

Instruction For Use for emergency ventilator MakAir



MakAir



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Part 1. Indications and contraindications

Indications

Makair, is a standalone ventilator using air (propelled by a blower) used for patients when there is no conventional ventilator available, for example during the COVID-19 public health emergency.

Contraindications

- When there is a conventional ventilator available
- Outside the public health emergency
- Children under 18 years old
- Pregnancy
- Pneumothorax or pneumomediastinum
- Hemodynamic instability
- Intracranial hypertension
- Severe acute respiratory distress ($PaO_2/FiO_2 < 100$)

General warnings:

WARNING 1: The side door of the MAKAIR respirator must not be opened except for authorized technical personnel: Electric risk 220V

WARNING 2: The MAKAIR respirator should always be stored or transported in an upright position

WARNING 3: In operation, the MAKAIR respirator must be kept away from any obstacle that may obstruct the air vents

Warning to authorized technical personnel:

WARNING 4: Before opening the side door of the ventilator, it is essential to make sure that the power cable is properly disconnected.

WARNING 5: Do not open the side door of the ventilator during or after its operation: risk of burns on certain parts of the ventilator (ex: blower, valves)

Part 2. General Safety Instructions

All volume, flow and leakage specifications must be expressed in STPD conditions, with the exception of those associated with VBS which must be expressed in BTPS conditions.

a) Use of oxygen

- Precautions in case of oxygen leak:
 - no smoking;
 - avoid any flame or source of sparks;
 - disconnect the oxygen source;
 - ventilate room during leakage and at least 20 minutes after leakage;
 - air one's own clothing.
- The device must not be in operations near any incandescent source.
- This ventilator must not be used with inflammable anaesthetic agents or explosive products.
- Do not use the equipment with helium or helium mixed with another gas.
- Do not use Makair with nitric oxide.
- Do not use the device with components that have been contaminated by inflammable substances (e.g. grease, oil, etc.).
- The internal components of the device were degreased before delivery or use a type of grease which is compatible with oxygen. Do not grease or lubricate any part of the device.
- When the device is not in use, it is recommended that you disconnect all oxygen sources from it.
- Medical grade oxygen must be used (i.e. dust-free and dry, H₂O < 20 mg/m³).

b) Use with a defibrillator

- When using Makair and a defibrillator simultaneously, the defibrillation shock in the presence of enriched oxygen and combustibles (such as textiles) can cause an explosion or fire which could injure the patient and bystanders.
- It is recommended to use adhesive electrodes.
- During the defibrillation:
 - remove the oxygen mask or the nasal cannula and keep it at least 1 m from the patient's torso;
 - if the patient is intubated, leave the ventilator connected;
 - ensure that the oxygen-enriched air at the outlet of the expiratory valve is not facing the patient's torso.

c) Electrical power supply

- Check that the voltage in the mains socket used matches the electrical characteristics of the ventilator (indicated on the rear panel of the power supply adaptor).
- Use only the mains cable and mains power supply box supplied with the device.

- If an external power supply is used, check that the voltage and current used match the electrical characteristics of the ventilator (indicated on the side of the ventilator).
- The mains power supply adaptor is not protected from splashes of water (IPX0), unlike the device itself, which complies with IPX4 during battery-powered operation.
- This ventilator has an internal battery. The device must be connected to the mains regularly to maintain the battery charge at a suitable level.
- In the event of any doubt about the condition of the mains power supply cable, use the device on its internal battery only.
- The operating time of Makair on battery is 20 minutes at minimum.
- Do not use antistatic or electrically conductive pipes.
- The user must not touch the patient and the equipment enclosures at the same time.

d) IP Protection

- To ensure the IP protection level of the device is maintained during normal use, it is essential that all removable components (air filter, expiratory assembly, O2 sensor cover and the rear plastic panel) are fitted in place.

e) Electromagnetic compatibility

- The presence of equipment as diathermy units, high frequency electrosurgical equipment, defibrillators and cellular telephones or of electromagnetic interferences exceeding EN 60601-1-2 levels in its vicinity may interfere with the normal operation of the ventilator.
- The Makair device should not be placed next to or on top of this equipment. If it is not possible to do otherwise, the Makair device should be monitored to make sure that it operates correctly where placed.
- Do not use this ventilator in a specifically magnetic environment (MRI, NMR, etc.).
- Precautionary measures are required with this device in terms of CEM.

f) Connection to other electrical devices

- Do not connect the device to other electrical appliances not mentioned in this user manual without first consulting the manufacturers concerned or a specialist.

g) Set-up

- The device must not be put into service immediately after storage or transportation where the temperature and humidity were different from the recommended operating conditions.
- A visual control of the ventilator must be performed before switching ON the device: no external shocks visible on the device must be noticed
- Check that the device runs when unplugged (battery not disconnected)
- Before each use, when you turn ON the device, check that the audible and visual alarms are working correctly and carry out the checks.

- The ventilator should not be covered or positioned in such a way that its functioning or performance are affected. Always leave some space around the device: for example, never place the ventilator close to a curtain which could impede the fresh air flow and cause overheating.
- During infectious episode uses, the HEPA filter (or similar devices) must be connected to the patient circuit (inspiratory and expiratory branch) before connecting the patient. These devices are provided by the Health Care Provider.
- The accuracy of the Makair can be degraded by the gases added when using a nebulizer.

h) Use

- The MakAir device should be use inside hospital
- The manufacturer has tried to anticipate most of the possible malfunction scenarios of this ventilator, and these are normally monitored by the internal monitoring system. It is nevertheless recommended, in cases of complete patient dependence, that you provide an additional, fully autonomous system which can be used to check the effectiveness of the ventilation, as well as a back-up device, such as a suitable manual insufflator.
- Lack of an alternative means of ventilation may result in patient death should the ventilator fail.
- If the accessories used are not compliant with the manufacturer's recommendations, the manufacturer accepts no responsibility in the event of an incident.
- The accessories HEPA filters (i.e. From InterSurgical or Covidien) and patient circuit (i.e. Intersurgical) are provided by the Health Care Provider. This range of products must offer outstanding validated filtration efficiency for use in anaesthesia and intensive care.
- Nebulization may increase the resistance of the filters used in the patient circuit. The filters should be tested frequently to check for an increase in resistance or blockage.
- Do not expose the device to direct sunlight.
- Do not use Makair in a hyperbaric chamber.
- The device and its accessories (masks, circuits, etc.) are Latex-free.
- The air inlets must be completely unobstructed.
- Do not use the ventilator in an explosive or nicotinladen atmosphere (cigarette smoke, fire, etc.).
- In order to prevent dust from entering:
 - check that the filters are correctly placed:
 - the HEPA filter on the air inlet of the blower;
 - anti-pollution filters on every ambient air outlets;
 - electrostatic or ruffled membrane bacteriological filters on expiratory outlets.
 - during cleaning, leave a bacteriological filter or a patient circuit on the inspiratory outlet of the ventilator.
- You can use a Makair ventilator only in standard Pressure, temperature and humidity in an intensive care room.
- There is risk of damage when used with non-compliant accessories
- Accessories must be provided by the HCP (mainly the patient circuit and the filters)

- The effectiveness of ventilation and alarms should be checked, including after all modification of ventilation settings, after any change of the circuit or after a change in concomitant treatment (e.g. nebulization, oxygen flow)
- The MakAir device and AC power supply can get hot during operation. To avoid possible skin damage, do not leave the device or alternating current power supply in direct contact with the patient for an extended period.

i) Transportation

- The case must be securely fastened in the vehicle using the strap loops provided for the purpose.
- The MakAir must be transported in an upright position
- The device must not be subjected to violent impact.
- The device should not be used outside of hospital

j) Risk of cross-contamination

- Reusing single-use accessories or consumables carries the risk of patient cross-contamination. This risk also arises if reusable accessories or consumables are not sterilized between each use.
- The breathing tube, mask, patient circuit, bacteriological filters, expiratory valve, humidification chamber, CO₂ probe or nebulizer adapters are part of the air path and can be contaminated under normal operating conditions, and in the event of a single fault condition by bodily fluids, secretions or gas exhaled by the patient.

k) Maintenance

- Do not use abrasive powders, alcohol, acetone or other easily flammable solvents.
- The device must be disconnected from the mains during any procedure such as maintenance or cleaning.
- Use a wet wipe to clean to clean Makair components

l) Recommendations for aspiration

- Aspiration may be carried out according to different methods: fully unplugging the circuit, opening a respiratory circuit connection, or closed system.
- When using a breathing tube in a closed system, it is advised to adjust the parameters to the patient and, if tolerated, a PEEP of at least 3 cmH₂O

Part 3. Makair Overview

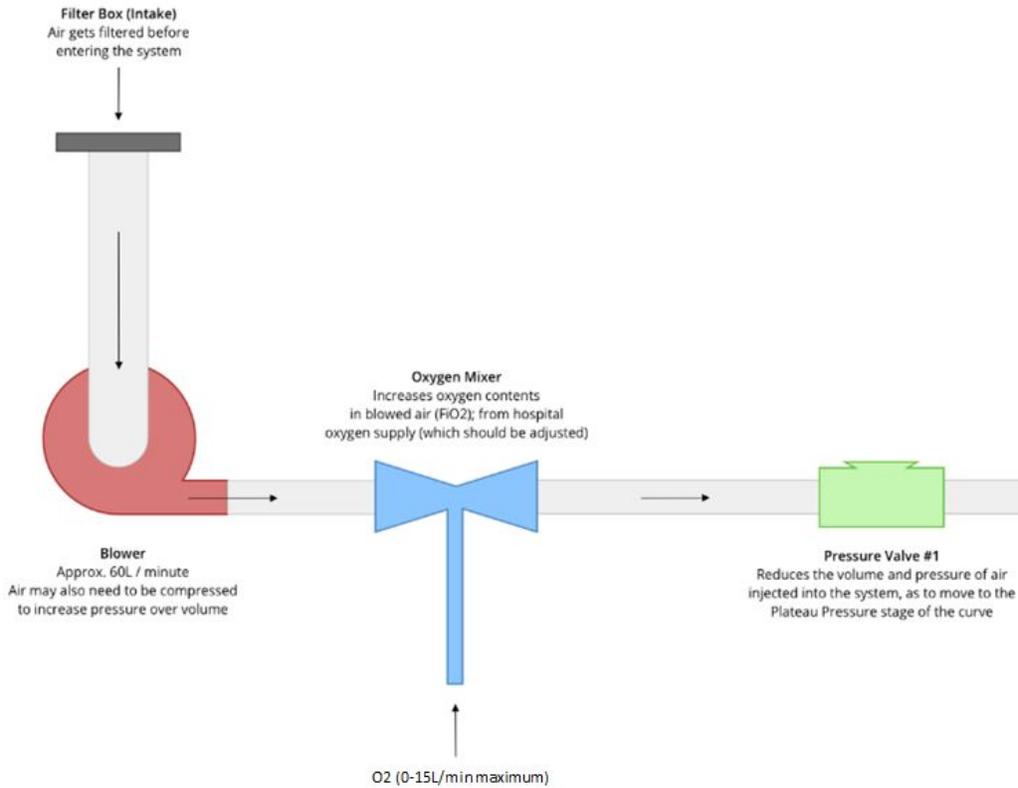
a. Main Features

Makair is a respirator adapted to Severe Acute Respiratory Syndrome (rigid lungs that induce a lack of body oxygenation).

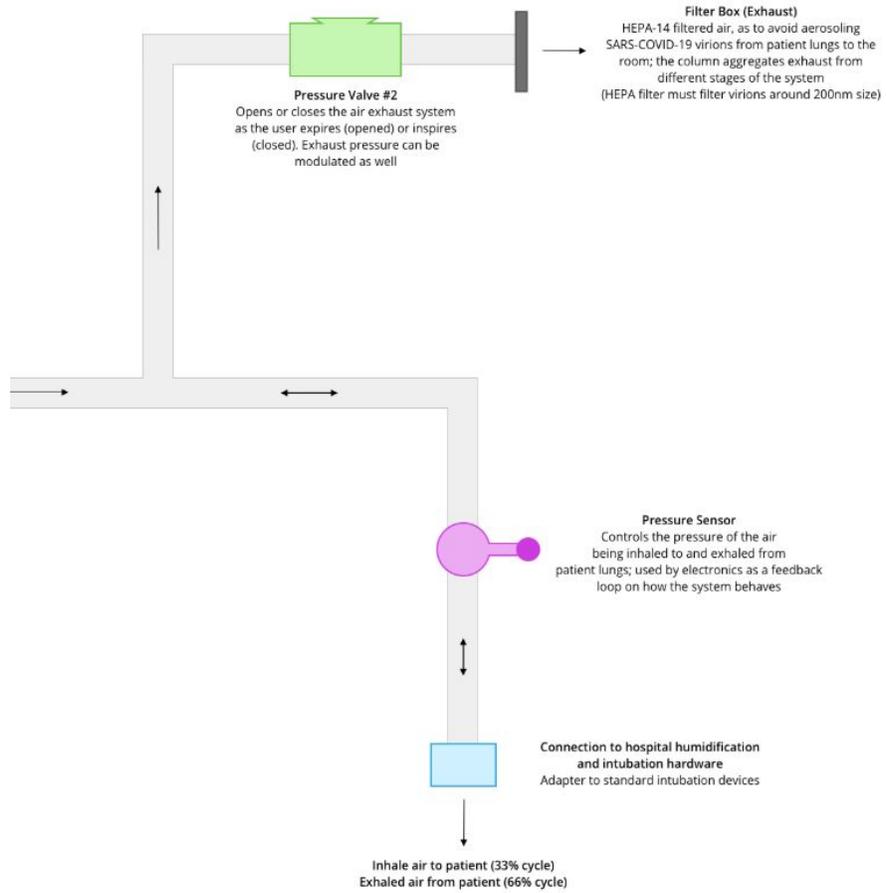
Here are the main characteristics of the Makair device:

- Mechanical invasive ventilation (medical tube to the lungs; no mask)
- Open circuit (filtering air exhaust is possible)
- Controlled pressure system (in opposition to a controlled volume system)
- An inspiratory pressure that allows to a low normal air volume (6mL/kg/min, with a possibility to push this value to 8), which gives a volume ranging from 300 to 600ml per inspiration)
- A Peak Pressure at 70cmH₂O maximum
- A PEEP (Positive end-expiratory pressure) that we should be able to configure from 5 to 30 cmH₂O
- A respiratory frequency that must be configured between 5 to 35 per minute
- An inspiration/expiration factor of 1:2
- An intake to allow regular air to be mixed with pure oxygen (before the blower, to increase the air oxygen content on demand)
- Oxygen flow from 0 to 15 L/min maximum
- A sensor able to measure the plateau pressure, which is allowed up to a maximum of 40 cm H₂O
- A screen that displays the plateau pressure and the peak pressure
- Tunable parameters by the medical operators: PEEP, pressure and frequency

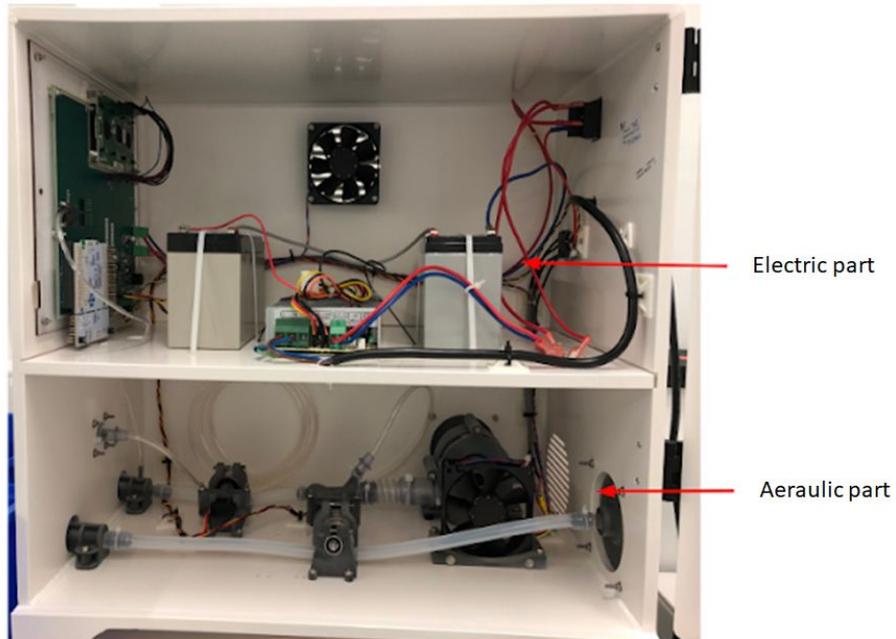
b. General System Scheme



Warning: Connect the ventilator's high- or low-pressure O₂ inlet to a valid source via an appropriate connector. If this oxygen source is a high pressure transport cylinder, it must be equipped **with a pressure reducer** to suit the allowable pressure range (oxygen flow from 0 to 15 L/min maximum). Start by connecting the O₂ connection hose to the ventilator before connecting it to the oxygen network. Check the capacity of the oxygen cylinder before using the ventilator



The following pictures present the general view of MakAir (inside and outside) :



c. The filters

The filter between the blower and Air transistor N1, is an high-efficiency particulate absorbing air filter which must remove—from the air that passes through—at least 99.95% of particles whose diameter is equal to 0.3 μm ; with the filtration efficiency increasing for particle diameters both less than and greater than 0.3 μm .

For each ambient air outlet, there is a pollution filter.

Warning: Only HEPA 14 filters shall be used in the MAkAir device

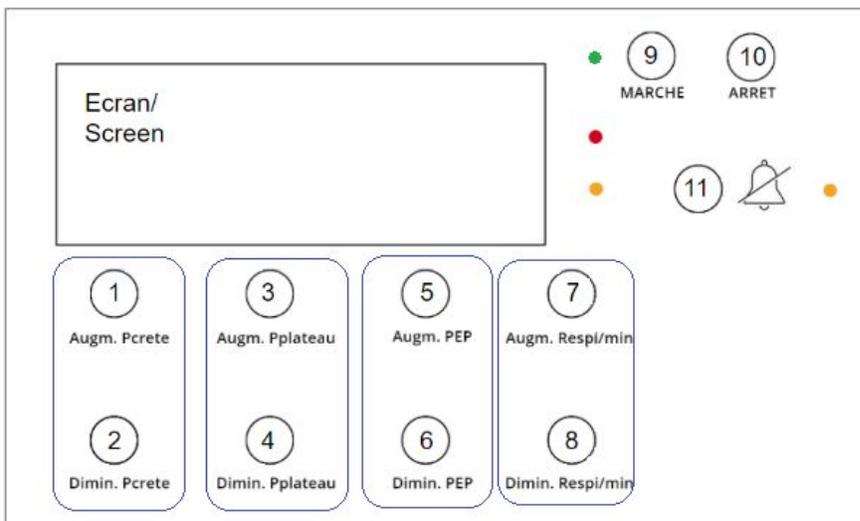
Warning: There is an anti bacteria filter before the invasive part to the patient. If there is an issue with this filter, the part contaminated by the exhaled air goes from the connection with intubation devices to anti reflux valve.

Warning: Always use an anti-bacterial filter to avoid contaminating the patient by the ambient air drawn in.

Warning: Additional components in the respiratory circuit, for instance a anti-bacterial or HME filters develop dead space, thereby causing an increase in compliance or resistance. This is why the use of additional components requires special attention and supervision.

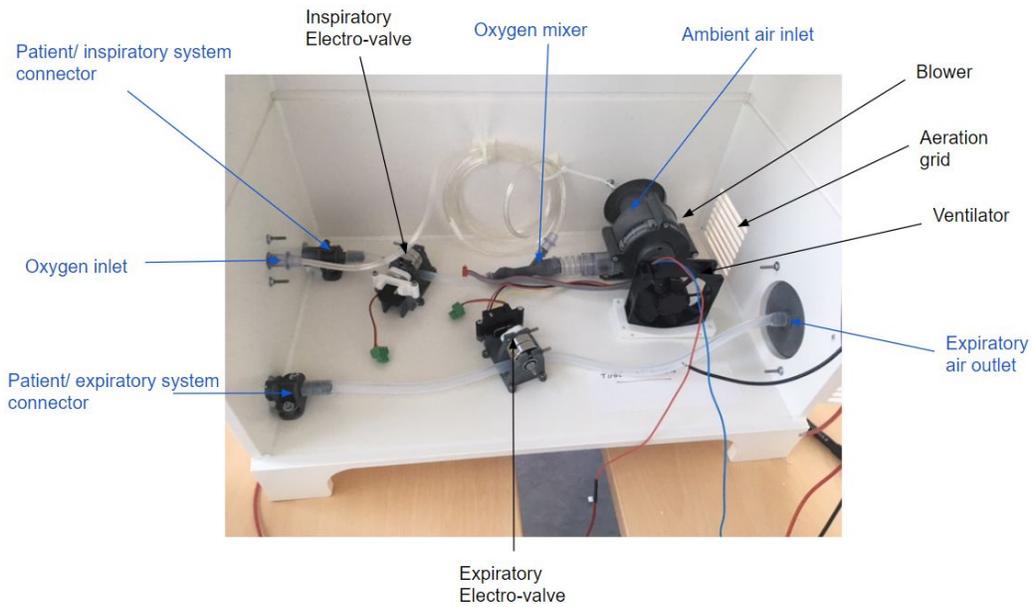
The Makair system does not include a water condensation trap. Since the system does not include an air humidifier this should not be required or useful. If for an unknown reason, condensation forms in the flexibles outside of the system and it is deemed that a water condensation trap is required, then it is advised that a standard water condensation trap is connected between the system and the patient, of the type commonly used in intensive care units.

d. The control interface



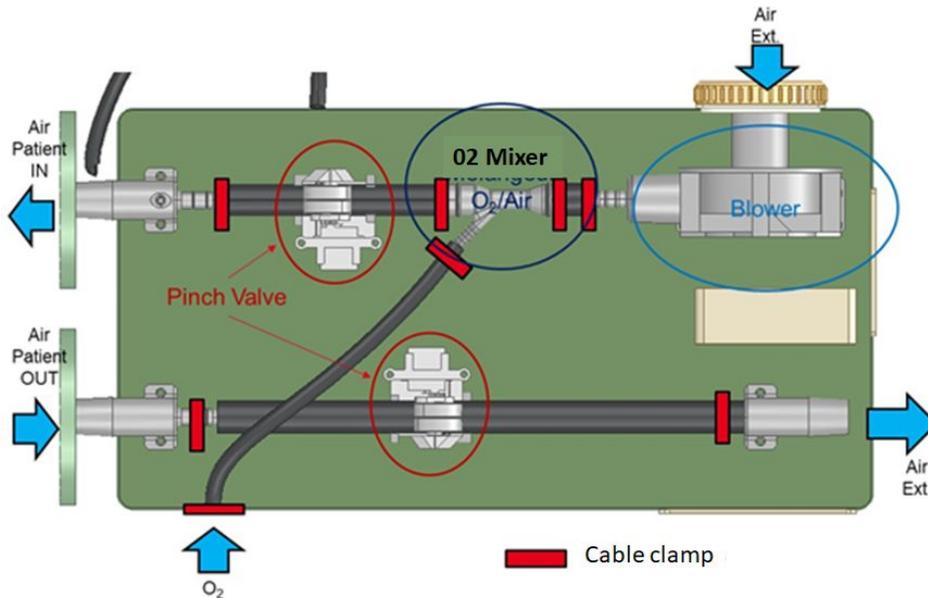
- Button 1 and 2 : to increase or decrease the peak pressure
- Button 3 and 4 : to increase or decrease the plateau pressure
- Button 5 and 6 : to increase or decrease the PEEP
- Button 7 and 8 : to increase or decrease the Cycle per minute
- Button 9: to turn on the MakAir
- Button 10 : to turn off the MakAir
- Button 11 : to mute for 120 s an alarm which occurs

e. The aeraulic part



Black arrows show the component of the system.
 Blue arrows show the pathway of fluids.

This following picture represent the 3D modelisation of the aeraulic part



f. The electrical part



Part 4. Use

a. Turn on Makair

For safety reasons, a battery terminal is disconnected preventing inadvertent starting during transport.

Before being able to equip a patient with the device, a qualified personnel must:

- Perform a visual check of the device to ensure that there are no visible shocks on the external part of the device during transport;
- Connect the internal battery of the device according to the following procedure (part 4.b)
- Switch on the device in order to connect the device's power supply to the mains. Start the makair device by pressing the button 9, and make sure that there is no alarm display.
- Disconnect the device from the mains to ensure that it continues to operate on battery.

Warning: Before opening the side door of the MAKAIR respirator, it is imperative to check that the respirator is disconnected from the 220V mains.

Do not place any metallic object that could create electrical contact between the two terminals of the two batteries.

Person authorized to carry out the start-up procedure: Only the technical staff of the biomedical service (authorized for example to carry out maintenance of biomedical devices) is authorized to carry out this start-up procedure.

b. Internal batteries connection instruction upon receipt

1- Battery connection

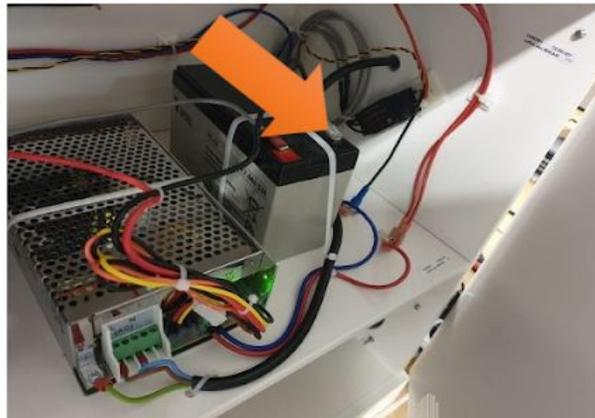
Upon receipt, the authorized operator must connect the batteries placed inside the respirator. In fact, during transport of the respirator, the batteries are disconnected.

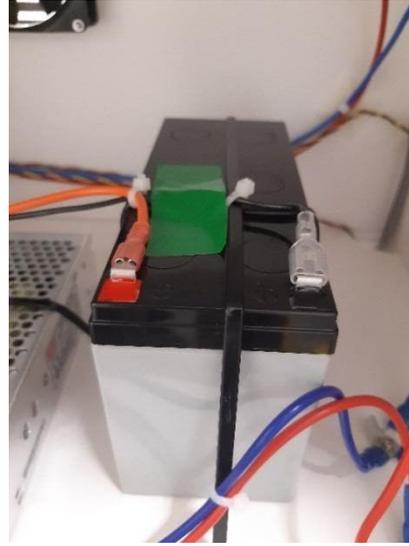
Before carrying out this operation, it is imperative to check that the power cable is disconnected and that the rear panel switch is placed in the high position.

2. Open the side door of the respirator - use the key provided if a lock is in the case



3. Remove the plastic protective lug from the right battery, and connect the lug of the black cord which is floating.





4. If the respirator has a locking key: Close the side door with a key. The key is taped inside the side door of the respirator.

The key must not remain on the case and must only be available to the technical staff of the biomedical service.

5. If the respirator does not have a locking key: Close the side door. Affix the label provided "Do not open except for authorized personnel" along the opening of the side door in order to seal the opening of the door and avoid any risk of opening by unauthorized personnel.

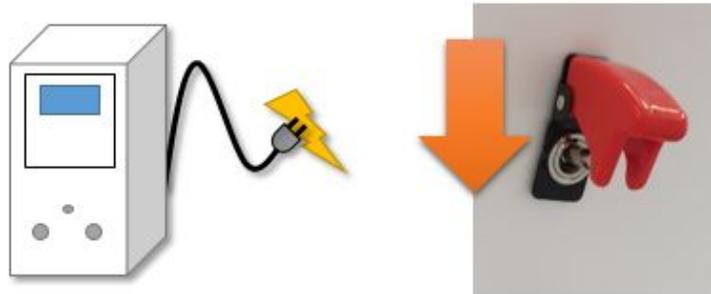
c. Makair startup instruction

WARNING: This procedure should not be performed with a patient.

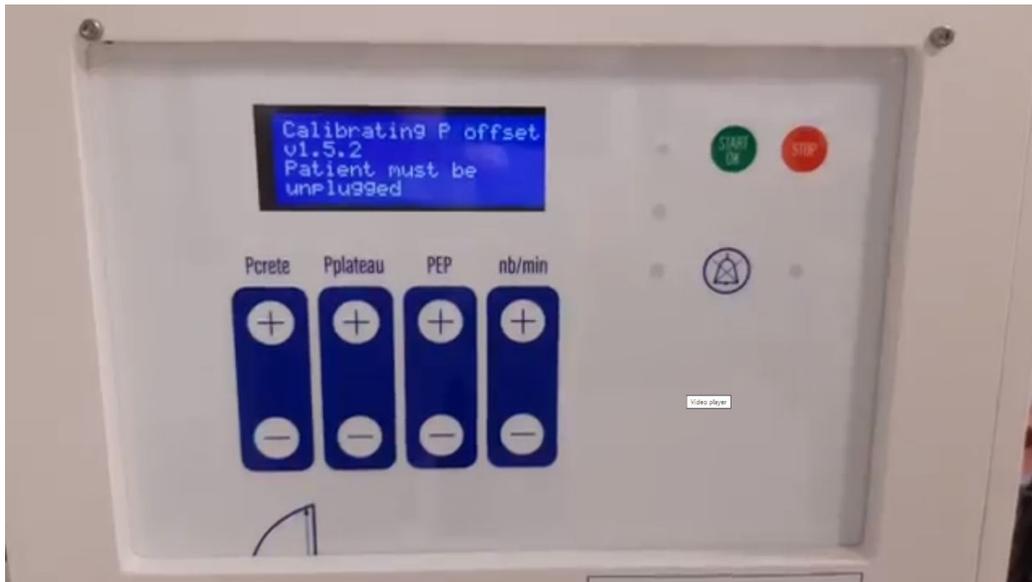
1- Connect the usual double branch circuit device with HEPA 14 filters. It must not be connected to an artificial test lung or to a patient.

WARNING: A HEPA 14 filter must be installed at the gas outlet to the patient / artificial test lung, to avoid any contamination.

2- Connect the MAKAIR power cable to the mains and switch the rear panel switch to the low position.



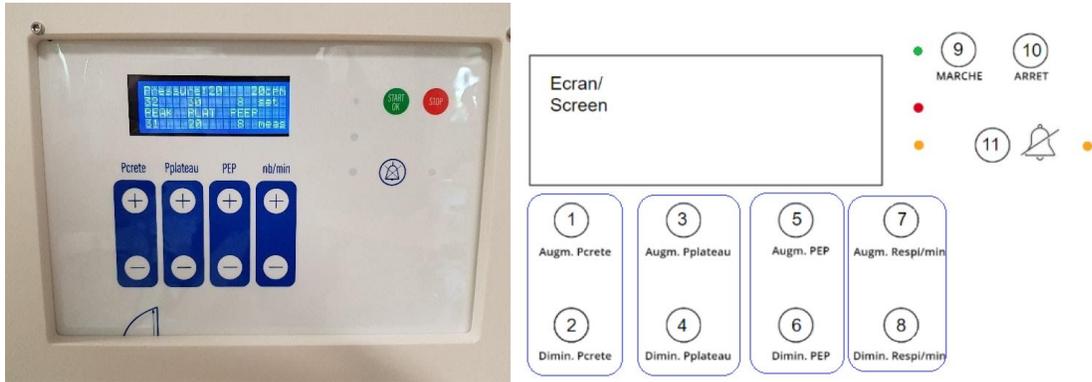
3 –Automatic tests are performed when the device is started, to verify that the alarm sounds and noises are triggered.



4- This device must now be connected to an artificial test lung. Press the button 9 (START OK)



5- Interface :



The upper line of the screen indicates the set points (Pcrete, Pplateau, PEEP and cycle per minute), the lower line indicates the internal measurement of Pcrete, Pplateau and Peep.

Make sure there is no alarm display, except possibly Pplateau alarms n ° 12 and n ° 22 if the setpoint is greater than 20% in absolute value of the recorded value.

Disconnect the device from the mains to ensure that it continues to operate on battery.

If all of these checks are successful, the device can then be used.

Before its use phase (storage of the MaKair), we recommend leaving the device plugged in as much as possible in order to protect against any risk of battery discharge.

6 - To switch off the device, press the STOP button twice



d. Automatic tests

When you turn on the device, tests will trigger the sound and the led of the alarms.

e. Install a patient

The MakAir device must only be used during the sedated phase of the patient.

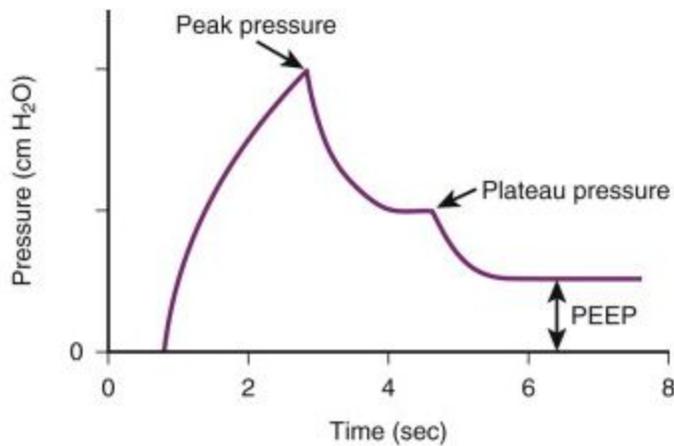
Connect the MakAir device to the patient via the usual device, once the patient is intubated sedated..

Connect oxygen inlet via the available mouth piece available on the ventilator if needed for the patient

Warning: An HEPA 14 filter must be used on the outlet gas to the patient, to avoid patient contamination.

In case of a patient infected by SRAS-Cov2 (identified as a COVID + patient) ideally an HEPA 14 filter has to be installed in the expiratory branch, electrostatic filter in the inspiratory branch and humidifier filter at the Y branch. In case of HEPA filter shortage, it will be removed by a hydrostatic filter. In case of COVID - patient, no hydrostatic filter in the inspiratory branch is recommended.

f. Ventilation settings



A la première utilisation, les paramètres par défaut du dispositif MakAir sont:

Pcrête: 27 cm H₂O

Pplateau: 25 cm H₂O

PEP: 10 cm H₂O

How to set the Peak Pressure?

Use the button 1 and 2 button (see part 3 section d) to set the “Peak Pressure” value to the optimal value for the patient.

Values of the Peak Pressure can be adjusted from 10 to 70 cm of H₂O.

Press the “1” button will increase the Peak Pressure by 1 cm of H₂O.

Press the “2” button will decrease the Peak Pressure by 1 cm of H₂O.

How to set the Plateau Pressure?

Use the button 3 and 4 button (see part 3 section d) to set the “Plateau Pressure” value to the optimal value for the patient.

Values of the Plateau Pressure can be adjusted from 10 to 40 cm of H₂O.

Press the “1” button will increase the Plateau Pressure by 1 cm of H₂O.

Press the “2” button will decrease the Plateau Pressure by 1 cm of H₂O.

How to set the PEEP?

Use the button 5 and 6 button (see part 3 section d) to set the PEEP value to the optimal value for the patient.

Values of the PEEP can be adjusted from 5 to 15 cm of H₂O.

Press the “5” button will increase the PEEP by 1 cm of H₂O.

Press the “6” button will decrease the PEEP by 1 cm of H₂O.

How to set the CPM?

Use the button 7 and 8 button (see part 3 section d) to set the respiratory rate (CPM).

Values of the CPM can be adjusted from 5 to 35 cycles per minute.

Press the “7” button will increase the CPM by 1 cycle per minute.

Press the “8” button will decrease the PEEP by 1 cycle per minute.

How to set the oxygen content?



O₂ supply to the respirator must be provided by a flow regulator connected to an O₂ source (bottle). The maximum authorized flow rate on the oxygen inlet of the ventilator (figure below) must be 15L / min. It is possible to manage the percentage of O₂ on the air flow supplied to the patient by adjusting the flow through the regulator on a range from 0 to 15L / min.

Warning: The oxygen saturation SaO₂ or SpO₂, must be monitored with another certified device.

g. Informations displayed on the screen

If no alarm is triggered

All pressure values are displayed in cmH2O

The respiratory cycle are displayed in cycle per minute

P	R	E	S	S	U	R	E	:	X	X					X	X	c	p	m
X	X					X	X					X	X			s	e	t	
P	E	A	K			P	L	A	T			P	E	P					
X	X					X	X					X	X			m	e	a	s

The first line display:

- The measured pressure
- The number of respiratory cycle

The second line displays the command instruction.

The third line displays the name of the associated pressure.

The fourth line displays the actual measure of the last cycle.

If an alarm is triggered

P	R	E	S	S	U	R	E	:	X	X					X	X	c	p	m
X	X					X	X					X	X			s	e	t	
A	L	A	R	M	:		X	X		X	X		X	X					
X	X					X	X					X	X			m	e	a	s

The alarms with the highest priority are displayed on the third line.

h. What should I do during ventilatory withdrawal?

As described in the contraindication part, MakAir device must only be used in the sedated phase but not during ventilatory withdrawal.

In consequence during the recovery phase, you must use a dedicated device compliant with the patient autonomous breathing.

Warning : Pause the device before disconnecting the patient.

Warning: To avoid SRAS-Cov2 contamination, you must turn OFF the air inlet, and then unplug the patient.

i. The battery

The MakAir device has a battery with an autonomy of 20 min at least. We recommend leaving the device on the power supply as much as possible.

A medium priority alarm is triggered when the battery level is lower than half-charge, then a high priority alarm is triggered when low battery, when the device needs to be quickly connected to the mains.

j. The cleaning

The cleaning procedure must be performed regularly and according to each instruction on care and maintenance of the accessories used with the MakAir device.

Patients treated with mechanical ventilation are highly susceptible to risk infection (other than SRAS-Covid2), requiring attention to all the devices involved in the ventilation circuit.

Always switch off and unplug the appliance before cleaning and make sure it is dry before reconnect it. Do not immerse the device, clean only the external surfaces of the MakAir device.

The box:

Use a dry cloth or slightly damp . The box can be cleaned with an antibacterial solution as on a non-disposable cloth dyed and clean too.

The screen:

Spray a cleaning solution on a cloth

Cleaning solution:

Non-abrasive, solvent-free solutions

Part 5. Alarms

To warn the user, an alarm is composed by sounds and colored LED.

For the sound:

Short is 100 ms

Long is 250 ms

In case of multiple alarms, the highest priority level will have priority.

High level priority alarms

Sound : Short-Short-Short-Long, 1 second pause, Short-Short-Short-Long, 10 second pause, new cycle

Light: Red Led

Error code	Brief description of the high level alarm
11	Plateau pressure < 2cm H ₂ O at the third cycle (Patient disconnection)
12	Plateau pressure is not reached (absolute difference > 20% in absolute value) from the third respiratory cycle
13	Battery weak voltage 24.0V
14	PEEP target is not reached (absolute difference > 2cmH ₂ O) during the third respiratory cycle
17	Peak pressure > 80 cm H ₂ O

Medium level priority alarms

Sound : Long-Long, 20 second pause, new cycle

Light: Blinking Yellow Led

Error code	Brief description of Medium level alarms
21	Battery weak voltage 24,6V
22	Plateau pressure is not reached (absolute difference > 20% in absolute value) until the second respiratory cycle
23	PEEP target is not reached (absolute difference > 2cmH ₂ O) until the second respiratory cycle
24	Plateau pressure < 2cm H ₂ O at the second cycle (Patient disconnection)

Low level priority alarms

Sound : Long, 20 second pause, new cycle

Light: Yellow Led

Error code	Brief description
31	Mains disconnected, switch to internal battery (battery voltage <27V)

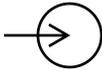
Quiet Mode

You can mute an alarm, by pressing the button 11 (see part 3, d - The control interface). The alarm will sound again after 120 seconds, if the cause is still there.

When an operator presses several times on mute button, the duration of silence is not added, the last press is used to begin for 120 sec mute.

Warning: During a mute of an alarm, if a new alarm occurs it will disable the mute and generate a sound.

Part 6. Symbols and marking on the device

	Catalogue number
	Serial number
	Electrical input
	Alternating current
	Type B applied part
	Refer to instruction manual
	General warning sign
	Do not re-use
	Do not throw in a conventional trash. Use a suitable recycling bin
	Earth (ground)
	Manufacturer
	Manufacturing Date

	ON/OFF
	Do not obstruct
	Do not obstruct
	Electrical risk

Part.7 system measures and accuracy

In accordance with ISO 80601-2-12 2011, the measurement uncertainty of the MakAir were performed with the the ASL 5000™ lung simulator, with the following technical specifications :

- Standard Tidal volumes: 2 mL - 2.5 L
- Volume uncertainty ranges:
 - up to 10 mL greater of $\pm 10\%$ of reading or 1mL
 - up to 100 mL greater of $\pm 2.5\%$ of reading or 2.5 mL
 - up to 1000 mL greater of $\pm 2\%$ of reading or 20 mL
- Functional Residual Capacity (FRC)200 – 1500 mL
- Spontaneous breathing capabilities
 - Passive patient: 0 breaths/min
 - Active patient: 3 - 150 breaths/minPeak flow280 L/min $\pm 10\%$ (t90Flow < 50 ms)
- Flow accuracy: +/- 2% of reading
- Resistance settings 3 - 500 cmH₂O/L/s (linear and parabolic resistor types)
- Resistance accuracy +/- 10% of reading
- Compliance settings0.5 - 250 mL/cmH₂O
- Compliance accuracy: +/- 5% of reading
- Small signal better than 15 Hz bandwidth (10 cm³ response - HF ventilation)
- Airway pressure uncertainty < 1% fso measurement
- Barometric pressure uncertainty < 1% (1kPa)

- Gas temperature uncertainty < 0.5 degrees C (20 – 45 degrees C)
- External Input/Output
- Digital output - TTL signals for inspiration/expiration, trigger pulse at beginning of patient effort, PWM signal for Chest Rise Module
- Analog output - 2 channels of configurable analog output,
-10V to 10V with scalable output range and offset for various real-time lung parameters
- Analog input - 2 channels of analog input, 0-10V single-ended or differential input with scalable software gain and offset to control real-time lung parameters
- Motion control
- High frequency (2 kHz) digital servo system and state-of-the-art brushless motor drive for smooth response to ventilator transients

Part 8. Glossary

Parameters glossary for Pressure Support device:

- Pip or Ppeak — Peak inspiratory pressure
- Pplat — Plateau pressure (airway)
- PEEP — Positive end-expiratory pressure, pressure created by a backpressure valve.
- I:E — Inspiratory:Expiratory ratio – constant 1:2 in Makair

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