

A touch of radiance for your life

# SMARTLUX

Advanced Photoactivation Technology



# Distribution Territory





# Origin for SMART PDT

## Advanced Photoactivation Technology



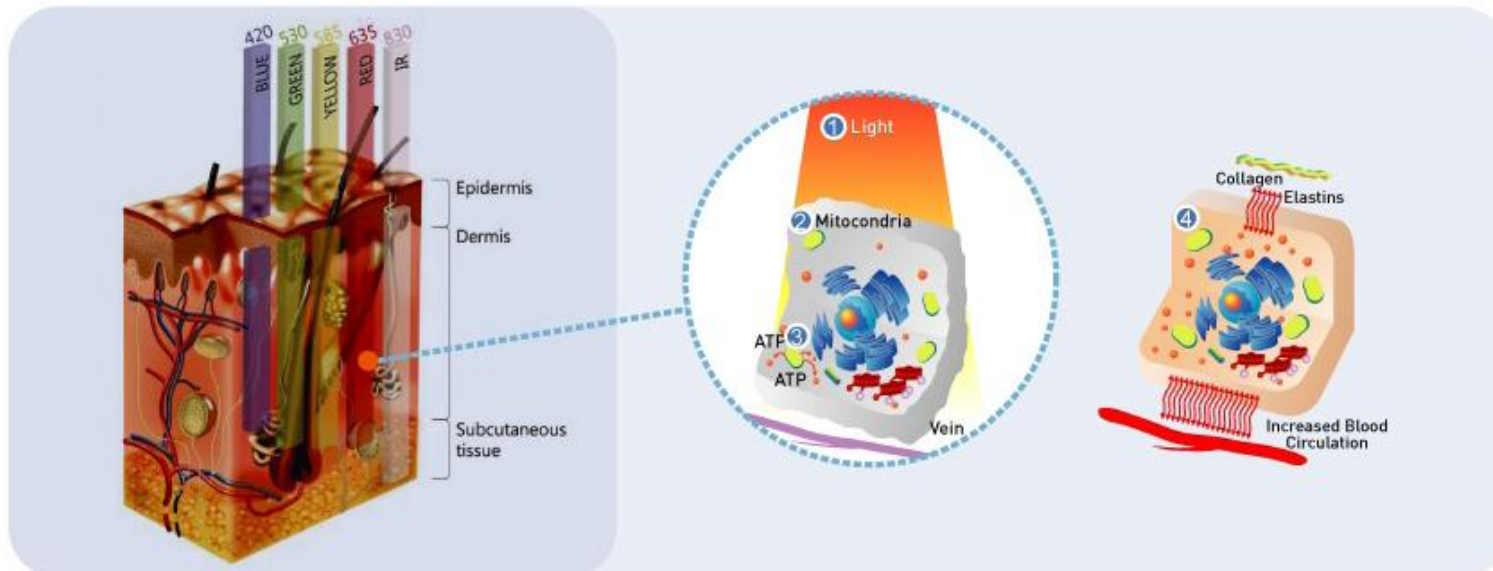
- Lupus vulgaris treatment with light by Finsen (Nobel prize winner in Medicine in 1903, founder of modern phototherapy)



- LED development using semiconductor heterostructures by Alferov (Nobel prize winner in Physics in 2000)

# Scientific Background

SMARTLU<sup>X</sup>



- ① Light penetrates into subcutaneous tissue.
- ② Mitochondria absorb the photon light energy and are energized.
- ③ The stimulated mitochondria produce more ATP, which stimulates cells to be reproduced faster and function like younger cells.
- ④ The super luminous light promotes cell wall exchange and stimulates the microcirculation of blood. By increasing cell reproduction and improving blood circulation, more collagen and elastin are produced, which leads to reduce wrinkles and decreased healing time. Skin recovers and looks younger, plumper, and healthier within 4-6 weeks.

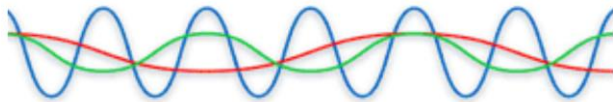
# Principals of Effective PDT Device

SMARTLUX

## ❖ Main 3 principals for bio stimulatory effects

1. Wavelength (color of the light)
2. Intensity (dosage of photons to activate the cell function)
3. Total energy delivered (Joules/cm<sup>2</sup>)

### Varied Wavelength



### Effective Intensity



- ❖ Efficacy and versatile usages on indications (Protocol)
- ❖ Larger irradiation area in proper time (Profitability)
- ❖ Easy to operate & Hands free operation
- ❖ Safety for patients and operator
- ❖ Low maintenance cost and Maintenance Service

# Directing point of SMARTLUX

SMARTLUX

**SMARTLUX** delivers healing power and the energy of light composed of red, blue, yellow, green, and infrared with high-intensity 2,450 SLDs (super luminous diodes) developed by SMART Phototherapy technologies. From wound healing and pain relief to improvement of dermatological conditions, anti-aging treatment, and a boost to skin's radiance, SMARTLUX effects exceptional results with its various wavelengths selection and wide variety of irradiation angles.



# New SMARTLUX Series

SMARTLUX



- \*BODY-Premium type
- \*HEAD-5 Panels



- \*BODY-Slim type
- \*HEAD-5 Panels



- \*BODY-Slim type
- \*HEAD-3 Panels

# BODY] PREMIUM vs. SLIM

SMARTLUX 

BODY Type	SMARTLUX PREMIUM	SMARTLUX SLIM
<b>Dimension</b>	39cm x 54cm x 84cm	27cm x 39cm x 84cm
<b>Arm Length</b>	120cm	92cm
<b>Weight</b>	50KG	35KG
<b>Mood light</b>	O	X
<b>LCD Size</b>	10.4 Inch	7 Inch
<b>Head Panel Selection</b>	O	X
<b>Continuous Wave Mode</b>	O	O
<b>Burst Pulse Mode</b>	5 levels (1~5Hz)	8 levels (1~500Hz)
<b>Half Pulse Mode</b>	O	X
<b>Auto Testing Mode</b>	O	O
<b>Program updated input</b>	O	X







# HEAD] 5 Panels vs. 3 panels







SMARTLUX

HEAD Type	5 Panels	3 Panels
<b>Dimension (Overall)</b>	32cm x 41cm	32cm x 25cm
<b>Dimension (Active area)</b>	19cm x 41cm	19cm x 25cm
<b>Weight</b>	3.2~4.5kg	2~3kg
<b>Wavelength Classification</b>	Red, Blue, IR, FX(RD+IR), FX Plus, Yellow, Yellow Plus, Dual(YL+IR), GX (Hair)	Red, Blue, IR, FX(RD+IR), FX Plus
<b>Compatibility with Body</b>	PREMIUM, SLIM	SLIM






# Premium : 5 Panels

	RED	BLUE	FX PLUS (RED+IR)	GX (Hair)	
HEAD					
OUTPUT	Number of SLDs	2400 EA	RED - 1120 EA IR - 1330 EA	RED - 1632 EA IR - 798 EA	
	TOTAL POWER	90 W +/- 8 W	58 W +/- 5 W	51 W +/- 3 W 66.5 W +/- 2 W 105 W +/- 5 W	56W +/- 3 W 51W +/- 2 W 93.5W +/- 5 W
	INTENSITY (MAX)	115 mW / cm <sup>2</sup>	75 mW / cm <sup>2</sup>	65 mW 85 mW 135 mW	72 mW 65 mW 120 mW
	WAVELENGTH [nm]	635 +/- 6 nm	420 +/- 5 nm	635 +/- 6 nm 830 +/- 5 nm	635 +/- 6 nm 830 +/- 5 nm
	Dose range (adjustable)	1~276 J/cm <sup>2</sup>	1~180 J/cm <sup>2</sup>	1~156 J/cm <sup>2</sup> 1~204 J/cm <sup>2</sup> 1~324 J/cm <sup>2</sup>	1~173 J/cm <sup>2</sup> 1~156 J/cm <sup>2</sup> 1~288 J/cm <sup>2</sup>
	Clinical Indications	cell reproduction, reducing cellulite	acne treatment	cell reproduction, wound healing	hair implant hair loss treatment scalp treatment

# SLIM : 5 Panels

		FX (RED+IR)	DUAL (YL+IR)	YELLOW PLUS	YELLOW	IR	GREEN
<b>HEAD</b>							
<b>OUTPUT</b>	<b>Number of SLDs</b>	RED - 700 EA IR - 500 EA	YEL - 1120 EA IR - 1330 EA	2400 EA	1040 EA	800 EA	1000 EA
	<b>TOTAL POWER</b>	43 W +/- 3 W	14 W +/- 3 W	27.5 W +/- 3 W	14 W +/- 2 W	46 W +/- 4 W	15.5 W +/- 2 W
		35 W +/- 2 W	66.5 W +/- 2 W				
<b>INTENSITY (MAX)</b>	70 W +/- 5 W	80 W +/- 5 W	35 mW / cm <sup>2</sup>	18 mW / cm <sup>2</sup>	60 mW / cm <sup>2</sup>	20 mW / cm <sup>2</sup>	
	55 mW	18 mW					
	45 mW	85 mW					
<b>WAVELENGTH [nm]</b>	90 mW	95 mW	585 +/- 5 nm	585 +/- 5 nm	830 +/- 5 nm	530 +/- 5 nm	
	635 +/- 6 nm	585 +/- 5 nm					
<b>Dose range (adjustable)</b>	830 +/- 5 nm	830 +/- 5 nm	1~86 J/cm <sup>2</sup>	1~44 J/cm <sup>2</sup>	1~144 J/cm <sup>2</sup>	1~48 J/cm <sup>2</sup>	
	1~132 J/cm <sup>2</sup>	1~44 J/cm <sup>2</sup>					
	1~108 J/cm <sup>2</sup>	1~204 J/cm <sup>2</sup>					
<b>Clinical Indications</b>	1~216 J/cm <sup>2</sup>	1~228 J/cm <sup>2</sup>	vascular lesion treatment, reducing bruises and swelling	vascular lesion treatment, reducing bruises and swelling	wound healing, pain relief	skin tone improvement	
	cell reproduction, wound healing	wound healing, reducing bruises and swelling					

# MINI : 3 Panels

	FX - 3	FX PLUS - 3	RED - 3	BLUE - 3	IR - 3	
HEAD						
OUTPUT	Number of SLDs	RED - 420 EA IR - 300 EA	RED - 672 EA IR - 798 EA	1440 EA	900 EA	480 EA
	TOTAL POWER	21 W +/- 3 W 17 W +/- 2 W 36 W +/- 4 W	26 W +/- 3 W 33 W +/- 4 W 55 W +/- 8 W	33 W +/- 4 W	31 W +/- 3 W	21 W +/- 3 W
INTENSITY (MAX)		45 mW / cm <sup>2</sup> 35 mW / cm <sup>2</sup> 75 mW / cm <sup>2</sup>	55 mW / cm <sup>2</sup> 70 mW / cm <sup>2</sup> 115 mW / cm <sup>2</sup>	85 mW / cm <sup>2</sup>	65 mW / cm <sup>2</sup>	45 mW / cm <sup>2</sup>
	WAVELENGTH [nm]	635 +/- 6 nm 830 +/- 5 nm	635 +/- 6 nm 830 +/- 5 nm	635 +/- 6 nm	420 +/- 5 nm	830 +/- 5 nm
	Dose range (adjustable)	1~108 J/cm <sup>2</sup> 1~84 J/cm <sup>2</sup> 1~180 J/cm <sup>2</sup>	1~132 J/cm <sup>2</sup> 1~168 J/cm <sup>2</sup> 1~276 J/cm <sup>2</sup>	1~204 J/cm <sup>2</sup>	1~156 J/cm <sup>2</sup>	1~108 J/cm <sup>2</sup>
Clinical Indications	cell reproduction, wound healing	cell reproduction, wound healing	cell reproduction, reducing cellulite	acne treatment	wound healing, pain relief	

# Main Features

SMARTLUX

## 5 Different Heads

Various wavelength selections

## 2,450 SLDs

High-Intensity super luminous diodes

## 20°~30° Divergence Angle

Narrow divergence angle for intensified treatment results

## 19cm X 41cm Active Area

Wide variety of irradiation for any part of the body

## 1-5 Energy Intensity Levels

Diversified energy intensity for various conditions

## Under 60°C

Temperature management for SLD lifetime

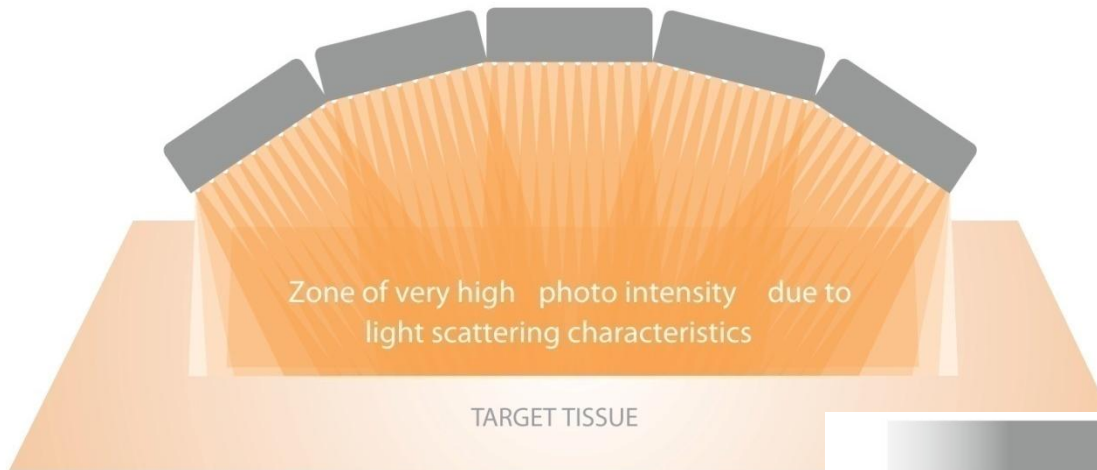
## 3 Usage Benefits

User-friendly interface, no requisites, fast and easy maintenance system



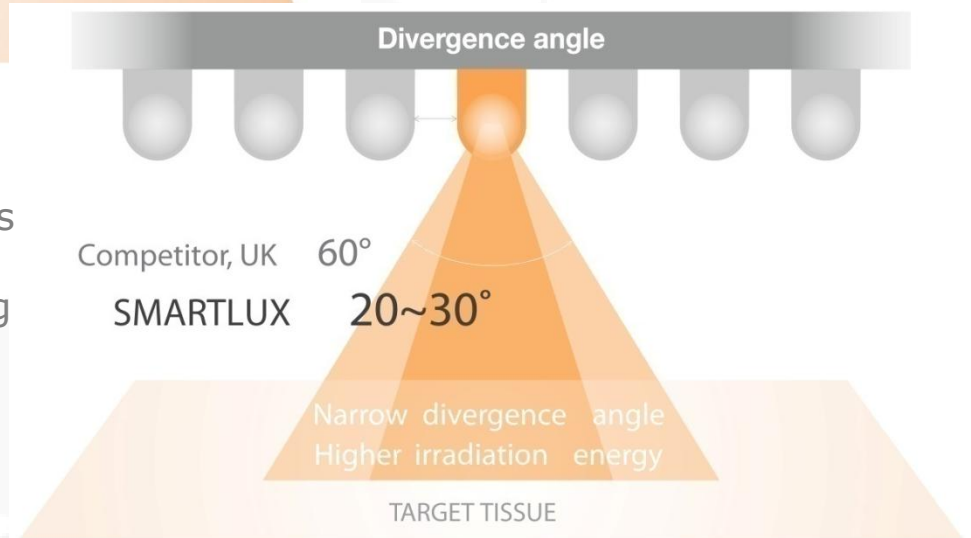
# Divergence Angle

SMARTLUX



Higher irradiation energy

Narrow and precise positioning of the SLDs in the array panel results in multiple intersections of the light beams generating the highest photon intensity zone on the target surface of the skin, providing intensified effects.



Narrower divergence angle

# How SMARTLUX Works

SMARTLUX

Nominal Wavelength (nm)	Cell Types/Action Level						
	Inflammation			Proliferation		Remodeling	All
	Mast	Neutro	Macro	Fibro	Endo	Fibro-Myo	Keratino
<b><i>SMARTLUX YELLOW</i></b> 585-595				+++			
<b><i>SMARTLUX RED</i></b> 630-670	++	+	++	+++	+++	+	+++
790	++			++			
<b><i>SMARTLUX IR</i></b> 830	+++	+++	+++	+	++	+++	+++
904	-		+/-	-			

\*Mast : Mast Cell / Neutro : Neutrophils / Macro : Macrophages / Fibro : Fibroblasts / Fibro-Myo : Fibroblast to myofibroblast transformation / Keratino : Keratinocytes

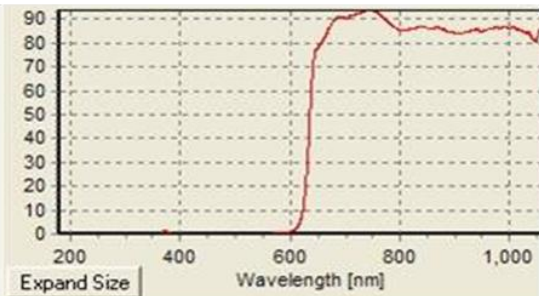
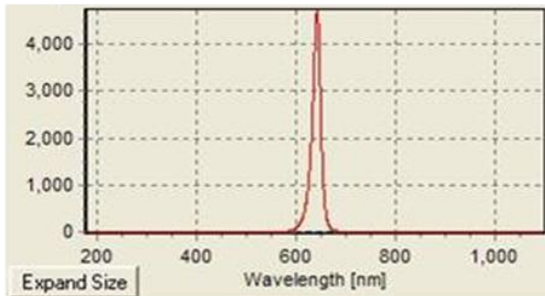
\*Source : Calderhead, R. Glen. *Lasers in Dermatology and Medicine*, Springer London. 2012, 254p

# Purity of wavelength

SMARTLUX

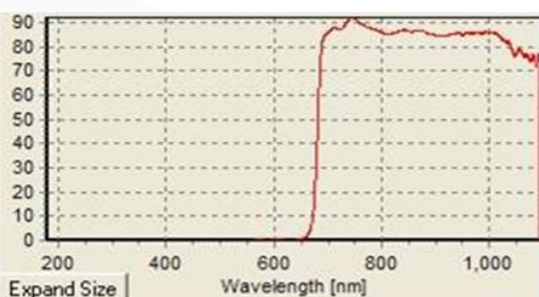
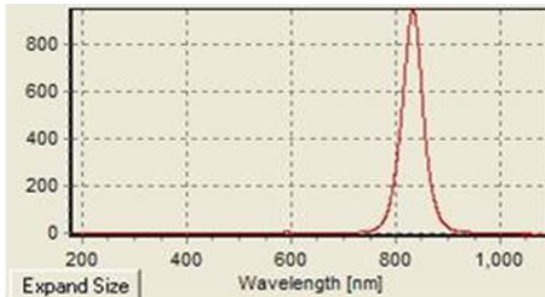
vs. Low quality PDT device SMARTLUX

Red



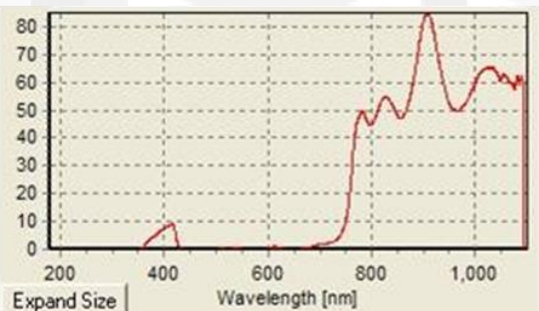
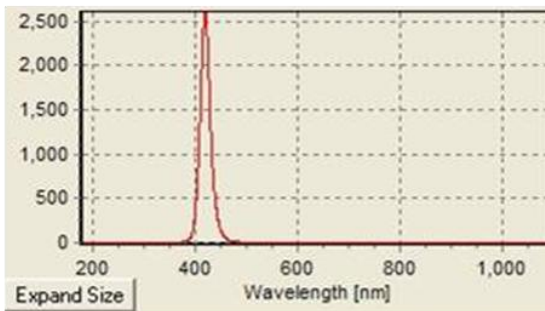
Red

IR



IR

Blue



Blue (?)



Stable wavelength

Unstable wavelength



# Intensive SLDs of SMARTLUX

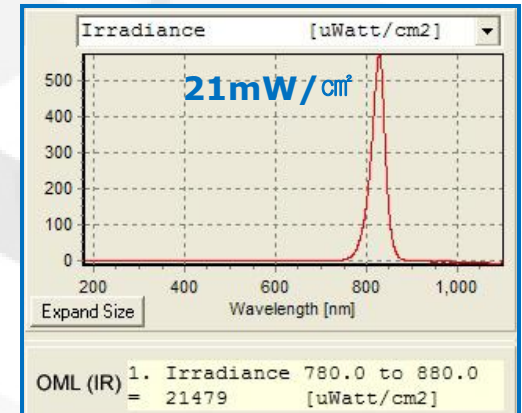
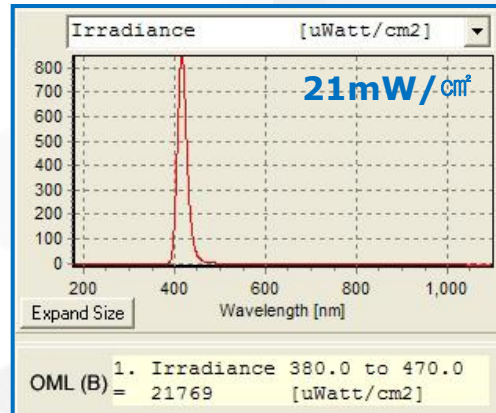
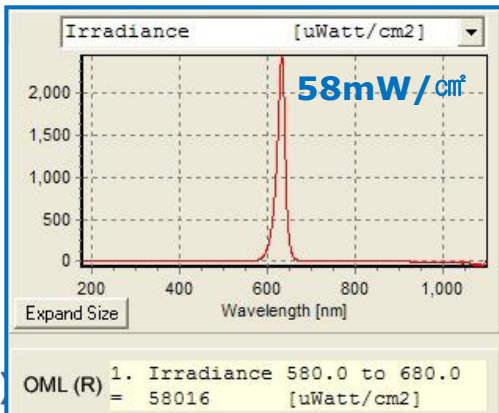
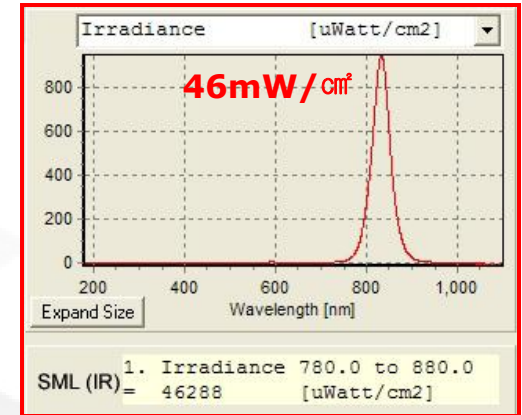
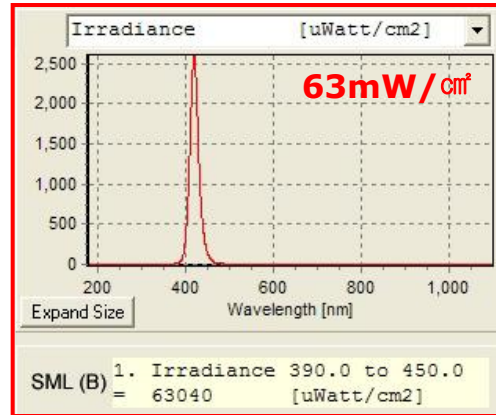
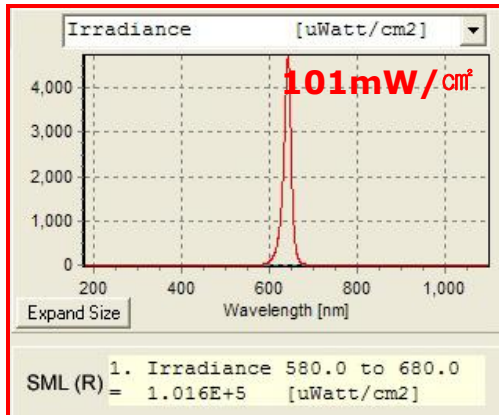
❖ **SMARTLUX** is designed with **much more LED numbers** than the other devices



<b>SMARTLUX</b> <b>RED</b> (635nm)	<b>SMARTLUX</b> <b>BLUE</b> (420nm)	<b>SMARTLUX</b> <b>IR</b> (830nm)	<b>SMARTLUX</b> <b>YELLOW PLUS</b> (585nm)	<b>SMARTLUX</b> <b>DUAL</b> (585 & 830nm)	<b>SMARTLUX</b> <b>FX PLUS</b> (635 & 830nm)
<b>2400 SLDs</b>	<b>1500 SLDs</b>	<b>800 SLDs</b>	<b>2400 SLDs</b>	<b>2450 SLDs</b>	<b>2450 SLDs</b>
					
<b>OMNILUX</b> <b>1680 LEDs</b>	<b>OMNILUX</b> <b>1300 LEDs</b>	<b>OMNILUX</b> <b>520 LEDs</b>	<b>No</b> <b>comparison</b>	<b>HEALITE</b> <b>1800 LEDs</b>	<b>No</b> <b>comparison</b>

# Comparison of Intensity

Products	RED			BLUE			IR		
	Intensity (Test)	Intensity (Spec.)	Number of LEDs	Intensity (Test)	Intensity (Spec.)	Number of LEDs	Intensity (Test)	Intensity (Spec.)	Number of LEDs
<b>SMARTLUX</b>	<b>101</b>	<b>115</b>	<b>2400</b>	<b>63</b>	<b>75</b>	<b>1500</b>	<b>46</b>	<b>60</b>	800
<b>OMNILUX</b>	<b>58</b>	105	1680	<b>21</b>	40	1300	<b>21</b>	55	520
<b>Conclusion</b>	SML : 74% stronger than OML			SML : 200% stronger than OML			SML : 119% / 24% stronger than OML / HL		



# How to use SMARTLUX

SMARTLUX

## [Arm]

- Adjustable structure for various height
- Angles up to 355 degree

## [HEAD]

- Choosable 5 panels
- 15 different type of heads
- Easy rotation up to 180 degree

## [Touch Screen]

- Easy to operate
- Decompression

## [Wheel]

- Smooth moving
- Locking tab

## [BODY]

- Mood lamp by heads

# SMARTLUX's Irradiation Mode

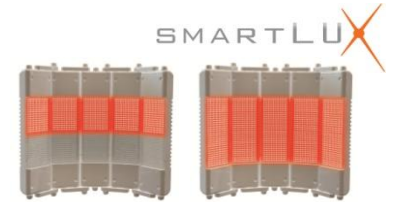
## ❖ 3 irradiation Modes

- CW mode: Continuous irradiation mode
- BP mode: blinks up to 5 times per second
- HP mode: Intensity(brightness) switching mode

## ❖ Selective 5 brightness level(intensity)

- Depends on the patient's skin type and the severity of the indication

Selective targeting irradiation



5 level intensity



**Selective Targeting :**  
10-section divided head offers optimal irradiation design

**Brightness : 5-level intensity control**

Customized treatment is achieved through various modes such as CW(continuous wave), HP(half pulse waves), BP(burst pulse waves)

**Continuous Irradiation mode**

**Intensity Switching Mode** (Blinks between brightness level 1 and selected brightness; time interval of the blinking is adjustable from 1 to 9 seconds)

**Burst irradiation Mode** (Blinks 1 to 5 times per second)



❖ **Easy to control with Simple User Interface**

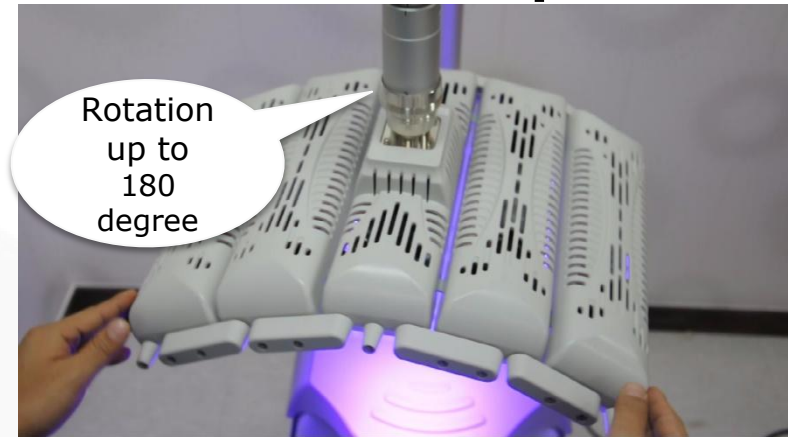
**\*PREMIUM – Touch Screen 10.4"**



**\*SLIM – Touch Screen 7"**



❖ **Head's rotation up to 180°**



❖ **Easy to switch the Heads and auto detecting system**

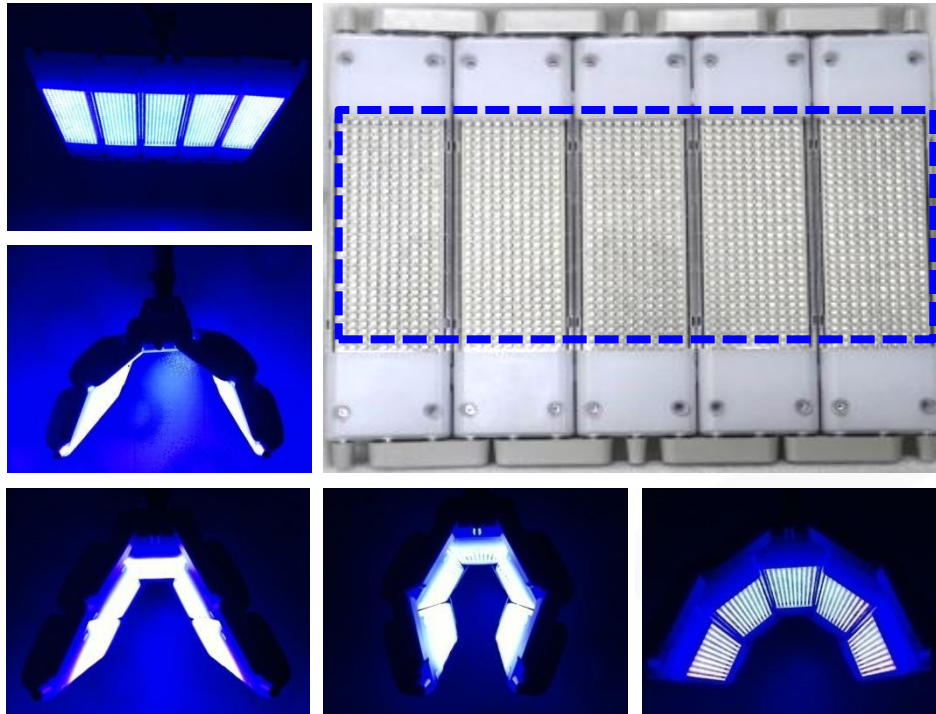


# Various Irradiation Area

## ❖ Easy to bend the head's direction

(Irradiation area: 19cm\*41cm )

- 3 Dimensional treatment
- Simultaneous Tx for face and neck

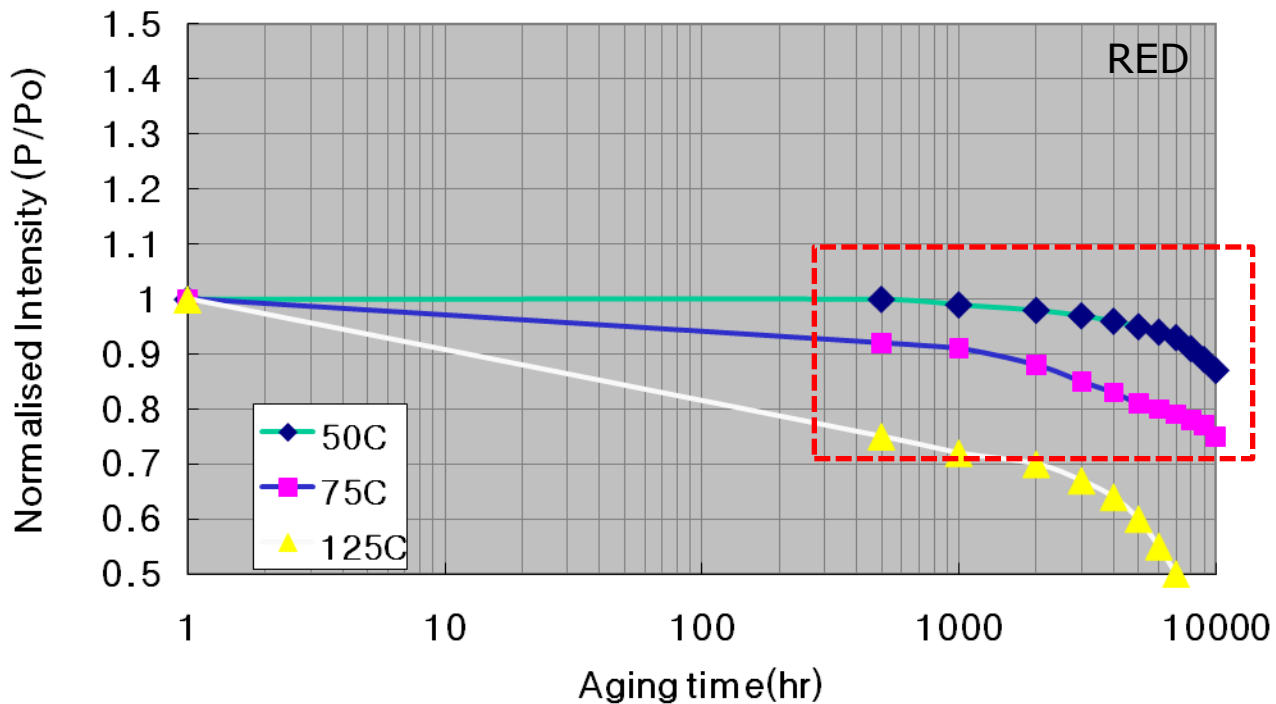


# Long lasting LED System :Over Temperature Protection

Reliability of LED lifetime depends on \*RTOL



\*Room Temperature Operating Life  
(I=50mA) (50C,75C,125C)



[Example]  
9 hours/Day  
6 days/Week  
=====  
=====  
80% intensity  
by 4 years  
later

\* SMARTLUX has an internal cooling pan system and a sensor for maintaining the temperature under 60 degree.

# Maintenance & Management

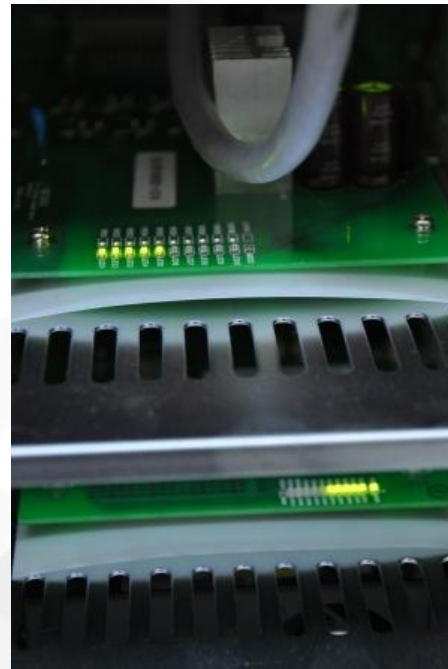
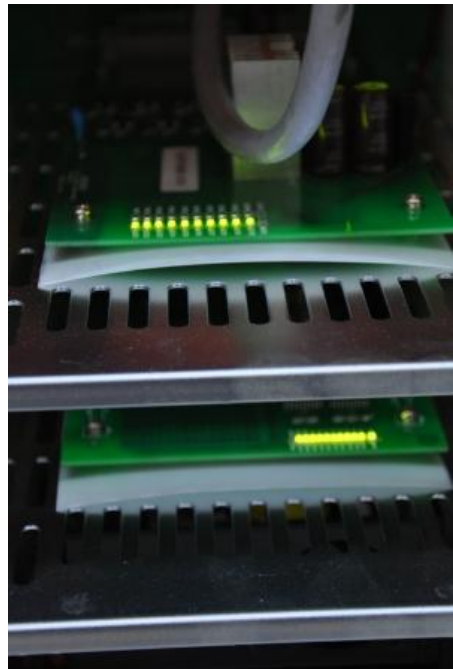
SMARTLUX

## ❖ **AUTO TESTING SYSTEM**

- SMARTLUX runs automatically for testing the defectives of the operation.

## ❖ **Rack Structure for fast repair**

- Auto detecting LED system
- Enable to repair within 10 minutes





# SMARTLUX – KFDA Certificate

인정번호(No.) : KCL-ABB-130028

## 의료기기 제조 및 품질관리 기준 적합인정서 (Certificate of GMP)

■ 업체명 / 허가번호 (Company name of Applicant / License No.)

(주)메드믹스 / 제 3183호  
MEDMIX Co., Ltd.

■ 대표자 (Representative)

강혁 (Kang hyuk)

■ 업체 소재지 (Company address of Applicant)

인천광역시 연수구 송도미래로 30 비-707(송도동, 송도비알씨스마트밸리지식산업센터)  
비-707, 30, Songdomirae, Yeonsu-gu, Incheon, KOREA

■ 제조소명 (Name of Manufacturer)

(주)메드믹스  
MEDMIX Co., Ltd.

■ 제조소 소재지 (Address of Manufacturer)

인천광역시 연수구 송도미래로 30 비-707(송도동, 송도비알씨스마트밸리지식산업센터)  
비-707, 30, Songdomirae, Yeonsu-gu, Incheon, KOREA

■ 품목군 및 등급 : 불임합조

(Category and Classification of Product(s)) : See attached list

의료기기 제조 및 품질관리기준에 적합함을 인정합니다.

(We hereby certify that the above manufacturer complies with Korea Good Manufacturing Practices of Medical Devices for the product(s) listed above)

발행일자(Date of Issue) : 2013. 08. 20

유효기간(Date of Expiration) : 2016. 08. 19



194 Tongiro, Eunpyeong-gu Seoul, 122-704 Republic of Korea  
Tel: +82-2-380-1643, Fax: +82-2-386-6583

No. of Certificate : 20100098810

Date : 2010/09/16

### Certificate of Free Sales

Exporting(certifying) country : Republic of Korea

Importing(requesting) country : Not Determined

The Korea Food and Drug Administration, certifies that the following firm is authorized to manufacture medical devices under the Medical Device Act and the following item(s) is(are) permitted to be freely sold in domestic and overseas markets.

Manufacturer (Registered No. : 3183)

MEDMIX CO., LTD

1310 Hanla Sigma Valley 345-90 Gasan-dong, Geumcheon-gu, Seoul, Korea

Product-License No.	Classification
10-935	Combination stimulator, class 2

※ Attached : List of Product Classification and Model

Director of Diagnostic Medical Device Div.  
Medical Device Safety Bureau  
Korea Food & Drug Administration

# SMARTLUX – CE Certificate

SMARTLUX

EC Certificate Full Quality Assurance System: Certificate KR10/01479

The management system of

**MEDMIX Co., Ltd.**

B-707 Smartvalley, 30, Songdomirae-ro, Yeonsu-gu, Incheon 406-840, Korea

has been assessed and certified as meeting the requirements of

**Directive 93/42/EEC**  
on medical devices, Annex II (excluding Section 4)

For the following products

**Phototherapy Unit (Model: SMARTLUX and SMARTLUXSLIM)**

For placing on the market of Class III devices covered by this certificate, an EC Design Examination Certificate according to Annex II (Section 4) is required.

This certificate is valid from 16 August 2013 until 15 July 2016 and remains valid subject to satisfactory surveillance audits. Re certification audit due before 29 June 2016 Issue 4. Certified since 15 July 2010

Certification is based on reports numbered KRSEL Y-PC10236

Authorized by

SGS United Kingdom Ltd, Notified Body 0120

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Certificate KR10/01477

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The management system of

**MEDMIX Co., Ltd.**

1310 Hanja Sigma Valley, 345-90, Gasan-dong, Geumcheon-gu, Seoul, 153-802, Korea

has been assessed and certified as meeting the requirements of

**ISO 9001:2008**

For the following activities

**Design, Development and Manufacture of Phototherapy Unit.**

Further clarifications regarding the scope of this certificate and the applicability of ISO 9001:2008 requirements may be obtained by consulting the organization

This certificate is valid from 15 July 2013 until 15 July 2016 and remains valid subject to satisfactory surveillance audits. Re certification audit due before 29 June 2016 Issue 2. Certified since 15 July 2010

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Certificate KR10/01478

The management system of

**MEDMIX Co., Ltd.**

1310 Hanja Sigma Valley, 345-90, Gasan-dong, Geumcheon-gu, Seoul, 153-802, Korea

has been assessed and certified as meeting the requirements of

**ISO 13485:2003**  
**EN ISO 13485:2012**

For the following activities

**Design, Development and Manufacture of Phototherapy Unit.**

This certificate is valid from 15 July 2013 until 15 July 2016 and remains valid subject to satisfactory surveillance audits. Re certification audit due before 29 June 2016 Issue 2. Certified since 15 July 2010

Authorized by

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# SMARTLUX – FDA 510(K)

SMARTLUX

## DRLM Device Registration & Listing Module



FDA

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### View All Listings

Get Help ?

Owner/Operator: 10044660

Select the listing that you would like to view in more detail.

Listing Number	Listing Status	Premarket Submission Number	Product Code (s)	Device Name
<input checked="" type="radio"/> D198850	Active	K120480	GEX	Powered laser surgical instrument

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> VIEW SELECTED LISTING



**MEDMIX**  
Total Medical Solution Company

# SMARTLUX – FDA 510(K)

SMARTLUX

<b>Device Classification Name</b>	<u>Powered Laser Surgical Instrument</u>
<b>510(K) Number</b>	K120460
<b>Device Name</b>	SMARTLUX
<b>Applicant</b>	MEDMIX CO., LTD 300 Atwood Pittsburgh, PA 15213
<b>Contact</b>	Peter Chung
<b>Regulation Number</b>	<u>878.4810</u>
<b>Classification Product Code</b>	<u>GEX</u>
<b>Date Received</b>	02/15/2012
<b>Decision Date</b>	10/01/2012
<b>Decision</b>	Substantially Equivalent (SE)
<b>Classification Advisory Committee</b>	General & Plastic Surgery
<b>Review Advisory Committee</b>	General & Plastic Surgery
<b>Type</b>	Traditional
<b>Reviewed By Third Party</b>	No
<b>Expedited Review</b>	No
<b>Combination Product</b>	No