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1.0 PURPOSE

The document is a report of the test results of the ETP-044 NeoShades Phototherapy Light Blockage Test Plan. The objective of the test was to measure the percentage of light transmitted through the material of the NeoShades device under conditions similar to those used during phototherapy sessions for the treatment of hyperbilirubinemia.

2.0 SCOPE

2.1 This document provides a test report for ETP-044 NeoShades – Phototherapy Light Blockage Test Report.

3.0 SUMMARY

- 3.1 The test procedure was developed to determine the percentage of light transmitted through the material in the NeoShades which covers the eyes of the patient. A set of five (5) samples of each NeoShades PN: N722 and NeoShades with Ocular Pockets PN: N726 were tested, for light transmission.
- 3.2 A light chamber was constructed using a 27 gallon black plastic tote, a 2 ft fluorescent light fixture, and a pair of 2 ft “Bilirubin lights”.
- 3.3 The light was powered on and allowed to “warm-up” for 15 minutes prior to testing. It was noted that during the test, the measured light level continued to rise, even after the testing was complete.
- 3.4 Prior to testing any samples, a baseline measurement of the light inside the chamber was measured with an EXTECH EasyView 33 Light Meter with a fixture installed over the sensor to allow the securing of test samples.
- 3.5 Next, 5 pieces of N722 were tested by securing the sample in the test fixture and placing the fixture and sample inside the light chamber. The values from the light meter were read and recorded. Both sides of the sample were tested in succession, first the left side, then the right side. After the N722 samples were tested, another baseline reading was recorded. After that, 5 pieces of N726 were tested in the same manner as N722. A final baseline measurement was taken.
- 3.6 The mean reading of N722 was 0.40 lx with a baseline of 210.65 lx (average of measurement before and after the samples were tested). The calculated light transmitted was 0.19%, which translates into 99.81% blockage of light. The mean reading of N726 was 0.0 lx, translating into 100% blockage of the light.

4.0 REFERENCES

4.1 Testing Procedure document (ETP-044)

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5.0 DEFINITIONS

6.0 EQUIPMENT / MATERIALS

6.1 Test samples include the standard NeoShades Large N722, and the NeoShades with Ocular Pockets N726. Table 1 and Figure 1. Figure 2 shows a cross section of the two products where the N726 is compressed to form the pocket over the eye socket.

Product	Part Number	Product Size	LOT Number (No. pc)
NeoShades	N722	Large	2015-0187 (5 pieces)
NeoShades with Ocular Pockets	N726	Large	2015-0399 (5 pieces)

Table 1 – Test Samples by Part Number with LOT Numbers

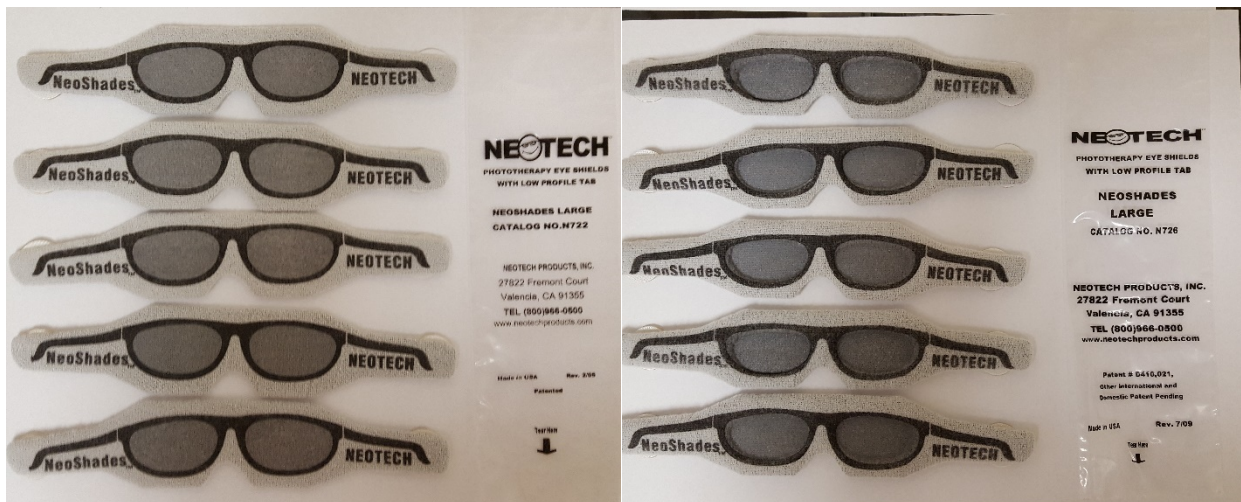


Figure 1 – N722 (Left) and N726 (Right)

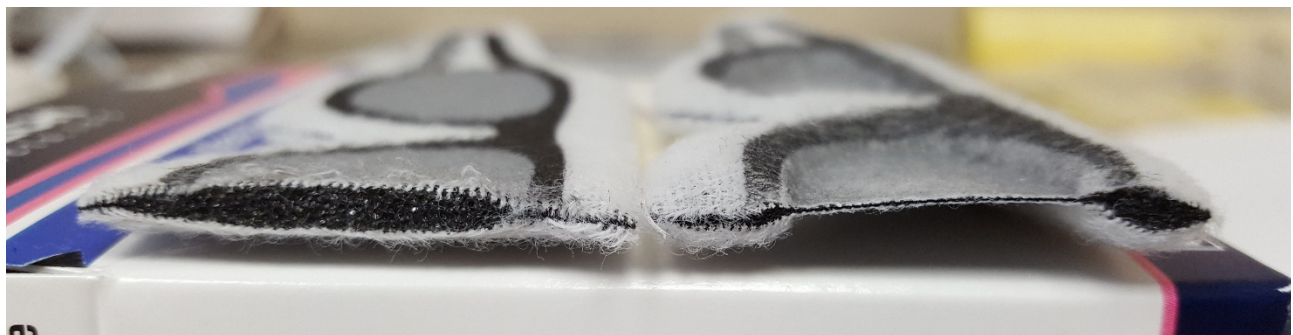


Figure 2 – Cross section of N722 (left) and N726 with Ocular Pockets (right)

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7.0 RESPONSIBILITY

7.1 Engineering conducting testing and creating ETP/ETR.

8.0 METHODS, PROCEDURES, AND STUDY ENDPOINTS

8.1 Method of determining light blocked – Devices are placed in light meter test fixture then under “Bilirubin lights.” Light readings for multiple samples are averaged. The average is divided by the mean light reading (before and after the samples are tested) without a device in the fixture. Result is subtracted from 1 and multiplied by 100% to obtain the percentage of light blocked.

8.2 Endpoints – Percentage of light transmitted / blocked by the device.

9.0 PASS / FAIL CRITERIA

9.1 The minimum allowable light blockage is 99%.

10.0 RESULTS SUMMARY

10.1 All five samples, on both sides of the NeoShades N722 showed 99.8% blockage of the light. All five samples of the NeoShades with Ocular Pockets showed 100% blockage of the light. See Table 2.

Product	PN	LOT	Sample #	Light Reading (left)	Light Reading (right)	Light Blockage (Left)	Light Blockage (Right)
Baseline	N/A	N/A	N/A	206.3			
NeoShades Large	N722	2015-0187	1	0.43	0.41	99.80%	99.81%
NeoShades Large	N722	2015-0187	2	0.4	0.45	99.81%	99.79%
NeoShades Large	N722	2015-0187	3	0.38	0.36	99.82%	99.83%
NeoShades Large	N722	2015-0187	4	0.39	0.29	99.81%	99.86%
NeoShades Large	N722	2015-0187	5	0.37	0.47	99.82%	99.78%
Baseline	N/A	N/A	N/A	215			
NeoShades Large with Ocular Pockets	N726	2015-0399	1	0.0	0.0	0.0	0.0
NeoShades Large with Ocular Pockets	N726	2015-0399	2	0.0	0.0	0.0	0.0
NeoShades Large with Ocular Pockets	N726	2015-0399	3	0.0	0.0	0.0	0.0
NeoShades Large with Ocular Pockets	N726	2015-0399	4	0.0	0.0	0.0	0.0

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NeoShades Large with Ocular Pockets	N726	2015-0399	5	0.0	0.0	0.0	0.0
Baseline	N/A	N/A	N/A	219			

Table 1 – Results

11.0 CONCLUSIONS & RECOMMENDATIONS

- 11.1 The standard NeoShades N722 product surpassed the requirement with 99.8% of light blocked. While the NeoShades with Ocular Pockets N726 100% of detectable light.
- 11.2 The compression of the foam in the Ocular Pockets of the N726 appear to present a barrier, impermeable to light, while the uncompressed polyethane foam appeared to allow approximately 0.2% of the light through.

12.0 HISTORY OF CHANGES:

CO No.	Revision		Date	Short description of Change	By:
	From	To			
1567	N/A	A	2/23/17	Initial Release	L. Kiliszewski