New Sunscreen Test Methods – Withband Without Humans

May 2023 John Staton SciPharm Pty Ltd



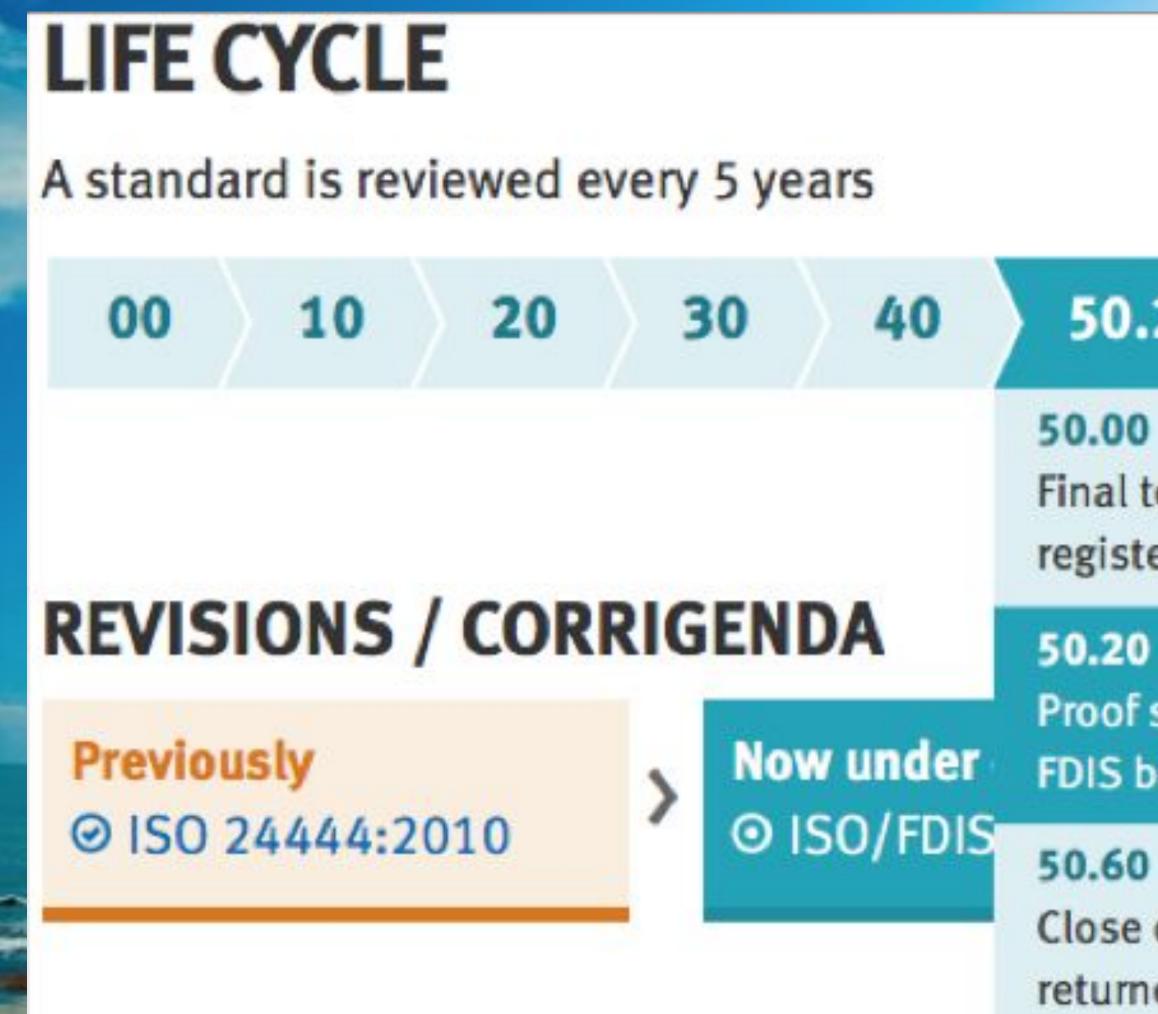
I. Main Changes in Sunscreen Standard ISO 24444

2. New Alternatives Overview

3. Progress with SPF Tests Development



1. ISO 24444 : 2019



50.20 Approval ~

2019-07-26

60

Final text received or FDIS registered for formal approval

2019-09-13

Proof sent to secretariat or FDIS ballot initiated: 8 weeks

Close of voting. Proof returned by secretariat from here... up to 6 mths or more

90



95

1. ISO 24444 : 2019

Replaces 2010 version (first)

Main Changes in 2019 - Methodology

Amendments 2021 - minor



FINAL DRAFT

INTERNATIONAL STANDARD

ISO 24444

ISO/TC 214

Secretariat ISIRI

Voting begins on: 2010-02-25

Voting terminates on: 2010-04-25

Cosmetics — Sun protection test methods - In vivo determination of SPF (sun protection factor)

Please see the administrative notes on page iii

Cosmétiques - Méthodes d'essai de protection solaire -Détermination in vivo du FPS (facteur de protection sclaire)

RECEPTING OF THE DRUFT ARE INVITED TO SLEMIT, WITH THEIR COMMENDS, NO THEATON OF MY RELEVANT PATENT NO. HT I// REHICH THEY ARE AD ARE AND TO PROVIDE SUPPORT. ING DOCLMENTATION.

IN ADDITION TO THER INALIATION AS BEING ACCEPTABLE FOR INDUSTRIAL, BECHNO-LODICAL COMMERCIAL AND LIBER PURPOSED. DEAPT INTERNATIONAL STANDARDS MAY ON OCCASION HAVE TO BE CONSIDERED IN THE LIGHT OF THER FOTENTIAL TO BECOME ETAN-DARDE TO INHICH REPERENCE MAY BE MADE IN NATIONAL REGLE ATIONS.



Reference number ISO/FDIS 24444:2010(E)



CHANGE ONE

How we of Test Subjects

Subjective Fitpatrick Approach Now defunct



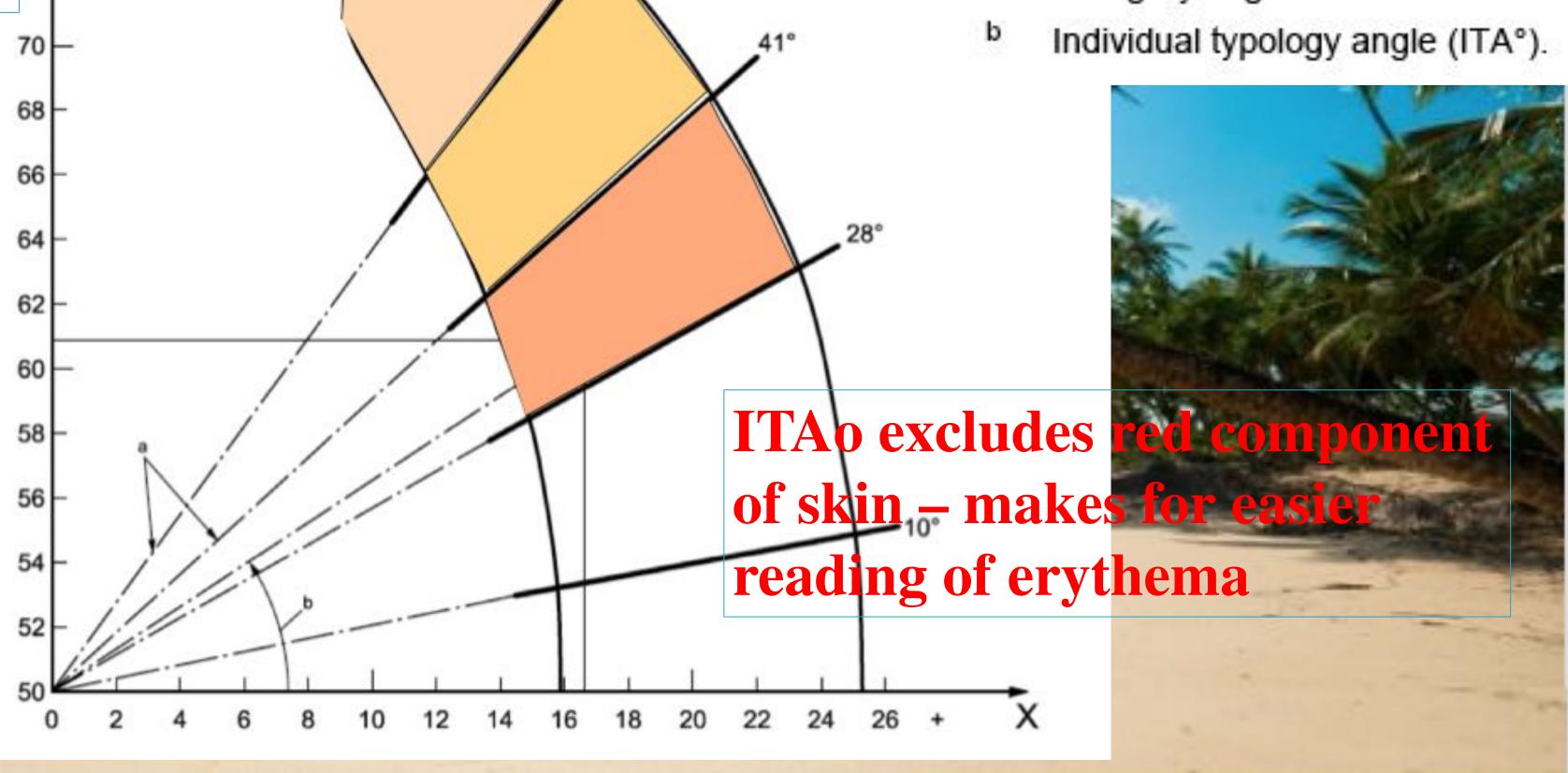


CHANGE ONE

Individual Typology Angle

80

Objective Measurement 78by Spectrophotometer now applies!



Skin Type versus ITA

Key

- b* (Yellow chroma) х
- L* (Luminance) Y
- "very light"
- "light"
- "intermediate"
- "tan"
- "brown"
- Category angles.

CHANGE ONE

ITA^o based Mix of Skin Types

"average ITA° for the test panel to be within the range 41° to 55°, with a minimum of three subjects within two of the three ITA° ranges."

To accommodate differing populations



CHANGETWO

Different Product FORMS – Different Methods

Form	Reco
Lotion	Method A
Cream	Method A
Oil	Method A
Liquid	Method A
Gel	Method A
Stick	Method B
Balm	Method B
Aerosol spray	Degas ther
Pump spray	Method A
Roll on	Method A
Powder	Method C
Foaming Formulations	Method D

ommended application method

- direct from syringe
- weighing boat and finger dip
- weighing boat and finger dip
- en Method A

- or B
- moisten and apply with applicator
- allow to defoam







CHANGE FOUR

CALIBRATION OF SOLAR SIMULATOR

Around 15 times sunlight intensity

SOLAR



5 or 6 exposures simultaneously

Multiport Exposures



RELATED

W.R. NEW ISO METHOD 16217

Additional if water Resistance Claim...

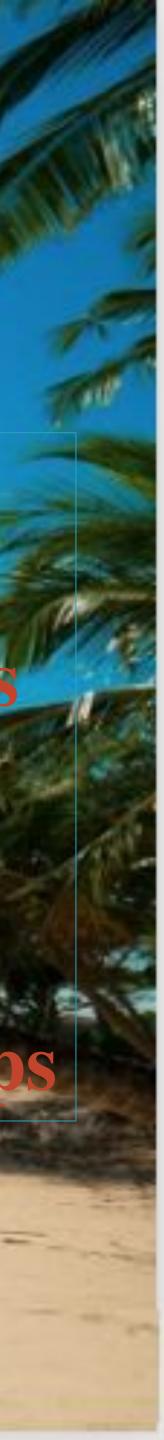
Cosmetics — Sun protection test methods — Water resistance — Water immersion procedure

spa and equilibrate

le in and out periods

Air dry test subject

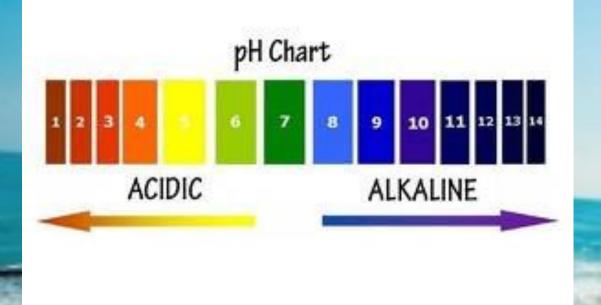
Revert to stat



RELATED

Water Resistance PARAMETERS





PH

Lab Tem

ISO 16217:2021

CirculationSpeed





Temperature



Sanitising

Temperature



Not Specified in ISO 16217...

NO WASH OF CREDIT!

Cosmetics — Sun protection test methods — Water resistance — Water immersion procedure

RELATED



.. and similar



RELATED

Not Specified in ISO 16217... **Additional method ISO 18861 applies**

Cosmetics — Sun protection test methods — Water resistance — **Percentage of water resistance.**





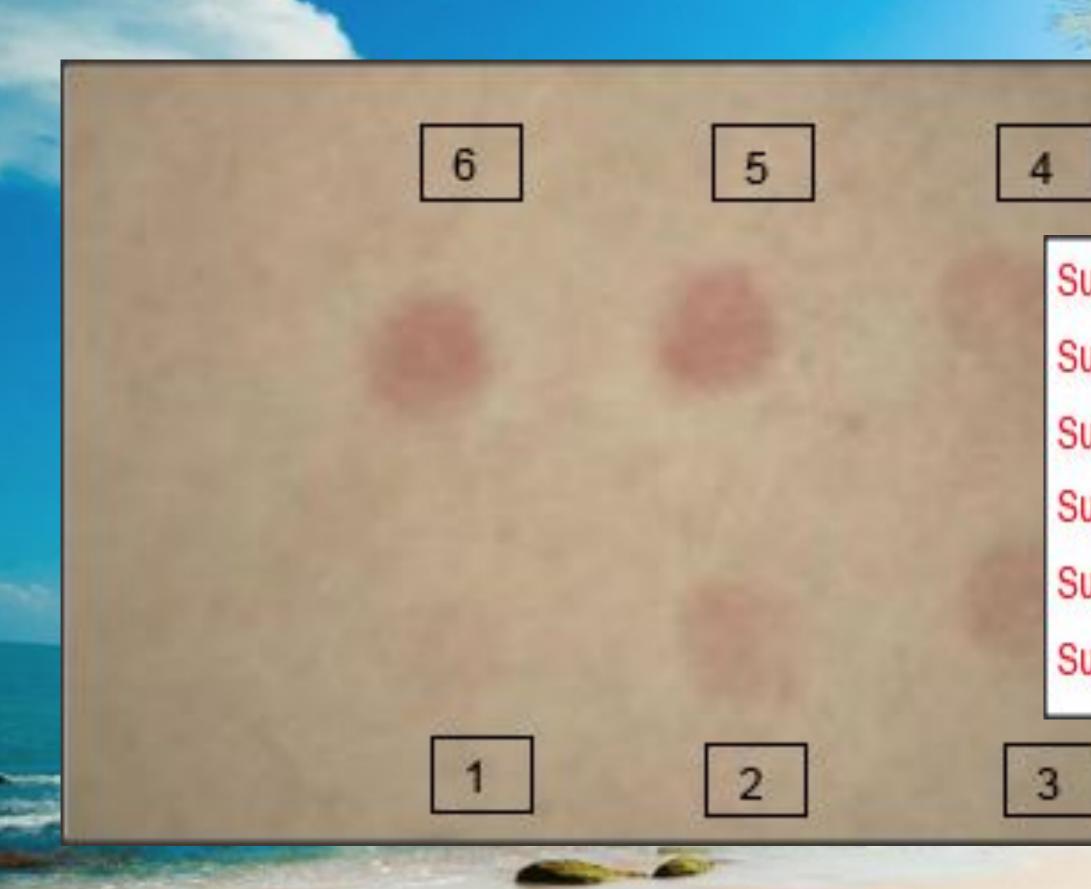
MERCOSUR

DISCOUNT for these markets



CHANGE FIVE

Visualisation of the MED



Reading of Results – 5 or 6 exposure spots



Subsite 1: ambiguous erythema, – no clear border Grade 0.5 Subsite 2: unambiguous erythema, >50% of area, clear border: Grade 1 = MED Subsite 3: unambiguous erythema, >50% of area, clear border: Grade 1 Subsite 4: unambiguous erythema, >50% of area, clear border: Grade 1 Subsite 5: unambiguous erythema, >50% of area, clear border: Grade 2 Subsite 6 unambiguous erythema, > 50% of area, clear border: Grade 2





CHANGE SIX

Calculation of the SPF

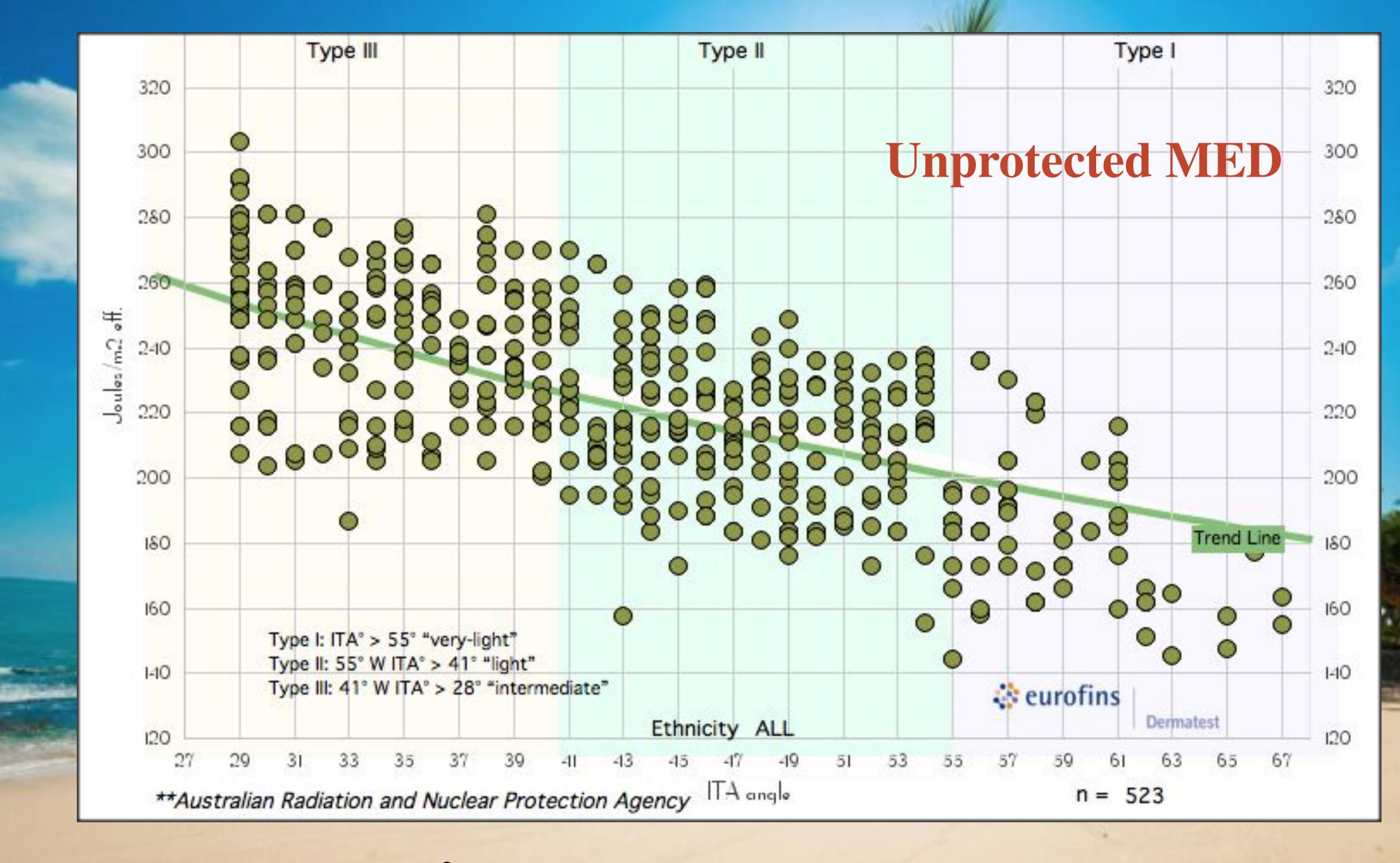
FACTOR is the Protected value Divided by the Unprotected value (1)

SPF previously arrived at from seconds of exposure ... but now arrived at from Joules per m2.



CHANGE SIX

Plotting Skin Types in Joules /m2



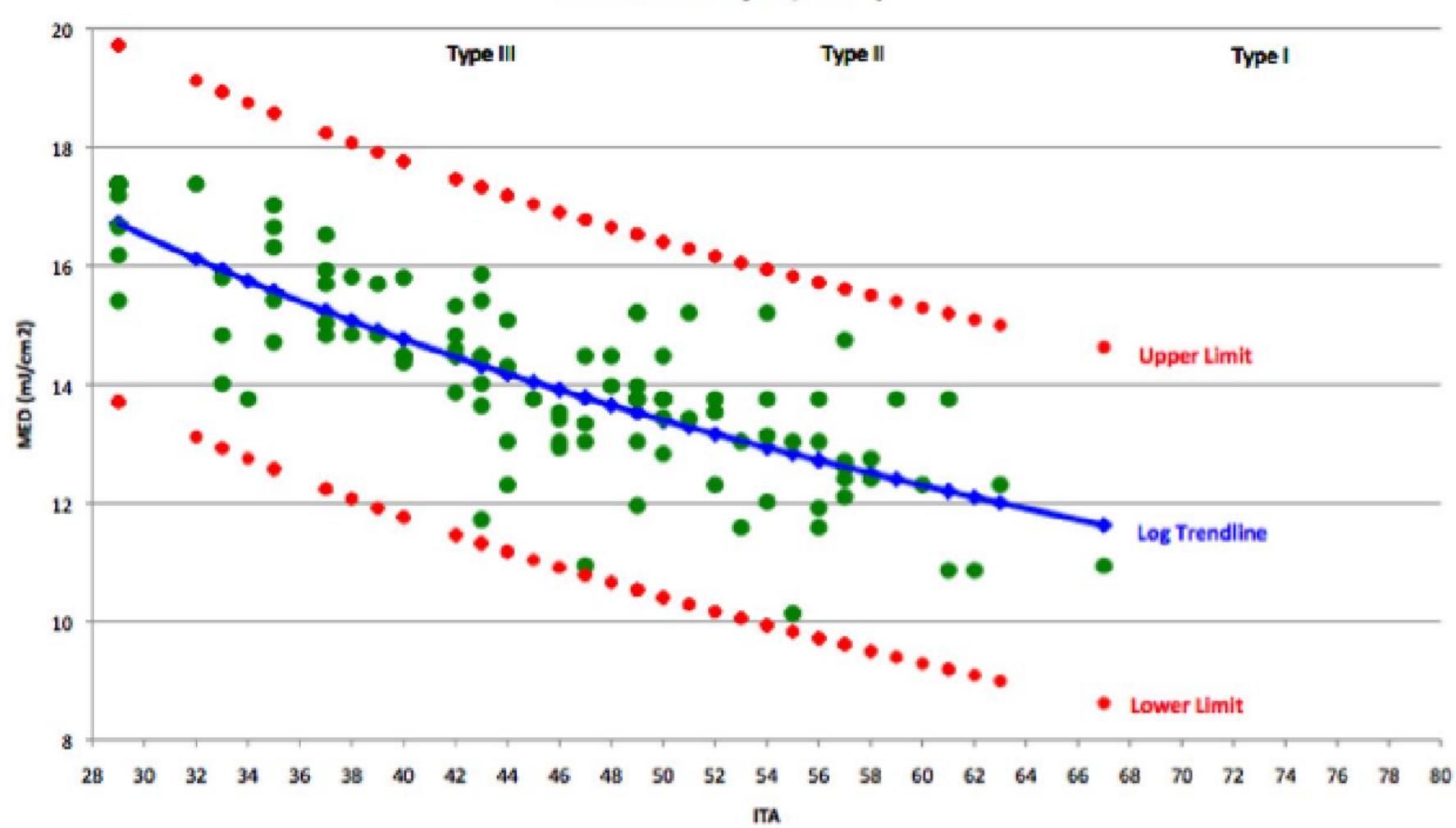
ISO 24444:2019 Annex E Fig E.2 MEDu versus ITA^O Value for Known Subjects



CHANGE SIX

Limits set in the Future?





Would further Improve Consistency

ITA vs MED (mJ/cm2)



CHANGE SEVEN

Reference Sunscreen Formulation	Mean SPF
P2	16.1
P3	15.7
P5	30.6
P6	43.0
P8	63.I

Now 5 Reference Sunscreens!

ISO 24444:2019

ADDED SPF REFERENCE SUNSCREENS

Lower Limit	Upper Limit
13.7	18.5
13.7	17.7
23.7	37.4
31.0	54.9
43.9	82.3



CHANGE EIGHT

eurofins Dermatest ISO 24444 SPF Test Method- 2019. All Results Table G1

		-															Dose Ir	crements:	Single	Port 1.	.12. N	Multipo	nt 1.1	>					
			TES	Т				SIM		1	EST SUBJEC	CTS																	
			Subj	Subject Exposure. Appl. Exp. Read		Sim EE (highest)	Subject	Skin	MEDu	MEDu N		SPFi	Rej?	P2 Reference Standard			High Reference Standard				ıdard								
			No	date	by	by	by	W/m² eff	code	ITA [®]	secs. J/m ² eff	secs	J/m ² eff			sec	s. J/m ²	ff SPF	. p#	secs	s J/n	n² eff	SPI	P					
			1	29/4/22	HL	H. L	HF	13.06	92747	60	10 139	908	7786	56.0	No	232	20	16 14	5 00	002) 0	000	60						
			2	2/5/22	HL.	H. L	HF	13.06	92655	51						T	able	1 - Da	ita i	ejec	tion	ı cri	iteri	a					
			3	17/5/22	2 HL	H. L	HF	11.57	92749	32									-	100						r			
		-	4	20/5/22	2 HL	H. L	HF	11.80	92518	46	Ob	serva	ation	-1		M	Dw					ME	Dw			Reference stand			
			5	23/5/22		HL	HF	13.67	92366	51	Nograd	e of a	tleast 1	1 Da	ta for	subie	ctisr	ejected	D	ata fo	orte	est vr	rodu	ctis		Data for subject is re			
			6	26/5/22		HL	HE	11.73	00843	56	for any							2		ejecte		-							
IN	CL	UD	JES			A]		D 1	D TES		sites			all	owabl	ereje		nst tota umber	ם	oesn	lotc			in st to		Pailure counts a gain allowable rejected n			
SPFi	I ST	TR			R	RS	T	ТТ	S	54 45				of	subjec	ts				llowa f subj			:ted :	numbe	er	ofsubjects			
				CT RESULTS 45							Alltest				tafor	subje	ctisr	ejected	C 12.	ata fo		est pr	rodu	ctis		Data for subject is re			
55.2	YES	MEDp	below 1									erythema of at least grade 1 ^b Does not count against rejected								Counts a gainst num									
	YES	Non-co	mpliant	test subj	ject						Erade T.			nu	mber	oftot	alallo	wable			_			iber o		total allowable reject			
	YES	MEDu	below 1											re	ection	S		e coso e sec.	te	otala	llow	vable	reje	ctions	s				
62.0	YES	MEDr	below 1						_		erythen	ial re	spon-	Da	ta for	subje	ctisr	ejected	D	ata fo	or su	ubjec	tis	rejecte	ed	Data for subject is re			
75.0	YES	MEDra	all spots	show Er	ythem	na					se(s) is (se(s) is (are) ab sent Does not count against Counts against number of								Counts a gainst num									
											for expo			r				wable			_			ctions		total allowable reject			
									-		than the			1 mot	ection			ALL DIC			4014				-				
-									-	ļ	MED do	-	mdomly	7		5													
									(g spf	5 absent)	0.022			0 90	27132			_	0.000			-2003		20				
											Non-cor	-	nce of t	he Da	tafor	subje	ctisr	ejected	D	ata fo	or su	ubjec	tist	rejecte	ed	Data for subjectisre			
											2 subject ^d			Do	esnot	coun	tagai	nst	D	oesn	otc	ount	aga	inst		Doesnot countagair			
1000	-				0.0				Io	59.4	OR						_	wable					_	wable	e	number of total allow			
			Test	Conditi	on: S	tatic	Test	ina			Technic	alfail	lure®	rej	ection	s	Contraction		r	ejecti	ons		1.000			rejections			
			1031	Condin	011. 0	latio	1001						Signot	t Studi	Direct	or													
											00 011	11.0	2040	A 10.10															

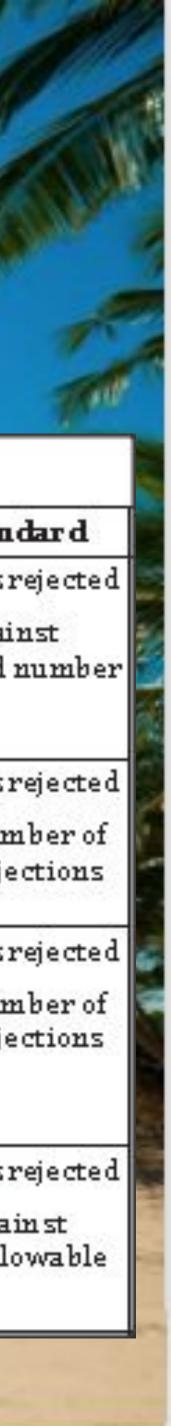
Normative Report Formats - 3

Report Reference Number:

Report Date:

Dose Increments: Single Port 1.12. Multiport 1.15

ISO 24444:2019 Annex G



Multiple Beam Simulator

Specification for P8 Ref Std Viscosity



ISO 24444: 2019 Amendment 1 – 2021

Multiport)

Removal of Stats test for Reference Standards

Very minor changes !



based	<i>In</i> IS d on VSO 24443	0
STEPS	ISO 24443	
PMMA Plates	Moulded	M Sa
Application of Product	Manual or Robot	Ro
Pre-irradiation UV Measurement	Yes	Ye
UV exposure	Yes	Ye
Post-irradiation UV Measurement	Yes	Ye
Calculation	UVAPF in vitro	SF

23675

ISO 23675

Moulded AND Sandblasted

Robot

les

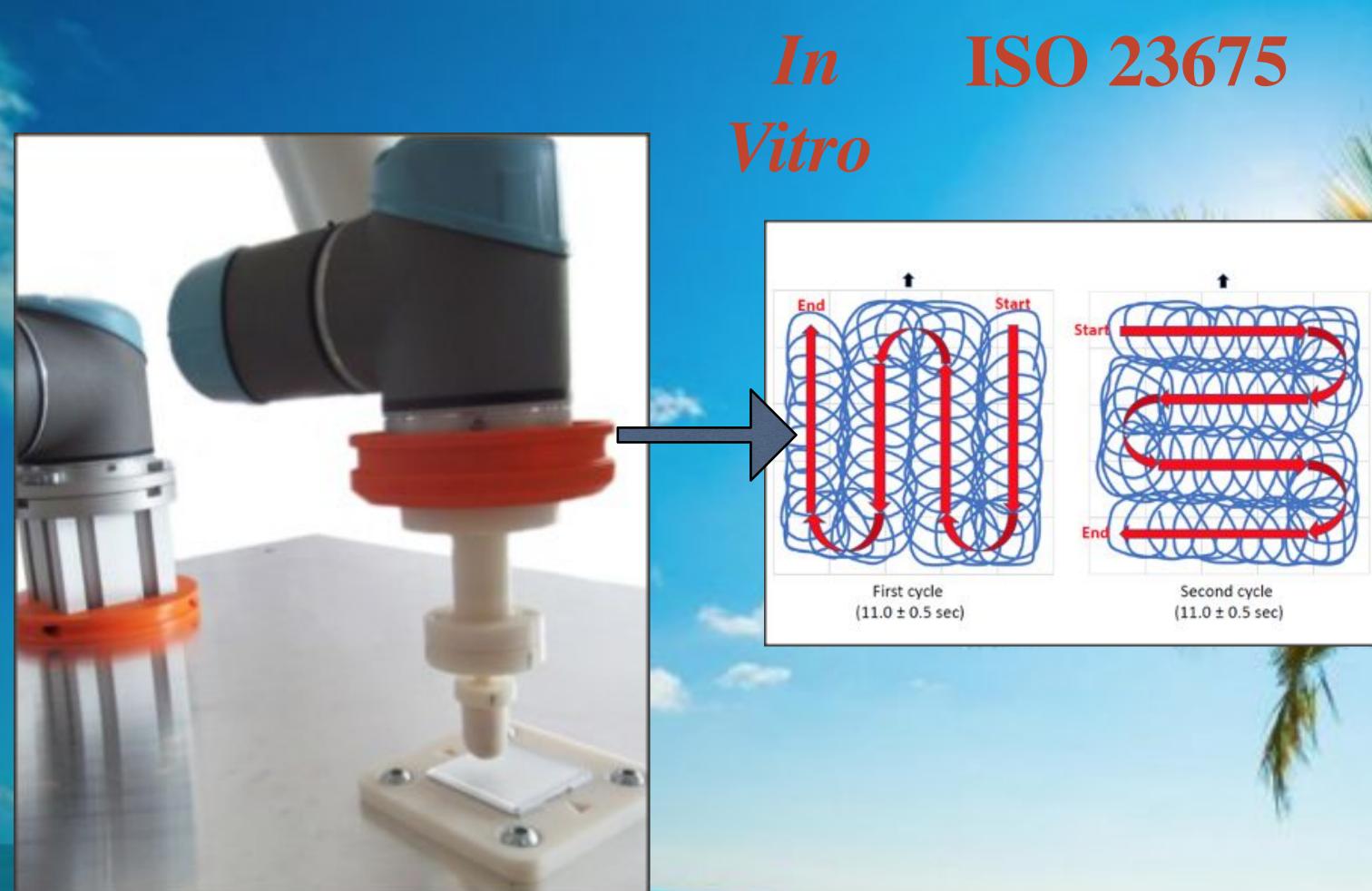
les

les

SPF in vitro







HelioScreen Spreadmaster

Requires use of a robot

2 kinds of PMAA plates... ... moulded and sand blasted

Third cycl (11.0 ± 0.5





Hybrid In Vitro ISO 23698 Diffuse Reflectance Spectroscopy

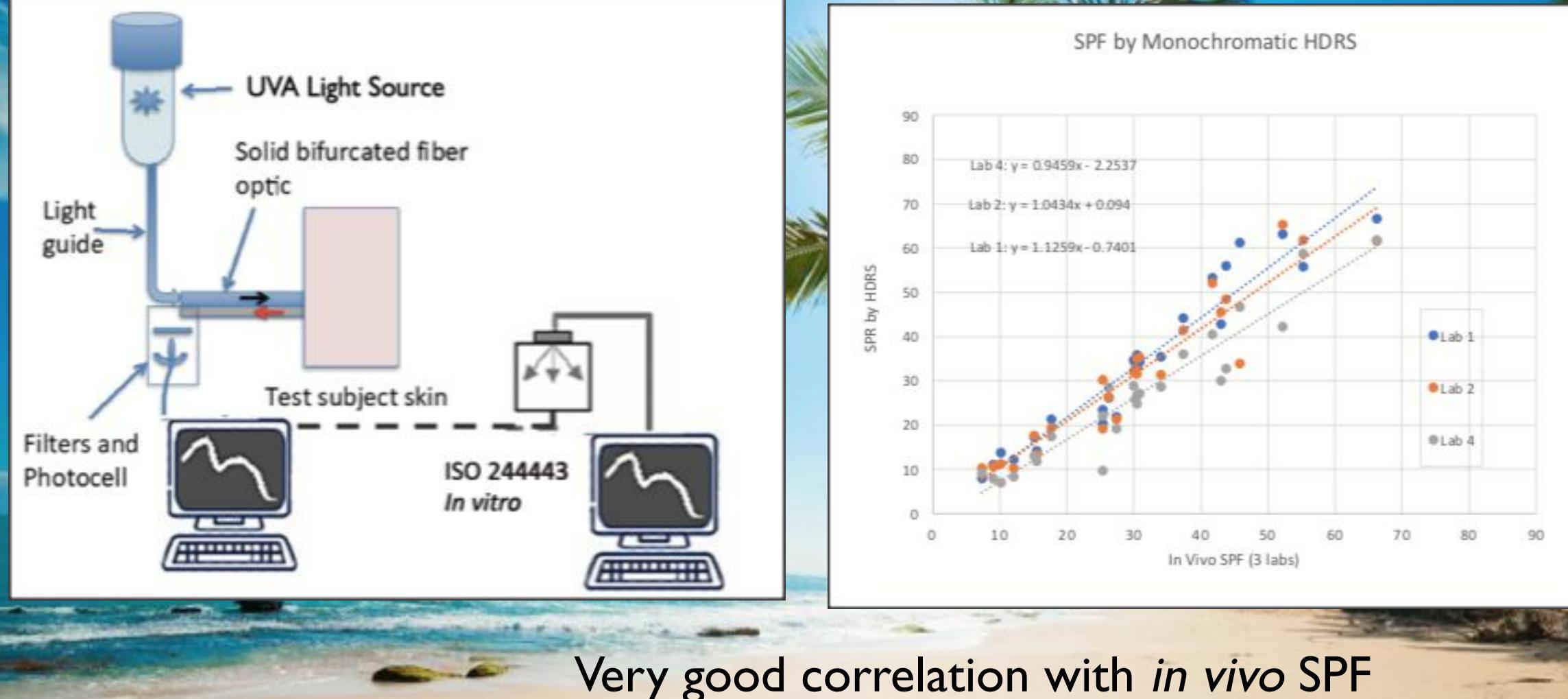


Solar Light Co





Hybrid In Vitro ISO 23698



Cole C, Silverman J, Bonitatibus M. Evaluating sunscreen ultraviolet protection using a polychromatic diffuse reflectance device. Photodermatol. Photoimmunol. Photomed. 2019, 35(6), 436-441.



FILTER SELECTIO	ON STATE		
FILTER SELECTR	Max.		
- BP3	10%	6	
- BMDBM	10%	3	
- EHS	10%	5	
- HMS	15%	7	
- OCR	10%	3	
Total:		24.00	
SPE (SUN PROTE	CTION	ACTOR	
SPF (SUN PROTE	CTION	ACTOR	
SPF:	0	23.1	
Rating:	0	20	
Filter Efficiency:	0	0.96	
ECOSUN PASS V			
UVA-METRICS	100		
EU, AUS, MER			
Rating:	0	(UVA)	
	(ISO 24	443)	
UVA-PF in vitro	1.00 21		
UVA-PF in vitro		9.2	
		9.2 0.4	

Creatic

-BASF

In Silico



Europe Target SPF	1
Add filter	ð
× PARSOL EHS (5.0%)	5 🗘
× PARSOL HMS (10.0%) i	7 🌲
× PARSOL 340 (10.0%) i	3 🌲
× BP-3 (6.0%) i	6 🌲
× PARSOL 1789 (5.0%) i	3 🌲
Add parameter	
× Total (%) i	24.0
× SPF i	25.7
× SPF Rating (EU) i	25
× UVA-PF/SPF (EU) i	0.53
× CW (ISO) i	378
× CW (USA) i	378
× FDA UVA Rating i	broad
× UVA-PF in vitro i	13.5
× UVA-PF in vivo i	13.9
× JCIA Rating <i>i</i>	PA+++



🕲 ISO 2020 - All rights reserved



ISO/TC 217/WG 7

Date : 2020-0-7-15

ISO/CD 23698:2020(E)

Cosmetics Europe Recognise both methods for R & D

Cosmetics — Measurement of the Sunscreen Efficacy by Diffuse Reflectance Spectroscopy

Cosmétiques — Mesure de l'efficacité de l'écran solaire par spectroscopie de réflectance diffuse

Committee Draft

Warning for WDs and CDs

This document is not an ISO International Standard. It is distributed for review and comment. It is subject to change without notice and may not be referred to as an International Standard.

Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

... but ISO is sitting on "CDs" i.e CLOCK STOPPED

©ISO 23675 - All rights reserved

ISO 23675

ISO TC 217/WG 7

Secretariat AFNOR



In Vitro Determination of

Cosmétiques — Mesure de l'efficacité de l'écran solaire par spectroscopie de réflectance diffuse

Committee Draft

Warning for WDs and CDs

This document is not an ISO International Standard. It is distributed for review and comment. It is subject to change without notice and may not be referred to as an International Standard.

Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.





Too expensive and complex for ISO 70 Started 2021 Administered by Cosmetics Europe **32 Sunscreens involved** -C-Stage 2 : Testing SPF by ISO 23675 [Robot]

https://www.alt-spf.com

ISO awaits **ALT-SPF...**

Euros

Stage 1 : Testing SPF by ISO 24444 "Gold Standard" and ISO 23698 [HDRS]



Value of testing to ISO 24444 in vivo method

Region	
Australia	
New Zealand	-
European Union 28 countries	
India	
China	
Japan	
Taiwan	
Korea	1/1
MERCOSUR 6 countries	
USA	
Canada	
ASEAN 10 countries	
South Africa	
Mexico	
Chile 5	
Russia	91
Israel	
India	

ISO 24444

YES

YES

NO – sort off!

YES YES YES

YES

YES

YES

YES

YES

YES

YES

YES

YES





