

 <p>La Région Auvergne-Rhône-Alpes</p>	<p>VENTILATOR DESIGN QUALIFICATION TEST RESULT</p> <p>12-HOUR TEST</p> <p>COVRESP-QA-QTR-002</p>	 <p>MakAir</p>
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Record name: COVRESP-QA-QTR-002-Rev1

The objective of this test is to evaluate the stability and reliability of the MAKAIR ventilator over time. This is important for the treatment of the patients because a drift or instability of the air flow (pressure & volume curves) over time could either create lung damage, deteriorate the ventilation of the patient, or require significant medical staff oversight and constant tuning. If the ventilation created by the device is stable over time then this is a very strong indication of stability of the treatment of the patient.

Protocol

Parameters glossary for Pressure Support device:

- Pip or Ppeak — Peak inspiratory pressure
- Pplat — Plateau pressure (airway)
- PEEP — Positive end-expiratory pressure, pressure created by a backpressure valve.
- I:E — Inspiratory:Expiratory ratio – constant 1:2 in Makair

1. General characteristics according to conception

Several characteristics will be recorded and/or measured: volumetry (inspiration/expiration), PEEP pressure; Plateau Pressure; stability of breath rate.

The main objective is to measure the stability of the aforementioned characteristics over time. The reality of the measurement versus the set point of the equipment will also be evaluated.

2. General environmental characteristics

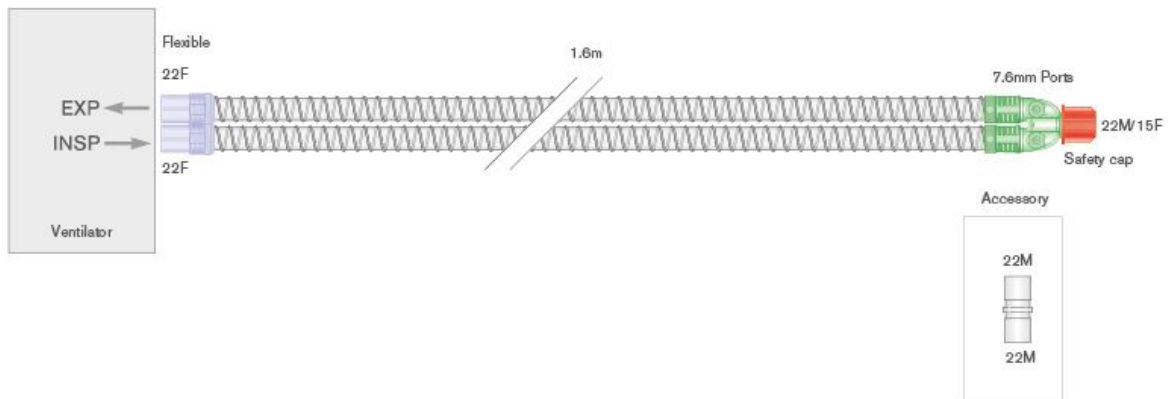
Our setup will comprise of the following items:

- (1) ASL 5000 lung model (IngMar Medical, Pittsburg, Pennsylvania)
- (2) MakAir, ICU ventilator provided, for the purpose of the present study

(3) An adult double circuit diameter 22mm, length 1,6m or an adult double circuit diameter 22mm, length including water traps (InterSurgiqua),)

(4) A filter ref 0.22 micron (at the inspiratory circuit, typically high-efficiency particulate air (HEPA) filter)

The setup used in the test campaign shall be documented in the test report.



All measures will be performed at dry ambient atmospheric pressure, constant room temperature (around 22°C) and test-lung temperature (37°C), (ATPD) conditions, and will be converted into body temperature and pressure, saturated (BTPS).

Data acquisition will be performed at 512 Hz and stored in a desktop computer. Offline measurements and curves analysis will be performed on a breath-by-breath basis using LabVIEW (National Instruments, Austin, TX, USA) and a dedicated software (ASL 5000 acquisition software v3.5).

3. Technical performance evaluation

We will therefore use an ASL5000™ lung simulator (Ingmar, Pittsburgh, PA, USA). The ASL5000™ simulator is a computerized mechanical lung simulator consisting of a piston moving inside a cylinder. The lung model uses the equation of motion to control the movement of the piston. Flow and airway pressure were measured by flow and pressure sensors at the entrance of the piston, and volume was obtained by flow integration over time. The user sets compliance, resistance, and the P_{mus} (Pression musculaire sinusoidale) waveform. Test-lung temperature will be set at the beginning of the experiments, but measurements will be performed only after temperature stabilization.

Ventilators will be allowed to stabilize in each test condition for **3 to 5 min**, after which at least one minute of ventilation with stable signals will be recorded.

Test is made with no additional O₂ (23%), with a restrictive scenario ($R=10 \text{ cmH}_2\text{O}\cdot\text{L}^{-1}\cdot\text{s}^{-1}$; $C=30 \text{ ml}\cdot\text{cmH}_2\text{O}^{-1}$), with no inspiratory effort.

Pressurization accuracy will assess PEEP (PEEP = 10 cm H₂O) and inspiratory pressure (PI = 25 cm H₂O) stability in the pressure support mode (PC), with breathing cycles at 20 / minute.

Volume-controlled-Continuous Mandatory Ventilation reliability will be evaluated at VT = 500 mL, RR = 20 b/min, PEEP = 5 and 10 cm H₂O.

A 10% error value for all these parameters will be *a priori* considered clinically relevant for reliability (*Pass/Fail*).

For each test, the parameters set in the ASL 5000 lung in order to simulate the patient profile will be recorded. This record will be implemented as well with the targeted VM (6 to 8 ml/kg IBW), or VT expected (300 to 600 ml), monitored.

The results from the test will be downloaded from the test equipment and recorded. This record will be integrated in a test report with a conclusion written by the evaluator.

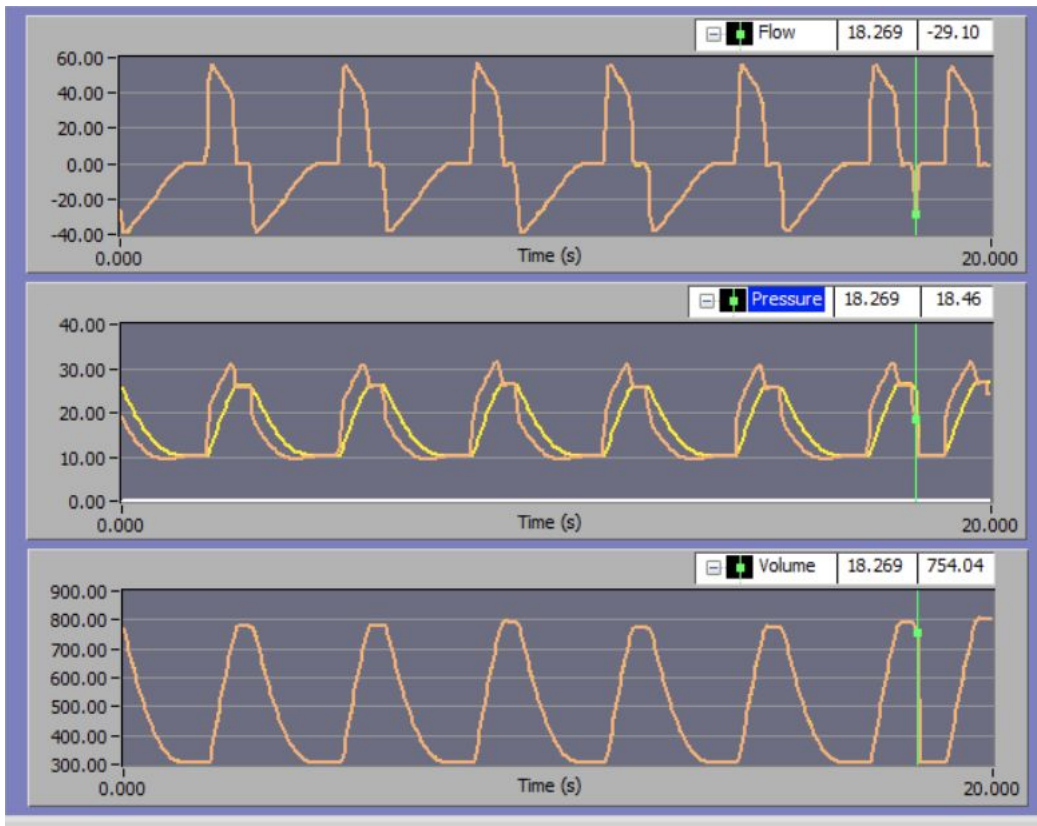
REST RESULT

Material used:

- Test using ASL 5000 (Serial 1623)
- MakAir (serial 202004-006), ICU ventilator provided, for the purpose of the present study
- An adult double circuit diameter 22mm, length 1,6m or an adult double circuit diameter 22mm, length including water traps (InterSurgiquial,)
- Filter ref 0.22 micron (at the expiratory circuit, typically high-efficiency particulate air (HEPA) filter)



Start time: 24/04/2020 19h00



INGMAR MEDICAL Breath Detection / RT - Analysis Version 3.6

Enable Analysis **Conditions** **Pressure Filter**

Save Waveform Data

Auxiliary Compensation Parameters **Breath Detection Settings**

Inspiratory Circuit Resistance (cm H₂O/L/s) Breath Start Volume Threshold (mL)
 Expiratory Circuit Resistance (cm H₂O/L/s) Exp Start Volume Threshold (mL)
 Circuit Compliance (mL/cm H₂O) Effort Start Threshold (cm H₂O)

Breath Rate (BPM)	20.211	PEEP (cmH ₂ O)	10.111
I/E	0.357	P _{mean} Insp (cmH ₂ O)	24.651
Max Pres Drop During Trig (cmH ₂ O)	-0.858	Patient Insp Vt (mL)	531.945
Perc of Peak Flow at Start of Exp (%)	21.516	Vent Exp Vt (mL)	532.235

Breath-by-Breath Volume Plot (mL)

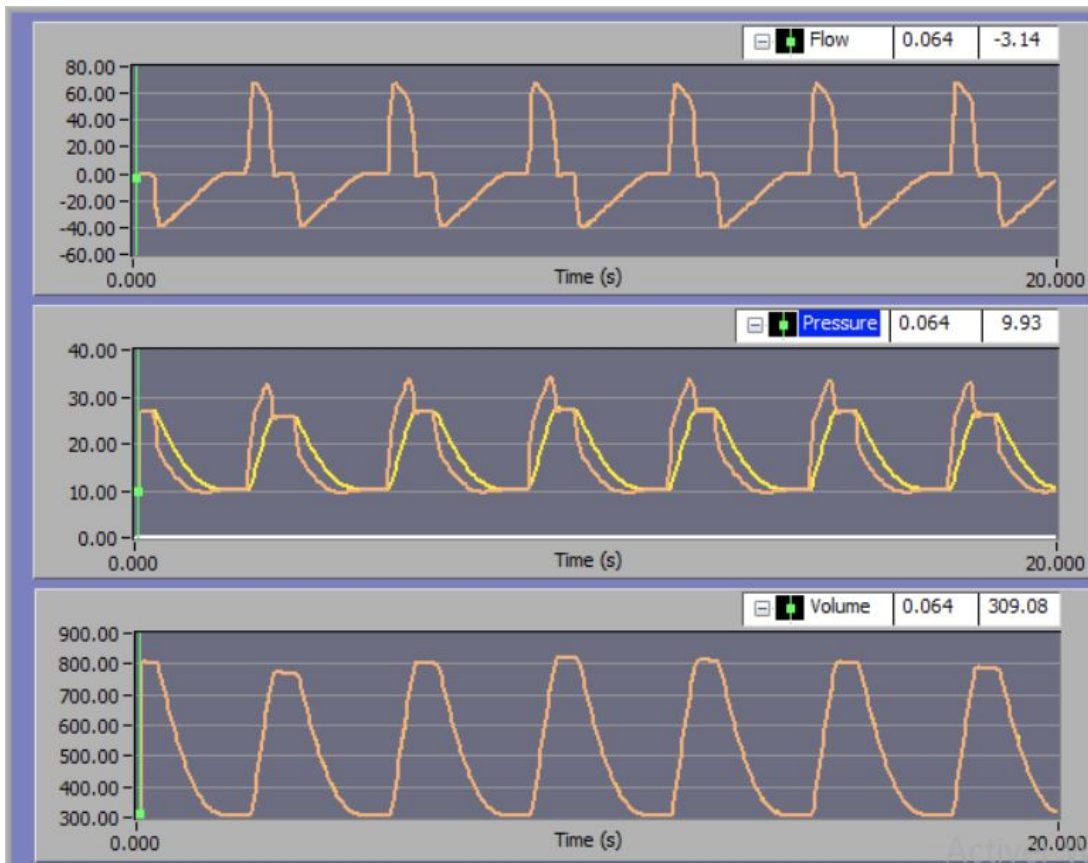
Display Uncompensated Volume

Volume
 Start Pat Insp Effort
 Start Insp.
 Vol Max.
 Start Exp.
 End Exp.

Cycle number	Breath Rate	Peep	Plateau Pressure	Patient Insp	Patient Exp
1	20.317	10.103	24.482	520.501	520.749
2	20.211	10.106	23.935	503.898	503.635
3	20.211	10.073	24.255	518.28	518.752
4	20.211	10.099	24.359	511.825	511.466
5	20.535	10.119	24.56	519.857	519.659
6	20.105	10.096	23.867	525.242	525.874
7	20.105	10.133	24.159	520.189	519.063
8	20.211	10.097	23.683	474.449	475.397
9	20.426	10.123	24.49	518.955	518.328
10	20.105	10.118	23.57	498.214	498.251
11	20.211	10.108	24.576	525.154	525.601
12	20.317	10.116	24.617	526.208	525.817
13	20.211	10.124	24.629	540.009	539.676
14	20.426	10.14	24.076	497.418	497.051
15	20.105	10.102	23.925	517.945	519.15
16	20.211	10.125	24.247	518.252	517.477
17	20.317	10.099	24.847	538.518	539.375
18	20.105	10.125	24.114	511.452	510.807
19	20.317	10.1	24.015	498.325	498.907
20	20.211	10.134	24.631	538.467	537.45
21	20.211	10.133	24.583	531.837	531.926
22	20.317	10.104	24.416	517.655	518.516
23	20.317	10.088	24.5	526.484	526.781
24	20.105	10.118	24.1	519.225	518.433
25	20.211	10.103	24.452	519.172	519.645
26	20.317	10.103	24.81	540.453	540.597

27	20.211	10.14	24.423	521.209	519.982
28	20.211	10.099	24.048	499.955	501.148
29	20.317	10.114	24.212	508.192	507.893
30	20.105	10.124	24.056	507.975	507.351
31	20.211	10.114	24.091	493.037	493.385
32	20.426	10.123	25.075	548.445	548.077
33	20.105	10.097	23.895	504.19	505.037
34	20.211	10.124	24.295	510.746	510.171
35	20.317	10.115	24.158	500.716	500.834
Mean Measure	20.242	10.112	24.290	516.355	516.350
Standard Deviation	0.109	0.015	0.336	15.521	15.374
Coefficient of variation	0.54%	0.15%	1.38%	3.01%	2.98%
Target	20	10	25	500	500
Mean Error to target (%)	1.21%	1.13%	2.84%	3.27%	3.27%

End time: 25/04/2020 09h00



INGMAR MEDICAL **Breath Detection / RT - Analysis** Version 3.6

Enable Analysis Save Waveform Data Conditions Pressure Filter

Auxiliary Compensation Parameters

Inspiratory Circuit Resistance (cm H2O/L/s)
 Expiratory Circuit Resistance (cm H2O/L/s)
 Circuit Compliance (mL/cm H2O)

Breath Detection Settings

Breath Start Volume Threshold (mL)
 Exp Start Volume Threshold (mL)
 Effort Start Threshold (cm H2O)

Breath Rate (BPM)	20.211	PEEP (cmH2O)	10.158
I/E	0.275	P_mean Insp (cmH2O)	24.734
Max Pres Drop During Trig (cmH2O)	-0.865	Patient Insp Vt (mL)	502.978
Perc of Peak Flow at Start of Exp (%)	23.673	Vent Exp Vt (mL)	503.488

Breath-by-Breath Volume Plot (mL)

Volume
 Start Pat Insp Effort
 Start Insp.
 Vol Max.
 Start Exp.
 End Exp.

Display Uncompensated Volume


Cycle number	Breath Rate	Peep	Plateau Pressure	Patient Insp	Patient Exp
1	20.105	10.151	24.733	503.795	504.109
2	20.317	10.16	25.683	539.127	538.906
3	20.105	10.17	24.511	494.066	493.653
4	20.317	10.172	25.405	521.138	521.187
5	20.211	10.156	25.428	541.067	541.454
6	20.211	10.152	24.912	512.956	513.199
7	20.317	10.156	24.865	504.303	504.013
8	20.105	10.17	24.922	513.861	513.421
9	20.317	10.181	25.123	502.117	501.752
10	20.211	10.141	24.683	494.849	496.126
11	20.211	10.164	25.319	529.969	529.288
12	20.317	10.166	25.094	513.446	513.594
13	20.211	10.167	25.191	523.051	522.861
14	20.211	10.167	25.145	518.745	518.674
15	20.426	10.148	24.707	493.873	494.401
16	20	10.17	25.023	549.703	549.107
17	20.317	10.159	25.159	514.033	514.476
18	20.211	10.148	24.599	493.409	493.576
19	20.105	10.171	25.321	524.959	524.436
20	20.105	10.153	25.52	515.077	515.701
21	20.105	10.183	25.446	493.291	492.628
22	20.211	10.175	27.038	556.953	559.65
23	20	10.151	26.503	525.138	523.313
24	20.87	10.172	26.999	521.338	521.108
25	20.105	10.164	24.893	522.489	522.83

26	20.211	10.133	25.435	522.181	523.148
27	20.317	10.155	25.736	533.725	532.999
28	20.211	10.151	25.175	513.531	513.736
29	20.105	10.161	25.603	541.341	540.904
30	20.317	10.172	25.185	512.619	512.457
31	20.211	10.16	25.201	520.434	520.755
32	20.317	10.171	25.411	531.871	531.436
33	20.211	10.173	24.412	494.001	493.922
34	20.211	10.177	25.138	534.172	533.904
35	20.211	10.144	24.526	495.941	497.104
Mean Measure	20.227	10.162	25.258	517.788	517.824
Standard Deviation	0.149	0.012	0.602	17.000	17.010
Coefficient of variation	0.74%	0.12%	2.38%	3.28%	3.28%
Target	20	10	25	500	500
Mean Error to target (%)	1.13%	1.62%	1.03%	3.56%	3.56%

Conclusion:

Target	20	10	25	500	500
Mean Measure initial	20.242	10.112	24.290	516.355	516.350
Mean Measure Final	20.227	10.162	25.258	517.788	517.824
Deviation initial-final (%)	-0.07%	0.49%	3.99%	0.28%	0.29%
Coefficient of variation initial	0.54%	0.15%	1.38%	3.01%	2.98%
Coefficient of variation final	0.74%	0.12%	2.38%	3.28%	3.28%

The characteristics of the Makair device are indeed stable over time, after 14 hours of continuous operation.

Date	2020-04-24
Name of the person who did the test	Baptiste Jamin
Signature	

Version	Description	Effective date
0	Creation	2020-04-23
1		