

LIFE CONTROL®
DISPOSABLE MECHANICAL VENTILATOR

⚠ Disposable Mechanical Ventilator Instructions for Use with document code KT-731030-3E is valid for the devices in Table.1 below.

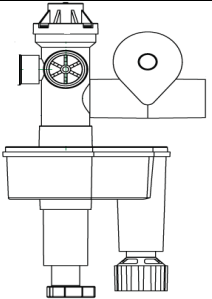
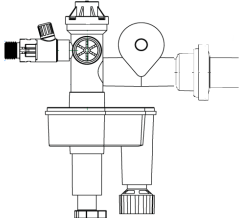
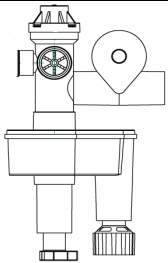
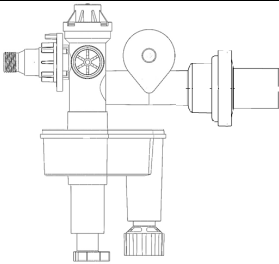
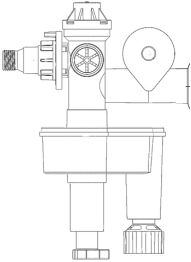
Reference Code	Device Description	Accessories						Weight	Pneumatic Visual	
		HME Filter	Catheter Mount	Oxygen Mixing Apparatus		Manometer	Profix® Fixing Device			
				Mixport	Oxygen Mixing Port					
MV112	Life Control® Mechanical Ventilator		√	√			√	√	90gr	
MXH112	Life Control® Mix Mechanical Ventilator with Mixport and HME filter	√	√				√	√	145gr	
MX112	Life Control® Mix Mechanical Ventilator with Mixport			√			√	√	123gr	
MREST	Life Control® Rest Mechanical Ventilator with Restport and HME filter	√				√	√	√	123gr	
MREST112	Life Control® Rest Mechanical Ventilator with Restport					√	√	√	105gr	

Table.1 Device Models

**LIFE CONTROL®
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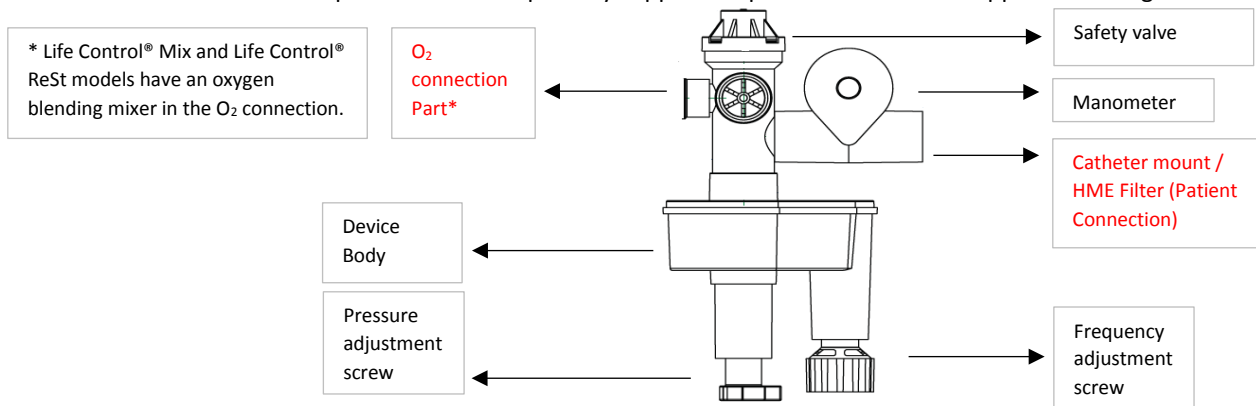
- ⚠ Please read these instructions for use carefully before using this device.
- ⚠ PLEASE DO NOT USE THE DEVICE WITHOUT READING THE INSTRUCTIONS MANUAL
- ⚠ THIS DEVICE IS USED BY MEDICAL PERSONNEL TRAINED IN CPR APPLICATIONS.
- ⚠ This device is intended for use under Emergency, Open Field Environment use and "CONTINUOUS USER SUPERVISION" in normal use. ⚠⚠
The patient should not be left alone while the device is operating.
- ⚠ The device must be disposed of in accordance with The Medical Waste Regulations.
- ⚠ An Oxygen supply is required to operate the Life Control® branded Disposable Mechanical Ventilator. The device will not operate without a compressed air supply. Without an air supply with a pressure range of 2,5 – 5,5 bar or an air supply with a flow rate of 8-40 L / min, the device will not operate. The diaphragm valve inside the device does not operate without oxygen pressure.

This instructions for use includes followings;

1. What is the Life Control®; what is it used for?
2. What should be considered before using?
3. What are the important information about Life Control®?
4. How to use Life Control®?
5. What are the indications of Life Control®?
6. What are the contraindications of Life Control®?
7. What are the complications of Life Control®?
8. What are the precautions, risks and advantages?
9. Operational features
10. Component summary information
11. Manufacturer information

1. What is the Life Control®; what is it used for

- Life Control® is a single-use, air-pressure operated mechanical ventilator (resuscitator)
- It is used to provide active respiratory support for patients who have stopped breathing

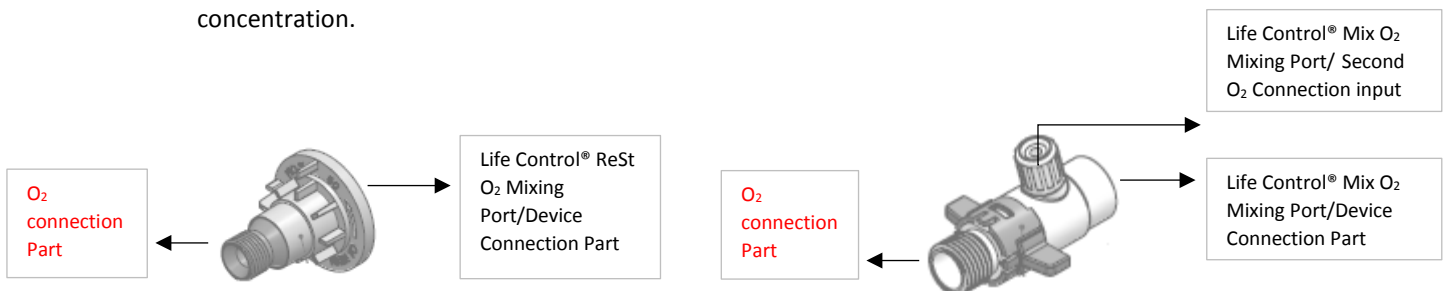


2. What should be considered before using

- This device can operate in 10-50 cmH₂O (± 5 cmH₂O) pressure range
- The device is set approximately to 25-30 cmH₂O factory setting.
- For intubated cases it is recommended to provide 35cmH₂O pressure. In intubated cases, pressure should be increased because the airway lengthens and shrinks.
- Life Control® IS A DISPOSABLE DEVICE AND IS NOT USED FOR A SECOND TIME.
- Disassembling the device for second-time use, washing its parts, disinfecting with various solutions, replacing its parts, may cause all values to change as well as harming the patient.
- Any section in Life Control® or its oxygen line should not be lubricated in any way. Contact of pure oxygen with oil causes flammable, caustic, explosive results.
- Please note that intense oxygen (O₂) is used during operation of the device. Do not approach with smoking, fire or any other substances/events which may react with O₂.
- The Excess pressure relief valve will be activated at , ≥ 55-60 cmH₂O.
- The device does not require any maintenance or calibration. Do not interfere with the device for technical repair, maintenance, etc. purposes for any reason, you may cause unintended consequences.
- Check the robustness of the Oxygen Connection Hose contained in the package.

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- If the frequency and pressure adjustment screws are turned further than specified indicators (threads become visible), it will cause the screws to come off and the spring inside to fall. Do not turn the pressure and frequency adjustment screws more than they should be.
- Make sure that the oxygen mixing port is at the desired concentration (50% -100%) for **Life Control® Mix** and **Life Control® ReSt** model mechanical ventilators.
If the device used is Life Control® Mix with reference code MXH112 and MX112;
- Make sure that the cap on the mixport is tightly closed.
- If you are going to make a standard single air supply connection on the mixport, make sure that you make the connection to the exposed main air supply port and not to the top port.
- If you are going to make a dual connection with MixPort (Main Input = Air Supply - Top Input = Oxygen Supply), make sure that the orange switch is at the 100% position to achieve Manual Oxygen concentration.



3. What are the important information about Life Control®?

- 3.1 Verify the cmH₂O pressure values with the manometer while the device is running.
- 3.2 For all interventions, ensure that the airway is clean and open. The mouth should be cleaned from foreign and unwanted materials such as secretion, vomit, glass fracture, tooth fracture, etc.
- 3.3 The values read through the pressure gauge are approximate values.
- 3.4 In the case of intervention with a mask, ensure that the mask airbag is properly sealed. If necessary, inflate the airbag
- 3.5 If necessary, you can aspirate without interrupting ventilation by opening the aspiration port on the catheter mount.
- 3.6 An audible vibration sound (disturbing) or a non-rhythm (vibrating) operation of the cmH₂O manometer while the device is running may be a sign of blockage in the airway.
- 3.7 If vomit or secretion from the patient has come to the filter and has damaged the filter, do not waste time with cleaning the device. In such a case, follow the steps below;
 - Remove the catheter mount, remove the filter and change it.
 - Connect the catheter mount to the cmH₂O manometer if the filter will not be replaced.

All this operations should be done within 20 seconds. Dispose of dirty filter according to medical waste regulations.
- 3.8 This device can be used in patients over 10 kg
- 3.9 If the device suddenly switches to half rhythm (unusual frequency) while the device continues to ventilate in a normal rhythm or the frequency cycle stops while the device continues to ventilate in a normal rhythm even though the airflow continues, in both cases, there may be a high risk of lung damage or single-lung deflation. Intervene by listening with a stethoscope and observing with the eye.
- 3.10 Modifying or tampering with any part of the device will void all warranties and terminates the manufacturer's responsibility

4. How to use Life Control® ?

For the device models of Life Control® ReSt and MV112:

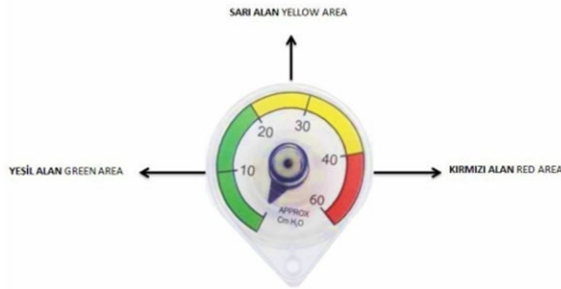
- 4.1 Life Control® is in the package. Open the packaging, the oxygen connection hose is connected to the device, connect the other end to the oxygen source.

Flow (L/min)	Inspiration Time (sec)					
	0.5	1	1.5	2	2.5	3
15	125	250	375	500	625	750
20	167	333	500	667	833	1000
25	208	417	625	833	1042	1250
30	250	500	750	1000	1250	1500
35	292	583	875	1167	1458	1750
40	333	667	1000	1333	1667	2000

Table.2 Estimated Tidal Volume (mL) Delivered at Various Flow (L/min) and Inspiratory Time (seconds)

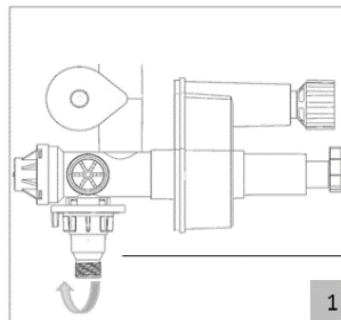
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- 4.2 Set desired flow (Q), adjust PIP pressure dial to obtain desired inspiratory time (t_{insp}) to attain tidal volume (TV = Q x t_{insp} see Tidal Volume Table 1). The gas flow, patient's lung compliance, and PIP settings controls the inspiratory time and tidal volume. Afterwards adjust the frequency adjustment screw to achieve the desired breathing rate.
- 4.3 Confirm the pressure values with the cmH₂O manometer. Manometer scales showing the pressure values and the color definition are as follows;

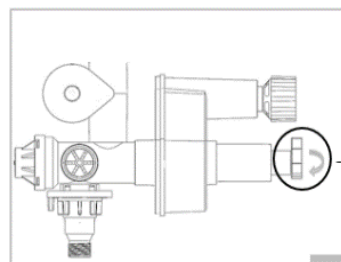


Visual.1 Manometer Scale

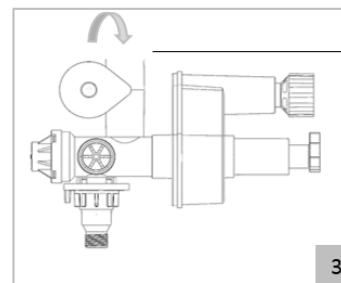
- 4.4 In intubated cases, connect the catheter mount directly to the intubation tube. In the case of mask use, training on "mask ventilation" techniques is required.
- 4.5 In both forms of ventilation, the mouth should be cleaned of foreign objects before ventilation (if there is any).
- 4.6 When ventilation starts, check the number of respirations on a time basis.
- 4.7 To achieve a particularly low frequency, you must lower the flow with the flowmeter. Low flows can be obtained by reducing the pressure by a "manometer with a pressure adjustment valve" that is connected to the oxygen supply.
- 4.8 When adjusting the frequency adjustment screw by turning clockwise (slower), the frequency may stop due to uncontrolled adjustment. Turn the frequency adjustment knob clockwise (faster) until it comes to the stable frequency to regain the pressure cycle
- 4.9 Whether chest movements are inspiratory and expiratory compatible and that ventilation continues smoothly can be confirmed by observing with the eye and hearing with the stethoscope.
- 4.10 If the patient vomits: Please read the 3. What are the important information about Life Control® /Item 3.7.
- 4.11 When Life Control® is connected to a 50 PSIG gas supply, it will automatically deliver oxygen at 40 L/min (667 mL/sec). The ideal pressure for operating the device is between 2,5 – 5,5 bar (~36-80 psig).
- 4.12 When Life Control® is connected to an oxygen source with an adjustable flow, it can operate comfortably within a pressure range of 10-50



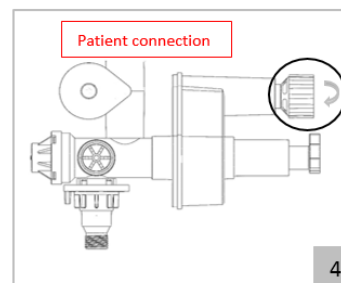
Connect the Oxygen Mixer to the oxygen connection hose. Connect the Oxygen Connection hose to the flow meter. Set the flow in the flow meter.



Adjust the pressure adjustment screw according to Table.1. The device is factory set to about 25-30 cmH₂O pressure.



If there is HME Filter, first HME filter, then Catheter Mount; If there is no HME Filter, connect the Catheter Mount directly to the Patient Connection Inlet.



Perform the Frequency adjustment with frequency adjustment screw.

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cmH₂O(±5 cmH₂O) and a flow rate of 8 l/min - 40 l/min.

- 4.13 When life Control® is taken from a horizontal position to a vertical position or from a vertical position to a horizontal position, the cmH₂O pressure may vary by a ratio of 1-3 due to increased or decreasing spring strength to the diaphragm.
- 4.14 Oxygen (O₂) mixer on Life Control® (Mix and ReSt models) can be converted to 50% (± 10%) or 100% (> 85%) oxygen transfer according to the oxygen concentration requirement.

On Life Control® Mix / MXH112 and MX112 reference code devices:

Implementation steps from 3.1 to 3.14 are valid. In addition, the Mixport oxygen mixing port optionally has two connection ports. The following should be considered when using these connections.

- *Mixport Standard Single Air Source Connection:* When the mixport is operated with a single air source at a 100% concentration, if the orange switch is turned and the 50% mode is adjusted, there will be changes in frequency due to the change of air flow rate and this may require a re-adjustment on the frequency. While the Mixport is operating in 50% mode, high cmH₂O pressure settings may create the need of increasing the flow rate.
- *Two Air Source Connections with MixPort:* Open the cap on the MixPort and connect the oxygen supply here.

When connecting the dual oxygen concentration control with MixPort, Mixport orange switch should be in 100% mode.

It is possible to adjust concentrations in the range of 21% to 85% by controlling the mixing ratio of the oxygen that is connected to the second connection point of the MixPort with the flowmeter or manometer connected to the oxygen source.

Manual oxygen concentration can be adjusted with the second connection port on the MixPort. While the pressure required for the main port is provided using the air source (21%), a 100% oxygen source is connected to the second connection port on the Life Control® MixPort. While the air source provides an oxygen concentration of about 21%, a 100% oxygen source connected to the MixPort is increased in the desired amount to provide an oxygen mixture to the air source connected to the device. Thus, all oxygen concentrations are obtained on the LifeControl Mix with MixPort at Min 21% to Max 85% (eg = 35%, 42%, 76.3%).

Fixing The Device To The Patient

There is a male fixing pin in the center of the round (circular) polyurethane foam stabilizer

On the Life Control® body, there is female version of the male pin on the foam

Connect the male pin on the foam with the female and hear the "click". Remove the transparent polyester on the foam bottom surface and adhere to the appropriate area on the patient.

5. What are the indications of Life Control® ?

- Patients in need of emergency, short term, constant flow, pressure cycled ventilatory support
- Patients unable to maintain an adequate acid-base status during unassisted ventilation

6. What are the contraindications of Life Control® ?

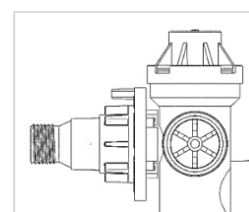
- Patients requiring greater than 60 cmH₂O PIP
- Patients below 10 kg body weight

7. What are the complications of Life Control®?


- Aspiration
- O₂ Cable disconnection
- Displacement of the intubation tube
- Device failure
- Vomiting
- Pneumothorax

8. What are the precautions, risks and advantages

8.1 Precautions



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- The patient should be monitored continuously by a medical staff with "CPR training" when connected to the device. The patient should not be left alone.
- Life Control® is a resuscitation management system and is not an automatic ventilation system.  to leave the patient on its own.
- The additional inspiration valve on the Life Control® should never be switched off-closed or clogged, as the patient may request additional air.
- Positive End Expiratory Pressure (PEEP) is programmed into the device and is equal to 1/5 of the PIP value and is between 2 and 10 cmH₂O (±1 cmH₂O).
- If the device is used with an oxygen cylinder, the operating time of the device can be adjusted by the oxygen flow rate so that the oxygen in the cylinder is sufficient to reach the hospital.
- The average working time of a 625-liter fully charged oxygen cylinder is calculated as follows;

Additional
Inspiration
Valve

Adjusted Flow Rate	Liter/minute	15	20	25	30	35	40
Average Working Time	Minute	40	30	25	22	18	16

8.2 Risks

- Re-use of a single-use device may put the patient at risk.
- Failure to follow the patient's respiratory rate while the device is being used.
- Leaving the patient alone when using the device.
- Failure to follow the oxygen level in the patient's blood.
- Chemical and physical properties are not taken into consideration in the selection of materials used in gas transmission.
- The use of materials that can be drained from the parts during the use of the device can create health risks to the patient.
- Sharp or pointy edges that can be found on the device and the materials used in gas transmission, can cause harm to patients, users and third parties.
- Possibility of finding toxic effects of materials reacting with gases.
- The user cannot observe the device mechanism.
- The parts of the device are not fully compatible.
- When the device is contaminated with secretion or vomit during use, it takes more than 20 seconds to clean and return to normal operation.
- Missing and / or insufficient information on label and the instructions for use of the device
- Biological contamination of the device due to environmental factors
- Inadequate ventilation formation due to a non-fit oxygen mask
- Central Medical Gas System* is inadequate or malfunctioning

8.3 Advantages

- The device is disposable, so there is no risk of cross-contamination.
- It is light and easy to use.
- The device can be used as a transport ventilator.
- The device is used for resuscitation and short-term ventilation support.
- It can be used safely with MR.
- Device detects spontaneous breathing.
- The device allows cardiac massage during ventilation.
- The device can be operated in 1:1 to 1:3 I/E range.
- The device is PEEP sensitive.
- Ventilation pressure can be monitored where it reaches the patient.
- Offers 50% - 100% oxygen transfer option for Life Control® Mix and Life Control® ReSt models.

9. Operational features

Patient Weight : 10 kg and above
 Number of breaths per minute : 10 – 60


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I/E Ratio	: 1/1 – 1/3
Adjustable Peak Pressure Range	: 10 - 50 cm H ₂ O (±5 cmH ₂ O)
PEEP Value (1/5 of PIP)	: 2 - 10 cmH ₂ O (±1 cmH ₂ O)
Dead Space	: 4 +/- 3 ml
Pressure Safety Valve Audible Alarm	: ≥ 55-60 cmH ₂ O
Inspiratory Resistance	: 3 ± 1 cmH ₂ O / liter/second
Expiratory Resistance	: 3 ± 1 cmH ₂ O / liter/second
Operating Environment Temperature	: -18 °C / +50 °C
Storage Environment Temperature	: -40 °C - +60 °C
Pressure Input Range	: 2,5 – 5,5 bar
Oxygen Connection	: DISS Gas connection
Patient Connector	: Corresponding to connector Male Ø22mm - Female Ø15mm connector
Device Dimensions	: 18 x 10 x 6 cm
Oxygen Concentration	: %50 - %100
Manometer Accuracy	: ±3cmH ₂ O below 15cmH ₂ O ±5cmH ₂ O above 15cmH ₂ O

10. Component summary information

- Mechanical Ventilator is a pressure-operated device that is categorized as a non-sterile disposable device. The HME filter included in the device is made of material with a 99.997% retaining property
- The pressure gauge in the device shows the pressure values in 10 units increments (except 40-60 cmH₂O). (Visual.1)
- The fixing apparatus ProFix® included in the package, which has direct contact with the patient and which ensures that the Life Control® Mechanical Ventilator device remains on the patient during transportation, is made of adhesive medical foam material.
- The length of the catheter mount included in the package is 15 cm.
- The length of the oxygen hose included in the package is 3 m.

11. Manufacturer information

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Warehouse Address:

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EC REP Emergo Europe:
Prinsessegracht 20, 2514 AP The Hague, **The Netherlands.**

Devices belonging to the Life Control® brand are not manufactured from human blood or human plasma using human or animal tissue cells.

Devices belonging to the Life Control® brand do not contain phthalates.

Devices belonging to the Life Control® brand are drug-free and not supplied with the drug.

Devices belonging to the Life Control® brand are not manufactured from substances in the carcinogenic, mutagenic or toxic (CMR) category.

IPX4 IPX4 is the International Protection code, which shows that the device is protected from splashing water from any angle. The device protection code of the Life Control® Mechanical Ventilator device according to ISO 60529 standard is IPX4.



Consult instructions for use



Keep dry



Do not re-use



Humidity limitation



Electronic instruction for use (eIFU)
www.egemen.com.tr



Keep away from sunlight



Use-by date



Temperature limit



Batch code



Non-sterile



Serial Number



Do not use if package is damaged



INSTRUCTION FOR USE



LIFE CONTROL®
DISPOSABLE MECHANICAL VENTILATOR



Does not contain DEHP.