PARAVENT PATe

High-frequency jet ventilator

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Features

- active inpulsion and expulsion modes (lungs cleaning)
- non-invasive as well as endotracheal applications
- possibility of ventilation frequency switching from conventional frequency to high-frequency (HF)
- controlled electronically (mains feed or internal reserve power supply)
- further possibility to work as pneumatic device
- ventilate full spectrum of patients on single device

Safety features

The construction of MNJI ensures the principle of so called physical safety feature, that means that instantaneous insuflation pressure and topical nozzle in MNJI corresponds to maximum ventilation pressure of MNJI which represents maximum reachable level of over-pressure in lungs, even in case of zero airflow capacity of lungs (e.g. in case of permanent inspiration caused by possible break-down of ventilator).

Along with this safety feature, the ventilator is equipped with pneumatic system for continuous monitoring and evaluation of pressure at the end of endo-tracheal tube which enables realisation of further safety element – over-pressure safety device. The over-pressure safety device automatically stops the ventilation process, resp. disconnects the air supply to the insuflation catheter once the pressure limit of 5 kPa is over-passed, that subsequently recalls the acoustic and visual alarm (red LED in ALARM field). The fall of pressure in endo-tracheal tube below the chosen level automatically initiates the further inspiration. The acoustic and visual alarm is realized from the instant of over-passing pressure limit of 5 kPa until the beginning of further inspiration. Measuring catheter is permanently rinsed out by a small flow. In case the measuring catheter is clogged, the pressure within the catheter accumulates and once it surpasses the pressure limit of 5 kPa, the appliance stops the ventilation and initiates the alarm.

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Technical specifications

Control Units	insufflation pressure PIN ventilation frequency F time ratio: TI: TE manual inspiration button
Alarms	exceeding pressure limits low level of back-up reserve
Supply pressure	min. 50 l/min. 1)12V DC (external adapter for 220 V AC / 12 V DC) 2) back-up reserve – 4x NiMH battery size AA (ensures 8 working hours when fully charged) 3) reserve source – pneumatic
Frequency	adjustable: 20 c/min ± 5 % 40 c/min ± 5 % 120 c/min ± 5 % 180 c/min ± 5 %
Time ratio Ti : Te	adjustable: 1:2 ± 5 % (inpulsion mode) 1: 1 ± 5 % 2: 1 ± 5 % (expulsion mode)
Cha	– 300 kPa min. monitored by pressure gauge on the front panel
Max. ventilation power	for insuflation pressure is 160 kPa: - nozzle No. I max. 2,5 kPa - nozzle No. I I max. 4,5 kPa - nozzle No. I II max. 7,0 kPa - expiration nozzle max. 4,0 kPa at
Pressure limit	fixed: 5 kPa ± 5 % (static), reaction time max. 120 ms
Minute Volume / Tidal Volume	based on frequency and other parameters – use Brychta's Ventilation Equation and refer to Paravent User's manual/ Quick Reference Guide
Ventilation application	1) intubational – endotracheal, transtracheal 2) by mask – non-invasive ventilation
Pressure gauge of ventilation	- whole course of breathing cycle (Paw) for frequency of 20 and 40 c/min - peak pressure at the end of inspiration (PIP) for frequency of 120 and 180 c/min
Dimensions W, H, L	235 x 100 x 250 mm
Weight	4,3 kg
Noise	max. 74 dB
Working conditions	temperature: –10 až + 40 °C humidity max. 80 %

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Classification

1. Type of protection against electricity accident:
- external adapter 230V AC / 12V DC (SZ 12/2/100 from the company Enco) is of the class II
- when mains feeding by external adapter 230V AC / 12V DC the whole machine is of the class II B as per ČSN EN60601-1
- when using NiMH batteries as a reserve power supply, the machine is using
- internal power supply

2. Level of protection against electricity accident: machine is of the type B as per ČSN EN 60601-1

3. Level of protection against harmful penetration of water:
external adapter 230V AC / 12V DC (SZ 12/2/100 and the machine itself are protected against leaking water (IPX1) as per ČSN EN 60601-1

4. Working mode: Machine can be used in permanent operation

5. Protection against the danger of inflammation of flammable anaesthetic mixtures: The machine must not be used in environment where flammable anaesthetic mixtures are present as per ČSN EN 60601-1.

Certification

The Electrotechnical Testing Institute Certification Body No. 3004 for certification of management systems, acredited by the Czech Acreditation Institute p. p. s in accordance with ČSN EN ISO/ IEC 17021-1 grants the certificates for the Quality Management System in accordance with:

- EN ISO 13485: 2015
- ČSN EN ISO 9001:2016

See the certificates in the attachments.

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Unique technology

PARAVENT PAT is a high frequency jet ventilator designed for the short term use for urgent medicine, including the possibility to ventilate in conventional frequencies. It's well appropriated for urgent and critical care applications and transportation as well as other uses in specific medicial areas. This unique technology, originated in former Czechoslovakia, won three gold, worldknown, awards (Japan, Netherlands, Czech Republic).

High Frequency Lung Ventilation

HFV is artificial lung ventilation where supra-physiologic frequencies of ventilation cycles are being used (frequencies exceeding 60 – 80 cycles/min; in compare, spontaneous breathing frequencies are 10 – 40 breaths/min in adults and up to 60/min in small children)
divided into several groups (according to frequencies and type of technology):
1. HFPPV (High frequency positive pressure ventilation), freq. from 60 to 200 b/min.
2. HFJV (High frequency jet ventilation), freq. applied: 80 – 600 b/min
3. HFO (High frequency oscillation), freq. exceeding 600 b/min.

Advantages

Distinguishing features from other respiratory products (HF ventilators as well as conventional ventilators) are:

- true advantages of high-frequency jet ventilation (higher oxygenation, no interference with spontaneous breathing, etc.)
- introduction of Inpulsion and Expulsion effects (lung lavage)
- ventilation of full weight and age spectrum of patients on the single ventilators (from neonatal to over-weight adults)
- ventilation over a longer distance (up to 10 – 11 m)
- possibility to ventilate more than two patients on single device

The technology is based on more than 20 years of experience and testing results.

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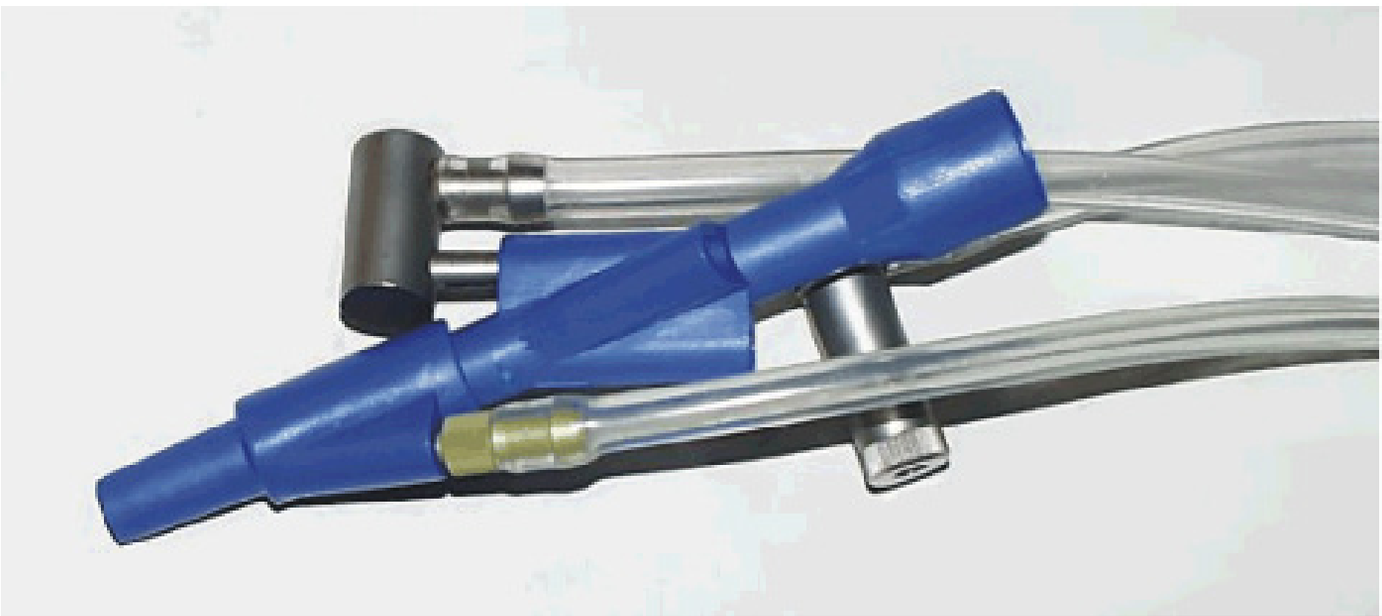
of HFJV research on clinical and experimental working sites in Czech republic and Slovakia

Multi Nozzle Jet Injector (MNJI)

The device is based on the principle of Multi Nozzle Jet Injector (MNJI) that functions as the generator of constant pressure and originates the jet stream. The set of MNJI allows safe and comparable ventilation of all weight and age spectrum of patients including new-born babies.



The set of MNJIs contains 8 different sizes of MNJI adapted to the endotracheal tubes of diameters from 2,5 to 10,5 mm (i.e. MNJI no. 7 fits ET tube no. 7 ± 0,5 sizes). Each MNJI is equipped with three inspiration and one expiration nozzles (jets) and measuring connector sized according to particular MNJI. The ventilator's performance can be change in the range of 100% by changing the inspiration nozzle (I, II, III) without a need to adjust insuflation pressure Pin.

The Set of MNJIs allows:

- safe and comparable ventilation of all weight and age spectrum of patients, including new-born babies (600 grams (premature babies) up to 140 kg (adults)
- application of the expulsion and inpulsion effects

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Application ranges

1. Ventilation in critical cases model -urgent ventilation

Target Users:

Emergency Medical Service (EMS), Cardio Pulmonary Resuscitation (CPR), Delivery Room, Rescuers, standby ventilation in the case of electric current damp or ventilator failure in the critical care unit etc. - generally in cases that require instantaneous support.

Important advantages:

- acknowledged contribution of HFJV as such
- implicity and safety of operations with Paravent (performance determined by the selection of the suitable endotrachael tube (ETT) and corresponding MNJI and corresponds with the weight category of the patient)
- minimized personnel attendance in ventilator set-up
- also advantageous ventilation with untight ETT

2. Transportation

Target Users:

Primary transportation requiring ventilation support: EMS

Secondary transportation: Critical Care Unit (CCU), Intensive Care Unit (ICU), Pathological New-born Unit (PNU) (secondary transportation including inside oneroentgenology, computer tomography examination, operating theatre, etc.)

Important advantages:

- the possibility of spontaneous ventilation, respectively hard ventilation with superposition of HFJV on spontaneous breathing
- patient's depression and dependency on ventilator is decreased

- non-existence of interference with ventilator
- brings down the necessity of intubation and relaxation

3. Airways cleaning/ lavage of lungs/ Tracheo-bronchial Toilette

Of significant use the possibility of longer manipulation in the airways without necessity to interrupt ventilation especially in the case of limiting hypoxy status. The inpulsion (1:2) and expulsion (2:1) modes create inpulsion and expulsion effects that can be utilized for :

- Lung cleaning / tracheo-bronchial toilette
- Application of medical solutions (e.g. surfactant, mukolytics, therapeutic aerosols, local anaesthetics, catecholamines, etc.)
- Programmable movement / extraction of foreign objects or obstructions in airways (solid, semi-solid or liquid)

Target Users:

CCU, delivery room, PNU, ICU during conventational ventilation for lavage, mucolytics instalation, suction etc.

Important advantages:
Possibility of realization of inpulsion and expulsion mode of HFJV during conventional ventilation - predominant contributions of HFJV for clinical practice

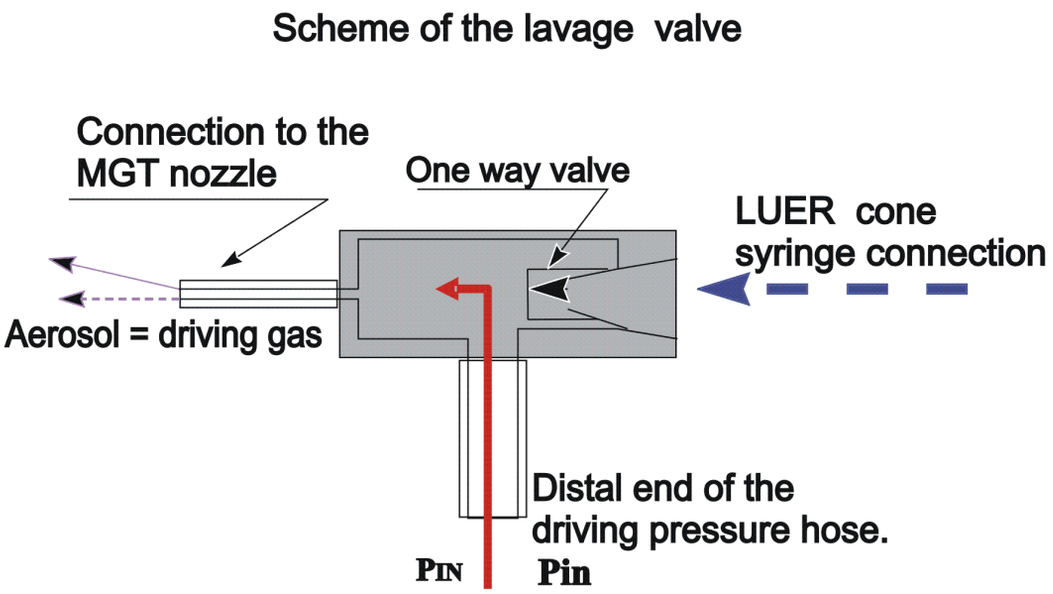
Inpulsion mode

- for application of mukolytics, therapeutic aerosols, local anaesthetics, catecholamines etc. with the use of lavage valve

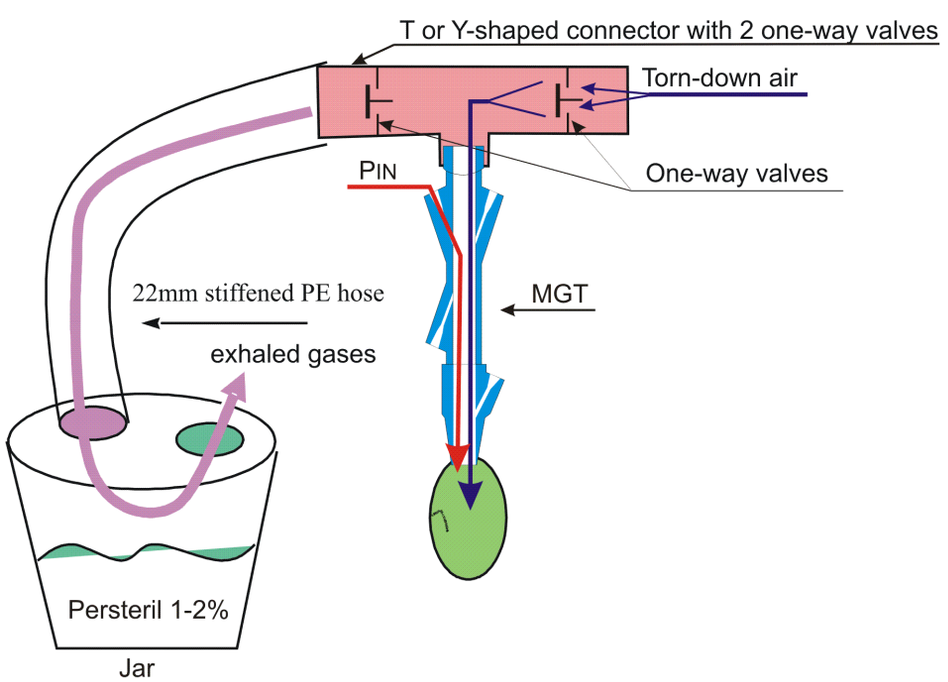
Expulsion mode

- for mobilization / extraction of expectorations, foreign body (dirt, vomit, etc.) or other obstructions from distal part of breathing ways (accumulated at ET tube from where drained without traumatization of mucous => very good results in chronic obstructive bronchopulmonal disease, massive aspiration, atelectation -> significantly reduced time need for ventilation, lower mortality of critical care patients

Example of inpulsion and expulsion modes



Expulsion set (aerosol infection preventing) connection scheme .



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4. Critical care and intensive care model

Target Users:

Critical Care Unit (CCU), Intensive Care Unit (ICU), Pathological New-born Unit (PNU) or Pediatric ICU (PICU)

Important advantages:

- airways ventilation analog to periodical respiration „ambuing“
- short-term hyperventilation in the case of intracranial hypertension with significant decreasing of intracranial pressure
- certain hypoxy status cases not reacting to conventional ventilation manoeuvres
- replacing of ventilators and breathing circuits, etc.

5. Mask ventilation model

Target Users:

Critical Care Unit (CCU), Intensive Care Unit (ICU), Pathological New-born Unit (PNU)

In clinical practice, HFJV-M is a nearly ideal way to solve ventilatory problems in cardiac and non-cardiac lung edema, used in cases of re–curarisation in the post-operative period, in chest trauma, partial respiratory insufficiency, replacing of ventilators and breathing circuits, airways ventilation analog to periodical respiration „ambuing“, certain hypoxy status cases not reacting to conventional ventilation manoeuvres, etc.

Important advantages:

- a noninvasive ventilatory support
- quick application and low aggressivity => no need for sedation or anaesthesia for intubation
- doesn’t interfere with spontaneous breathing (doesn’t exclude patient’s cooperation)
- HFJV-M significantly decreases ventilation work => crucial in any acute respiratory failure situations

6. Bronchoscopy / Jet relief bronchography

Bronchoscopy is:

- modification of bronchoscope in a way that MNJI is attached to the proximal end of the tubus (ventilation during the whole procedure)
- intubation using a thinner ET tube (size 4-5) without a cuff (enough space for flexible bronchoscope)
- intubation with larger ET tube and MNJI -> flexible bronchoscope introduced through MNJI and ET tube into the bronchial tree

Jet relief bronchography is:

- instillation of contrast substance (radio–opaque medium) via inpulsion mode (create fine relief filling of airways)

Target Users:

Critical Care Unit (CCU), Intensive Care Unit (ICU), Pathological New-born Unit (PNU), Roentgenology

Important advantages:

- minimizes amount of the instilled contrast substance and possible complications
- lavage possibility in inpulsion and expulsion modes

7. Special applications in otolaryngologic and thorax surgery

Bi-bronchial or selective synchronous lungs ventilation

- there is a wide range of lung pathologies affecting lungs unilaterally (pneumonia, contusion, haematoma etc.) => require selective lung ventilation the way that healthy and impaired lungs will be ventilated differently in accordance with their actual status
- possibility of selective ventilation of particular bronchi during broncho-pulmonary surgery

For otolaryngologic surgery in the larynx area with specially adapted ventilation instrumentation for the subglottic and supraglottic ventilation.

- cleanliness of the operational area
- comfort of operator and patient
- increases ventilation safety during the action

For special lung surgery possibility of synchronous selective ventilation for operations for open bronchus, lung resection, etc.

8. HFJV during special examination in Nuclear magnetic resonant tunnels

The ventilation issue: all parts of ventilation circuit must be non-magnetic (ventilation with ventilation tubes long as much as 10m)

HFJV by Paravent ventilator offers an effective resolve by use of 10 – 11 m long hose and MNJI (non-magnetic) without the risk of significant change of parameters of the fictive circuit

9. Other special applications (examples of critical cases)

Application after being landed-up, in Cases of Decreased Compliance of the Rib-cage, in Ichtyosis, etc.

Ventilation of patients unable to breathe because of extreme pressure applied to their thorax and abdomen (application of conventional ventilation in these situations ineffective (no space for chest and diaphragm movements)

- HFJV proves very effective, ensures satisfactory gas exchange in majority of cases enabling bringing off the victim

Solution in Upper Airways Critical Obstruction

- gain life saving time necessary for the preparation of a proper tracheostomy or other intervention
- as an alternative solution in extreme emergency cases, an application of a special bi-lumen needle advanced into trachea with following trans-tracheal HFJV

Attachments:

ELEKTROTECHNICKÝ ZKUŠEBNÍ ÚSTAV

ELECTROTECHNICAL TESTING INSTITUTE - CZECH REPUBLIC
ELEKTROTECHNISCHE PRUFANSTALT - TSCHECHISCHE REPUBLIK
INSTITUT ELECTROTECHNIQUE D'ESSAIS - REPUBLIQUE TCHEQUE
ЭЛЕКТРОТЕХНИЧЕСКИЙ ИСПЫТАТЕЛЬНЫЙ ИНСТИТУТ - ЧЕШСКАЯ РЕСПУБЛИКА

Pod lisem 129/2, 171 02 Praha 8 - Troja

The Electrotechnical Testing Institute Certification Body No. 3004 for certification of management systems, accredited by the Czech Accreditation Institute, o.p.s. in accordance with ČSN EN ISO/IEC 17021-1, grants the

CERTIFICATE

No.: 8180090

for the Quality Management System in accordance with

EN ISO 13485:2015

to the Firm

ELMET, spol. s r.o.

Nádražní 889, 535 01 Přelouč, Czech Republic

in localities: -

because it ascertained that the Quality Management System of the Firm in localities and processes:

Production and service of active medical devices - general active medical devices

complies with all requirements of the above mentioned Standard documented by the Report No.: 801566-01 of 22.08.2018

The validity of the Certificate is limited till: 30 08 2021

The Certified Organization is subject to annual check-ups carried out by the Certification Body. Any change within the organization concerning the certification shall be followed up and approved by the Electrotechnical Testing Institute. The validity of this Certificate may be suspended or cancelled in the event of non-compliance with the Standard on the basis of which the Certificate was issued.

Certificate granted: 31 08 2018

Prague

Mgr. Miroslav Sedláček
Head of Certification Body

elektrotechnický zkušební ústav ezú -1- Pod lisem 129/2, 171 02 Praha 8 - Troja

Stamp

CER/8180090

801566-01

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ELECTROTECHNICAL TESTING INSTITUTE - CZECH REPUBLIC
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Pod lisem 129/2, 171 02 Praha 8 - Troja

Certifikační orgán EZÚ pro certifikaci systémů managementu č. 3004, akreditovaný Českým institutem pro akreditaci, o.p.s. podle ČSN EN ISO/IEC 17021-1, uděluje

CERTIFIKÁT

č.: 8180091

na systém managementu kvality podle

ČSN EN ISO 9001:2016

firmě

ELMET, spol. s r.o.

Nádražní 889, 535 01 Přelouč, Česká republika

v lokalitách: -

neboť shledal, že její systém managementu kvality v lokalitách a procesech:

Elektrovýroba, kovovýroba

splňuje všechny požadavky výše uvedené normy, což je doloženo zprávou č.: 801566-02 ze dne 28.08.2018

Platnost certifikátu je omezena do: 30.08.2021

Certifikovaná organizace podléhá každoroční kontrole certifikačního orgánu. Každá změna v organizaci, týkající se certifikace, podléhá evidenci a schválení Elektrotechnickým zkušebním ústavem. Platnost tohoto certifikátu může být pozastavena nebo zrušena v případě porušení shody s normou, na základě které byl vystaven.

Certifikát udělen: 31.08.2018

V Praze dne

Mgr. Miroslav Sedláček
Vedoucí certifikačního orgánu

elektrotechnický zkušební ústav ezú -1- Pod lisem 129/2, 171 02 Praha 8 - Troja
razítko

CER/8180091

801566-02

AEN MEDICAL

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