






ES Instrucciones de uso de Ventrain® FR Mode d'emploi de Ventrain®
I Instructions for use Ventrain® DE Bedienungsanleitung für Ventrain®
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Instruction for use Ventrain®

Name Ventinova Medical B.V.



Product name	> ventrain <	Single Use	
Product number	REF	Phthalates present	
Sterile	STERILE EO	Consult instructions for use	

Read these instructions for use prior to using the product. Refer to the product website www.ventinovamedical.com/products/ventrain for further information and training materials related to this product.

Operator

Device specific training is mandatory before using Ventrain®. Ventrain® is intended to be applied by, or under supervision of, medical personnel trained and experienced in airway management.

Intended use

Ventrain® is intended to be used for ventilation through a small bore lumen in patients with a difficult airway where conventional ventilation by mask and/or a large-bore endotracheal tube is not preferred.

Patient group

All patients, however for patients with body mass < 40 kg (e.g. children, infants) Ventrain® should only be used for lifesaving maneuvers.

Contraindications

Unknown

Potential complications

- barotrauma
- aspiration
- pneumomediastinum
- emphysema

Product description

- Ventrain® is a manually controlled, single-use difficult airway ventilator to be used with a transtracheal or endotracheal small lumen catheter. It consists of a handheld with tubing for connection to a flow meter on one end and a male luer connector for the catheter on the other end.
- Ventrain® is intended for single use.
- The dead space volume of Ventrain® is 5 mL.

Packaging

- The packaging contains Ventrain®.
- It is packed in a peel-open package sterilized by use of ethylene oxide.
- Ventrain® is sterile as long as the packaging is undamaged and unopened. Do not use Ventrain® if any doubt exists on the integrity of the packaging.

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- Store the packaged product in a dry place at room temperature.
- Avoid extended exposure to light.

Required additional material

- High pressure oxygen supply (3,5 – 5,0 bar, 100%):
 - medical oxygen cylinder with flow regulator. A full 2 liter cylinder generally contains 400 l oxygen (uncompressed); at a flow of 15 L/min this provides for 20 minutes of Ventrain® ventilation.
 - medical oxygen supply system with pressure compensated flow regulator with a maximum flow between 10 and 15 L/min.
- Suitable catheter (Table 1)

Table 1: attainable minute volumes and proposed I:E ratios for recommended catheter dimensions in different situations.

patient group/situation	catheter type	set inspiration flow (L/min)	catheter ID (mm)	length (cm)	I : E ratio	minute volume (L/min)
healthy adult patient	transtracheal	15	2.0	7	1 : 1.1	7
	endotracheal	15	2.3	40	1 : 0.9	7.5
		15	3.0	100	1 : 1.0	7
paediatric patient		6	1.6	40	1 : 1.7	2
collapsed adult lung	bronchial blocker	6	1.7	78	1 : 2.5	1.5

Test conditions: Values in table 1 were obtained with the ASL 5000, Ingmar Medical Ltd. An inspiration time of 2.5 seconds and values for compliance and resistance, i.e. $C = 50$ mL/mbar, $R = 10$ mbar/(L.s) were used for the tests with set inspiration flow of 15 L/min, resulting in a tidal volume of 600 mL. An inspiration time of 0.5 seconds and values for compliance and resistance, i.e. $C = 10$ mL/mbar, $R = 32$ mbar/(L.s) were used for the tests with set inspiration flow of 6 L/min, resulting in a tidal volume of 50 mL. For the collapsed lung situation values for compliance and resistance, i.e. $C = 100$ mL/mbar, $R = 10$ mbar/(L.s) were used in the test.

Caution! The values for I:E ratio and minute volume mentioned in Table 1 are based on simulations with a completely obstructed upper airway. In (partially) open upper airway situations, Ventrain® ventilation and oxygenation may be less efficient, due to the bypass flow through the upper trachea.

Optional additional material

Side stream capnometer and tubing with male Luer connector.

Caution! In case of an obstruction in the respiratory circuit, the resulting high pressure may damage the capnometer

Warnings and precautions

- Before use of Ventrain®, read these instructions for use carefully. Incorrect use of Ventrain® can be hazardous to the patient.
- Ventrain® is designed to be used in combination with recommended catheter dimensions (Table 1). Use of Ventrain® with other catheter dimensions may result in insufficient ventilation.
- Ventrain® is designed for continuous manual control. Holding Ventrain® too long in the inspiration, expiration or equilibration position may lead respectively to overpressure, negative pressure

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or lack of ventilation, resulting in harm to the patient (refer to 'potential complications').

- Don't use Ventrain® longer than 20 minutes. Use of Ventrain® longer than 20 minutes may result in dehydration based complications.
- Do not connect Ventrain® directly to the flow output of an anesthesia machine; flow output may be too limited and the flow regulator may not be pressure compensated.
- Use of Ventrain® together with a high oxygen concentration in a hazardous or explosive atmosphere can be dangerous.
- Use of Ventrain® nearby flames or smoke is dangerous.
- For single use only. Do not reuse, reprocess or re-sterilize. Reuse, reprocessing or re-sterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death.
- As the system gets pressurized, be sure that tight and pressure-resistant connections are used.
- In case of using a side stream capnometer, the capnogram should only be used to check proper positioning of the catheter and/or to evaluate the relative trend in EtCO₂ concentration (applicable for closed or obstructed airways, not for (half)-open airways).
- Be aware that in the expiration phase debris may exit the thumb-hole. Therefore, always point the thumb-hole away from user and bystanders or cover Ventrain during use without obstructing the holes.

Operating instructions



Figure 1: Views on Ventrain®

Ⓟ = thumb hole, Ⓠ = index finger hole

- 1 Pre-oxygenate the patient (if possible)
- 2 When no suitable ventilation lumen is intubated, insert a catheter according to its user instructions.
- 3 Connect the oxygen tubing of Ventrain® to the oxygen supply.
- 4 To confirm correct positioning of the catheter connect capnometer to T-Piece of Ventrain® (refer to point 10), when using no capnometer, make sure the cap is tightened.
- 5 Open the oxygen supply and set a relatively low initial flow (rule of thumb: start with 1 L/min per year of age with a minimum of 2 L/min and a maximum of 15 L/min). In case of ventilation of a collapsed adult lung use an initial flow of 4 L/min.
- 6 Hold Ventrain® in the equilibration position as shown in Figure 2: no oxygen is flowing into the lungs and almost no gas is sucked out.

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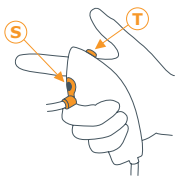


Figure 2:
Equilibration

- 7 Attach the male luer connector of Ventrain® to the catheter.
- 8 Make a choice whether to start Ventrain® ventilation with inspiration or expiration. Expiration is started by securely closing the index finger hole **S**. Inspiration is started by closing both the index finger hole **S** and thumb hole **T**. Both modes are shown in Figure 3 and 4.
- 9 Alternately open (assisted expiration) and close (inspiration) the thumb hole **T** to apply ventilation, while keeping the index finger hole **S** closed, as shown in Figure 3 and 4. Use an initial inspiration time and an expiration time of 1-2 seconds (depending on aimed tidal volume, see Table 2) each in case of adults. For paediatric situations or collapsed lung ventilation use an inspiration time and an expiration time of 0.5 s each.

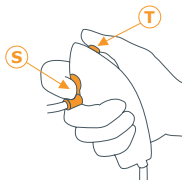


Figure 3:
Inspiration

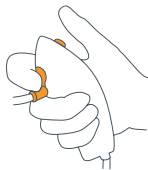


Figure 4:
Expiration

- 10 To monitor the end tidal CO₂ trend, connect capnometer to T-Piece inspirate to PEAK and use equilibration phase until the plateau is reached in the capnometer. Disconnect again and close the cap of the T-Piece.
- 11 If necessary, slowly increase flow to obtain higher minute volumes.
- 12 Make sure the chest is able to make excursions upwards and downwards. Adjust inspiration and expiration times based on closely observation of the chest excursions of the patient. Ensure inspiration and expiration volumes are in balance. In case of any doubt regarding lung pressure, use the equilibration position, as shown in Figure 2, for at least 5 seconds.
- 13 In case of an (almost) completely obstructed airway, use the equilibrium position of Ventrain®, after each 5 ventilation cycles, to equilibrate the thorax excursion avoiding excessive positive or negative pressure in the lungs.

flow setting (L/min)	tidal volume (mL) after 1 second inspiration
2	33
4	67
6	100
10	167
12	200
15	250

Table 2: Tidal volume at different inspiratory flow settings

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Caution! Always observe the patient's chest excursions closely during ventilation and adjust the time for inspiration and expiration where needed or use the equilibration position. In case of abdominal movement immediate re-access position of catheter and re-evaluate SaO₂ status.

Caution! Tidal and minute volumes are depending on the flow meter setting, the inspiration time, expiration time and patient characteristics. For guidelines see Table 2.

Caution! For low compliance situations (e.g. paediatric cases or collapsed lung (closed chest) ventilation) and/or catheter < 2 mm inner diameter, apply a flow of max. 6 L/min to avoid excessive pressure build-up in the oxygen tubing.

Caution! Use of the equilibration position results in fewer breaths per minute and, consequently, a lower respiratory minute volume.

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