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VersaStream Sampling Line Test

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1. Summary

Purpose:	The purpose of this test is to analyze and verify the accuracy and functional compatibility of VersaStream sampling lines compared to Nomoline sampling lines.
Method:	Measure and verify the CO₂ and RR (Respiratory Rate) measurement accuracy of the VersaStream sampling lines with a CO₂ respiration simulator. The CO₂ measurement accuracy specification: $RMS \leq 0.2$. The RR measurement accuracy specification: $RMS \leq 1$. Measure and verify the negative pressure of the VersaStream sampling lines with a precision digital manometer. The negative pressure accuracy specification: ≤ 25 mbar
Results:	The VersaStream sampling line test is passed.
Observations:	The CO₂ measurement accuracy is: $RMS \leq 0.2$. The RR measurement accuracy is: $RMS \leq 1$. The negative pressure accuracy are: ≤ 25 mbar
Conclusion:	The CO₂ and RR test verifies that the accuracy of the tested VersaStream sampling lines is observed. The Pressure Test shows no significant differences between the Nomoline and the VersaStream sampling lines.

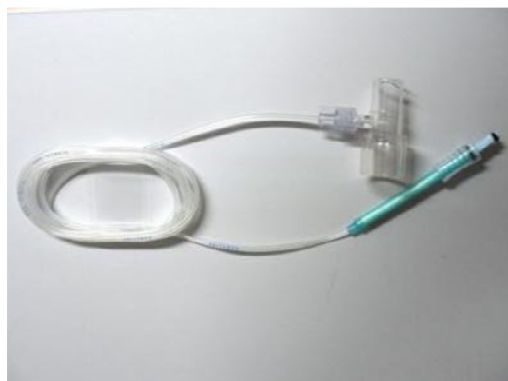
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2. Equipment under Test (EuT)

Manufacturer	Type	Part No.	Lot Number
Masimo Sweden AB	NomoLine	108210	15020096
Viamed Limited	VersaStream Short Term	4420821	2618.12.16
Viamed Limited	VersaStream Long Term	4420823	2711.12.16

Three examples of each type were used for evaluation testing and the results averaged.

Photos of EuT



Nomoline with Airway Adapter



VersaStream Short Term with Airway Adapter



VersaStream Long Term with Airway Adapter

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3. Method

3.1 Measurement Accuracy

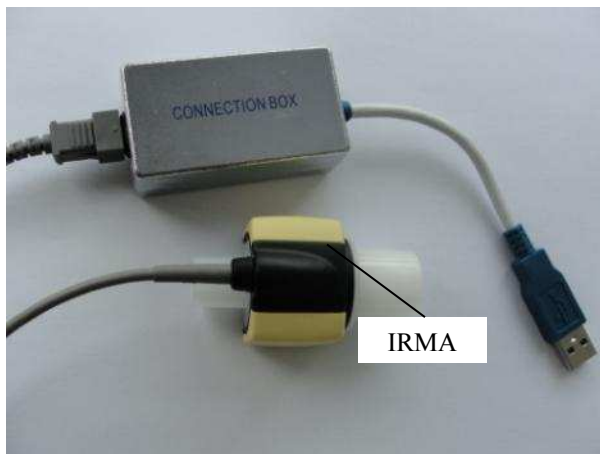
3.1.1 Test equipment



CapnoCheck , CO₂-Respiratory-Simulator



Test gas 3, 5, 7.5 Vol% $\pm$ 0.1 Vol%



UART-USB-Converter for mainstream CO₂ UART-USB-Converter with integrated IRMA-Sensor as reference side stream CO₂ ISA-module

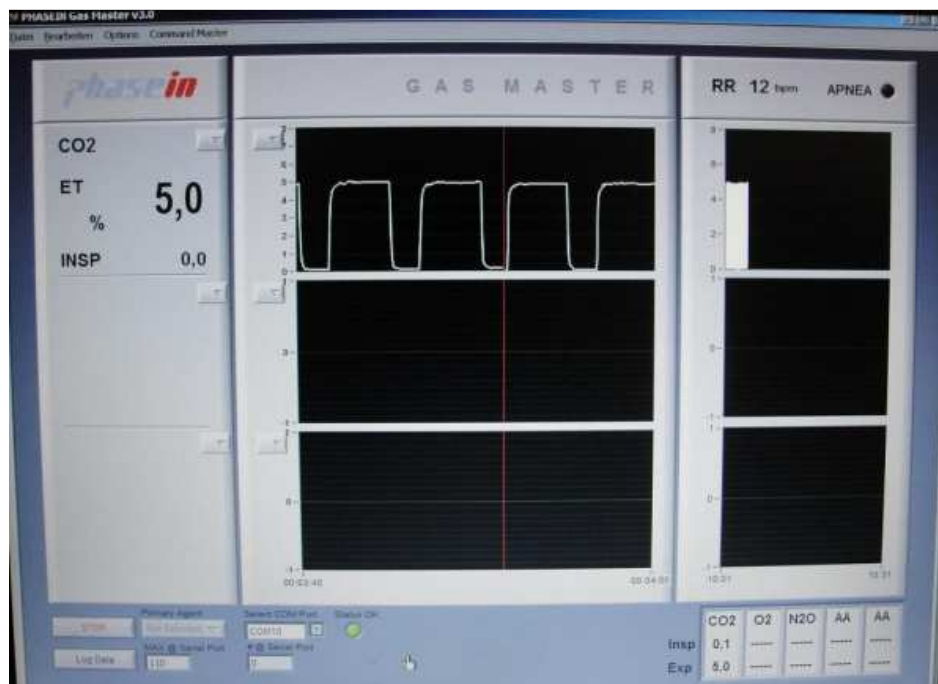


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3.1.2 Test Setup



Test set-up



Software Gas Master V3.0 user interface

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Test description

Use the Gas Master V3.0 software to record the measurement data.

12 respiratory rate steps are simulated with 3 CO₂ test gas concentrations according to table:

Parameter	Parameter
CO ₂ test gas	3Vol%, 5Vol%, 7.5Vol%,
Respiratory rate	10, 20, 30, 40, 50, 60, 70, 80, 90, 100, 110, 120

Connect the UART-USB mainstream converter with to the PC and the IRMA CO₂ sensor for reference CO₂ data. Connect the UART-USB side stream converter with integrated ISA-CO₂ module to the PC and the EuT.

Connect the IRMA and the EuT with the outlet valve of the CapnoCheck. Start the CapnoCheck with the parameters in the table above.

Each respiratory rate test step has duration 120 seconds.

In the first 60 seconds the values and simulator are allowed to stabilize. Thereafter the respiratory rate and CO₂ value are recorded

The functional performance criteria required to pass the test:

- CO₂ measurement accuracy: RMS* $\leq$ 0.2
- RR measurement accuracy: RMS $\leq$ 1

*RMS: Root Mean Squared difference

$$RMS = \sqrt{\frac{\sum_{i=1}^n (UUT \text{ measured }_i - \text{Target }_i)^2}{n}}$$

UUT: Measured value

Target: Target value

n: Number of recorded UUT

The recorded raw data were additional illustrated as a capnogram.

Ambient temperature: 22°C

Rel. Humidity: 34%

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3.2 Negative pressure Test

3.2.1 Test equipment

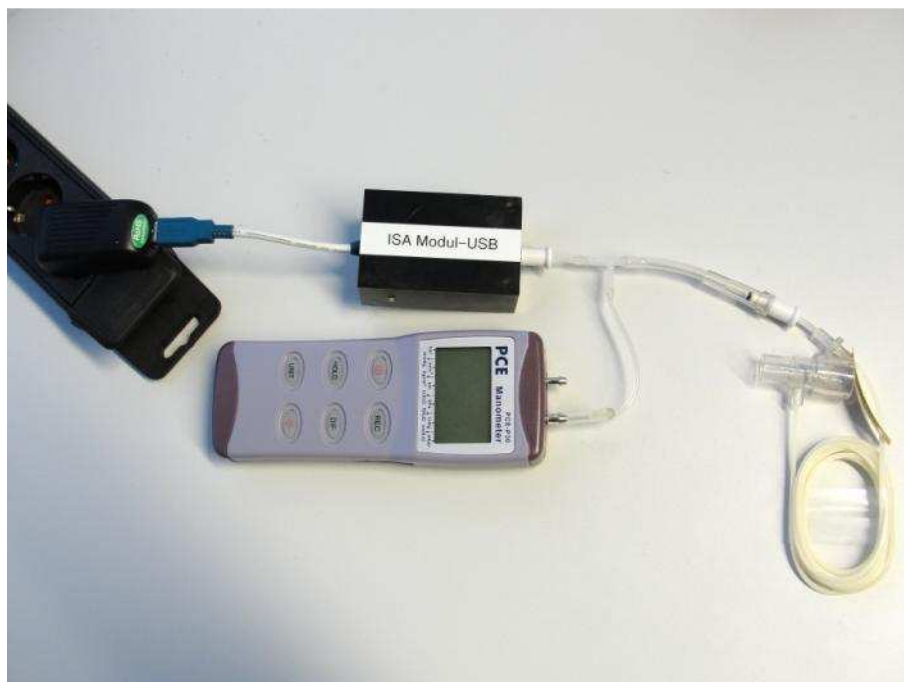


Digital Manometer with adapter



UART-USB-Converter for side stream
CO₂ ISA-Sensor

3.2.2 Test Setup



Test set-up

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3.2.3 Test description

Connect the UART-USB side stream converter with integrated ISA-CO₂ module with a power supply. Switch on the digital manometer.

In the first 60 seconds the values are allowed to stabilize. Thereafter the momentary pressure value is recorded.

The functional performance criteria required to pass the test:

- Negative pressure accuracy: ≤ 25 mbar

Ambient temperature: 22°C

Rel. Humidity: 34%

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4. Results

4.1 Measurement Accuracy

4.1.1 CO₂ Accuracy

Respiratory Rate (RR): 10 bpm to 120 bpm. CO₂ test gas concentration: 3 Vol%

CapnoCheck RR [bpm]	IRMA et CO ₂	NomoLine et CO ₂	VersaStream Short Term et CO ₂	VersaStream Long Term et CO ₂
10	3.0	3.0	2.9	3.0
20	3.0	3.0	2.9	3.0
30	3.0	3.0	2.9	3.0
40	3.0	3.0	2.9	3.0
50	3.0	3.0	2.9	3.0
60	3.0	3.0	2.8	3.0
70	3.0	3.0	2.8	3.0
80	3.0	3.0	2.8	3.0
90	3.0	3.0	2.8	2.9
100	3.0	2.9	2.8	2.9
110	3.0	2.9	2.8	2.9
120	2.9	2.9	2.8	2.8
RMS	0.029	0.050	0.165	0.076

Respiratory Rate (RR): 10 bpm to 120 bpm. CO₂ test gas concentration: 5 Vol%

CapnoCheck RR [bpm]	IRMA et CO ₂	NomoLine et CO ₂	VersaStream Short Term et CO ₂	VersaStream Long Term et CO ₂
10	5.0	5.0	5.0	5.0
20	5.0	5.0	4.9	5.0
30	5.0	5.0	4.9	4.9
40	5.0	5.0	4.9	5.0
50	5.0	5.0	4.9	4.9
60	5.0	5.0	4.8	5.0
70	5.0	4.9	4.9	5.0
80	5.0	4.9	4.8	4.9
90	5.0	4.9	4.8	4.9
100	4.9	4.8	4.8	4.9
110	4.9	4.8	4.8	4.9
120	4.9	4.8	4.7	4.8
RMS	0.050	0.112	0.168	0.091

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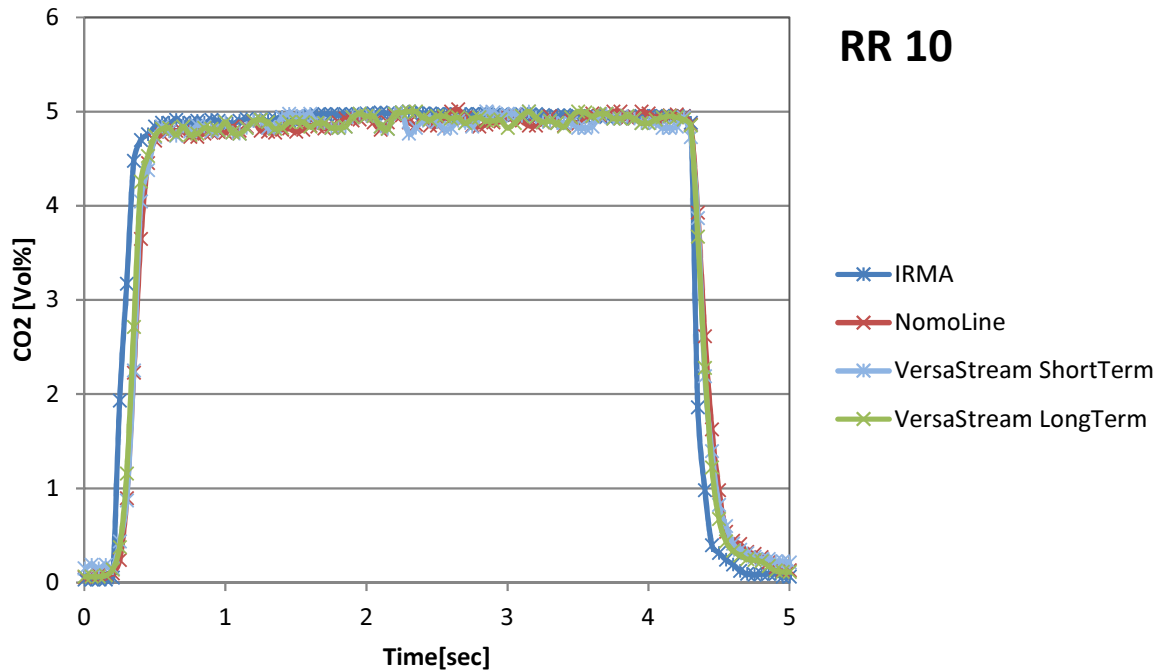
Respiratory Rate (RR): 10 bpm to 120 bpm. CO₂ test gas concentration: 7.5 Vol%

CapnoCheck RR [bpm]	IRMA et CO ₂	NomoLine et CO ₂	VersaStream Short Term et CO ₂	VersaStream Long Term et CO ₂
10	7.5	7.5	7.5	7.4
20	7.5	7.5	7.4	7.4
30	7.5	7.5	7.4	7.4
40	7.5	7.4	7.4	7.4
50	7.5	7.4	7.4	7.4
60	7.5	7.4	7.3	7.4
70	7.5	7.4	7.3	7.3
80	7.5	7.4	7.3	7.3
90	7.4	7.3	7.3	7.3
100	7.4	7.3	7.2	7.3
110	7.4	7.3	7.2	7.2
120	7.4	7.2	7.2	7.2
RMS	0.058	0.147	0.197	0.180

Capnogram

Respiratory Rate (RR): 10 bpm

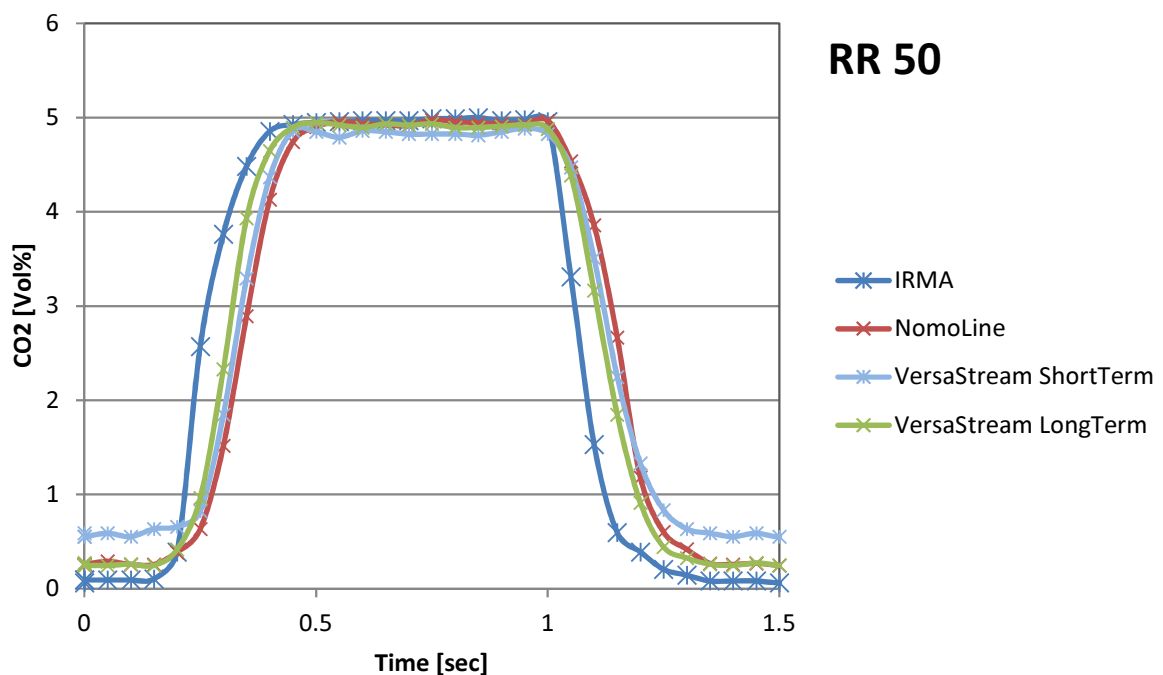
CO₂ test gas concentration: 5 Vol%



Capnogram

Respiratory Rate (RR): 50 bpm

CO₂ test gas concentration: 5 Vol%

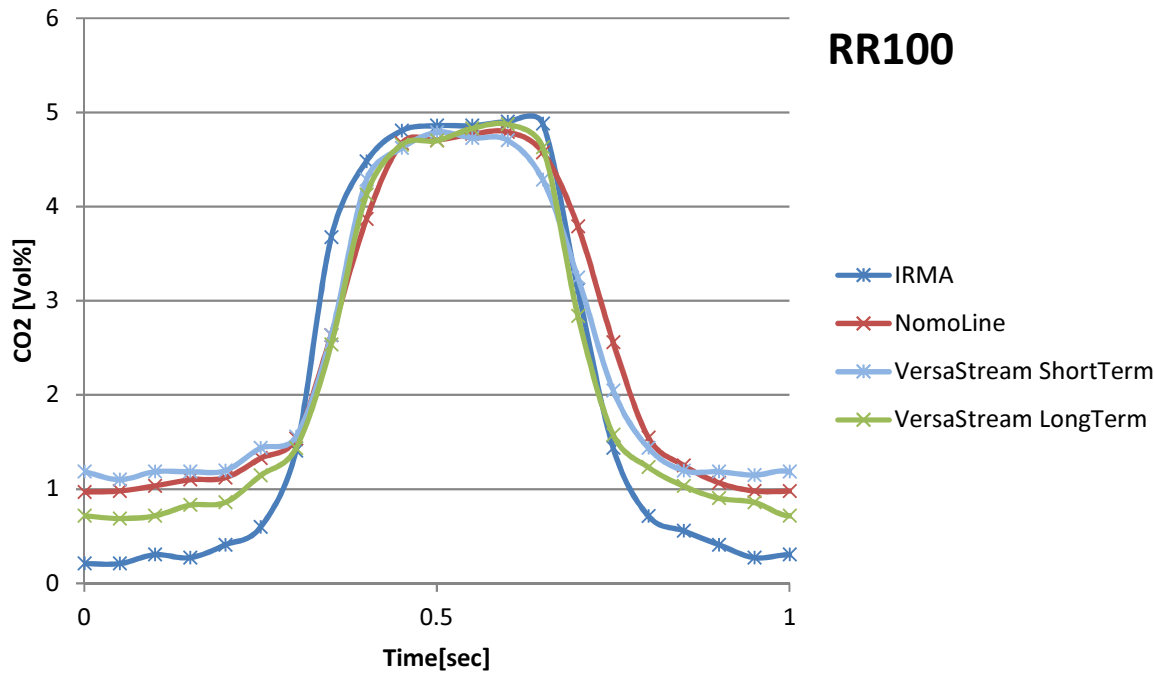


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Capnogram

Respiratory Rate (RR): 100 bpm

CO₂ test gas concentration: 5 Vol%



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4.1.2 Respiratory Rate (RR) Accuracy

Respiratory Rate (RR): 10 bpm to 120 bpm

CO₂ test gas concentration: 3 Vol%

CapnoCheck RR [bpm]	IRMA RR [bpm]	NomoLine RR [bpm]	VersaStream Short Term RR [bpm]	VersaStream Long Term RR [bpm]
10	10	10	10	10
20	19	20	19	20
30	30	30	30	30
40	40	40	39	40
50	50	50	50	50
60	59	59	60	60
70	70	70	69	69
80	80	80	80	80
90	90	90	90	90
100	99	99	100	100
110	110	110	109	109
120	120	120	119	119
RMS	0.50	0.41	0.64	0.50

Respiratory Rate (RR): 10 bpm to 120 bpm

CO₂ test gas concentration: 5 Vol%

CapnoCheck RR [bpm]	IRMA RR [bpm]	NomoLine RR [bpm]	VersaStream Short Term RR [bpm]	VersaStream Long Term RR [bpm]
10	9	10	10	9
20	20	20	19	20
30	30	30	30	30
40	40	40	40	40
50	49	50	50	50
60	60	60	59	60
70	70	70	70	70
80	80	80	80	80
90	90	89	89	89
100	101	100	100	100
110	110	110	109	110
120	121	119	119	120
RMS	0.58	0.41	0.64	0.41

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Respiratory Rate (RR): 10 bpm to 120 bpm
CO₂ test gas concentration: 7.5 Vol%

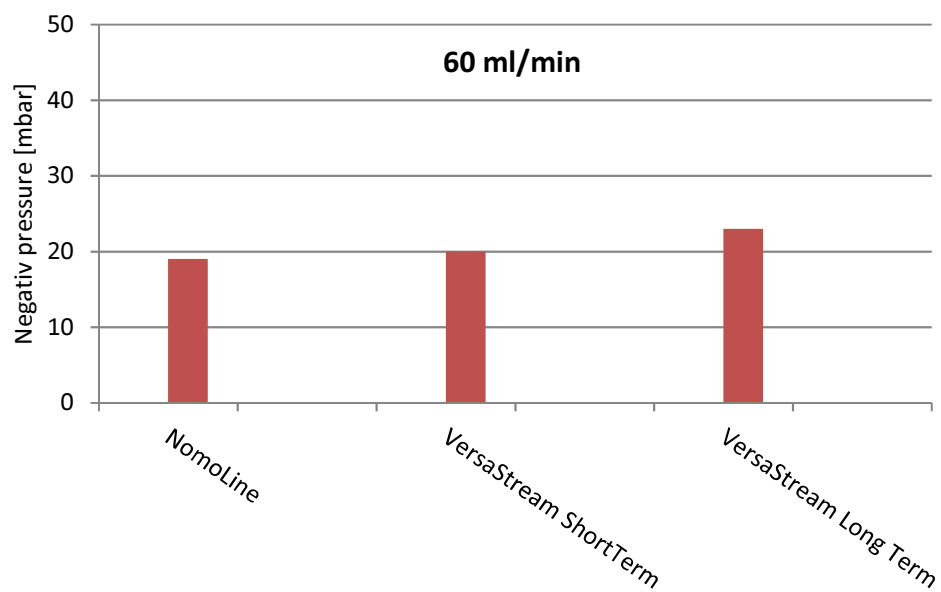
CapnoCheck RR [bpm]	IRMA RR [bpm]	NomoLine RR [bpm]	VersaStream Short Term RR [bpm]	VersaStream Long Term RR [bpm]
10	10	10	10	10
20	20	19	20	19
30	30	30	29	30
40	40	40	39	40
50	50	49	49	49
60	60	60	59	60
70	69	70	70	70
80	80	80	80	80
90	90	89	89	89
100	100	100	100	100
110	110	109	109	109
120	119	119	119	120
RMS	0.41	0.64	0.76	0.57

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4.2 Negative pressure Test

Sample volume	NomoLine	VersaStream Short Term	VersaStream Long Term
60ml/min	19 mbar	20 mbar	23 mbar

Diagram



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5. Conclusion

5.1 Measurement Accuracy

5.1.1 CO₂ Accuracy

The CO₂ Test verifies that the accuracy of the tested VersaStream sampling lines is observed. The Root Mean Square is ≤ 0.2 .

5.1.2 Respiratory Rate (RR) Accuracy

The Respiratory Rate Test verifies that the accuracy of the tested VersaStream sampling lines is observed. The Root Mean Square is ≤ 1 .

5.2 Negative pressure Test

The Pressure Test shows no significant differences between the Nomoline and the VersaStream sampling lines. The pressure difference is ≤ 25 mbar.