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Official Solaris 36 SPEED™ 205 Re-certification Notice

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January 8, 2001

Re: Re-certification of the Solaris TM SPEED 175 SystemTM

Dear Salon Owner:

Thank you for purchasing the *SPEED*<sup>TM</sup> lamp upgrade kit. This letter will serve as the official recertification notice from the manufacturer of your sunbed. **Please retain this letter, keeping it with your sunbed's original user manual. State or local inspectors may ask to see it.** 

Solaris <sup>TM</sup> 36 SPEED 175<sup>TM</sup> sunbeds have been re-certified to allow the use of the SPEED<sup>TM</sup> 205 Wolff® Model SPD71-T12-205 Bi-Pin lamps in the sunbed's canopy. Included with this letter you will find a new white Quick Clip profile that has the new certification wording silk-screened onto it. Please remove the existing profile from your sunbed and replace it with the new one provided.

The sunbeds included in this re-certification were originally labeled:

Solaris SPEED 175 System<sup>TM</sup> or Solaris 36 SPEED<sup>TM</sup> 175 System<sup>TM</sup>

These units were produced both with and without facetanners.

Please note that the notation "SPEED<sup>TM</sup> 175<sup>TM</sup> System" has been changed to "SPEED<sup>TM</sup> System" to allow for the lamp upgrade. This notation change extends to the ballasts located in your sunbed. The ballasts labeled "SPEED<sup>TM</sup> 175 system" are fully compatible with the new lamps.

The labeling provided on the updated profile has been reproduced and is located on the back of this letter to satisfy the requirements set out in 21 CFR 1040.20 (e) (i).

This upgrade is voluntary and may be performed if the sunbed owner desires. If you choose not to upgrade your equipment rest assured that it is still fully FDA compliant as originally manufactured.

Office of Regulatory Affairs Spectrum Products, Inc.

DANGER Ultraviolet radiation. Follow instructions. Avoid overexposure. As with natural sunlight, overexposure can cause eye and skin injury and allergic reactions. Repeated exposure may cause premature aging of the skin and skin cancer. WEAR PROTECTIVE EYEWEAR; FAILURE TO MAY RESULT IN SEVERE BURNS OR LONG-TERM INJURY TO THE EYES.

Medications or cosmetics may increase your sensitivity to the ultraviolet radiation. Consult physician before using sunlamp if you are using medications or have a history of skin problems or believe yourself especially sensitive to sunlight. If you do not tan in the sun, you are unlikely to tan from the use of this product.

To use, lie down under the canopy and pull down as far as adjustment will allow. Minimum use distance from face tanner (if equipped) is 1 inch or 2.5 centimeters. Minimum use distance elsewhere is touching the clear plastic panels. Do not use without clear plastic panels in place.

Untanned persons should not tan on consecutive days during their first week of tanning. Never tan more than once a day. Tanning normally appears after the first few sessions and maximizes after approximately four weeks. Tan once or twice per week thereafter to maintain appearance. Persons already having a base tan may begin at advanced levels corresponding to the extent of their base tan.

RE	COMMEND	ED EXPOSURE TIMES IN MINUTES	N	//AXIMUM	<b>EXPOSURE</b>	TIME IS 2	0 MINUTES
Ski	n Type:		Level 1/Week 1 1st-3rd sessions	Level 2	Level 3	Level 4	Subsequent Maximum
I	Sensitive Skin	(Burns easily and severely and does not tan.)		NOT RECOMMENDED FOR TANNING			
II	Light	(Burns easily and severely and tans minimally.)	4	8	12	16	20
III	Normal	(Burns moderately and tans average.)	6	10	15	20	20
IV	Dark	(Burns minimally, tans easily and above averag	je.) 8	12	16	20	20

<u>WARNING</u>: Read the instructions booklet before using this sunlamp product. All persons in the room should wear protective eyewear when lamps are on. Recommended eyewear: Provided eyeshields (Lucas Products Super Sunnies or Intrexco No. 5635/1) or equivalent eyewear as defined under 21 CFR 1040.20. Other types of eyewear may not provide adequate protection. <u>Disconnect power before attempting to clean, relamp, or engage in the maintenance of this product.</u>

ONLY THE FOLLOWING LAMPS HAVE BEEN CERTIFIED FOR USE IN THIS EQUIPMENT:

SPEED<sup>TM</sup> 175 Wolff® Model SPD75-T12 PREHEAT-BIPIN (Bench lamps) SPEED<sup>TM</sup> 205 Wolff® Model SPD71-T12-205 BIPIN (Canopy lamps)

(And, If Equipped With SolarMax™ IFT Facial Unit)

Heraeus E400 HPT, Philips Model HPA 400/30s or CosmoTech Model 23045 THIS PRODUCT IS IN CONFORMITY WITH PERFORMANCE STANDARDS FOR SUN LAMP PRODUCTS UNDER 21 CFR PART 1040.20