Approval of handcrafted respirators within the framework of the pandemic by Covid 19 in Uruguay.


NEW PTB PROJECT
TECHNICAL EXCHANGE AND KNOWLEDGE TRANSFER
VIRTUAL WORKSHOP
Metrologists and experts from America share experiences in the fight against a worldwide historical pandemic crisis.
DECEMBER
2
WEDNESDAY
Registration required
https://forms.gle/G1nhoCvEWsD3UPtp8
14:00 to 16:30
UTC time
FREE ACTIVITY
Activity organized by SIM with support from PTB, included in recently approved project:
Development of basic metrology infrastructure to support medical testing equipment, ventilators as a priority, in the Americas.
SIM
PTB


LATU

Pandemic situation in Uruguay

- The first case of covid 19 was confirmed on 13 th March.
- At the beginning of the Pandemic there were 615 CTI beds with mechanical ventilation available.
- In order to increase the number of respirators, equipment's that were out of service, were repaired.
- On the same line, the MIEM and ANII decided to call for projects for the manufacture of 50 respirators for human use.

Handmade respirators manufacture

ON APRIL, THE PROJECT WAS ADJUDGED TO TWO COMPANIES FOR THE MANUFACTURE OF 25 EQUIPMENTS EACH ONE.

THESE COMPANIES, SPECIALIZED IN INDUSTRIAL INSTRUMENTATION, MANUFACTURED THESE RESPIRATORS WITH COMMON INDUSTRIAL PIECES.

DESIGNED AND BUILT LAST A MONTH.

25 RESPIRATORS ARE MECHANICAL AND 25 ARE PNEUMATIC.

PRELIMINARY MEASUREMENTS WERE CARRIED OUT BEFORE ITS DELIVERY

ALL THOSE HANDS MADE FANS THAT APPROVED THE DIFERENTS CONTROL LEVELS, WIL BE AVAILABLE IN CRITICAL SITUATION.

Handcrafted respirators´ homologation

- Here in Uruguay, the organism responsible for the approval is the Ministry of Public Health (MSP).
- The MSP criterias were written in the document "Minimum acceptable conditions in clinical practice for the development of prototypes of mechanical ventilators during the CoVid 19 pandemic" by the Uruguayan Society of Intensive Medicine (SUMI)
- The SUMI document is based on the requirements presented in the following link:https://www.gov.uk/government/publications/coronavirus-covid-19-ventilator-supply-specification/rapidly-manufactured-ventilator-system-specification.

LATU's role

- LATU has not any standardized procedures about respirator calibration.
- To achieve the fast homologation of respirators, the MSP agreemented with a private laboratory which has the necessary standards for the purpose.
- The MSP grants the LATU the responsibility of supervising the calibrations and reports´ preparation.

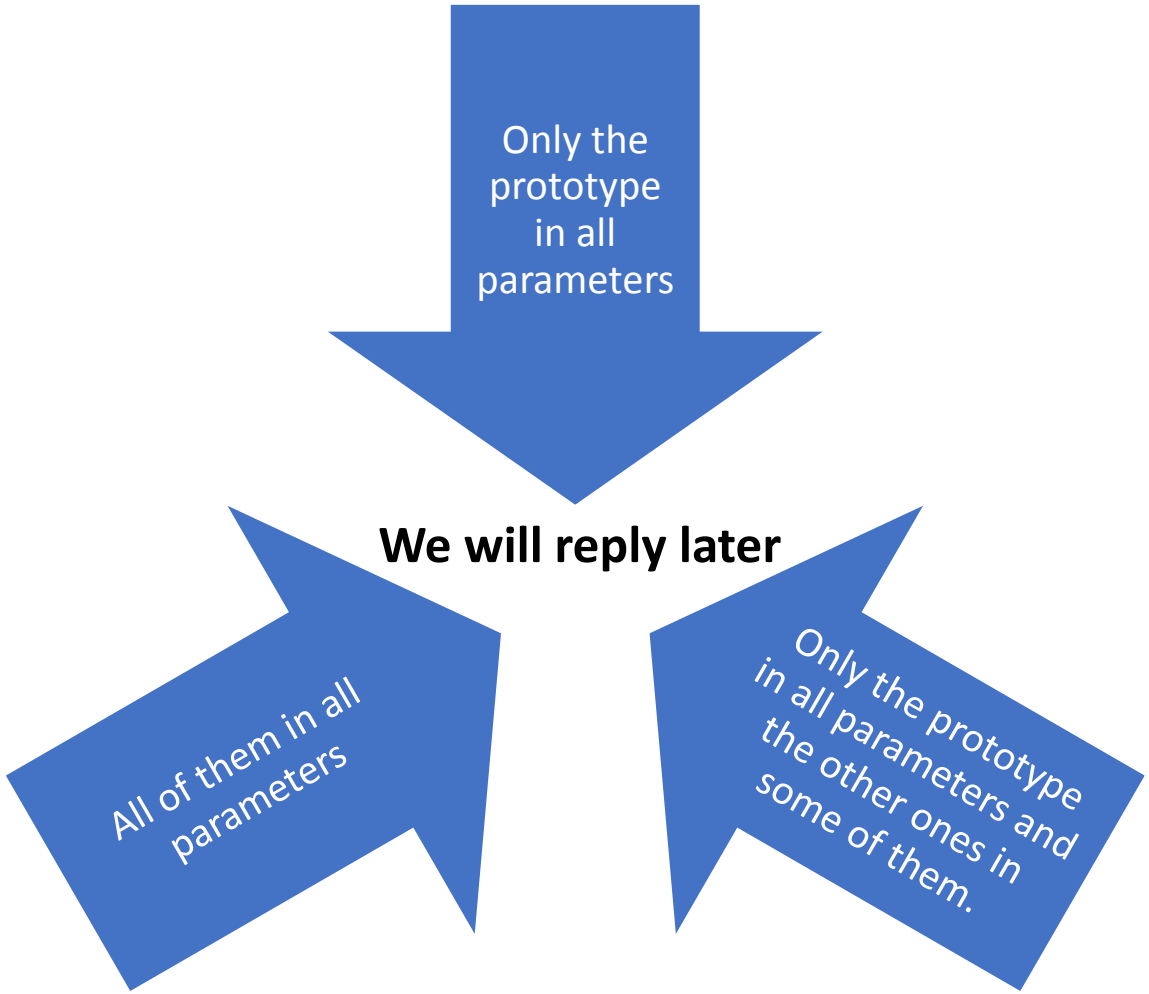
LATU's role

- The LATU work team was formed by three specialists in project management and 5 metrology´s specialists.
- The MSP is who finally qualifies the homologation of the respirators.

Homologation´s criterias

- General characteristics
- Ventilatory parameters ranges
- Fatigue test
- Alarms
- Monitoring
- Additional security features

How many must we control?



General characteristics

- The device must be protected, with only standard connectors for air and oxygen, connectors for the patient circuit and user interface exposed.
- The devices´surface must be easy to clean.
- Any element in contact with the patient's inspiratory gases must be medical grade.
- The design of the devices should not add more than 50 ml of dead volume to the patient circuit.

General characteristics

- The device must have at least a ventilatory mode control by the volume (VCV) or pressure (PCV).
- Volume-controlled mode: ventilatory parameters that must be under control are: respiratory rate, tidal volume (Vt), inspiratory time or I: E ratio, and positive pressure at the end of expiration (PEEP).
- Pressure-controlled mode: the ventilatory parameters which must be under control are: respiratory rate, inspiratory pressure (Pi), inspiratory time or I: E ratio, and positive pressure at the end of expiration (PEEP).

General characteristics

- Devices must allow oxygen-inspired fractions in a range between 0.21 and 0.85 at least, with an inspired oxygen fraction of 1.0 desirable.
- Devices should have a respiratory cycle activation mechanism, based on the detection of the patient's inspiring effort.

VENTILATORY PARAMETERS´ RANGE

- RESPIRATORY RATE (cycles per minute):
  - Between 10 and 30 RPM. If the variation is not continuous, with less than 2 RPM intervals.

- INSPIRATORY TIME:
  - Between 0.7 and 1.2 seconds. If the variation is not continuous, the intervals should be less than 0.2 seconds. If breathing cycle times´ control is based on the adjustment of relationship I:E, this should be: 1: 1, 1: 1.5, 1: 2, 1: 2.5, 1:3.

VENTILATORY PARAMETERS´ RANGES

- POSITIVE PRESSURE AT THE END OF EXPIRATION (PEEP):
  - Between 5 and 15 cmH2O over PEEP. If the variation is not continuous, the intervals must be less than 2 cmH2O.

- INSPIRATORY PRESSURE (PCV mode)
  - Between 5 and 20 cmH2O over PEEP. If the variation is not continuous, the intervals must be less than 2 cmH2O.

- TIDAL VOLUME (VCV mode)
  - Between 250 and 700 ml. If the variation is not continuous, the intervals should be less than 50 ml.

MEASURING RESPIRATORY PARAMETERS´ CONSIDERATIONS

The testing of the mentioned variables for both modes must be carried out under:

- Standard conditions (airway resistance normal and lung compliance normal)
- In simulated conditions of high resistance, and low, normal and high conformity.
- Each measurement will involve, at least, the following respiratory parameters: Vt inspiratory, Pmax, PEEP y FiO2.
- Each test consists of measurements of at least 30 breathing cycles

RESPIRATORY PARAMETER MEASURES EXAMPLES

- Controlled volume compliance test

Test	Complacency ml/CmH2O	Resistance CmH2O/l/s	Tidal Volumen (Vt) / ml	Breathing frequency /min	I:E Relationship	O2% (FiO2)	PEEP
1	80	5	500	12	1:2	21	5
2	80	5	350	15	1:3	21	10
3	80	5	500	18	1:2	21	15
4	50	5	350	12	1:3	21	5
5	50	5	500	15	1:2	21	10
6	50	5	350	18	1:3	21	15
7	20	5	500	12	1:2	21	5
8	20	5	350	15	1:1	21	10
9	20	5	500	18	1:1	21	15

RESPIRATORY PARAMETER MEASURES EXAMPLES

- Controlled volume resistance test

Test	Complacency ml/CmH2O	Resistance CmH2O/l/s	Tidal Volumen (Vt) / ml	Breathing frequency /min	I:E Relationship	O2% (FiO2)	PEEP
10	50	5	500	12	1:2	21	5
11	50	5	350	15	1:1	21	10
12	50	5	500	18	1:2	21	15
13	50	20	350	12	1:3	21	5
14	50	20	500	15	1:2	21	10
15	50	20	350	18	1:3	21	15
16	50	50	500	12	1:2	21	5
17	50	50	350	15	1:3	21	10
18	50	50	500	18	1:2	21	15

RESPIRATORY PARAMETER MEASURES EXAMPLES

- Volume Controlled Assay with R / C Combination

Test	Complacency ml/CmH2O	Resistance CmH2O/l/s	Tidal Volumen (Vt) / ml	Breathing frequency /min	I.E Relationship	O2% (FiO2)	PEEP
19	50	50	500	12	1:2	21	5
20	50	50	350	15	1:1	21	10
21	50	50	500	18	1:2	21	15
22	20	20	350	12	1:3	21	5
23	20	20	500	15	1:2	21	10
24	20	20	350	18	1:3	21	15
25	10	5	500	12	1:2	21	5
26	10	5	350	15	1:3	21	10
27	10	5	500	18	1:2	21	15

RESPIRATORY PARAMETER MEASURES EXAMPLES

- Volume Controlled Assay with R / C Combination (FiO2 variation)

Test	Complacency ml/CmH2O	Resistance CmH2O/l/s	Tidal Volumen (Vt) / ml	Breathing frequency /min	I:E Relationship	O2% (FiO2)	PEEP
28	20	20	350	12	1:2	30	10
29	20	20	350	15	1:1	40	10
30	20	20	350	18	1:2	50	10
31	20	20	350	12	1:3	60	10
32	20	20	350	15	1:2	70	10
33	20	20	350	18	1:3	80	10
34	20	20	350	12	1:2	90	10
35	20	20	350	15	1:3	100	10
28	20	20	350	12	1:2	30	10

RESPIRATORY PARAMETER TOLERANCES

- The maximum variations allowed:

  - PEEP: 2 cmH2O ± 5 %
  - Peak Pressure: 2 cmH2O ± 5 %
  - V expiratory: 4 ml ± 15 %
  - FiO2: 0 ± 5 %

FATIGUE RESISTANCE CHECK

- The respirator must endure fatigue resistance minimum for 14 consecutive days under operation without any problem detected.

POST FATIGUE TEST

All the equipment that approved the Post Fatigue Test need to be tested with others test including some parameters performed previously to confirm that works properly.

POST FATIGUE TEST

Test	Complacency ml/CmH2O	Resistance CmH2O/l/s	Tidal Volumen (Vt) / ml	Breathing frequency /min	I:E Relationship	O2% (FiO2)	PEEP
1	20	5	500	15	1:1	21	5
2	20	5	350	15	1:1	21	5
3	20	5	500	15	1:2	21	5
4	20	5	350	15	1:2	21	5
5	20	5	500	15	1:3	21	5
6	20	5	350	15	1:3	21	5

POST FATIGUE TEST

FiO2 variation

Config	Complacencia ml/CmH2O	Resistencia CmH2O/l/s	Volumen Corriente Vc ml	Frecuencia Respiratoria min	Relación I:E	O2% FiO2	PEEP
10	20	5	350	15	1:2	30	10
11	20	5	350	15	1:2	40	10
12	20	5	350	15	1:2	50	10
13	20	5	350	15	1:2	60	10
14	20	5	350	15	1:2	70	10
15	20	5	350	15	1:2	80	10
16	20	5	350	15	1:2	90	10
17	20	5	350	15	1:2	100	10

ALARMS

Alarms must be listened and seeable from a distance of 5 meters away.

All devices should have at least alarms that indicates:

- Low gas supply pressure alarm (when pressures are below the device's requirements for correct operation)
- Power supply interruption.
- Disconnection of patient circuit (when inspiratory pressure is below 4 cm H2O)
- High inspiratory pressure (when pressures exceed 45 cm H2O)

ALARMS

- Minimum volume delivered (when the delivered volume is less than 90% of the programmed volume in VCV modes and less than 300 ml in PCV modes).
- Minimum respiratory rate (when respiratory rate is less than 10 rpm)
- Maximum respiratory rate (when the respiratory rate is greater than 30 rpm)
- General system failure. The high pressure and volume alarms, in addition to emitting a visual and audible alert, will abort the inspiratory cycle by opening the exhalation valve and restarting the inspiratory cycle.

MONITORING

The following parameters must be monitored:

- Pressures Peaks (maximum) and end-expiratory pressures (in VCV modes)
- Tidal volume and end-expiratory pressure (in PCV modes).

- Volume monitoring must be controlled on the expired volume.

ADDITIONAL SECURITY ELEMENTS

- The device must have a safety valve to release any mechanical overpressure in the patient circuit. This valve should open when the pressure exceeds 45 cmH2O.
- The device will have an anti-suffocation valve, since this mechanism is not guaranteed by design.
- The devices must have a **battery backup** that lasts no less than 30 minutes, with an authomatic switching system capable of restarting the patient's ventilation in less than 10 seconds, after the loss of the external power supply.

ADDITIONAL SECURITY ELEMENTS

- The system must be safe for operators and the environment in order to avoid mechanical, electrical, electromagnetic injuries, etc.
- The system must allow the placement of HEPA filter systems between the tracheal tube and the device, and at the outlets of the inspiratory and expiratory branches.
- The design of the programming system must avoid accidental or inadvertent activation, which may occur during cleaning or normal activities on the patient.

ADDITIONAL SECURITY ELEMENTS

- Systems based on self-inflating bag (AMBU), it must be ensured not movement, or an alarm warns about it.

- In AMBU-based systems, the system must allow the bag rotation to minimize material fatigue and frictional wear.

LESSONS LEARNT

For Manufacturers

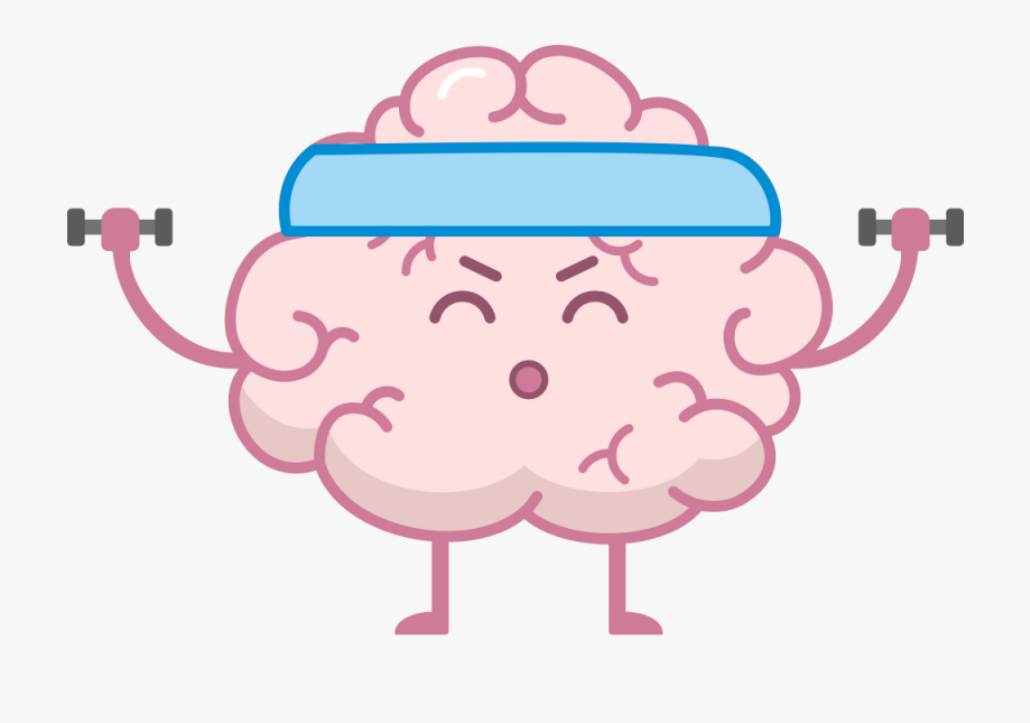
- Work in conjunction with physicians who contribute to a better understanding of the requirements of equipment's uses.

- Acquire more knowledge about parameters and tolerance of ventilatory process to be measured in order to design an equipment that works properly that accomplish it purpose

LESSONS LEARNT

Organization responsible for approval

- Work together with the National Metrological Institute (NMI) in the measurement process.
- Because they are handcrafted it is important to measure in all parameters each of the equipment.



There is still much to do and to learn.

¡THANKS VERY MUCH!