Verification Report (Animal Trials) - AAU Pandemic Ventilator (RI-001)

Revision History			
Rev	**ECO**	**Changes**	**Author**
1	N/A	Initial release	SR

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1 AAU Pandemic Ventilator animal trial

The purpose of this trial was to evaluate whether the ventilator could be used in an animal model of healthy and diseased lungs. A 27 kg pig was intubated and initially ventilated using a standard CE-marked anesthesia ventilator (Dameca Dream). Ventilation using the standard ventilator was continued during insertion of catheters for arterial and venous blood sampling, Swan-Ganz catheters for cardiac output measurements, blood pressure, ECG, esophageal pressure, and the initiation of intravenous anesthesia. Subsequently, the standard ventilator was exchanged for the AAU pandemic ventilator.

Figure 1 below shows the trial running from 8am in the morning until 4pm in the afternoon with the AAU Pandemic Ventilator used for ventilation during the last half of the trial (green part). During the trial a number of measurements were made as indicated on the figure, these were made at varying tidal volume and frequency settings so as to evaluate whether such settings could be delivered by the AAU pandemic ventilator.

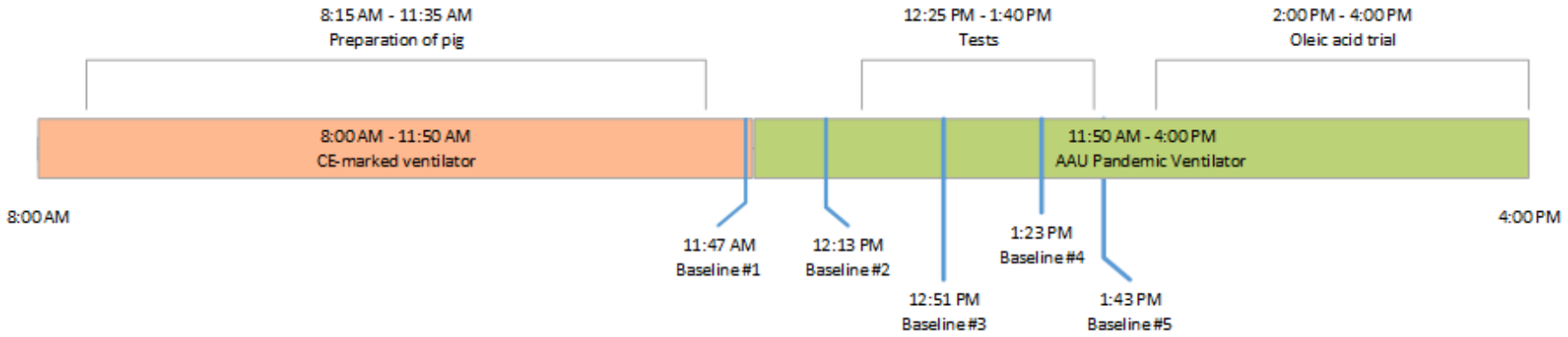

Figure 1: Overview of the animal trial

Following approximately two hours of ventilation using the AAU pandemic ventilator, 3ml of oleic acid was infused over a period of about 1 hour, this inducing a lung damage. The timing of measurements in this part of the trial is seen in figure 2.

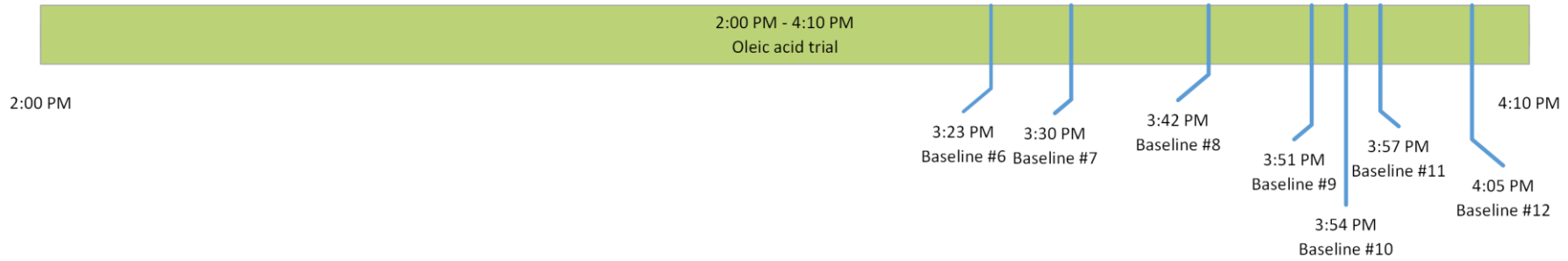

Figure 2: Oleic acid trial

1.1 Equipment and test setup

The following equipment was used during the trial in addition to the AAU Pandemic Ventilator:

- CE-marked ventilator: Dameca Dream (Dameca A/S, Denmark)
- BEACON Caresystem (Mermaid Care A/S, Denmark) – Measurement of O_2 and CO2 partial pressures in respiratory gasses and respiratory flow and pressure traces, and calculated values of Vt.
- Vigilance Monitor (Edwards Lifesciences, USA) – Heamodynamic measurements

1.2 Results

At no time during the trial there were any issues in relation to the AAU Pandemic Ventilator which would cause a switch back to the CE-marked ventilator. Following initiation of oleic acid infusion and the resulting circulatory compromise, measurements of cardiac output and ECG were not available. All blood samples were drawn from a catheter and analysed on a ABL series 800 blood gas analyser (Radiometer, Denmark).

The CE-marked ventilator's settings, immediately before the switch were:

- Vt = 250ml
- RR = 16 breaths/minute
- FIO2 = 60%
- I:E = 1:2
- Pause time 0%

Table 1 provides all measurements, the timing of which is shown in figures 1 and 2. Set values of Vt were 250 ml at baseline both for the CE marked and AAU pandemic ventilators. Measured values of Vt at baseline, obtained from the Beacon Caresystem, were 270 for the CE marked ventilator and 250 for the AAU Pandemic Ventilator. This difference explains the higher arterial PCO_2 level seen in the baseline value of the blood sample taken in conjunction with the AAU pandemic ventilator.

Table 1: Measurements during the entire trial. Arterial blood gases were analyzed immediately after sampling. Vt, RR, FiO_2, IE, and PEEP are setting from the ventilators. Pressures are measured by BEACON Caresystem.

	1	2	3	4	5	6	7	8	9	10	11	12
Time	11:51am	00:12pm	00:51pm	01:24pm	01:43pm	03:23pm	03:30pm	03:42pm	03:51pm	03:54pm	03:57pm	04:05pm
pH	7,469	7,416	7,362	7,351	7,343	7,139	7,204	7,185	7,164	7,156	7,183	7,199
PCO_2 (kPa)	5	5,72	6,22	6,21	6,41	7,35	7,33	7,84	8,49	8,44	7,65	7,42
PO_2 (kPa)	40,4	37,2	39	37,1	42,6	16,1	14,6	13,8	11,4	9,89	21,5	41
BE (mmol/L)	3,4	3	1,1	0,3	0,4	-6,5	-5,8	-5,7	-5,4	-6	-6,3	-5,9
HCO_3 (mmol/L)	27,6		25,2	24,5	24,6	18,3	18,7	18,7	18,5	18	18,3	18,6
SO_2 (frac)	0,996	1	0,998	0,993	0,996	0,962	0,951	0,941	0,894	0,836	0,98	0,997
LAC (mmol/L)	0,6	0,5	0,5	0,5	0,4	1,5	1,9	1,8	2,2	2	2,1	2,3
HR	59	65	60	58	64							
BP (mmHg)	103/54	93/43	91/40	83/55	89/47							
CO (L/min)	3	3,2	2,9	2,8	2,9							
Vt (ml)	250	250	450	250	300	300	300	300	300	300	300	300
RR	16	16	6	16	18	18	18	18	22	22	22	22
FiO_2	60	60	60	60	60	60	60	60	60	80	80	80

IE	1,2	1,2	1,2	1,2	1,2	1,2	1,2	1,2	1,2	1,2	1,2	1,2
PEEP	5	5	5	5	5	5	5	5	5	10	10	15
Dynamic compliance	18,9	19,5	26,0	15,7	25,9	10,2	10,4	9,5	9,8	10,1	10,1	13,2
Static compliance		26,0	33,6	20,2	34,1	12,8	13,3	12,1	13,8	14,0	13,3	17,0
Peak pressure	18,2	17,8	22,3	20,9	16,6	34,5	33,9	36,6	40,7	39,7	39,7	37,8
Driving pressure	13,2	12,8	17,3	15,9	11,6	29,5	28,9	31,6	30,7	29,7	29,7	22,8
Plateau pressure		14,6	18,4	17,4	13,8	28,4	27,5	29,7	31,7	31,4	32,5	32,6
Ventilator	CE	AAU	AAU	AAU	AAU	AAU	AAU	AAU	AAU	AAU	AAU	AAU

1.3 Major conclusions

1) The AAU pandemic ventilator could sustain life and provide adequate ventilation in the healthy and diseased lung.
2) Standard ventilator settings could be applied and adjusted to maintain oxygenation and carbon dioxide levels.
3) Positive End Expiratory Pressure (PEEP) could be elevated to keep the lungs open and hence increase the compliance of the lungs and improve oxygenation in the diseased lung
4) There were no negative consequences of using the AAU pandemic ventilator such as the effects of the humidity of respiratory gas. Ventilation could be applied over a 4 hour period.

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VENTILATOR
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