



p r e m i e r o 2 s o l u t i o n s

Spectral Transmittance Test Summary Report

Safety and Efficacy Testing: To ensure patient safety and product efficacy, Maxtec, Inc. performed spectral transmittance testing for neonatal eye protection in accordance ISO 10993-1 Section 1.3 (<2% from 290-380nm) on the EyeMax2 Phototherapy Mask materials and design.

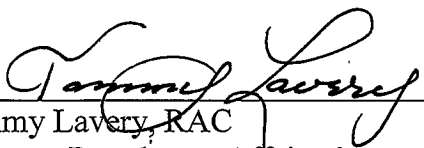
Method & Testing: Spectral transmittance was determined by spectrally measuring the xenon light source with and without a sample in the light path. The xenon source was selected due to its smooth and continuous spectrum and high output across the entire wavelength range (whereby the wavelength range used in phototherapy for hyperbilirubinemia (jaundice) was appropriately considered).

A monochromator was configured with a UV-enhanced silicon detector and 2.5nm slits. The xenon light source was placed 10" from the entrance of the monochromator. The system was calibrated in 10nm steps from 280-600nm. After calibrating, each sample was placed in the light path successively at the entrance of the monochromator and scans were made. The ratio of the spectral irradiance with and without the sample provided the spectral transmittance of the involved sample. Samples from other eye pad materials were also reviewed for comparison.

Testing of the materials used in the EyeMax2 Phototherapy Mask resulted in no measurable transmission across the spectrum of 290-600nm.

Conclusion: The results of the testing as noted above, demonstrated that the EyeMax2 Phototherapy Mask meets the requirements of ISO 10993-1 Section 1.3 specification (<2% from 290-380nm). In addition, testing performed demonstrates not only that the EyeMax2 Phototherapy Mask meets the requirement, but exceeds expectations for optimal neonatal eye protection with no spectral transmittance across a full spectrum range of 290 through 600nm.

Therefore, Maxtec deems the EyeMax2 Phototherapy Mask for neonatal phototherapy eye protection suitable for the indication for use.



Tammy Lavery, RAC
Director, Regulatory Affairs &
Quality Assurance

12-16-2009

Date

Spectral Transmittance of Supplied Material

Six Samples of Neonatal Eye Protection
Supplied by Maxtec, Inc., Salt Lake City, UT

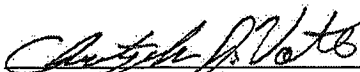
May 5, 2009

Spectral Transmittance of Supplied Material

**Six Samples of Neonatal Eye Protection
Supplied by Maxtec, Inc., Salt Lake City, UT**

May 5, 2009

Measurements performed by:



Christopher Voth
Solar Light Co.

EXPERIMENT SUMMARY

Six types of neonatal eye protection were tested for spectral transmission.

- MAXTEC EYEMAX REGULAR (BLUE) – EYEPATCH + HEADBAND
- MAXTEC EYEMAX 2 REGULAR (WHITE) – EYEPATCH + HEADBAND
- POSEY (GREY)
- BILIBAND NASCOR PREEMIE (SKY BLUE) – EYEPATCH + HEADBAND
- BILIBAND NATUS PREEMIE (DARK BLUE) – EYEPATCH + HEADBAND
- MAXTEC EYEMAX REGULAR (BLACK) – EYEPATCH + HEADBAND

The wavelengths tested were from 280 nm to 600 nm.

All samples were below the ISO 10993-1 Section 1.3 specification (<2% from 290-380nm)

Five of the types were tested without the headband:

- MAXTEC EYEMAX REGULAR (BLUE) – EYEPATCH ALONE
- MAXTEC EYEMAX 2 REGULAR (WHITE) – EYEPATCH ALONE
- BILIBAND NASCOR PREEMIE (SKY BLUE) – EYEPATCH ALONE
- BILIBAND NATUS PREEMIE (DARK BLUE) – EYEPATCH ALONE
- MAXTEC EYEMAX REGULAR (BLACK) – EYEPATCH ALONE

Comparing the samples tested with the headband:

- The Eyemax Blue, Eyemax Black, and the Biliband Dark Blue had no measurable transmission across the entire spectrum.
- Eyemax White, Biliband Sky Blue, and Posey had some small transmission in the visible, less than 0.2%

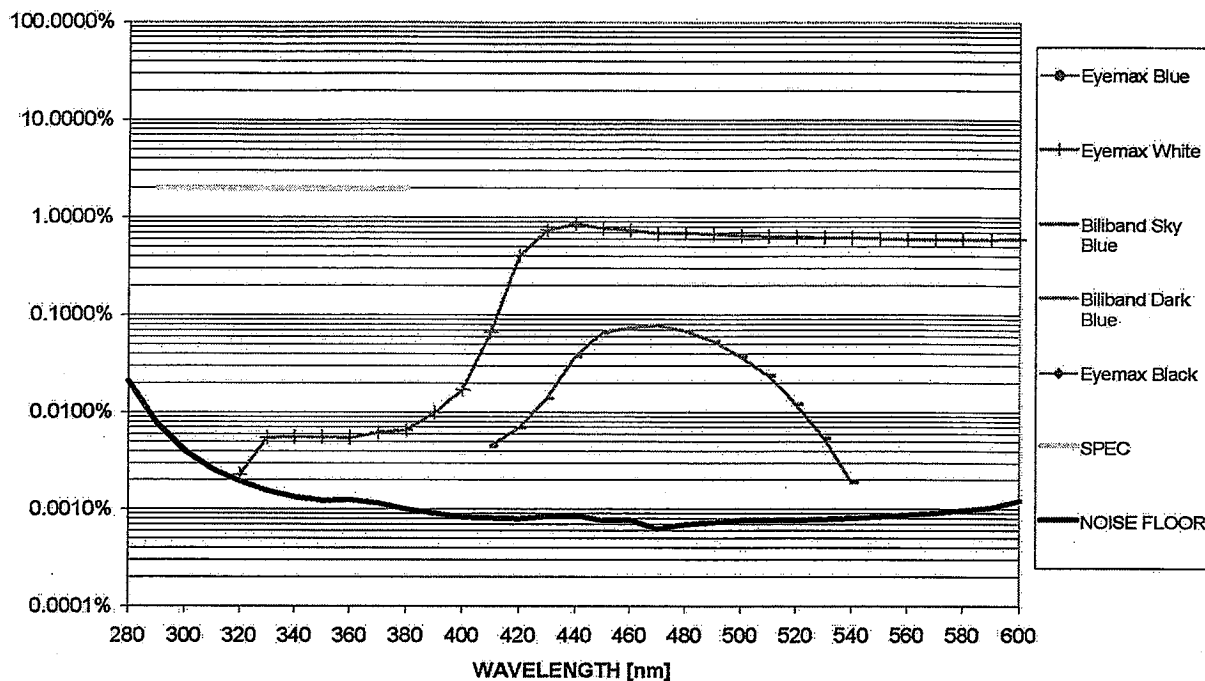
Comparing the samples tested without the headband

- The Eyemax Blue had no measurable transmission across the entire spectrum.
- The Eyemax Black had no measurable transmission across the entire spectrum.
- The Biliband Dark Blue had no measurable transmission across the entire spectrum.
- The Biliband Sky Blue had a small transmission in the visible, <0.1%.
- The Eyemax White had a small transmission in the UV, <0.01% and low transmission in the visible, < 1%.

SPECTRAL TRANSMITTANCE OF SUPPLIED MATERIAL

Specification: ISO 10993-1 Section 1.3

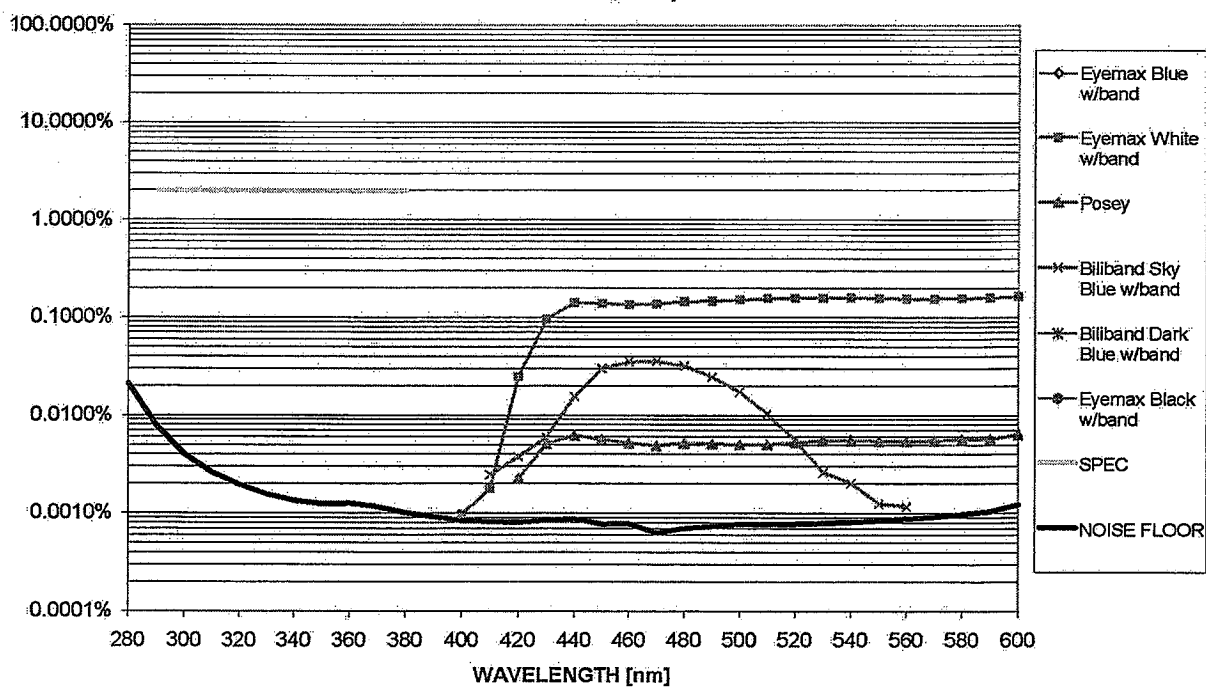
LOGARITHMIC SCALE, Samples alone (without band)



SPECTRAL TRANSMITTANCE OF SUPPLIED MATERIAL

Specification: ISO 10993-1 Section 1.3

LOGARITHMIC SCALE, Samples with band



OBJECTIVE and MATERIALS TESTED

1. To measure the spectral transmittance of neonatal eye protection (eyepatch and headband together) – Sample A,B,D,E,F, from 280 to 600 nanometers with data points every 10 nanometers.
2. To measure the spectral transmittance of neonatal eye protection (eyepatch only) – Sample A',B',D',E',F', from 280 to 600 nanometers with data points every 10 nanometers.
3. To measure the spectral transmittance of neonatal eye protection – Sample C, from 280 to 600 nanometers with data points every 10 nanometers.
4. To determine conformance of neonatal eye protection to ISO 10993-1 section 1.3 – less than 2% transmittance of light between 290nm and 380nm.

Sample A – MAXTEC EYEMAX REGULAR (BLUE) – EYEPATCH AND HEADBAND

Sample B – MAXTEC EYEMAX 2 REGULAR (WHITE) – EYEPATCH AND HEADBAND

Sample C – POSY (GREY)

Sample D – BILIBAND NASCOR PREEMIE (SKY BLUE) – EYEPATCH AND HEADBAND

Sample E – BILIBAND NATUS PREEMIE (DARK BLUE) – EYEPATCH AND HEADBAND

Sample F – MAXTEC EYEMAX REGULAR (BLACK) – EYEPATCH AND HEADBAND

Sample A' – MAXTEC EYEMAX REGULAR (BLUE) – EYEPATCH ONLY

Sample B' – MAXTEC EYEMAX 2 REGULAR (WHITE) – EYEPATCH ONLY

Sample D' – BILIBAND NASCOR PREEMIE (SKY BLUE) – EYEPATCH ONLY

Sample E' – BILIBAND NATUS PREEMIE (DARK BLUE) – EYEPATCH ONLY

Sample F' – MAXTEC EYEMAX REGULAR (BLACK) – EYEPATCH ONLY

MEASUREMENT EQUIPMENT

Optronic Laboratories Model 740 A/D Monochromator SN 88200395

Optronic Laboratories Model 730A Radiometer SN 88200298

Ushio Model UXL-S150MO 150W Super-Quiet Short Arc Xenon lamp S/N HB2101

Solar Light Model XPS 200 Xenon Power Supply S/N 13987

MEASUREMENT METHODS

The spectral transmittance was determined by spectrally measuring the xenon light source with and without the sample in the light path. A xenon source was chosen due to its smooth continuous spectrum and high output across the entire wavelength range.

The monochromator was configured with a UV-enhanced silicon detector and 2.5nm slits. The xenon light source was placed 10" from the entrance of the monochromator. The system was calibrated in 10nm steps from 280-600nm. After calibration each sample was placed in the light path successively at the entrance of the monochromator and scans made. The ratio of the spectral irradiance with and without the sample is the spectral transmittance of that sample.

The samples were mounted on a fixture and pulled just taught to remove wrinkles without stretching the material.

MEASUREMENT RESULTS

All samples conform to the ISO 10993-1 section 1.3 specification of less than 2% transmittance of light between 290nm and 380nm.

Graphs of the spectral transmittance of the samples on linear and logarithmic scales are shown in Figures 1 and 2. The ISO 10993-1 section 1.3 specification is shown on both graphs. The system detection limit (noise floor) is shown on Figure 2. Sample transmittance values below the noise floor have been omitted. A graph of the spectral irradiance of the xenon source is shown in Figure 3. Table 1 contains percent transmittance of the xenon source for the UVA+B band (290-380nm). Table 2 contains the spectral transmittance data for the samples. Table 3 contains the system detection limit values and spectral irradiance of the xenon source.

SPECTRAL TRANSMITTANCE OF SUPPLIED MATERIAL Specification: ISO 10993-1 Section 1.3 LINEAR SCALE

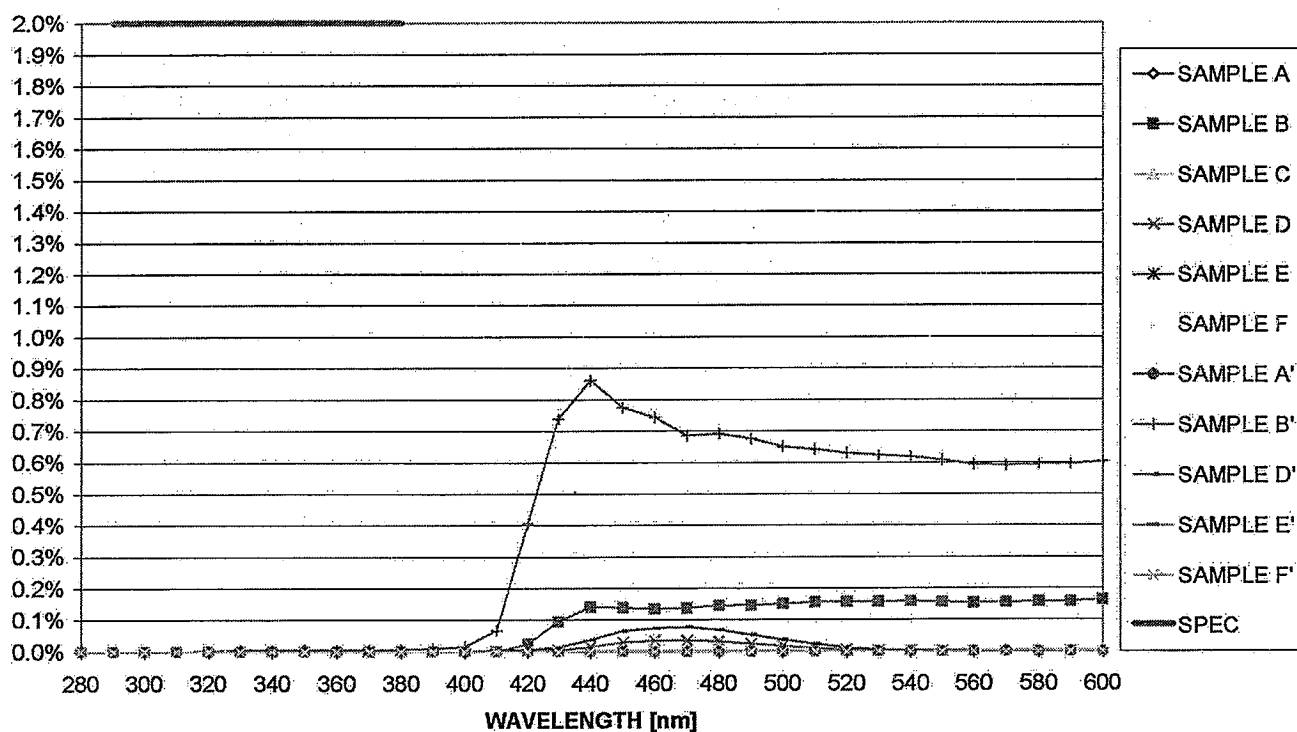


Fig. 1 Spectral Transmittance of Neonatal Eye Protection Samples – Linear Scale.

SPECTRAL TRANSMITTANCE OF SUPPLIED MATERIAL
Specification: ISO 10993-1 Section 1.3
LOGARITHMIC SCALE

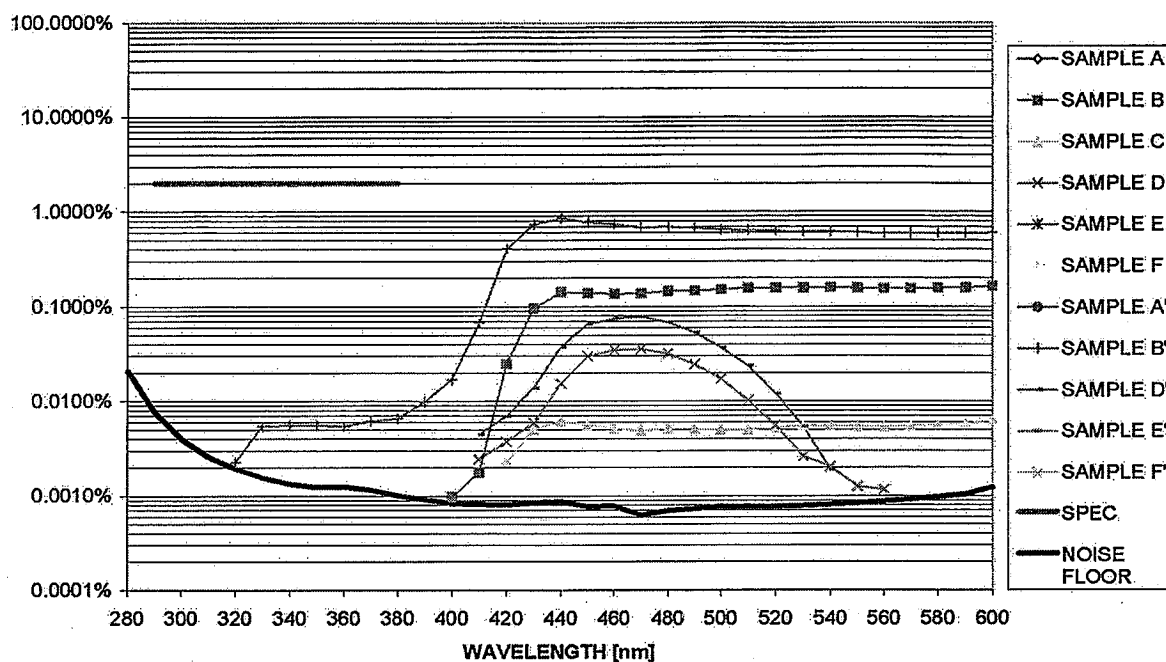


Fig. 2 Spectral Transmittance of Neonatal Eye Protection Samples – Log Scale.
Values below the noise floor have been omitted.

SPECTRAL IRRADIANCE OF XENON SOURCE

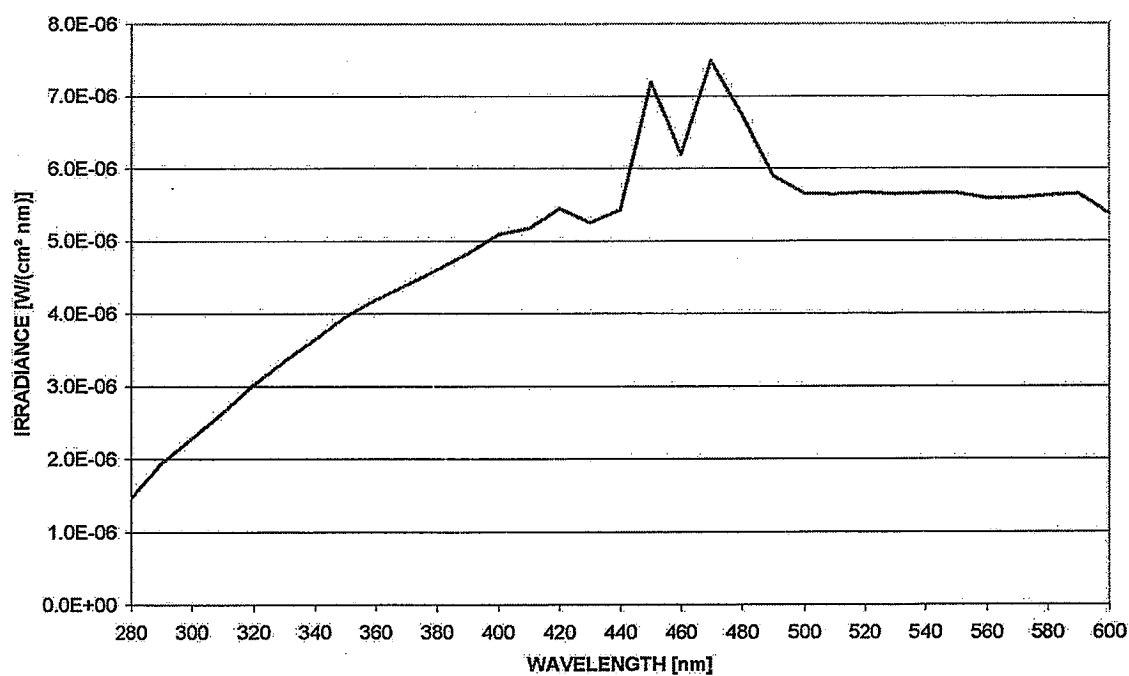


Fig. 3. Spectral Irradiance of Xenon Source.

Table 1. Percent transmittance of xenon source in selected wavelength bands.

 λ – Wavelength band%T_(A,B,C,D,E,F,A',B',D',E',F') – Percent transmittance of respective sample%T_{SPEC} – Percent transmittance requirement specified in ISO 10993-1 section 1.3

λ	%T _A	%T _B	%T _C	%T _D	%T _E	%T _F	%T _{A'}	%T _{B'}	%T _{D'}	%T _{E'}	%T _{F'}	%T _{SPEC}
UVA+B (290-380nm)	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	<2%

Table 2. Spectral Transmittance of Tabular Data.

*Spectral transmittance data in electronic format can be supplied upon request.
Values below the noise floor have been set to zero.*

λ – Wavelength in nm

$T_{(A,B,C,D,E,F,A',B',D',E',F')\lambda}$ – Spectral transmittance of respective sample centered at λ

$T_{SPEC\lambda}$ – Spectral transmittance requirement specified in ISO 10993-1 section 1.3

λ	T_{AA}	T_{BA}	T_{CA}	T_{DA}	T_{EA}	T_{FA}	$T_{A'A}$	$T_{B'A}$	$T_{D'A}$	$T_{E'A}$	$T_{F'A}$	$T_{SPEC\lambda}$
280	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	
290	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	2.000E-02
300	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	2.000E-02
310	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	2.000E-02
320	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	2.3E-05	0.0E+00	0.0E+00	0.0E+00	2.000E-02
330	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	5.5E-05	0.0E+00	0.0E+00	0.0E+00	2.000E-02
340	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	5.6E-05	0.0E+00	0.0E+00	0.0E+00	2.000E-02
350	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	5.6E-05	0.0E+00	0.0E+00	0.0E+00	2.000E-02
360	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	5.4E-05	0.0E+00	0.0E+00	0.0E+00	2.000E-02
370	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	6.2E-05	0.0E+00	0.0E+00	0.0E+00	2.000E-02
380	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	6.6E-05	0.0E+00	0.0E+00	0.0E+00	2.000E-02
390	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	9.9E-05	0.0E+00	0.0E+00	0.0E+00	
400	0.0E+00	9.7E-06	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	1.7E-04	0.0E+00	0.0E+00	0.0E+00	
410	0.0E+00	1.8E-05	0.0E+00	2.5E-05	0.0E+00	0.0E+00	0.0E+00	6.7E-04	4.5E-05	0.0E+00	0.0E+00	
420	0.0E+00	2.5E-04	2.3E-05	3.7E-05	0.0E+00	0.0E+00	0.0E+00	4.1E-03	7.0E-05	0.0E+00	0.0E+00	
430	0.0E+00	9.6E-04	5.1E-05	5.9E-05	0.0E+00	0.0E+00	0.0E+00	7.4E-03	1.4E-04	0.0E+00	0.0E+00	
440	0.0E+00	1.4E-03	6.2E-05	1.6E-04	0.0E+00	0.0E+00	0.0E+00	8.6E-03	3.8E-04	0.0E+00	0.0E+00	
450	0.0E+00	1.4E-03	5.7E-05	3.0E-04	0.0E+00	0.0E+00	0.0E+00	7.7E-03	6.6E-04	0.0E+00	0.0E+00	
460	0.0E+00	1.4E-03	5.2E-05	3.5E-04	0.0E+00	0.0E+00	0.0E+00	7.4E-03	7.5E-04	0.0E+00	0.0E+00	
470	0.0E+00	1.4E-03	4.9E-05	3.6E-04	0.0E+00	0.0E+00	0.0E+00	6.9E-03	7.9E-04	0.0E+00	0.0E+00	
480	0.0E+00	1.5E-03	5.2E-05	3.2E-04	0.0E+00	0.0E+00	0.0E+00	6.9E-03	6.9E-04	0.0E+00	0.0E+00	
490	0.0E+00	1.5E-03	5.1E-05	2.5E-04	0.0E+00	0.0E+00	0.0E+00	6.8E-03	5.4E-04	0.0E+00	0.0E+00	
500	0.0E+00	1.5E-03	5.0E-05	1.7E-04	0.0E+00	0.0E+00	0.0E+00	6.5E-03	3.7E-04	0.0E+00	0.0E+00	
510	0.0E+00	1.6E-03	5.0E-05	1.0E-04	0.0E+00	0.0E+00	0.0E+00	6.4E-03	2.4E-04	0.0E+00	0.0E+00	
520	0.0E+00	1.6E-03	5.3E-05	5.5E-05	0.0E+00	0.0E+00	0.0E+00	6.3E-03	1.2E-04	0.0E+00	0.0E+00	
530	0.0E+00	1.6E-03	5.5E-05	2.6E-05	0.0E+00	0.0E+00	0.0E+00	6.2E-03	5.4E-05	0.0E+00	0.0E+00	
540	0.0E+00	1.6E-03	5.5E-05	2.0E-05	0.0E+00	0.0E+00	0.0E+00	6.2E-03	1.9E-05	0.0E+00	0.0E+00	
550	0.0E+00	1.6E-03	5.4E-05	1.3E-05	0.0E+00	0.0E+00	0.0E+00	6.1E-03	0.0E+00	0.0E+00	0.0E+00	
560	0.0E+00	1.6E-03	5.4E-05	1.2E-05	0.0E+00	0.0E+00	0.0E+00	5.9E-03	0.0E+00	0.0E+00	0.0E+00	
570	0.0E+00	1.6E-03	5.5E-05	0.0E+00	0.0E+00	0.0E+00	0.0E+00	5.9E-03	0.0E+00	0.0E+00	0.0E+00	
580	0.0E+00	1.6E-03	5.7E-05	0.0E+00	0.0E+00	0.0E+00	0.0E+00	5.9E-03	0.0E+00	0.0E+00	0.0E+00	
590	0.0E+00	1.6E-03	5.7E-05	0.0E+00	0.0E+00	0.0E+00	0.0E+00	6.0E-03	0.0E+00	0.0E+00	0.0E+00	
600	0.0E+00	1.6E-03	6.3E-05	0.0E+00	0.0E+00	0.0E+00	0.0E+00	6.0E-03	0.0E+00	0.0E+00	0.0E+00	

Table 3. System Detection Limit and Spectral Irradiance of Xenon Source.

Spectral data in electronic format can be supplied upon request.

λ – Wavelength in nm

T_{NA} – Transmittance detection limit of the system centered at λ

I_{λ} – Spectral Irradiance of xenon lamp in $W\ cm^{-2}\ nm^{-1}$ centered at λ

λ	T_{NA}	I_{λ}
280	2.101E-04	1.469E-06
290	7.833E-05	1.946E-06
300	4.019E-05	2.287E-06
310	2.601E-05	2.643E-06
320	1.952E-05	3.023E-06
330	1.558E-05	3.352E-06
340	1.341E-05	3.650E-06
350	1.238E-05	3.961E-06
360	1.256E-05	4.192E-06
370	1.159E-05	4.393E-06
380	1.008E-05	4.607E-06
390	9.146E-06	4.829E-06
400	8.333E-06	5.094E-06
410	8.174E-06	5.178E-06
420	8.032E-06	5.449E-06
430	8.463E-06	5.253E-06
440	8.696E-06	5.433E-06
450	7.722E-06	7.196E-06
460	7.792E-06	6.200E-06
470	6.276E-06	7.489E-06
480	6.961E-06	6.742E-06
490	7.317E-06	5.896E-06
500	7.712E-06	5.655E-06
510	7.712E-06	5.644E-06
520	7.722E-06	5.669E-06
530	7.884E-06	5.646E-06
540	8.108E-06	5.657E-06
550	8.380E-06	5.658E-06
560	8.759E-06	5.586E-06
570	9.146E-06	5.591E-06
580	9.740E-06	5.625E-06
590	1.040E-05	5.648E-06
600	1.229E-05	5.368E-06