Product Support Information

ITEMS: Ritmed® DisTech® Level 2 Procedure Earloop Face Mask 2115
Date of issuance: 28-Jun-2021

To Whom It May Concern:

The procedure masks are intended to be worn by personnel during medical procedures to protect both the patient and the operating personnel from transfer of microorganisms, body fluids and particulate material.

This statement is issued to confirm that *Ritmed® DisTech® Level 2 Procedure Earloop Face Mask 2115* has undergone the testing by qualified third-party laboratories as per ASTM F2100 requirements.

Please refer to the attached test report # 21-PPE-00462 in which you could find the detailed test results. If you have any question, please feel free to contact us.

Issued by: 

Electronically signed by: Ke Xing
Reason: I authored this document
Date: Jun 28, 2021 16:28 EDT

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ANALYTICAL REPORT ID	21-PPE-00462	PRODUCT ID	PD21054_PED_BL
DATE RECEIVED	20-May-2021	LOT/BATCH#	n/a
REPORT DATE	31-May-2021	MATERIAL	SMS
MANUFACTURER	AMD Medicom Inc.	DESCRIPTION	Blue; 3-ply

MEDICAL MASK TEST SUMMARY

ASTM F2100: Standard Specification for Performance of Materials used in Medical Face Masks

			ASTM F2100		
Test Method	**AVERAGED RESULT**	Not Rated	Level 1	Level 2	Level 3
Flammability 16 CFR 1610	Class 1	Class 3	Class 1		
Particulate Filtration Efficiency ASTM F2299	99.21	< 95%	≥ 95%	≥ 98%	
Differential Pressure EN 14683 Annex C	2.85	≥ 6.0 mm H_2O/cm^2	< 5.0 mm H_2O/cm^2	< 6.0 mm H_2O/cm^2	
Bacterial Filtration Efficiency ASTM F 2101	99.65	< 95%	≥ 95%	≥ 98%	
Fluid Resistance to Synthetic Blood ASTM F1862	120 mmHg	Failure at 80 mmHg	80 mmHg	120 mmHg	160 mmHg

Highlighted box indicates the performance level of the mask for the given test.

The samples tested meet the acceptance criteria for **ASTM F2100 performance LEVEL 2.**

Test results only apply to the samples submitted for analysis. Samples are randomly selected for each test from the submitted batch. It is the responsibility of the distributor to ensure the tested batch is compliant to the required sampling methodology as per ANSI/ASQ Z1.4 or ISO 2859-1. Additional test information is available upon request. Kinectrics is accredited to ISO 17025:2017 by the Standards Council of Canada for ASTM F2100

Reviewed By: Rob Taylor 2021.05.31 14:19:46 -04'00'

Approved By: Ruwan Wijesundera 2021.05.31 14:51:55 -04'00'

FLAMMABILITY

Test Summary A conditioned mask or test specimen was affixed to a sample holder and placed in a flammability test chamber. The specimen was exposed to a 16 mm flame for 1 second at an angle of 45°. If the material ignited during this exposure, it was noted whether the flame extinguished before spreading, or if it continued to burn. If the specimen continued to burn, the time of flame spread was measured. Any observations of burning behavior were also recorded. The specimen was tested in its original state as directed in 16 CFR Part 1610.6 (a) step 1 - 'Testing in the original state', (2) 'Plain surface textile fabrics'. As medical masks are intended for one-time use 16 CFR Part 1610.6 (b) step 2- 'Refurbishing and testing after refurbishing' was not performed. The tests were performed in accordance with 16 CFR Part 1610 'Standard for the Flammability of Clothing Textiles'

Date Tested 28-May-2021
Test Side: Outside
Test Type Original State
Direction Tested: Length
Conditioning Parameters 105 +/- 3°C for 30 +/- 2 minutes
Acceptance Criteria Class 1: Burn time ≥ 3.5s
Class 3: Burn time < 3.5s

TEST LOT NUMBER

Article No.	Time of Flame Spread
1	DNI
2	DNI
3	DNI
4	DNI
5	DNI

Article No.	Time of Flame Spread
6	n/a
7	n/a
8	n/a
9	n/a
10	n/a

DNI: Did not ignite
IBE: Ignited, but extinguished

PARTICULATE FILTRATION EFFICIENCY (PFE)

Test Summary Filtered and dried air was passed through an atomizer to produce an aerosol containing suspended polystyrene latex (PSL) spheres. The aerosol was then mixed and diluted with additional preconditioned air to produce a stable, non-neutralized, and dried aerosol of latex spheres. The aerosol was passed through the mask material. An optical particle counter was used to sample upstream and downstream aerosol concentrations to determine the particulate filtration efficiency of the mask. The test was conducted in accordance with Test Method ASTM F2299 with the exception that a non-neutralized particle challenge was used in place of a neutralized challenge as per FDA guidance document on surgical facemasks (FDA-2003-D-0305)

Date Tested 31-May-2021

Test Side and Area Inside, Centre (28.3 cm^2)

Conditioning Parameters 30-50% ± 5% relative humidity and 21 ± 3°C

Face Velocity 6 to 7 cm/s

Laboratory Conditions 32.1 % Relative Humidity; 21.4 °C

Particle Size 0.1 µm

Acceptance Criteria ASTM Level 1: ≥ 95% PFE

ASTM Level 2,3: ≥ 98% PFE

TEST LOT NUMBER

Article No.	PFE %
1	99.37
2	98.99
3	99.25
4	99.29
5	99.14

Article No.	PFE %
6	n/a
7	n/a
8	n/a
9	n/a
10	n/a

Average Filtration Efficiency 99.21

Standard Deviation 0.147

DIFFERENTIAL PRESSURE

Test Summary Differential pressure testing was performed to determine the breathability of the sample material. Air was passed through a prescribed surface area of the sample material at a constant air flow rate of 8 litres per minute, measured by a calibrated flow meter. A manometer was used to measure the differential pressure across the sample.
The test was conducted as directed in EN 14683:2019 Annex C

Date Tested 28-May-2021
Test Side and Area Inside, Centre (4.9 cm^2)
Conditioning Parameters 85 ± 5% relative humidity and 21 ± 5°C for a minimum of 4h
Flow Rate 8 L/min
Acceptance Criteria Flow rate must be maintained at 8 L/min throughout testing
ASTM Level 1: < 5.0 mm H_2O/cm^2
ASTM Level 2,3: < 6.0 mm H_2O/cm^2

TEST LOT NUMBER

Article No.	Delta P (mm H_2O/cm^2)
1	2.82
2	2.82
3	2.5
4	3.09
5	3.01

Article No.	Delta P (mm H_2O/cm^2)
6	n/a
7	n/a
8	n/a
9	n/a
10	n/a

Average Delta P 2.85
Standard Deviation 0.228

BACTERIAL FILTRATION EFFICIENCY (BFE)

Test Summary The mask was clamped between a six-stage cascade impactor and an aerosol chamber. A bacterial suspension of *Staphylococcus aureus* was introduced into the aerosol chamber using a four-Jet atomizer. The aerosol was drawn through the sample material using a vacuum pump attached to the cascade impactor. The cascade impactor collects aerosol droplets that penetrate the mask material onto agar plates and sorts them by particle size. Positive control samples were also collected with no test specimen clamped in the test apparatus to verify the bacterial challenge rate (upstream counts). Following the incubating period, the colony forming units (CFU) on the agar plates were counted (downstream counts). The ratio of the upstream counts from the positive control, to the downstream counts collected for the test specimen, was calculated and reported as the bacterial filtration efficiency (BFE). This test was conducted in accordance with Test Method ASTM F2101.

Date Tested 27-May-2021

Test Side and Area Inside, Centre (40 cm^2)

Conditioning Parameters 85 ± 5% relative humidity and 21 ± 5°C for a minimum of 4h

Flow Rate 28.3 L/min

Mean Particle Size (MPS) 3 µm

Negative Control Count 0 CFU

Positive Control Average 2757 CFU

Acceptance Criteria Control average must be 1.7 to 3.0 x 10^3 CFU

MPS of aerosol must be 3.0 ± 0.3 µm

ASTM Level 1: ≥95% BFE

ASTM Level 2 and 3: ≥98% BFE

TEST LOT NUMBER

Article No.	BFE %
1	99.67
2	99.75
3	99.89
4	99.75
5	99.17

Article No.	BFE %
6	n/a
7	n/a
8	n/a
9	n/a
10	n/a

Average Filtration Efficiency 99.65

Standard Deviation 0.278

BLOOD PENETRATION RESISTANCE

Test Summary A volume of synthetic blood was disbursed at the mask to simulate the impact (splatter) of blood or other body fluid onto the specimen. Any evidence of synthetic blood penetration on the inner facing of the mask (side contacting the wearer's face) constitutes a failure. Samples are evaluated at one or more velocities of 450, 500, and 635 cm/s, corresponding to the velocity of blood exiting a small arterial puncture at human blood pressures of 80, 120, and 160 mmHg. The distance from the target area to the tip of the cannula is 30.5 cm, with the impact of the spurt normal to the target area. Test results are reported at each tested velocity or corresponding pressure, and the medical face mask is rated at the highest corresponding blood pressure for which the mask demonstrates an acceptable quality limit of 4.0. The test was conducted in accordance with Test Method ASTM F1862.

Date Tested 28-May-2021

Test Side and Area Outside, Centre

Conditioning Parameters 85 ± 5% relative humidity and 21 ± 5°C for a minimum of 4h

Laboratory Conditions 34.3 % Relative Humidity; 21.2 °C

Acceptance Criteria The output of synthetic blood before and after 16 articles must be within 2% of the theoretical output

29 of 32 tests must show a passing result

ASTM Level 1: Pass at 80 mmHg

ASTM Level 2: Pass at 120 mmHg

ASTM Level 3: Pass at 160 mmHg

TEST LOT NUMBER

Article No.	80 mmHg	120 mmHg	160 mmHg	Article No.	80 mmHg	120 mmHg	160 mmHg
1	n/a	Pass	n/a	17	n/a	Pass	n/a
2	n/a	Pass	n/a	18	n/a	Pass	n/a
3	n/a	Pass	n/a	19	n/a	Pass	n/a
4	n/a	Pass	n/a	20	n/a	Pass	n/a
5	n/a	Pass	n/a	21	n/a	Pass	n/a
6	n/a	Pass	n/a	22	n/a	Pass	n/a
7	n/a	Pass	n/a	23	n/a	Pass	n/a
8	n/a	Pass	n/a	24	n/a	Pass	n/a
9	n/a	Pass	n/a	25	n/a	Pass	n/a
10	n/a	Pass	n/a	26	n/a	Pass	n/a
11	n/a	Pass	n/a	27	n/a	Pass	n/a
12	n/a	Pass	n/a	28	n/a	Pass	n/a
13	n/a	Pass	n/a	29	n/a	Pass	n/a
14	n/a	Pass	n/a	30	n/a	Pass	n/a
15	n/a	Pass	n/a	31	n/a	Pass	n/a
16	n/a	Pass	n/a	32	n/a	Pass	n/a

Passes at 80 mmHg n/a

Passes at 120 mmHg 32/32

Passes at 160 mmHg n/a

NOTES

This section is to provide general comments on observations and/or exceptions that were noted during analysis.

No observations or exceptions to report