

Endoscope-i Ltd.

SNAP Face Mask

Splash Resistance

Test Report

Scientific Solution

September 2020

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Test Report

Customer: Ajith George FRCS Medical Director
Endoscope-i Ltd.
Somerset House
37 Temple Street
Birmingham
B2 5DP

Study Location: Medical Engineering Technologies Ltd.

Study Date: September 2020

Test Technicians: Elena Couzens & Mark Saxby

Order Number: Endoscope-I #1

References: **ASTM F1862/F1862M-17** - *Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)*

MET-SOP-QUAL-007 - *Creation, Authorisation & Distribution of MET Test Protocols & Reports (Issue 2)*

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Summary

Endoscope-i Ltd. commissioned Medical Engineering Technologies Ltd. (MET) to test SNAP mask performance, in accordance with ASTM F1862/F1862M-17 - *Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)*.

Products Tested

Product Name:	SNAP Face Mask
Lot Number:	20200422
Manufacture Date:	2020 04 22
Expiry Date:	2023 04 21

Objectives of Study

To observe any leakage (or absence thereof) on the test sample, in order to establish splash-resistant qualities as per ASTM F1862/F1862M-17 - *Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)*.

Product Admittance

The following process was applied to all samples in the programme:

1. The submitted product was checked for testing against the Sample Submission Form and Quotation.
2. The Sample Receipt Acknowledgement (SRA) was completed with test and sample details, as well as completion dates. A copy of the completed SRA was sent to both the client and the test laboratory.

Design of Experiment

The effectiveness of the test article in preventing the penetration of nasal fluids (saline solution was used for the test) was examined; the protection of those surrounding the mask user from possible exposure to bodily fluids was assessed.

The SNAP Face Mask (with the base assembled) was supplied to Medical Engineering Technologies Ltd. by Endoscope-i Ltd.

A cannula was used to spray 2ml of saline solution at the masks from a distance of 10 ± 1 mm. A target plate test method was used, complying with ASTM F1862/F1862M-17.

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Number of Test Articles: 10 SNAP Face Masks, 1 Type IIR Mask (see **Table 1**, below)
Test Side: Inside
Pre-Conditioning: Minimum of 4 hours at $21 \pm 5^\circ\text{C}$ / $85 \pm 5\%$ Relative Humidity

The saline solution was sprayed onto the inside of the masks (see **Figure 1**, below). Any penetration to the outside of the mask was considered a failure.

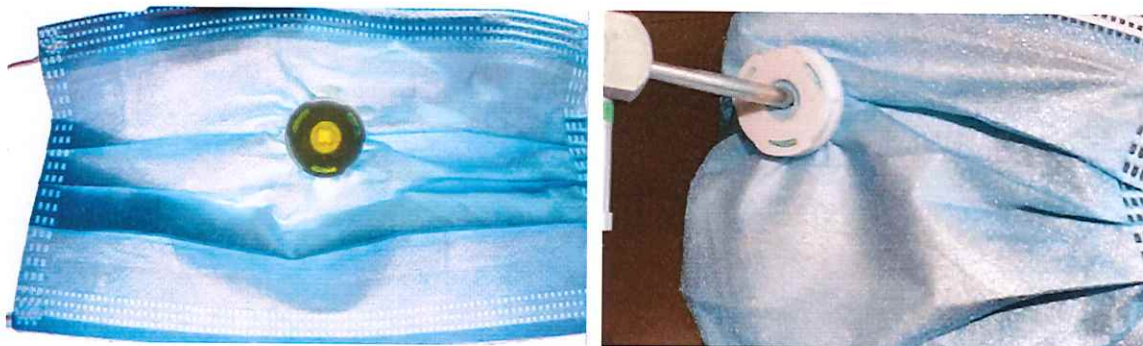


Figure 1 - Test Sample with the SNAP-base attached inside (left) and "in use" with endoscope (right)

Test Zone	Sample Quantity	Pressure 80mmHg	Pressure 120mmHg	Pressure 140mmHg	Pressure 160mmHg
Control: Type IIR Mask	1	1	1	1	1
SNAP Face Mask: Edge of Mask	10	10	10	10	10
SNAP Face Mask: Between Edge and SNAP	10	10	10	10	10
SNAP Face Mask: Weld Lines at the SNAP Base*	10	10	10	10	10

Table 1 - Sample Test Requirements

*Splash test at the SNAP base was performed in four phases:

1. Type IIR Mask (Control)
2. SNAP base attached prior to Endoscope insertion
3. SNAP base attached with Endoscope inserted
4. SNAP base attached after Endoscope removed

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Test Equipment

Item	MET ID	Date of Last Calibration
Manometer	17-0213	18 th February 2020
Constant Pressure System	N/A	N/A
Flow Trigger	N/A	N/A
Timer	14-0146	19 th December 2018

Table 2 - Test Equipment

Deviations From Test Protocol MET P1952

1. Number of test articles changed from 32 to 10. This was agreed upon with the client before testing was performed.
2. 'Design of Experiment' section reworded due to error in test protocol; the masks are designed to protect those around the user, not the mask user themselves.

Acceptance Criterion

The result was recorded as "Fail" if the saline solution penetrated through the SNAP Face Mask or "Pass" if it did not.

ASTM F1862/F1862M-17 allows a 4.0% AQL.

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Test Results

Sample Tested / Test Zone	Test Pressure (P = Pass, F = Fail)				Location of Leak	Comments
	80mmHg	120mmHg	140mmHg	160mmHg		
Control Type IIR Mask	P	P	P	P	None	None
1 / Edge of Mask	P	P	P	P	None	None
2 / Edge of Mask	P	P	P	P	None	None
3 / Edge of Mask	P	P	P	P	None	None
4 / Edge of Mask	P	P	P	P	None	None
5 / Edge of Mask	P	P	P	P	None	None
6 / Edge of Mask	P	P	P	P	None	None
7 / Edge of Mask	P	P	P	P	None	None
8 / Edge of Mask	P	P	P	P	None	None
9 / Edge of Mask	P	P	P	P	None	None
10 / Edge of Mask	P	P	P	P	None	None
1 / Between Edge and SNAP	P	P	P	P	None	None
2 / Between Edge and SNAP	P	P	P	P	None	None
3 / Between Edge and SNAP	P	P	P	P	None	None
4 / Between Edge and SNAP	P	P	P	P	None	None
5 / Between Edge and SNAP	P	P	P	P	None	None
6 / Between Edge and SNAP	P	P	P	P	None	None
7 / Between Edge and SNAP	P	P	P	P	None	None
8 / Between Edge and SNAP	P	P	P	P	None	None
9 / Between Edge and SNAP	P	P	P	P	None	None
10 / Between Edge and SNAP	P	P	P	P	None	None
1 / Weld Lines at SNAP Base	P	P	P	P	None	None
2 / Weld Lines at SNAP Base	P	P	P	P	None	None
3 / Weld Lines at SNAP Base	P	P	P	P	None	None
4 / Weld Lines at SNAP Base	P	P	P	P	None	None
5 / Weld Lines at SNAP Base	P	P	P	P	None	None
6 / Weld Lines at SNAP Base	P	P	P	P	None	None
7 / Weld Lines at SNAP Base	P	P	P	P	None	None
8 / Weld Lines at SNAP Base	P	P	P	P	None	None
9 / Weld Lines at SNAP Base	P	P	P	P	None	None
10 / Weld Lines at SNAP Base	P	P	P	P	None	None

Table 3 - Test Results

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Discussion

For all 10 samples, the saline solution did not penetrate through the SNAP Face Mask material. As a result, all samples complied with the acceptance criterion.

Authorisation



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Angela Bell
Laboratory Manager

24TH September 2020

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Date

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