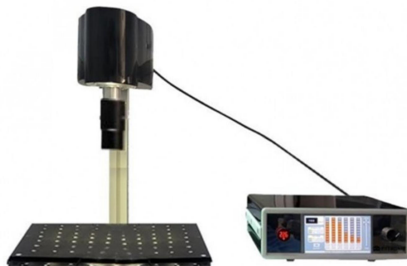


AAA CLASS SUNSCREEN SOLAR SIMULATOR

FYTRONIX- SCSM-800



Housing of solar simulator can be changed according to the required specifications

AAA Class Solar Simulator – Sunscreen Applications

Overview

The **AAA Class Solar Simulator** is specifically designed for **sunscreen testing and in vivo SPF determinations**. It provides a **high-precision ultraviolet (UV) spectrum** for reliable measurement of skin protection factors and other UV-sensitive experiments.

The simulator uses a **150 W Xenon lamp** with specialized filters to deliver the **UVB (290–320 nm) and UVA (320–400 nm) spectral ranges**, ensuring compliance with international SPF test standards.

Technical Specifications

Feature	Specification
Class	AAA
Application	Sunscreen / In Vivo SPF Determination
Wavelength Range	290 – 400 nm
Spectral Match	AAA ($\pm 25\%$, JIS C 8912 or JIS C 8933 Class A)
Temporal Stability	$\leq 1\%/h$ (JIS C 8912 Class A)
Light Source	150 W Xenon Lamp
Filter	AM1.5G, WG-320, UG-11 for UVA (320–400 nm) and UVB (290–320 nm)
Effective Illumination Area	30 × 30 mm or 40 mm
Input Voltage	100–120 V or 200–240 V (switch selectable)
Warranty	2 Years

Applications

- In vivo **SPF (Sun Protection Factor) testing**
 - Sunscreen efficacy evaluation
 - UV-induced photobiology studies
 - Dermatological research requiring controlled UVA/UVB exposure
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Additional Information

- In vivo SPF determinations were performed according to the **International Harmonized SPF Test Method**.
- Studies included **healthy volunteers (Fitzpatrick skin type I–III)** with informed consent.
- The solar simulator provides **reliable and reproducible UV spectral output** for research and regulatory testing.

1. GENERAL EQUATIONS

1.1 Individual Sun Protection Factor (SPFi)

The individual SPFi of each product on each subject is calculated from the individual MED on unprotected skin (MEDui) and the individual MED on product protected skin (MEDpi) according to the equation:

$$\text{SPFi} = \text{MEDpi} / \text{MEDui} \quad (1)$$

1.2 Product Sun Protection Factor

The SPF of the product is the arithmetical mean of the individual SPFi values obtained from the total number (n) of subjects used, expressed to one decimal point:

$$\text{SPF} = (\sum \text{SPFi}) / n \quad (2)$$

Its standard deviation (s) is:

$$s = \sqrt{[(\sum (\text{SPFi}^2) - ((\sum \text{SPFi})^2 / n)) / (n - 1)]} \quad (3)$$

1.3 95% confidence interval

The 95% confidence interval (95%CI) for the mean SPF is expressed as:

$$95\% \text{CI} = \text{SPF} - c \text{ to } \text{SPF} + c \quad (4)$$

c is calculated as: $c = (t \text{ value}) \cdot \text{SEM} = (t \text{ value}) \cdot s / \sqrt{n}$

$$c = t \cdot s / \sqrt{n} \quad (5)$$

$$\text{CI}[\%] = 100 \cdot c / \text{SPF} \quad (6)$$

where:

SEM = the standard error of the mean,

n = total number of subjects used,

t = t value from the "two-sided" Student-t distribution table (7) at a probability level $p = 0.05$ and with degrees of freedom $v = (n - 1)$

N	10	11	12	13	14	15	16	17	18	19	20
t value	2.26	2.22	2.20	2.17	2.16	2.14	2.13	2.12	2.11	2.10	2.09
	2	8	1	9	0	5	1	0	0	1	3

For spreadsheet calculation t value can be modelled by: $t = 2.03 + 12.7 / n^{1.75}$
(for $n \geq 4$)

2. EXPERIMENTAL CALCULATION PROCEDURE

2.1 Sequential procedure

An SPF test is begun by testing the product on an initial panel of n' subjects (n' must be at least 10). The individual sun protection factors (SPFi) for the product on each subject are then calculated according to equation (1), i.e.:

$$SPFi = MEDpi / MEDui \quad (1)$$

From these individual SPFi values, a provisional mean sun protection factor for the initial n' subjects ($SPF_{n'}$) is calculated according to equation (2), together with a provisional 95% confidence interval ($95\%CI_{n'}$) using equations (4), (5) and (6) and t-table (7), i.e.:

$$SPF_{n'} = \sum SPFi / n' \quad (9)$$

$$95\%CI_{n'} = SPF_{n'} - c_{n'} \text{ to } SPF_{n'} + c_{n'} \quad (10)$$

$$c_{n'} \text{ is calculated as } c_{n'} = t_{n'} \cdot s_{n'} / \sqrt{n'} \quad (11)$$

where $s_{n'}$ = standard deviation from the first n' subjects calculated according to equation (3):

$$s_{n'} = \sqrt{[(\sum SPFi^2) - ((\sum SPFi)^2 / n')] / (n' - 1)} \quad (12)$$

$$CI_{n'}[\%] = 100 \cdot c_{n'} / SPF_{n'} \quad (13)$$

If the calculated provisional $CI_{n'}[\%]$ is greater than 17 % of the provisional mean $SPF_{n'}$ value, then testing of the product shall continue on additional subjects until the provisional $CI_{n'}[\%]$ is ≤ 17 % of the mean provisional SPF.

If this criterion is not fulfilled after 20 subjects, then the entire test shall be repeated.

2.2 Predicted number of subjects (n^*)

If the $CI_{n'}[\%]$ on the provisional $SPF_{n'}$ is greater than 0.17 $SPF_{n'}$, then the predicted, likely total number of subjects (n^*) necessary to meet the statistical criterion can be estimated according to the following formula and rounded-up to the nearest integer:

$$n^* = (t_{n'} \cdot s_{n'} / C_{n'})^2 \quad (14)$$

where:

$t_{n'}$ = t statistic from t-table or equation (7), with n' results,

$s_{n'}$ = best estimate of population standard deviation (ie from the n' results),

$C_{n'}$ = 17% of mean $SPF_{n'}$, representing the required confidence interval.

EXAMPLE : When n^* is calculated after the first 10 data, then:

$$\begin{aligned} n^* &= (2.262 s_{n'} / 0.17 SPF_{n'})^2 \\ \text{i.e. } n^* &= (13.30 s_{n'} / SPF_{n'})^2 \end{aligned} \quad (15)$$

3. EXAMPLES

3.1. Example 1

TABLE 6 is an example of a table gathering data, calculations and results. When data are entered in spreadsheet software, all calculations can be performed automatically.

TABLE 6 shows the results for product EX1 with expected SPF 10. After 10 subjects had been exposed, the results were:

$$\begin{aligned} SPF_{n'} &= 11.4 & (9) \\ s_{n'} &= 2.4 & (12) \\ c_{n'} &= 1.7 & (11) \\ 95\%CI_{n'} &= 9.7 \text{ to } 13.1 & (10) \\ CI_{n'}[\%] &= 14.9 \% & (13) \end{aligned}$$

Since the $CI_{n'}[\%]$ was smaller than 17 % of the mean SPF, no further testing was necessary and the final SPF of the product EX1 was:

$$\mathbf{SPF = 11.4 \quad \text{with} \quad CI[\%] = 14.9 \% \quad (2,6)}$$

3.2. Example 2

TABLE 7 shows the results for product EX2 with expected SPF 20. After 10 subjects had been exposed, the results were:

$$\begin{aligned} SPF_{n'} &= 21.3 & (9) \\ s_{n'} &= 6.0 & (12) \\ c_{n'} &= 4.3 & (11) \\ 95\%CI_{n'} &= 17.0 \text{ to } 25.6 & (10) \\ CI_{n'} [\%] &= 20.3 \% & (13) \end{aligned}$$

The relative variation of the results was higher than in Example 1 and the statistical criterion was not met ($CI_{n'}$ [%] was greater than 17 % of the mean SPF). The test had to be continued and the likely total number n of subjects necessary was calculated as:

$$n = (t_{n'} \cdot s_{n'} / C_{n'})^2 = (2.262 \times 6.0 / 3.61)^2 = 14.1 \quad (12)$$

Therefore, five subjects were added and the newly calculated provisional results were:

$$\begin{aligned} SPF_{15} &= 21.2 & (9) \\ s_{15} &= 6.2 & (12) \\ c_{15} &= 3.4 & \text{with } n = 15 \text{ and } t_{15} = 2.145 & (11) \\ 95\%CI_{15} &= 17.8 \text{ to } 24.6 & (10) \\ CI [\%]_{15} &= 16.2 \% & (13) \end{aligned}$$

The criterion was met after the fifteenth subject ($CI_{n'}$ [%] smaller than 17 % of the mean SPF) and the final SPF of product EX2 was:

$$SPF = 21.2 \quad \text{with} \quad CI[\%] = 16.2 \% \quad (2,6)$$

TABLE 6 : Example of calculation with 10 subjects (expected SPF 10)

Harmonised SPF TEST Result Table										Laboratory:					
Product Code:EX1.....			Expected SPF: ...10....				Date: Data sheet N°: 2. of ..3..			UV source: ...Xe..MP.....					
Subj N°	TEST		SUBJECTS					RESULTS					CONCLUSION: $CI_n[\%] \leq 17\% ?$	COMMENTS	
	Exposure date	Technician name	Subject code	Skin ITA°	Photo type	MEDu (mJ.cm ⁻²)	MEDp (mJ.cm ⁻²)	SPFi	SPF _n	s _n	c _n	CI _n [%] (100.c _n /SPF _n)			n
1				56,4	I	19	290	15,3	-	-	-	-		-	
2				48,6	II	29	370	12,8	-	-	-	-		-	
3				58,1	I	23	230	10,0	-	-	-	-		-	
4				43,5	II	37	420	11,4	-	-	-	-		-	
5				44,0	II	29	230	7,9	-	-	-	-		-	
6				42,7	II	23	290	12,6	-	-	-	-		-	
7				34,9	III	46	370	8,0	-	-	-	-		-	
8				57,0	I	19	260	13,7	-	-	-	-		-	
9				54,8	II	29	370	12,8	-	-	-	-		-	
10				45,3	II	23	230	10,0	11,4	2,4	1,73	15,1%	8	Complies	
11															
12															
13															
14															
15															
16															
17															
18															
19															
20															
FINAL RESULT:			Mean SPF = 11	11,4		s = 2,4		c = 1,7	CI[%] = 15,1 %					95%CI: 9.7 - 13.1 (n = 10)	

TABLE 7 : Example of calculation with 15 subjects (expected SPF 20)

Harmonised SPF TEST Result Table									Laboratory:						
Product Code:EX2.....				Expected SPF: 20....					Date: Data sheet N°: .3. of .3.			UV source: ..XE..MP.....			
Subj. N°	TEST		SUBJECTS						RESULTS					CONCLUSION:	COMMENTS
	Exposure date	Technician name	Subject code	Skin ITA°	Photo type	MEDu (sec.)	MEDp (sec.)	SPFI	SPF _r	s _r	c _r	CI _r [%] (100.c _r /SPF _r)	n	CI _r [%] =< 17% ?	
1				56,2	I	35	700	20,0	-	-	-	-		-	
2				42,5	II	44	1094	24,9	-	-	-	-		-	
3				50,6	II	35	875	25,0	-	-	-	-		-	
4				32,8	III	68	875	12,9	-	-	-	-		-	
5				45,1	II	44	1094	24,9	-	-	-	-		-	
6				47,9	II	35	875	25,0	-	-	-	-		-	
7				29,4	III	85	1367	16,1	-	-	-	-		-	
8				54,3	II	44	560	12,7	-	-	-	-		-	
9				43,3	II	35	1094	31,3	-	-	-	-		-	
10				59,9	I	44	875	19,9	21,3	6,0	4,31	20,3%	14	Does not comply	
11				35,0	III	68	875	12,9	20,5	6,3	4,20	20,5%	17	Does not comply	
12				48,8	II	44	1367	31,1	21,4	6,7	4,26	19,9%	18	Does not comply	
13				36,5	I	35	875	25,0	21,7	6,5	3,92	18,1%	16	Does not comply	
14				47,1	II	44	700	15,9	21,2	6,4	3,71	17,5%	16	Does not comply	
15				38,1	III	55	1094	19,9	21,2	6,2	3,43	16,2%	15	Complies	
16															
17															
18															
19															
20															
FINAL RESULT:			Mean SPF =	21.2		s =	19.9	c =	21.2	CI[%] =	16.2 %		95%CI: 17.8 - 24.6 (n = 15)		