

**The GENERATOR Trial**

**INTRAOPERATIVE  
CASE REPORT FORM**

**Driving Pressure During General  
Anesthesia For Minimally Invasive  
Abdominal Surgery**

Patient Identification Number:

Day of Surgery (*dd-mm-yy*):

Local Investigator 1 or 2 (preoperative) \_\_\_\_\_

Local Investigator 1 (intraoperative) \_\_\_\_\_

Local Investigator 2 (postoperative) \_\_\_\_\_

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**Print and store pre- and intraoperative CRF separately from postoperative CRF**

**Intraoperative**

**1. Anesthetic overview**

Predicted bodyweight: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> kg <i>For calculation see preoperative CRF page 4 or preoperative eCRF</i>	Tidal Volume: <input type="text"/> <input type="text"/> <input type="text"/> ml <i>Tidal volume = 8 x predicted bodyweight. For automatic calculation see preoperative eCRF.</i>
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Start of anesthesia <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> (hh:mm) <i>i.e. time of induction</i>	End of anesthesia <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> (hh:mm) <i>i.e. time of extubation or discharge from operation room in case patient remains on mechanical ventilation</i>	Body temperature at end of surgery >35.0 °C <input type="checkbox"/> Yes <input type="checkbox"/> No
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Maintenance of anesthesia  Volatile  TIVA (total intravenous anesthesia)  Combined

Epidural  Yes  No *If yes:*  Thoracic  Lumbar

Neuromuscular blocking agents administered  Yes  No *If yes:*  Non-depolarizing (e.g., rocuronium)  Depolarizing (e.g., succinylcholine) *If non-depolarizing agent:*

What was used for maintenance of muscle relaxation after succinylcholine?  No maintenance  Non-depolarizing  Depolarizing

Neuromuscular function monitoring during surgery  Yes  No

TOF ≥ 90 at end of surgery without antagonization  Yes  No *If no:*

Used antagonist:  Sugammadex  Cholinesterase inhibitor  No antagonist

**2. Surgical overview**

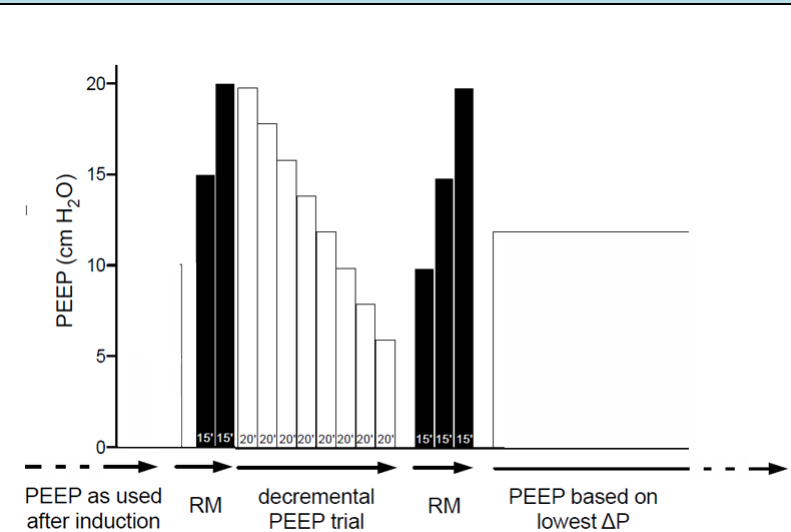
Start of surgery <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> (hh:mm) <i>i.e. time of surgical incision</i>	End of surgery <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> (hh:mm) <i>i.e. time skin closed</i>
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**3. Randomization**

Randomization group:  Individualized high PEEP group *See mechanical ventilation settings on the next page. Complete the entire intraoperative CRF.*  Standard PEEP group *See mechanical ventilation settings on the next page, after continue to page 5 'intraoperative variables' (skip page 4).*

**Mechanical ventilation settings**

<b>Mechanical ventilation settings for both randomization groups</b>	Volume controlled mechanical ventilation during the entire period of surgery
	FiO <sub>2</sub> 0.40 or higher (target SpO <sub>2</sub> >90%)
	I:E ratio = 1:2
	Respiratory rate adjusted to normocapnia (ETCO <sub>2</sub> between 35-45 mm Hg or 4.6-5.9 kPa)
	Tidal volume 8 ml/kg Predicted Body Weight (PBW)
	PEEP 5 cm H <sub>2</sub> O at starting point and continued intraoperative for the control group
	Inspiratory pause of 15%.



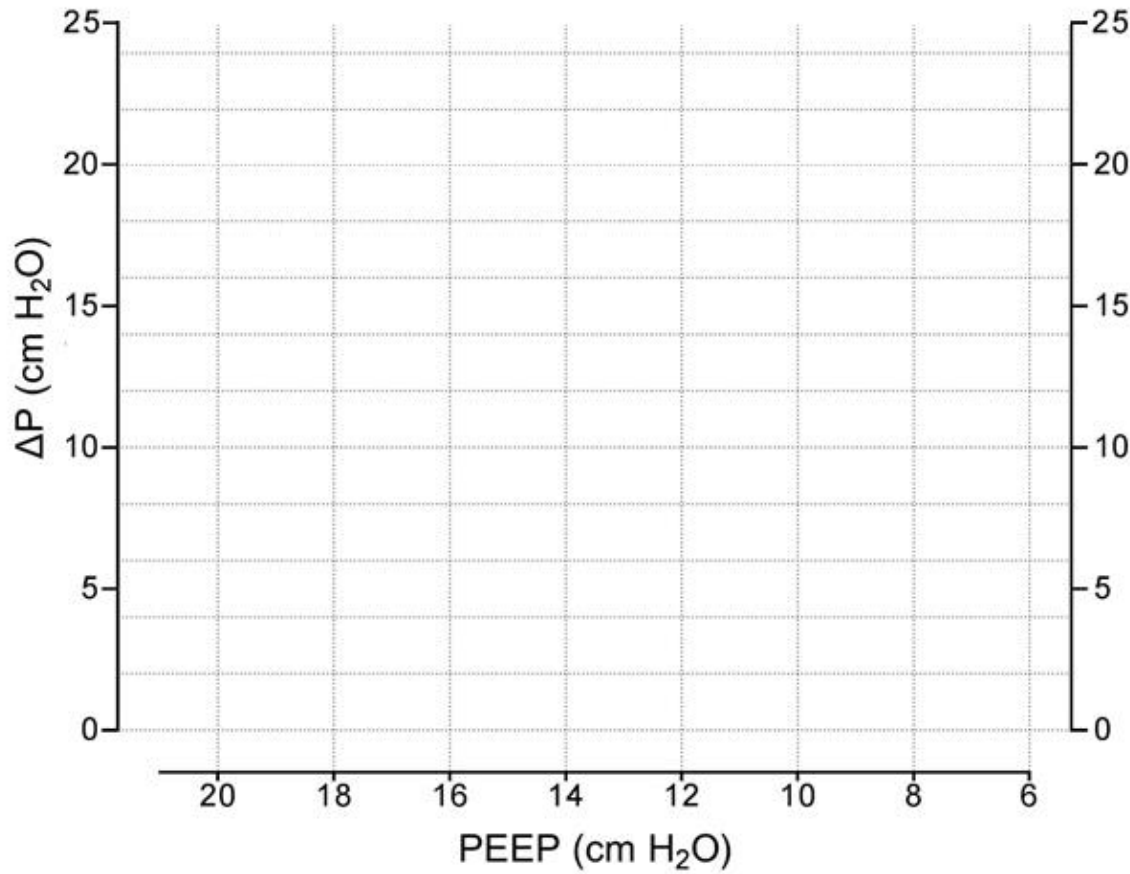
**Mechanical ventilation settings for the intervention group only**

<b>How to perform recruitment maneuver (RM)</b>  <i>Performed before and after the decremental PEEP trial or after any disconnection from the mechanical ventilator. Only performed in the intervention group and only in hemodynamically stable patients.</i>	Ventilator remains in volume controlled mode
	Tidal volume remains at 8 ml/kg Predicted Body Weight (PBW)
	Respiratory rate set at 15 breaths per minute
	<b>PEEP starts at 10 cm H<sub>2</sub>O after intubation</b>
	Increase PEEP in steps of 5 cm H <sub>2</sub> O every 15 seconds – up to PEEP of 20 cm H <sub>2</sub> O. End of recruitment maneuver.
<b>How to perform decremental PEEP trial</b>  <i>Performed after the first recruitment maneuver to determine the optimal PEEP. Only performed in the intervention group. The decremental PEEP trial is repeated after: (i.) a radical change in patient position or (ii.) a radical change in intra-abdominal pressure (e.g. conversion to laparotomy). Accordingly, if the additional decremental PEEP trial results in a different optimal PEEP level, this PEEP will be used until the end of surgery or until another radical change in patient position or intra-abdominal pressure. If the decremental PEEP trial has been repeated, please proceed to section 13 on page 11.</i>	Ventilator remains in volume controlled mode
	Respiratory rate set at 15 breaths per minute
	PEEP starts at 20 cm H <sub>2</sub> O
	Decrease PEEP in steps of 2 cm H <sub>2</sub> O every 20 seconds – till PEEP of 6 cm H <sub>2</sub> O. List the measured driving pressures in table 4 on the next page. Use table 4 to fill in figure 1 on the next page. For graph examples see next page.

**4. Recruitment (RM) and decremental PEEP trial for the intervention group only.**  
 Follow these steps and fill in the open white fields

**TIME OF INTERVENTION:** ..... (hh:mm)

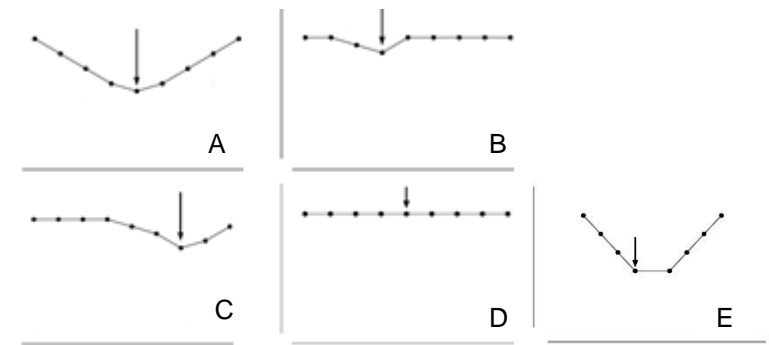
Step					
1	Document the intraoperative variables on page 6, the first column 'after induction'				
2	Select 'inspiratory pause' on the ventilation machine and set inspiratory pause at 15%. If applicable, increase the maximum pressure limit of the ventilator to 50 cm H <sub>2</sub> O.				
		<b>Time phase (hh:mm:ss)</b>	<b>PEEP level</b>		
3	<b>RM 1, step 1</b>	Start: t=00:00:00 – 00:00:15	15		
4	<b>RM 1, step 2</b>	00:00:15 - 00:00:30	20		
				<b>Plateau pressure (Pplat)</b>	<b>Driving pressure (ΔP)</b>
5	<b>DPT, step 1</b>	00:00:30 – 00:00:50	20	..... cm H <sub>2</sub> O	..... cm H <sub>2</sub> O
6	<b>DPT, step 2</b>	00:00:50 – 00:01:10	18	..... cm H <sub>2</sub> O	..... cm H <sub>2</sub> O
7	<b>DPT, step 3</b>	00:01:10 – 00:01:30	16	..... cm H <sub>2</sub> O	..... cm H <sub>2</sub> O
8	<b>DPT, step 4</b>	00:01:30 – 00:01:50	14	..... cm H <sub>2</sub> O	..... cm H <sub>2</sub> O
9	<b>DPT, step 5</b>	00:01:50 – 00:02:10	12	..... cm H <sub>2</sub> O	..... cm H <sub>2</sub> O
10	<b>DPT, step 6</b>	00:02:10 – 00:02:30	10	..... cm H <sub>2</sub> O	..... cm H <sub>2</sub> O
11	<b>DPT, step 7</b>	00:02:30 – 00:02:50	8	..... cm H <sub>2</sub> O	..... cm H <sub>2</sub> O
12	<b>DPT, step 8</b>	00:02:50 – 00:03:10	6	..... cm H <sub>2</sub> O	..... cm H <sub>2</sub> O
13	Calculate the ΔP of the previous steps (5-12): ΔP = Pplat - PEEP				
14	Draw the ΔP/PEEP-graph in the figure on page 5				
15	<b>RM 2, step 1</b>	Start: t=0 – 00:00:15	10		
16	<b>RM 2, step 2</b>	00:00:15 - 00:00:30	15		
17	<b>RM 2, step 3</b>	00:00:30 - 00:00:45	20		
18	Set PEEP at the optimal level				
19	<b>Check if all driving pressures from all PEEP levels have a difference of ≤ 2 cm H<sub>2</sub>O.</b> If yes, this is considered as a DPT without nadir. <b>IN THIS CASE, SELECT PEEP 12.</b>				
20	<b>If the difference is &gt; 2 cm H<sub>2</sub>O, select HIGHEST</b> PEEP level resulting in de <b>LOWEST</b> driving pressure.				
21	Are the RM and DMT performed conform protocol? <input type="checkbox"/> Yes <input type="checkbox"/> No, reason: .....				



**Figure 1.** Please fill in this figure with the collected values in the decremental PEEP trial (table above, page 4). This chart MUST be used during the decremental PEEP trial. With every step calculate the resulting driving pressure by subtracting PEEP from the plateau pressure after 20 seconds. Draw a smooth line using the 8 PEEP - driving pressure points. Determine the nadir of the driving pressure and use this level of PEEP till end of anesthesia. This chart MUST be filed in the local site investigator file, either digitally or on paper.

Patient identification number:   
 (study number of patient)

**! Chosen PEEP LEVEL:**   cm H<sub>2</sub>O !



**Figure 2.**  $\Delta P$ /PEEP-graph examples. The arrow represents the optimal PEEP to be chosen. **If the  $\Delta P$  curve shows no  $\Delta P$  nadir ( $\leq 2$  cm H<sub>2</sub>O) (figure D), PEEP will be set at 12 cm H<sub>2</sub>O.** If multiple PEEP levels result in the lowest  $\Delta P$  (E), choose the highest PEEP! For more  $\Delta P$ /PEEP-graph examples see page 16 of this CRF.

**5. Intraoperative variables\***

Individualized high PEEP  Standard PEEP group

\* Record intraoperative variables hourly after induction and immediately after the RM.

	After induction directly after induction	Before RM 1 in surgical starting position <input type="checkbox"/> N/A: control group	After RM2 after PEEP is set at lowest Δp <input type="checkbox"/> N/A	hr 1 <input type="checkbox"/> N/A	hr 2 <input type="checkbox"/> N/A	hr 3 <input type="checkbox"/> N/A	hr 4 <input type="checkbox"/> N/A
Respiratory parameters	Time [hh:mm]						
	PEEP [cm H <sub>2</sub> O]						
	VT [mL]						
	Ppeak [cm H <sub>2</sub> O]						
	Pplateau [cmH <sub>2</sub> O]						
	I:E	1:	1:	1:	1:	1:	1:
	RR [/min]						
	FiO <sub>2</sub> [0-1]						
	SPO <sub>2</sub> [%]						
	ETCO <sub>2</sub> [kPa or mmHg]						
IAP [cm H <sub>2</sub> O]							
HD	Systolic BP [mmHg]						
	Diastolic BP [mmHg]						
Position* Trendelenburg: 15-30 degrees head-down; *Extreme Trendelenburg: >30 degrees head-down.	<input type="checkbox"/> Neutral <input type="checkbox"/> Trendelenburg <input type="checkbox"/> Extreme Trendelenburg <input type="checkbox"/> Anti Trendelenburg	<input type="checkbox"/> Neutral <input type="checkbox"/> Trendelenburg <input type="checkbox"/> Extreme Trendelenburg <input type="checkbox"/> Anti Trendelenburg	<input type="checkbox"/> Neutral <input type="checkbox"/> Trendelenburg <input type="checkbox"/> Extreme Trendelenburg <input type="checkbox"/> Anti Trendelenburg	<input type="checkbox"/> Neutral <input type="checkbox"/> Trendelenburg <input type="checkbox"/> Extreme Trendelenburg <input type="checkbox"/> Anti Trendelenburg	<input type="checkbox"/> Neutral <input type="checkbox"/> Trendelenburg <input type="checkbox"/> Extreme Trendelenburg <input type="checkbox"/> Anti Trendelenburg	<input type="checkbox"/> Neutral <input type="checkbox"/> Trendelenburg <input type="checkbox"/> Extreme Trendelenburg <input type="checkbox"/> Anti Trendelenburg	<input type="checkbox"/> Neutral <input type="checkbox"/> Trendelenburg <input type="checkbox"/> Extreme Trendelenburg <input type="checkbox"/> Anti Trendelenburg
<b>Did the following intraoperative complications occur in the corresponding hour or RM:</b>							
<b>Rescue strategy for desaturation (SpO<sub>2</sub> ≤ 90% or if preoperative SpO<sub>2</sub> &lt;90% an absolute decrease in SpO<sub>2</sub>&gt;5%)</b> <span style="float:right">* see page 8 for rescue therapy</span>							
	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> yes <input type="checkbox"/> no
<b>A decrease in mean arterial pressure (MAP) below 65 mmHg and lasting for &gt;1 minute</b>							
	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> yes <input type="checkbox"/> no
<b>Vasoactive drugs defined as more than needed to compensate for vasodilating effects of anesthesia, according to decision of the anesthesiologist in charge</b>							
	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> yes <input type="checkbox"/> no
<b>New arrhythmias needing intervention as suggested by the Advanced Cardiac Life Support Guidelines</b>							
	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> yes <input type="checkbox"/> no

6. Intraoperative variables\*

\* Record intraoperative variables hourly after induction and immediately after the RM.

		hr 5 <input type="checkbox"/> N/A	hr 6 <input type="checkbox"/> N/A	hr 7 <input type="checkbox"/> N/A	hr 8 <input type="checkbox"/> N/A	hr 9 <input type="checkbox"/> N/A	hr 10 <input type="checkbox"/> N/A	hr 12 <input type="checkbox"/> N/A
Respiratory parameters	Time [hh:mm]							
	PEEP [cm H <sub>2</sub> O]							
	VT [mL]							
	Ppeak [cm H <sub>2</sub> O]							
	Pplateau [cmH <sub>2</sub> O]							
	I:E	1:	1:	1:	1:	1:	1:	1:
	RR [/min]							
	FiO <sub>2</sub> [0-1]							
	SPO <sub>2</sub> [%]							
	ETCO <sub>2</sub> [kPa or mmHg]							
HD	IAP [cm H <sub>2</sub> O]							
	Systolic BP [mmHg]							
	Diastolic BP [mmHg]							
	Position* *Trendelenburg: 15-30 degrees head-down; Extreme Trendelenburg: >30 degrees head-down.	<input type="checkbox"/> Neutral <input type="checkbox"/> Trendelenburg <input type="checkbox"/> Extreme Trendelenburg <input type="checkbox"/> Anti Trendelenburg	<input type="checkbox"/> Neutral <input type="checkbox"/> Trendelenburg <input type="checkbox"/> Extreme Trendelenburg <input type="checkbox"/> Anti Trendelenburg	<input type="checkbox"/> Neutral <input type="checkbox"/> Trendelenburg <input type="checkbox"/> Extreme Trendelenburg <input type="checkbox"/> Anti Trendelenburg	<input type="checkbox"/> Neutral <input type="checkbox"/> Trendelenburg <input type="checkbox"/> Extreme Trendelenburg <input type="checkbox"/> Anti Trendelenburg	<input type="checkbox"/> Neutral <input type="checkbox"/> Trendelenburg <input type="checkbox"/> Extreme Trendelenburg <input type="checkbox"/> Anti Trendelenburg	<input type="checkbox"/> Neutral <input type="checkbox"/> Trendelenburg <input type="checkbox"/> Extreme Trendelenburg <input type="checkbox"/> Anti Trendelenburg	<input type="checkbox"/> Neutral <input type="checkbox"/> Trendelenburg <input type="checkbox"/> Extreme Trendelenburg <input type="checkbox"/> Anti Trendelenburg
<b>Did the following intraoperative complications occur in the corresponding hour or RM:</b>								
<b>Rescue strategy for desaturation (SpO<sub>2</sub> ≤ 90% or if preoperative SpO<sub>2</sub> &lt;90% an absolute decrease in SpO<sub>2</sub>&gt;5%)</b> <span style="float: right;">* see page 8 for rescue therapy</span>								
	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> yes <input type="checkbox"/> no
<b>A decrease in mean arterial pressure (MAP) below 65 mmHg and lasting for &gt;1 minute</b>								
	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> yes <input type="checkbox"/> no
<b>Vasoactive drugs defined as more than needed to compensate for vasodilating effects of anesthesia, according to decision of the anesthesiologist in charge</b>								
	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> yes <input type="checkbox"/> no
<b>New arrhythmias needing intervention as suggested by the Advanced Cardiac Life Support Guidelines</b>								
	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> yes <input type="checkbox"/> no

**Rescue therapy for desaturation high individualized PEEP group**

**Rescue therapy for desaturation standard PEEP group**

Step	PEEP	FiO <sub>2</sub>	Step	PEEP	FiO <sub>2</sub>
1	20	0.4	1	5	0.4
2	18	0.4	2	5	0.5
3	16	0.4	3	5	0.6
4	14	0.4	4	5	0.7
5	12	0.4	5	5	0.8
6	12	0.5	6	6	0.8
7	12	0.6	7	RM	
8	10	0.6			
9	8	0.6			
10	6	0.6			
11	6	0.7			
12	6	0.8			

- Perform rescue strategy if SpO<sub>2</sub> ≤ 90%
- Start at the level of PEEP set after the decremental PEEP trial
- Please note (encircle) to which step rescue strategy is performed

**7. Did the patient receive the allocated PEEP level during surgery?**  yes  no *If no, adjusted PEEP level to: [ ][ ] cm H<sub>2</sub>O* *If no, specify reason:*

Decrease in mean arterial pressure below 65 mmHg for more than one minute not responding to fluids and/or vasoactive drugs  yes  no

New arrhythmias not responding to the treatment suggested by the Advanced Cardiac Life Support Guidelines  yes  no

Need for a dosage of vasoactive drugs at the highest level tolerated, according to decision of the anesthesiologist in charge  yes  no

Need of massive transfusion, more than 5 units of blood to maintain Ht>21% (Hb>7 mg/dl)  yes  no

Surgical complication determining life-threatening situations  yes  no

Other reason (specify):  yes  no

**8. Where other ventilation settings changed (TV, FiO<sub>2</sub>, e.g.) for clinical reasons (pre-approved protocol deviations)**  yes  no

If yes, specify:

**9. Protocol violation?** *Misinterpretation of study protocol, thus no clinical reason for changing ventilation.*  yes  no

If yes, specify:  Difference between selected PEEP and correct PEEP >2 cm H<sub>2</sub>O  Difference between selected PEEP and correct PEEP ≤2 cm H<sub>2</sub>O  Other

If other, specify:

**10. Conversion to laparotomy?** *If intervention group, please repeat the decremental PEEP trial.*  yes  no

If yes, in which corresponding hour was the conversion? \_\_\_\_\_

**11. Decremental PEEP trial repeated?** *If the decremental PEEP trial has been repeated, please proceed to section 13 on page 11.*  yes  no



**12. Intraoperative medication**

		Cumulative dose		Cumulative dose mL		Cumulative dose mL							
Vasoactive or inotropic drugs	Dobutamine	<input type="checkbox"/> Yes	<input type="checkbox"/> No	_____ mg	Fluids	Crystalloids	<input type="checkbox"/> Yes	<input type="checkbox"/> No	Transfusion	Red blood cells*	<input type="checkbox"/> Yes	<input type="checkbox"/> No	_____
	Dopamine	<input type="checkbox"/> Yes	<input type="checkbox"/> No	_____ mg		If yes, cumulative dose: _____	FFP	<input type="checkbox"/> Yes		<input type="checkbox"/> No	_____		
	Epinephrine	<input type="checkbox"/> Yes	<input type="checkbox"/> No	_____ mg		Colloids	<input type="checkbox"/> Yes	<input type="checkbox"/> No		Platelets	<input type="checkbox"/> Yes	<input type="checkbox"/> No	_____
	Ephedrine	<input type="checkbox"/> Yes	<input type="checkbox"/> No	_____ mg		If yes, cumulative dose: _____	Omniplasma	<input type="checkbox"/> Yes		<input type="checkbox"/> No	_____		
	Norepinephrine	<input type="checkbox"/> Yes	<input type="checkbox"/> No	_____ µg		Albumin	<input type="checkbox"/> Yes	<input type="checkbox"/> No		Other	<input type="checkbox"/> Yes	<input type="checkbox"/> No	_____
	Phenylephrine	<input type="checkbox"/> Yes	<input type="checkbox"/> No	_____ µg		If yes, cumulative dose: _____	If other, specify: _____	* E.g. packed red blood cells, cell saver					
	Other	<input type="checkbox"/> Yes	<input type="checkbox"/> No	_____									
	If other, specify:	_____											
<b>Cumulative mL</b>													
Total Out	Urine production	<input type="checkbox"/> Yes	<input type="checkbox"/> No	_____	<input type="checkbox"/> NM*								
	Blood loss	<input type="checkbox"/> Yes	<input type="checkbox"/> No	_____	<input type="checkbox"/> NM*								
	Ascites	<input type="checkbox"/> Yes	<input type="checkbox"/> No	_____	<input type="checkbox"/> NM*								
	Other	<input type="checkbox"/> Yes	<input type="checkbox"/> No	_____	<input type="checkbox"/> NM*								
	If other, specify:	_____											

\*NM = Not measured

**13. Intraoperative blood gas variables\***

*\*only if deemed clinically necessary*

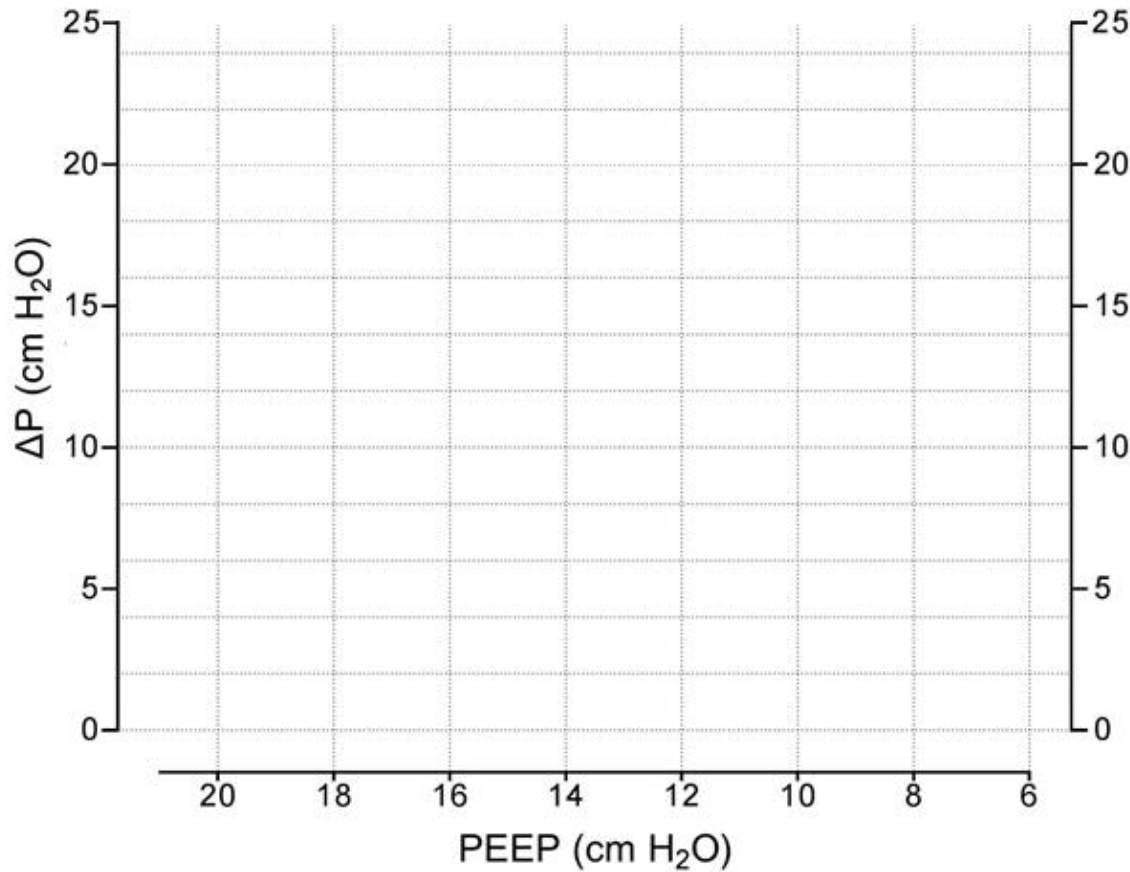
	After induction	After RM2	hr 1	hr 2	hr 3	hr 4	hr 5
pH							
PaO <sub>2</sub>							
PaCO <sub>2</sub>							
HCO <sub>3</sub>							
	hr 6	hr 7	hr 8	hr 9	hr 10	hr 11	hr 12
pH							
PaO <sub>2</sub>							
PaCO <sub>2</sub>							
HCO <sub>3</sub>							

Measurement unit PaO <sub>2</sub>	<input type="checkbox"/> mmHg	<input type="checkbox"/> kPa
Measurement unit PaCO <sub>2</sub>	<input type="checkbox"/> mmHg	<input type="checkbox"/> kPa
Measurement unit HCO <sub>3</sub>	<input type="checkbox"/> mmol/L	<input type="checkbox"/> mEq/L

<b>14. Central venous catheter*</b>	
<i>*only if deemed clinically necessary</i>	
	<b>CVD</b>
<b>After placement</b>	
<b>Before RM1*</b>	
<b>After RM2*</b>	
<b>Hour 1</b>	
<b>Hour 2</b>	
<b>Hour 3</b>	
<b>Hour 4</b>	
<b>Hour 5</b>	
<b>Hour 6</b>	
<b>Hour 7</b>	
<b>Hour 8</b>	
<b>Hour 9</b>	
<b>Hour 10</b>	
<b>Hour 11</b>	
<b>Hour 12</b>	

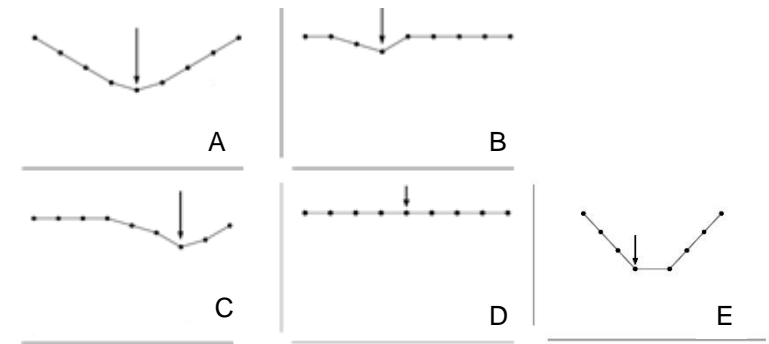
\*Not applicable to the control group

<b>15. Repeated recruitment (RM) and decremental PEEP trial (DPT) for the <u>intervention group only</u></b>					
Follow these steps and fill in the open white fields					
Corresponding hour of repeated decremental PEEP trial: <input type="text"/> <input type="text"/> <input type="text"/>					
Step		Time phase (hh:mm:ss)	PEEP level		
1	RM 1, step 1	Start: t=00:00:00 – 00:00:15	15		
2	RM 1, step 2	00:00:15 - 00:00:30	20		
				<b>Plateau pressure (Pplat)</b>	<b>Driving pressure (<math>\Delta P</math>)</b>
3	DPT, step 1	00:00:30 – 00:00:50	20	..... cm H <sub>2</sub> O	..... cm H <sub>2</sub> O
4	DPT, step 2	00:00:50 – 00:01:10	18	..... cm H <sub>2</sub> O	..... cm H <sub>2</sub> O
5	DPT, step 3	00:01:10 – 00:01:30	16	..... cm H <sub>2</sub> O	..... cm H <sub>2</sub> O
6	DPT, step 4	00:01:30 – 00:01:50	14	..... cm H <sub>2</sub> O	..... cm H <sub>2</sub> O
7	DPT, step 5	00:01:50 – 00:02:10	12	..... cm H <sub>2</sub> O	..... cm H <sub>2</sub> O
8	DPT, step 6	00:02:10 – 00:02:30	10	..... cm H <sub>2</sub> O	..... cm H <sub>2</sub> O
9	DPT, step 7	00:02:30 – 00:02:50	8	..... cm H <sub>2</sub> O	..... cm H <sub>2</sub> O
10	DPT, step 8	00:02:50 – 00:03:10	6	..... cm H <sub>2</sub> O	..... cm H <sub>2</sub> O
11	Calculate the $\Delta P$ of the previous steps (3-10): $\Delta P = P_{plat} - PEEP$				
12	RM 2, step 1	Start: t=0 – 00:00:15	10		
13	RM 2, step 2	00:00:15 - 00:00:30	15		
14	RM 2, step 3	00:00:30 - 00:00:45	20		
15	Set PEEP at the optimal level				
16	<b>Check if all driving pressures from all PEEP levels have a difference of <math>\leq 2</math> cm H<sub>2</sub>O.</b> If yes, this is considered as a DPT without nadir. <b>IN THIS CASE, SELECT PEEP 12.</b>				
17	<b>If the difference is <math>&gt; 2</math> cm H<sub>2</sub>O, select HIGHEST</b> PEEP level resulting in de <b>LOWEST</b> driving pressure.				
18	Are the RM and DMT performed conform protocol? <input type="checkbox"/> Yes <input type="checkbox"/> No, reason: .....				
<b>If the additional decremental PEEP trial results in a different optimal PEEP level, this PEEP will be used until the end of surgery or until another radical change in patient position or intra-abdominal pressure.</b>					
Chosen PEEP level		<input type="text"/> <input type="text"/>			
Specify reason for repetition of the decremental PEEP trial		<input type="checkbox"/> Radical change in position	<input type="checkbox"/> Conversion to laparotomy	<input type="checkbox"/> Other radical change in intra-abdominal pressure	
How long did it take before the decremental PEEP trial was repeated?		<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> minutes	Has the decremental PEEP trial been repeated again?		<input type="checkbox"/> No <input type="checkbox"/> Yes, please proceed to page 14



Patient identification number:          
 (study number of patient)

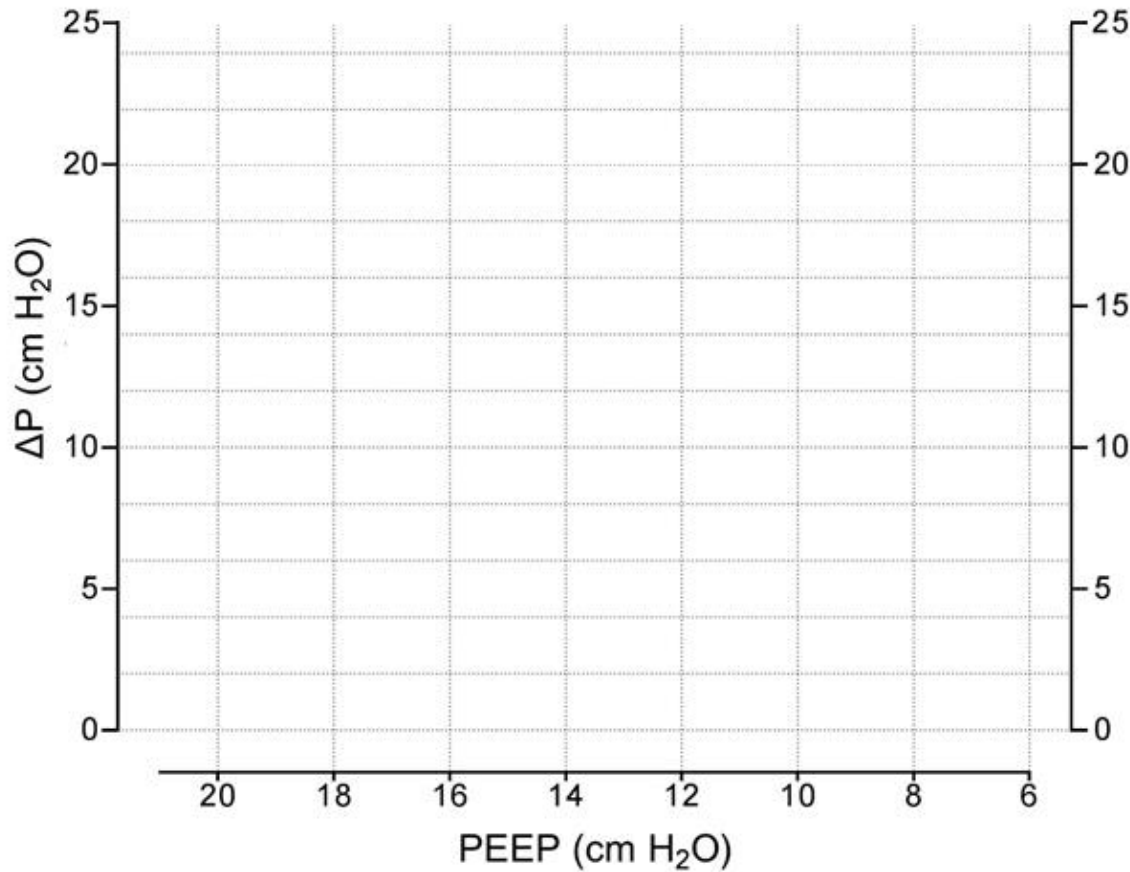
! Chosen PEEP LEVEL:   cm H<sub>2</sub>O !



**Figure 1.** Please fill in this figure with the collected values in the decremental PEEP trial (table above, page 4). This chart **MUST** be used during the decremental PEEP trial. With every step calculate the resulting driving pressure by subtracting PEEP from the plateau pressure after 20 seconds. Draw a smooth line using the 8 PEEP - driving pressure points. Determine the nadir of the driving pressure and use this level of PEEP till end of anesthesia. This chart **MUST** be filed in the local site investigator file, either digitally or on paper.

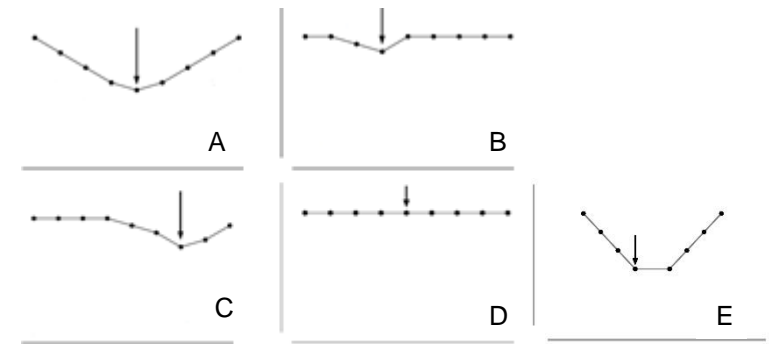
**Figure 2.** ΔP/PEEP-graph examples. The arrow represents the optimal PEEP to be chosen. **If the ΔP curve shows no ΔP nadir (≤ 2 cm H<sub>2</sub>O) (figure D), PEEP will be set at 12 cm H<sub>2</sub>O.** If multiple PEEP levels result in the lowest ΔP (E), choose the highest PEEP! For more ΔP/PEEP-graph examples see page 16 of this CRF.

<b>16. Repeated recruitment (RM) and decremental PEEP trial for the <u>intervention group only</u></b>					
Follow these steps and fill in the open white fields					
Corresponding hour of repeated decremental PEEP trial:  _ _					
Step		Time phase (hh:mm:ss)	PEEP level		
1	RM 1, step 1	Start: t=00:00:00 – 00:00:15	15		
2	RM 1, step 2	00:00:15 - 00:00:30	20		
				<b>Plateau pressure (Pplat)</b>	<b>Driving pressure (ΔP)</b>
3	DPT, step 1	00:00:30 – 00:00:50	20	..... cm H <sub>2</sub> O	..... cm H <sub>2</sub> O
4	DPT, step 2	00:00:50 – 00:01:10	18	..... cm H <sub>2</sub> O	..... cm H <sub>2</sub> O
5	DPT, step 3	00:01:10 – 00:01:30	16	..... cm H <sub>2</sub> O	..... cm H <sub>2</sub> O
6	DPT, step 4	00:01:30 – 00:01:50	14	..... cm H <sub>2</sub> O	..... cm H <sub>2</sub> O
7	DPT, step 5	00:01:50 – 00:02:10	12	..... cm H <sub>2</sub> O	..... cm H <sub>2</sub> O
8	DPT, step 6	00:02:10 – 00:02:30	10	..... cm H <sub>2</sub> O	..... cm H <sub>2</sub> O
9	DPT, step 7	00:02:30 – 00:02:50	8	..... cm H <sub>2</sub> O	..... cm H <sub>2</sub> O
10	DPT, step 8	00:02:50 – 00:03:10	6	..... cm H <sub>2</sub> O	..... cm H <sub>2</sub> O
11	Calculate the ΔP of the previous steps (3-10): ΔP = Pplat - PEEP				
12	RM 2, step 1	Start: t=0 – 00:00:15	10		
13	RM 2, step 2	00:00:15 - 00:00:30	15		
14	RM 2, step 3	00:00:30 - 00:00:45	20		
15	Set PEEP at the optimal level				
16	<b>Check if all driving pressures from all PEEP levels have a difference of ≤ 2 cm H<sub>2</sub>O.</b> If yes, this is considered as a DPT without nadir. <b>IN THIS CASE, SELECT PEEP 12.</b>				
17	<b>If the difference is &gt; 2 cm H<sub>2</sub>O, select HIGHEST</b> PEEP level resulting in de <b>LOWEST</b> driving pressure.				
18	Are the RM and DMT performed conform protocol? <input type="checkbox"/> Yes <input type="checkbox"/> No, reason: .....				
<b>If the additional decremental PEEP trial results in a different optimal PEEP level, this PEEP will be used until the end of surgery or until another radical change in patient position or intra-abdominal pressure.</b>					
Chosen PEEP level		_ _			
Specify reason for repetition of the decremental PEEP trial		<input type="checkbox"/> Radical change in position		<input type="checkbox"/> Conversion to laparotomy	
		<input type="checkbox"/> Other radical change in intra-abdominal pressure			
How long did it take before the decremental PEEP trial was repeated?		_ _ _  minutes			



Patient identification number:   
 (study number of patient)

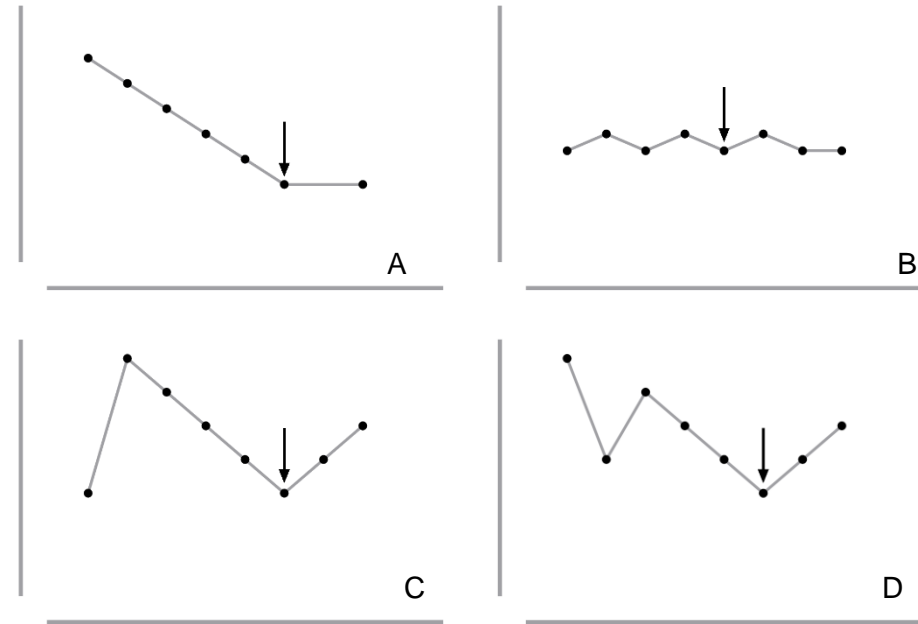
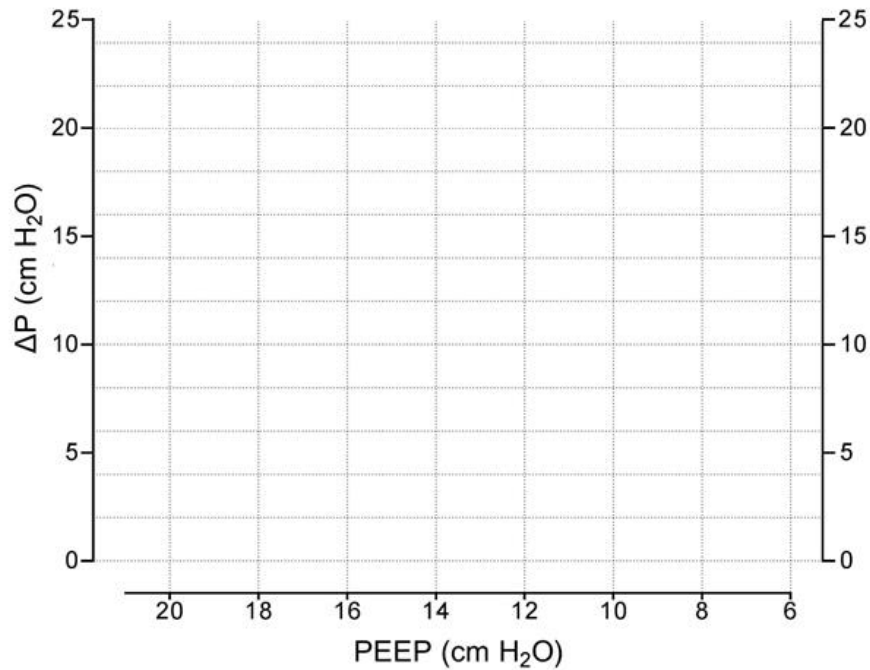
! Chosen PEEP LEVEL:  cm H<sub>2</sub>O !



**Figure 1.** Please fill in this figure with the collected values in the decremental PEEP trial (table above, page 4). This chart **MUST** be used during the decremental PEEP trial. With every step calculate the resulting driving pressure by subtracting PEEP from the plateau pressure after 20 seconds. Draw a smooth line using the 8 PEEP - driving pressure points. Determine the nadir of the driving pressure and use this level of PEEP till end of anesthesia. This chart **MUST** be filed in the local site investigator file, either digitally or on paper.

**Figure 2.** ΔP/PEEP-graph examples. The arrow represents the optimal PEEP to be chosen. **If the ΔP curve shows no ΔP nadir (≤ 2 cm H<sub>2</sub>O) (figure D), PEEP will be set at 12 cm H<sub>2</sub>O.** If multiple PEEP levels result in the lowest ΔP (E), choose the highest PEEP! For more ΔP/PEEP-graph examples see page 16 of this CRF.

**Appendix** Additional  $\Delta P$ /PEEP-graph examples



**Appendix I.**  $\Delta P$ /PEEP-graph examples. The arrow represents the optimal PEEP to be chosen. If multiple PEEP levels result in the lowest  $\Delta P$  (A), choose the highest PEEP. If no clear nadir is present and driving pressure is fluctuating between a difference of  $\leq 2$  cm H<sub>2</sub>O at maximum (B) a flat line should be considered and PEEP 12 cm H<sub>2</sub>O should be selected.

Physiologically, the curve cannot be biphasic, if you find a biphasic curve, consider repeating the intervention or critically check whether (multiple) measuring points is/are invalid.

Some ventilators have their maximum pressure limited at 30 cm H<sub>2</sub>O as a default setting. When this is the case, the PEEP titration may result in 'incorrect' lower P<sub>plateau</sub> values at high PEEP levels (C). To prevent this, we strongly advise to manually increase the maximum pressure limit of the ventilator to 40 cm H<sub>2</sub>O.

Manipulation of the abdomen by surgeon, insertion of instruments (e.g. gastric tube) or changes of patient position can influence the measurement of P<sub>plateau</sub>, resulting in invalid measurements (D). In this casus the second PEEP point is invalid due manipulation of the abdomen, the arrow represents the correct PEEP.