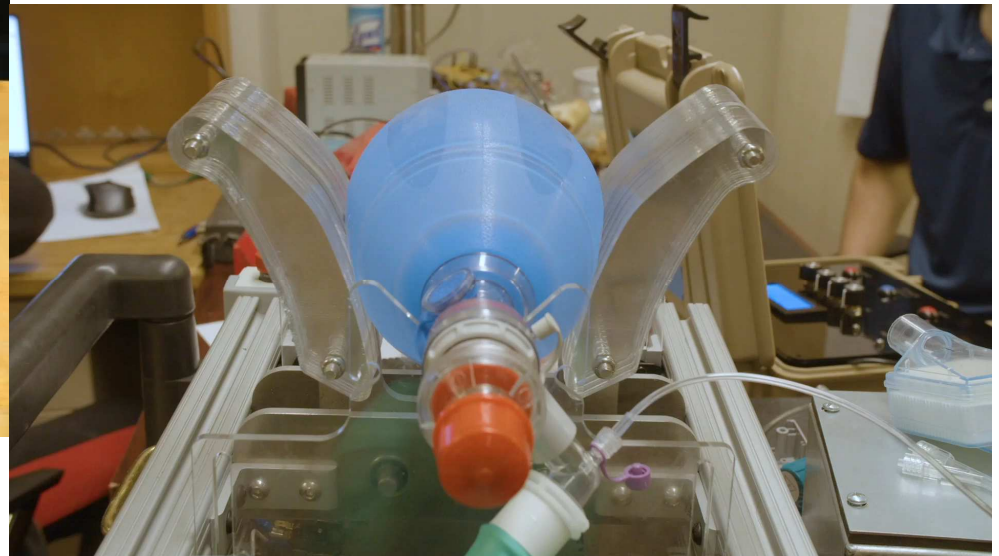
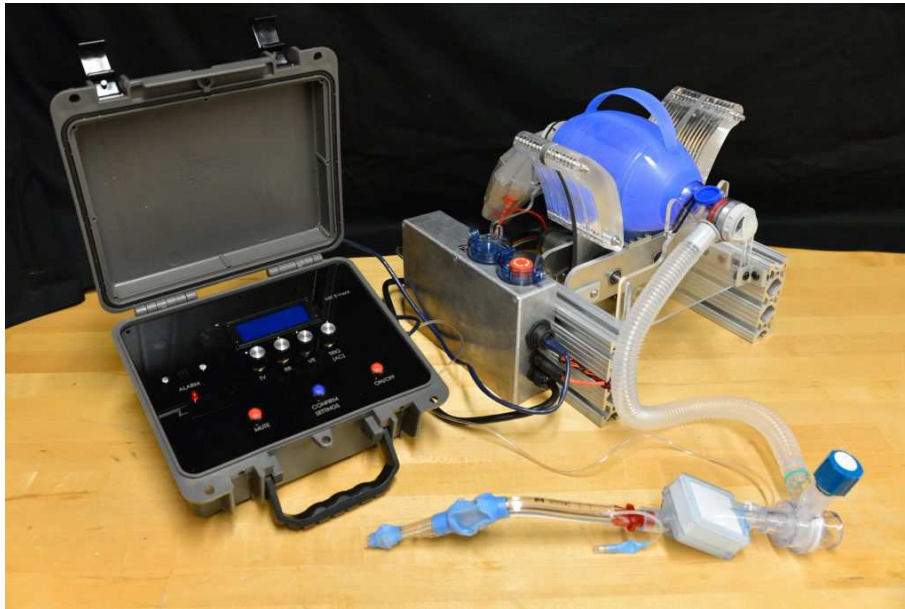
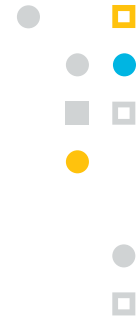


The project in pictures



MIT Emergency Ventilator

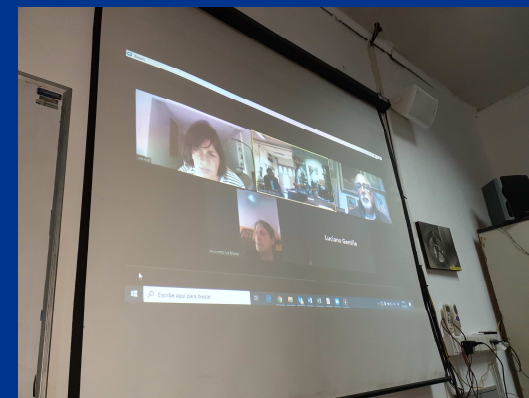
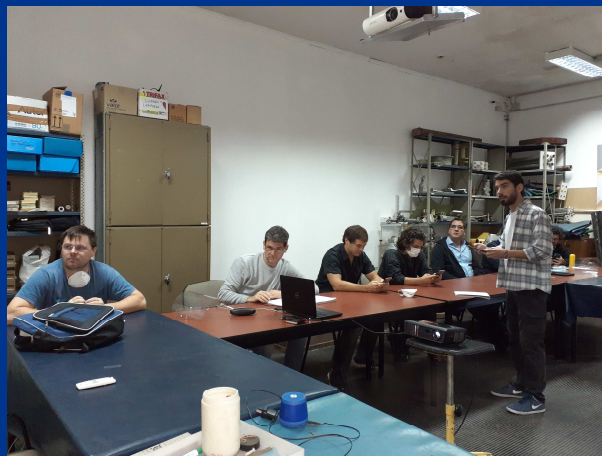
Massachusetts Institute of Technology - EEUU



Meeting March 31, 2020



Meeting April 02, 2020



Meeting April 14, 2020



SATI (Argentine Society of Intensive Care)

Document 04-2020



MÍNIMOS CLÍNICAMENTE ACEPTABLES PARA EL DESARROLLO DE DISPOSITIVOS CAPACES DE DAR SOPORTE VENTILATORIO DURANTE LA PANDEMIA GENERADA POR COVID 19

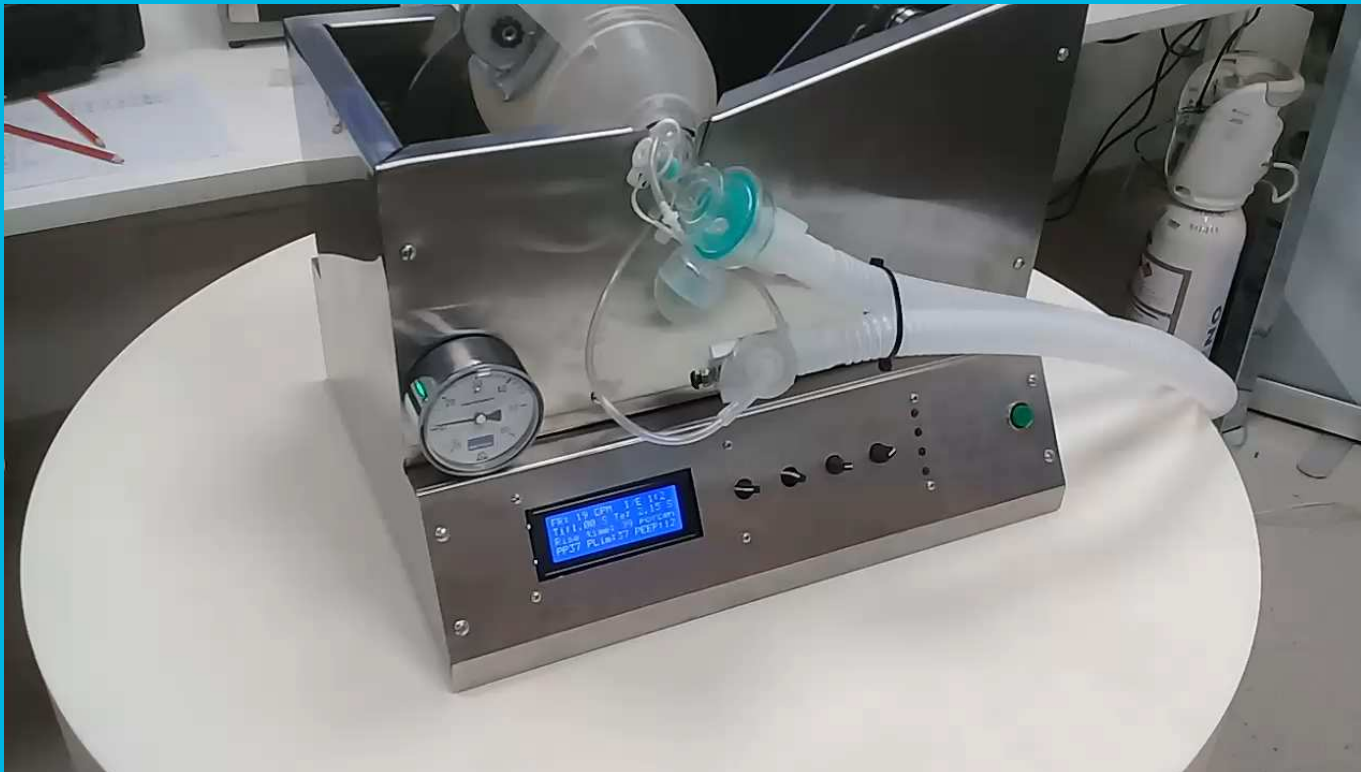
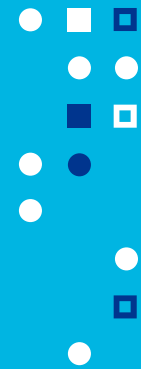
CONSIDERANDOS

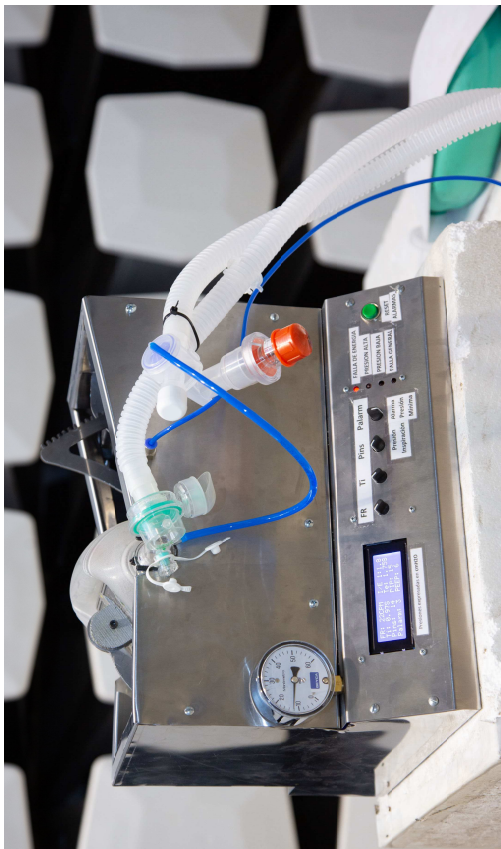
La Pandemia generada por COVID 19 se ha mostrado única en su capacidad de diseminarse en un mundo globalizado. Si bien no son más del 20% de los pacientes los que revisten gravedad como para necesitar medidas de soporte vital, la cinética con la que los casos se han presentado en algunos de los países afectados ha producido el desborde del sistema sanitario y ha imposibilitado que muchos pacientes accedan a cuidados estándar de su salud.

**CLINICALLY
ACCEPTABLE MINIMUM
REQUIREMENTS
FOR THE DEVELOPMENT
OF
DEVICES CAPABLE OF
GIVING
VENTILATORY SUPPORT
DURING
PANDEMIC GENERATED
BY COVID 19**

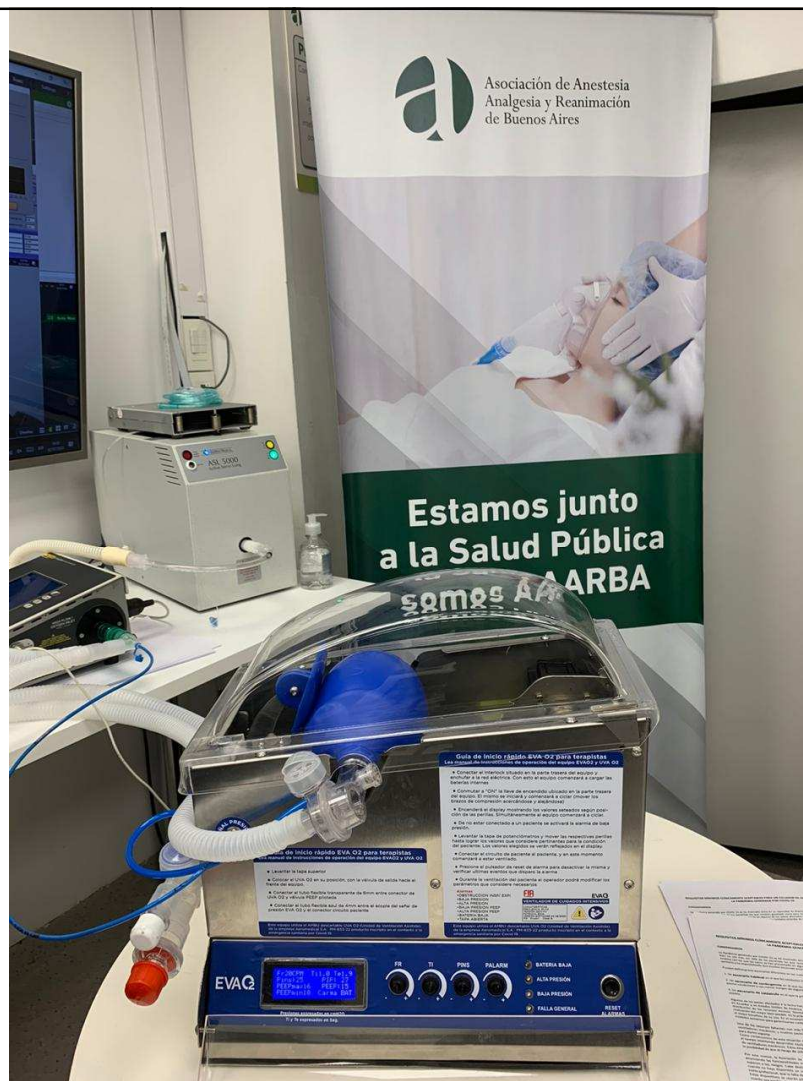


AAARBA (Association of Anesthesia, Analgesia and Resuscitation of Buenos Aires) Tests April 13, 2020





AAARBA Tests July 2, 2020



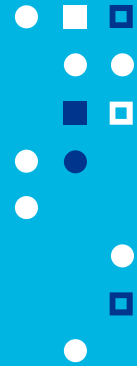


Asociación de Anestesia
Analgesia y Reanimación
de Buenos Aires

REQUISITOS MÍNIMOS CLÍNICAMENTE ACEPTABLES PARA UN CICLADOR DE AMBU EN EL MARCO DE LA PANDEMIA GENERADA POR COVID-19

El presente informe se confecciona a partir del requerimiento efectuado por Rafael E. Dahl a fin de obtener el asesoramiento del equipo de profesionales de la Asociación de Anestesia, Analgesia y Reanimación de Buenos Aires en cuanto a los requisitos mínimos de seguridad y eficacia que deberían reunir los aparatos de transición que podieren llegar a utilizarse ante un escenario de catástrofe y/o durante la pandemia COVID-19, en ausencia de un ventilador mecánico convencional, siempre que la falta de soporte ventilatorio inmediato importare un riesgo cierto para la vida y/o integridad física del paciente.

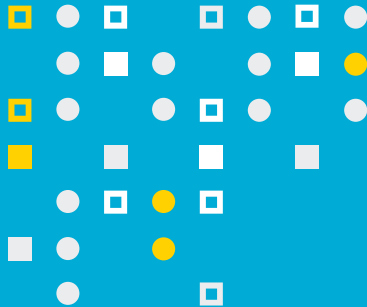
El dispositivo mencionado es considerado de uso compasivo y en manera alguna reemplaza y/o sustituye a los ventiladores mecánicos convencionales.



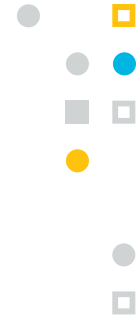
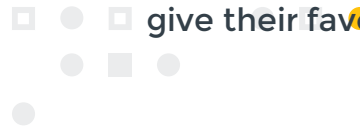
**CLINICALLY
ACCEPTABLE
MINIMUM
REQUIREMENTS FOR
AN AMBU CYCLER IN
THE FRAMEWORK OF
THE COVID-19
PANDEMIC**



Lessons learned



- The empathy, collaboration, commitment, responsibility and sense of belonging of all the members of the team. That led to the development of good interpersonal relationships and the improvement of ideas and decisions, resulting in higher quality in the execution of the project and in the final product.
- Improvement of planning, analyze all the necessary aspects to carry out the project - valuation of the project, intellectual property, technical areas, other public and private institutions- to be able to summon the necessary people to participate and they can give their favorable or unfavorable opinions.





Future challenges



Develop the laboratory For ventilator verification



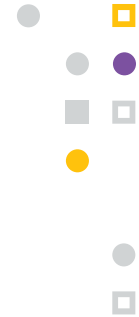
Accreditation of tests



Define a common language between the intervening areas, the need for training in project management is detected.



Expand the application of the documents developed by INTI's Innovation Management area for this type of multidisciplinary projects.



Thank you!!

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Argentina