Nelson Labs
A Sotera Health company

Sponsor:
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ISO 18562 Particulates and VOC GLP Report

Test Article:	ABS M30i samples - Printer 455 2 contours 4 contours
Purchase Order:	800075575
Study Number:	1313496-S01
Study Received Date:	24 Jun 2020
Testing Facility:	Nelson Laboratories, LLC 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0104 Rev 03
Deviation(s):	None

Summary: ISO 18562 is the standard for biocompatibility evaluation of material or medical device with a breathing gas pathway. When the gas pathway is expected to contact a patient via the respiratory tract it is necessary to evaluate the contaminants from the air emitted from the device for particulate matter and Volatile Organic Compounds (VOCs).

VOCs and particulate matter testing was performed according to ISO 18562-2 and -3. The VOC sampling was performed by Nelson Laboratories, LLC. (NL) and the analysis was performed by ALS Global Laboratories. The particulate matter sampling and analysis was performed by NL. The ANAB ISO/IEC 17025 accreditation does not apply to the analysis performed by ALS Global Laboratories.

All test method acceptance criteria were met.

Particulate Flow Rate:	120 Liters per minute (L/min)
Particulate Temperature:	23.3°C (2 contours) 24.0°C (4 contours)
Particulate Sampling Duration:	24 hours
VOC Flow Rate:	4.92 – 5.13 L/min (2 contours) 4.99 – 5.18 L/min (4 contours)
VOC Temperature:	71.2 – 72.3°C (2 contours) 68.8 – 70.5°C (4 contours)
VOC Sampling Duration:	48 hours
Appendix A Number of Pages:	2

Sarah Guzman electronically approved Technical Reviewer	06 Aug 2020 15:39 (+00:00) Date and Time
Curtis Gerow electronically approved Study Director Curtis Gerow	06 Aug 2020 15:54 (+00:00) Study Completion Date and Time

Particulate Matter Results:

2 contours:

Particulate Matter (µg/m^3)	Average	Minimum	Maximum
PM2.5	0	0	6
PM10	0	0	7

4 contours:

Particulate Matter (µg/m^3)	Average	Minimum	Maximum
PM2.5	0	0	1
PM10	0	0	1

Summary of Quantitative Results: All results are blank corrected. Daily exposure values calculated using the maximum value. Manual calculations may differ slightly from reported values due to rounding.

Volatile Organic Compounds:

2 contours:

Analyte Name	CAS #	0-24 Hour (µg/m^3)	24-48 Hour (µg/m^3)	Adult (µg/day)	Pediatric (µg/day)	Infant (µg/day)	Neonate (µg/day)
Hexane[a]	110-54-3	ND	~1.3	~26	~6.5	~2.6	~0.27
Acetone	67-64-1	2.0	24	470	120	47	5.0
Chloromethane	74-87-3	ND	0.1	2	0.5	0.2	0.02
Dichlorodifluoromethane[a]	75-71-8	~0.1	~0.1	~2	~0.5	~0.2	~0.02
2-Butanone	78-93-3	ND	2.8	56	14	5.6	0.60

[a] The compound was detected at a value below the reporting limit and above the detection limit; thus results are only an estimate.
ND = Non-detect

4 contours:

Analyte Name	CAS #	0-24 Hour (µg/m^3)	24-48 Hour (µg/m^3)	Adult (µg/day)	Pediatric (µg/day)	Infant (µg/day)	Neonate (µg/day)
Acetone	67-64-1	ND	4.0	80	20	8.0	0.84
Chloromethane	74-87-3	ND	0.1	2	0.5	0.2	0.02
Methylene chloride	75-09-2	1	ND	20	5	2	0.2
Freon 11[a]	75-69-4	ND	~0.1	~2	~0.5	~0.2	~0.02
Dichlorodifluoromethane[a]	75-71-8	ND	~0.1	~2	~0.5	~0.2	~0.02
2-Butanone[a]	78-93-3	ND	~0.51	~10	~2.6	~1.0	~0.11

[a] The compound was detected at a value below the reporting limit and above the detection limit; thus results are only an estimate.

Summary of Semi-Quantitative Results: Concentrations estimated using the calibration curve of an internal standard, identification through comparison with the NIST Database. Daily exposures calculated using the maximum value. Manual calculations may differ slightly from reported values due to rounding.

Semi-Quantitative Volatile Organic Compounds (Gas Path):
2 contours:

Analyte Name	0-24 Hour (µg/m^3)	24-48 Hour (µg/m^3)	Adult (µg/day)	Pediatric (µg/day)	Infant (µg/day)	Neonate (µg/day)
Isopropyl Alcohol	56	260	5,200	1,300	520	55

4 contours:

Analyte Name	0-24 Hour (µg/m^3)	24-48 Hour (µg/m^3)	Adult (µg/day)	Pediatric (µg/day)	Infant (µg/day)	Neonate (µg/day)
Ethane, 1,1-diflouro-	8	ND	200	40	20	2
Acetophenone	11	ND	230	57	23	2.4

Test Method Acceptance Criteria:
Particulate Matter: The zero calibration on the particle measuring device (Dusttrak™ DRX) was performed prior to testing.

VOCs: The initial vacuum on the sampling canisters was at least 20 inHg prior to sampling.

Particulates Interpretation of Results: ISO 18562-2 provides acceptance criteria for both PM2.5 and PM10 particulates and is as follows:

Particulate Acceptance Criteria	
Particulate Category	Acceptable Concentration
$PM_{2.5}$	12 µg/m^3
PM_{10}	150 µg/m^3

VOCs Interpretation of Results: ISO 18562-1 provides standardized breathing rates that are used and shown below.

Standardized Breathing Rates per 18562-1 (m^3/day)	
Patient Population	Breathing Rate
Adults	20.00
Pediatric	5.00
Infant	2.00
Neonate	0.21

ISO 18562-3 also recommends a TTC for different durations of exposure to gas from respiratory devices as shown below.

Recommended TTC per 18562-3 [µg/day] vs Time Period of Exposure			
Device Contact Duration	First 24 Hrs	Greater than 24 Hrs Less than 30 days	Greater than 30 days
Limited	360	n/a	n/a
Prolonged	360	120	n/a
Permanent	360	120	40

The potential exposure to different population groups were found by multiplying the concentration of the observed compound at the maximum detected value by the breathing rate of that population.

Procedure: Particulate matter was collected by directing clean, dry air through the test article and sampling particulates from the output using a light scatter laser photometry analyzer. The photometry analyzer samples air at a rate of 3.0 LPM. PM2.5 and PM10 particulate matter levels were monitored every 6 seconds over a 24 hour period. The minimum, maximum, and average particulate concentrations were reported.

VOCs were collected by directing clean, dry air through and around the test article in a controlled environment over two 24 hour periods. Two 24 hour gas samples were taken, sampling at a constant rate of 4 mL/min for the duration of testing, and analyzed for VOCs by gas chromatography-mass spectrometry (GC/MS) per EPA Method TO-15. The concentration of VOCs in $\mu g/m^3$ was reported. Background air samples were collected concurrently with the test articles and were subtracted from the results before the results were converted to daily exposures.

Quality Assurance Statement

Compliance Statement: The test was conducted in accordance with the USFDA (21 CFR Parts 58, 210, 211, and 820) Regulations. This final report reflects the raw data.

Activity	Date
Study Initiation	09 Jul 2020
Phase Inspected by Quality Assurance: VOC, CO, CO2 Sampling	22 Jul 2020
Audit Results Reported to Study Director	22 Jul 2020
Audit Results Reported to Management	23 Jul 2020

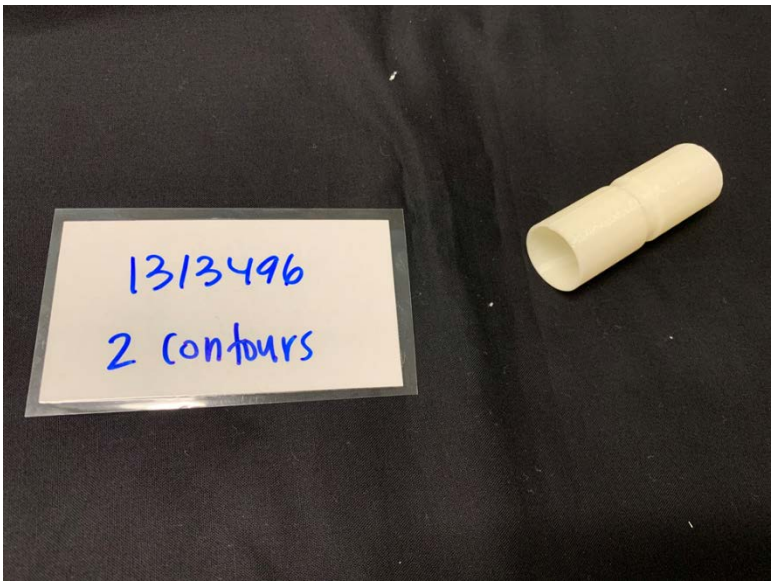
Scientists	Title
Sarah Smit	Supervisor
Curtis Gerow	Study Director

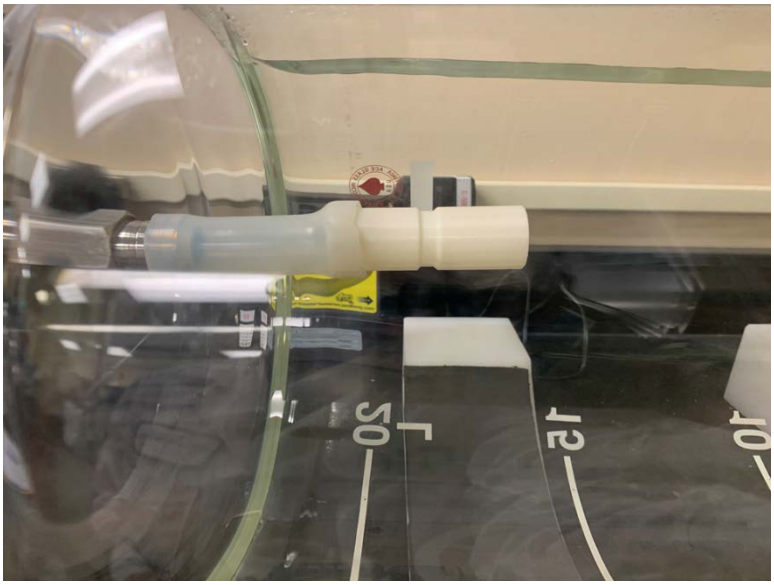
Data Disposition: The study plan, raw data and final report from this study are archived at Nelson Laboratories, LLC or an approved off-site location.

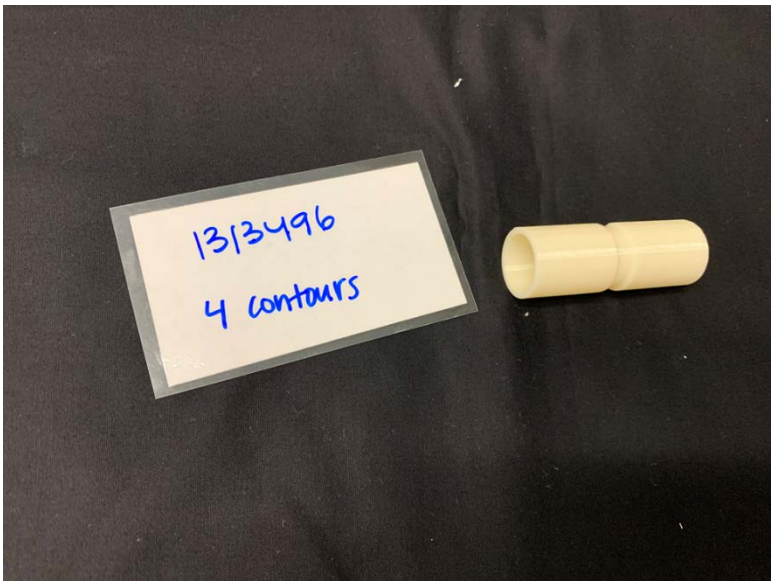
Eric Stembridge electronically approved
Quality Assurance

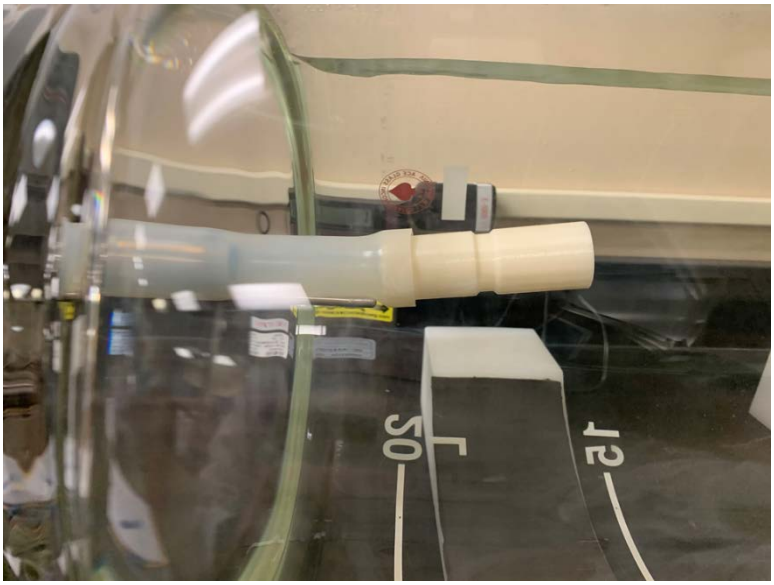
05 Aug 2020 20:56 (+00:00)
Date and Time

Appendix A


1313496
2 contours




1313496
4 contours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