

The **PROBESE** Randomized  
Controlled Trial

**Case Report Form**  
**version 1.2.1**

Protective Ventilation with Higher versus Lower PEEP during General  
Anesthesia for Surgery in Obese Patients

Patient Serial Number

--	--	--	--	--	--	--	--

center patient

Local investigator 1 (intraoperative)

---

Local investigator 2 (postoperative)

---

**Principal Investigator: Prof. Marcelo Gama de Abreu, Department of Anesthesiology and Intensive Care Medicine, University of Dresden**

**Contact: Thomas Bluth, Department of Anesthesiology and Intensive Care Medicine, University of Dresden, [probese@peg-dresden.de](mailto:probese@peg-dresden.de)**



Case ID	<table border="1"> <tr> <td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td> </tr> <tr> <td colspan="4">center</td> <td colspan="4">patient</td> </tr> </table>									center				patient			
center				patient													

**1. Inclusion Criteria**

	yes	no
Patient scheduled for surgery under general anesthesia	<input type="checkbox"/>	<input type="checkbox"/>
Intermediate-to-high risk for PPCs following surgery, <b>ARISCAT risk score <math>\geq 26</math></b>	<input type="checkbox"/>	<input type="checkbox"/>
BMI $\geq 35$ kg/m <sup>2</sup>	<input type="checkbox"/>	<input type="checkbox"/>
Expected duration of surgery $\geq 2$ h	<input type="checkbox"/>	<input type="checkbox"/>

**2. Exclusion Criteria**

	yes	no
Previous lung surgery (any)	<input type="checkbox"/>	<input type="checkbox"/>
Persistent hemodynamic instability, intractable shock (considered hemodynamically unsuitable for the study by the patient's managing physician)	<input type="checkbox"/>	<input type="checkbox"/>
History of previous severe chronic obstructive pulmonary disease (COPD) (non-invasive ventilation and/or oxygen therapy at home, repeated systemic corticosteroid therapy for acute exacerbations of COPD)	<input type="checkbox"/>	<input type="checkbox"/>
Recent immunosuppressive medication (patients receiving chemotherapy or radiation therapy up to two months prior to surgery)	<input type="checkbox"/>	<input type="checkbox"/>
Severe cardiac disease (New York Heart Association class III or IV, acute coronary syndrome or persistent ventricular tachyarrhythmia)	<input type="checkbox"/>	<input type="checkbox"/>
Invasive mechanical ventilation longer than 30 minutes (e.g., general anesthesia for surgery) within last 30 days	<input type="checkbox"/>	<input type="checkbox"/>
Pregnancy (excluded by anamneses and/or laboratory analysis)	<input type="checkbox"/>	<input type="checkbox"/>
Prevalent acute respiratory distress syndrome expected to require prolonged postoperative mechanical ventilation	<input type="checkbox"/>	<input type="checkbox"/>
Severe pulmonary arterial hypertension, defined as systolic pulmonary artery pressure $> 40$ mmHg	<input type="checkbox"/>	<input type="checkbox"/>
Intracranial injury or tumor	<input type="checkbox"/>	<input type="checkbox"/>
Neuromuscular disease (any)	<input type="checkbox"/>	<input type="checkbox"/>
Need for intraoperative prone or lateral decubitus position	<input type="checkbox"/>	<input type="checkbox"/>
Need for one-lung ventilation	<input type="checkbox"/>	<input type="checkbox"/>
Cardiac surgery or neurosurgery	<input type="checkbox"/>	<input type="checkbox"/>
Planned reintubation following surgery	<input type="checkbox"/>	<input type="checkbox"/>
Enrolled in other interventional study or refusal of informed consent	<input type="checkbox"/>	<input type="checkbox"/>
<b>Patient excluded from the study?</b>	<input type="checkbox"/>	<input type="checkbox"/>

Investigator _____ Signature _____
------------------------------------

Case ID	<table border="1"> <tr> <td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td> </tr> <tr> <td colspan="4">center</td> <td colspan="4">patient</td> </tr> </table>									center				patient			
center				patient													

3. ARISCAT Score (modified according to study design)

	Points		Points		Points	
Age	≤ 50	<input type="checkbox"/> 0	51-80	<input type="checkbox"/> 3	> 80	<input type="checkbox"/> 16
Preoperative SpO <sub>2</sub> [%] 10 min in room air, beach chair position	≥ 96	<input type="checkbox"/> 0	91-95	<input type="checkbox"/> 8	≤ 90	<input type="checkbox"/> 24
Respiratory Infection (last month)	No	<input type="checkbox"/> 0	Yes	<input type="checkbox"/> 17		
Preoperative Anemia (Hb ≤ 6,2 mmol/l or ≤10 g/dl)	No	<input type="checkbox"/> 0	Yes	<input type="checkbox"/> 11		
Emergency procedure	No	<input type="checkbox"/> 0	Yes	<input type="checkbox"/> 8		
Surgical Incision	peripheral	<input type="checkbox"/> 0	upper abdominal	<input type="checkbox"/> 15		
Planned duration of surgery [hr]			> 2-3	<input type="checkbox"/> 16	> 3	<input type="checkbox"/> 23
<b>Total Risk Score</b>		<input type="checkbox"/>	<b>+</b>	<input type="checkbox"/>	<b>+</b>	<input type="checkbox"/> = <input type="checkbox"/>

Investigator _____	Signature _____
--------------------	-----------------

Case ID	<table border="1"> <tr> <td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td> </tr> <tr> <td colspan="4">center</td> <td colspan="4">patient</td> </tr> </table>									center				patient			
center				patient													

**4 Patient details**

Written informed consent	yes <input type="checkbox"/>	no <input type="checkbox"/>	Date informed consent signed	/	/	20
Age [yrs]			Gender	male <input type="checkbox"/>	female <input type="checkbox"/>	
Height [cm]			Weight [kg]			
Waist/Hip Ratio according to WHO (definition page 34)						

**5 History of previous disease**

ASA Score [1-5]						
Cumulated Ambulation Score (page 34) [0-6]:						
Heart failure	yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes	NYHA Score [1-4]:		
Coronary heart disease	yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes	CCS Score [0-4]:		
Atrial flutter / fibrillation	yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes	acute <input type="checkbox"/>	paroxysmal <input type="checkbox"/>	chronic <input type="checkbox"/>
Obstructive sleep apnea	yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes	Apnea/Hypopnea Index [events/hr]:		
			if no	STOP-Bang Score (page 34) [0-8]:		
COPD	yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes	steroids use	yes <input type="checkbox"/>	no <input type="checkbox"/>
				inhalation therapy	yes <input type="checkbox"/>	no <input type="checkbox"/>
Respiratory infection within last month	yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes	upper <input type="checkbox"/>	lower <input type="checkbox"/>	respiratory infection
Smoking status	never <input type="checkbox"/>	former (cessation >3months) <input type="checkbox"/>	current <input type="checkbox"/>			
Use of noninvasive ventilatory support	yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes	CPAP <input type="checkbox"/>	NPPV <input type="checkbox"/>	
				duration [hrs/day]:	intensity [pressure level]:	
Active cancer	yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes	cancer type:		
				actual cancer classification: T__M__N__		
Diabetes mellitus	yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes	dietary <input type="checkbox"/>	oral medication <input type="checkbox"/>	insulin <input type="checkbox"/>
			if oral medication, specify	type:	dose [mg/day]:	
Arterial hypertension	yes <input type="checkbox"/>	no <input type="checkbox"/>				
Gastroesophageal reflux	yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes	events ≥1/day <input type="checkbox"/>	≥1/week <input type="checkbox"/>	≥1/month <input type="checkbox"/>
Alcohol status (past 2 weeks)	0-2 drinks/day <input type="checkbox"/>	>2 drinks/day <input type="checkbox"/>				
Use of antibiotics (last 3 months)	yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes	indication:		
Use of statins	yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes	type:	dose [mg/day]:	
Use of aspirin	yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes	dose [mg/day]:		

Investigator _____	Signature _____
--------------------	-----------------

Case ID	<table border="1"> <tr> <td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td> </tr> <tr> <td colspan="5">center</td> <td colspan="5">patient</td> </tr> </table>											center					patient				
center					patient																

**6.1 Actual organ function – mandatory measurements**

SpO <sub>2</sub> beach chair position + 10 min in room air possible?	yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes	SpO <sub>2</sub> [%]:	
			if no	SpO <sub>2</sub> [%]: and FiO <sub>2</sub> [%] (page 35):	
RR [/min]					
HR [/min]	ABP mean [mmHg]				
Temperature [°C]	tympenic <input type="checkbox"/>	axillar <input type="checkbox"/>	inguinal <input type="checkbox"/>	oral <input type="checkbox"/>	rectal <input type="checkbox"/>
	other <input type="checkbox"/>	if other specify:			
Airway secretion	yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes	purulent <input type="checkbox"/>	not purulent <input type="checkbox"/>
VAS dyspnea [1-10cm]	VAS thoracic pain [1-10cm]				
VAS abdominal rest pain [1-10cm]	VAS abdominal incident pain [1-10cm]				

**6.2 Non-mandatory measurements**

Spirometry			Laboratory tests		
FVC [L]	FVC[% predicted]		Hb	mmol/l <input type="checkbox"/>	g/dl <input type="checkbox"/>
FEV <sub>1</sub> [L/1sec]	FEV <sub>1</sub> [% predicted]		WBC	GPT/L	
			Platelets	GPT/L	
Chest X-ray obtained	yes <input type="checkbox"/>	no <input type="checkbox"/>	PT	INR	
if yes			PTT	sec	
infiltrates	yes <input type="checkbox"/>	no <input type="checkbox"/>	Creatinine	µmol/l <input type="checkbox"/>	mg/dl <input type="checkbox"/>
pleural effusion	yes <input type="checkbox"/>	no <input type="checkbox"/>	BUN	mmol/l <input type="checkbox"/>	mg/dl <input type="checkbox"/>
atelectasis	yes <input type="checkbox"/>	no <input type="checkbox"/>	ALT	µmol/s*1 <input type="checkbox"/>	U/L <input type="checkbox"/>
pneumothorax	yes <input type="checkbox"/>	no <input type="checkbox"/>	AST	µmol/s*1 <input type="checkbox"/>	U/L <input type="checkbox"/>
cardiopulmonary edema	yes <input type="checkbox"/>	no <input type="checkbox"/>	Bilirubin	µmol/l <input type="checkbox"/>	mg/dl <input type="checkbox"/>

Investigator _____	Signature _____
--------------------	-----------------

Case ID

center			patient		

Randomization

Low PEEP without RM

High PEEP with RM

**1 Anesthetic Overview****1.1 Induction**

Duration of anesthesia [min]

from intubation to extubation (or exit from OR if on mechanical ventilation)

Antibiotic prophylaxis	yes <input type="checkbox"/>	no <input type="checkbox"/>	Central venous line	yes <input type="checkbox"/>	no <input type="checkbox"/>				
Arterial line	yes <input type="checkbox"/>	no <input type="checkbox"/>	Cardiac output measurements	yes <input type="checkbox"/>	no <input type="checkbox"/>				
Regional anesthesia	yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes	epidural	thoracic <input type="checkbox"/>	lumbar <input type="checkbox"/>			
				plexus	cervical <input type="checkbox"/>	brachial <input type="checkbox"/>	lumbar <input type="checkbox"/>		
other:				peripheral nerve	upper <input type="checkbox"/>	lower <input type="checkbox"/>	extremity <input type="checkbox"/>		
Use of NIV during induction	yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes	CPAP <input type="checkbox"/>	NPPV <input type="checkbox"/>				
Patient's position during induction	angle of head elevation . 0-15° <input type="checkbox"/>						15-30° <input type="checkbox"/>	30-45° <input type="checkbox"/>	>45° <input type="checkbox"/>

**1.2 Drugs, Fluids, Transfusion**

			<i>cumulative dose</i>				<i>cumulative dose</i>
Analgetics [mg]	Alfentanil	yes <input type="checkbox"/>	_____	Anesthetics [mg]	Dexmedetomidine	yes <input type="checkbox"/>	_____
	Fentanyl	yes <input type="checkbox"/>	_____		Etomidate	yes <input type="checkbox"/>	_____
	Lidocaine	yes <input type="checkbox"/>	_____		Ketamine	yes <input type="checkbox"/>	_____
	Morphine	yes <input type="checkbox"/>	_____		Midazolam	yes <input type="checkbox"/>	_____
	NSAIDs	yes <input type="checkbox"/>	_____		Propofol	yes <input type="checkbox"/>	_____
	Piritramide	yes <input type="checkbox"/>	_____		Thiopental	yes <input type="checkbox"/>	_____
	Procaine	yes <input type="checkbox"/>	_____		other	yes <input type="checkbox"/>	_____
	Remifentanil	yes <input type="checkbox"/>	_____		if other	type:	_____
	Sufentanil	yes <input type="checkbox"/>	_____		type:	_____	
if other	other	yes <input type="checkbox"/>	_____	Muscle	Atracurium	yes <input type="checkbox"/>	_____
	type:		_____	Relaxants	Cis-Atracurium	yes <input type="checkbox"/>	_____
	type		_____	[mg]	Mivacurium	yes <input type="checkbox"/>	_____
Vapors [vol%*min]	Desflurane	yes <input type="checkbox"/>	_____	Pancuronium	yes <input type="checkbox"/>	_____	
	Enflurane	yes <input type="checkbox"/>	_____	Rocuronium	yes <input type="checkbox"/>	_____	
	Halothane	yes <input type="checkbox"/>	_____	Succinylcholine	yes <input type="checkbox"/>	_____	
	Isoflurane	yes <input type="checkbox"/>	_____	Vecuronium	yes <input type="checkbox"/>	_____	
	Sevoflurane	yes <input type="checkbox"/>	_____	other	yes <input type="checkbox"/>	_____	
	if other	other	yes <input type="checkbox"/>	_____	if other	type:	_____
	type:		_____	type:	_____		

Investigator \_\_\_\_\_ Signature \_\_\_\_\_

Case ID

center				patient			

## The PROBESE Randomized Controlled Trial

## 2 Intraoperative Visit

			<i>cumulative dose</i>				<i>cumulative dose</i>
Artificial	HES	yes	<input type="checkbox"/>	Crystalloids [ml]	yes	<input type="checkbox"/>	
Colloids	Gelatine	yes	<input type="checkbox"/>	Albumin [ml]	yes	<input type="checkbox"/>	
[ml]	Dextran	yes	<input type="checkbox"/>				
Transfusion	PRBC	yes	<input type="checkbox"/>	Vaso-	Dobutamine	yes	<input type="checkbox"/>
[ml]	FFP	yes	<input type="checkbox"/>	active	Dopamine	yes	<input type="checkbox"/>
	FP24	yes	<input type="checkbox"/>	Drugs	Epinephrine	yes	<input type="checkbox"/>
	Fibrinogen [g]	yes	<input type="checkbox"/>	[mg]	Norepinephrine	yes	<input type="checkbox"/>
	Cryoprecipitate	yes	<input type="checkbox"/>		Phenylephrine	yes	<input type="checkbox"/>
	PPSB [IU]	yes	<input type="checkbox"/>		other	yes	<input type="checkbox"/>
	Platelets	yes	<input type="checkbox"/>	if other	type:		
	other	yes	<input type="checkbox"/>		type:		
if other	type:						

## 1.3 End of anesthesia

$\Sigma$ Blood loss [ml]	$\Sigma$ Urine output [ml]
Temperature [°C] at end of surgery	tympanic <input type="checkbox"/> axillar <input type="checkbox"/> inguinal <input type="checkbox"/> oral <input type="checkbox"/> rectal <input type="checkbox"/>
	other <input type="checkbox"/> if other specify:
Neuromuscular function monitored?	Residual curarization at extubation
yes <input type="checkbox"/> no <input type="checkbox"/> if yes	yes <input type="checkbox"/> no <input type="checkbox"/>
Curarization antagonized?	sugammadex <input type="checkbox"/> cholinesterase inhibitor <input type="checkbox"/>
yes <input type="checkbox"/> no <input type="checkbox"/> if yes	

Investigator \_\_\_\_\_ Signature \_\_\_\_\_

Case Report Form PROBESE study  
Version 1.2.1, Aug. 2014, Thomas Bluth



Case ID	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	center		patient				

2 Intraoperative Visit

2 Surgical overview

Duration of surgery [min]  
from incision to closure

		cumulative dose			cumulative dose	
Transfusion PRBC	yes <input type="checkbox"/>	<input type="text"/>		FFP	yes <input type="checkbox"/>	<input type="text"/>
<b>before</b> FP24	yes <input type="checkbox"/>	<input type="text"/>		Fibrinogen [g]	yes <input type="checkbox"/>	<input type="text"/>
surgery Cryoprecipitate	yes <input type="checkbox"/>	<input type="text"/>		PPSB [IU]	yes <input type="checkbox"/>	<input type="text"/>
(last 6hrs) Platelets	yes <input type="checkbox"/>	<input type="text"/>		other	yes <input type="checkbox"/>	<input type="text"/>
[ml]			if other	type:		

Priority of surgery (definition see below) elective  urgent  emergency

Surgical wound classification (definition see below) clean  clean-contaminated  contaminated  dirty

Surgical procedure visceral  thoracic  vascular  orthopedic  gynecologic  urologic  other   
specify procedure:

Patient's position during surgery supine  trendelenburg  reverse trendelenburg  lithotomy  seated

Surgical approach laparoscopic  if abdominal intraabdominal pressure [mmHg]  
assisted laparoscopic  if abdominal intraabdominal pressure [mmHg]  
open   
conversion from laparoscopic to open

3 Definitions

Surgical wound classification

Clean	Elective, not emergency, non-traumatic, primarily closed; no acute inflammation; no break in technique; respiratory, gastrointestinal, biliary and genitourinary tracts not entered.
Clean-contaminated	Urgent or emergency case that is otherwise clean; elective opening of respiratory, gastrointestinal, biliary or genitourinary tract with minimal spillage (e.g. appendectomy) not encountering infected urine or bile; minor technique break.
Contaminated	Non-purulent inflammation; gross spillage from gastrointestinal tract; entry into biliary or genitourinary tract in the presence of infected bile or urine; major break in technique; penetrating trauma <4 hours old; chronic open wounds to be grafted or covered.
Dirty	Purulent inflammation (e.g. abscess); preoperative perforation of respiratory, gastrointestinal, biliary or genitourinary tract; penetrating trauma >4 hours old.

Priority of surgery

Elective	Surgery that is scheduled in advance because it does not involve a medical emergency
Urgent	Surgery required within < 48 hrs
Emergency	Non-elective surgery performed when the patient's life or well-being is in direct jeopardy

Investigator _____	Signature _____
--------------------	-----------------

Case ID        
center patient

**4 Protocol adherence**

Any deviation from the protocol?      yes     no       if yes

- 1) Hypotension (BPsys < 90mmHg) unresponsive to fluids and/or vasoactive drugs yes
- 2) New arrhythmias unresponsive to intervention (according to ACLS-Guidelines) yes
- 3) Need for a dosage of vasoactive drugs at the tolerance limit yes
- 4) Need of massive transfusion (replacement of >50% of blood volume in 4 hours to maintain Hct ≥ 21% (Hb > 4,2 mmol/l or 7 g/dl) yes
- 5) Life-threatening surgical complication (injury to the hemodynamic and respiratory system and brain, including major bleeding, tension pneumothorax, intracranial injury) yes
- 6) Other reason, specify: yes

Specify protocol deviation:

Could the protocol be continued?      yes     no

**5 Adverse events (AE) / severe adverse events (SAE)**

Any adverse events      yes     no       if yes    specify according to table:

Event (details, including treatment)	Serious	Intervention	Recovery	Outcome
		unrelated <input type="checkbox"/>	mild <input type="checkbox"/>	resolved - no sequelae <input type="checkbox"/>
	yes <input type="checkbox"/>	possible <input type="checkbox"/>	moderate <input type="checkbox"/>	resolved - sequelae <input type="checkbox"/>
	no <input type="checkbox"/>	probable <input type="checkbox"/>	severe <input type="checkbox"/>	unresolved <input type="checkbox"/>
		unassessable <input type="checkbox"/>	unassessable <input type="checkbox"/>	death <input type="checkbox"/>
				unknown <input type="checkbox"/>
		unrelated <input type="checkbox"/>	mild <input type="checkbox"/>	resolved - no sequelae <input type="checkbox"/>
	yes <input type="checkbox"/>	possible <input type="checkbox"/>	moderate <input type="checkbox"/>	resolved - sequelae <input type="checkbox"/>
	no <input type="checkbox"/>	probable <input type="checkbox"/>	severe <input type="checkbox"/>	unresolved <input type="checkbox"/>
		unassessable <input type="checkbox"/>	unassessable <input type="checkbox"/>	death <input type="checkbox"/>
				unknown <input type="checkbox"/>
		unrelated <input type="checkbox"/>	mild <input type="checkbox"/>	resolved - no sequelae <input type="checkbox"/>
	yes <input type="checkbox"/>	possible <input type="checkbox"/>	moderate <input type="checkbox"/>	resolved - sequelae <input type="checkbox"/>
	no <input type="checkbox"/>	probable <input type="checkbox"/>	severe <input type="checkbox"/>	unresolved <input type="checkbox"/>
		unassessable <input type="checkbox"/>	unassessable <input type="checkbox"/>	death <input type="checkbox"/>
				unknown <input type="checkbox"/>

Investigator \_\_\_\_\_ Signature \_\_\_\_\_

Case ID

center			patient		

**6 Mechanical ventilation protocol**

Patient's height [cm]	IBW [kg] M: $50+0.91*(\text{height}-152.4)$ , F: $45.5+0.91*(\text{height}-152.4)$
Modus	Volume controlled ventilation
FiO <sub>2</sub>	≥40%, adjust to maintain SpO <sub>2</sub> ≥93%
I:E ratio	1:2
RR	adjust to normocapnia (ETCO <sub>2</sub> 35-45mmHg or 4,6-6kPa)
PEEP	according to randomization: 4 vs. 12 cmH <sub>2</sub> O
Inspiratory V <sub>T</sub>	7 ml/kg IBW = _____ ml
Recruitment maneuver (perform directly after induction or hourly recording or disconnection)	<ol style="list-style-type: none"> <li>1. Peak inspiratory pressure limit = 55 cmH<sub>2</sub>O</li> <li>2. V<sub>T</sub> = 7 ml/kg IBW and RR ≥ 6/min, while PEEP = 12 cmH<sub>2</sub>O (or higher during rescue)</li> <li>3. I:E = 1:1</li> <li>4. Increase V<sub>T</sub> in steps of 4 ml/kg IBW until Pplat reaches 40 – 50 cmH<sub>2</sub>O</li> <li>5. If Pplat &lt;40 cmH<sub>2</sub>O with highest possible V<sub>T</sub>, increase PEEP to maximum 20 cmH<sub>2</sub>O</li> <li>6. Allow three breaths while maintaining Pplat = 40 – 50 cmH<sub>2</sub>O</li> <li>7. Set RR, I:E, inspiratory pause and V<sub>T</sub> back to pre-recruitment values, while maintaining PEEP at 12 cmH<sub>2</sub>O (or higher if during rescue)</li> </ol>

**7 Rescue strategy (if SpO<sub>2</sub> ≤ 92%)**

First exclude airway problems, auto-PEEP, hemodynamic impairment and ventilator malfunction!

**Conventional group**

Step	FiO <sub>2</sub>	PEEP
1	0.5	4 cmH <sub>2</sub> O
2	0.6	4 cmH <sub>2</sub> O
3	0.7	4 cmH <sub>2</sub> O
4	0.8	4 cmH <sub>2</sub> O
5	0.9	4 cmH <sub>2</sub> O
6	1.0	4 cmH <sub>2</sub> O
7	1.0	5 cmH <sub>2</sub> O
8	1.0	6 cmH <sub>2</sub> O
9	1.0	7 cmH <sub>2</sub> O (+RM)
(+RM), recruitment maneuver optional		

**Protective Group**

Step*	FiO <sub>2</sub>	PEEP
1 Exclude any hemodynamic impairment		
2	0.4	14 cmH <sub>2</sub> O (+RM)
3	0.4	16 cmH <sub>2</sub> O (+RM)
4	0.4	18 cmH <sub>2</sub> O (+RM)
5	0.5	18 cmH <sub>2</sub> O
6	0.6	18 cmH <sub>2</sub> O
7	0.7	18 cmH <sub>2</sub> O
8	0.8	18 cmH <sub>2</sub> O
9	0.9	18 cmH <sub>2</sub> O
10	1.0	18 cmH <sub>2</sub> O
11	1.0	20 cmH <sub>2</sub> O (+RM)
(+RM), recruitment maneuver optional		
*At any step: If SpO <sub>2</sub> deteriorates further in an otherwise hemodynamic stable patient, consider reducing the PEEP to 10 and then 8 cmH <sub>2</sub> O		

Investigator \_\_\_\_\_ Signature \_\_\_\_\_

Case ID	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
	center				patient							

2 Intraoperative Visit

8 Intraoperative variables

- Record variables *within 5 min* after anesthesia induction and hourly thereafter (Induction, Hr 1, Hr 2...)
- Record recruitment variables *during* peak phase of recruitment maneuver (RM 1, RM 2...)

	Induc- tion	RM 1	Hr1	RM 2	Hr 2	RM 3	Hr 3	RM 4	Hr 4	RM 5	Hr 5
Time [hh:mm]											
Ppeak [cmH <sub>2</sub> O]											
Pplat [cmH <sub>2</sub> O]											
PEEP [cmH <sub>2</sub> O]											
V <sub>T</sub> insp [ml]											
RR [/min]											
I:E [x:x]											
FiO <sub>2</sub> [%]											
SpO <sub>2</sub> [%]											
ETCO <sub>2</sub> [mmHg / kPa]											
MAP [mmHg]											
HR [bpm]											

AE/SAE

New hypotension (BP <sub>sys</sub> < 90mmHg or BP <sub>sys</sub> drop > 10mmHg, if BP <sub>sys</sub> < 90 before)											
	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no
New bradycardia (HR <50bpm or HR drop > 20%, if HR < 50 before)											
	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no
New hypoxemia (SpO <sub>2</sub> ≤ 92% or SpO <sub>2</sub> drop > 5%, if SpO <sub>2</sub> < 92% before)											
	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no
Other event (please specify on page 10)											
	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no
Disconnection from the ventilator											
	_____	_____	yes / no	_____	yes / no	_____	yes / no	_____	yes / no	_____	yes / no
Rescue according to page 11 (if SpO <sub>2</sub> ≤ 92%)											
	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no

Investigator _____	Signature _____
--------------------	-----------------

Case ID	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
	center				patient						

9 Intraoperative variables continuation

	RM 6	Hr 6	RM 7	Hr 7	RM 8	Hr 8	RM 9	Hr 9	RM 10	Hr 10	RM 11
Time [hh:mm]											
Ppeak [cmH <sub>2</sub> O]											
Pplat [cmH <sub>2</sub> O]											
PEEP [cmH <sub>2</sub> O]											
V <sub>T</sub> insp [ml]											
RR [/min]											
I:E [x:x]											
FiO <sub>2</sub> [%]											
SpO <sub>2</sub> [%]											
ETCO <sub>2</sub> [mmHg / kPa]											
MAP [mmHg]											
HR [bpm]											

AE/SAE

New hypotension (BP <sub>sys</sub> < 90mmHg or BP <sub>sys</sub> drop > 10mmHg, if BP <sub>sys</sub> < 90 before)											
	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no
New bradycardia (HR < 50bpm or HR drop > 20%, if HR < 50 before)											
	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no
New hypoxemia (SpO <sub>2</sub> ≤ 92% or SpO <sub>2</sub> drop > 5%, if SpO <sub>2</sub> < 92% before)											
	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no
Other event (please specify on page 10)											
	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no
Disconnection from the ventilator											
	_____	yes / no	_____	yes / no	_____	yes / no	_____	yes / no	_____	yes / no	_____
Rescue according to page 11 (if SpO <sub>2</sub> ≤ 92%)											
	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no

Investigator _____	Signature _____
--------------------	-----------------

Case ID	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	center			patient			

10 Intraoperative variables continuation

	Hr 11	RM 12	Hr 12	RM 13	Hr 13	RM 14	Hr 14	RM 15	Hr 15	RM 16	Hr 16
Time [hh:mm]											
Ppeak [cmH <sub>2</sub> O]											
Pplat [cmH <sub>2</sub> O]											
PEEP [cmH <sub>2</sub> O]											
V <sub>T</sub> insp [ml]											
RR [/min]											
I:E [x:x]											
FiO <sub>2</sub> [%]											
SpO <sub>2</sub> [%]											
ETCO <sub>2</sub> [mmHg / kPa]											
MAP [mmHg]											
HR [bpm]											

AE/SAE

New hypotension (BP <sub>sys</sub> < 90mmHg or BP <sub>sys</sub> drop > 10mmHg, if BP <sub>sys</sub> < 90 before)											
	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no
New bradycardia (HR < 50bpm or HR drop > 20%, if HR < 50 before)											
	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no
New hypoxemia (SpO <sub>2</sub> ≤ 92% or SpO <sub>2</sub> drop > 5%, if SpO <sub>2</sub> < 92% before)											
	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no
Other event (please specify on page 10)											
	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no
Disconnection from the ventilator											
	yes / no	—	yes / no	—	yes / no	—	yes / no	—	yes / no	—	yes / no
Rescue according to page 11 (if SpO <sub>2</sub> ≤ 92%)											
	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no	yes / no

Investigator _____	Signature _____
--------------------	-----------------

Case ID

center				patient			

**POSTOPERATIVE DAY 1 (first 24hrs period)**  
report events within this period if not stated otherwise

**1 Recovery**

Lost to follow up	yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes	reason
Continuation of MV directly after surgery	yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes	duration [hrs]                      indication:
New requirement of NIV	yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes	CPAP <input type="checkbox"/> NPPV <input type="checkbox"/> duration [hrs]
	maximum intensity [pressure level]:			
	indication    standard of care <input type="checkbox"/> resp. failure <input type="checkbox"/>			
New requirement of invasive MV	yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes	duration [hrs]
	indication    resurgery <input type="checkbox"/> resp. failure <input type="checkbox"/> other <input type="checkbox"/>			
ICU stay	yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes	preop scheduled <input type="checkbox"/> unscheduled <input type="checkbox"/>
PONV	yes <input type="checkbox"/>	no <input type="checkbox"/>		
Physiotherapy	yes <input type="checkbox"/>	no <input type="checkbox"/>		
Breathing exercises	yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes	incentive spirometry                      yes <input type="checkbox"/> no <input type="checkbox"/>
Cumulated Ambulation Score (page 34) [0-6]:				
Impairment of wound healing	yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes	superficial <input type="checkbox"/> deep <input type="checkbox"/>
Surgical wound infection	yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes	superficial <input type="checkbox"/> deep <input type="checkbox"/>
	if yes    abscess <input type="checkbox"/> empyema <input type="checkbox"/> phlegmon <input type="checkbox"/>			
Return of bowel function	yes <input type="checkbox"/>	no <input type="checkbox"/>		

**2 Fluids/ Drugs**

		<i>cumulative dose</i>		<i>cumulative dose</i>	
Artificial	HES	yes <input type="checkbox"/>	_____	Crystalloids [ml]	yes <input type="checkbox"/>
Colloids [ml]	Gelatine	yes <input type="checkbox"/>	_____	Albumin [ml]	yes <input type="checkbox"/>
	Dextran	yes <input type="checkbox"/>	_____		
Transfusion [ml]	PRBC	yes <input type="checkbox"/>	_____	FFP	yes <input type="checkbox"/>
	FP24	yes <input type="checkbox"/>	_____	Fibrinogen [g]	yes <input type="checkbox"/>
	Cryoprecipitate	yes <input type="checkbox"/>	_____	PPSB [IU]	yes <input type="checkbox"/>
	Platelets	yes <input type="checkbox"/>	_____	other	yes <input type="checkbox"/>
				if other	type: _____
Antibiotics		yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes	prophylaxis <input type="checkbox"/> therapy <input type="checkbox"/>
Vasoactive drugs		yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes	Dobutamine <input type="checkbox"/> Dopamine <input type="checkbox"/> Epinephrine <input type="checkbox"/>
		Norepinephrine <input type="checkbox"/> Phenylephrine <input type="checkbox"/> other <input type="checkbox"/>			
		if other    type _____			

Investigator \_\_\_\_\_ Signature \_\_\_\_\_

Case ID

center				patient			

**3.1 Actual organ function – mandatory measurements (status at visit, 12-24hrs after end of surgery)**SpO<sub>2</sub> beach chair position + 10 min in room air possible?yes  no if yes SpO<sub>2</sub> [%]:if no SpO<sub>2</sub> [%]: and FiO<sub>2</sub> [%] (page 35):

RR [/min]

HR [/min]

ABP mean [mmHg]

Temperature [°C]

 tympanic  axillar  inguinal  oral  rectal 
other  if other specify:

Airway secretion

yes  no if yes purulent  not purulent 

VAS dyspnea [1-10cm]

VAS thoracic pain [1-10cm]

VAS abdominal rest pain [1-10cm]

VAS abdominal incident pain [1-10cm]

**3.2 Non-mandatory measurements****Spirometry**

FVC [L]

FVC[% predicted]

FEV<sub>1</sub> [L/1sec]FEV<sub>1</sub> [% predicted]**Laboratory tests**Hb mmol/l  g/dl 

WBC GPt/L

Platelets GPt/L

**Chest X-ray** obtainedyes  no 

if yes

infiltrates

yes  no 

pleural effusion

yes  no 

atelectasis

yes  no 

pneumothorax

yes  no 

cardiopulmonary edema

yes  no 

PT INR

PTT sec

Creatinine μmol/l  mg/dl BUN mmol/l  mg/dl ALT μmol/s\*1  U/L AST μmol/s\*1  U/L Bilirubin μmol/l  mg/dl 

Investigator \_\_\_\_\_ Signature \_\_\_\_\_



Case ID	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	center		patient				

3 Postoperative Visit Day 1

4 Pulmonary complications (see also detailed definitions, page 36)

Aspiration pneumonia resp. failure after inhalation of gastric contents	yes <input type="checkbox"/>	no <input type="checkbox"/>	
Bronchospasm newly expiratory wheezing treated with bronchodilators	yes <input type="checkbox"/>	no <input type="checkbox"/>	
Mild respiratory failure SpO <sub>2</sub> <90% or PaO <sub>2</sub> <60mmHg for 10min in room air, responding to oxygen ≤ 2l/min	yes <input type="checkbox"/>	no <input type="checkbox"/>	
Moderate respiratory failure SpO <sub>2</sub> <90% or PaO <sub>2</sub> <60mmHg for 10min in room air, responding to oxygen > 2l/min	yes <input type="checkbox"/>	no <input type="checkbox"/>	
Severe respiratory failure need for non-invasive or invasive mechanical ventilation	yes <input type="checkbox"/>	no <input type="checkbox"/>	
ARDS according to Berlin definition	yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes mild <input type="checkbox"/> moderate <input type="checkbox"/> severe <input type="checkbox"/>
Pulmonary infection new/ progressive infiltrates + 2: antibiotics, fever, leukocytosis/ leucopenia and/or purulent secretions	yes <input type="checkbox"/>	no <input type="checkbox"/>	no CXR <input type="checkbox"/>
Atelectasis lung opacification with shift of surrounding tissue/ organ towards the affected area	yes <input type="checkbox"/>	no <input type="checkbox"/>	no CXR <input type="checkbox"/>
Cardiopulmonary edema clinical signs of congestion + interstitial infiltrates/ increased vascular markings on chest X-ray	yes <input type="checkbox"/>	no <input type="checkbox"/>	no CXR <input type="checkbox"/>
Pleural effusion blunting of costophrenic angle (standing)/ hazy opacity in one hemithorax (supine) on chest X-ray	yes <input type="checkbox"/>	no <input type="checkbox"/>	no CXR <input type="checkbox"/>
Pneumothorax free air in the pleural space on chest X-ray/ ultrasonic imaging	yes <input type="checkbox"/>	no <input type="checkbox"/>	no CXR <input type="checkbox"/>
New pulmonary infiltrates monolateral/ bilateral infiltrates without other clinical signs	yes <input type="checkbox"/>	no <input type="checkbox"/>	no CXR <input type="checkbox"/>

5 Extrapulmonary complications (see also detailed definitions, page 37)

SIRS ≥2 findings: Temp < 36 °C or > 38 °C; HR > 90 bpm, RR > 20 bpm; WBC < 4.000 or > 12.000/μl	yes <input type="checkbox"/>	no <input type="checkbox"/>	
Sepsis SIRS in response to a confirmed infective process	yes <input type="checkbox"/>	no <input type="checkbox"/>	
Severe Sepsis Sepsis with organ dysfunction, hypoperfusion or hypotension	yes <input type="checkbox"/>	no <input type="checkbox"/>	
Septic shock Sepsis with refractory hypoperfusion or hypotension despite adequate fluid resuscitation	yes <input type="checkbox"/>	no <input type="checkbox"/>	
Extrapulmonary infection wound infection + any other (extrapulmonary) infection	yes <input type="checkbox"/>	no <input type="checkbox"/>	
Coma Glasgow-Coma-Scale ≤ 8 without therapeutic coma/ sedatives	yes <input type="checkbox"/>	no <input type="checkbox"/>	
Acute myocardial infarction rise/ fall of cardiac markers + symptoms/ ECG changes/ /imaging of cardiac ischemia/sudden death	yes <input type="checkbox"/>	no <input type="checkbox"/>	
Acute renal failure Risk: increased Crea x1.5/ GFR decrease > 25% or urine output (UO) < 0.5 ml/kg/h x 6 hr Injury: increased Crea x2 or GFR decrease > 50% or UO < 0.5 ml/kg/h x 12 hr Failure: increase Crea x3 or GFR decrease > 75% or UO < 0.3 ml/kg/h x 24 hr or anuria x 12 hrs Loss: complete loss of kidney function > 4 weeks	yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes R <input type="checkbox"/> I <input type="checkbox"/> F <input type="checkbox"/> L <input type="checkbox"/>
Disseminated intravascular coagulation according to DIC score > 5	yes <input type="checkbox"/>	no <input type="checkbox"/>	
Hepatic failure bilirubin on postop day5/day1 > 1,7 + INR on postop day5/day1 > 1,0	yes <input type="checkbox"/>	no <input type="checkbox"/>	
Gastrointestinal failure 1 = enteral feeding with under 50% of calculated needs or no feeding 3 days after surgery 2 = food intolerance (FI) or intra-abdominal hypertension (IAH) 3 = FI and IAH 4 = abdominal compartment syndrome (ACS)	yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/>

Investigator _____	Signature _____
--------------------	-----------------

Case ID	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	center		patient				

**POSTOPERATIVE DAY 2 (last 24hrs period)**  
report events within this period of not stated otherwise

**1 Recovery**

Lost to follow up	yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes	reason
New requirement of NIV	yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes	CPAP <input type="checkbox"/> NPPV <input type="checkbox"/> duration [hrs] intensity [pressure level]: standard of care <input type="checkbox"/> treatment of resp. failure <input type="checkbox"/>
New requirement of invasive MV	yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes	duration [hrs] indication resurgery <input type="checkbox"/> resp. failure <input type="checkbox"/> other <input type="checkbox"/>
ICU stay	yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes	preop scheduled <input type="checkbox"/> unscheduled <input type="checkbox"/> indication:
Physiotherapy	yes <input type="checkbox"/>	no <input type="checkbox"/>		
Breathing exercises	yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes	incentive spirometry yes <input type="checkbox"/> no <input type="checkbox"/>
Cumulated Ambulation Score (page 34) [0-6]:				
Impairment of wound healing	yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes	superficial <input type="checkbox"/> deep <input type="checkbox"/>
Surgical wound infection	yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes	superficial <input type="checkbox"/> deep <input type="checkbox"/> if yes abscess <input type="checkbox"/> empyema <input type="checkbox"/> phlegmon <input type="checkbox"/>
Return of bowel function	yes <input type="checkbox"/>	no <input type="checkbox"/>		

**2 Fluids/ Drugs**

		yes <input type="checkbox"/>	no <input type="checkbox"/>		<i>cumulative dose</i>		yes <input type="checkbox"/>	no <input type="checkbox"/>		<i>cumulative dose</i>
Transfusion	PRBC					FFP				
[ml]	FP24					Fibrinogen [g]				
	Cryoprecipitate					PPSB [IU]				
	Platelets					other				
				if other		type:				
Antibiotics		yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes		prophylaxis <input type="checkbox"/>			therapy <input type="checkbox"/>	
Vasoactive drugs		yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes		Dobutamine <input type="checkbox"/>		Dopamine <input type="checkbox"/>	Epinephrine <input type="checkbox"/>	
						Norepinephrine <input type="checkbox"/>		Phenylephrine <input type="checkbox"/>	other <input type="checkbox"/>	
				if yes		type				

Investigator _____	Signature _____
--------------------	-----------------

Case ID	<table border="1"> <tr> <td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td> </tr> <tr> <td colspan="4">center</td> <td colspan="4">patient</td> </tr> </table>									center				patient			
center				patient													

**3.1 Actual organ function – mandatory measurements (status at visit)**

SpO <sub>2</sub> beach chair position + 10 min in room air possible?	yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes	SpO <sub>2</sub> [%]:	
			if no	SpO <sub>2</sub> [%]:	and FiO <sub>2</sub> [%] (page 35):
RR [/min]					
HR [/min]	ABP mean [mmHg]				
Temperature [°C]	tympanic <input type="checkbox"/> axillar <input type="checkbox"/> inguinal <input type="checkbox"/> oral <input type="checkbox"/> rectal <input type="checkbox"/> other <input type="checkbox"/> if other specify:				
Airway secretion	yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes	purulent <input type="checkbox"/>	not purulent <input type="checkbox"/>
VAS dyspnea [1-10cm]	VAS thoracic pain [1-10cm]				
VAS abdominal rest pain [1-10cm]	VAS abdominal incident pain [1-10cm]				

**3.2 Not mandatory measurements**

Spirometry			Laboratory tests		
FVC [L]	FVC[% predicted]		Hb	mmol/l <input type="checkbox"/>	g/dl <input type="checkbox"/>
FEV <sub>1</sub> [L/1sec]	FEV <sub>1</sub> [% predicted]		WBC	GPt/L	
			Platelets	GPt/L	
<b>Chest X-ray</b> obtained	yes <input type="checkbox"/>	no <input type="checkbox"/>	PT	INR	
if yes			PTT	sec	
infiltrates	yes <input type="checkbox"/>	no <input type="checkbox"/>	Creatinine	µmol/l <input type="checkbox"/>	mg/dl <input type="checkbox"/>
pleural effusion	yes <input type="checkbox"/>	no <input type="checkbox"/>	BUN	mmol/l <input type="checkbox"/>	mg/dl <input type="checkbox"/>
atelectasis	yes <input type="checkbox"/>	no <input type="checkbox"/>	ALT	µmol/s*1 <input type="checkbox"/>	U/L <input type="checkbox"/>
pneumothorax	yes <input type="checkbox"/>	no <input type="checkbox"/>	AST	µmol/s*1 <input type="checkbox"/>	U/L <input type="checkbox"/>
cardiopulmonary edema	yes <input type="checkbox"/>	no <input type="checkbox"/>	Bilirubin	µmol/l <input type="checkbox"/>	mg/dl <input type="checkbox"/>

Investigator _____	Signature _____
--------------------	-----------------

Case ID	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	center		patient				

4 Postoperative Visit Day 2

**4 Pulmonary complications (see also detailed definitions, page 36)**

Aspiration pneumonia resp. failure after inhalation of gastric contents	yes <input type="checkbox"/>	no <input type="checkbox"/>	
Bronchospasm newly expiratory wheezing treated with bronchodilators	yes <input type="checkbox"/>	no <input type="checkbox"/>	
Mild respiratory failure SpO <sub>2</sub> <90% or PaO <sub>2</sub> <60mmHg for 10min in room air, responding to oxygen ≤ 2l/min	yes <input type="checkbox"/>	no <input type="checkbox"/>	
Moderate respiratory failure SpO <sub>2</sub> <90% or PaO <sub>2</sub> <60mmHg for 10min in room air, responding to oxygen > 2l/min	yes <input type="checkbox"/>	no <input type="checkbox"/>	
Severe respiratory failure need for non-invasive or invasive mechanical ventilation	yes <input type="checkbox"/>	no <input type="checkbox"/>	
ARDS according to Berlin definition	yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes mild <input type="checkbox"/> moderate <input type="checkbox"/> severe <input type="checkbox"/>
Pulmonary infection new/ progressive infiltrates + 2: antibiotics, fever, leukocytosis/ leucopenia and/or purulent secretions	yes <input type="checkbox"/>	no <input type="checkbox"/>	no CXR <input type="checkbox"/>
Atelectasis lung opacification with shift of surrounding tissue/ organ towards the affected area	yes <input type="checkbox"/>	no <input type="checkbox"/>	no CXR <input type="checkbox"/>
Cardiopulmonary edema clinical signs of congestion + interstitial infiltrates/ increased vascular markings on chest X-ray	yes <input type="checkbox"/>	no <input type="checkbox"/>	no CXR <input type="checkbox"/>
Pleural effusion blunting of costophrenic angle (standing)/ hazy opacity in one hemithorax (supine) on chest X-ray	yes <input type="checkbox"/>	no <input type="checkbox"/>	no CXR <input type="checkbox"/>
Pneumothorax free air in the pleural space on chest X-ray/ ultrasonic imaging	yes <input type="checkbox"/>	no <input type="checkbox"/>	no CXR <input type="checkbox"/>
New pulmonary infiltrates monolateral/ bilateral infiltrates without other clinical signs	yes <input type="checkbox"/>	no <input type="checkbox"/>	no CXR <input type="checkbox"/>

**5 Extrapulmonary complications (see also detailed definitions, page 37)**

SIRS ≥2 findings: Temp < 36 °C or > 38 °C; HR > 90 bpm, RR > 20 bpm; WBC < 4.000 or > 12.000/μl	yes <input type="checkbox"/>	no <input type="checkbox"/>	
Sepsis SIRS in response to a confirmed infective process	yes <input type="checkbox"/>	no <input type="checkbox"/>	
Severe Sepsis Sepsis with organ dysfunction, hypoperfusion or hypotension	yes <input type="checkbox"/>	no <input type="checkbox"/>	
Septic shock Sepsis with refractory hypoperfusion or hypotension despite adequate fluid resuscitation	yes <input type="checkbox"/>	no <input type="checkbox"/>	
Extrapulmonary infection wound infection + any other (extrapulmonary) infection	yes <input type="checkbox"/>	no <input type="checkbox"/>	
Coma Glasgow-Coma-Scale ≤ 8 without therapeutic coma/ sedatives	yes <input type="checkbox"/>	no <input type="checkbox"/>	
Acute myocardial infarction rise/ fall of cardiac markers + symptoms/ ECG changes/ /imaging of cardiac ischemia/sudden death	yes <input type="checkbox"/>	no <input type="checkbox"/>	
Acute renal failure Risk: increased Crea x1.5/ GFR decrease > 25% or urine output (UO) < 0.5 ml/kg/h x 6 hr Injury: increased Crea x2 or GFR decrease > 50% or UO < 0.5 ml/kg/h x 12 hr Failure: increase Crea x3 or GFR decrease > 75% or UO < 0.3 ml/kg/h x 24 hr or anuria x 12 hrs Loss: complete loss of kidney function > 4 weeks	yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes R <input type="checkbox"/> I <input type="checkbox"/> F <input type="checkbox"/> L <input type="checkbox"/>
Disseminated intravascular coagulation according to DIC score > 5	yes <input type="checkbox"/>	no <input type="checkbox"/>	
Hepatic failure bilirubin on postop day5/day1 > 1,7 + INR on postop day5/day1 > 1,0	yes <input type="checkbox"/>	no <input type="checkbox"/>	
Gastrointestinal failure 1 = enteral feeding with under 50% of calculated needs or no feeding 3 days after surgery 2 = food intolerance (FI) or intra-abdominal hypertension (IAH) 3 = FI and IAH 4 = abdominal compartment syndrome (ACS)	yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/>

Investigator _____	Signature _____
--------------------	-----------------

Case ID

center			patient		

The PROBESE Randomized Controlled Trial

5 Postoperative Visit Day 3

**POSTOPERATIVE DAY 3 (last 24hrs period)**  
report events within this period of not stated otherwise

**1 Recovery**

Lost to follow up	yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes	reason
New requirement of NIV	yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes	CPAP <input type="checkbox"/> NPPV <input type="checkbox"/> duration [hrs] intensity [pressure level]: standard of care <input type="checkbox"/> treatment of resp. failure <input type="checkbox"/>
New requirement of invasive MV	yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes	duration [hrs] indication: resurgery <input type="checkbox"/> resp. failure <input type="checkbox"/> other <input type="checkbox"/>
ICU stay	yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes	preop scheduled <input type="checkbox"/> unscheduled <input type="checkbox"/> indication:
Physiotherapy	yes <input type="checkbox"/>	no <input type="checkbox"/>		
Breathing exercises	yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes	incentive spirometry yes <input type="checkbox"/> no <input type="checkbox"/>
Cumulated Ambulation Score (page 34) [0-6]:				
Impairment of wound healing	yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes	superficial <input type="checkbox"/> deep <input type="checkbox"/>
Surgical wound infection	yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes	superficial <input type="checkbox"/> deep <input type="checkbox"/> if yes abscess <input type="checkbox"/> empyema <input type="checkbox"/> phlegmon <input type="checkbox"/>
Return of bowel function	yes <input type="checkbox"/>	no <input type="checkbox"/>		

**2 Fluids/ Drugs**

				<i>cumulative dose</i>				<i>cumulative dose</i>
Transfusion	PRBC	yes <input type="checkbox"/>		_____	FFP	yes <input type="checkbox"/>		_____
[ml]	FP24	yes <input type="checkbox"/>		_____	Fibrinogen [g]	yes <input type="checkbox"/>		_____
	Cryoprecipitate	yes <input type="checkbox"/>		_____	PPSB [IU]	yes <input type="checkbox"/>		_____
	Platelets	yes <input type="checkbox"/>		_____	other	yes <input type="checkbox"/>		_____
					if other			
					type:			
Antibiotics		yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes	prophylaxis <input type="checkbox"/>	therapy <input type="checkbox"/>		
Vasoactive drugs		yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes	Dobutamine <input type="checkbox"/>	Dopamine <input type="checkbox"/>	Epinephrine <input type="checkbox"/>	
					Norepinephrine <input type="checkbox"/>	Phenylephrine <input type="checkbox"/>	other <input type="checkbox"/>	
				if yes	type			

Investigator \_\_\_\_\_ Signature \_\_\_\_\_

Case Report Form PROBESE study  
Version 1.2.1, Aug. 2014, Thomas Bluth

Case ID

center				patient			

**3.1 Actual organ function – mandatory measurements (status at visit)**

SpO <sub>2</sub> beach chair position + 10 min in room air possible?	yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes	SpO <sub>2</sub> [%]:	
			if no	SpO <sub>2</sub> [%]:	and FiO <sub>2</sub> [%] (page 35):
RR [/min]					
HR [/min]	ABP mean [mmHg]				
Temperature [°C]	tympanic <input type="checkbox"/> axillar <input type="checkbox"/> inguinal <input type="checkbox"/> oral <input type="checkbox"/> rectal <input type="checkbox"/> other <input type="checkbox"/> if other specify:				
Airway secretion	yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes	purulent <input type="checkbox"/>	not purulent <input type="checkbox"/>
VAS dyspnea [1-10cm]	VAS thoracic pain [1-10cm]				
VAS abdominal rest pain [1-10cm]	VAS abdominal incident pain [1-10cm]				

**3.2 Non-mandatory measurements**

Spirometry			Laboratory tests		
FVC [L]	FVC[% predicted]		Hb	mmol/l <input type="checkbox"/>	g/dl <input type="checkbox"/>
FEV <sub>1</sub> [L/1sec]	FEV <sub>1</sub> [% predicted]		WBC	GPt/L	
			Platelets	GPt/L	
<b>Chest X-ray</b> obtained	yes <input type="checkbox"/>	no <input type="checkbox"/>	PT	INR	
if yes			PTT	sec	
infiltrates	yes <input type="checkbox"/>	no <input type="checkbox"/>	Creatinine	μmol/l <input type="checkbox"/>	mg/dl <input type="checkbox"/>
pleural effusion	yes <input type="checkbox"/>	no <input type="checkbox"/>	BUN	mmol/l <input type="checkbox"/>	mg/dl <input type="checkbox"/>
atelectasis	yes <input type="checkbox"/>	no <input type="checkbox"/>	ALT	μmol/s*1 <input type="checkbox"/>	U/L <input type="checkbox"/>
pneumothorax	yes <input type="checkbox"/>	no <input type="checkbox"/>	AST	μmol/s*1 <input type="checkbox"/>	U/L <input type="checkbox"/>
cardiopulmonary edema	yes <input type="checkbox"/>	no <input type="checkbox"/>	Bilirubin	μmol/l <input type="checkbox"/>	mg/dl <input type="checkbox"/>

Investigator \_\_\_\_\_ Signature \_\_\_\_\_

Case ID	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	center		patient				

**4 Pulmonary complications (see also detailed definitions, page 36)**

Aspiration pneumonia resp. failure after inhalation of gastric contents	yes <input type="checkbox"/>	no <input type="checkbox"/>	
Bronchospasm newly expiratory wheezing treated with bronchodilators	yes <input type="checkbox"/>	no <input type="checkbox"/>	
Mild respiratory failure SpO <sub>2</sub> <90% or PaO <sub>2</sub> <60mmHg for 10min in room air, responding to oxygen ≤ 2l/min	yes <input type="checkbox"/>	no <input type="checkbox"/>	
Moderate respiratory failure SpO <sub>2</sub> <90% or PaO <sub>2</sub> <60mmHg for 10min in room air, responding to oxygen > 2l/min	yes <input type="checkbox"/>	no <input type="checkbox"/>	
Severe respiratory failure need for non-invasive or invasive mechanical ventilation	yes <input type="checkbox"/>	no <input type="checkbox"/>	
ARDS according to Berlin definition	yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes mild <input type="checkbox"/> moderate <input type="checkbox"/> severe <input type="checkbox"/>
Pulmonary infection new/ progressive infiltrates + 2: antibiotics, fever, leukocytosis/ leucopenia and/or purulent secretions	yes <input type="checkbox"/>	no <input type="checkbox"/>	no CXR <input type="checkbox"/>
Atelectasis lung opacification with shift of surrounding tissue/ organ towards the affected area	yes <input type="checkbox"/>	no <input type="checkbox"/>	no CXR <input type="checkbox"/>
Cardiopulmonary edema clinical signs of congestion + interstitial infiltrates/ increased vascular markings on chest X-ray	yes <input type="checkbox"/>	no <input type="checkbox"/>	no CXR <input type="checkbox"/>
Pleural effusion blunting of costophrenic angle (standing)/ hazy opacity in one hemithorax (supine) on chest X-ray	yes <input type="checkbox"/>	no <input type="checkbox"/>	no CXR <input type="checkbox"/>
Pneumothorax free air in the pleural space on chest X-ray/ ultrasonic imaging	yes <input type="checkbox"/>	no <input type="checkbox"/>	no CXR <input type="checkbox"/>
New pulmonary infiltrates monolateral/ bilateral infiltrates without other clinical signs	yes <input type="checkbox"/>	no <input type="checkbox"/>	no CXR <input type="checkbox"/>

**5 Extrapulmonary complications (see also detailed definitions, page 37)**

SIRS ≥2 findings: Temp < 36 °C or > 38 °C; HR > 90 bpm, RR > 20 bpm; WBC < 4.000 or > 12.000/μl	yes <input type="checkbox"/>	no <input type="checkbox"/>	
Sepsis SIRS in response to a confirmed infective process	yes <input type="checkbox"/>	no <input type="checkbox"/>	
Severe Sepsis Sepsis with organ dysfunction, hypoperfusion or hypotension	yes <input type="checkbox"/>	no <input type="checkbox"/>	
Septic shock Sepsis with refractory hypoperfusion or hypotension despite adequate fluid resuscitation	yes <input type="checkbox"/>	no <input type="checkbox"/>	
Extrapulmonary infection wound infection + any other (extrapulmonary) infection	yes <input type="checkbox"/>	no <input type="checkbox"/>	
Coma Glasgow-Coma-Scale ≤ 8 without therapeutic coma/ sedatives	yes <input type="checkbox"/>	no <input type="checkbox"/>	
Acute myocardial infarction rise/ fall of cardiac markers + symptoms/ ECG changes/ /imaging of cardiac ischemia/sudden death	yes <input type="checkbox"/>	no <input type="checkbox"/>	
Acute renal failure Risk: increased Crea x1.5/ GFR decrease > 25% or urine output (UO) < 0.5 ml/kg/h x 6 hr Injury: increased Crea x2 or GFR decrease > 50% or UO < 0.5 ml/kg/h x 12 hr Failure: increase Crea x3 or GFR decrease > 75% or UO < 0.3 ml/kg/h x 24 hr or anuria x 12 hrs Loss: complete loss of kidney function > 4 weeks	yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes R <input type="checkbox"/> I <input type="checkbox"/> F <input type="checkbox"/> L <input type="checkbox"/>
Disseminated intravascular coagulation according to DIC score > 5	yes <input type="checkbox"/>	no <input type="checkbox"/>	
Hepatic failure bilirubin on postop day5/day1 > 1,7 + INR on postop day5/day1 > 1,0	yes <input type="checkbox"/>	no <input type="checkbox"/>	
Gastrointestinal failure 1 = enteral feeding with under 50% of calculated needs or no feeding 3 days after surgery 2 = food intolerance (FI) or intra-abdominal hypertension (IAH) 3 = FI and IAH 4 = abdominal compartment syndrome (ACS)	yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/>

Investigator _____	Signature _____
--------------------	-----------------

Case ID

center				patient			

The PROBESE Randomized Controlled Trial

6 Postoperative Visit Day 4

**POSTOPERATIVE DAY 4 (last 24hrs period)**  
report events within this period of not stated otherwise

**1 Recovery**

Lost to follow up	yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes	reason
New requirement of NIV	yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes	CPAP <input type="checkbox"/> NPPV <input type="checkbox"/> duration [hrs] intensity [pressure level]: standard of care <input type="checkbox"/> treatment of resp. failure <input type="checkbox"/>
New requirement of invasive MV	yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes	duration [hrs] indication: resurgery <input type="checkbox"/> resp. failure <input type="checkbox"/> other <input type="checkbox"/>
ICU stay	yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes	preop scheduled <input type="checkbox"/> unscheduled <input type="checkbox"/> indication:
Physiotherapy	yes <input type="checkbox"/>	no <input type="checkbox"/>		
Breathing exercises	yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes	incentive spirometry yes <input type="checkbox"/> no <input type="checkbox"/>
Cumulated Ambulation Score (page 34) [0-6]:				
Impairment of wound healing	yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes	superficial <input type="checkbox"/> deep <input type="checkbox"/>
Surgical wound infection	yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes	superficial <input type="checkbox"/> deep <input type="checkbox"/> if yes abscess <input type="checkbox"/> empyema <input type="checkbox"/> phlegmon <input type="checkbox"/>
Return of bowel function	yes <input type="checkbox"/>	no <input type="checkbox"/>		

**2 Fluids/ Drugs**

				<i>cumulative dose</i>				<i>cumulative dose</i>
Transfusion	PRBC	yes <input type="checkbox"/>		_____	FFP	yes <input type="checkbox"/>		_____
[ml]	FP24	yes <input type="checkbox"/>		_____	Fibrinogen [g]	yes <input type="checkbox"/>		_____
	Cryoprecipitate	yes <input type="checkbox"/>		_____	PPSB [IU]	yes <input type="checkbox"/>		_____
	Platelets	yes <input type="checkbox"/>		_____	other	yes <input type="checkbox"/>		_____
			if other		type:			
Antibiotics		yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes	prophylaxis <input type="checkbox"/>	therapy <input type="checkbox"/>		
Vasoactive drugs		yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes	Dobutamine <input type="checkbox"/>	Dopamine <input type="checkbox"/>	Epinephrine <input type="checkbox"/>	
				if yes	Norepinephrine <input type="checkbox"/>	Phenylephrine <input type="checkbox"/>	other <input type="checkbox"/>	
				if yes	type			

Investigator \_\_\_\_\_ Signature \_\_\_\_\_

Case Report Form PROBESE study  
Version 1.2.1, Aug. 2014, Thomas Bluth



Case ID

center			patient		

**3.1 Actual organ function – mandatory measurements (status at visit)**SpO<sub>2</sub> beach chair position + 10 min in room air possible?yes  no if yes SpO<sub>2</sub> [%]:if no SpO<sub>2</sub> [%]: and FiO<sub>2</sub> [%] (page 35):

RR [/min]

HR [/min]

ABP mean [mmHg]

Temperature [°C]

 tympanic  axillar  inguinal  oral  rectal 
other  if other specify:

Airway secretion

yes  no if yes purulent  not purulent 

VAS dyspnea [1-10cm]

VAS thoracic pain [1-10cm]

VAS abdominal rest pain [1-10cm]

VAS abdominal incident pain [1-10cm]

**3.2 Non-mandatory measurements****Spirometry**

FVC [L]

FVC[% predicted]

FEV<sub>1</sub> [L/1sec]FEV<sub>1</sub> [% predicted]**Laboratory tests**

Hb

mmol/l g/dl 

WBC

GPt/L

Platelets

GPt/L

**Chest X-ray** obtainedyes  no 

if yes

infiltrates

yes  no 

pleural effusion

yes  no 

atelectasis

yes  no 

pneumothorax

yes  no 

cardiopulmonary edema

yes  no 

PT

INR

PTT

sec

Creatinine

μmol/l mg/dl 

BUN

mmol/l mg/dl 

ALT

μmol/s\*1 U/L 

AST

μmol/s\*1 U/L 

Bilirubin

μmol/l mg/dl 

Investigator \_\_\_\_\_ Signature \_\_\_\_\_

Case ID	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	center		patient				

**4 Pulmonary complications (see also detailed definitions, page 36)**

Aspiration pneumonitis resp. failure after inhalation of gastric contents	yes <input type="checkbox"/>	no <input type="checkbox"/>	
Bronchospasm newly expiratory wheezing treated with bronchodilators	yes <input type="checkbox"/>	no <input type="checkbox"/>	
Mild respiratory failure SpO <sub>2</sub> <90% or PaO <sub>2</sub> <60mmHg for 10min in room air, responding to oxygen ≤ 2l/min	yes <input type="checkbox"/>	no <input type="checkbox"/>	
Moderate respiratory failure SpO <sub>2</sub> <90% or PaO <sub>2</sub> <60mmHg for 10min in room air, responding to oxygen > 2l/min	yes <input type="checkbox"/>	no <input type="checkbox"/>	
Severe respiratory failure need for non-invasive or invasive mechanical ventilation	yes <input type="checkbox"/>	no <input type="checkbox"/>	
ARDS according to Berlin definition	yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes mild <input type="checkbox"/> moderate <input type="checkbox"/> severe <input type="checkbox"/>
Pulmonary infection new/ progressive infiltrates + 2: antibiotics, fever, leukocytosis/ leucopenia and/or purulent secretions	yes <input type="checkbox"/>	no <input type="checkbox"/>	no CXR <input type="checkbox"/>
Atelectasis lung opacification with shift of surrounding tissue/ organ towards the affected area	yes <input type="checkbox"/>	no <input type="checkbox"/>	no CXR <input type="checkbox"/>
Cardiopulmonary edema clinical signs of congestion + interstitial infiltrates/ increased vascular markings on chest X-ray	yes <input type="checkbox"/>	no <input type="checkbox"/>	no CXR <input type="checkbox"/>
Pleural effusion blunting of costophrenic angle (standing)/ hazy opacity in one hemithorax (supine) on chest X-ray	yes <input type="checkbox"/>	no <input type="checkbox"/>	no CXR <input type="checkbox"/>
Pneumothorax free air in the pleural space on chest X-ray/ ultrasonic imaging	yes <input type="checkbox"/>	no <input type="checkbox"/>	no CXR <input type="checkbox"/>
New pulmonary infiltrates monolateral/ bilateral infiltrates without other clinical signs	yes <input type="checkbox"/>	no <input type="checkbox"/>	no CXR <input type="checkbox"/>

**5 Extrapulmonary complications (see also detailed definitions, page 37)**

SIRS ≥2 findings: Temp < 36 °C or > 38 °C; HR > 90 bpm, RR > 20 bpm; WBC < 4.000 or > 12.000/μl	yes <input type="checkbox"/>	no <input type="checkbox"/>	
Sepsis SIRS in response to a confirmed infective process	yes <input type="checkbox"/>	no <input type="checkbox"/>	
Severe Sepsis Sepsis with organ dysfunction, hypoperfusion or hypotension	yes <input type="checkbox"/>	no <input type="checkbox"/>	
Septic shock Sepsis with refractory hypoperfusion or hypotension despite adequate fluid resuscitation	yes <input type="checkbox"/>	no <input type="checkbox"/>	
Extrapulmonary infection wound infection + any other (extrapulmonary) infection	yes <input type="checkbox"/>	no <input type="checkbox"/>	
Coma Glasgow-Coma-Scale ≤ 8 without therapeutic coma/ sedatives	yes <input type="checkbox"/>	no <input type="checkbox"/>	
Acute myocardial infarction rise/ fall of cardiac markers + symptoms/ ECG changes/ /imaging of cardiac ischemia/sudden death	yes <input type="checkbox"/>	no <input type="checkbox"/>	
Acute renal failure Risk: increased Crea x1.5/ GFR decrease > 25% or urine output (UO) < 0.5 ml/kg/h x 6 hr Injury: increased Crea x2 or GFR decrease > 50% or UO < 0.5 ml/kg/h x 12 hr Failure: increase Crea x3 or GFR decrease > 75% or UO < 0.3 ml/kg/h x 24 hr or anuria x 12 hrs Loss: complete loss of kidney function > 4 weeks	yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes R <input type="checkbox"/> I <input type="checkbox"/> F <input type="checkbox"/> L <input type="checkbox"/>
Disseminated intravascular coagulation according to DIC score > 5	yes <input type="checkbox"/>	no <input type="checkbox"/>	
Hepatic failure bilirubin on postop day5/day1 > 1,7 + INR on postop day5/day1 > 1,0	yes <input type="checkbox"/>	no <input type="checkbox"/>	
Gastrointestinal failure 1 = enteral feeding with under 50% of calculated needs or no feeding 3 days after surgery 2 = food intolerance (FI) or intra-abdominal hypertension (IAH) 3 = FI and IAH 4 = abdominal compartment syndrome (ACS)	yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/>

Investigator _____	Signature _____
--------------------	-----------------

Case ID

center			patient		

The PROBESE Randomized Controlled Trial

7 Postoperative Visit Day 5

**POSTOPERATIVE DAY 5 (last 24hrs period)**  
report events within this period of not stated otherwise

**1 Recovery**

Lost to follow up	yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes	reason
New requirement of NIV	yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes	CPAP <input type="checkbox"/> NPPV <input type="checkbox"/> duration [hrs] intensity [pressure level]: standard of care <input type="checkbox"/> treatment of resp. failure <input type="checkbox"/>
New requirement of invasive MV	yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes	duration [hrs] indication: resurgery <input type="checkbox"/> resp. failure <input type="checkbox"/> other <input type="checkbox"/>
ICU stay	yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes	preop scheduled <input type="checkbox"/> unscheduled <input type="checkbox"/> indication:
Physiotherapy	yes <input type="checkbox"/>	no <input type="checkbox"/>		
Breathing exercises	yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes	incentive spirometry yes <input type="checkbox"/> no <input type="checkbox"/>
Cumulated Ambulation Score (page 34) [0-6]:				
Impairment of wound healing	yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes	superficial <input type="checkbox"/> deep <input type="checkbox"/>
Surgical wound infection	yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes	superficial <input type="checkbox"/> deep <input type="checkbox"/> if yes abscess <input type="checkbox"/> empyema <input type="checkbox"/> phlegmon <input type="checkbox"/>
Return of bowel function	yes <input type="checkbox"/>	no <input type="checkbox"/>		

**2 Fluids/ Drugs**

				<i>cumulative dose</i>				<i>cumulative dose</i>
Transfusion	PRBC	yes <input type="checkbox"/>		_____	FFP	yes <input type="checkbox"/>		_____
[ml]	FP24	yes <input type="checkbox"/>		_____	Fibrinogen [g]	yes <input type="checkbox"/>		_____
	Cryoprecipitate	yes <input type="checkbox"/>		_____	PPSB [IU]	yes <input type="checkbox"/>		_____
	Platelets	yes <input type="checkbox"/>		_____	other	yes <input type="checkbox"/>		_____
					if other			
					type:			
Antibiotics		yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes	prophylaxis <input type="checkbox"/>	therapy <input type="checkbox"/>		
Vasoactive drugs		yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes	Dobutamine <input type="checkbox"/>	Dopamine <input type="checkbox"/>	Epinephrine <input type="checkbox"/>	
					Norepinephrine <input type="checkbox"/>	Phenylephrine <input type="checkbox"/>	other <input type="checkbox"/>	
				if yes	type			

Investigator \_\_\_\_\_ Signature \_\_\_\_\_

Case Report Form PROBESE study  
Version 1.2.1, Aug. 2014, Thomas Bluth

Case ID

center			patient		

**3.1 Actual organ function – mandatory measurements (status at visit)**SpO<sub>2</sub> beach chair position + 10 min in room air possible?yes  no if yes SpO<sub>2</sub> [%]:if no SpO<sub>2</sub> [%]: and FiO<sub>2</sub> [%] (page 35):

RR [/min]

HR [/min]

ABP mean [mmHg]

Temperature [°C]

 tympanic  axillar  inguinal  oral  rectal 
other  if other specify:

Airway secretion

yes  no if yes purulent  not purulent 

VAS dyspnea [1-10cm]

VAS thoracic pain [1-10cm]

VAS abdominal rest pain [1-10cm]

VAS abdominal incident pain [1-10cm]

**3.2 Non-mandatory measurements****Spirometry**

FVC [L]

FVC[% predicted]

FEV<sub>1</sub> [L/1sec]FEV<sub>1</sub> [% predicted]**Laboratory tests**Hb mmol/l  g/dl 

WBC GPt/L

Platelets GPt/L

**Chest X-ray** obtainedyes  no 

if yes

infiltrates

yes  no 

pleural effusion

yes  no 

atelectasis

yes  no 

pneumothorax

yes  no 

cardiopulmonary edema

yes  no 

PT INR

PTT sec

Creatinine μmol/l  mg/dl BUN mmol/l  mg/dl ALT μmol/s\*1  U/L AST μmol/s\*1  U/L Bilirubin μmol/l  mg/dl 

Investigator \_\_\_\_\_ Signature \_\_\_\_\_

Case ID	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	center		patient				

**4 Pulmonary complications (see also detailed definitions, page 36)**

Aspiration pneumonia resp. failure after inhalation of gastric contents	yes <input type="checkbox"/>	no <input type="checkbox"/>	
Bronchospasm newly expiratory wheezing treated with bronchodilators	yes <input type="checkbox"/>	no <input type="checkbox"/>	
Mild respiratory failure SpO <sub>2</sub> <90% or PaO <sub>2</sub> <60mmHg for 10min in room air, responding to oxygen ≤ 2l/min	yes <input type="checkbox"/>	no <input type="checkbox"/>	
Moderate respiratory failure SpO <sub>2</sub> <90% or PaO <sub>2</sub> <60mmHg for 10min in room air, responding to oxygen > 2l/min	yes <input type="checkbox"/>	no <input type="checkbox"/>	
Severe respiratory failure need for non-invasive or invasive mechanical ventilation	yes <input type="checkbox"/>	no <input type="checkbox"/>	
ARDS according to Berlin definition	yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes mild <input type="checkbox"/> moderate <input type="checkbox"/> severe <input type="checkbox"/>
Pulmonary infection new/ progressive infiltrates + 2: antibiotics, fever, leukocytosis/ leucopenia and/or purulent secretions	yes <input type="checkbox"/>	no <input type="checkbox"/>	no CXR <input type="checkbox"/>
Atelectasis lung opacification with shift of surrounding tissue/ organ towards the affected area	yes <input type="checkbox"/>	no <input type="checkbox"/>	no CXR <input type="checkbox"/>
Cardiopulmonary edema clinical signs of congestion + interstitial infiltrates/ increased vascular markings on chest X-ray	yes <input type="checkbox"/>	no <input type="checkbox"/>	no CXR <input type="checkbox"/>
Pleural effusion blunting of costophrenic angle (standing)/ hazy opacity in one hemithorax (supine) on chest X-ray	yes <input type="checkbox"/>	no <input type="checkbox"/>	no CXR <input type="checkbox"/>
Pneumothorax free air in the pleural space on chest X-ray/ ultrasonic imaging	yes <input type="checkbox"/>	no <input type="checkbox"/>	no CXR <input type="checkbox"/>
New pulmonary infiltrates monolateral/ bilateral infiltrates without other clinical signs	yes <input type="checkbox"/>	no <input type="checkbox"/>	no CXR <input type="checkbox"/>

**5 Extrapulmonary complications (see also detailed definitions, page 37)**

SIRS ≥2 findings: Temp < 36 °C or > 38 °C; HR > 90 bpm, RR > 20 bpm; WBC < 4.000 or > 12.000/μl	yes <input type="checkbox"/>	no <input type="checkbox"/>	
Sepsis SIRS in response to a confirmed infective process	yes <input type="checkbox"/>	no <input type="checkbox"/>	
Severe Sepsis Sepsis with organ dysfunction, hypoperfusion or hypotension	yes <input type="checkbox"/>	no <input type="checkbox"/>	
Septic shock Sepsis with refractory hypoperfusion or hypotension despite adequate fluid resuscitation	yes <input type="checkbox"/>	no <input type="checkbox"/>	
Extrapulmonary infection wound infection + any other (extrapulmonary) infection	yes <input type="checkbox"/>	no <input type="checkbox"/>	
Coma Glasgow-Coma-Scale ≤ 8 without therapeutic coma/ sedatives	yes <input type="checkbox"/>	no <input type="checkbox"/>	
Acute myocardial infarction rise/ fall of cardiac markers + symptoms/ ECG changes/ /imaging of cardiac ischemia/sudden death	yes <input type="checkbox"/>	no <input type="checkbox"/>	
Acute renal failure Risk: increased Crea x1.5/ GFR decrease > 25% or urine output (UO) < 0.5 ml/kg/h x 6 hr Injury: increased Crea x2 or GFR decrease > 50% or UO < 0.5 ml/kg/h x 12 hr Failure: increase Crea x3 or GFR decrease > 75% or UO < 0.3 ml/kg/h x 24 hr or anuria x 12 hrs Loss: complete loss of kidney function > 4 weeks	yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes R <input type="checkbox"/> I <input type="checkbox"/> F <input type="checkbox"/> L <input type="checkbox"/>
Disseminated intravascular coagulation according to DIC score > 5	yes <input type="checkbox"/>	no <input type="checkbox"/>	
Hepatic failure bilirubin on postop day5/day1 > 1,7 + INR on postop day5/day1 > 1,0	yes <input type="checkbox"/>	no <input type="checkbox"/>	
Gastrointestinal failure 1 = enteral feeding with under 50% of calculated needs or no feeding 3 days after surgery 2 = food intolerance (FI) or intra-abdominal hypertension (IAH) 3 = FI and IAH 4 = abdominal compartment syndrome (ACS)	yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/>

Investigator _____	Signature _____
--------------------	-----------------

Case ID

center				patient			

The PROBESE Randomized Controlled Trial

8 Discharge/Day90

**DISCHARGE (period from last visit to discharge) + POSTOPERATIVE DAY 90**

report events within this period of not stated otherwise

**1 Recovery**

Lost to follow up	yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes	reason
Date of discharge	/ / 20		Postop day of discharge [1-90]	
Hospital free days on day 90				
New requirement of NIV	yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes	CPAP <input type="checkbox"/> NPPV <input type="checkbox"/> duration [hrs]
	intensity [pressure level]:			
	standard of care <input type="checkbox"/> treatment of resp. failure <input type="checkbox"/>			
New requirement of invasive MV	yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes	duration [hrs]
	indication: resurgery <input type="checkbox"/> resp. failure <input type="checkbox"/> other <input type="checkbox"/>			
ICU stay	yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes	preop scheduled <input type="checkbox"/> unscheduled <input type="checkbox"/>
	indication:			
Cumulated Ambulation Score (actual state, page 34) [0-6]:				
Impairment of wound healing	yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes	superficial <input type="checkbox"/> deep <input type="checkbox"/>
Surgical wound infection	yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes	superficial <input type="checkbox"/> deep <input type="checkbox"/>
	if yes: abscess <input type="checkbox"/> empyema <input type="checkbox"/> phlegmon <input type="checkbox"/>			
Antibiotics	yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes	prophylaxis <input type="checkbox"/> therapy <input type="checkbox"/>

Investigator \_\_\_\_\_ Signature \_\_\_\_\_

Case Report Form PROBESE study  
Version 1.1, Sep. 2013, Thomas Bluth

Case ID

center			patient		

**2.1 Actual organ function – mandatory measurements (status at visit)**SpO<sub>2</sub> beach chair position + 10 min in room air possible?yes  no if yes SpO<sub>2</sub> [%]:if no SpO<sub>2</sub> [%]: and FiO<sub>2</sub> [%] (page 35):

RR [/min]

HR [/min]

ABP mean [mmHg]

Temperature [°C]

 tympanic  axillar  inguinal  oral  rectal 
other  if other specify:

Airway secretion

yes  no if yes purulent  not purulent 

VAS dyspnea [1-10cm]

VAS thoracic pain [1-10cm]

VAS abdominal rest pain [1-10cm]

VAS abdominal incident pain [1-10cm]

**2.2 Non-mandatory measurements****Spirometry**

FVC [L]

FVC[% predicted]

FEV<sub>1</sub> [L/1sec]FEV<sub>1</sub> [% predicted]**Laboratory tests**Hb mmol/l  g/dl 

WBC GPt/L

Platelets GPt/L

**Chest X-ray** obtainedyes  no 

if yes

infiltrates

yes  no 

pleural effusion

yes  no 

atelectasis

yes  no 

pneumothorax

yes  no 

cardiopulmonary edema

yes  no 

PT INR

PTT sec

Creatinine μmol/l  mg/dl BUN mmol/l  mg/dl ALT μmol/s\*1  U/L AST μmol/s\*1  U/L Bilirubin μmol/l  mg/dl 

Investigator \_\_\_\_\_ Signature \_\_\_\_\_

Case ID	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	center		patient				

**3 Pulmonary complications (see also detailed definitions, page 36)**

Aspiration pneumonia resp. failure after inhalation of gastric contents	yes <input type="checkbox"/>	no <input type="checkbox"/>	
Bronchospasm newly expiratory wheezing treated with bronchodilators	yes <input type="checkbox"/>	no <input type="checkbox"/>	
Mild respiratory failure SpO <sub>2</sub> <90% or PaO <sub>2</sub> <60mmHg for 10min in room air, responding to oxygen ≤ 2l/min	yes <input type="checkbox"/>	no <input type="checkbox"/>	
Moderate respiratory failure SpO <sub>2</sub> <90% or PaO <sub>2</sub> <60mmHg for 10min in room air, responding to oxygen > 2l/min	yes <input type="checkbox"/>	no <input type="checkbox"/>	
Severe respiratory failure need for non-invasive or invasive mechanical ventilation	yes <input type="checkbox"/>	no <input type="checkbox"/>	
ARDS according to Berlin definition	yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes mild <input type="checkbox"/> moderate <input type="checkbox"/> severe <input type="checkbox"/>
Pulmonary infection new/ progressive infiltrates + 2: antibiotics, fever, leukocytosis/ leucopenia and/or purulent secretions	yes <input type="checkbox"/>	no <input type="checkbox"/>	no CXR <input type="checkbox"/>
Atelectasis lung opacification with shift of surrounding tissue/ organ towards the affected area	yes <input type="checkbox"/>	no <input type="checkbox"/>	no CXR <input type="checkbox"/>
Cardiopulmonary edema clinical signs of congestion + interstitial infiltrates/ increased vascular markings on chest X-ray	yes <input type="checkbox"/>	no <input type="checkbox"/>	no CXR <input type="checkbox"/>
Pleural effusion blunting of costophrenic angle (standing)/ hazy opacity in one hemithorax (supine) on chest X-ray	yes <input type="checkbox"/>	no <input type="checkbox"/>	no CXR <input type="checkbox"/>
Pneumothorax free air in the pleural space on chest X-ray/ ultrasonic imaging	yes <input type="checkbox"/>	no <input type="checkbox"/>	no CXR <input type="checkbox"/>
New pulmonary infiltrates monolateral/ bilateral infiltrates without other clinical signs	yes <input type="checkbox"/>	no <input type="checkbox"/>	no CXR <input type="checkbox"/>

**4 Extrapulmonary complications (see also detailed definitions, page 37)**

SIRS ≥2 findings: Temp < 36 °C or > 38 °C; HR > 90 bpm, RR > 20 bpm; WBC < 4.000 or > 12.000/μl	yes <input type="checkbox"/>	no <input type="checkbox"/>	
Sepsis SIRS in response to a confirmed infective process	yes <input type="checkbox"/>	no <input type="checkbox"/>	
Severe Sepsis Sepsis with organ dysfunction, hypoperfusion or hypotension	yes <input type="checkbox"/>	no <input type="checkbox"/>	
Septic shock Sepsis with refractory hypoperfusion or hypotension despite adequate fluid resuscitation	yes <input type="checkbox"/>	no <input type="checkbox"/>	
Extrapulmonary infection wound infection + any other (extrapulmonary) infection	yes <input type="checkbox"/>	no <input type="checkbox"/>	
Coma Glasgow-Coma-Scale ≤ 8 without therapeutic coma/ sedatives	yes <input type="checkbox"/>	no <input type="checkbox"/>	
Acute myocardial infarction rise/ fall of cardiac markers + symptoms/ ECG changes/ /imaging of cardiac ischemia/sudden death	yes <input type="checkbox"/>	no <input type="checkbox"/>	
Acute renal failure Risk: increased Crea x1.5/ GFR decrease > 25% or urine output (UO) < 0.5 ml/kg/h x 6 hr Injury: increased Crea x2 or GFR decrease > 50% or UO < 0.5 ml/kg/h x 12 hr Failure: increase Crea x3 or GFR decrease > 75% or UO < 0.3 ml/kg/h x 24 hr or anuria x 12 hrs Loss: complete loss of kidney function > 4 weeks	yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes R <input type="checkbox"/> I <input type="checkbox"/> F <input type="checkbox"/> L <input type="checkbox"/>
Disseminated intravascular coagulation according to DIC score > 5	yes <input type="checkbox"/>	no <input type="checkbox"/>	
Hepatic failure bilirubin on postop day5/day1 > 1,7 + INR on postop day5/day1 > 1,0	yes <input type="checkbox"/>	no <input type="checkbox"/>	
Gastrointestinal failure 1 = enteral feeding with under 50% of calculated needs or no feeding 3 days after surgery 2 = food intolerance (FI) or intra-abdominal hypertension (IAH) 3 = FI and IAH 4 = abdominal compartment syndrome (ACS)	yes <input type="checkbox"/>	no <input type="checkbox"/>	if yes 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/>

Investigator _____	Signature _____
--------------------	-----------------



**DEFINITIONS and SCORES****1 Waist-Hip-Ratio measurement according to WHO protocol**

Waist circumference should be measured at the midpoint between the lower margin of the least palpable rib and the top of the iliac crest, using a stretch - resistant tape that provides a constant 100 g tension. Hip circumference should be measured around the widest portion of the buttocks, with the tape parallel to the floor.

For both measurements, the subject should stand with feet close together, arms at the side and body weight evenly distributed, and should wear little clothing. The subject should be relaxed, and the measurements should be taken at the end of a normal expiration. Each measurement should be repeated twice; if the measurements are within 1 cm of one another, the average should be calculated. If the difference between the two measurements exceeds 1 cm, the two measurements should be repeated

(WHO. Waist Circumference and Waist–Hip Ratio: Report of a WHO Expert Consultation. Geneva, World Health Organization (WHO), 2008)

**2 STOP-BANG Score**

1. Snoring	Do you snore loudly (loud enough to be heard through closed doors)?	yes <input type="checkbox"/>	no <input type="checkbox"/>
2. Tired	Do you often feel tired, fatigued, or sleepy during daytime?	yes <input type="checkbox"/>	no <input type="checkbox"/>
3. Observed	Has anyone observed you stop breathing during your sleep?	yes <input type="checkbox"/>	no <input type="checkbox"/>
4. Blood pressure	Do you have or are you being treated for high blood pressure?	yes <input type="checkbox"/>	no <input type="checkbox"/>
5. BMI	BMI more than 35 kg m <sup>-2</sup> ?	yes <input type="checkbox"/>	no <input type="checkbox"/>
6. Age:	Age over 50 years old?	yes <input type="checkbox"/>	no <input type="checkbox"/>
7. Neck circumference	Neck circumference >40 cm?	yes <input type="checkbox"/>	no <input type="checkbox"/>
8. Gender	Male?	yes <input type="checkbox"/>	no <input type="checkbox"/>
<b>Total score</b>	<b>Yes to _____ questions</b>		

**3 Cumulated Ambulation Score (CAS)**

The patient is assessed on the following functions:

	Able to perform function independently	Only able to perform function with assistance from one or two people	Unable to perform function despite assistance from two people
Transfer from supine-to-sitting-to-supine	2	1	0
Transfer from sitting-to-standing-to-sitting (from armchair)	2	1	0
Walking (with appropriate walking aid)	2	1	0

**Total Score [Sum of all values on a given day]: \_\_\_\_\_**

4 Converting oxygen therapy from O<sub>2</sub> to FiO<sub>2</sub>

Method	O <sub>2</sub> flow (l/min)	Estimated FiO <sub>2</sub> (%)
Nasal cannula	1	24
	2	28
	3	32
	4	35
	5	40
	6	44
Nasopharyngeal catheter	4	40
	5	50
	6	60
Face mask	5	40
	6-7	50
	7-8	60
Face mask with reservoir	6	60
	7	70
	8	80
	9	90
	10	95

## 6 DEFINITIONS of pulmonary post-operative complications

- Aspiration pneumonitis:  
Defined as respiratory failure after the inhalation of regurgitated gastric contents
- Bronchospasm:  
Defined as newly detected expiratory wheezing treated with bronchodilators
- Mild respiratory failure:  
 $\text{PaO}_2 < 60 \text{ mmHg}$  or  $\text{SpO}_2 < 90\%$  in room air during at least 10 min air *but responding* to supplemental oxygen (excluding hypoventilation)
- Moderate respiratory failure:  
 $\text{PaO}_2 < 60 \text{ mmHg}$  or  $\text{SpO}_2 < 90\%$  *despite* supplemental oxygen (excluding hypoventilation)
- Severe respiratory failure:  
Need for non-invasive or invasive mechanical ventilation (excluding hypoventilation)
- ARDS:  
Mild, moderate or severe according to the Berlin definition:

<b>Time</b>	Within one week of a known clinical insult, or new/worsening respiratory symptoms		
<b>Chest imaging*</b>	Bilateral opacities not fully explained by effusions, lobar/lung collapse or nodules		
<b>Origin of edema</b>	Respiratory failure not fully explained by cardiac failure or fluid overload; need objective assessment to exclude hydrostatic edema if no risk factor present (e.g., echocardiography)		
	<b>Mild</b>	<b>Moderate</b>	<b>Severe</b>
<b>Oxygenation**</b>	$200 < \text{PaO}_2 / \text{FiO}_2 < 300$	$100 < \text{PaO}_2 / \text{FiO}_2 < 200$	$\text{PaO}_2 / \text{FiO}_2 \leq 100$
	$\text{PEEP or CPAP} \geq 5 \text{ cmH}_2\text{O}^{***}$	$\text{PEEP} \geq 5 \text{ cmH}_2\text{O}$	$\text{PEEP} \geq 5 \text{ cmH}_2\text{O}$

ARDS: acute respiratory distress syndrome;  $\text{PaO}_2$ : partial pressure of arterial oxygen;  $\text{FiO}_2$ : inspired fraction of oxygen; PEEP: positive end-expiratory pressure; CPAP: continuous positive airway pressure

\*: chest X-ray or CT scan

\*\*: if altitude higher than 1,000 meters, correction factor should be made as follows:  $\text{PaO}_2 / \text{FiO}_2 \cdot 9$  (barometric pressure/760)

\*\*\*: this may be delivered non-invasively in the mild ARDS group

- Pulmonary infection:  
Defined as new or progressive radiographic infiltrate plus at least two of the following: antibiotic treatment, tympanic temperature  $> 38^\circ\text{C}$ , leukocytosis or leucopenia (WBC count  $< 4,000\text{cells}/\text{mm}^3$  or  $> 12,000\text{cells}/\text{mm}^3$ ) and/or purulent secretions

**9 Definitions**

- **Atelectasis:**  
Suggested by lung opacification with shift of the mediastinum, hilum, or hemidiaphragm towards the affected area, and compensatory overinflation in the adjacent nonatelectatic lung
- **Cardiopulmonary edema:**  
Defined as clinical signs of congestion, including dyspnea, edema, rales and jugular venous distention, with the chest X–ray demonstrating increase in vascular markings and diffuse alveolar interstitial infiltrates
- **Pleural effusion:**  
Chest X–ray demonstrating blunting of the costophrenic angle, loss of the sharp silhouette of the ipsilateral hemidiaphragm in upright position, evidence of displacement of adjacent anatomical structures, or (in supine position) a hazy opacity in one hemithorax with preserved vascular shadows
- **Pneumothorax:**  
Defined as air in the pleural space with no vascular bed surrounding the visceral pleura
- **New pulmonary infiltrates:**  
Chest X–ray demonstrating new monolateral or bilateral infiltrate without other clinical signs

**7 DEFINITIONS of extra–pulmonary post–operative complications**

- **Systemic inflammatory response syndrome (SIRS):**  
Presence of two or more of the following findings: Body temperature  $< 36^{\circ}\text{C}$  or  $> 38^{\circ}\text{C}$  – Heart rate  $> 90$  beats per minute – Respiratory rate  $> 20$  breaths per minute or, on blood gas, a  $\text{P}_{\text{a}}\text{CO}_2 < 32$  mmHg (4.3 kPa) – WBC count  $< 4,000$  cells/mm<sup>3</sup> or  $> 12,000$  cells/mm<sup>3</sup> or  $> 10\%$  band forms
- **Sepsis:**  
SIRS in response to a confirmed infectious process; infection can be suspected or proven (by culture, stain, or polymerase chain reaction (PCR)), or a clinical syndrome pathognomonic for infection. Specific evidence for infection includes WBCs in normally sterile fluid (such as urine or cerebrospinal fluid (CSF)), evidence of a perforated viscera (free air on abdominal x–ray or CT scan, signs of acute peritonitis), abnormal chest x–ray (CXR) consistent with pneumonia (with focal opacification), or petechiae, purpura, or purpura fulminans
- **Severe sepsis:**  
Sepsis with organ dysfunction, hypoperfusion, or hypotension
- **Septic shock:**  
Sepsis with refractory arterial hypotension or hypoperfusion abnormalities in spite of adequate fluid resuscitation; signs of systemic hypoperfusion may be either end-organ dysfunction or serum lactate greater than 4 mmol/dL. Other signs include oliguria and altered mental status. Patients are defined as having septic shock if they have sepsis plus hypotension after aggressive fluid resuscitation, typically upwards of 6 liters or 40 ml/kg of crystalloid
- **Extra–pulmonary infection:**  
Wound infection + any other infection

- Coma:  
Glasgow Coma Score  $\leq 8$  in the absence of therapeutic coma or sedation
- Acute myocardial infarction:  
Detection of rise and/or fall of cardiac markers (preferably troponin) with at least one value above the 99<sup>th</sup> percentile of the upper reference limit, together with: symptoms of ischemia, ECG changes indicative of new ischemia, development of pathological Q-waves, or imaging evidence of new loss of viable myocardium or new regional wall motion abnormality *Or*: sudden unexpected cardiac death, involving cardiac arrest with symptoms suggestive of cardiac ischemia (but death occurring before the appearance of cardiac markers in blood)
- Acute renal failure:  
Renal failure documented as follows: Risk: increased creatinine x1.5 or GFR decrease  $> 25\%$  *or* urine output (UO)  $< 0.5$  ml/kg/h x 6 hr – Injury: increased creatinine x2 or GFR decrease  $> 50\%$  *or* UO  $< 0.5$  ml/kg/h x 12 hr – Failure: increase creatinine x3 or GFR decrease  $> 75\%$  *or* UO  $< 0.3$  ml/kg/h x 24 hr or anuria x 12 hrs – Loss: persistent ARF = complete loss of kidney function  $> 4$  weeks
- Disseminated intravascular coagulation:  
DIC score documented as follows: Platelet count  $< 50$  (2 points),  $< 100$  (1 point), or  $\geq 100$  (0 points) – D-dimer  $> 4$   $\mu\text{g/ml}$  (2 points),  $> 0.39$   $\mu\text{g/ml}$  (1 point) or  $\leq 0.39$   $\mu\text{g/ml}$  (0 points) – prothrombin time  $> 20.5$  seconds (2 points),  $> 17.5$  seconds (1 point) or  $\leq 17.5$  seconds (0 points); if  $\geq 5$  points: overt DIC
- Hepatic failure:  
Hepatic failure during short term follow up (5 postoperative days) is considered as follows: Ratio of total bilirubin on postoperative day 5 to postoperative day 1  $> 1,7$  and ratio of international normalized ratio (INR) on postoperative day 5 to postoperative day 1  $> 1,0$ ; during long term follow up (until postoperative day 90) at new presence of hepatic encephalopathy and coagulopathy (INR  $> 1,5$ ) within 8 weeks after initial signs of liver injury (e.g. jaundice) without evidence for chronic liver disease
- Gastro-intestinal failure:  
Gastro-intestinal bleeding  
Gastro-intestinal failure (GIF) score documented as follows: 0 = normal gastrointestinal function; 1 = enteral feeding with under 50% of calculated needs or no feeding 3 days after abdominal surgery; 2 = food intolerance (FI) *or* intra-abdominal hypertension (IAH); 3 = FI and IAH; and 4 = abdominal compartment syndrome (ACS)

**A Postoperative adverse events**

**Adverse events (AE) / severe adverse events (SAE)**

Any adverse events      yes     no       if yes    specify according to table:

Event (details, including treatment)	Serious	Intervention	Recovery	Outcome
		unrelated <input type="checkbox"/>	mild <input type="checkbox"/>	resolved - no sequelae <input type="checkbox"/>
yes <input type="checkbox"/>		possible <input type="checkbox"/>	moderate <input type="checkbox"/>	resolved - sequelae <input type="checkbox"/>
no <input type="checkbox"/>		probable <input type="checkbox"/>	severe <input type="checkbox"/>	unresolved <input type="checkbox"/>
		unassessable <input type="checkbox"/>	unassessable <input type="checkbox"/>	death <input type="checkbox"/>
				unknown <input type="checkbox"/>
<hr/>				
		unrelated <input type="checkbox"/>	mild <input type="checkbox"/>	resolved - no sequelae <input type="checkbox"/>
yes <input type="checkbox"/>		possible <input type="checkbox"/>	moderate <input type="checkbox"/>	resolved - sequelae <input type="checkbox"/>
no <input type="checkbox"/>		probable <input type="checkbox"/>	severe <input type="checkbox"/>	unresolved <input type="checkbox"/>
		unassessable <input type="checkbox"/>	unassessable <input type="checkbox"/>	death <input type="checkbox"/>
				unknown <input type="checkbox"/>
<hr/>				
		unrelated <input type="checkbox"/>	mild <input type="checkbox"/>	resolved - no sequelae <input type="checkbox"/>
yes <input type="checkbox"/>		possible <input type="checkbox"/>	moderate <input type="checkbox"/>	resolved - sequelae <input type="checkbox"/>
no <input type="checkbox"/>		probable <input type="checkbox"/>	severe <input type="checkbox"/>	unresolved <input type="checkbox"/>
		unassessable <input type="checkbox"/>	unassessable <input type="checkbox"/>	death <input type="checkbox"/>
				unknown <input type="checkbox"/>
<hr/>				
		unrelated <input type="checkbox"/>	mild <input type="checkbox"/>	resolved - no sequelae <input type="checkbox"/>
yes <input type="checkbox"/>		possible <input type="checkbox"/>	moderate <input type="checkbox"/>	resolved - sequelae <input type="checkbox"/>
no <input type="checkbox"/>		probable <input type="checkbox"/>	severe <input type="checkbox"/>	unresolved <input type="checkbox"/>
		unassessable <input type="checkbox"/>	unassessable <input type="checkbox"/>	death <input type="checkbox"/>
				unknown <input type="checkbox"/>
<hr/>				
		unrelated <input type="checkbox"/>	mild <input type="checkbox"/>	resolved - no sequelae <input type="checkbox"/>
yes <input type="checkbox"/>		possible <input type="checkbox"/>	moderate <input type="checkbox"/>	resolved - sequelae <input type="checkbox"/>
no <input type="checkbox"/>		probable <input type="checkbox"/>	severe <input type="checkbox"/>	unresolved <input type="checkbox"/>
		unassessable <input type="checkbox"/>	unassessable <input type="checkbox"/>	death <input type="checkbox"/>
				unknown <input type="checkbox"/>