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Maxtec Test Report

TITLE: EyeMax Post Accelerated Aging Validation

DOCUMENT NO. QD-0445
REVISION No. 01

PREPARED BY: Kevin Durst **DATE: 28 Feb 05**
Engineer

AMENDED BY: **DATE:**

REVISIONS:

A – DCO # 4229 - Initial Release
01 – Changed Document number from 04022 to QD-0445, changed revision from A to 01 and placed into new MasterControl.

1.0 Purpose

This document reports the findings as per the test protocol QD-0444

2.0 Scope

This testing applies to the eyeMAX product developed at Maxtec. It is the intent of this test is to determine the self-life parameter for the eyeMAX.

3.0 Reference Documents

- Maxtec Doc. # QD-0444 EyeMax Post Accelerated Aging Validation Protocol
- Maxtec Doc. # QD-0443 EyeMax Design and Performance Validation Test Report

4.0 Materials

9 packages of 20 bands each have been taken to the outside laboratory. Scheduled deliveries at 6.5, 13, and 19.5 weeks will arrive for testing. This represents the equivalent of 1, 2 and 3 year aged samples. The tests are to be repeated 3 times as each group of parts arrive. Measurements of the mechanical integrity of the material and the assembly will be determined in-house. To perform the in-house measurements simple measuring tools are to be used. General familiarity with a force gauge is helpful in performing these tests.

5.0 Test Equipment Used

Extech Instruments – Force Gauge
Model # 475044
S.N. R400060
Calibration: MFE 1 By: TB
Date: 08 Oct 2004
Due: 08 Oct 2005

6.0 Parameters to be tested

5.1 Assembly integrity

Parts from the fabricator will be inspected for the mechanical strength and adhesion of the Velcro to the band material. This also includes the Velcro that is adhered to the eye pad material.

Test # 1

Purpose:

To test the shear force / strength of the Velcro adhesive joint at the attachment point to the band material. The desired results of this test would be comparable to test data equivalent to the non-aged samples. The intent is for the adhesive to be at least as strong as the Velcro Joint proved in the prior test. As a note the variability of Velcro attachments makes scientific evaluation and conclusions rather difficult and data evaluation will be based on the mean of the sampling between the devices under test.

Data collection table:

Non-Aged		Year 1		Year 2		Year 3	
Sample No.	Ounces	Sample No.	Ounces	Sample No.	Ounces	Sample No.	Ounces
M1	1.73	M1	2.03	MX	1.34	MX	2.5
M2	1.15	M2	1.78	MX	1.42	MX	1.01
M3	1.58	M3	0.89	MX	1.79	MX	1.47
M4	2.06	M4	1.42	MX	1.40	MX	1.16
M5	2.05	M5	1.17	MX	1.25	MX	1.96
P1	1.62	P1	1.49	PX	0.81	PX	1.22
P2	1.12	P2	0.14	PX	1.28	PX	0.97
P3	1.79	P3	0.67	PX	0.98	PX	1.68
P4	1.67	P4	1.45	PX	0.48	PX	1.09
P5	1.53	P5	2.03	PX	1.30	PX	1.01
R1	3.31	R1	2.29	RX	1.36	RX	1.78
R2	2.25	R2	1.97	RX	2.74	RX	1.98
R3	1.66	R3	2.41	RX	1.14	RX	1.42
R4	2.62	R4	1.70	RX	1.16	RX	1.60
R5	2.81	R5	1.58	RX	2.61	RX	1.53

Results:

On average the samples showed a drop initially and then little or no change in adhesive strength from non-aged samples to the aged samples.

The non-aged samples were:

Micro – 1.71 lbs.
Preemie – 1.55 lbs.

Regular – 2.53 lbs.
for each of the three groups of samples.

The one-year aged samples were:
Micro – 1.46 lbs.
Preemie – 1.16 lbs.
Regular – 1.99 lbs.
for each of the three group samples.

The two-year aged samples were:
Micro – 1.44 lbs.
Preemie - .097 lbs.
Regular – 1.80 lbs.
for each of the three groups of samples.

The three-year aged samples were:
Micro – 1.62 lbs.
Preemie – 1.19 lbs.
Regular – 1.66 lbs.
for each of the three groups of samples.

Test # 2

Purpose:

To test the shear force / strength of the Velcro adhesive joint at the attachment point to the eye pad material. The desired results of this test would be comparable to test data equivalent to the non-aged samples. The intent is for the adhesive to be at least as strong as the Velcro Joint proved in the prior test. As a note the variability of Velcro attachments makes scientific evaluation and conclusions rather difficult and data evaluation will be based on the mean of the sampling between the devices under test.

Data collection table:

Non-Aged		Year 1		Year 2		Year 3	
Sample No.	Ounces	Sample No.	Ounces	Sample No.	Ounces	Sample No.	Ounces
MX1	0.66	MX1	0.53	MX	0.3	MX	0.29
MX2	0.27	MX2	0.37	MX	0.84	MX	0.37
MX3	0.34	MX3	0.35	MX	0.36	MX	0.30
MX4	0.51	MX4	0.23	MX	0.47	MX	0.37
MX5	0.38	MX5	0.42	MX	0.46	MX	0.35
PX1	0.82	PX1	1.01	PX	0.71	PX	0.56
PX2	0.82	PX2	1.07	PX	0.47	PX	0.34
PX3	1.74	PX3	1.17	PX	0.74	PX	0.46
PX4	0.81	PX4	1.34	PX	0.52	PX	0.33

PX5	1.53	PX2	1.18	PX	0.52	PX	0.42
RX1	0.57	RX1	0.38	RX	0.32	RX	0.51
RX2	0.67	RX2	0.59	RX	0.38	RX	0.47
RX3	0.86	RX3	0.59	RX	0.16	RX	0.54
RX4	0.67	RX4	0.82	RX	0.43	RX	0.51
RX5	0.77	RX5	0.88	RX	0.42	RX	0.71

Results:

On average the samples showed a little or no drop in adhesive strength from non-aged samples to the aged samples.

The non-aged samples were:

Micro – 0.43 lbs.
Preemie – 1.14 lbs.
Regular – 0.71 lbs.

The one-year aged samples were:

Micro – 0.38 lbs.
Preemie – 1.15 lbs.
Regular – 0.65 lbs.

The two-year aged samples were:

Micro – 0.50 lbs.
Preemie – 0.59 lbs.
Regular – 0.34 lbs.

The three-year aged samples were:

Micro – 0.34 lbs.
Preemie – 0.42 lbs.
Regular – 0.55 lbs.

Test # 3

Purpose:

To test the shear force / strength of the eyeMAX label adhesive joint at the attachment point to the band material. The desired results of this test would be comparable to test data produced in Test Protocol QD-0443. The intent is for the adhesive to be at least as strong as the eyeMAX label joint proved in the prior test. Data evaluation will be based on the mean of the sampling between the devices under test.

Data collection table:

QD-0443 Data		Non-Aged		Year 1		Year 2		Year 3	
Sample No.	Ounces	Sample No.	Ounces	Sample No.	Ounces	Sample No.	Ounces	Sample No.	Ounces
MX1	8.30	MX1	3.64	MX1	5.54	MX	9.41	MX	7.93
MX2	10.04	MX2	4.75	MX2	6.53	MX	6.64	MX	7.42
MX3	5.28	MX3	5.51	MX3	6.73	MX	7.81	MX	9.39
MX4	6.41	MX4	7.49	MX4	5.28	MX	9.02	MX	6.17
MX5	8.82	MX5	6.09	MX5	3.57	MX	8.38	MX	7.71
PX1	1.14	PX1	4.37	PX1	5.61	PX	4.95	PX	8.36
PX2	1.24	PX2	6.43	PX2	5.57	PX	7.80	PX	6.19
PX3	2.10	PX3	4.74	PX3	6.41	PX	5.64	PX	4.33
PX4	2.4	PX4	5.17	PX4	5.36	PX	5.30	PX	4.37
PX5	3.72	PX5	6.76	PX5	4.31	PX	4.88	PX	5.71
RX1	8.53	RX1	8.08	RX1	10.68	RX	8.09	RX	9.20
RX2	8.84	RX2	7.78	RX2	8.08	RX	8.25	RX	10.33
RX3	10.19	RX3	7.55	RX3	9.03	RX	7.64	RX	10.30
RX4	10.59	RX4	9.82	RX4	7.64	RX	9.13	RX	8.11
RX5	10.19	RX5	8.03	RX5	8.12	RX	9.68	RX	8.60

Results:

On average the samples showed no drop in adhesive strength from non-aged samples to the aged samples.

The non-aged samples were:

Micro – 5.50 lbs.
Preemie – 5.50 lbs.
Regular – 8.25 lbs.

The one-year aged samples were:

Micro – 5.53 lbs.
Preemie – 5.45 lbs.
Regular – 8.71 lbs.

The two-year aged samples were:

Micro – 8.25 lbs.
Preemie – 5.71 lbs.
Regular – 8.56 lbs.

The three-year aged samples were:

Micro – 7.72 lbs.
Preemie – 5.79 lbs.
Regular – 9.31 lbs.

This is compared to the test completed prior in QD-0443 which showed:

Micro – 7.77 lbs.

Preemie – 2.05 lbs.
Regular – 9.67 lbs.
for each of the three groups of samples

6.2 Material Integrity

Again from the samples that were used in the previous two tests, visually and tacitly inspect the materials that were aged. Report on the following parameters:

- Is the band material still soft and pliable?
- Is the eye pad material still soft and pliable?
- Can you notice any degradation of the inner foam layer on the eye pad?
- Did the Velcro material turn stiff?
- Has the eyeMAX label become stiff and brittle?
- Have any of the materials yellowed with age?
- Does the elastic nature of the material return the product to the original shape after flexing?

Test # 4

Purpose:

To test the aged material. The desired results of this test would be comparable to test data from newer, NOT aged samples.

Data collection table:

Non-Aged Sample No.	Ounces	Did the Material Return to shape?	Aged Sample No.	Ounces	Did the material Return to shape?
R0X	10.78	YES	R0X	10.11	YES
R0X	10.20	YES	R0X	10.89	YES
R0X	10.31	YES	R0X	10.64	YES
R0X	10.04	YES	R0X	10.22	YES
R0X	10.56	YES	R0X	10.85	YES

Results:

Generally, no discernable difference was noted between the non-aged and aged sample.

Test # 5

Purpose:

To test the aged material. The desired results of this test would be comparable to test data from newer, NOT aged samples.

Data collection table:

Non-Aged Sample No.	Ounces	Did the Material Return to shape?	Aged Sample No.	Ounces	Did the material Return to shape?
R0X	5.08	YES	R0X	5.32	YES
R0X	5.01	YES	R0X	5.13	YES
R0X	5.20	YES	R0X	5.09	YES
R0X	5.57	YES	R0X	5.38	YES
R0X	5.56	YES	R0X	5.15	YES

Results:

Generally, no discernable difference was noted between the non-aged and aged sample.

7.0 Conclusions:

At this time, it is concluded that there is some adhesive degradation between the Velcro and the materials.

The EyeMax label material currently showed no adhesive degradation.

The material itself has shown to have no changes in elasticity for the first round of tests.

If initially the adhesive degradation was noted then it seems that the adhesive does not continue to fail. Therefore, at this time it is not a requirement to date and maintain a shelf life for these products.

Signature Manifest

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Title: Test Report, EyeMax Post Accelerated Aging Validation

All dates and times are in US/Mountain.

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Name/Signature	Title	Date	Meaning/Reason
Diana Larsen (DLARSEN)	Document Control Specialist	07 Dec 2018, 11:41:01 AM	Approved