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

Mechanical ventilation settings **control group**

For duration of anesthesia	Volume controlled mechanical ventilation during the entire period of surgery
	PEEP 5 cm H_2O after intubation and continued for duration of anesthesia
	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) as calculated in Castor EDC
	FiO_2 0.40 or higher (target SpO_2 >90%)
	Inspiratory pause of 15%.

Mechanical ventilation settings **intervention group**

Mechanical ventilation settings after intubation	Volume controlled mechanical ventilation during the entire period of surgery
	PEEP 10 cm H_2O. Maintained until start of intervention
	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)
	FiO_2 0.40 or higher (target SpO_2 >90%)
	Inspiratory pause of 15%.
Recruitment maneuver and decremental PEEP trial instructions: go to page 6	

Intraoperative

1. Anesthetic overview

Predicted bodyweight: |__|__|__|,|__| kg
For calculation see preoperative CRF page 4 or preoperative eCRF in Castor

Tidal Volume: |__|__|__| ml
Tidal volume = 8 x predicted bodyweight. For automatic calculation see preoperative eCRF in Castor EDC.

Start of anesthesia |__|__|:|__|__| (hh:mm)
i.e. time of induction

End of anesthesia |__|__|:|__|__| (hh:mm)
i.e. time of extubation or discharge from operation room in case patient remains on mechanical ventilation

Body temperature at end of surgery >35.0 °C ☐Yes ☐No

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

Surgical overview

Start of surgery |__|__|:|__|__| (hh:mm)
i.e. time of surgical incision

End of surgery |__|__|:|__|__| (hh:mm)
i.e. time skin closed

Randomization

Randomization group:

☐Individualized high PEEP group
See mechanical ventilation settings on page 2 and intervention instructions on page 6. Complete the entire intraoperative CRF.

☐Standard PEEP group
See mechanical ventilation settings on page 2, skip intervention pages and intraoperative variables before RM1 and after RM2

2. Intraoperative variables* □ Individualized high PEEP □ Standard PEEP group

** Record intraoperative variables after induction and hourly thereafter for intervention group. For control group, also capture before RM1 and after RM2.*

		After induction *directly after induction*	**Before RM 1** *in surgical starting position* □N/A: control group	**After RM2** *after PEEP is set at lowest Δp* □N/A control group	**hr 1** □N/A	**hr 2** □N/A	**hr 3** □N/A	**hr 4** □N/A
Respiratory parameters	Time [*hh:mm*]							
	PEEP [*cm H_2O*]							
	VT [*mL*]							
	Ppeak [*cm H_2O*]							
	Pplateau [*cmH_2O*]							
	I:E	1:	1:	1:	1:	1:	1:	1:
	RR *[/min]*							
	FiO_2 *[0-1]*							
	SPO_2 [%]							
	$ETCO_2$ *[kPa or mmHg]*							
	IAP [*cm H_2O*]							
HD	Systolic BP [*mmHg*]							
	Diastolic BP [*mmHg*]							
	Position* *Trendelenburg: 15-30 degrees head-down; *Extreme Trendelenburg: >30 degrees head-down.*	☐Neutral ☐Trendelenburg ☐Extreme Trendelenburg ☐Anti Trendelenburg	☐Neutral ☐Trendelenburg ☐Extreme Trendelenburg ☐Anti Trendelenburg	☐Neutral ☐Trendelenburg ☐Extreme Trendelenburg ☐Anti Trendelenburg	☐ Neutral ☐ Trendelenburg ☐Extreme Trendelenburg ☐ Anti Trendelenburg	☐Neutral ☐Trendelenburg ☐Extreme Trendelenburg ☐Anti Trendelenburg	☐Neutral ☐Trendelenburg ☐Extreme Trendelenburg ☐Anti Trendelenburg	☐Neutral ☐Trendelenburg ☐Extreme Trendelenburg ☐Anti Trendelenburg
	Did the following intraoperative complications occur in the corresponding hour or RM:							
	Rescue strategy for desaturation (SpO_2 ≤ 90% or if preoperative SpO_2 <90% an absolute decrease in SpO_2>5%) ** see page 9 for rescue therapy*	☐ yes ☐ no	☐ yes ☐ no	☐ yes ☐ no	☐ yes ☐ no	☐ yes ☐ no	☐ yes ☐ no	☐ yes ☐ no
	A decrease in mean arterial pressure (MAP) below 65 mmHg and lasting for >1 minute	☐ yes ☐ no	☐ yes ☐ no	☐ yes ☐ no	☐ yes ☐ no	☐ yes ☐ no	☐ yes ☐ no	☐ yes ☐ no
	Vasoactive drugs defined as more than needed to compensate for vasodilating effects of anesthesia, according to decision of the anesthesiologist in charge	☐ yes ☐ no	☐ yes ☐ no	☐ yes ☐ no	☐ yes ☐ no	☐ yes ☐ no	☐ yes ☐ no	☐ yes ☐ no
	New arrhythmias needing intervention as suggested by the Advanced Cardiac Life Support Guidelines	☐ yes ☐ no	☐ yes ☐ no	☐ yes ☐ no	☐ yes ☐ no	☐ yes ☐ no	☐ yes ☐ no	☐ yes ☐ no

2. Intraoperative variables*

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

		hr 5 □N/A	**hr 6** □N/A	**hr 7** □N/A	**hr 8** □N/A	**hr 9** □N/A	**hr 10** □N/A	**hr 12** □N/A
Respiratory parameters	Time [*hh:mm*]							
	PEEP [*cm H_2O*]							
	VT [*mL*]							
	Ppeak [*cm H_2O*]							
	Pplateau [*cmH_2O*]							
	I:E	1:	1:	1:	1:	1:	1:	1:
	RR *[/min]*							
	FiO_2 *[0-1]*							
	SPO_2 [%]							
	$ETCO_2$ *[kPa or mmHg]*							
	IAP [*cm H_2O*]							
HD	Systolic BP [*mmHg*]							
	Diastolic BP [*mmHg*]							
	Position* **Trendelenburg: 15-30 degrees head-down; Extreme Trendelenburg: >30 degrees head-down.*	☐Neutral ☐Trendelenburg ☐Extreme Trendelenburg ☐Anti Trendelenburg	☐Neutral ☐Trendelenburg ☐Extreme Trendelenburg ☐Anti Trendelenburg	☐Neutral ☐Trendelenburg ☐Extreme Trendelenburg ☐Anti Trendelenburg	☐ Neutral ☐ Trendelenburg ☐Extreme Trendelenburg ☐ Anti Trendelenburg	☐Neutral ☐Trendelenburg ☐Extreme Trendelenburg ☐Anti Trendelenburg	☐Neutral ☐Trendelenburg ☐Extreme Trendelenburg ☐Anti Trendelenburg	☐Neutral ☐Trendelenburg ☐Extreme Trendelenburg ☐Anti Trendelenburg
	Did the following intraoperative complications occur in the corresponding hour or RM:							
	Rescue strategy for desaturation (SpO_2 ≤ 90% or if preoperative SpO_2 <90% an absolute decrease in SpO_2>5%) ** see page 9 for rescue therapy*							
		☐ yes ☐ no	☐ yes ☐ no	☐ yes ☐ no	☐ yes ☐ no	☐ yes ☐ no	☐ yes ☐ no	☐ yes ☐ no
	A decrease in mean arterial pressure (MAP) below 65 mmHg and lasting for >1 minute							
		☐ yes ☐ no	☐ yes ☐ no	☐ yes ☐ no	☐ yes ☐ no	☐ yes ☐ no	☐ yes ☐ no	☐ yes ☐ no
	Vasoactive drugs defined as more than needed to compensate for vasodilating effects of anesthesia, according to decision of the anesthesiologist in charge							
		☐ yes ☐ no	☐ yes ☐ no	☐ yes ☐ no	☐ yes ☐ no	☐ yes ☐ no	☐ yes ☐ no	☐ yes ☐ no
	New arrhythmias needing intervention as suggested by the Advanced Cardiac Life Support Guidelines							
		☐ yes ☐ no	☐ yes ☐ no	☐ yes ☐ no	☐ yes ☐ no	☐ yes ☐ no	☐ yes ☐ no	☐ yes ☐ no

INTERVENTION GROUP ONLY **Recruitment maneuver and decremental PEEP Trial**	**(see page 17 for additional chronological figure visualizing all PEEP steps and their duration)**
How to perform recruitment maneuver (RM) *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.*	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_2O
	Increase PEEP in steps of 5 cm H_2O every 15 seconds – up to PEEP of 20 cm H_2O. End of recruitment maneuver.
How to perform decremental PEEP trial *Performed after the first recruitment maneuver to determine the optimal PEEP.* *(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 12 on page 13.)*	**Starts directly after recruitment maneuver**
	Ventilator remains in volume controlled mode
	Respiratory rate remains at 15 breaths per minute
	PEEP is at 20 cm H_2O
	Decrease PEEP in steps of 2 cm H_2O every 20 seconds – until PEEP of 6 cm H_20. Use table 4 on the next page to note plateau pressures at each step and calculate ΔP. Use the results to fill in figure 1 afterwards on page 9.
Check for nadir in decremental PEEP trial	A nadir is defined as a difference in ΔP between the highest and lowest value of > 2 cm H_2O. See below
Correct PEEP selection **without nadir** in decremental PEEP trial	If all obtained driving pressures differ ≤ 2 cm H_2O, no nadir is found. **PEEP is set at 12 cm H_2O**. For example, you find the following ΔP values: 12-11-10-12-11-10-11-12. Max difference is 2 cm H_2O, hence choose PEEP 12 cm H_2O for the duration of anesthesia
Correct PEEP selection **including nadir** in decremental PEEP trial	Identify the **highest** PEEP with the **lowest** ΔP For example, you find the following ΔP values: 14-14-15-15-16-17-18-18. Max difference is more than 2 cm H_2O (4), hence choose **highest** PEEP with the **lowest** ΔP for the duration of anesthesia. In this example PEEP 20, because both PEEP 18 and PEEP 20 have ΔP 14.

3. 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 and before RM1'				
2	Ensure 'inspiratory pause' on the ventilation machine is enabled and set inspiratory pause at 15%. If applicable, increase the maximum pressure limit of the ventilator to 50 cm H_2O.				
		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 (∆P)**
5	**DPT**, step 1	00:00:30 – 00:00:50	20	..... cm H_2O	..... cm H_2O
6	**DPT**, step 2	00:00:50 – 00:01:10	18	..... cm H_2O	..... cm H_2O
7	**DPT**, step 3	00:01:10 – 00:01:30	16	..... cm H_2O	..... cm H_2O
8	**DPT**, step 4	00:01:30 – 00:01:50	14	..... cm H_2O	..... cm H_2O
9	**DPT**, step 5	00:01:50 – 00:02:10	12	..... cm H_2O	..... cm H_2O
10	**DPT**, step 6	00:02:10 – 00:02:30	10	..... cm H_2O	..... cm H_2O
11	**DPT**, step 7	00:02:30 – 00:02:50	8	..... cm H_2O	..... cm H_2O
12	**DPT**, step 8	00:02:50 – 00:03:10	6	..... cm H_2O	..... cm H_2O
13 14	Calculate the ∆P of the previous steps (5-12): ∆P = Pplat - PEEP Draw the ∆P/PEEP-graph in figure 1 on page 8				
15	**Check if all driving pressures from all PEEP levels have a difference of ≤ 2 cm H_2O**. If yes, this is considered as a DPT without nadir**. In this case, PEEP 12 cm H_2O is chosen for the duration of anesthesia after RM2** **If the difference is > 2 cm H_2O, identify highest** PEEP level resulting in de **lowest** driving pressure.Use this PEEP after RM2 for the duration of anesthesia				
16	**RM 2,** step 1	Start: t=0 – 00:00:15	10		
17	**RM 2,** step 2	00:00:15 - 00:00:30	15		
18	**RM 2,** step 3	00:00:30 - 00:00:45	20		
19	Set PEEP at the optimal individualized level found in step 15				
21	Are the RM and DMT performed conform protocol?	☐Yes ☐No, reason: ……			

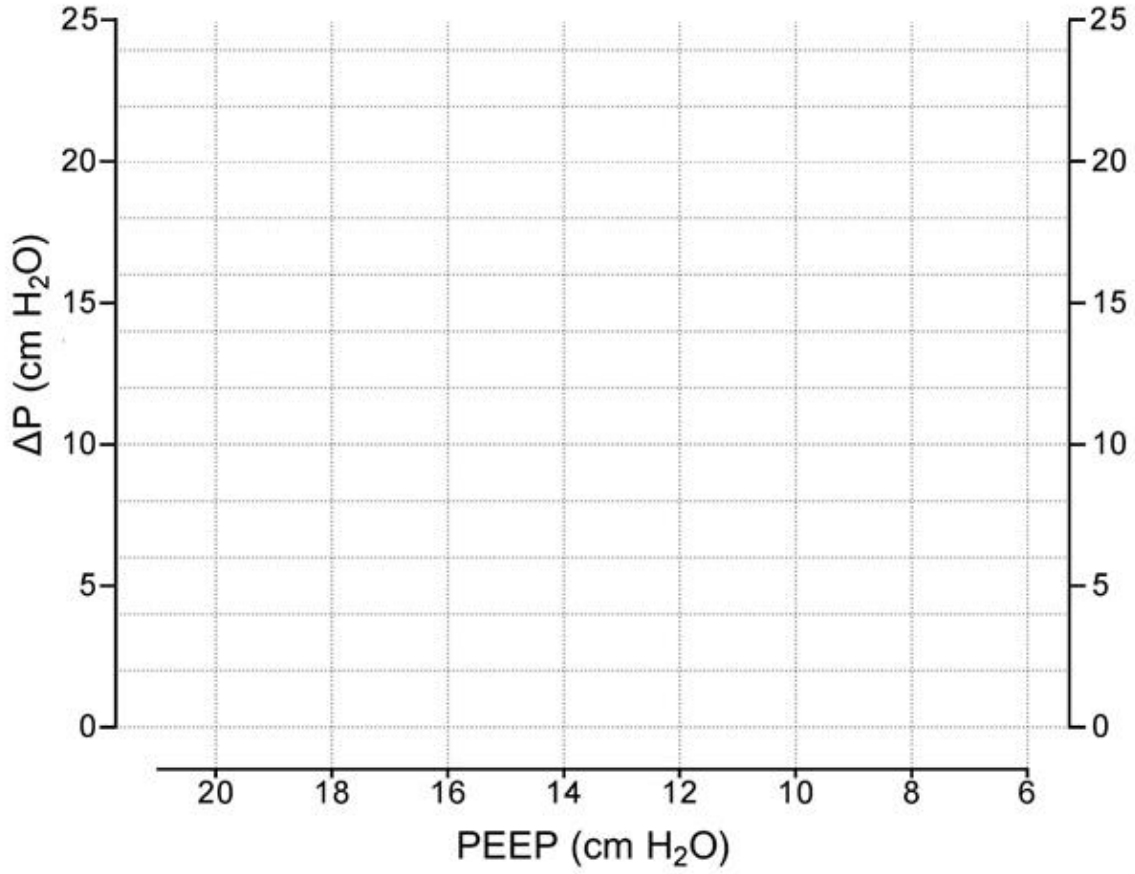


Figure 1. Please fill in this figure with the collected values in the decremental PEEP trial (table above, page 4). This chart MUST be used during the decremental PEEP trial. With every step calculate the resulting driving pressure by subtracting PEEP form the plateau pressure after 20 seconds. Draw 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_2O !

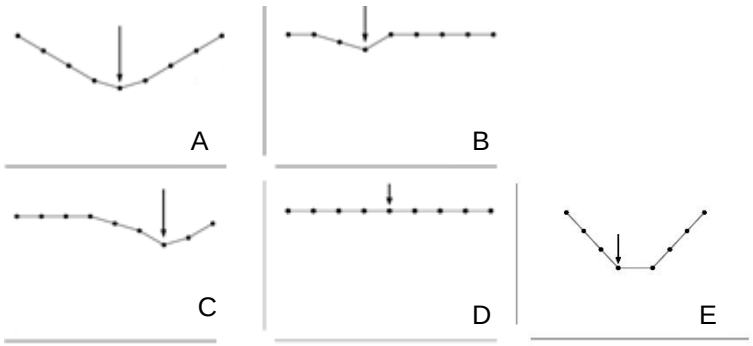


Figure 2. ΔP/PEEP-graph examples. The arrow represents the optimal PEEP to be chosen**. If the ΔP curve shows no ΔP nadir (≤ 2 cm H_2O) (figure D), PEEP will be set at 12 cm H_2O**. If multiple PEEP levels result in the lowest ΔP (E), choose the highest PEEP!
For more ΔP/PEEP-graph examples see page 16 of this CRF.

Rescue therapy for desaturation individualized high PEEP group				Rescue therapy for desaturation standard low PEEP group		
Step	**PEEP**	**FiO_2**		**Step**	**PEEP**	**FiO_2**
1	20	0.4	▪ **Perform rescue strategy if $SpO_2 \leq 90\%$**	1	5	0.4
2	18	0.4	▪ **Start at the level of PEEP set after the decremental PEEP trial**	2	5	0.5
3	16	0.4	▪ **Please note (encircle) to which step rescue strategy is performed**	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			▪ **Perform rescue strategy if $SpO_2 \leq 90\%$**	
10	6	0.6			▪ **Please note (encircle) to which step rescue strategy is performed**	
11	6	0.7				
12	6	0.8				

4. Did the patient receive the allocated PEEP level during surgery? ☐ yes ☐ no *If no, adjusted PEEP level to:* |__|__| cm H_2O *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

5. Where other ventilation settings changed (TV, FiO_2, e.g.) for clinical reasons (pre-approved protocol deviations) ☐ yes ☐ no

If yes, specify:

6. 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_2O ☐ Difference between selected PEEP and correct PEEP ≤2 cm H_2O ☐ Other

If other, specify:

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

If yes, in which corresponding hour was the conversion? _____

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

9. Intraoperative medication

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

*NM = Not measured

10. 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 PaO2	☐mmHg	☐kPa
Measurement unit PaCO2	☐mmHg	☐kPa
Measurement unit HCO3	☐mmol/L	☐mEq/L

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

*Not applicable to the control group

12. Repeated recruitment maneuver (RM) and decremental PEEP trial for the intervention group only.
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	**Check current PEEP level and use RM1 steps as applicable**				
2	**RM 1,** step 1	Start: t=00:00:00 – 00:00:15	10		
3	**RM 1,** step 1	Start: t=00:00:15 – 00:00:30	15		
4	**RM 1,** step 2	00:00:30 - 00:00:45	20		
				Plateau pressure (Pplat)	**Driving pressure (∆P)**
5	**DPT**, step 1	00:00:45 – 00:01:05	20	..... cm H_2O	..... cm H_2O
6	**DPT**, step 2	00:01:05 – 00:01:25	18	..... cm H_2O	..... cm H_2O
7	**DPT**, step 3	00:01:25 – 00:01:45	16	..... cm H_2O	..... cm H_2O
8	**DPT**, step 4	00:01:45 – 00:02:05	14	..... cm H_2O	..... cm H_2O
9	**DPT**, step 5	00:02:05 – 00:02:25	12	..... cm H_2O	..... cm H_2O
10	**DPT**, step 6	00:02:25 – 00:02:45	10	..... cm H_2O	..... cm H_2O
11	**DPT**, step 7	00:02:45 – 00:03:05	8	..... cm H_2O	..... cm H_2O
12	**DPT**, step 8	00:03:05 – 00:03:25	6	..... cm H_2O	..... cm H_2O
13 **14**	Calculate the ∆P of the previous steps (5-12): ∆P = Pplat - PEEP Draw the ∆P/PEEP-graph in figure 1 on page 8				
15	**Check if all driving pressures from all PEEP levels have a difference of ≤ 2 cm H_2O**. If yes, this is considered as a DPT without nadir**. In this case, PEEP 12 cm H_2O is chosen for the remaining duration of anesthesia after RM2** **If the difference is > 2 cm H_2O, identify highest** PEEP level resulting in de **lowest** driving pressure.Use this PEEP after RM2 for the remaning duration of anesthesia				
16	**RM 2,** step 1	Start: t=0 – 00:00:15	10		
17	**RM 2,** step 2	00:00:15 - 00:00:30	15		
18	**RM 2,** step 3	00:00:30 - 00:00:45	20		
19	Set PEEP at the optimal individualized level found in step 15				
20	Are the RM and DMT performed conform protocol? ☐Yes ☐No, reason: ……				

	Specify reason for repetition of the decremental PEEP trial	☐Radical change in position	☐Conversion to laparotomy	☐Other radical change in intra-abdominal pressure
	How long did it take before the decremental PEEP trial was repeated?	|__|__|__| minutes	Has the decremental PEEP trial been repeated again?	☐No ☐Yes, please proceed to page 15

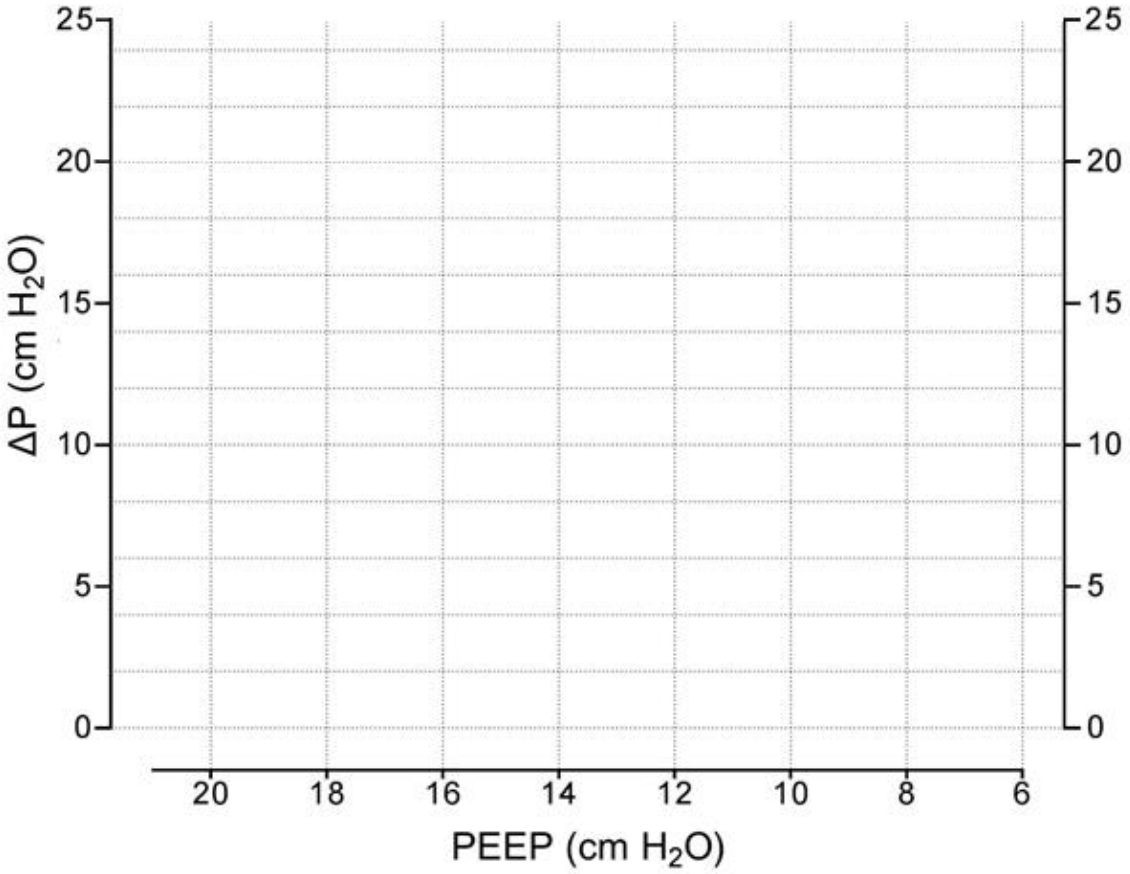


Figure 1. Please fill in this figure with the collected values in the decremental PEEP trial (table above, page 4). This chart MUST be used during the decremental PEEP trial. With every step calculate the resulting driving pressure by subtracting PEEP form the plateau pressure after 20 seconds. Draw 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_2O !

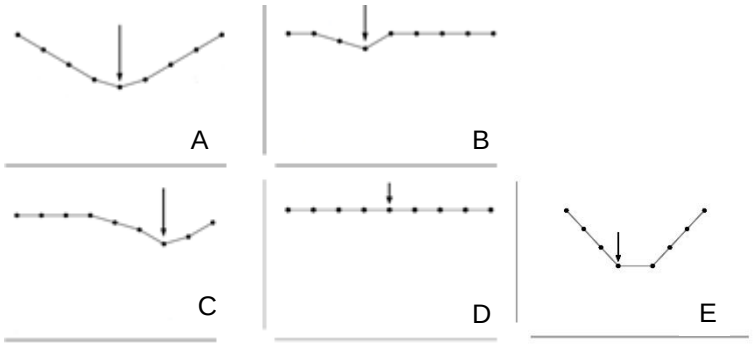


Figure 2. ΔP/PEEP-graph examples. The arrow represents the optimal PEEP to be chosen**. If the ΔP curve shows no ΔP nadir (≤ 2 cm H_2O) (figure D), PEEP will be set at 12 cm H_2O**. If multiple PEEP levels result in the lowest ΔP (E), choose the highest PEEP!
For more ΔP/PEEP-graph examples see page 16 of this CRF.

13. Second repeated recruitment maneuver (RM) and decremental PEEP trial for the intervention group only.
Follow these steps and fill in the open white fields

Corresponding hour of 2nd repeated decremental PEEP trial: |__|__|

Step		Time phase *(hh:mm:ss)*	PEEP level		
1	**Check current PEEP level and use RM1 steps as applicable**				
2	**RM 1,** step 1	Start: t=00:00:00 – 00:00:15	10		
3	**RM 1,** step 1	Start: t=00:00:15 – 00:00:30	15		
4	**RM 1,** step 2	00:00:30 - 00:00:45	20		
				Plateau pressure (Pplat)	**Driving pressure (∆P)**
5	**DPT**, step 1	00:00:45 – 00:01:05	20	..... cm H_2O	..... cm H_2O
6	**DPT**, step 2	00:01:05 – 00:01:25	18	..... cm H_2O	..... cm H_2O
7	**DPT**, step 3	00:01:25 – 00:01:45	16	..... cm H_2O	..... cm H_2O
8	**DPT**, step 4	00:01:45 – 00:02:05	14	..... cm H_2O	..... cm H_2O
9	**DPT**, step 5	00:02:05 – 00:02:25	12	..... cm H_2O	..... cm H_2O
10	**DPT**, step 6	00:02:25 – 00:02:45	10	..... cm H_2O	..... cm H_2O
11	**DPT**, step 7	00:02:45 – 00:03:05	8	..... cm H_2O	..... cm H_2O
12	**DPT**, step 8	00:03:05 – 00:03:25	6	..... cm H_2O	..... cm H_2O
13 14	Calculate the ∆P of the previous steps (5-12): ∆P = Pplat - PEEP Draw the ∆P/PEEP-graph in figure 1 on page 8				
15	**Check if all driving pressures from all PEEP levels have a difference of ≤ 2 cm H_2O**. If yes, this is considered as a DPT without nadir**. In this case, PEEP 12 cm H_2O is chosen for the remaining duration of anesthesia after RM2** **If the difference is > 2 cm H_2O, identify highest** PEEP level resulting in de **lowest** driving pressure.Use this PEEP after RM2 for the remaining duration of anesthesia				
16	**RM 2,** step 1	Start: t=0 – 00:00:15	10		
17	**RM 2,** step 2	00:00:15 - 00:00:30	15		
18	**RM 2,** step 3	00:00:30 - 00:00:45	20		
19	Set PEEP at the optimal individualized level found in step 15				
20	Are the RM and DMT performed conform protocol? ☐Yes ☐No, reason: ……				
	Specify reason for 2nd repetition of the decremental PEEP trial	☐Radical change in position	☐Conversion to laparotomy	☐Other radical change in intra-abdominal pressure	
	How long did it take before the decremental PEEP trial was repeated again for 2nd time?	|__|__|__| minutes		

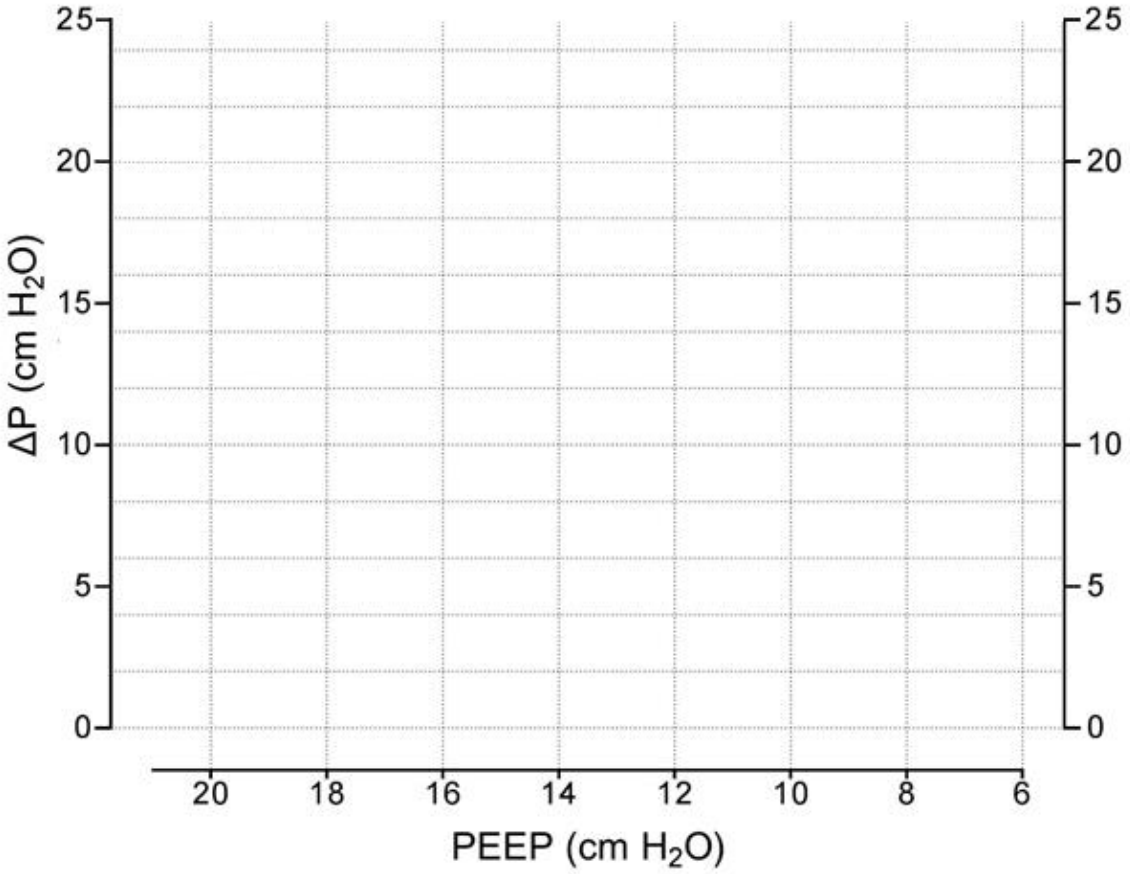


Figure 1. Please fill in this figure with the collected values in the decremental PEEP trial (table above, page 4). This chart MUST be used during the decremental PEEP trial. With every step calculate the resulting driving pressure by subtracting PEEP form the plateau pressure after 20 seconds. Draw 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_2O !

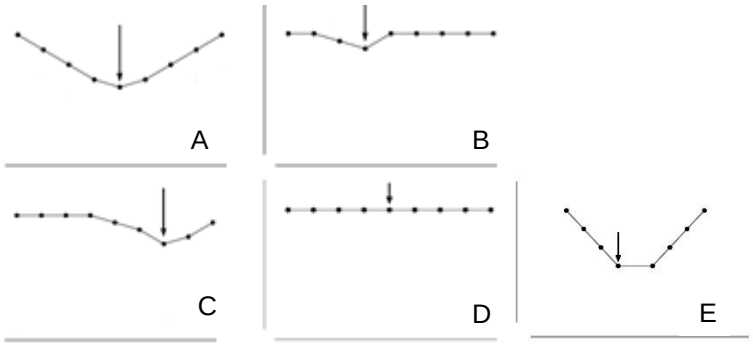
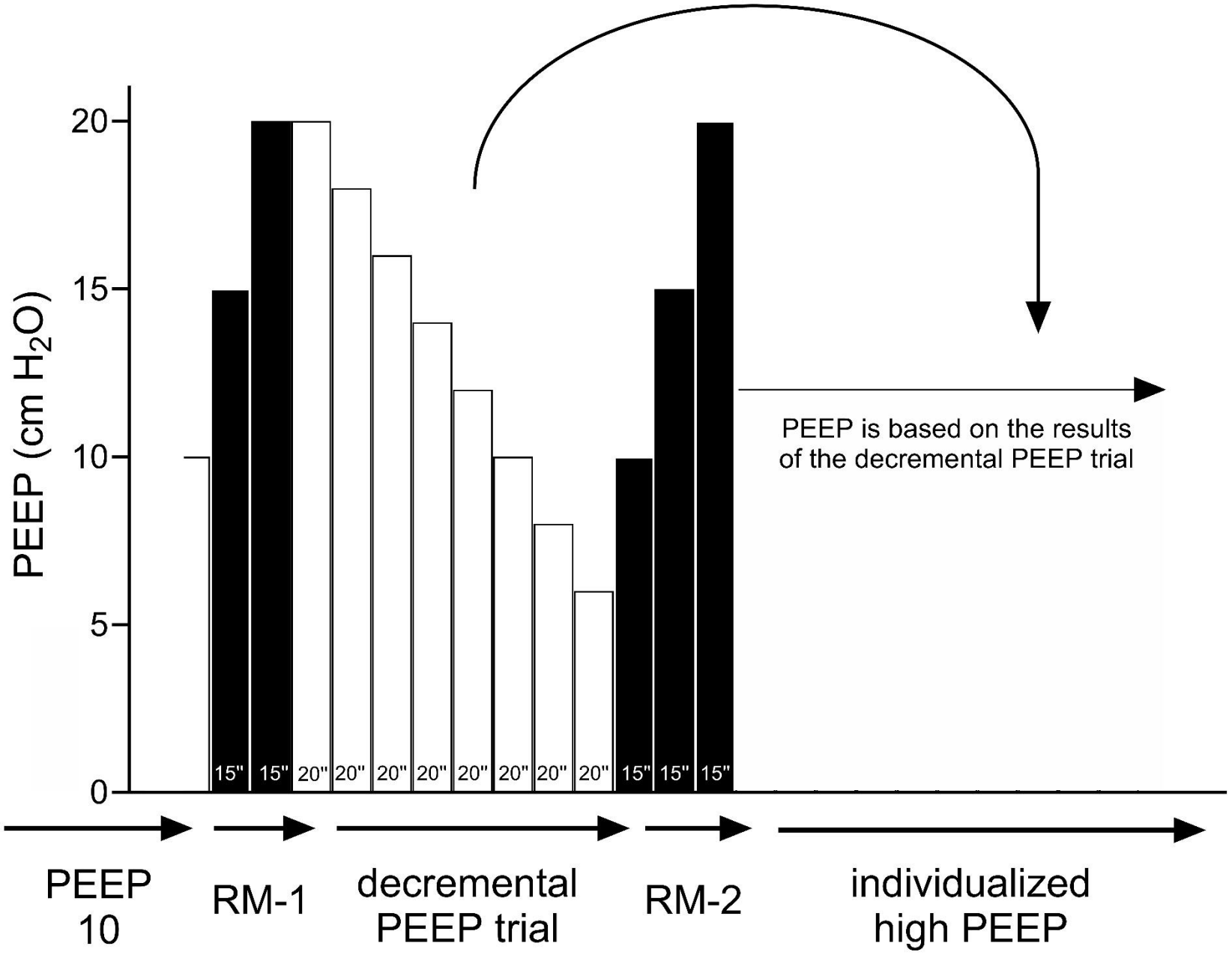
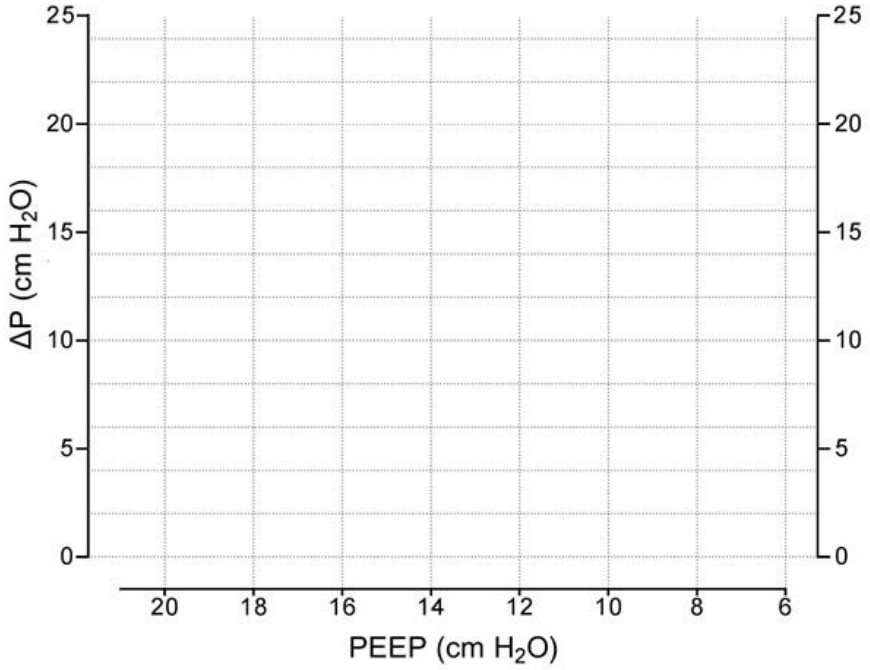
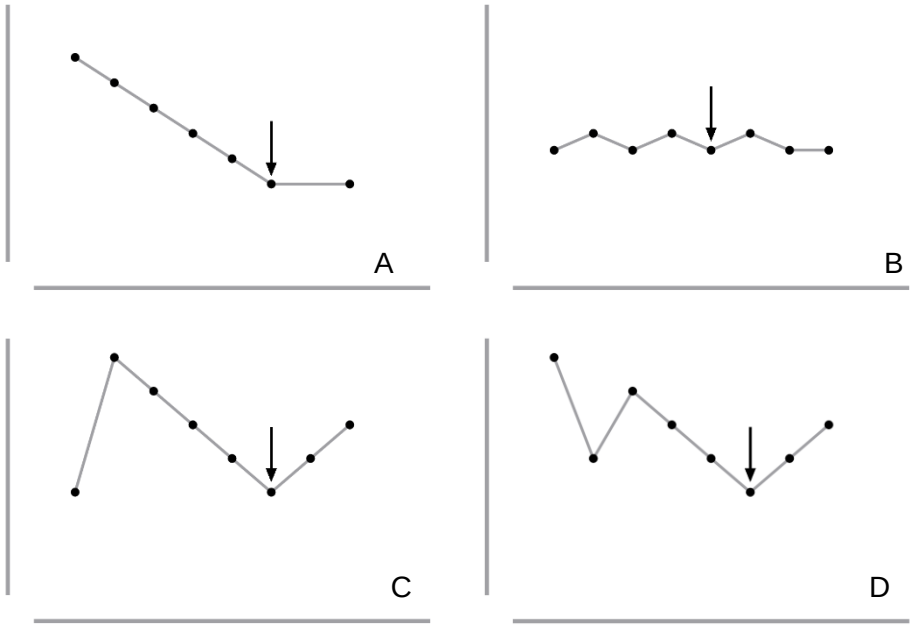


Figure 2. ΔP/PEEP-graph examples. The arrow represents the optimal PEEP to be chosen**. If the ΔP curve shows no ΔP nadir (≤ 2 cm H_2O) (figure D), PEEP will be set at 12 cm H_2O**. If multiple PEEP levels result in the lowest ΔP (E), choose the highest PEEP!
For more ΔP/PEEP-graph examples see page 16 of this CRF.


20
15
10
5
0
PEEP (cm H_2O)
15" 15" 20" 20" 20" 20" 20" 20" 20" 20" 15" 15" 15"
PEEP is based on the results of the decremental PEEP trial
PEEP 10
RM-1
decremental PEEP trial
RM-2
individualized high PEEP

Appendix INTERVENTION GROUP ONLY
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 H_2O at maximum (B) a flat line should be considered and PEEP 12 cm H_2O 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_2O as a default setting. When this is the case, the PEEP titration may result in 'incorrect' lower Pplateau 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_2O.
Manipulation of the abdomen by surgeon, insertion of instruments (e.g. gastric tube) or changes of patient position can influence the measurement of Pplateau, 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.