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Serial Number	
ID Number	12345678
Serial Number ASL 5000	0123

Advanced
Verification



Date	
Date performed	DD/MMM/JJJJ

Person in charge	
Signature	
Name	

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1 GENERAL INFORMATION

1.1 Purpose

The purpose of this document is to provide an advanced verification to the ASL 5000 lung simulator. The advanced verification provides additional testing and verification to the standard calibration document. This document includes verification of the Standard ASL5000 3L, 5L, 6L, and Premie ASL attachment.

1.2 Scope

The scope of this document is to provide the end user with the results of additional verification information related to the functionality of the ASL5000 lung simulator. Most of the verification procedures utilize or can be referenced to a NIST traceable standard, including a 1L, 100mL, and 10mL syringe, pressure meter, and temperature probe.

The main procedures for the testing can be found in the “ASL 5000 Advanced Verification Standard Operating Procedure (SOP)” document. This document provides the results of the testing and verification.

To obtain all data files, excel files, etc., please contact [Coretec-Service GmbH](#)

1.3 ASL Installed Software

Software: **3.6.2.1e**

Firmware: **4.7.99**

Ball Screw: **4mm**

Premie Installed (Y/N): **N**

2 VERIFICATION TESTING

Physical verification consists of static and dynamic testing of the ASL5000 mechanics. This relates to pressure transducers, TEMPERATURE, FLOW and VOLUME MEASUREMENTS.

2.1 Testing and Procedures

2.1.0 ASL 5000 Installed Components

This process is to record the relevant hardware and software versions that the customer is using such that the verification testing will be based on the correct versions.

Results:

	Software	Firmware	TAI
IngMar Master Records	3.6.2.1e	4.7.99	
Terminal		4.7.76	
TAI	3.5.0.46	4.7.76	1.0.0.138

Changed firmware for TAI testing purpose then changed back to 4.7.99 before shipping

2.1.1 Pressure Sensor Verification – Temperature drift uncertainty

This process will verify the voltage output of the pressure sensor such that there is a minimum drift uncertainty during operation. The test will compare the amount of change to the pressure sensor voltage output at the sensor as well as in the embedded firmware program.

Testing utilizes onboard software called ad_test.exe and compares the drift to a NIST traceable digital multimeter.

This process is to record the relevant hardware and software versions that the customer is using such that the verification testing will be based on the correct versions.

Expected Results:

A drift of less than 0.1 cmH₂O which equates to a voltage drift of less 0.2 mV

Measured Results:

Time (min)	0	15	30	45	60
PuTTY Terminal Voltage (mV)	2.334	2.333	2.334	2.334	2.333
Fluke 175 DMM Voltage Reading (mV)	2.397	2.397	2.396	2.396	2.395

2.1.2 Pressure Sensor Verification – Pressure zero calibration statistics

This process will verify the pressure and volume deviations within a simulation at the end of the expiration or the idle time before the next breath.

The breath rate is set to 8BPM (or 7.5s per breath). This verification analyzes the idle time of the last 1.5s of the expiratory phase.

Expected Results:

Volume deviations of less than ± 10 mL and Pressure deviations of less than ± 0.1 cmH₂O

Measured Results:

Breath	1	2	3	4	5	AVERAGE
Airway Pressure Offset [cmH₂O]	0.0200	0.0169	0.0182	0.0230	0.0313	0.0219
Volume Offset	0.0444	0.0853	0.0341	0.0739	0.0337	0.0543

2.1.3 Volume Verification with Calibrated Syringe

This process will verify the volume accuracy with three (3) NIST traceable syringes.

Approximately 5 strokes will be made with each syringe based on the type of testing (3L, 5L, 6L, or Premie). The 100mL and 10mL syringes utilize an additional ~18mL of compressible gas as the pressure release adapter.

The syringes used in this test are:

- 1L Calibration syringe
- 100mL Calibration syringe
- 10mL Calibration syringe

Expected Results:

Standard ASL configuration with 1L syringe – less than 20mL deviation or 2% of reading

Standard ASL configuration with 100mL syringe – less than 2.5mL deviations or 2.5% of reading

Standard ASL configuration with 10mL syringe – less than 1mL deviation or 10% of reading

Premie ASL attachment configuration with 100mL syringe – less than 1mL deviation or 1% of reading

Premie ASL attachment configuration with 10mL syringe – less than 0.2mL deviation or 2% of reading

Measured Results:

Standard ASL 1L calibrated syringe

Cycle	1	2	3	4	5
Measured	999.8	999.6	999.5	999.3	999.6
% Error	0.02	0.04	0.05	0.07	0.04

Standard ASL 100mL calibrated syringe

Cycle	1	2	3	4	5
Measured	100.3	100.2	100.3	100.3	100.3
% Error	0.30	0.20	0.30	0.30	0.30

Standard ASL 10mL calibrated syringe

Cycle	1	2	3	4	5
Measured	10.5	10.28	10.29	10.29	10.34
% Error	5.00	2.80	2.90	2.90	3.40

Premie ASL attachment 100mL calibrated syringe

Cycle	1	2	3	4	5
Measured					
% Error					

Preemie ASL attachment 10mL calibrated syringe

Cycle	1	2	3	4	5
Measured					
% Error					

2.1.4 Compliance verification

This process will verify the calculated compliance for a range of compliance values. This covers the 6L, 5L, 3L, and Preemie ASL options. Compliance values of 50, 20, 3, 1, and 0.5 mL/cmH₂O will be verified based on the Standard (6L, 5L, 3L) or Preemie configurations.

The 100mL and 10mL syringes utilize an additional ~18mL of compressible gas as the pressure release adapter

Expected Results:

All calculated compliance values must be within 5% or 0.2mL/cmH₂O, whichever is greater

Measured Results:

	Standard ASL Configuration			Preemie ASL Attachment Configuration (Option)	
	1000	100	10	10	10
Syringe Discharge [mL]	1000	100	10	10	10
Reported Pressure [cmH ₂ O]	19.3	10.2	10.0		
Set C [mL/cmH ₂ O] (incl. compensations, accounts for compressible gas volume in "deadspace")	50	10	1		
Parasity C [mL/cmH ₂ O] (from additional compressible volume in the "stroke")	1	0.1	0.01	0.01	0.01
Volume "lost" [mL] (due to parasitary compliance)(reported P*Parasitic C)	19.3	1.02	0.10017		
Adjusted Volume Discharge [mL] (Piston displacement)(Syringe Discharge - Volume "lost")	980.7	98.98	9.89983		
C Actual [mL/cmH ₂ O] (Adjusted Volume / Reported P)	50.81	9.70	0.99		
Error [%] from Set C	1.63	2.96	1.16		

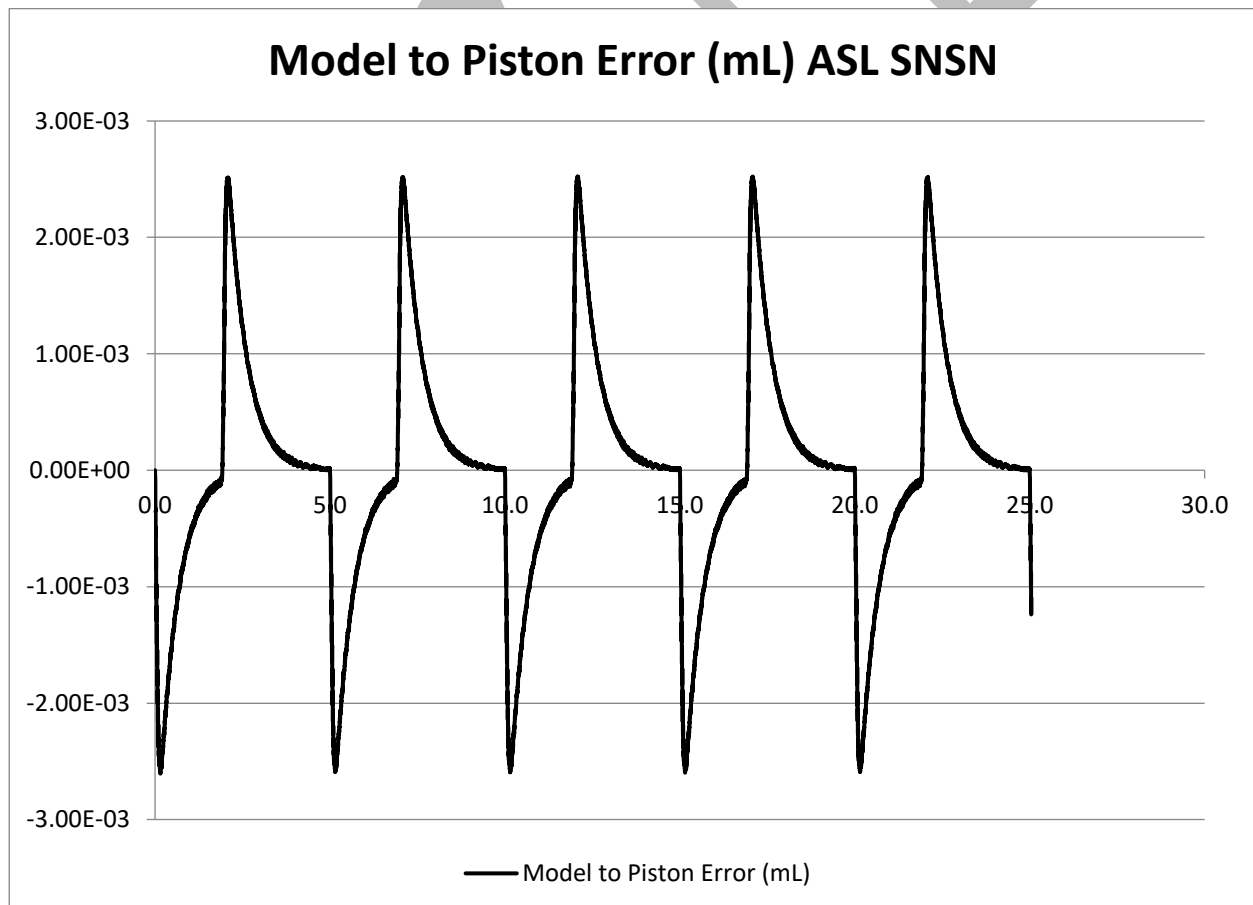
2.1.5 Spontaneous Breathing Simulator

This process will verify the response of the ASL5000 to a spontaneous muscle pressure. The goal is to assure the error between the calculated model and the measured piston movement is minimized.

Expected Results:

Peak volume error within 30mL of target volume

Measured Results:



Notes:

2.1.6 Pump Mode

This process will verify the dynamic response of the ASL5000 to a flow-pump model with varying breath rates (5, 10, 12, 15, 20, 25).

Expected Results:

Deviation of $\pm 2\%$ from the target volume of 500/100 mL

Measured Results:

Standard ASL Configuration (500mL)

Breath Rate [BPM]	Measured Volume [mL]	Error [%]
5	500.1	0.02
10	499.7	0.06
12	500.4	0.08
15	499.8	0.04
20	499.8	0.04
25	499.5	0.10

Preemie ASL attachment Configuration (100mL)

Breath Rate [BPM]	Measured Volume [mL]	Error [%]
5		
10		
12		
15		
20		
25		

2.1.7 Peak Flow

This process verifies piston accuracy at high flow rates. These rates differ based on the ASL5000 configuration used in the testing (6L, 5L, 3L, and Premie).

Expected Results:

Model and piston results are within $\pm 1\%$

Measured Results:

	Standard ASL Configuration		Premie ASL Attachment Configuration	
Model Peak Flow [L/min]	257.15	%error		%error
Piston Peak Flow [L/min]	257.17			
Model Peak Volume [mL]	2240.79			
Piston Peak Volume [mL]	2241.29			
Piston/Model Difference (Flow) [L/min]	0.020	0.008		
Piston/Model Difference (Volume) [mL]	0.500	0.020		

NOTE:

2.1.8 Resistance Verification

This process verifies the resistance settings on the ASL5000. The resistance verification is based on a step function input and utilization of the RC time constant, where RC is equal to 63.2% of the maximum tidal volume.

Expected Results:

Resistance values to be within 12% based on ASTM F-1100

Measured Results:

Set Resistance [cmH₂O/L/s]	5	20	50	200	500
Compliance [mL/cmH₂O]	100	20	10	2.5	1
V_t [mL] (max volume from spreadsheet)	499.320	299.921	299.888	74.951	29.987
V_t @ RC_t (V_t * 0.632)	315.570	189.550	189.529	47.369	18.952
RC [ms] (time at V_t@RC)	550.781	412.109	505.859	500.000	501.953
Calculated R [cmH₂O/L/s] (RC / Compliance)	5.5	20.6	50.6	200.0	502.0
% Error	10.2	3.0	1.2	0.0	0.4

3 FINAL APPROVAL

3.1 Traceability

Coretec-Service GmbH ensures that the above instrument has been verified using standards traceable to the International System of Units (SI) through National Institute of Standards and Technology (NIST) or other national metrology institutes, or to accepted values of natural physical constants, or derived by the ratio type of self-calibration techniques.

- **Hans Rudolph 1 Liter Volume Calibration Syringe – S/N 554-2362 (ID: VS 01)**
Traceable to NIST via ISO 13485:2016 accredited Calibration Lab Hans Rudolf, Calibration Certificate ID: 2022001066. Range: 1 L, uncertainty = 0.0034 L.
- **Hans Rudolph 100 mL Volume Calibration Syringe – S/N 551-2148 (ID: VS 02)**
Traceable to NIST via ISO 13485:2016 accredited Calibration Lab (A2LA Cert.2171.01), Calibration Certificate ID: 2022001065. Range: 100 mL, uncertainty = 0.28 mL
- **Hans Rudolph 10 mL Volume Calibration Syringe – S/N 552-509 (ID: VS 03)**
Traceable to NIST via ISO 13485:2016 accredited Calibration Lab (A2LA Cert.2171.01), Calibration Certificate ID: 2022001067. Range: 10 mL, uncertainty = 0.015 mL.
- **Mensor DPG 2400 Digital Pressure Meter – S/N 41000J1C (ID: PM 05)**
Traceable to NIST via ISO 17025:2017 accredited Calibration Lab ZMK (D-K-15186-01-00), Calibration Certificate ID: 02-1651. Range: -40 to 150 cmH₂O, uncertainty = 0.006 cmH₂O.
- **Mensor DPG 2400 Digital Pressure Meter – S/N 41000J1A (ID: PM 04)**
Traceable to NIST via ISO 17025:2017 accredited Calibration Lab ZMK (D-K-15186-01-00), Calibration Certificate ID: 02-1659. Range: 8 to 17 PSIA, uncertainty = 0.0006 PSIA.
- **Ebro TFX 410 RTD Thermometer – S/N 15239826 (ID: TM 01)**
Traceable to NIST via ISO 17025:2017 accredited Calibration Lab (A2LA Cert.1894.01), Calibration Certificate ID: CAL255638. Range: 0 to 300 °C, uncertainty = 0.06 °C.
- **Fluke 175 True RMS Digital Multimeter – S/N 96840413 (ID: MM01)**
Traceable to NIST via ISO 17025:2005 accredited Calibration Lab (KSW Cert.1894.01), Calibration Certificate ID: 212421.

Reported uncertainties represents an expanded uncertainty expressed at approximately the 95% confidence level using a factor of $k=2$.