

# **USER MANUAL**

Rev. 1.0.7



# **INDEX**

**1. Introduction** 1.1 Intended use

2. Theory and the technical 2.1 Principal of treatment	information	2.2 Treatment tar	rget
<ul><li>3. Transportation</li><li>3.1 Transportation</li><li>3.3 Condition in Operating</li><li>4. Safety</li></ul>		3.2 Unpacking ar 3.4 Condition in D	nd Inspection Delivering and Storing
4.1 Overview		4.2 General Safe	ty
4.3 Electrical Protection		4.4 Vision Protec	tion
4.5 Risk of Fire		4.6 Protection of	the Instrument
4.7 Power Switch		4.8 Method of Re	esuming
4.9 Skin hazard distance or/and	Ocular hazard dist	ance	
4.10 contraindications and side e	effects		
<b>5. Description of Instrument</b> 5.1 General Description	t	5.2 Power Part	
5.3 Head Part		5.4 Product Com 5.4.1 Rocker S 5.4.1.2 How to 5.4.2 Color To	Switch replace fuse
5.5 Head 5.5.1 General Specification		3.4.2 00101 100	acii ocieeli
5.5.2 BRI(BLUE/RED/IR) 5.5.2.1 BLUE 5.5.2.4 BLUE+RED 5.5.2.7 BLUE+RED+IR	5.5.2.2 RED 5.5.2.5 BLUE+IR		5.5.2.3 IR 5.5.2.6 RED+IR
5.5.3 RRI(RED/RED/IR) 5.5.3.1 RED1 5.5.3.4 RED1+RED2 5.5.3.7 RED1+RED2+IR	5.5.3.2 RED2 5.5.3.5 RED1+IR	ł	5.5.3.3 IR 5.5.3.6 RED2+IR
5.5.4 YRI(YELLOW/RED/IR) 5.5.4.1 YELLOW 5.5.4.4 YELLOW+RED 5.5.4.7 YELLOW+RED+IR	5.5.4.2 RED 5.5.4.5 YELLOW	'+IR	5.5.4.3 IR 5.5.4.6 RED+IR
5.5.5 BRY(BLUE/RED/YELLO) 5.5.5.1 BLUE 5.5.5.4 BLUE+RED 5.5.5.7 BLUE+RED+YELLO	5.5.5.2 RED 5.5.5.5 BLUE+YI	ELLOW	5.5.5.3 YELLOW 5.5.5.6 RED+YELLOW

# 6. Specifications

# 7. Operation the Instrument

7.1 Introduction 7.2 Start 7.3 Color Touch Screen

7.4 Main Menu(Standard)

7.4.1 START/STOP/PAUSE 7.4.2 Head Type 7.4.3 Brightness

7.4.4 Mode

7.4.4.1 CW(Continuous Wave) Mode 7.4.4.2 B-P(Burst Pulse) Mode

7.4.5 Time 7.4.6. Total Energy

7.5 Main Menu BRI 7.6 Main Menu RRI

7.5.1 BRI(BLUE/RED/IR) Select 7.6.1 RRI(RED/RED/IR) Select

7.7 Main Menu YRI 7.8 Main Menu BRY

7.7.1 YRI(YELLOW/RED/IR) Select 7.8.1 BRY(BLUE/RED/YELLOW) Select

# 8. Care and Maintenance Safety Warnings

8.1 Service Method 8.2 Regular Monitoring

8.3 Cleaning 8.4 Trouble Shooting

# 9. Order

9.1 Order number

# 10. Label Information

10.1 Label for safety 10.2 Label location

# 11. Declaration of Conformity – Electromagnetic Compatibility

#### 1. Introduction

SMARTLUX MINI is the combination of low power beam irradiator and infrared irradiator, and it is KC, CE/MDD class II-a class medical equipment. Your attention to prevent danger or injury is required. Please read User's Manual carefully before you use medical equipment, and if you have any questions on safety, application, or operation of the equipment, please contact MEDMIX Co., Ltd. or its distributor.

1.1 Intended use

SMARTLUX MINI is medical device that the energy emitted provides topical heating for acceleration in wound Healing and temporary relief of pain.

#### 2. Theory and the technical information

SMARTLUX MINI is consisted of head module from which light is irradiated, power module, control module and touch screen. SMARTLUX MINI is medical equipment that uses a kind of light. The light is safe and pure to stimulate and heal damaged skin. It can be used for acne treatment, reducing wrinkles, scar reduction and anti-aging treatment.

2.1

Principal of treatment

The light energy of SMARTLUX activates mitochondria, promoting cell regeneration and making cells act younger. It also improves blood circulation and stimulates collagen and elastic production, restoring youthful and healthy skin while delivering powerful anti-inflammatory, wound healing and pain relief benefits.

2.2 Treatment target

SMARTLUX MINI can be applied to the face, head, and body (including the limbs).

# 3. Transportation

3.1 Transportation

SMARTLUX MINI has passed full quality assurance testing before shipment. Thus, the unit should be operational upon delivery. The unit should be unpacked only by our agency.

3.2 Unpacking and Inspection

SMARTLUX MINI is packed precisely and safely before transportation. Customer should check whether there are any damages in outside packing and the instrument or not after receiving the equipment. When you open the package, you need to check if all components are included as per check list, and they are should be kept well, because they are needed when the hospital returns the equipment or when it is repaired.

3.3 Condition in Humidity: 20~75%

Operating Atmospheric pressure : 70kPa ~ 106kPa

Operating temperature : 5°C ~ 30°C

3.4
Condition in
Delivering and Storing

When delivering and storing the machine, make sure it stands on. Use packaging materials for exports (double wall corrugated fiberboard, PE foam, pallet) to protect the products from various environmental factors. Refer to the information stated in the

Clause 3.4 when storing the product

#### 4.Safety

4.1 Overview

SMARTLUX MINI has been developed completely and it is produced by perfect quality system. Also, it is thoroughly tested before shipment. Please read this chapter carefully in order to keep the equipment longer and for the safety of the operator and the patient during

the treatment. Furthermore, the person who handles SMARTLUX MINI should have special training associated with the equipment before operating this system. When SMARTLUX MINI is used, safety related precautions should be taken in order to reduce the risks such as fire, electric shock or injury.

#### 4.2 General Safety



#### Caution!

- 1) Read all instructions and be well aware of them.
- 2) Follow all warnings and instructions marked on SMARTLUX MINI
- 3) Unplug the main power cord from outlet before cleaning SMARTLUX MINI.
- 4) Do not use SMARTLUX MINI around the water such as sink or water bottle, etc.
- 5) Do not use SMARTLUX MINI around the water such as sink or water bottle, etc.
- 6) SMARTLUX MINI is equipped with ventilation device, so do not open or dismantle the instrument.
- 7) Do not install SMARTLUX MINI around thermal instruments or unventilated area.
- 8) Use rated power indicated in SMARTLUX MINI.
- 9) SMARTLUX MINI is provided with molded power cord. If the cord doesn't fit properly, ask MEDMIX to replace it. Provided power cord should be used for the safety.
- 10) Do not place over the power cord. Install SMARTLUX MINI at the place where power cord is not stepped on.
- 11) Do not use power extension cord. It may cause fire or electric shock.
- 12) To prevent electric shock, do not dismantle SMARTLUX MINI. Opening or removing the cover may expose you to high voltage or other dangers.
- 13) When the followings occur, separate the power plug from SMARTLUX MINI, and follow the instruction of MEDMIX Co., Ltd or authorized agent.
- -. The power cord or plug is damaged
- -. Liquid has been spilled into the LED Lamp.
- -. SMARTLUX MINI has been exposed to rain or water
- -. SMARTLUX MINI does not work normally by following the operating instruction.
- -. SMARTLUX MINI has been physically damaged.
- -. When there is remarkable change in the functions of SMARTLUX MINI

# 4.3 Electrical Protection



### Caution!

When SMARTLUX MINI is uncovered or repaired, it should be done by authorized person by MEDMIX Co., Ltd or its agent.

- 1) MEDMIX Co., Ltd is not responsible for the damages caused by uncovering SMARTLUX MINI without the consent of MEDMIX or its agent.
- 2) When SMARTLUX MINI is operated, make sure to check if grounding is done properly.
- 3) Treatment room where SMARTLUX MINI is installed should maintain cleaning, and constant temperature and humidity.

# 4.4 Vision Protection



# Caution!

When SMARTLUX MINI is used for the treatment properly, light output of SMARTLUX MINI is lower than maximum value of recommended MPEs (Maximum Permissible Exposure). Nevertheless, have the patient close the eyes during the treatment. It is recommended that patient wears opaque protective goggles when receiving the treatment on the face. Patient should not see the beam or reflected/dispersed beam directly. Never have the patient see the beam output directly, since it may cause the damage of retina. Patients should access to protective goggles easily at the treatment room where

SMARTLUX MINI is installed. When SMARTLUX MINI is turned on, everyone including patient should wear protective goggles. Protective goggles that correspond to each wavelength are used for eye protection.

# 4.5 Risk of Fire



Do not place the equipment near to flammable area, easily combustible anesthetic or other solvent. Remove paper or plastic materials around the equipment. When the equipment is not used or patient is changed or during the intermission of the treatment, press STOP button of SMARTLUX MINI to convert it to standby mode.

4.6 Protection of the Instrument

As mentioned above, The light should not irradiate to the flammable material. Equipment should not be operated by a third person.

4.7 Power Switch

Power switch of SMARTLUX MINI is Rocker switch located in the rear of the instrument. Rocker switch runs SMARTLUX MINI. When you press Rocker switch to the position of I, system operates and it will be ready to use after self-test.

4.8 Method of Resuming When SMARTLUX MINI is not normal, stop the power supply of SMARTLUX MINI immediately. To resume the instrument, press Rocker switch to the position of O and cut the power supply. And after 5 minutes, run SMARTLUX MINI by pressing Rocker switch to the position of I. If the failure occurs repeatedly, please contact MEDMIX Co., Ltd. immediately.

4.9 Skin hazard distance or/and Ocular hazard distance The patient or the user must use the device more than 20cm space out in the light source of the devices to protect the skin and vision

4.10 contraindications and side effects

The side effects found in clinical evaluation report: None

General contraindications and side effects

- Buring
- Mild Erythema
- Photodamage

# 5. Description of Instrument

5.1 SMARTLUX MINI is consisted of two major parts.

General 1) Power Part Description 2) Head Part

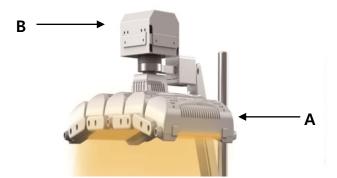
5.2 Power part is consisted of SMPS and power conversion board.

Power Part

5.3 Head part is consisted of LCD touch module, control module and LED module...

Head Part

5.4 Product Composition









A. Head

B. Color touch screen

C. Rocker switch

5.4.1 Rocker Switch It is an important switch for the power supply of SMARTLUX MINI, and when you press I, power is supplied to the instrument and instrument information can be seen through color touch screen. Only the user who had special training on SMARTLUX MINI should access to Rocker switch

5.4.1.2 How to replace fuse



Hang a wrench in the middle of the fuse holder and press.



When the fuse holder comes out, put a wrench into the area and push the fuse.



Pull out the fuse and put a new fuse from the inside while pressing it

Push the fuse holder as hard as possible.

# 5.4.2 Color Touch Screen

Color Touch Screen is the contact area for human and machine.

Control and operating conditions of SMARTLUX MINI are being done through this Touch Screen.



Caution!

Do not push Touch Screen with sharp object. Do not sprinkle any liquid on the surface of Touch Screen.

#### 5.5 Head

5.5.1

General Specification

-. Light Source

-. Head Overall Dimensions(L X W)

-. Total Weight-. Input Power

: 100-240V~, 50/60Hz

: 320mm X 410mm

: LED 420nm ~ 830nm

-. Power consumption-. Cooling System

: 600W : Air Cooling

: 28kg

# 5.5.2 BRI (BLUE/RED/IR)

5.5.2.1 BLUE -. Output Wavelength

: 420nm +/- 10nm

Output IntensityStandard Dose

: 41mW/cm² : 24J/cm²

-. Treatment Time(Standard Dose)-. Treatment Time(Max)

: 10minutes : 40minutes

-. Dose Range(Adjustable)

: 1~98J/cm²

5.5.2.2 RED -. Output Wavelength

-. Output Intensity

: 635nm +/- 10nm : 50mW/cm²

-. Standard Dose

: 30J/cm²

-. Treatment Time(Standard Dose)

: 10minutes

-. Treatment Time(Max)-. Dose Range(Adjustable)

: 40minutes

: 1~120J/cm²

5.5.2.3 -. Output Wavelength : 830nm +/- 10nm **IR** -. Output Intensity : 28mW/cm² -. Standard Dose : 16J/cm² -. Treatment Time(Standard Dose) : 10minutes -. Treatment Time(Max) : 40minutes -. Dose Range(Adjustable) : 1~67J/cm² 5.5.2.4 -. Output Intensity : 90mW/cm² **BLUE+RED** -. Standard Dose : 54J/cm² -. Treatment Time(Standard Dose) : 10minutes -. Treatment Time(Max) : 40minutes -. Dose Range(Adjustable) : 1~216J/cm² -. Output Intensity 5.5.2.5 : 71mW/cm² BLUE+IR -. Standard Dose : 42.6J/cm² -. Treatment Time(Standard Dose) : 10minutes -. Treatment Time(Max) : 40minutes -. Dose Range(Adjustable) : 1~170J/cm² 5.5.2.6 -. Output Intensity : 75mW/cm² RED+IR -. Standard Dose : 45J/cm² -. Treatment Time(Standard Dose) : 10minutes -. Treatment Time(Max) : 40minutes -. Dose Range(Adjustable) : 1~180J/cm² -. Output Intensity 5.5.2.7 : 77mW/cm² **BLUE+RED+IR** -. Standard Dose : 46J/cm² -. Treatment Time(Standard Dose) : 10minutes -. Treatment Time(Max) : 40minutes -. Dose Range(Adjustable) : 1~184J/cm² 5.5.3 RRI (RED/RED/IR) 5.5.3.1 -. Output Wavelength : 635nm +/- 10nm RED1 -. Output Intensity : 50mW/cm² -. Standard Dose : 30J/cm² -. Treatment Time(Standard Dose) : 10minutes -. Treatment Time(Max) : 40minutes -. Dose Range(Adjustable) : 1~120J/cm² 5.5.3.2 -. Output Wavelength : 635nm +/- 10nm -. Output Intensity RED2 : 50mW/cm² -. Standard Dose : 30J/cm² -. Treatment Time(Standard Dose) : 10minutes -. Treatment Time(Max) : 40minutes -. Dose Range(Adjustable) : 1~120J/cm² 5.5.3.3 -. Output Wavelength : 830nm +/- 10nm IR -. Output Intensity : 28mW/cm² -. Standard Dose : 16J/cm² -. Treatment Time(Standard Dose) : 10minutes

-. Treatment Time(Max) : 40minutes -. Dose Range(Adjustable) : 1~67J/cm²

5.5.3.4 -. Output Intensity : 70mW/cm² RED1+RED2 -. Standard Dose : 42,J/cm²

-. Treatment Time(Standard Dose) : 10minutes
-. Treatment Time(Max) : 40minutes
-. Dose Range(Adjustable) : 1~168/cm²

5.5.3.5 -. Output Intensity : 75mW/cm²
RED1+IR -. Standard Dose : 45J/cm²
-. Treatment Time(Standard Dose) : 10minutes

-. Treatment Time(Standard Dose) : 10minutes
-. Treatment Time(Max) : 40minutes
-. Dose Range(Adjustable) : 1~180J/cm²

5.5.3.6 -. Output Intensity : 75mW/cm²
RED2+IR -. Standard Dose : 45J/cm²

-. Treatment Time(Standard Dose) : 10minutes
-. Treatment Time(Max) : 40minutes
-. Dose Range(Adjustable) : 1~180J/cm²

5.5.3.7 -. Output Intensity : 68mW/cm²
RED1+RED2+IR -. Standard Dose : 40J/cm²

-. Treatment Time(Standard Dose) : 10minutes -. Treatment Time(Max) : 40minutes -. Dose Range(Adjustable) : 1~163J/cm²

# 5.5.4 YRI (YELLOW/RED/IR)

5.5.4.1 -. Output Wavelength : 585nm +/- 10nm

YELLOW -. Output Intensity : 20mW/cm² -. Standard Dose : 12J/cm²

-. Treatment Time(Standard Dose) : 10minutes
-. Treatment Time(Max) : 40minutes
-. Dose Range(Adjustable) : 1~48J/cm²

5.5.4.2 -. Output Wavelength : 635nm +/- 10nm

RED -. Output Intensity : 50mW/cm²
-. Standard Dose : 30J/cm²
-. Treatment Time(Standard Dose) : 10minutes

-. Treatment Time(Max) : 10minutes -. Dose Range(Adjustable) : 1~120J/cm²

5.5.4.3 -. Output Wavelength : 830nm +/- 10nm

IR -. Output Intensity : 28mW/cm² -. Standard Dose : 16J/cm²

-. Treatment Time(Standard Dose) : 10minutes -. Treatment Time(Max) : 40minutes -. Dose Range(Adjustable) : 1~67J/cm²

5.5.4.4 -. Output Intensity : 58mW/cm²
YELLOW+RED -. Standard Dose : 34J/cm²

-. Treatment Time(Standard Dose) : 10minutes
-. Treatment Time(Max) : 40minutes
-. Dose Range(Adjustable) : 1~139J/cm²

5.5.4.5 -. Output Intensity :  $43 \text{mW/cm}^2$ YELLOW+IR -. Standard Dose :  $25 \text{J/cm}^2$ 

-. Treatment Time(Standard Dose) : 10minutes
-. Treatment Time(Max) : 40minutes
-. Dose Range(Adjustable) :1~103J/cm²

5.5.4.6 -. Output Intensity : 75mW/cm² RED+IR -. Standard Dose : 45J/cm²

-. Treatment Time(Standard Dose) : 10minutes
-. Treatment Time(Max) : 40minutes
-. Dose Range(Adjustable) : 1~180J/cm²

5.5.4.7 -. Output Intensity : 57mW/cm²
YELLOW+RED+IR -. Standard Dose : 34,J/cm²

-. Treatment Time(Standard Dose) : 10minutes
-. Treatment Time(Max) : 40minutes
-. Dose Range(Adjustable) : 1~136J/cm²

# 5.5.5 BRY (BLUE/RED/YELLOW)

5.5.5.1 -. Output Wavelength : 420nm +/- 10nm

BLUE -. Output Intensity : 41mW/cm²
-. Standard Dose : 24J/cm²

-. Treatment Time(Standard Dose) : 10minutes -. Treatment Time(Max) : 40minutes -. Dose Range(Adjustable) : 1~98J/cm²

5.5.5.2 -. Output Wavelength : 635nm +/- 10nm

RED -. Output Intensity : 50mW/cm²
-. Standard Dose : 30J/cm²
-. Treatment Time(Standard Dose) : 10minutes
-. Treatment Time(Max) : 40minutes

-. Treatment Time(Max) : 40minutes -. Dose Range(Adjustable) : 1~120J/cm²

5.5.5.3 -. Output Wavelength : 585nm +/- 10nm

YELLOW -. Output Intensity : 20mW/cm²
-. Standard Dose : 12J/cm²
-. Treatment Time(Standard Dose) : 10minutes

-. Treatment Time(Max) : 40minutes -. Dose Range(Adjustable) : 1~48J/cm²

5.5.5.4 -. Output Intensity : 90mW/cm²
BLUE+RED -. Standard Dose : 54J/cm²

-. Treatment Time(Standard Dose) : 10minutes -. Treatment Time(Max) : 40minutes -. Dose Range(Adjustable) : 1~216J/cm²

5.5.5.5 - Output Intensity : 52mW/cm²

BLUE+YELLOW -. Standard Dose : 32J/cm²

-. Treatment Time(Standard Dose) : 10minutes
-. Treatment Time(Max) : 40minutes
-. Dose Range(Adjustable) : 1~129J/cm²

5.5.5.6 -. Output Intensity : 58mW/cm² RED+YELLOW -. Standard Dose : 34J/cm²

-. Treatment Time(Standard Dose) : 10minutes
-. Treatment Time(Max) : 40minutes
-. Dose Range(Adjustable) : 1~139J/cm²

5.5.7 -. Output Intensity : 57mW/cm²

BLUE+YELLOW+RED -. Standard Dose : 34J/cm²

-. Treatment Time(Standard Dose) : 10minutes
-. Treatment Time(Max) : 40minutes
-. Dose Range(Adjustable) : 1~136J/cm²

#### 6. Specifications

\* Model Name : SMARTLUX MINI

\* Power Dimensions(W X L X H) : 280mm X 239mm X 214mm \*Head Dimensions(W X L X H) : 493.5mm X 365.3mm X 487mm

\* Output Intensity : Refer to the specifications of each head

\* Operation Interface : 4.3 Inch Color Touch Screen LCD

\* Input Power : 100-240V~, 50/60Hz

\* Fuse : 250V, 8A \* Power consumption : 600W

\* Cooling System : Air Cooling

\* Total Weight : 28kg

\* Life cycle :10,000 hours \* Humidity : 20~75%

\* Atmospheric pressure : 70 kPa ~ 106 kPa

\* Operating Temperature : 5  $^{\circ}$   $^{\circ}$   $^{\circ}$  30  $^{\circ}$ 

\* Software version : 1.0

### 7. Operating the Instrument



Caution!

SMARTLUX MINI should be used by the user who had special training on the use of SMARTLUX MINI. Only the technical use of SMARTLUX MINI is described here without medical explanation.

7.1 You should check the followings before using SMARTLUX MINI,

Introduction -. Is main power being connected?

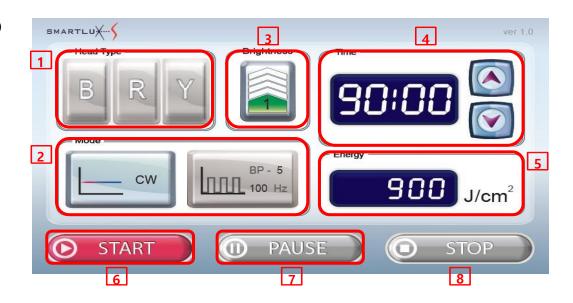
-. Protective goggles are in the treatment room and are they used for operator and patient?

7.2 Press Rocker switch to the position of 'I' to start SMARTLUX MINI. SMARTLUX MINI Start performs self-test for about 10 seconds, and when there is problem, related messages are

shown on Touch Screen.

7.3 Color Touch Screen SMARTLUX MINI provides Touch Screen operated with high sensitivity. To operate the buttons in Touch Screen, use finger or touch pen, and you can make settings of many modes by button operation.

7.4 Main Menu(Standard)

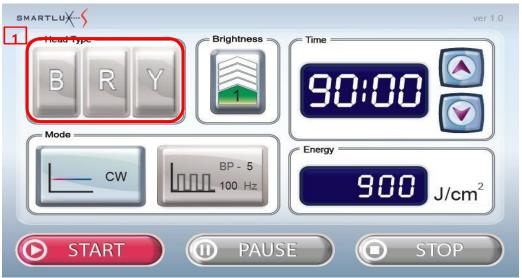


- 1. Head Type
- 2. Mode
- 3. Brightness
- 4. Time Select

- 5. Total Energy
- 6. START
- 7. PAUSE
- 8. STOP

7.4.1 START/STOP /PAUSE When SMARTLUX MINI is on STOP state, all operations can be controlled, and when the START button is pressed, SMARTLUX MINI is operated by user-selected mode. When PAUSE button is pressed while operating SMARTLUX MINI, operation of SMARTLUX MINI will stop, and in order to change the state of SMARTLUX MINI, STOP button should be pressed to make SMARTLUX MINI as STOP state.

7.4.2 Head Type



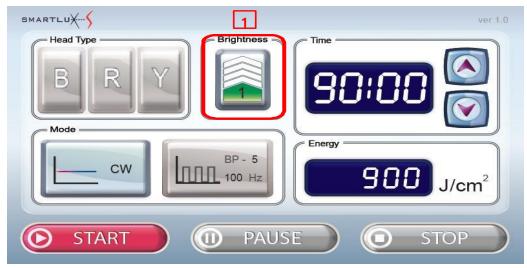
1. Head Type Selection Button: When you press inactivated button, it will be activated. Total number of activation is 2 and simultaneous irradiation is feasible.

Kinds of heads are total 4 as below.





7.4.3 Brightness

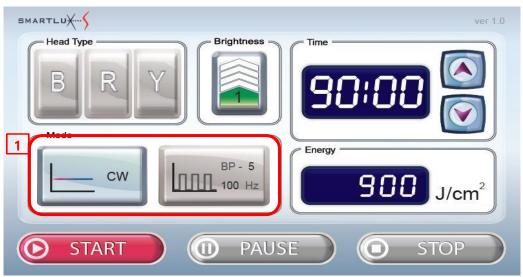


1. Brightness: When you click this button, you can adjust the brightness of the head from Stage 1 to Stage 5.



This is the button to select the brightness of head lamp. There are total 5 Stages and Stage 1 is minimum brightness and Stage 5 is maximum brightness.





- 1. Mode Button: When you click this button, you can adjust head lamp in CW mode or B-Pulse mode. CW' mode is programmed as a basic setting. The lamp mode changes each time that the buttons are touched.
- 7.4.4.1 2. CW: The 'CW' button refers to continuous wave mode. The brightness of the light can

CW(Continuous Wave) Mode

be adjustable using the Brightness button.



7.4.4.2 B-P(Burst Pulse) Mode

3. B-P: It stands for Burst Pulse mode and you can adjust it with Stage 1, 2, 3, 4, 5, 6, 7, 8. In case of Stage 1, On/Off is done once per second, in case of Stage 2, 5 times per second, and in case of Stage 8, 500 times per second.

-. Frequency (Hz) is the number of On/Off per second.



10 Hz

100 Hz

BP - 3

BP - 5

Level 1

- On Time: 0.5Sec

- Off Time: 0.5Sec



- On Time: 0.05Sec

- Off Time: 0.05Sec



- On Time: 0.005Sec

- Off Time: 0.005Sec



Level 7

- On Time: 0.0025Sec

- Off Time: 0.0025Sec



Level 2

- On Time: 0.1Sec - Off Time: 0.1Sec

Level 4

- On Time: 0.01Sec - Off Time: 0.01Sec

Level 6

BP - 6 150 Hz

500 Hz

- On Time: 0.0033Sec

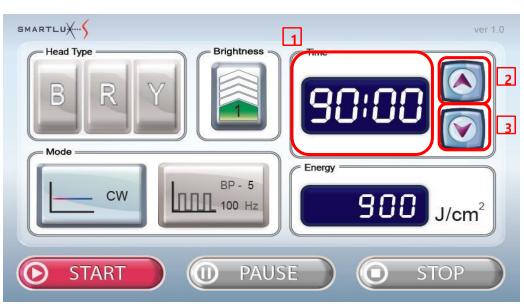
- Off Time: 0.0033Sec

Level 8 BP - 8

- On Time: 0.001Sec

- Off Time: 0.001Sec

7.4.5 Time



1. Time Display: Selected time is displayed. When you press START button after setting the time, timer runs in units of 1 second, and when timer reaches to 0, it stops. You can make setting up to 40 minutes in units of 1 minute.

2. UP



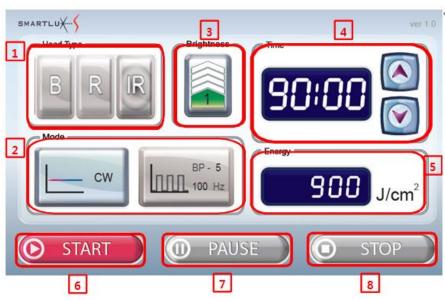
: It increases in units of 1 minute.



7.4.6 Total Energy When the operation of SMARTLUX MINI is activated by the click on START button after finishing all settings, total energy value is displayed. Total Energy is determined by irradiation area of head lamp, brightness and treatment time.

- Total Energy = Head Lamp(Irradiation Area) X Brightness (Intensity of Brightness) X Time (Set Time)

7.5 Main Menu BRI



Above screen shows BRI (BLUE/RED/IR) heads.

1. BLUE/RED/IR Select

5. Total Energy

2. Mode

6. START

3. Brightness

7. PAUSE

4. Time Select

8. STOP

7.5.1 BRI(BLUE/RED/IR) Select



When you click BLUE button, it is activated as shown in the picture. If you want to inactivate it, click BLUE button again. When you press START button, only BLUE light irradiates. When you click STOP button while light is irradiating, all three buttons are inactivated and light irradiation stops also.



When you click RED button, it is activated as shown in the picture. If you want to inactivate it, click RED button again. When you press START button, only RED light irradiates. When you click STOP button while light is irradiating, all three buttons are inactivated and light irradiation stops also.



When you click IR button, it is activated as shown in the picture. If you want to inactivate it, click IR button again. When you press START button, only IR light irradiates. When you click STOP button while light is irradiating, all three buttons are inactivated

and light irradiation stops also.



When you click BLUE and RED buttons, they are activated as shown in the picture. When you press START button, BLUE and RED lights irradiate. When you click STOP button while lights are irradiating, all three buttons are inactivated and light irradiation stops also.



When you click BLUE and IR buttons, they are activated as shown in the picture. When you press START button, BLUE and IR lights irradiate. When you click STOP button while lights are irradiating, all three buttons are inactivated and light irradiation stops also.



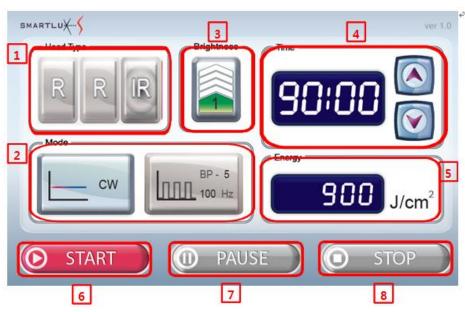
When you click RED and IR buttons, they are activated as shown in the picture. When you press START button, RED and IR lights irradiate. When you click STOP button while lights are irradiating, all three buttons are inactivated and light irradiation stops also.



When you click BLUE, RED and IR buttons, they are activated as shown in the picture. When you press START button, 3 lights irradiate. When you click STOP button while lights are irradiating, all three buttons are inactivated and light irradiation stops also

In addition to the above, same method applies to from Brightness to STOP. (Refer to Article 7.4)

7.6 Main Menu RRI



Above screen shows RRI (RED/RED/IR) head.

1. RED/RED/IR Select

5. Total Energy

2. Mode

6. START

3. Brightness

7. PAUSE

4. Time Select

8. STOP

7.6 RRI (RED/RED/IR) Select



When you click RED button, it is activated as shown in the picture. If you want to inactivate it, click RED button again. When you press START button, only RED light irradiates. When you click STOP button while light is irradiating, all three buttons are inactivated and light irradiation stops also.



When you click RED button, it is activated as shown in the picture. If you want to inactivate it, click RED button again. When you press START button, only RED light irradiates. When you click STOP button while light is irradiating, all three buttons are inactivated and light irradiation stops also.



When you click IR button, it is activated as shown in the picture. If you want to inactivate it, click IR button again. When you press START button, only IR light irradiates. When you click STOP button while light is irradiating, all three buttons are inactivated and light irradiation stops also.



When you click two RED buttons, they are activated as shown in the picture. When you press START button, two RED lights irradiate. When you click STOP button while lights are irradiating, all three buttons are inactivated and light irradiation stops also.



When you click first RED and IR buttons, they are activated as shown in the picture. When you press START button, RED and IR lights irradiate. When you click STOP button while lights are irradiating, all three buttons are inactivated and light irradiation stops also.



When you click second RED and IR buttons, they are activated as shown in the picture. When you press START button, RED and IR lights irradiate. When you click STOP button while lights are irradiating, all three buttons are inactivated and light irradiation stops also.



When you click 2 RED and IR buttons, they are activated as shown in the picture. When you press START button, 2 RED and IR lights irradiate. When you click STOP button while lights are irradiating, all three buttons are inactivated and light irradiation stops also.

In addition to the above, same method applies to from Brightness to STOP. (Refer to Article 7.4)i

7.7 Main Menu YRI



Above screen shows YRI (YELLOW/RED/IR) head.

- 1. YELLOW/RED/IR Select
- 2. Mode
- 3. Brightness
- 4. Time Select

5. Total Energy

- 6. START
- 7. PAUSE 8. STOP

7.7.1 YRI (YELLOW/RED/IR) Select



When you click YELLOW button, it is activated as shown in the picture. If you want to inactivate it, click YELLOW button again. When you press START button, only YELLOW light irradiates. When you click STOP button while light is irradiating, all three buttons are inactivated and light irradiation stops also.



When you click RED button, it is activated as shown in the picture. If you want to inactivate it, click RED button again. When you press START button, only RED light irradiates. When you click STOP button while light is irradiating, all three buttons are inactivated and light irradiation stops also.



When you click IR button, it is activated as shown in the picture. If you want to inactivate it, click IR button again. When you press START button, only IR light irradiates. When you click STOP button while light is irradiating, all three buttons are inactivated and light irradiation stops also.



When you click YELLOW and RED buttons, they are activated as shown in the picture. When you press START button, first YELLOW and RED lights irradiate. When you click STOP button while lights are irradiating, all three buttons are inactivated and light irradiation stops also.



When you click YELLOW and IR buttons, they are activated as shown in the picture. When you press START button, YELLOW and IR lights irradiate. When you click STOP button while lights are irradiating, all three buttons are inactivated and light irradiation stops also.



When you click second RED and IR buttons, they are activated as shown in the picture. When you press START button, RED and IR lights irradiate. When you click STOP button while lights are irradiating, all three buttons are inactivated and light irradiation stops also.



When you click YELLOW, RED and IR buttons, they are activated as shown in the picture. When you press START button, 3 lights irradiate. When you click STOP button while lights are irradiating, all three buttons are inactivated and light irradiation stops also.

In addition to the above, same method applies to from Brightness to STOP. (Refer to Article 7.4)

7.8 Main Menu **BRY** 



Above screen shows BRY (BLUE/RED/YELLOW0 head

1. BLUE/RED/YELLOW Select

5. Total Energy

2. Mode

6. START

3. Brightness

7. PAUSE

4. Time Select

8. STOP

7.8.1 **BRY** (BLUE/RED/YELLOW) Select



When you click BLUE button, it is activated as shown in the picture. If you want to inactivate it, click BLUE button again. When you press START button, only BLUE light irradiates. When you click STOP button while light is irradiating, all three buttons are inactivated and light irradiation stops also.



When you click RED button, it is activated as shown in the picture. If you want to inactivate it, click RED button again. When you press START button, only RED light irradiates. When you click STOP button while light is irradiating, all three buttons are inactivated and light irradiation stops also.



When you click YELLOW button, it is activated as shown in the picture. If you want to inactivate it, click YELLOW button again. When you press START button, only YELLOW light irradiates. When you click STOP button while light is irradiating, all three buttons are inactivated and light irradiation stops also.



When you click BLUE and RED buttons, they are activated as shown in the picture. When you press START button, BLUE and RED lights irradiate. When you click STOP button while lights are irradiating, all three buttons are inactivated and light irradiation stops also.



When you click BLUE and YELLOW buttons, they are activated as shown in the picture. When you press START button, BLUE and YELLOW lights irradiate. When you click STOP button while lights are irradiating, all three buttons are inactivated and light irradiation stops also.



When you click RED and YELLOW buttons, they are activated as shown in the picture. When you press START button, RED and YELLOW lights irradiate. When you click STOP button while lights are irradiating, all three buttons are inactivated and light irradiation

#### stops also.



When you click BLUE, RED and YELLOW buttons, they are activated as shown in the picture. When you press START button, 3 lights irradiate. When you click STOP button while lights are irradiating, all three buttons are inactivated and light irradiation stops also.

In addition to the above, same method applies to from Brightness to STOP. (Refer to Article 7.4)

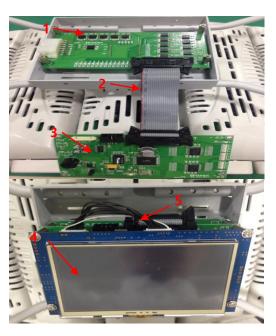
# 8. Care and Maintenance Safety Warnings



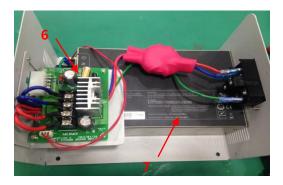
This system is special medical equipment. Therefore only properly trained users should be allowed to handle the equipment.

The safety of this technology for the treatment of children, pregnant women and in patients with light sensitive conditions has not been confirmed. An alternative treatment is recommended for these patients. And this system should not be applied to patients with heart disease, mental disorder or hypertension or those who have been determined to be inappropriate for the procedure. Clients are advised to rest for 5 minutes after treatment.

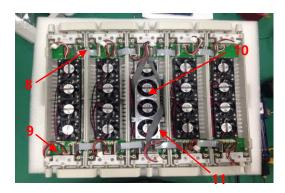
8.1 Service Method



- 1. FET BOARD
- LED Output, FAN Power Control
- 2. FALT CABLE
- FET, CPU Data Transmission
- 3. CPU BOARD
- Control of All SMARTLUX MINI Programs
- 4. LCD
- Control of screen
- 5. LCD CABLE
- LCD Power and Communication



- 6. INVERTER BOARD
- FAN Power Conversion
- 7. SMPS
- Power Supply



- 8. HEAD TO HEAD CABLE -LED, FAN Motion
- 9. Power CABLE LED, FAN
- 10. CENTER CABLE(5,10P)
- LED Output
- 11. CENTER CABLE(10P)
- +36V Power

# 8.2 Regular Monitoring

Monitoring should be conducted on a regular basis in order to maintain the accuracy of the pulse and output value. A qualified engineer examines the pulse and output value using a calibrated instrument once a year.

# 8.3 Cleaning

- 1) Make sure to put a cleaner you want to use on a soft cloth and wipe. Use the cleaner by diluting it with water in the ratio 1:10.
- 2) If the dust is on the power plug pin and the contact area, thoroughly wipe with a dry cloth.
- 3) Pull out the plug when cleaning the machine.



#### COUTION

You need to be cautious as it can cause color change, cracks or LCD panel peeling in the product when using a surfactant that contains large amounts of alcohol and solvent or strong substances.

#### 8.4 Trouble shooting

Troubleshooting must be carried out by skilled engineers. SMARTLUX MINI not displayed error messages on the LCD touch panel. Please call MEDMIX or authorized agency technician except to user action information below.

Problem	Advised Action
POWER doesn't work.	Check the following points.  1. Check that AC cord is plugged into the AC POWER socket. 2. Check the fuse embedded in the AC POWER socket. (Refer to 5.4.1.2)  If the problem still exists, call to MEDMIX or sales agents quickly.
LCD Touch screen doesn't displayed.	Check the following points.  1. Check that 12P MOLEX cable(gray) is plugged into the POWER part or MAIN part.  If the problem still exists, call to MEDMIX or sales agents quickly.

# Maintenance

The unit should be maintenance and serviced to maintain it in optimum condition. A recommended routine inspection and maintenance schedule are in the table below

Inspection/Service	Frequency	Performed By
Before using Smartlux MINI, please check if the arm is working properly	Before every operation	Staff
Before using Smartlux MINI , please conduct visual check to ensure that LED light is working properly.	Before every operation	Staff
Before using Smartlux MINI , please inspect system exterior to ensure that there are no loose electrical connections or damage	Before every operation	Staff
Please make sure there is a correct reaction to the safety catch of Smartlux MINI .	At least once a month	Staff
Please check if the image display and touch pad of LCD are working properly	Before every operation	Staff

. If you find some problem, please ask for a repair to Medmix or an authorized technician

# 9. Order

9.1 Order number

\_\_\_\_

When you place an additional order of SMARTLUX LITE, check the followings and then proceed to purchase.

Product Name	P/N	Product Name	P/N
SMPS	SMPWR01	STAND	SMST01
HEAD 1 (BRI)	SMH1	HEAD 2 (RRI)	SMH2
HEAD 3 (YRI)	SMH3	HEAD 3 (BRY)	SMH4
eye-protector	MMC1	SHIELD	MMC2
*P/N: Product Number	ſ	<u>.</u>	•



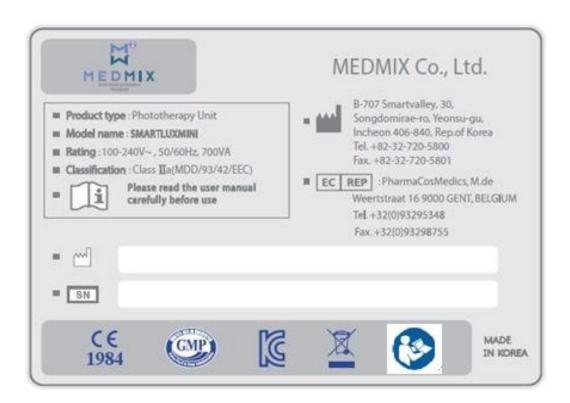
# CAUTION!

Following cautions are required for the use, management and maintenance of SMARTLUX MINI.

- 1) You need to read and understand this User's Guide fully before using SMARTLUX MINI.
- 2) SMARTLUX MINI should not be exposed to flammable liquid or gas. There is a danger of an explosion.
- 3) You should not see the light while lamp is operating since SMARTLUX MINI irradiates strong beam. If you close your eyes, you can reduce the impact of dangerous light.
- 4) SMARTLUX MINI doesn't emit UV and skin will not be burned by light irradiation for long hours.
- 5) Do not block air vent of the head. Be careful not to block the vent due to foreign substances. Proper cooling is necessary for safe operation of the lamp.

- 6) Secure the extra space with more than 15cm at the sides and rear of SMARTLUX MINI.
- 7) Grounding of SMARTLUX MINI is completed when it is connected to the socket that has grounding function.
- 8) Correct operation of SMARTLUX MINI is guaranteed when it is used with proper accessories. Do not use other lamps except the one which is provided by MEDMIX Co., Ltd.
- 9) When a continuous brightness mode emit for more than 30 minutes in five steps, then it must have the emit completed 5 minutes waiting time.
- 10) If FAN is malfunction, user turns off power and do not touch a head. After grabbing the STAND, user moves the equipment to safe place. Please ask to manufacturer or sales agents quickly.

#### 10. Label Information



### 10.1 Label for safety

Used symbol	Description	Used symbol	Description
***	Symbol for 'Manufacturer'	<b>( (</b> 1984	Symbol for 'CE marking approved by
EC REP	Symbol for `Authorized Representative in the EC'	SN	Serial number
M	Symbol for 'Manufacture Date'	Ĩ	Read usage instructions
GMP	Korea good manufacturing practice symbol		Korea certification mark
	Disposal WEE Symbol		Follow instructions for use
RISK GRUOP 1  CAUTIONS  UV emitted from this device. IR emitted from this device. Do not stare at the IR source.	Laser safety label	LED Light  Do not stare into the beam or view directly with optical instruments. Light Source : 4/20m - 850m  Output Interestry : 20mWta*=90mWta* Pulse duration : CW mode & 1 second	Laser safety label

#### 10.2 Label location



# 11. Declaration of Conformity - Electromagnetic Compatibility

# Guidance and manufacturer' declaration -electromagnetic emissions The SMARTLUX MINI is intended for use in the electromagnetic environment specified below. The customer or the

user of the SMARTLUX MINI should assure that it is used in such an environment

Emissions test	Compliance	Electromagnetic environment-guidance	
RF emissions CISPR 11	Group 1	The SMARTLUX MINI use RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.	
RF emissions CISPR 11	Class A	The SMARTLUX MINI is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies building used for domestic purposes.  Warning: This equipment is intended for use by healthcare professionals only. This equipment may cause radio interference or may disrupt the operation of nearby equipment. Is may be necessary to take mitigation measures, re-orienting or relocating the Triple 1470 or shielding the location	
Harmonic emissions IEC 61000-3-2	Class A		
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Class A		

# Guidance and manufacturer' declaration -electromagnetic immunity

The SMARTLUX MINI is intended for use in the electromagnetic environment specified below. The customer or the user of the SMARTLUX MINI should assure that it is used in such an environment

Immunity test	IEC60601	Compliance level	Electromagnetic
	test level		environment-guidance
Electrostatic discharge SMARTLUX MINI IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast	±2 kV for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical

transient/burst IEC 61000-4-2	±1 kV for input / output lines	±1 kV for input / output lines	commercial or hospital environment
Surge IEC61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment
Voltage dips, short interruptions and voltage variations on power supply lines IEC6100-4-11	<5% UT (>95%dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 seconds	<5% UT (>95%dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 seconds	Mains power quality should be that of a typical commercial or hospital environment If the user of the SMARTLUX MINI requires continued operation during power mains interruptions, it is recommended that the SMARTLUX SLIM be powered from an uninterruptible power supplied or a battery
Power frequency (50/60Hz) Magnetic field IEC61000-4-8	3 A/M oltage prior to the application	3 A/M	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment

# Guidance and manufacturer' declaration –electromagnetic immunity

The SMARTLUX MINI is intended for use in the electromagnetic environment specified below. The customer or the user of the SMARTLUX MINI should assure that it is used in such an environment

Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment-guidance
			Should be used no closer to any part of Triple1470 including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. $d = 1.2\sqrt{P}$
Conductive RF IEC61000-4-6	3Vrms 0.15MHz to 80MHz	3Vrms	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz
Radiated RF IEC61000-4-3	3V/m 80MHz to 2,5GHz	3V/m	$d=2,3\sqrt{P}$ 800 MHz to 2,5 GHz Recommended separation distance Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres(m).
			Field strengths from fixed RF transmitters, as determined by an electromagnetic survey <sup>a</sup> should be less than the compliance level in each frequency range <sup>b</sup> .

Interference may occur in the vicinity of equipment marked with the following symbol:



Note 1 At 80MHz and 800MHz the higher frequency range applies.

Note 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitted, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment in the location due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the SMARTLUX MINI is used exceeds the applicable RF compliance level above, the SMARTLUX MINI should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the SMARTLUX MINI.

Over the frequency range 150kHz to 80MHz, field strengths should be less than 3V/m.

Recommended separation distances between portable and mobile communication equipment and the HELIOS III

The SMARTLUX MINI is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the SMARTLUX MINI can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and the SMARTLUX MINI as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output	Separation distance according to frequency of transmitter (m)			
power of transmitter W	150kHz to 80MHz	80MHz to 800MHz	800MHz to 2.5GHz	
power of transmitter vv	d=1.2 P	d=1.2 P	d=2.3 P	
0.01	0.12	0.12	0.23	
0.1	0.38	0.38	0.73	
1.0	1.2	1.2	2.3	
10	3.8	3.8	7.3	
100	12	12	23	

For transmitter rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1. At 80MHz and 800MHz the higher frequency range applies.

Note 2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

* Manufacturer License Number	: 3183	: 3183	
* Product License Number	: 16-4134	: 16-4134	
* Product Type	: Phototherapy l	Jnit	
* Model Name	: SMARTLUX M	IINI	
Manufacturer	•	EC representative	
MEDMIX Co., Ltd		PharmaCosMedics	
B-707 Smartvalley, 30, Songdomirae-ro,		M. de Weertstraat 16 9000 GENT, Belgium	
Yeonsu-gu, Incheon 21990, Rep. of Korea		Tel. +32 (0) 93295348	
Tel. +82-32-720-5800, Fax. +82-32-720-5801		Fax. +32 (0) 93298755	

