



**New Sunscreen Test
Methods – With and
Without Humans**

May 2023

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SciPharm Pty Ltd**

- 
- 1. Main Changes in Sunscreen Standard ISO 24444**
 - 2. New Alternatives Overview**
 - 3. Progress with SPF Tests Development**

1. ISO 24444 : 2019

LIFE CYCLE

A standard is reviewed every 5 years



50.00 2019-07-26
Final text received or FDIS registered for formal approval

50.20 2019-09-13
Proof sent to secretariat or FDIS ballot initiated: 8 weeks

50.60
Close of voting. Proof returned by secretariat

REVISIONS / CORRIGENDA

Previously

© ISO 24444:2010



Now under

© ISO/FDIS

from here...
up to 6 mths
or more ☐

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:
2018-02-25

Voting terminates on:
2018-04-25

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

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

Please see the administrative notes on page iii

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LIGHT OF THEIR POTENTIAL TO BECOME STANDARDS
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NATIONAL REGULATIONS.

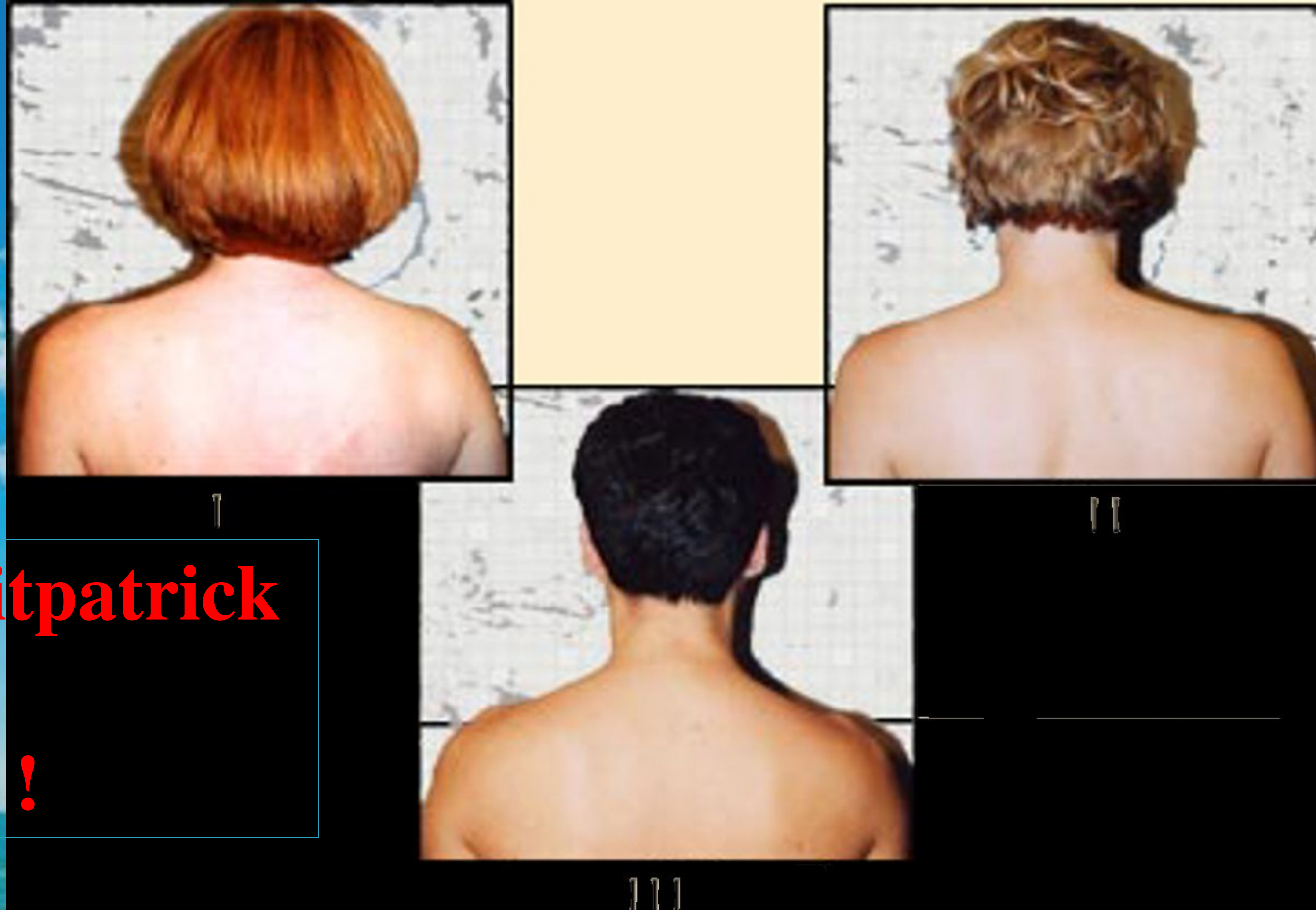


Reference number
ISO/FDIS 24444:2019(E)

©ISO 2019

CHANGE ONE

How we of Test Subjects



**Subjective Fitzpatrick
Approach
Now defunct !**

Skin Types range still the same

CHANGE ONE

Individual Typology Angle

Key

X b^* (Yellow chroma)

Y L^* (Luminance)

1 "very light"

2 "light"

3 "intermediate"

4 "tan"

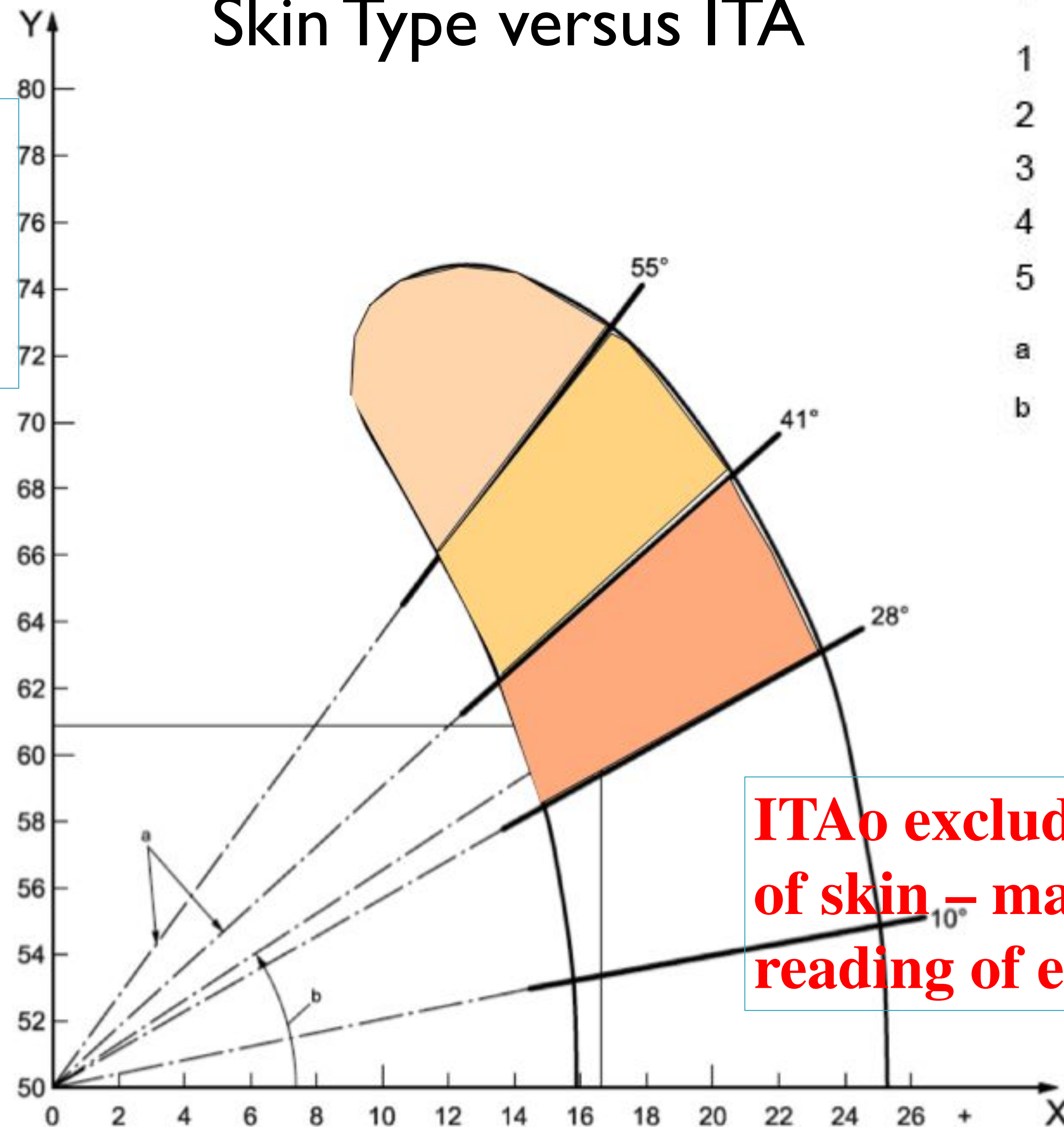
5 "brown"

a Category angles.

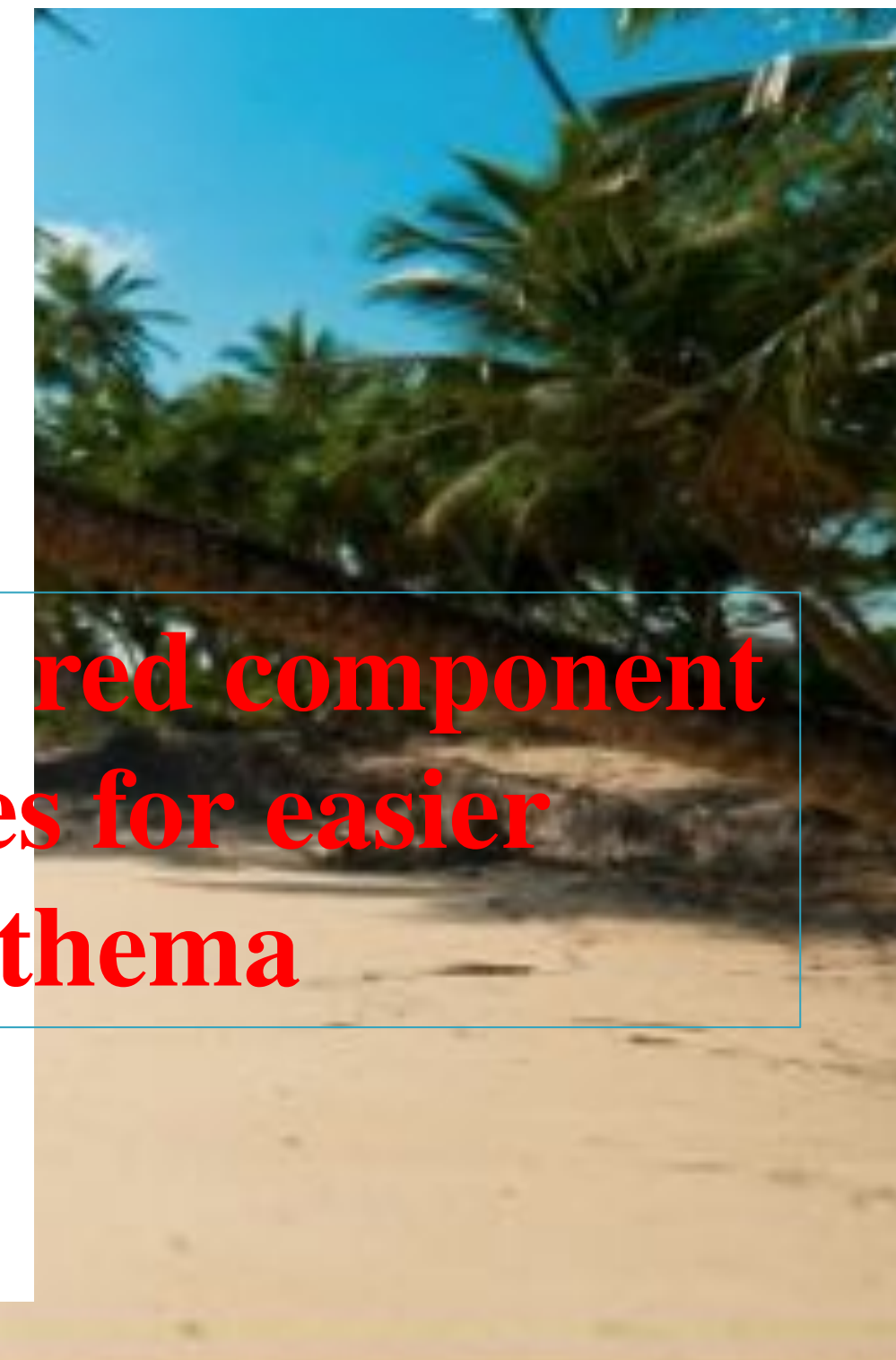
b Individual typology angle (ITA°).

**Objective Measurement
by Spectrophotometer
now applies!**

Skin Type versus ITA



**ITA₀ excludes red component
of skin – makes for easier
reading of erythema**



CHANGE ONE

ITA° 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





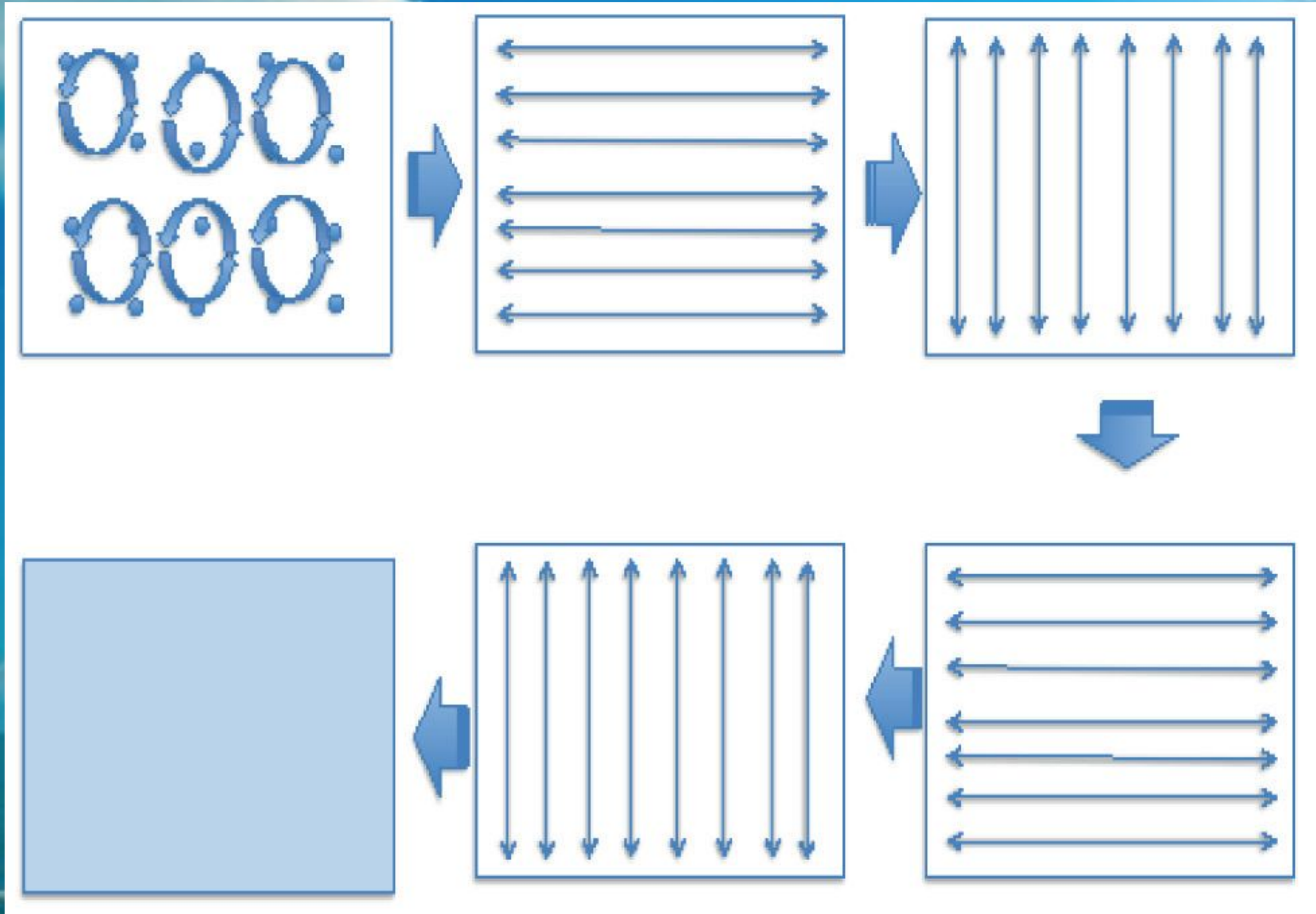
2 mg

Form	Recommended application method
Lotion	Method A - direct from syringe
Cream	Method A - direct from syringe
Oil	Method A - direct from syringe
Liquid	Method A - direct from syringe
Gel	Method A - direct from syringe
Stick	Method B – weighing boat and finger dip
Balm	Method B – weighing boat and finger dip
Aerosol spray	Degas then Method A
Pump spray	Method A
Roll on	Method A or B
Powder	Method C – moisten and apply with applicator
Foaming Formulations	Method D – allow to defoam



CHANGE THREE

RUB-OUT METHOD very specific



Product Application 35 Seconds!

CHANGE FOUR

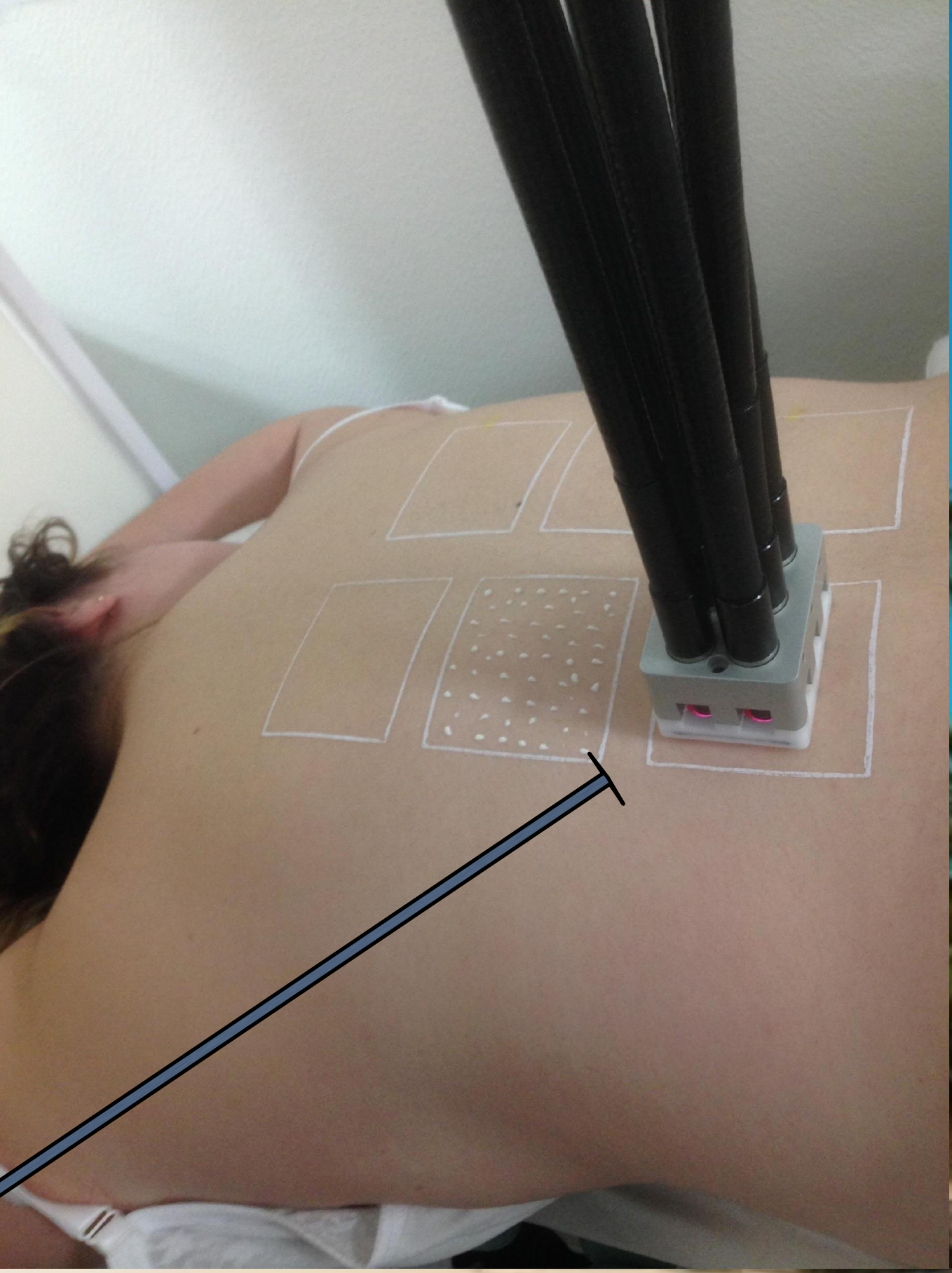
CALIBRATION OF SOLAR SIMULATOR



Around 15 times sunlight intensity



5 or 6 exposures simultaneously



Multipoint Exposures

RELATED

W.R. NEW ISO METHOD 16217

Additional if water Resistance Claim...

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

- Fill spa and equilibrate
- Cycle in and out periods
- Air dry test subject
- Revert to static SPF steps



RELATED

Water Resistance PARAMETERS



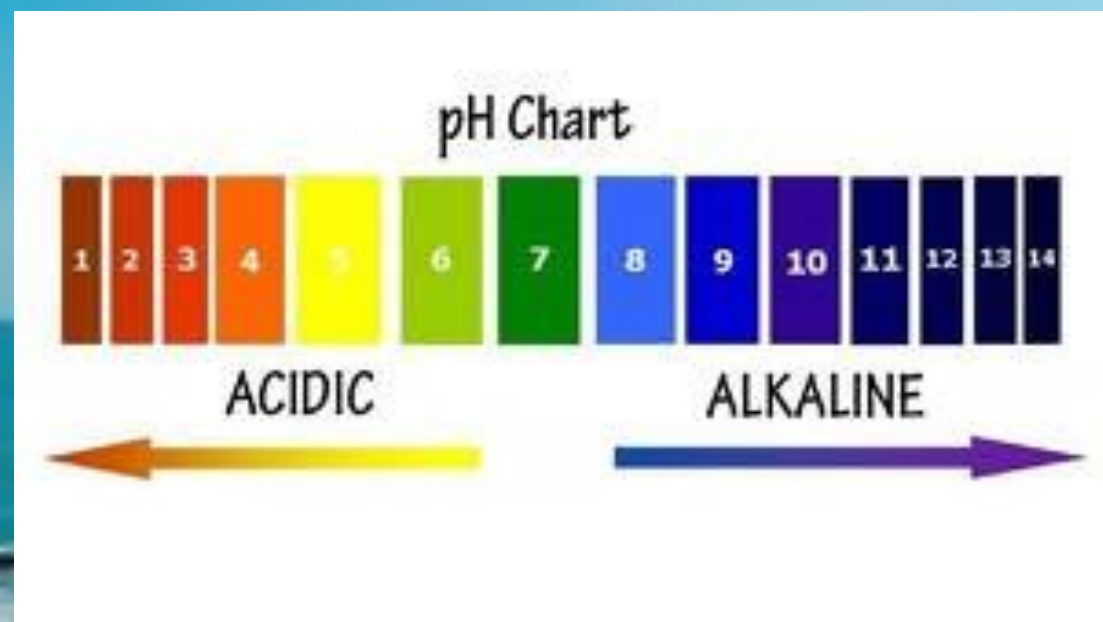
Conductivity



Circulation Speed



Temperature



pH



Lab
Temperature



Sanitising

RELATED

Not Specified in ISO 16217...

NO WASH OF CREDIT!

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



... and similar in...



RELATED

Not Specified in ISO 16217...

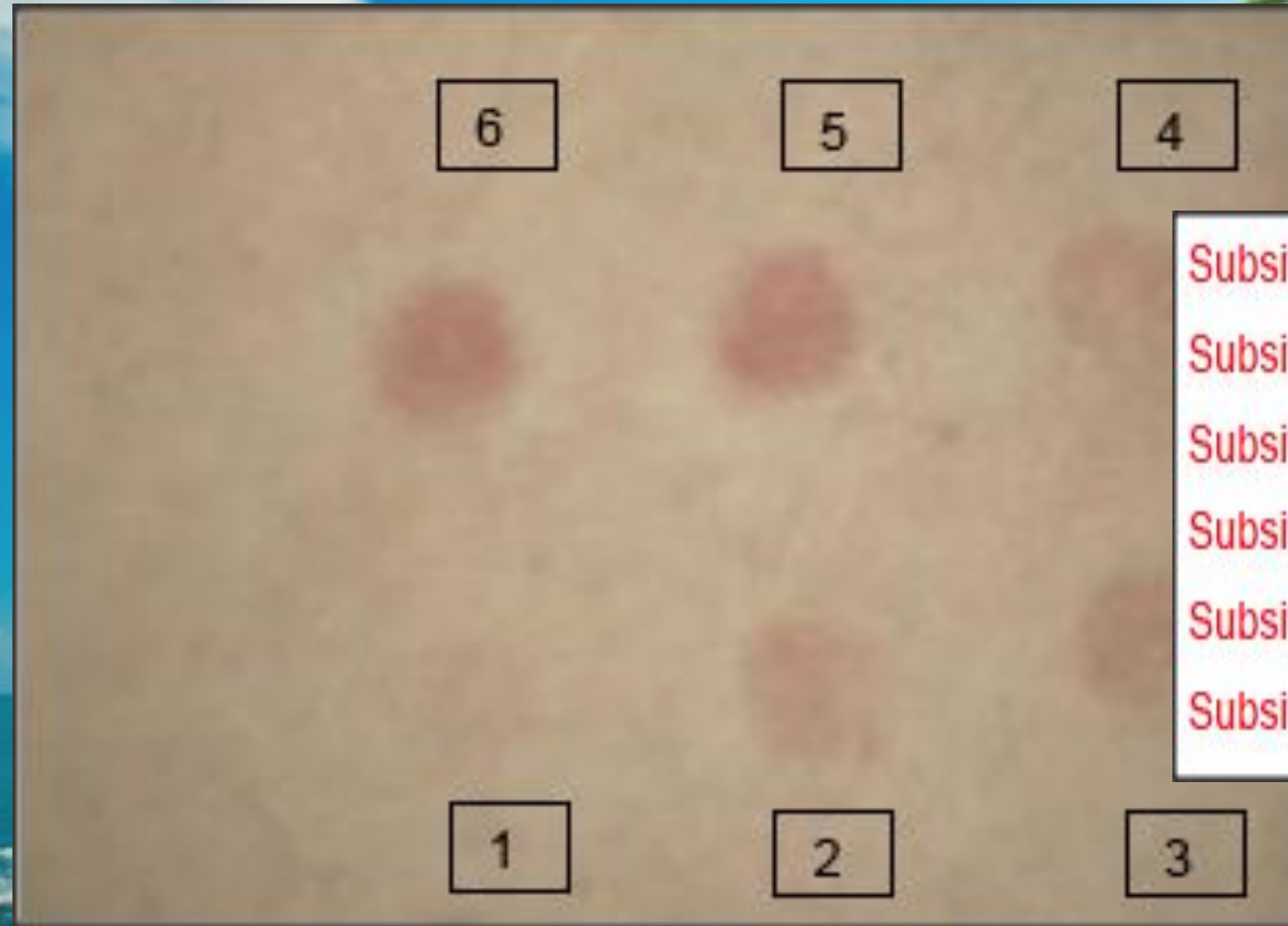
Additional method ISO 18861 applies...

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



50% Washoff DISCOUNT for these markets





- 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

Reading of Results – 5 or 6 exposure spots

CHANGE SIX

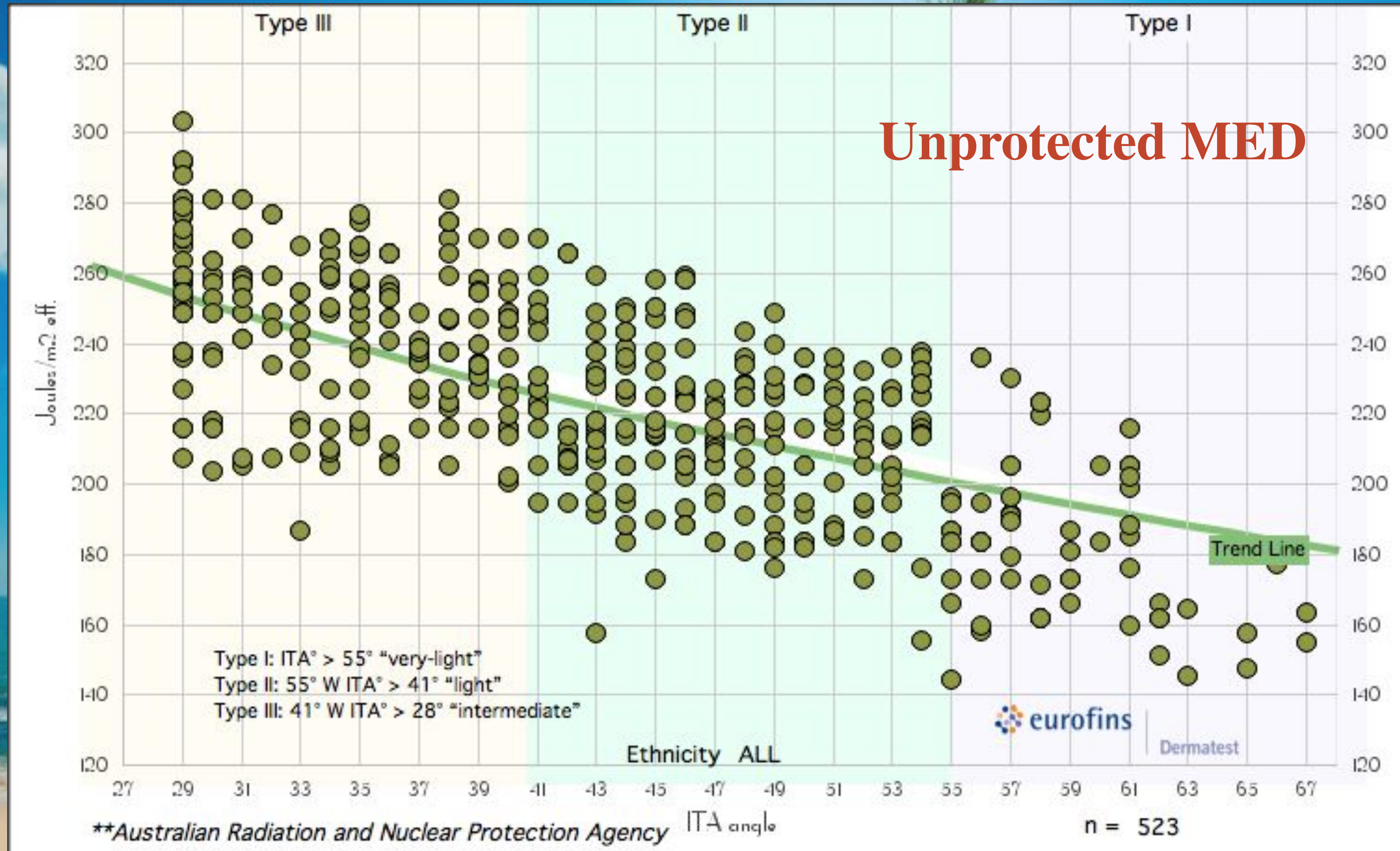
Calculation of the SPF

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

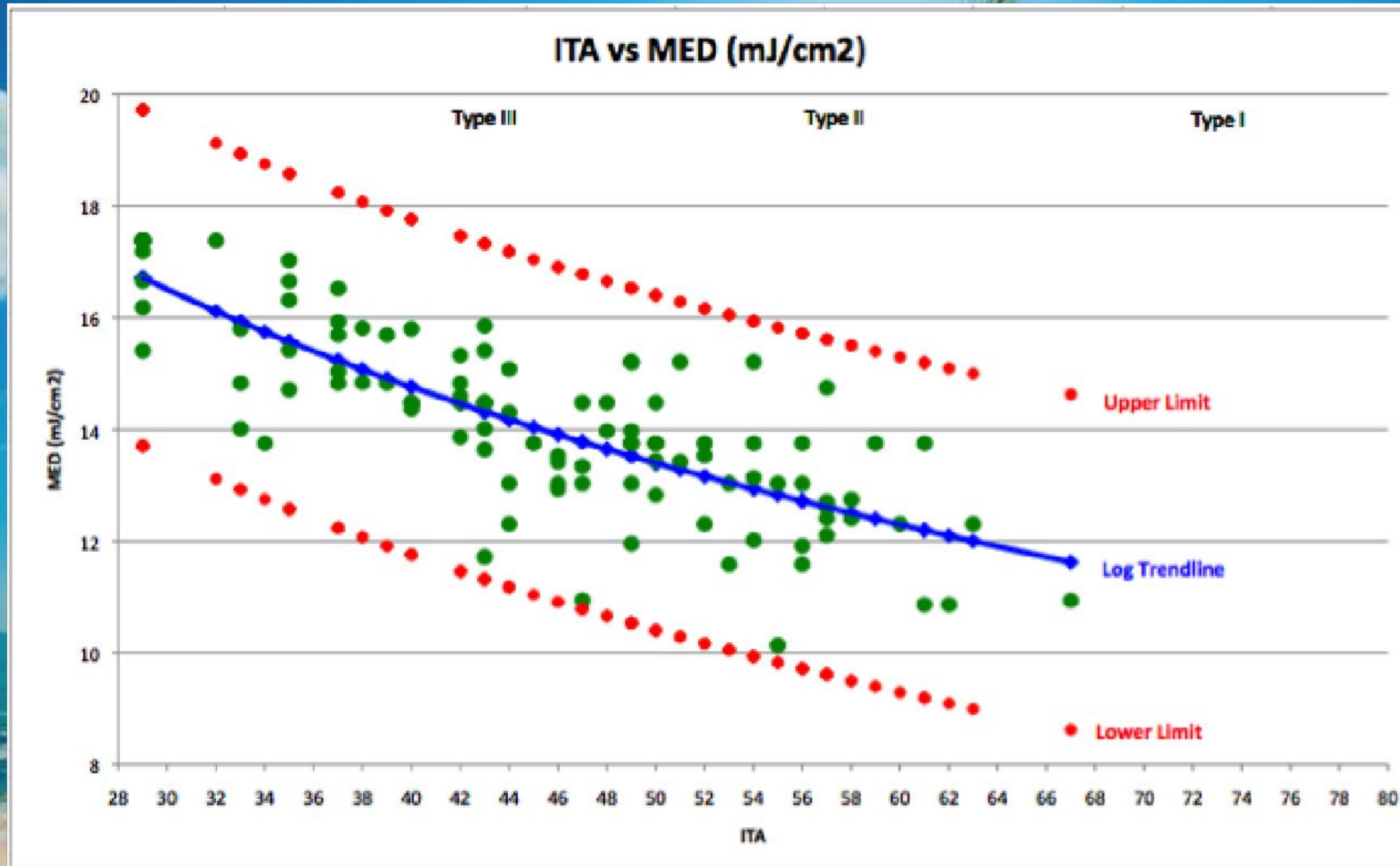
SPF previously arrived at from **seconds of exposure**
... but now arrived at from **Joules per m²**.



Plotting Skin Types in Joules /m²



Limits set in the Future?



Would further Improve Consistency

CHANGE SEVEN

ADDED SPF REFERENCE SUNSCREENS

Reference Sunscreen Formulation	Mean SPF		
		Lower Limit	Upper Limit
P2	16.1	13.7	18.5
P3	15.7	13.7	17.7
P5	30.6	23.7	37.4
P6	43.0	31.0	54.9
P8	63.1	43.9	82.3

Now 5 Reference Sunscreens!



ISO 24444: 2019
Amendment 1 – 2021

- Multiple Beam Simulator Spec (Multiport)**
- Removal of Stats test for Reference Standards**
- Specification for P8 Ref Std Viscosity**

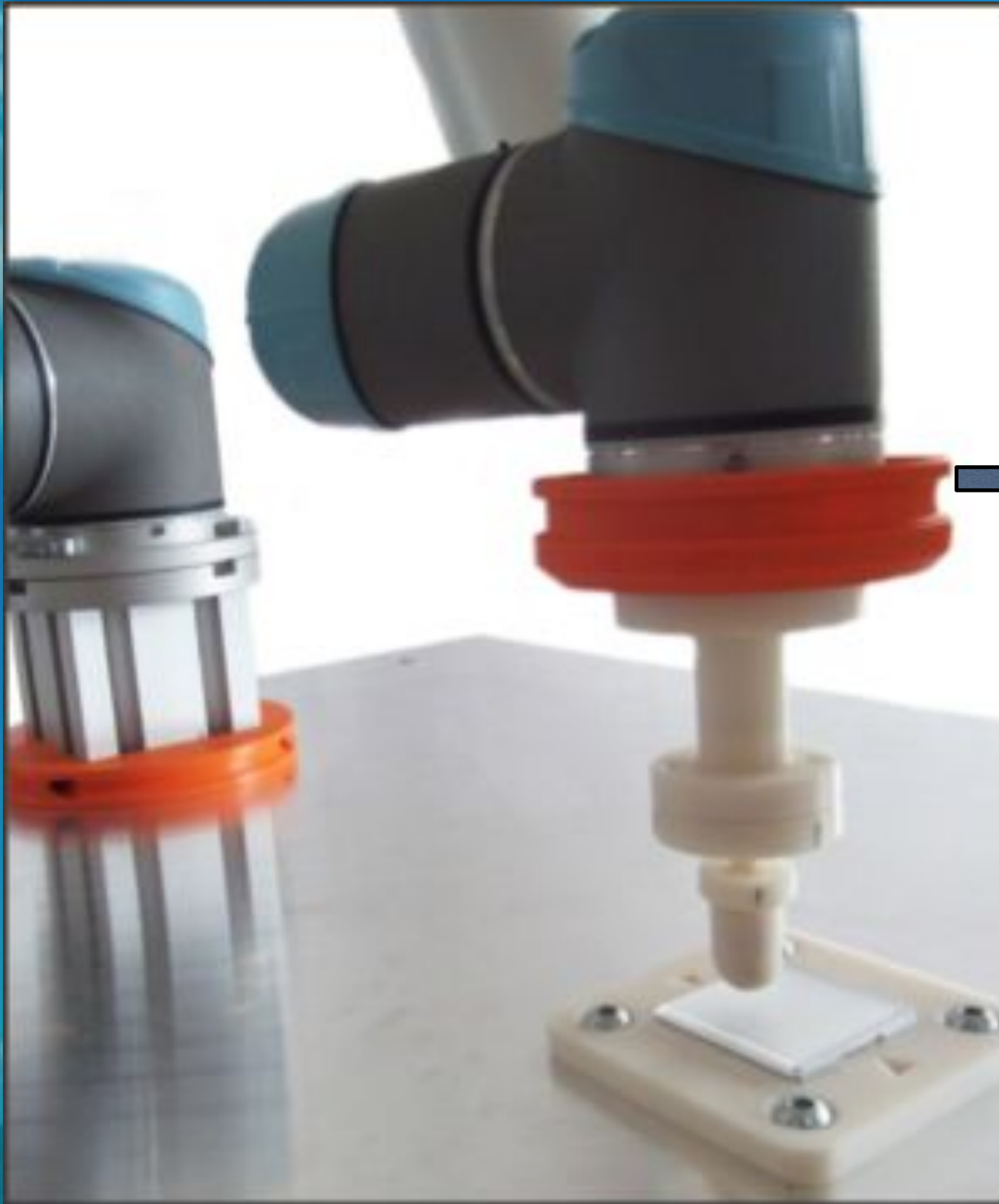
Very minor changes !

In **ISO 23675**
Vitro based on **ISO 24443**

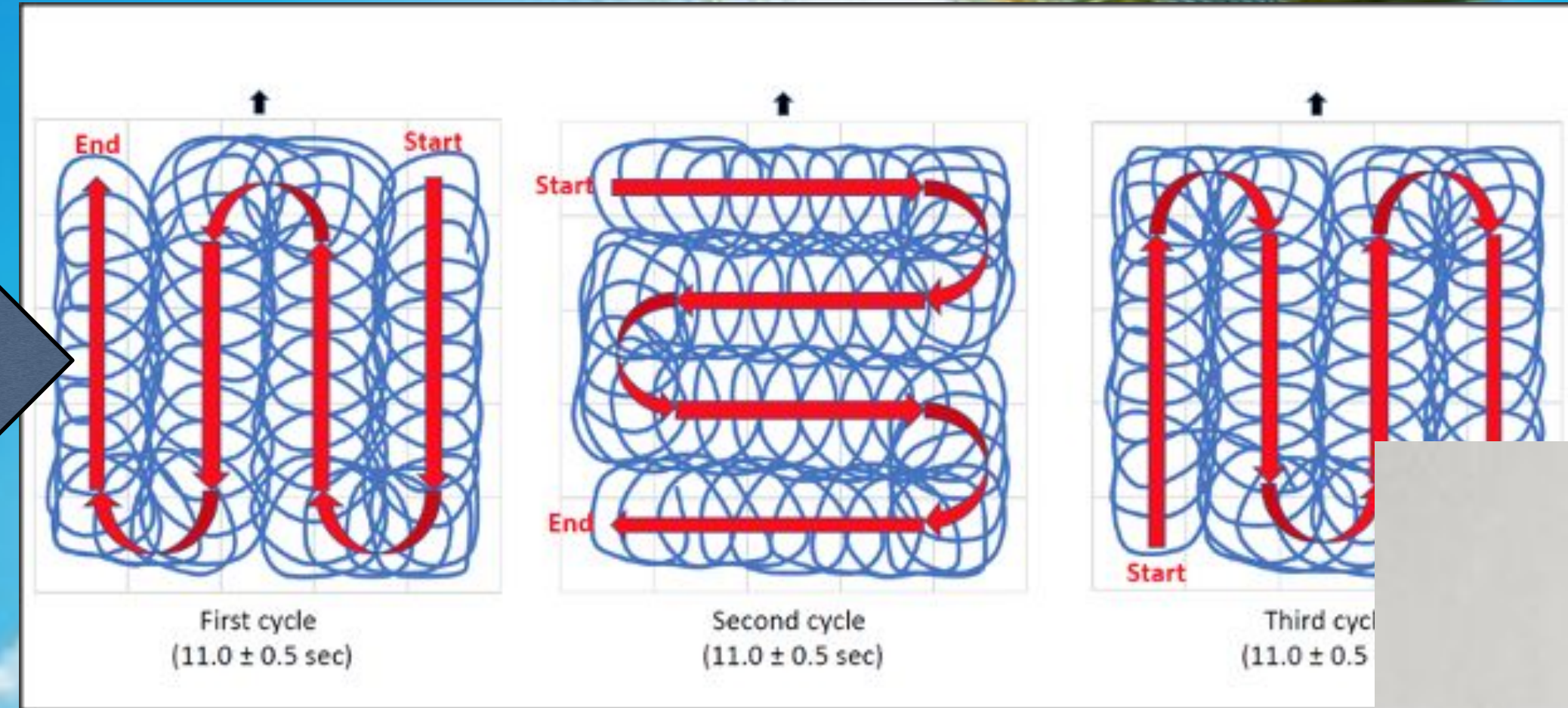
STEPS	ISO 24443	ISO 23675
PMMA Plates	Moulded	Moulded AND Sandblasted
Application of Product	Manual or Robot	Robot
Pre-irradiation UV Measurement	Yes	Yes
UV exposure	Yes	Yes
Post-irradiation UV Measurement	Yes	Yes
Calculation	UVAPF in vitro	SPF in vitro



In ISO 23675
Vitro



HelioScreen Spreadmaster



Labsphere 2000

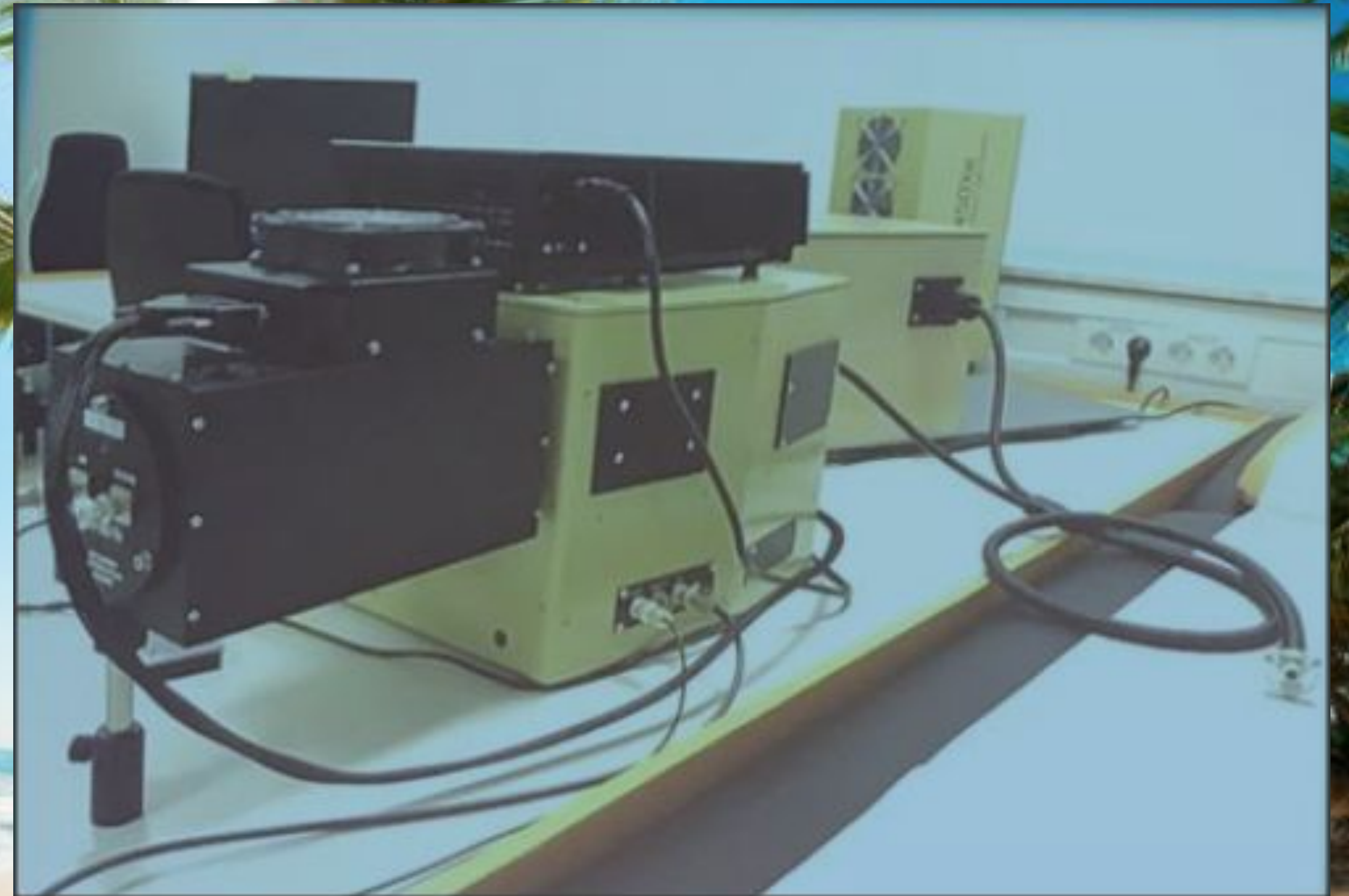
2 kinds of PMAA plates...
... moulded and
sand blasted

Requires use
of a robot

Hybrid In Vitro ISO 23698
Diffuse Reflectance Spectroscopy

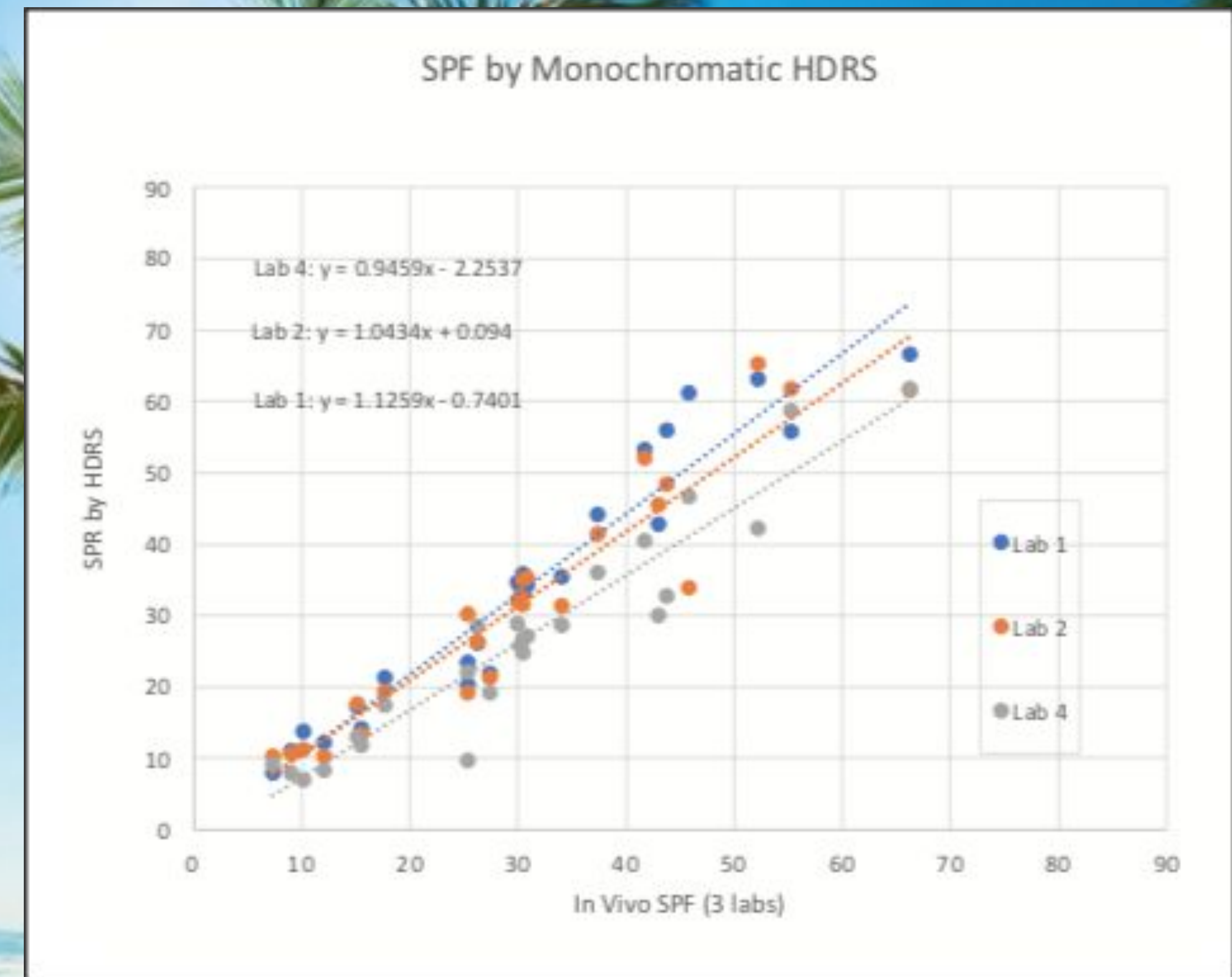
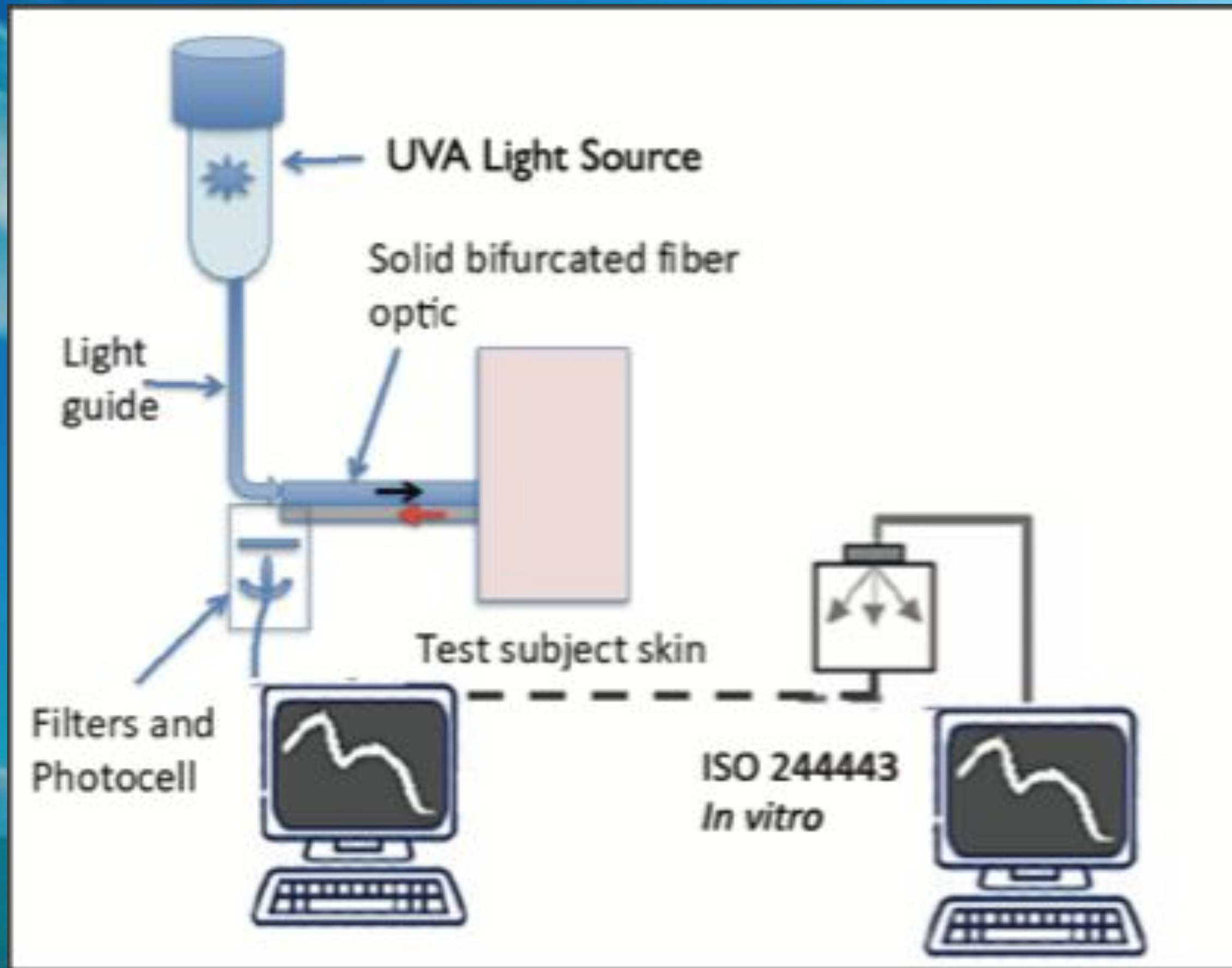


Solar Light Co



Bentham

Hybrid In Vitro ISO 23698



Very good correlation with *in vivo* SPF

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 SELECTION		
Max.		
- BP3	10%	6
- BMDBM	10%	3
- EHS	10%	5
- HMS	15%	7
- OCR	10%	3
Total:		24.00

SPF (SUN PROTECTION FACTOR)		
SPF:	i	23.1
Rating:	i	20
Filter Efficiency:	i	0.96

ECOSUN PASS VALUE <i>i</i>		
UVA-METRICS <i>i</i>		
EU, AUS, MERCOSUR		
Rating:	i	UVA
UVA-PF in vitro (ISO 24443)		
UVA-PF:		9.2
UVA-PF/SPF:		0.4
Critical Wavelength (nm):		373

In Silico



2 free access tools for SPF estimation

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



Where we are...

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ISO/TC 217/WG 7

Date : 2020-0-7-15

ISO/CD 23698:2020(E)



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

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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

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...but ISO is sitting on “CDs” i.e CLOCK STOPPED



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

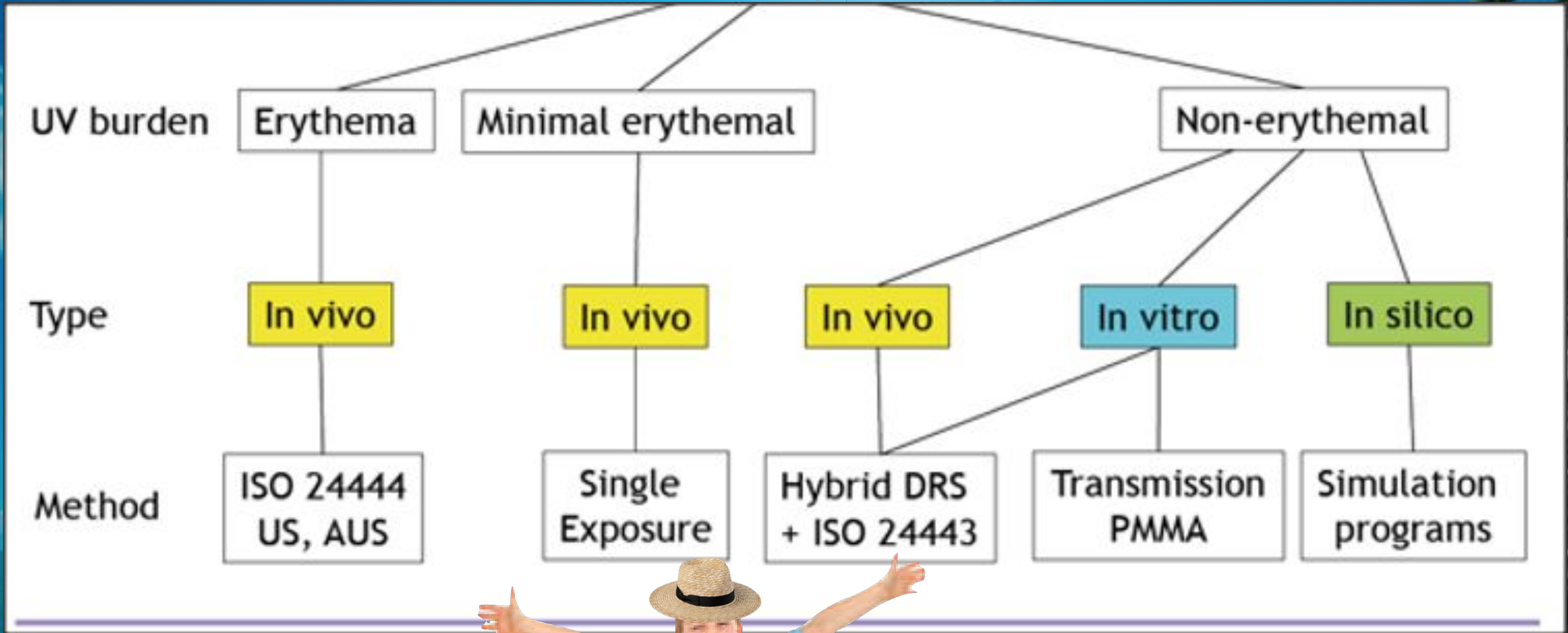
- Too expensive and complex for ISO 700,000 Euros**
- Started 2021**
- Administered by Cosmetics Europe**
- 32 Sunscreens involved**
- Stage 1 : Testing SPF by ISO 24444 “Gold Standard”**
- Stage 2 : Testing SPF by ISO 23675 [Robot]
and ISO 23698 [HDRS]**

Value of testing to ISO 24444 *in vivo* method

Region	ISO 24444
Australia	YES
New Zealand	YES
European Union 28 countries	YES
India	YES
China	NO – sort off!
Japan	YES
Taiwan	YES
Korea	YES
MERCOSUR 6 countries	YES
USA	NO
Canada	YES
ASEAN 10 countries	YES
South Africa	YES
Mexico	YES
Chile	YES
Russia	YES
Israel	YES
India	YES



Summary



FAR FROM

THE

END

