

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) _____

Principal Investigator: Prof dr. M.W. Hollmann, Department of Anesthesiology Amsterdam UMC.
Contact: Tom Vermeulen or Galina Dorland, Department of Anesthesiology Amsterdam UMC.
Mail: generator@amsterdamumc.nl, Tel: 20708

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>	
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	
Maintenance of anesthesia <input type="checkbox"/> Volatile <input type="checkbox"/> TIVA (total intravenous anesthesia) <input type="checkbox"/> Combined			
Epidural <input type="checkbox"/> Yes <input type="checkbox"/> No <i>If yes:</i> <input type="checkbox"/> Thoracic <input type="checkbox"/> Lumbar			
Neuromuscular blocking agents administered <input type="checkbox"/> Yes <input type="checkbox"/> No <i>If yes:</i> <input type="checkbox"/> Non-depolarizing (e.g., rocuronium) <input type="checkbox"/> Depolarizing (e.g., succinylcholine) <i>If non-depolarizing agent:</i>			
What was used for maintenance of muscle relaxation after succinylcholine? <input type="checkbox"/> No maintenance <input type="checkbox"/> Non-depolarizing <input type="checkbox"/> Depolarizing			
Neuromuscular function monitoring during surgery <input type="checkbox"/> Yes <input type="checkbox"/> No			
TOF ≥ 90 at end of surgery without antagonization <input type="checkbox"/> Yes <input type="checkbox"/> No <i>If no:</i>			
Used antagonist: <input type="checkbox"/> Sugammadex <input type="checkbox"/> Cholinesterase inhibitor <input type="checkbox"/> 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: <input type="checkbox"/> Individualized high PEEP group <i>See mechanical ventilation settings on the next page. Complete the entire intraoperative CRF.</i>	<input type="checkbox"/> Standard PEEP group <i>See mechanical ventilation settings on the next page, after continue to page 5 'intraoperative variables' (skip page 4).</i>
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Mechanical ventilation settings

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

Mechanical ventilation settings for the intervention group only

<p>How to perform recruitment maneuver (RM)</p> <p><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></p>	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
	PEEP starts at 10 cm H ₂ O after intubation
	Increase PEEP in steps of 5 cm H ₂ O every 15 seconds – up to PEEP of 20 cm H ₂ O. End of recruitment maneuver.
<p>How to perform decremental PEEP trial</p> <p><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></p>	Ventilator remains in volume controlled mode
	Respiratory rate set at 15 breaths per minute
	PEEP starts at 20 cm H ₂ O
<p>Decrease PEEP in steps of 2 cm H₂O every 20 seconds – till PEEP of 6 cm H₂O. 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.</p>	

4. Recruitment (RM) and decremental PEEP trial for the <u>intervention group only</u> .					
Follow these steps and fill in the open white fields					
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 ₂ O.				
		Time phase (hh:mm:ss)	PEEP level		
3	RM 1, step 1	Start: t=00:00:00 – 00:00:15	15		
4	RM 1, step 2	00:00:15 - 00:00:30	20		
				Plateau pressure (Pplat)	Driving pressure (ΔP)
5	DPT, step 1	00:00:30 – 00:00:50	20 cm H ₂ O cm H ₂ O
6	DPT, step 2	00:00:50 – 00:01:10	18 cm H ₂ O cm H ₂ O
7	DPT, step 3	00:01:10 – 00:01:30	16 cm H ₂ O cm H ₂ O
8	DPT, step 4	00:01:30 – 00:01:50	14 cm H ₂ O cm H ₂ O
9	DPT, step 5	00:01:50 – 00:02:10	12 cm H ₂ O cm H ₂ O
10	DPT, step 6	00:02:10 – 00:02:30	10 cm H ₂ O cm H ₂ O
11	DPT, step 7	00:02:30 – 00:02:50	8 cm H ₂ O cm H ₂ O
12	DPT, step 8	00:02:50 – 00:03:10	6 cm H ₂ O cm H ₂ 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	RM 2, step 1	Start: t=0 – 00:00:15	10		
16	RM 2, step 2	00:00:15 - 00:00:30	15		
17	RM 2, step 3	00:00:30 - 00:00:45	20		
18	Set PEEP at the optimal level (PEEP level resulting in de lowest driving pressure)				
19	Are the RM and DMT performed conform protocol? <input type="checkbox"/> Yes <input type="checkbox"/> No, reason:				

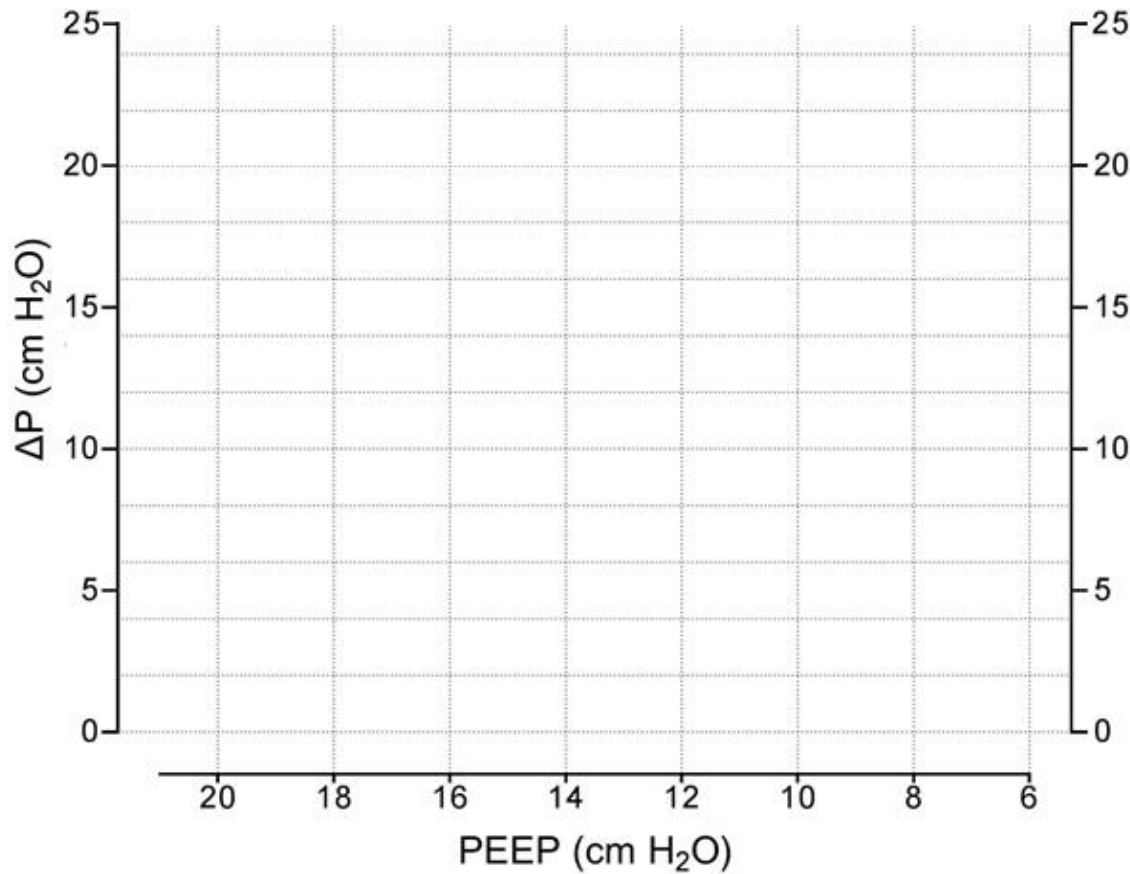


Figure 1. Please fill in this figure with the collected values in the decremental PEEP trial (table above, page 4). This chart MUST be used during the decremental PEEP trial. With every step calculate the resulting driving pressure by subtracting PEEP from the plateau pressure after 20 seconds. Draw 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 H₂O !

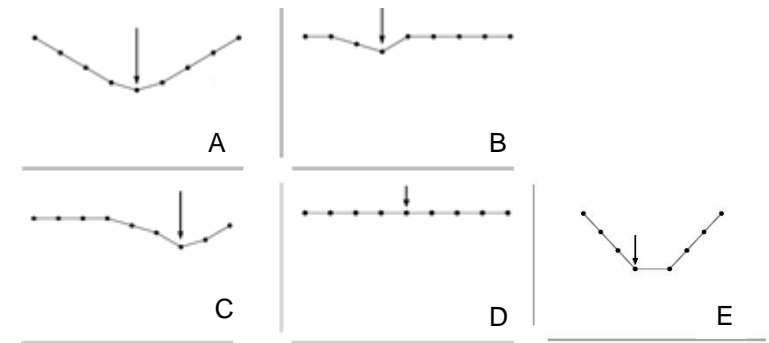


Figure 2. ΔP /PEEP-graph examples. The arrow represents the optimal PEEP to be chosen. If the ΔP curve shows a flat line (D), PEEP will be set at 12 cm H₂O. If multiple PEEP levels result in the lowest ΔP (E), choose the highest PEEP!
 For more ΔP /PEEP-graph examples see page 15 of this CRF.

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 ₂ O]						
	VT [mL]						
	Ppeak [cm H ₂ O]						
	Pplateau [cmH ₂ O]						
	I:E	1:	1:	1:	1:	1:	1:
	RR [/min]						
	FiO ₂ [0-1]						
	SPO ₂ [%]						
	ETCO ₂ [kPa or mmHg]						
IAP [cm H ₂ 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
Did the following intraoperative complications occur in the corresponding hour or RM:							
Rescue strategy for desaturation (SpO₂ ≤ 90% or if preoperative SpO₂ <90% an absolute decrease in SpO₂>5%) * see page 8 for rescue therapy							
	<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
A decrease in mean arterial pressure (MAP) below 65 mmHg and lasting for >1 minute							
	<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
Vasoactive drugs defined as more than needed to compensate for vasodilating effects of anesthesia, according to decision of the anesthesiologist in charge							
	<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
New arrhythmias needing intervention as suggested by the Advanced Cardiac Life Support Guidelines							
	<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 ₂ O]							
	VT [mL]							
	Ppeak [cm H ₂ O]							
	Pplateau [cmH ₂ O]							
	I:E	1:	1:	1:	1:	1:	1:	1:
	RR [/min]							
	FiO ₂ [0-1]							
	SPO ₂ [%]							
	ETCO ₂ [kPa or mmHg]							
HD	IAP [cm H ₂ 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
Did the following intraoperative complications occur in the corresponding hour or RM:								
Rescue strategy for desaturation (SpO₂ ≤ 90% or if preoperative SpO₂ <90% an absolute decrease in SpO₂>5%) * see page 8 for rescue therapy								
	<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
A decrease in mean arterial pressure (MAP) below 65 mmHg and lasting for >1 minute								
	<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
Vasoactive drugs defined as more than needed to compensate for vasodilating effects of anesthesia, according to decision of the anesthesiologist in charge								
	<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
New arrhythmias needing intervention as suggested by the Advanced Cardiac Life Support Guidelines								
	<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 ₂	Step	PEEP	FiO ₂
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 SpO₂ ≤ 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 H₂O* *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, FiO₂, 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 H₂O Difference between selected PEEP and correct PEEP ≤2 cm H₂O Other

If other, specify:

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

11. 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: _____													
Cumulative mL													
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

12. 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 ₂							
PaCO ₂							
HCO ₃							
	hr 6	hr 7	hr 8	hr 9	hr 10	hr 11	hr 12
pH							
PaO ₂							
PaCO ₂							
HCO ₃							

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

13. Repeated recruitment (RM) and decremental PEEP trial for the <u>intervention group only</u>					
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		
				Plateau pressure (Pplat)	Driving pressure (ΔP)
3	DPT, step 1	00:00:30 – 00:00:50	20 cm H ₂ O cm H ₂ O
4	DPT, step 2	00:00:50 – 00:01:10	18 cm H ₂ O cm H ₂ O
5	DPT, step 3	00:01:10 – 00:01:30	16 cm H ₂ O cm H ₂ O
6	DPT, step 4	00:01:30 – 00:01:50	14 cm H ₂ O cm H ₂ O
7	DPT, step 5	00:01:50 – 00:02:10	12 cm H ₂ O cm H ₂ O
8	DPT, step 6	00:02:10 – 00:02:30	10 cm H ₂ O cm H ₂ O
9	DPT, step 7	00:02:30 – 00:02:50	8 cm H ₂ O cm H ₂ O
10	DPT, step 8	00:02:50 – 00:03:10	6 cm H ₂ O cm H ₂ O
11	Calculate the ΔP 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 (PEEP level resulting in de lowest driving pressure)				
16	Are the RM and DMT performed conform protocol? <input type="checkbox"/> Yes <input type="checkbox"/> No, reason:				
<i>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.</i>					
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 the next page			

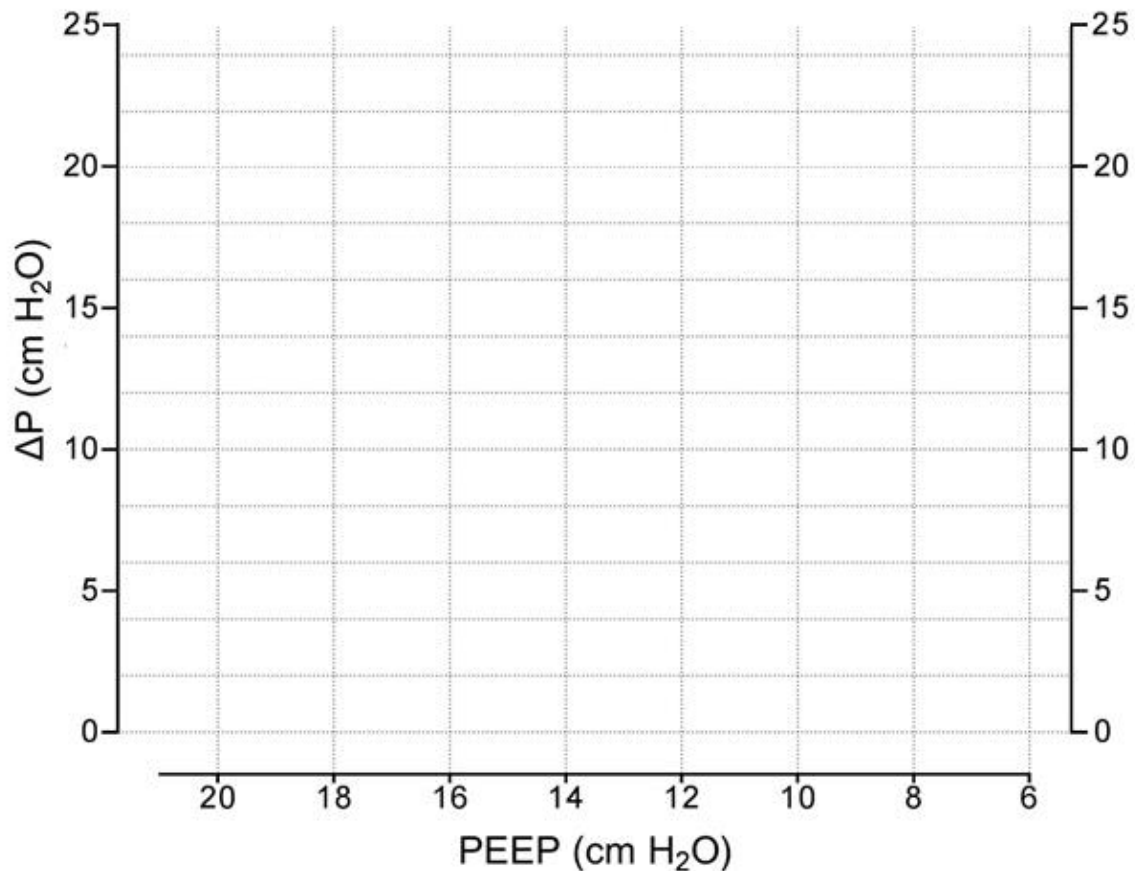


Figure 1. Please fill in this figure with the collected values in the decremental PEEP trial (table above, page 4). This chart MUST be used during the decremental PEEP trial. With every step calculate the resulting driving pressure by subtracting PEEP from the plateau pressure after 20 seconds. Draw 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 H₂O !

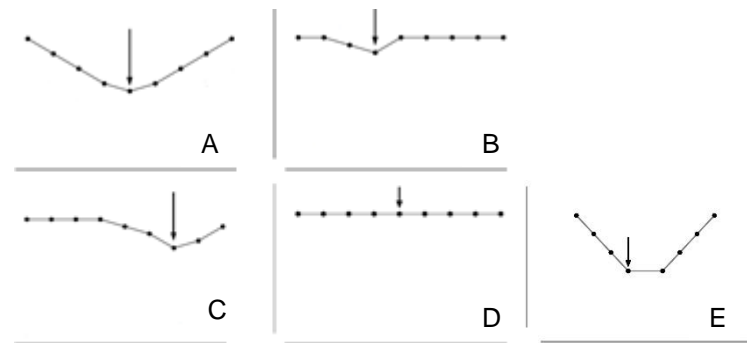


Figure 2. ΔP /PEEP-graph examples. The arrow represents the optimal PEEP to be chosen. If the ΔP curve shows a flat line (D), PEEP will be set at 12 cm H₂O. If multiple PEEP levels result in the lowest ΔP (E), choose the highest PEEP! For more ΔP /PEEP-graph examples see page 15 of this CRF.

14. Repeated recruitment (RM) and decremental PEEP trial for the <u>intervention group only</u>					
Follow these steps and fill in the open white fields					
Corresponding hour of repeated decremental PEEP trial: <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		
				Plateau pressure (Pplat)	Driving pressure (ΔP)
3	DPT, step 1	00:00:30 – 00:00:50	20 cm H ₂ O cm H ₂ O
4	DPT, step 2	00:00:50 – 00:01:10	18 cm H ₂ O cm H ₂ O
5	DPT, step 3	00:01:10 – 00:01:30	16 cm H ₂ O cm H ₂ O
6	DPT, step 4	00:01:30 – 00:01:50	14 cm H ₂ O cm H ₂ O
7	DPT, step 5	00:01:50 – 00:02:10	12 cm H ₂ O cm H ₂ O
8	DPT, step 6	00:02:10 – 00:02:30	10 cm H ₂ O cm H ₂ O
9	DPT, step 7	00:02:30 – 00:02:50	8 cm H ₂ O cm H ₂ O
10	DPT, step 8	00:02:50 – 00:03:10	6 cm H ₂ O cm H ₂ O
11	Calculate the ΔP 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 (PEEP level resulting in de lowest driving pressure)				
16	Are the RM and DMT performed conform protocol? <input type="checkbox"/> Yes <input type="checkbox"/> No, reason:				
<i>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.</i>					
Chosen PEEP level		<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"/> minutes			

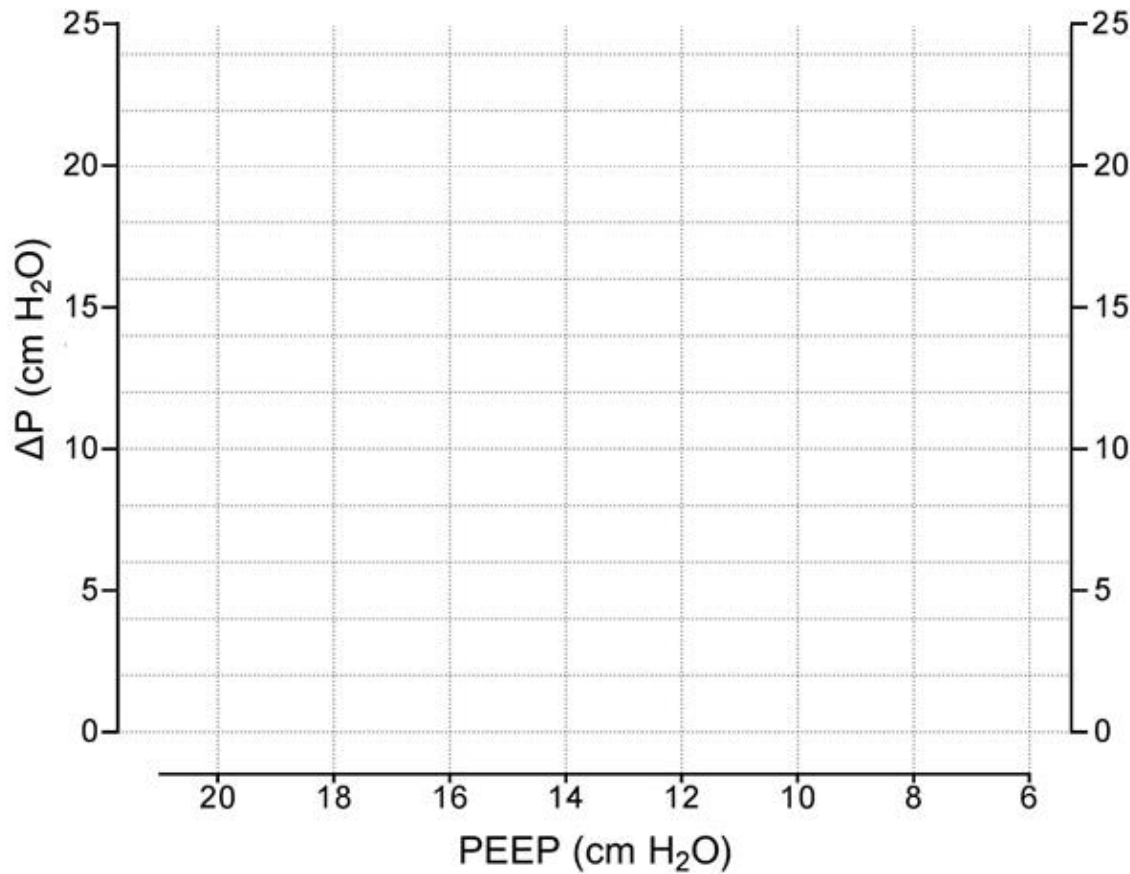


Figure 1. Please fill in this figure with the collected values in the decremental PEEP trial (table above, page 4). This chart MUST be used during the decremental PEEP trial. With every step calculate the resulting driving pressure by subtracting PEEP from the plateau pressure after 20 seconds. Draw 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 H₂O !

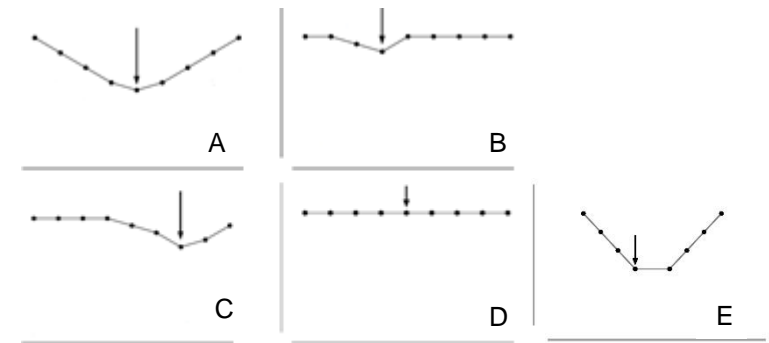
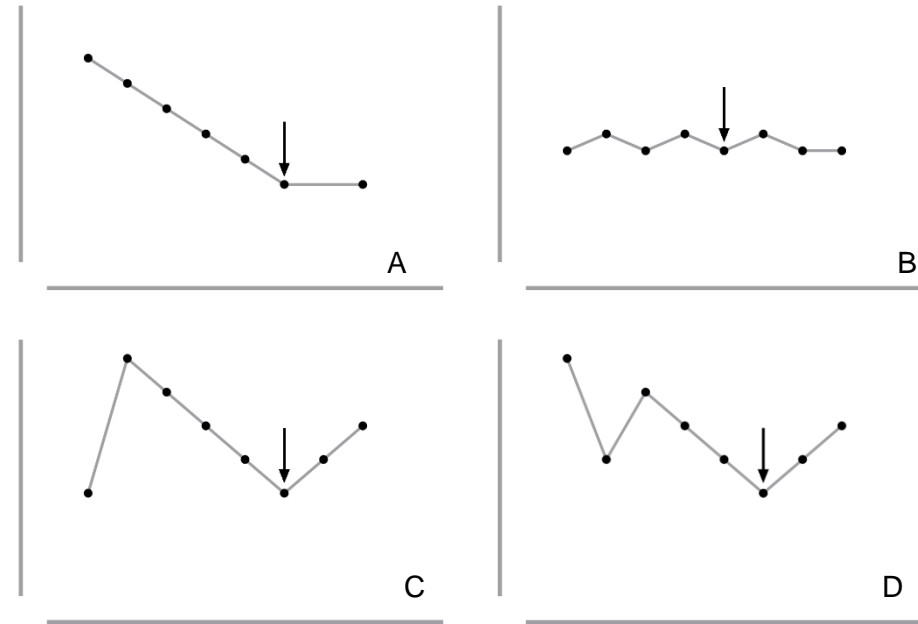
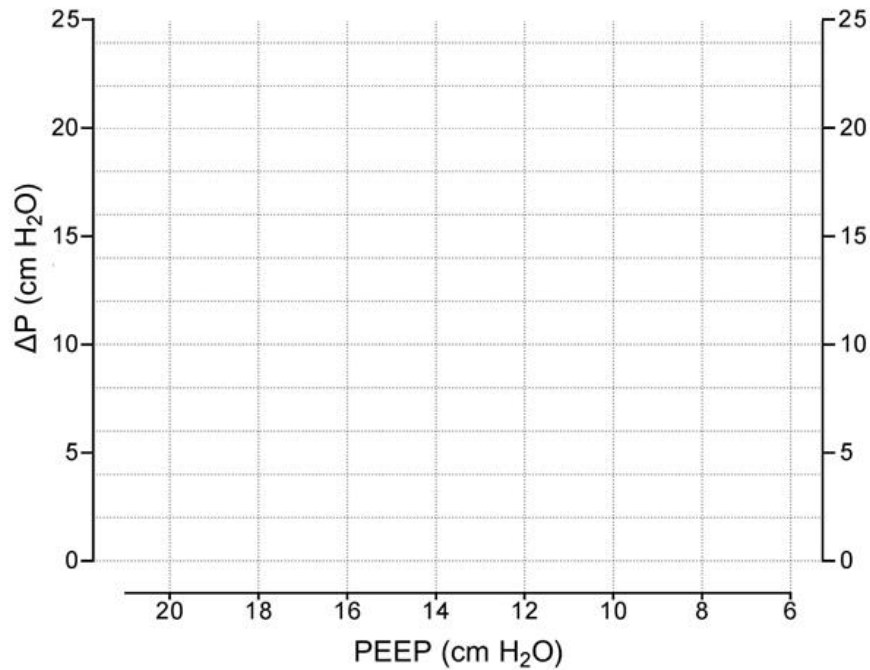


Figure 2. ΔP/PEEP-graph examples. The arrow represents the optimal PEEP to be chosen. If the ΔP curve shows a flat line (D), PEEP will be set at 12 cm H₂O. If multiple PEEP levels result in the lowest ΔP (E), choose the highest PEEP! For more ΔP/PEEP-graph examples see page 15 of this CRF.

Appendix Additional ΔP /PEEP-graph examples



Appendix I. ΔP /PEEP-graph examples. The arrow represents the optimal PEEP to be chosen. If multiple PEEP levels result in the lowest ΔP (A), choose the highest PEEP. If no clear nadir is present and driving pressure is fluctuating between a difference of 2 cm H₂O at maximum (B) a flat line should be considered and PEEP 12 cm H₂O 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 H₂O as a default setting. When this is the case, the PEEP titration may result in 'incorrect' lower P_{plateau} 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 H₂O.

Manipulation of the abdomen by surgeon, insertion of instruments (e.g. gastric tube) or changes of patient position can influence the measurement of P_{plateau}, 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.