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Solutions for Lung Failure

iLA Membrane Ventilator®

Pocket guide for clinical use

REMARK

Waiting too long to initiate certain medical therapies can significantly reduce the chances for a successful outcome. This may also result in the need for additional financial and/or human resources to achieve the same outcome. But when is the right time to implement treatment with the iLA Membrane Ventilator®?

CLINICAL EXPERIENCE

This pocket guide contains a broad range of practical information, ideas and tips that have been developed by users of the iLA Membrane Ventilator® and that have proven themselves useful over the past several years. The indications and treatment algorithms presented here are based on published scientific works and clinically implemented treatment protocols. The modifications are based on clinical experiences and should not be taken as specific recommendations for treatment. They are instead intended to serve as a tool in daily clinical practice to help define the moment for a given patient when the initiation of an iLA Membrane Ventilator® therapy could be expected to help achieve a successful treatment outcome.

24/7 CLINICAL SUPPORT

This handbook is not intended to replace user training at the Novalung Academy™ or the inservice training provided by our 24/7 Clinical Support team in Germany and by Novalung-trained Clinical Support Specialists around the world. The Novalung 24/7 Clinical Support team consists of highly trained intensive-care nurses who are available to support clinical activities in person or around-the-clock by telephone. Members of our 24/7 Clinical Support team and/or Novalung-trained Clinical Support Specialists are always available to attend and support the first applications of the iLA Membrane Ventilator®.

Call us. Day or night.
+49 69 1339 4115

NOVALUNG ACADEMY™

The Novalung Academy™ offers certified training courses in the specific handling and application of the iLA Membrane Ventilator®. Details on course content, dates, and registration are available online at: **www.novalung-academy.com**.

INDICATIONS

Lung healing as therapeutic target: The iLA Membrane Ventilator® is used to enable true lung protection, whereby adequate blood gases are used as control parameters not as therapeutic targets *per se*. Examples are: Exacerbated COPD, (difficult) Weaning, ARDS / ALI due to intra- or extrapulmonary causes.

Clinical Problem	Diagnostic Parameter	Function	Clinical Example
Undesirable hypercapnia	• Occurrence of undesirable »permissive« hypercapnia as an expression of the limitation of the invasiveness of ventilation.	• Reduction of $PaCO_2$	• Pneumonia • Fever • ALI, ARF • Primary or secondary ARDS
Non-permissive hypercapnia	• pH < 7.2	• Normalize pH	• ALI, ARF • Pneumonia • Primary or secondary ARDS
High airway pressure	• P_{aw}peak > 35 cmH_20. This value is still probably too high. A lower transpulmonary pressure below 15 cmH_20 would be preferable. • In individual cases the desired limit pressure can be considerably lower (pneumothorax, fistula).	• Reduction of airway pressure by reducing tidal volume (V_T).	• Pneumonia • Pneumothorax • Fistula • COPD • Exacerbated COPD • ALI, ARF • Primary or secondary ARDS
High tidal volumes	• V_T > 6 ml/kg IBW	• Reduction of V_T because lower minute volume is required.	• Pneumonia • Pneumothorax • Fistula • COPD • Exacerbated COPD • ALI, ARF • Primary or secondary ARDS

Clinical Problem	Diagnostic Parameter	Function	Clinical Example
Increased intracranial pressure	• CPP (= MAP-ICP) < 70 mmHg • ICP > 20 mmHg • Hypercapnia associated with intracranial processes	• Improvement of cerebral perfusion thanks to normocapnia. • Facilitation of »don't touch« therapy using less invasive respiratory parameters.	• Craniocerebral trauma • ICB • Neurosurgical intervention
Muscular exhaustion	• Rapid shallow breathing index (RSBI) • Neurological disturbance • Signs of exhaustion	• Reduction of work of breathing by lowering muscular ventilation.	• COPD • Asthma • Weaning • Weaning from longterm ventilation • Weaning in neuromuscular diseases • Critical care polyneuropathy • Non-invasive ventilation
Weaning	• Long weaning phase • Muscular exhaustion • Unsuccessful extubation	• Reduction of work of breathing by lowering muscular ventilation.	• COPD • Asthma • Weaning • Weaning from longterm ventilation • Weaning in neuromuscular diseases • Critical care polyneuropathy • Non-invasive ventilation
Avoid mechanical ventilation	• Pre-existing lung disease	• Reduction of work of breathing by lowering muscular ventilation. • Facilitation of non-invasive ventilation with reduced respiratory work and unhindered CO_2 elimination.	• COPD • Asthma • Non-invasive ventilation • Fibrosis • Preparation for lung transplantation • Post lung transplantation

VALI / VILI INDICATOR

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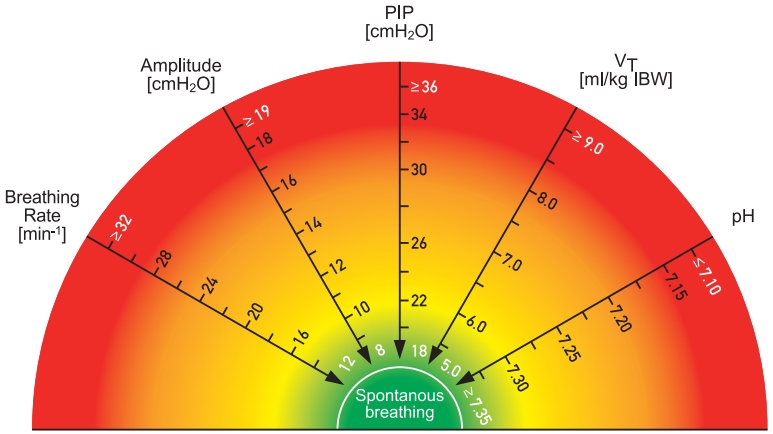

VALUES	ACTIVITIES
Green	little or no lung damage no need for immediate action
Predominantly Yellow	moderate lung damage monitor trends, correction of individual values recommended (e.g. iLA Membrane Ventilator®)
Predominantly Orange	significant lung damage correction of individual values necessary (e.g. iLA Membrane Ventilator®)
Predominantly Red	severe lung damage immediate correction of values necessary (e.g. iLA Membrane Ventilator®)

ARDS Algorithm

ALGORITHM: ARDS
THE FIRST 24 HOURS AFTER ICU ADMISSION

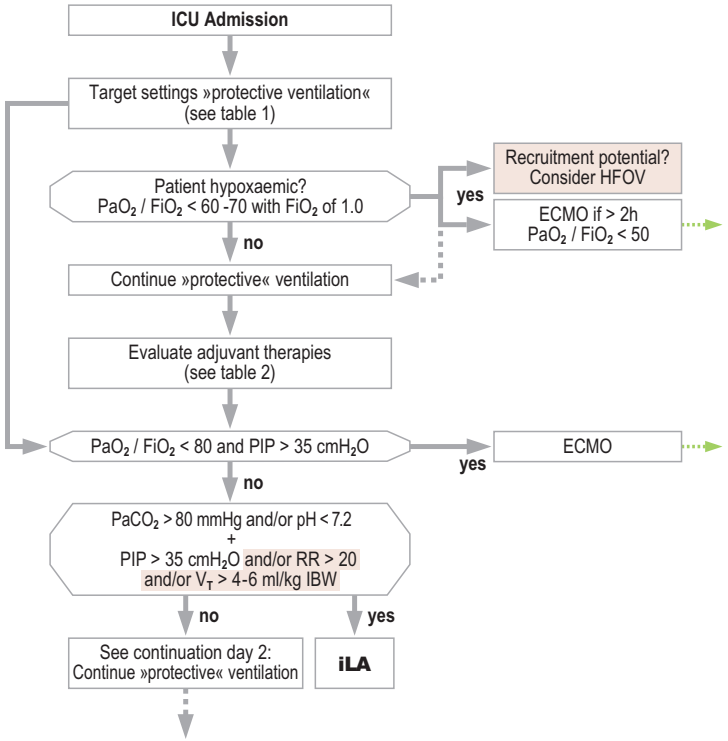

Table 1:

Target settings »protective ventilation« 1:
PCV / (Assisted) spontaneous breathing
PIP < 35 cmH_2O
Frequency 15-20/min
V_T 4-6 ml/kg IBW
Adequate PEEP (15-19 cmH_2O)
Permissive hypercapnia (pH> 7.2)

Table 2:

Evaluate adjuvant therapies:
(+Optimisation of ventilation parameters (best PEEP))
- Proning therapy 2x 4-8 h / 24 h
- Optimisation of haemodynamics
- Fluid management
- Treatment of the underlying disease (e. g. antibiotics)
- Pulmonary vasodilatation if pulmonary hypertension present

Caption: Novalung modifications | Algorithm continues, see original

ONGOING TREATMENT (FROM DAY 2)

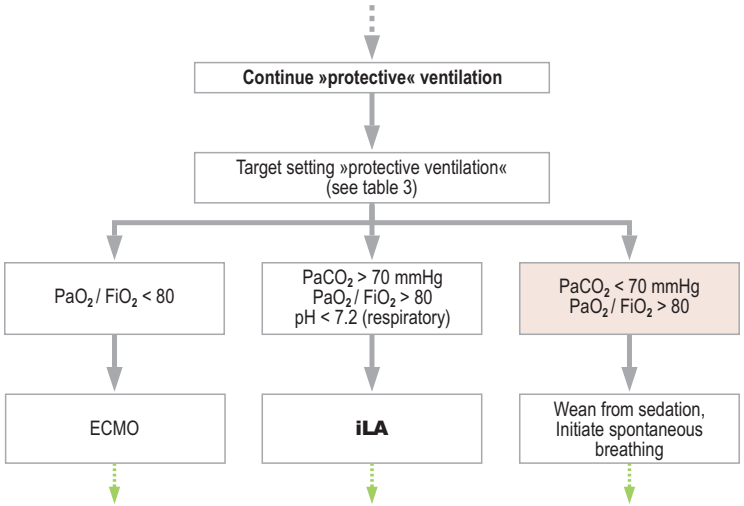

Table 3:

Target settings »protective ventilation« 2:
(Assisted) spontaneous breathing (5/min)
PIP < 32 cmH_2O
Delta-P 16 cmH_2O
Respiratory rate 12-16/min
V_T 4-6 ml/kg IBW
Adequate PEEP (10-14 cmH_2O)

Modified and simplified from Deja et al., Evidence-based Therapy of Severe Acute Respiratory Distress Syndrome: an Algorithm-guided Approach ; The Journal of International Medical Research, Volume 36, Number 2, March 2008 , pp. 211-221(11)

SPECIFIC DETAILS

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EVALUATION WITHIN 24 HOURS!

- Within 24 hours after admission of an ARDS patient to the ICU all adjuvant therapies should be evaluated in order to ensure the patient is ventilated within the defined »protective« parameters.

PRIMARILY HYPERCAPNIC ARDS: iLA

- In primarily hypercapnic ARDS the indication for extracorporeal therapies to remove CO_2 should be evaluated early on (within the first 24 hours) if »protective« mechanical ventilation is not otherwise possible.

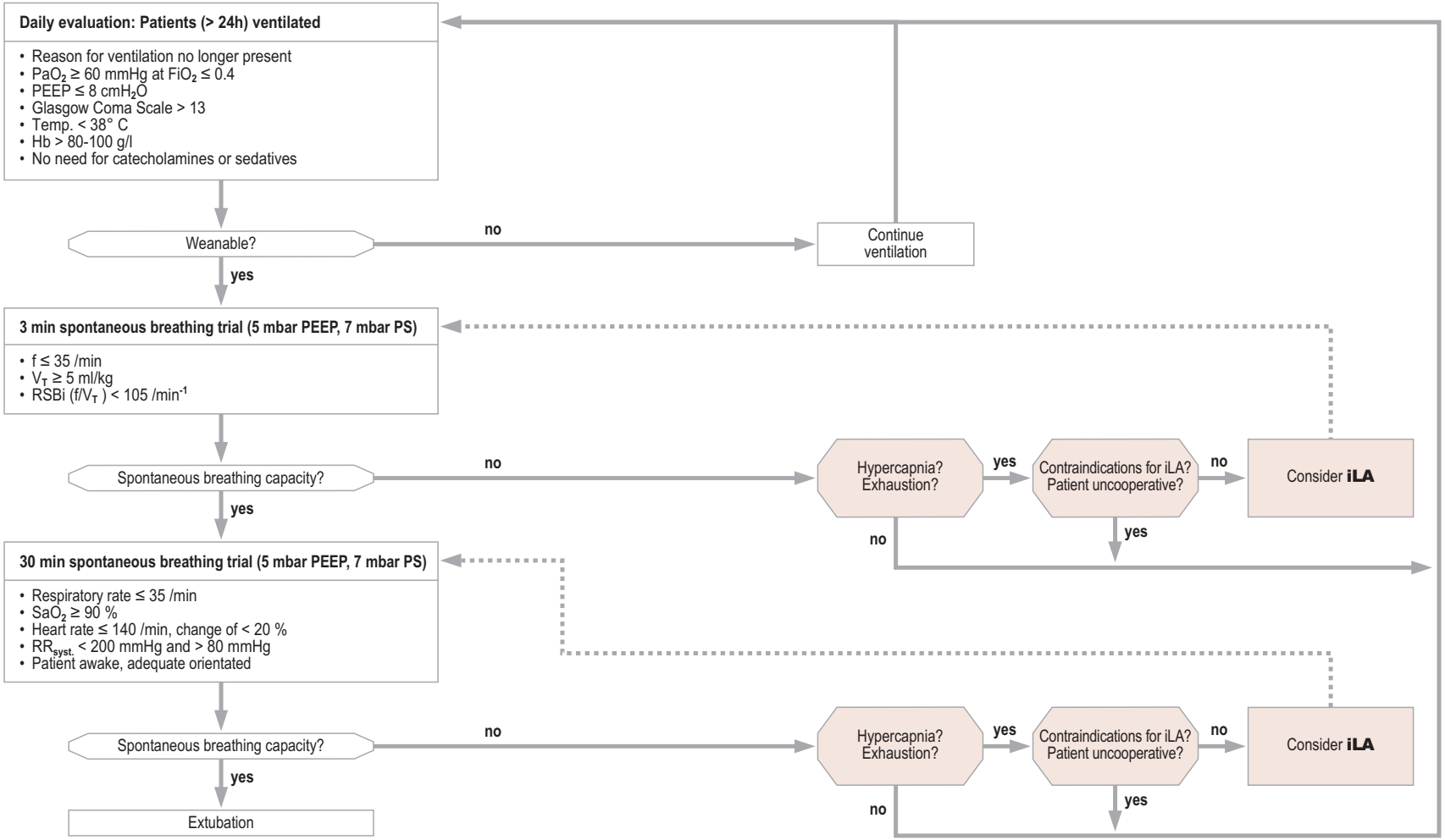
PRIMARILY HYPOXAEMIC: HFOV OR ECMO

- In cases that are primarily hypoxaemic less-invasive therapies than ECMO should be considered early on. High-frequency oscillatory ventilation (HFOV) for example can serve to improve oxygenation.
  However, if fast-entry and slow-entry criteria for ECMO are available these can be applied.

Weaning Algorithm

ALGORITHM: WEANING FAILURE IN HYPERCAPNIC RESPIRATORY ACIDOSIS

Mod. from protocol of the University Hospital Aachen, Germany



Caption: Novalung modifications

REASONS FOR WEANING FAILURE*

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INCREASED WORK OF BREATHING

- Increased resistance:
  - *Endotracheal tube, secretion, inflammation*
- Decreased compliance:
  - *Pulmonary causes: pleural effusion, infiltrates, atelectasis, edema*
  - *Extrapulmonary causes: elevated diaphragm due to ileus, ascites, meteorism*
  - *Dysfunction of the H_2O balance: positive balances, reverse shift, cardiac decompensation*

INSUFFICIENT BREATHING MECHANICS

- Muscle weakness
- Shallow breathing due to pain
- Residual analgesic/sedative
- Disco-ordination of the breathing musculature due to
  - *Electrolyte dysfunction (hypophosphataemia, hypomagnesaemia, hypocalcaemia, hypokaliemia)*
  - *Acid-base disorders (metabolic alkalosis, metabolic acidosis)*
  - *Catabolism*

INCREASED VENTILATION REQUIREMENTS

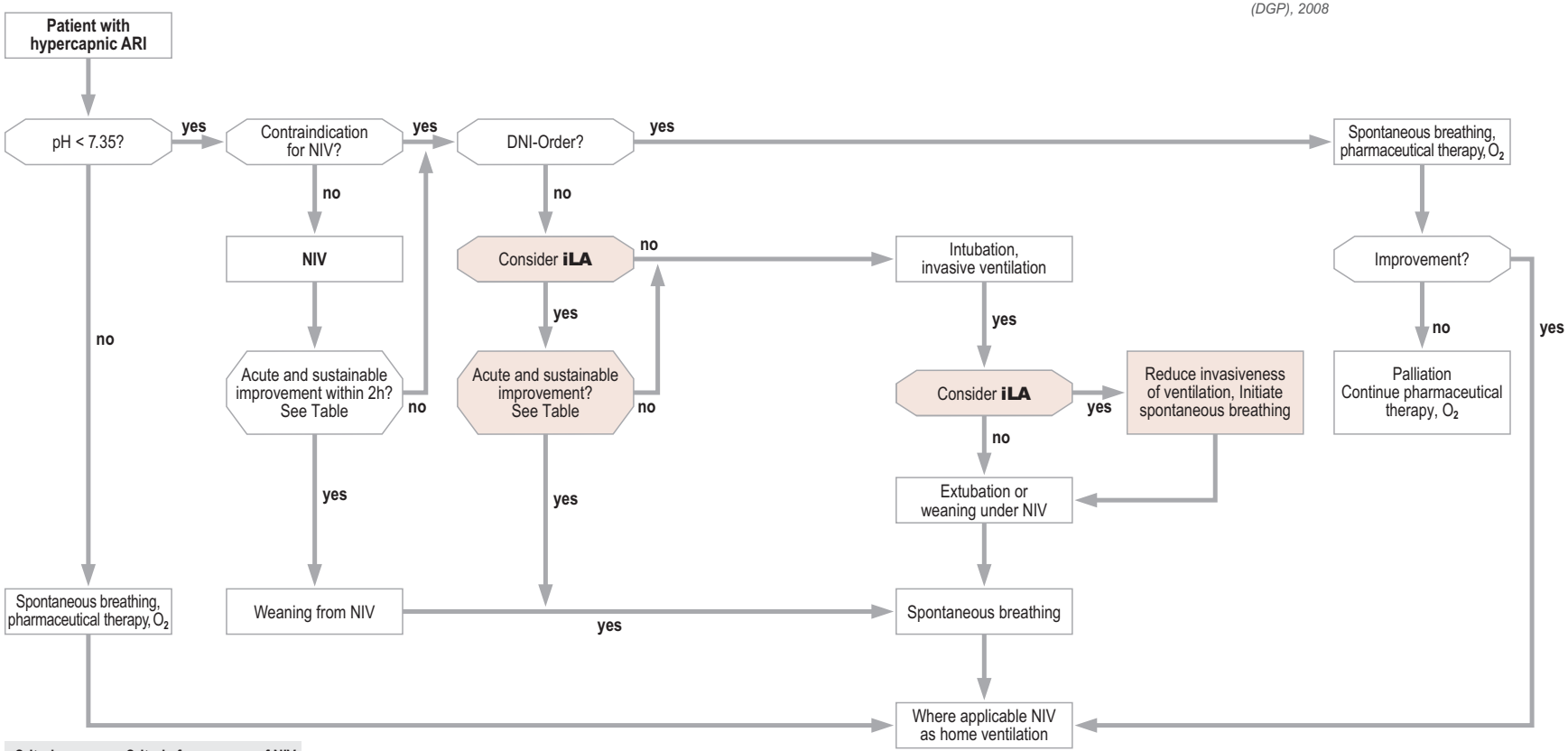
- Increased CO_2 production due to
  - *Infection, fever (active focus)*
  - *Shivering*
  - *Agitation from various causes (alcohol or drug withdrawal, organic psychosyndrome)*
  - *Alimentary: excessive carbohydrate intake*
- Increased dead-space ventilation

* *Modified and translated from Oczenski W. et al., Atmen-Atemhilfen, Thieme Verlag 2006*

ARI/COPD Algorithm

ALGORITHM: ARI / COPD
NON-INVASIVE VENTILATION FOR ARI / COPD

Translated and modified from the guideline »Noninvasive Ventilation as Therapy for Acute Respiratory Insufficiency« of the German Society for Pneumology and Ventilation Medicine (DGP), 2008



Criteria	Criteria for success of NIV
Dyspnea	reduction
Vigilance	increasing improvement
Respiratory rate	reduction
Ventilation	$PaCO_2$ reduction
pH	increase
Oxygenation	increase of $SaO_2 \geq 85$ %
Heart rate	reduction

Caption: Novalung modifications

CONTRAINDICATIONS FOR NIV INCLUDE:

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ABSOLUTE CONTRAINDICATIONS:*

- Respiratory arrest
- Cardiovascular instability (hypotension, arrhythmias, myocardial infarction)

RELATIVE CONTRAINDICATIONS:*

- Impaired mental status, somnolence
- Inability to cooperate
- Copious and/or viscous secretions with high aspiration risk
- Recent facial or gastro-oesophageal surgery
- Craniofacial trauma and/or fixed nasopharyngeal abnormality
- Burns
- Extreme obesity

HERE AGAIN THE MAXIM APPLIES: WEANING AS SOON AS POSSIBLE!**

Whenever practicable invasively-ventilated patients with COPD should be extubated as soon as possible and converted to NIV (recommendation level A). With these patients the weaning success rate compared to the invasively-ventilated control group has been significantly improved by extubation with subsequent NIV.

In addition the mortality, re-intubation, tracheotomy and complication rates are reduced.

* *American Thoracis Society and European Respiratoty Society 2004. Standards for the Diagnosis and Management of Patients with COPD.*

** *Clinical guideline, Schönhofer et al. Dtsch Arztebl 2008; 105(24): 424–33*

QUICK USER GUIDE

FUNCTION

- CO_2 elimination

REQUIREMENTS

- Stable hemodynamic situation and possibility for compensation of an acute arteriovenous shunt, mean arterial pressure (MAP) normally min. 60 mmHg
- Exclusion: Primary oxygenation failure, normally PaO_2 / FiO_2 ratio > 70

CONTRAINDICATIONS

- Heparin-induced thrombocytopenia (HIT) or known paradoxical reactions to heparin
- Severe restriction of cardiac function (e.g., shock)
- Body weight < 20 kg
- Relative: femoral, arterial vessel diameter ≤ 5.1 mm
- Relative: serious peripheral arterial occlusive disease

PREPARATION AND ANTICOAGULATION

- Passive/gravity filling of the iLA Membrane Ventilator® with crystalloid solution
- Systemic heparinisation (target PTT ≥ 55 sec)

GAS

- 100 % oxygen (non-humidified)
- Maximum gas flow through device: 10 l/min

RECOMMENDED NOVAPORT® ONE COMBINATIONS*

Depending on the size of the arterial vessel:

Ø artery	artery	vein
≥ 6 mm	15 F / 90 mm	17 F / 140 mm
5.2 mm - 5.9 mm	13 F / 90 mm	15 F / 140 mm

**Individual variations in the case of adipositas (artery 140 mm), borderline cardiovascular situations (artery 13 F, vein 15 F also if artery ≥ 6 mm).*

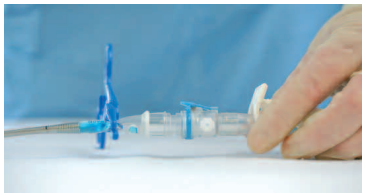
ONGOING MANAGEMENT

- Flush iLA Membrane Ventilator® daily 3 times to rinse the condensate:
  - *i.e. increase oxygen flow to > 15 l/min (about 25 l/min) for 1 sec*
  - *reset to initial value immediately after flush*
- Keep the arterial cannulated leg warm
- Maintain the iLA Membrane Ventilator® in view with the enclosed device holder
- Maintain the iLA Membrane Ventilator® below the heart level
- Continuous measurement of the blood flow at the venous thigh using the NovaFlow®
- Accurate fixation of the NovaPort® one cannulae and tubes with plasters
- Close AV-shunt at CPR (clamp on both sides, Cave: ventilation adaption necessary), afterwards change of the system

QUICK USER GUIDE SAFETY CONNECTOR™

STEP 1

The Novalung Safety Connector™ has a silicon seal which we recommend wetting for better lubrication. Connect the Novalung Safety Connector™ without twisting it by gently turning it to the first click stop.



Never force the connectors together. If you cannot connect the parts easily, disconnect and try again.

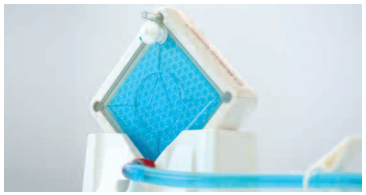
STEP 2

Deair the connectors using the blunt cannula provided by filling with crystalloid solution via the Luer connector.

After fully deairing the system, close the Luer connector with the white cap.

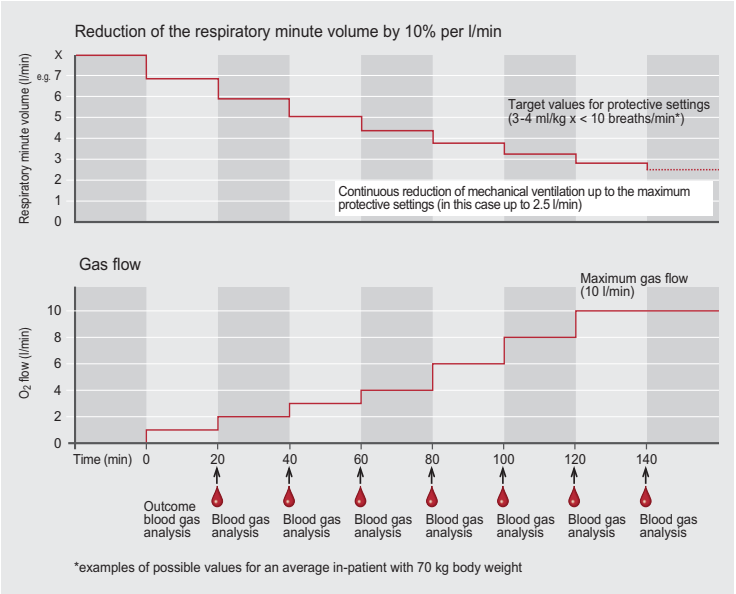
STEP 3

First release the safety clamps holding the tubing on the iLA Membrane Ventilator® and push the connectors together to the second click stop. Check that the connectors are firmly in place.



Check if the system still contains residual air. Small amounts of air can be released via the deairing ports by opening the AV shunt.

ADAPTION OF VENTILATION AND GAS FLOW



Gradually reduce settings on the ventilator. First try to reduce the tidal volume by reducing the inspiratory pressure. Perform a blood gas analysis after each step.

Further procedure will depend on the changes observed. If the PaO_2 drops, the interval between two steps should be increased. If the $PaCO_2$ drops too quickly (possible decrease in cerebral perfusion), reduce the minute volume on the ventilator.

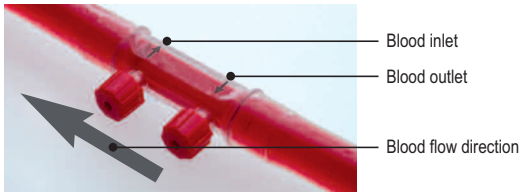
QUICK USER GUIDE CRRT CONNECTOR

REMARKS

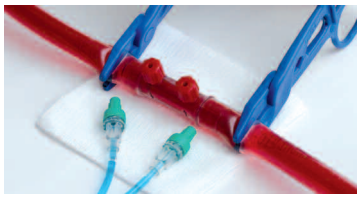
- Suitable for all CRRT therapies* with blood flows up to 500 ml/min. The blood flow through the iLA Membrane Ventilator® should not drop below 1.0 l/min.
- For connection and removal of the CRRT circuit the connectors have to be oriented vertically to avoid the introduction of air into the circuit.
- The blood flow must be restored as quickly as possible after connection or removal of the CRRT circuit (thrombosis risk).

E.g., hemofiltration, hemodialysis, hemodiafiltration, plasmapheresis

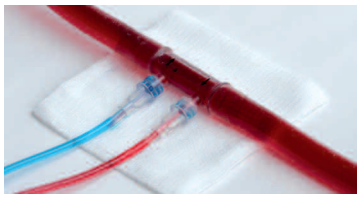
CONNECTING THE CRRT CIRCUIT



Remove the white safety clips from the caps. The blood flow direction for the connection is indicated by arrows on the connector.

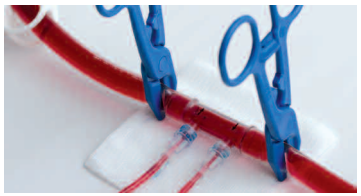


Immediately prior to connection clamp off blood flow on both sides of the CRRT connector.



Then connect the fully primed CRRT circuit.

REMOVAL OF THE CRRT CIRCUIT



Immediately prior to disconnection clamp off blood flow on both sides of the CRRT connector.

To seal the CRRT connector use the red Luer caps supplied with the iLA (to ensure a complete seal of the connector cone, otherwise thrombosis risk) and secure with the white safety clips.

TIDAL VOLUME
BASED ON IDEAL BODY WEIGHT (MEN)

To define the ideal tidal volume, the ideal body weight (IBW) has to be determined. The calculation of the ideal body weight of an adult man is based on the body height*:

IBW (kg) men = 50 + 0.91 x (height (cm) - 152.4)

Recommendation / adjustment for the tidal volume on the ventilator:

height (Inches)	height (cm)	IBW (kg) men	»protective«** V_T = 6 ml/kg IBW	»ultra-protective«*** V_T = 3 ml/kg IBW
59.8	152	50	300	150
61.0	155	52	312	156
61.8	157	55	330	165
63.0	160	57	342	171
63.8	162	59	354	177
65.0	165	62	372	186
65.7	167	64	384	192
66.9	170	66	396	198
67.7	172	68	408	204
68.9	175	71	426	213
69.7	177	73	438	219
70.9	180	75	450	225
71.7	182	78	468	234
72.8	185	80	480	240
73.6	187	82	492	246
74.8	190	85	510	255
76.0	193	87	522	261
76.8	195	89	534	267
77.6	197	91	546	273
78.7	200	94	564	282

Stated values are rounded.

* *ARDSnet Study (2000)*
Novalung is not responsible for the validity of the stated data.
The use of these data is in the attending physician's discretion.
** *»protective« 6 ml/kg IBW* *ARDSnet Study, N Engl J Med (2000); 342(18):1301-8*
*** *»ultra-protective« 3 ml/kg IBW* *Bein, et al. Anaesthesia (2009); 64: 195-198*

TIDAL VOLUME
BASED ON IDEAL BODY WEIGHT (WOMEN)

To define the ideal tidal volume, the ideal body weight (IBW) has to be determined. The calculation of the ideal body weight of an adult man is based on the body height*:

IBW (kg) women = 45.5 + 0.91 x (height (cm) - 152.4)

Recommendation / adjustment for the tidal volume on the ventilator:

height (Inches)	height (cm)	IBW (kg) women	»protective«** V_T = 6 ml/kg IBW	»ultra-protective«*** V_T = 3 ml/kg IBW
59.8	152	46	276	138
61.0	155	48	288	144
61.8	157	50	300	150
63.0	160	52	312	156
63.8	162	55	330	165
65.0	165	57	342	171
65.7	167	59	354	177
66.9	170	62	372	186
67.7	172	64	384	192
68.9	175	66	396	198
69.7	177	69	414	207
70.9	180	71	426	213
71.7	182	73	438	219
72.8	185	75	450	225
73.6	187	78	468	234
74.8	190	80	480	240
76.0	193	82	492	246
76.8	195	85	510	255
77.6	197	87	522	261
78.7	200	89	524	267

Stated values are rounded.

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NOTES

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