**CONFIDENTIAL**



**INTRAOPERATIVE ASSESSMENT**

**Case Report Form**

**version 1.8**

Protective Ventilation with Higher versus Lower PEEP during one-lung ventilation for thoracic surgery

**Patient Serial Number** |\_\_|\_\_|\_\_**|**\_\_|\_\_|\_\_|

 c e n t e r p a t i e n t

**Date of Surgery \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Local investigator 1 (intraoperative) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Local investigator 2 (postoperative) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Principal Investigator: Mert Sentürk, Department of Anesthesiology and Reanimation, Istanbul University, Turkey**

**Contact: Jakob Wittenstein, Department of Anesthesiology and Intensive Care Medicine, University of Dresden, Germany; Jakob.wittenstein@ukdd.de**

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# 1 Randomization

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Randomization** | **Low PEEP without RM** |  | **High PEEP with RM** |  |  |

|  |  |
| --- | --- |
| surgical procedure cancelled, postponed or changed and patient not treated | no 🞎 yes 🞎 |
| anesthesia management deviated from study protocolif yes please give details in section “protocol adherence” | no 🞎 yes 🞎 |

# 2 Anaesthetic Overview

|  |
| --- |
| Duration of anesthesia [min] from intubation to extubation (or exit from OR if on mechanical ventilation) |
| Duration of OLV [min]  |
| Duration of TLV [min] |
| Total Blood loss [ml] | Total Urine output [ml] |
| Side of OLV left 🞎 right 🞎 |
| Side of surgery left 🞎 right 🞎 |
| Method of OLV double lumen tube 🞎 endobronchial blocker 🞎 other🞎, specify:   double lumen tube(embedded camera) 🞎  |
| Confirmation of OLV fiberoptic bronchoscopy 🞎 embedded camera 🞎 other🞎, specify:   |
| Antibiotics | yes 🞎 no 🞎 | if yes, specify drug name: | prophylaxis 🞎 therapy 🞎 |
| Regional anesthesia | yes 🞎 no 🞎 | if yes  |  | epidural 🞎 paravertebral 🞎  |
|  |  |  |  | other  🞎, specify: |
|  |  |  |  |  |
| Use of NIV during induction | yes 🞎 no 🞎 | if yes  | CPAP 🞎 NPPV 🞎 |  |
| Patient’s position during induction | angle of upper body elevation. 0-15°🞎 15-30° 🞎 30-45° 🞎 >45° 🞎 |

|  |  |
| --- | --- |
| Temperature [°C] at end of surgery | tympanic 🞎 axillar 🞎 inguinal 🞎 oral 🞎 rectal 🞎 |
|  | other 🞎 | if other specify: |
| Neuromuscular function monitored? | yes 🞎 no 🞎 | if yes  | Residual curarization at Extubation (TOF < 90%) | yes 🞎 no 🞎 |
| Curarization antagonized? | yes 🞎 no 🞎 | if yes  | sugammadex 🞎 cholinesterase inhibitor 🞎other 🞎, specify: |

# 3 Surgical overview

|  |
| --- |
| Duration of surgery [min]from incision to closure |
| Priority of surgery | elective 🞎 urgent 🞎 emergency 🞎 |
| Surgical wound classification  | clean 🞎 clean-contaminated 🞎 contaminated 🞎 dirty 🞎 |
| Surgical procedure | thoracoscopic 🞎 open 🞎 conversion from thoracoscopic to open 🞎 |
| Type of resection (multiple answers are possible): pneumonectomy 🞎 lobectomy 🞎 wedge resection 🞎 sleeve lobectomy 🞎 segment resection 🞎pleurectomy 🞎 other 🞎, specify:  |
| Patient’s position during surgery | supine 🞎 lateral 🞎 prone 🞎 other 🞎,specify: |
| estimated amount of resection: (as a percentage of one lung) | 0-10%🞎 ≤20%🞎 ≤30%🞎 ≤40%🞎 ≤50%🞎 ≤60%🞎 ≤70%🞎 ≤80%🞎 ≤90%🞎 90-100%(e.g pneumonectomy) 🞎 |

# 4 Anesthesia Drugs

|  |  |
| --- | --- |
| *cumulative dose* | *cumulative dose* |
| Analgetics  | Alfentanyl | yes 🞎 |  | Anesthetics  | Dexmedetomidine | yes 🞎 |  |
| [mg] | Fentanyl | yes 🞎 |  | [mg] | Etomidate | yes 🞎 |  |
|  | Lidocaine | yes 🞎 |  |  | Midazolam | yes 🞎 |  |
|  | Morphine | yes 🞎 |  |  | Propofol | yes 🞎 |  |
|  | Procaine | yes 🞎 |  |  | Thiopental | yes 🞎 |  |
|  | Remifentanil | yes 🞎 |  |  | other | yes 🞎 |  |
|  | Sufentanil | yes 🞎 |  |  | other | yes 🞎 |  |
|  | Ketamine | yes 🞎 |  |  | other | yes 🞎 |  |
|  | other | yes 🞎 |  |  | other | yes 🞎 |  |
|  | other | yes 🞎 |  | Muscle  | Atracurium | yes 🞎 |  |
|  | other | yes 🞎 |  | Relaxants | Cis-Atracurium | yes 🞎 |  |
|  | other | yes 🞎 |  | [mg] | Mivacurium | yes 🞎 |  |
| Vapors  |  |  | *mean targeted MAC* |  | Pancuronium | yes 🞎 |  |
| [vol%\*min] | Desflurane | yes 🞎 |  |  | Rocuronium | yes 🞎 |  |
|  | Enflurane | yes 🞎 |  |  | Succinylcholine | yes 🞎 |  |
|  | Halothane | yes 🞎 |  |  | Vecuronium | yes 🞎 |  |
|  | Isoflurane | yes 🞎 |  |  | other | yes 🞎 |  |
|  | Sevoflurane | yes 🞎 |  |  | other | yes 🞎 |  |
|  | other | yes 🞎 |  |  |  |  |  |

Example: A surgery lasting 4 hours with Sevoflurane dose of 2Vol% --> 2x4\*60= 480 min vol%\*min

# 5 Fluids

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | *cumulative dose* |  |  | *cumulative dose* |
| Artificial | HES | yes 🞎 |  | Crystalloids [ml] | yes 🞎 |  |
| Colloids | Gelatine | yes 🞎 |  | Albumin (any concentration)[ml] | yes 🞎 |  |
| [ml] | Dextran | yes 🞎 |  | other, specify: | yes 🞎 |  |
|  | other, specify: | yes 🞎 |  |  |  |  |
|  | Dobutamine | yes 🞎 |  |  |  |  |  |
| Vaso-  | Ephedrine | yes 🞎 |  |  |  |  |  |
| active | Epinephrine | yes 🞎 |  |  |  |  |  |
| Drugs | Norepinephrine | yes 🞎 |  |  |  |  |  |
| [mg] | Phenylephrine | yes 🞎 |  |  |  |  |  |
|  | other | yes 🞎 |  |  |  |  |  |
|  | other | yes 🞎 |  |  |  |  |  |
|  | other: | yes 🞎 |  |  |  |  |  |
|  |  |  |  |  |  |  |  |

|  |
| --- |
| 6 Transfusion**Transfusion from anesthesia induction until end of anesthesia (or leaving OR if on mechanical ventilation)** |
|  | *cumulative dose(ml)* |  |  | *cumulative dose(ml)* |
| Packed red blood cells | yes 🞎 |  |  | Plasma | yes 🞎 |  |
| Autologous blood transfusion | yes 🞎 |  |  | Platelets | yes 🞎 |  |
|  |  |  |  |  |  |  |

|  |
| --- |
|  |

# 7 Protocol adherence

|  |  |  |  |
| --- | --- | --- | --- |
|  |  |  |  |
| 1. Hypotension (BPsys < 90mmHg) unresponsive to fluids and/or vasoactive drugs (give details below)
 | yes 🞎 |
| 1. New arrhythmias unresponsive to intervention (according to ACLS-Guidelines) (give details below)
 | yes 🞎 |
| 1. Need for a dosage of vasoactive drugs at the tolerance limit of the treating physician (give details below)
 | yes 🞎 |
| 1. Need for massive transfusion ( 4 units of PRBC in 4 hours) (give details below)
 | yes 🞎 |
| 1. Life-threatening surgical complication (injury to the hemodynamic and respiratory system and brain, including major bleeding, tension pneumothorax, intracranial injury) (give details below)
 | yes 🞎 |
| 1. Hypoxemia rescue other than prescribed was necessary due to prolonged SpO2<90% (give details below)
 | yes 🞎 |
| 1. Hypercapnia rescue other than prescribed was necessary due to respiratory acidosis pH<7.20 (give details below)
 | yes 🞎 |
| 1. Deviation from prescribed PEEP(give details below)
 | yes 🞎 |
| 1. Deviation from tidal volume(give details below)
 | yes 🞎 |
| 1. Other reason, specify: (give details below)
 | yes 🞎 |
| Any deviation from the protocol? | yes 🞎 no 🞎 | if yes, specify:  |  |
|  |  |  |  |
|  |
| Could the protocol be continued? | yes 🞎 no 🞎 |  |  |

# 8 Adverse events (AE) / severe adverse events (SAE)

Record variables only adverse events that can not be described in the Chapter “Intraoperative variables” “documentation of routine measurements” and “documentation of recruitment maneuver”

|  |  |  |  |
| --- | --- | --- | --- |
| Any adverse events  | yes 🞎 no 🞎 | if yes  | specify according to table: |
|  |  |  |  |
| Event (details, including treatment) | Severe AE | Causality | Severity | Outcome |
|  | yes 🞎no 🞎 | unrelated 🞎possible 🞎probable 🞎unassessable 🞎 | mild 🞎moderate 🞎severe 🞎unassessable 🞎 | resolved - no sequelae 🞎resolved - sequelae 🞎unresolved 🞎death 🞎unknown 🞎 |
|  | yes 🞎no 🞎 | unrelated 🞎possible 🞎probable 🞎unassessable 🞎 | mild 🞎moderate 🞎severe 🞎unassessable 🞎 | resolved - no sequelae 🞎resolved - sequelae 🞎unresolved 🞎death 🞎unknown 🞎 |
|  | yes 🞎no 🞎 | unrelated 🞎possible 🞎probable 🞎unassessable 🞎 | mild 🞎moderate 🞎severe 🞎unassessable 🞎 | resolved - no sequelae 🞎resolved - sequelae 🞎unresolved 🞎death 🞎unknown 🞎 |

# 9 Mechanical ventilation protocol

|  |  |
| --- | --- |
| Patient’s height [cm] | Measured bodyweight [kg] |
| Ideal bodyweight(IBW) [kg]M: 50+0.91\*(height-152.4), F: 45.5+0.91\*(height-152.4) |  |
| **TWO LUNG VENTILATION** |
| Modus | Volume controlled ventilation |
| FiO2 | ≥40%, adjust to maintain SpO2 ≥90% |
| I:E ratio | Range from 1:1 to 1:2 |
| RR  | adjust to normocapnia (ETCO2 35-45mmHg or 4,6-6kPa) |
| PEEP | according to randomizationwith suspected intrinsic-PEEP, resp. rate or I:E ratio change allowed acc. to physician |
| Inspiratory VT | 7 ml/kg ideal bodyweight = \_\_\_\_\_\_\_\_ml |
| **ONE LUNG VENTILATION** |
| Modus | Volume controlled ventilation |
| FiO2 | ≥40%, adjust to maintain SpO2 ≥90% |
| I:E ratio | Range from 1:1 to 1:2 (change to 1:1 if If Ppeak > 40 cm H2O, or Pplat > 30 cmH2O) |
| RR  | adjust to normocapnia (ETCO2 35-45mmHg or 4,6-6kPa) |
| PEEP | according to randomizationwith suspected intrinsic-PEEP, resp. rate or I:E ratio change allowed acc. to physician |
| Inspiratory VT | 5 ml/kg ideal body weight (change to 4ml/kg if Ppeak > 40 cm H2O, or Pplat > 30 cmH2O) **5 ml/kg** ideal bodyweight = \_\_\_\_\_\_\_\_ml**4 ml/kg** ideal bodyweight = \_\_\_\_\_\_\_\_ml |

## 9.1 Recruitment maneuver

|  |  |
| --- | --- |
| Recruitment maneuver of the ventilated lung(s) – HIGH PEEP GROUP | 1. Increase FIO2 to 1.02. Set peak inspiratory pressure limit to 45 cmH2O3. Set respiratory rate to 6 breaths/min 4. Set inspiratory to expiratory ratio (I:E) to 1:15. Increase VT in steps of around 2 mL/kg until plateau pressure reaches 30 to 40 cmH2O6. If the maximum VT allowed by the anesthesia ventilator is achieved and the plateau pressure is lower than 30 cmH2O, increase the PEEP as needed, but maximum 20 cmH2O7. Allow three breaths while maintaining plateau pressure of 30 to 40 cmH2O8. Set VT, PEEP, respiratory rate, and I:E back to pre-recruitment values |
|  | RM will be performed * after bronchoscopy,
* at begin of OLV,
* every one hour during OLV,
* at the end of OLV after switching from OLV to TLV,
* at end of surgery in supine position
* following each disconnection from the mechanical ventilator.
 |

|  |  |
| --- | --- |
| Recruitment maneuver of the non-ventilated lung – BOTH GROUPS | A recruitment maneuver of the non-ventilated lung may be necessary in both groups due to different reasons: a) detection of air leaks by request of surgeons; b) as part of a rescue strategy due to hypoxemia; c) before switching from OLV to TLV to re-expand the collapsed lung. |
|  | 1. Keep the non-ventilated under visual inspection2. Connect the CPAP device with adequate oxygen flow /FiO2 1,0) to the non-ventilated lung3. Set CPAP to 10 cmH2O during 20 seconds4. Set CPAP to 15 cmH2O during 20 seconds5. Set CPAP to 20 cmH2O during 20 seconds If performed as part of a rescue therapy, reduce CPAP to 10 cmH2O and then 5 cmH2O, otherwise disconnect the CPAP device. |

## 9.2 Hypoxemia rescue therapy

If hypoxemia, defined as **SpO2 < 90%** for **> 1 min**, occurs, rescue is performed.

|  |  |
| --- | --- |
| Hypoxemia Rescue – HIGH PEEP GROUP - before and after one-lung ventilation | 1. Apply “recruitment maneuver of the ventilated lung(s)”2. Increase PEEP to 12 cmH2O and apply “recruitment maneuver of the ventilated lung(s)”3. Increase FIO2 in steps of 0.1 until 1.04. Consider stepwise decrease of PEEP of the ventilated lung down to 8 cmH2O |

|  |  |
| --- | --- |
| Hypoxemia Rescue - LOW PEEP GROUP - before and after one-lung ventilation | 1. Increase FIO2 in steps of 0.1 until 1.02. Apply “recruitment maneuver of the ventilated lung(s)”3. Increase PEEP to 6 cmH2O4. Apply “recruitment maneuver of the ventilated lung(s)”5. Increase PEEP to 7 cmH2O6. Apply “recruitment maneuver of the ventilated lung(s)” |

|  |  |
| --- | --- |
| Hypoxemia Rescue - HIGH PEEP GROUP - during one-lung ventilation | 1. Apply “recruitment maneuver of the ventilated lung(s)”
2. Increase PEEP to 12 cmH2O and apply “recruitment maneuver of the ventilated lung(s)”
3. Increase FIO2 in steps of 0.1 up to 1.0
4. Apply oxygen to the non-ventilated lung, consider CPAP therapy (recruitment maneuver of the non-ventilated lung) up to a pressure of 20 cmH2O or selective oxygen insufflation via fiberscope
5. Consider stepwise decrease of PEEP of the ventilated lung down to 8 cmH2O
6. Consider surgical intervention (e.g. clamping of pulmonary artery)
7. Consider administration of inhalative nitric oxide or prostacyclin, or intravenous almitrin
8. Switch to TLV
 |

|  |  |
| --- | --- |
| Hypoxemia Rescue – LOW PEEP GROUP - during one-lung ventilation | 1. Increase FIO2 in steps of 0.1 up to 1.0
2. Apply oxygen to the non-ventilated lung, consider CPAP therapy (recruitment maneuver of the non-ventilated lung) up to a pressure of 20 cmH2O or selective oxygen insufflation via fiberscope
3. Apply “recruitment maneuver of the ventilated lung(s)”
4. Increase PEEP to 6 cmH2O
5. Apply “recruitment maneuver of the ventilated lung(s)”
6. Increase PEEP to 7 cmH2O
7. Apply “recruitment maneuver of the ventilated lung(s)”
8. Consider surgical intervention (clamping of pulmonary artery)
9. Consider administration of inhalative nitric oxide or prostacyclin, or intravenous almitrin
10. Switch to TLV
 |

## 9.3 Hypercapnia Rescue therapy

|  |  |
| --- | --- |
| Hypercapnia Rescue – BOTH GROUPS - during one-lung ventilation | PaCO2 > 60 mmHg with respiratory acidosis (pHarterial < 7.20)1. Increase the respiratory rate (maximum 30/min, while avoiding “intrinsic-PEEP”)2. Increase VT in steps up to 7 mL/kg3. Switch to TLV |

10 Intraoperative variables: documentation of routine measurements (in chronological order)

Record variables within 10 min after anesthesia induction, 5 minutes before OLV, hourly thereafter, at end of surgery

In case of several changing episodes of TLV and OLV record first episode of OLV after start of surgery and last episode of OLV before end of surgery

Document routine measurements first, take blood gas probe, perform the recruitment maneuver.

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|   | Induction | Patient in final surgical position with TLV | 10 min after OLV | 1 hour after OLV | 2 hour after OLV | 3 hour after OLV |  4 hour after OLV |  5 hour after OLV |  6 hour after OLV |  end of surgery with TLV in supine pos. |
|
| Time [hh:mm] |  |  |  |   |   |   |   | e.g. 14:20 |   |   |
| TLV/OLV |  |  |  |  |  |  |  | e.g. TLV |  |  |
| Ppeak [cmH2O] |  |  |  |   |   |   |   | e.g. 28 |   |   |
| Pplat [cmH2O] |  |  |  |   |   |   |   | e.g. 26 |   |   |
| PEEP [cmH2O] |  |  |  |   |   |   |   | e.g. 10 |   |   |
| VT insp [ml] |  |  |  |   |   |   |   | e.g. 420 |   |   |
| RR [/min] |  |  |  |   |   |   |   | e.g. 16 |   |   |
| I:E [x:x] |  |  |  |   |   |   |   | e.g. 1:1,3 |   |   |
| SpO2 [%] |  |  |  |   |   |   |   | e.g. 93 |   |   |
| etCO2 [mmHg/kPa] |  |  |  |   |   |   |   | e.g. 5,3 kPa |   |   |
| MAP [mmHg] |  |  |  |   |   |   |   | e.g. 82 |   |   |
| HR [bpm]Blood Gas Analysis |  |  |  |   |   |   |   | e.g. 77 |   |   |
| FiO2 [%] |  |  |  |   |   |   |   | e.g. 80 |   |   |
| paO2[mmHg/kPa] |  |  |  |   |   |   |   | e.g. 90 mmHg |   |   |
| paCO2[mmHg/kPa] |  |  |  |   |   |   |   | e.g. 4,6 kPa |   |   |
| pH |  |  |  |  |  |  |  | e.g. 7,33 |  |  |
| Hematocrit[%] |  |  |  |  |  |  |  | e.g. 33 |  |  |

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  ..continued | Induction | Patient in final surgical position with TLV | 10 min after OLV | 1 hour after OLV | 2 hour after OLV | 3 hour after OLV |  4 hour after OLV |  5 hour after OLV |  6 hour after OLV |  end of surgery with TLV |
| New hypotension | if sudden BPsys drop > 20% or equivalent increase of catecholamine dose |
|  | yes/no | yes/no | yes/no | yes/no | yes/no | yes/no | yes/no | yes/no | yes/no | yes/no |
| New bradycardia  | if sudden HR drop > 20%  |
|  | yes/no | yes/no | yes/no | yes/no | yes/no | yes/no | yes/no | yes/no | yes/no | yes/no |
| New hypoxemia  | SpO2 < 90% for > 1 minute |
|  | yes/no | yes/no | yes/no | yes/no | yes/no | yes/no | yes/no | yes/no | yes/no | yes/no |
| Disconnection from the ventilator | Disconnection of the ventilated lung or bronchoscopy |
|  | yes/no | yes/no | yes/no | yes/no | yes/no | yes/no | yes/no | yes/no | yes/no | yes/no |
| Hypoxemia rescue maneuver  | if SpO2 ≤ 90% for > 1 minute |
|  | yes/no | yes/no | yes/no | yes/no | yes/no | yes/no | yes/no | yes/no | yes/no | yes/no |
| Hypercapnia rescue maneuver  | PaCO2 > 60 mmHg and pHarterial < 7.20 |
|  | yes/no | yes/no | yes/no | yes/no | yes/no | yes/no | yes/no | yes/no | yes/no | yes/no |
| Other event, specify: |  |
|  | yes/no | yes/no | yes/no | yes/no | yes/no | yes/no | yes/no | yes/no | yes/no | yes/no |
| iNO/Prostacyclin/selective fiberoscope insufflation, specify: | use of inhalative nitrous oxygen, prostacyclin therapy or selective oxygenation through fiberoscopy |
|  | yes/no | yes/no | yes/no | yes/no | yes/no | yes/no | yes/no | yes/no | yes/no | yes/no |
| CPAP non ventilated lung | use of CPAP for the surgical/non-ventilated lung necessary |
|  | yes/no | yes/no | yes/no | yes/no | yes/no | yes/no | yes/no | yes/no | yes/no | yes/no |

11 intraoperative variables: Documentation of Recruitment maneuver (in chronological order)

Document routine measurements first, take blood gas probe, perform the recruitment maneuver. Record values when reaching target pressure Pplat 30-40 cmH2O

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Indication for RM(tick one) |  |  |  |  |  |  |  |  |  |  |
| RESCUEROUTINE | 🞎 | 🞎 | 🞎 | 🞎 | 🞎 | 🞎 | 🞎 | 🞎 | 🞎 | 🞎 |
| bronchoscopy/disconnection | 🞎 | 🞎 | 🞎 | 🞎 | 🞎 | 🞎 | 🞎 | 🞎 | 🞎 | 🞎 |
| after begin of OLV | 🞎 | 🞎 | 🞎 | 🞎 | 🞎 | 🞎 | 🞎 | 🞎 | 🞎 | 🞎 |
| every one hour during OLV | 🞎 | 🞎 | 🞎 | 🞎 | 🞎 | 🞎 | 🞎 | 🞎 | 🞎 | 🞎 |
| after lung re-expansion, measure in TLV | 🞎 | 🞎 | 🞎 | 🞎 | 🞎 | 🞎 | 🞎 | 🞎 | 🞎 | 🞎 |
| at end of surgery(supine) | 🞎 | 🞎 | 🞎 | 🞎 | 🞎 | 🞎 | 🞎 | 🞎 | 🞎 | 🞎 |
| TLV/OLV |  | e.g. TVL |  |  |  |  |  |  |  |  |
| Time [hh:mm] | e.g. 14:15 |  |  |  |  |  |  |  |  |  |
| Ppeak [cmH2O] |  | e.g. 30 |  |  |  |  |  |  |  |  |
| Pplat [cmH2O] |  | e.g. 28 |  |  |  |  |  |  |  |  |
| PEEP [cmH2O] |  | e.g. 10 |  |  |  |  |  |  |  |  |
| VT insp [ml] |  | e.g. 480 |  |  |  |  |  |  |  |  |
| RR [/min] |  | e.g. 16 |  |  |  |  |  |  |  |  |
| I:E [x:x] |  | e.g. 1:1,3 |  |  |  |  |  |  |  |  |
| FiO2 [%] |  | e.g. 80 |  |  |  |  |  |  |  |  |
| SpO2 [%] |  | e.g. 95 |  |  |  |  |  |  |  |  |
| MAP [mmHg] |  | e.g. 72 |  |  |  |  |  |  |  |  |
| HR [bpm] |  | e.g. 83 |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
| Adverse Events |  |  |  |  |  |  |  |  |  |  |
| New hypotension  | e.g. no |  |  |  |  |  |  |  |  |  |
| New bradycardia  | e.g. no |  |  |  |  |  |  |  |  |  |
| New hypoxemia  | e.g. no |  | e.g. yes |  |  |  |  |  |  |  |
| Other event, specify: | e.g. no |  |  |  |  |  |  |  |  |  |