



USER GUIDE

Document Number: PL-027 (Rev 3)

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1. Introduction

Thank you for choosing the Dermalux® Flex MD LED Phototherapy system. This User Guide covers the operational and technical aspects of the system.

For Client Assembly Instructions, please refer to the Dermalux Flex MD Assembly Guide (PL-028). Find instructions in section 19 of this guide.

For suggested treatment protocols and indications for use, please refer to the Dermalux® Flex MD Treatment Protocol Chart (PL-025) supplied with your system.

For a quick start guide refer to document (PL-029). Find instructions in section 6 of this guide.

Online materials available at: learn.dermaluxled.com

2. Important Safety Notice



Reading this User Guide is mandatory before attempting to operate the Dermalux® Flex MD system. It is important to follow the operating instructions and safety recommendations at all times. Any use of the Dermalux® Flex MD system other than outlined in this User Guide is considered to be improper and may cause damage which is not covered under the warranty or adverse response.

WARNING! Do not stare at operating lamp. May be harmful to the eye!

This product can come into contact with user's skin when in use on the body (not in Base). Always ensure the device is suitably positioned as required by the patient at all times.

This device is intended for the use by non-trained public and trained professionals at home and in a clinic environment via our training content.

WARNING: Do not connect or disconnect the power cable or controller when power is live to the device. Ensure power is off at all times when not in use.

WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

3. Intended Use

The Dermalux® Flex MD system is intended for the use by non-trained public and trained professionals at home and in a clinic environment via our training content. For use by suitably qualified and Dermalux® certified skin care professionals only within a home or professional environment (e.g. clinic, home environment).

- Skin Rejuvenation
- Complexion
- Dry Skin
- Pigmentation: Photo-damage
- Pigmentation
- Acne: Mild to Moderate
- Acne: Moderate to Severe
- Redness: Vascular
- Redness: Skin Tone
- Sensitive Skin
- Sensitive Skin: Problem conditions
- Psoriasis
- Wound Healing
- Pain

4. Device Description

The Dermalux® Flex MD is a Medical Device for use on a treatment bed with a floor standing option also available. The device emits specific wavelengths of low level, narrow band light for the treatment of certain cosmetic, dermatological and medical indications. The wavelengths used in the Dermalux® Flex MD system are Blue 415nm, Red 633nm and Near Infrared 830nm.

The system enables treatment of the face and the body via a flexible LED Array. The Array can be used in the Base for facial treatments or it can be removed from the Base to treat larger body areas by laying the device over the affected area.

The system consists of a Base unit, power supply unit (100-240Vac, 50/60Hz), capacitive touch Controller and flexible Array that contains Light Emitting Diodes (LEDs).

The power supply is designed to power the internal electronics for the system and the Light Emitting Diodes. The power supply is connected to a suitable mains outlet via a mains outlet and wall plug. The device is switched ON/OFF by a button located on the Controller.

The Dermalux® Flex MD system is operated by a capacitive touch Controller, which allows one of 7 treatments to be selected, through selecting various wavelength combinations.

The light is generated by Light Emitting Diodes (LED's) which are contained within the flexible LED Array. The LED Array can be placed into the Base, holding in the appropriate position to administer a facial treatment. For use on the body, the LED Array is removed from the Base unit and placed over the necessary body part.

Safety goggles are supplied for patient comfort and safety.

The equipment is not used to make measurements of any sort, or to draw any conclusions regarding the indication to treat. The equipment does not require checks on the light output as the LEDs do not dim with age to any practical extent.

5. Device Components

- Flex MD Base Unit
- Flexible LED Array
- Flex MD Controller
- RJ11 Cable (2m)
- Power Supply (with 1.5m lead)
- Patient Goggles
- Pillow
- Bag
- User Guide
- Protocol Manual

Device Components.



Figure 1: Flex Components.

6. Flex MD Quick Start Guide

1. Unpack and assemble the device as per PL-028 Assembly Guide found in section 19 of the user guide.
2. Once the Flex MD is unpacked, assembled and connected to a mains socket, switch on the mains switch, then press the power button on the Controller (Power button will illuminate in green).

Control Buttons

Name	Icon	Description
Power		Turns device on and off.
Blue		Activates blue LED's for treatment.
Red		Activates red LED's for treatment.
NIR		Activates near infra-red LED's for treatment.
Play		Initiates 30 minute treatment with pre-selected LED wavelengths.

Table 1: Flex Control Buttons.

3. Upon activation you will see the timer screen (in the centre of the controller) show the Dermalux® logo, then the Flex MD logo.



Figure 2: Flex Controller Overview.

Select the combination of wavelengths you require from the buttons on the right side of the Controller. See Flex MD Treatment Protocols Chart (PL-025)

4. When the appropriate wavelengths have been selected for the required treatment, press the PLAY button. The PLAY button light will then switch from red to green to indicate that the treatment has begun. If the treatment is paused it will revert to a red light until resumed.

7. Indications for Use

LED Phototherapy is well evidenced for its regenerative and anti-inflammatory benefits without creating trauma, making it safe and suitable for all skin types. Due to the non-invasive nature and high safety profile of the treatment, the scope for use extends across a wide range of applications.

The Dermalux® Flex MD system delivers three clinically proven wavelengths via 7 treatment options selected through the Controller. These wavelengths are 415nm, 633nm and 830nm.

Indications for use include but are not limited to the following:

- Skin Rejuvenation
- Complexion
- Dry Skin
- Pigmentation: Photo-damage
- Pigmentation
- Acne: Mild to Moderate
- Acne: Moderate to Severe
- Redness: Vascular
- Redness: Skin Tone
- Sensitive Skin
- Sensitive Skin: Problem conditions
- Psoriasis
- Wound Healing
- Pain

Refer to protocol manual (PL-025) for an extensive list of Pre-Set indication protocols.

8. Precautions and Contraindications

The Dermalux® LED Phototherapy treatment is safe and well tolerated, however there are certain circumstances and medical conditions in which treatment may prove to be unsuitable.

Prior to treatment, we strongly recommend that all clients complete and sign the Dermalux® Consent Form (PL-012, Available at learn.dermaluxled.com) and disclose any medications or medical conditions which may contraindicate the treatment at the current time (Available in our online materials). Failure to do so may increase the risk of an unwanted or adverse reaction. For more information about Adverse Reactions please refer to Section 14.

9. Contraindications

Indications for use include but are not limited to the following:

- Epilepsy or Seizures triggered by light
- Metabolic disorders such as Porphyrria
- Autoimmune disorders such as Systemic Lupus Erythematosus (SLE)
- Photosensitive disorders such as Photosensitive Eczema
- Active Cancers
- Use of Photosensitive Medications

10. Warning signs Associated with Photosensitivity

Certain medical conditions, medications and chemicals are known to induce Photosensitivity. Photosensitivity is a common side effect of various medications. These can include certain antibiotics, chemotherapy drugs, and diuretics.

10.1 Other substances known to increase the risk of sensitivity

St John's Wort, anti-perspirant, antibacterial soaps, artificial sweeteners, naphthalene (mothballs), petroleum products, brightening agents found in laundry detergent, and cadmium sulphide (a chemical injected into the skin during tattooing).

Photosensitivity may also be caused by the use of certain perfume applied in the treatment area.

10.2 Recognising Photosensitivity

Photosensitivity is a condition characterised by increased sensitivity to light, particularly UV light. It refers to the development of a skin reaction as a result of the combined effects of light and certain medications (oral and topical), hormonal changes, trauma or chemical causes. General symptoms present as an erythema reaction similar to sunburn.

Exposure to either a chemical or the light alone is not sufficient to induce a photosensitive reaction. When photo-activation of a chemical occurs, a phototoxic or photoallergic reaction may arise.

For a list of Photosensitive Medications, please refer to the Medications Explained Information sheet (PL-011, Available at learn.dermaluxled.com).

11. Pregnancy

The Dermalux® MD device has NOT been tested on pregnant women and therefore the risk to the foetus or pregnant woman is unknown. Administration of the treatment during pregnancy would strictly be at the users discretion.

For further Information about Contraindications please refer to the Dermalux Treatment Protocol Chart (PL-025) supplied with your system.

12. Precautions

Clients who present with any of the following medical conditions may be treated with caution and must be closely monitored.

Eye Disease and Conditions including Glaucoma, Cataracts, or recent laser eye surgery
Light Induced Migraines

13. Known Risks

There are no known allergic reactions to the materials used for the manufacture of this device, should reaction occur please seek medical advice and report as per Section 14.

Immediately after treatment:

- Skin may feel warm and may appear red, due to the increased blood circulation in your skin. Skin should return to normal with 1 to 2 hours.
- Temporary headaches immediately following the light treatment:
- Headaches can be treated with an appropriate pain killer and rehydration.

Should injury occur as a result of using this device please seek medical advice and report as per Section 14.

14. Adverse Event Reporting

In the unlikely event of a product fault or an adverse response to the Dermalux® Flex MD treatment, please report the issue to Aesthetic Technology as soon as possible. For all adverse reactions please complete form QOP-82-05-F1 following instructions provided with the form (Available at learn.dermaluxled.com).

- **A malfunction or deterioration in the characteristics or performance of the device.**
 - A malfunction or deterioration should be understood as a failure of the Dermalux® device to perform in accordance with its intended purpose as specified in the User guide.
- **An adverse reaction or unanticipated side effect.**
 - An adverse reaction is an incident which causes, or has the potential to cause, unexpected or unwanted effects involving the safety of persons receiving/or having received a Dermalux® treatment or users of the Dermalux® LED system.
 - An unanticipated side effect is one that exceeds the known side effects or is not listed as a potential side effect in the Dermalux® TM User guide (anticipated side effects)
- **Use the correct section of the form to report;**
 - A malfunction or deterioration of the device
 - An adverse reaction or unanticipated side effect

15. General Safety Warnings

The Dermalux® Flex MD system is an electrical device, which under certain circumstances could present an electrical shock hazard to the user. Please follow the directions stated in the manual and online training to assure maximum safety during operation.



WARNING: To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

WARNING: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Only use the power adapter and accessories supplied along with detachable parts with the system or specified by the manufacturer and rated for country of use. Using any other adapter may lead to an electrical fault or could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation

To fully isolate the device from the mains power unplug from the mains outlet socket. Ensure the mains outlet socket is able to be reached to isolate the device.

Using the long power lead we supply with the unit may present a trip hazard if installed incorrectly or in the main footpath of operation, always take caution when manoeuvring around the product.

The power lead may present itself as a strangulation hazard to infants if not correctly installed.

Always plug the system into a direct mains outlet socket. Do not use an extension cable or socket adaptor.

Do not use the system near water/liquids or where water/liquids could be spilt onto it.

Do not use the system if the LED head has come into contact with water/liquids.

Do not plug, unplug or activate the system with wet hands.

Do not use the system in the presence of flammable liquids or gases.

Do not disassemble any parts from the system. Opening or removing covers may expose the operator to dangerous voltages or other risks. Incorrect reassembly may lead to an electric shock.

Do not operate or handle the device when powered if it is damaged in any way. Contact our Customer Support team or your local Dermalux® representative for advice. If the head is damaged and powered it poses no risk to the user or operator due to low voltage supply.

Do not attempt to modify the system in any way as this may result in an electric shock when the system is used again. Unauthorised modification will also void the warranty.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Dermalux® Flex MD, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.



WARNING!

CAUTION! Avoid use around animals and children to prevent unnecessary risk.

16. To Reduce the Risk of Damaging the System



WARNING!

- Do not place the system in a dusty or dirty environment.
- The system should be kept away from high temperature sources including direct sunlight.
- When storing the system, place the LED Array in a flat position.
- The system may be cleaned by following the cleaning instructions in Section 20 of this User Guide.
- Do not use any other cleaning products other than those stated in this User Guide. Use of other cleaning products may damage the system.
- When not in use, it is advised to keep the system switched off.

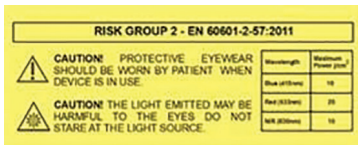
17. Eye Safety



WARNING!

Do not stare at operating lamp. May be harmful to the eye!

Take note of the Warning label found on the inside face of the Flex, example listed below.



CAUTION! Protective eyewear should be worn by patient when device is in use.

CAUTION! The light emitted may be harmful to the eyes Do Not Stare at the light source.

18. Receiving the Dermalux® Flex MD

Inspect the system for any visual damage that may have been caused during transit. Check warranty labels were intact at time of receiving product.

If any of the individual components are missing or damaged listed in section 5 of this document, please contact Aesthetic Technology Ltd or your local authorised representative within 24 hours of receiving the system.

For reference the Dermalux® Flex MD system consists of:

- Flex MD Base Unit
- Flexible LED Array
- Flex MD Controller
- RJ11 Cable (2m)
- Power Supply (with 1.5m lead)
- Patient Goggles
- Pillow
- Bag
- User Guide
- Protocol Manual

Refer to document PL-028 Assembly Guide for a step by step guide for end user assembly. In section 19 of this guide.



Figure 3: Flex Components.

19. Using the Device

19.1 Assembly Guide

Background:

The Flex MD is delivered in one box (the product box) wrapped in another box (the transport box). If being shipped overseas multiple Flex MD will be loaded into a carrier and palletised. Care should be taken when unloading from the pallet. Make sure each box remains in the correct orientation, follow markings on the box as a guide.

Warning:

- Do not connect or power the device up until instructed.
- Do not use sharp objects to cut open the packaging as it may cause damage to the product within.

Packaging:

All packaging has been specifically designed for transportation, please dispose of all waste appropriately and only remove from the transportation packaging when necessary.

Labelling:

All labels are positioned as required under the document guidelines of (PL-001)

Disclaimer:

Aesthetic Technology Ltd takes no responsibility for any damaged products from repackaged devices upon receipt of the shipped product.

19.1.1. Unpacking and Set Up of Flex MD

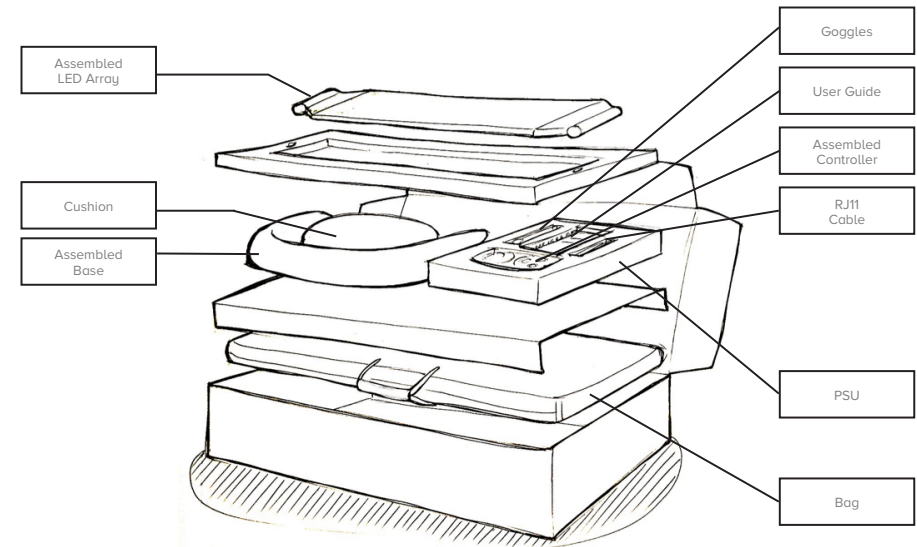


Figure 4: Flex In Packaging.

Step 1: Remove product from packaging, as shown in Image 1.

Step 2: Place Base flat onto surface and clip the LED Array into place, as shown in Image 2.



Figure 5: Assembled Flex.

Step 3: Connect Controller via ethernet cable, as shown in Image 3.

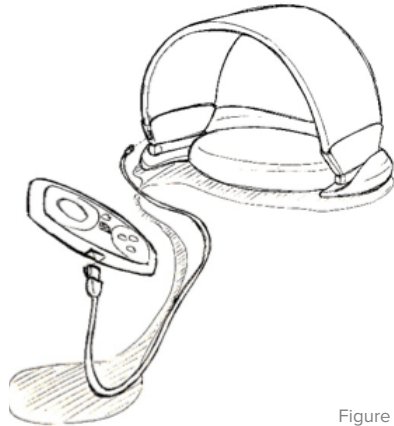


Figure 6: Connecting Controller.

Step 4: Connect PSU via port in LED array, then plug into the mains at the other end. See Image 4.

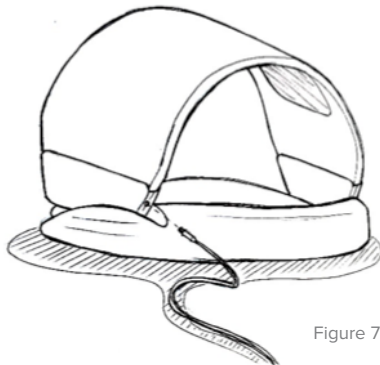


Figure 7: Connecting to Power.

Next steps: Now the full mechanical / electrical set up is complete, please refer to PL-029 Quick Start Guide for further instruction on how to operate the device. For full detailed instructions for the user interface please read PL-027 check section 19.2 of this guide..

19.2 Setup and First use

The device does not require a warm up period.

- Mount flex to base unit
- Connect the RJ11 cable to the controller
- Connect the opposite end of the RJ11 connector to the Flex
- Connect the psu to the flex using the 5mm barrel jack
- When plugging in to the mains (wall socket) ensure the socket is off when plugging in
 - Plug the PSU in
 - Switch the wall socket on
- Press the power button on the controller
- **Screen will illuminate with the following, in order:**
 - Dermalux
 - Flex
 - 30 minutes (displayed)
- When the controller is functional, you can press one, two or three colours. When pressed they will illuminate
 - To start the treatment, press play
 - To pause the treatment, press pause
- A switching LED will switch when play / pause if pressed (pause shows up as red, play shows up as green).
 - All outputs are constant
 - Time runs from 30 minutes only on countdown
 - When the treatment has finished a "00" will flash between black and white

19.3 Startup & Shutdown

19.3.1 Startup

Once the Dermalux® Flex MD is unpacked and connected to a mains socket, switch on using the power button on the Controller (the button will light up in green). Refer to icon in Table 2 on Page 24. Button reference ID 1.

19.3.2 Shutdown

To initiate a shutdown, press the power button on the Controller. When not in use unplug from the mains power socket. Refer to icon in Table 2 on Page 24. Button reference ID 1.

The device does not require a cool down period

19.4 Selecting a Program

The following table identifies the universal icons that shall be used throughout the Controller display software.

19.4.1 Icons






Name	Icon	Description	Button Reference ID
Power		Turn device on and off	1
Blue		Activates blue LED's for treatment	2
Red		Activates red LED's for treatment	3
NIR		Activates near infra-red LED's for treatment	4
Play		Initiates 30 minute treatment with pre-selected LED wavelengths.	5

Table 2: Flex Control Buttons.

*Note the key functions will be labelled throughout the document as their button reference number.

19.4.2 Detailed Software Walk Through

1. If the POWER button is pressed at any time the device will turn off and any treatment will be cancelled.
2. If the PLAY button is pressed any treatment in progress will pause until resumed (by pressing PLAY again) or cancelled (by pressing the POWER button).
3. If the RED, BLUE or NIR buttons are pressed at any time during a treatment, the corresponding wavelengths will be selected or deselected.

Button/ ID Function	Requirement
N/A	Upon successful completion of initialisation, the POWER button will illuminate in green.
2	In the HOME screen, if the BLUE button is pressed, the blue LED's will be selected for the treatment as indicated by the button being backlit in blue. *To deselect blue LED's press BLUE button again.
3	In the HOME screen, if the RED button is pressed, the red LED's will be selected for the treatment as indicated by the button being backlit in red. *To deselect red LED's press RED button again.
4	In the HOME screen, if the NIR button is pressed the near infra-red LED's will be selected for the treatment as indicated by the button being backlit in yellow. *To deselect near infra-red LED's press NIR button again.
5	In the HOME screen, if the PLAY button is pressed the treatment will initiate with whichever LED wavelengths were previously selected. *If no wavelengths have been selected (BLUE, RED, NIR) the PLAY button cannot be selected.

Table 3: Flex Function Overview.



Figure 8: Controller Overview, Home.

* Navigation:Home

19.4.3 Red 633nm Treatment

Button/ ID Function	Requirement
3	Press the RED button to activate the red LED's. This is indicated by the button illuminating in red.
5	In the RED TREATMENT screen, if the PLAY button is pressed the treatment is started or paused.

Table 4: Flex Function Overview for Red Treatment.



Table 4: Flex Function Overview for Red Treatment.

* Navigation: Home - Red Treatment

19.4.4 Blue 415nm Treatment

Button/ ID Function	Requirement
2	Press the BLUE button to activate the blue LED's. This is indicated by the button illuminating in blue.
5	In the BLUE TREATMENT screen, if the PLAY button is pressed the treatment is started or paused.

Table 5: Flex Function Overview for Blue Treatment.



Table 5: Flex Function Overview for Blue Treatment.

* Navigation: Home - Blue Treatment

19.4.5 NIR 830nm Treatment

Button/ ID Function	Requirement
4	Press the NIR button to activate near infra-red LED's. This is indicated by the button illuminating in yellow.
5	In the NIR TREATMENT screen, if the PLAY button is pressed the treatment is started or paused.

Table 6: Flex Function Overview for NIR Treatment.



Figure 11: Controller Overview, NIR Treatment.

* Navigation: Home - NIR Treatment

19.4.6 Blue & Red Treatment

Button/ ID Function	Requirement
2	Press the BLUE button to activate the blue LED's. This is indicated by the button illuminating in blue.
3	Press the RED button to activate red LED's. This is indicated by the button illuminating in red.
5	In the BLUE & RED TREATMENT screen, if the PLAY button is pressed the treatment is started or paused.

Table 7: Flex Function Overview for Blue & Red Treatment.



Figure 12: Controller Overview, Blue & Red Treatment

* Navigation: Home - Blue & Red Treatment

19.4.7 Blue & NIR Treatment

Button/ ID Function	Requirement
2	Press the BLUE button to activate blue LED's. This is indicated by the button illuminating in blue.
4	Press the NIR button to activate near infra-red LED's. This is indicated by the button illuminating in yellow.
5	In the BLUE & NIR TREATMENT screen, if the PLAY button is pressed the treatment is started or paused.

Table 8: Flex Function Overview for Blue & NIR Treatment.



Figure 13: Controller Overview, Blue & NIR Treatment.

* Navigation: Home - Blue & NIR Treatment

19.4.8 Red & NIR Treatment

Button/ ID Function	Requirement
3	Press the RED button to activate red LED's. This is indicated by the button illuminating in red.
4	Press the NIR button to activate near infra-red LED's. This is indicated by the button illuminating in yellow.
5	In the RED & NIR TREATMENT screen, if the PLAY button is pressed the treatment is started or paused.

Table 9: Flex Function Overview for Red & NIR Treatment.



Figure 14: Controller Overview, Red & NIR Treatment.

* Navigation: Home - Red & NIR Treatment

19.4.9 Tri-Wave Treatment

Button/ ID Function	Requirement
2	Press the BLUE button to activate blue LED's. This is indicated by the button illuminating in blue.
3	Press the RED button to activate red LED's. This is indicated by the button illuminating in red.
4	Press the NIR button to activate near infra-red LED's. This is indicated by the button illuminating in yellow.
5	In the TRI-WAVE TREATMENT screen, if the PLAY button is pressed the treatment is started or paused.

Table 10: Flex Function Overview for Tri-Wave Treatment.



Figure 15: Controller Overview, Tri-Wave Treatment.

* Navigation: Home - Tri-Wave Treatment

20. Cleaning Instructions

It is important that the Dermalux® Flex MD system is switched off and unplugged from the mains power socket before cleaning.

The entire surface of the system including the main body, treatment head, and control panel may be cleaned with an anionic detergent towelette or surface wipe. Excess moisture from the wipe may be removed by using a clean dry microfibre cloth.

Please refrain from using any other cleansing products as these may damage the plastics and/or electrical components if they were to become in contact with.

If the Dermalux® Flex MD system is used on the body, the device must be thoroughly cleaned before use on another client.

21. Maintenance

The product will require no manufacturing maintenance on an annual basis. The customer is expected to carry out routine maintenance such as cleaning and general health inspections of the device per quarter year.

No maintenance will be performed on the Dermalux® Flex MD system by the manufacturer. Any faults found with the system within the warranty period should be reported to the manufacturer and a replacement device will be issued if required.

22. Servicing Requirements

The Dermalux® Flex MD system contains no serviceable parts.

Calibration of the system is not required.

There is no annual health service with this product.

23. Storage & Transit Conditions

When not in use store the Dermalux® Flex MD system at room temperature in dry/low humidity conditions.

Environmental conditions for transport and storage: -25 to +70 degrees Celsius and up to 90% humidity (normal range for room temperature conditions). Atmospheric pressure range of 50 kPa to 106 kPa

Store away from direct heat and sunlight.

24. Operating Conditions

The Dermalux® Flex MD system should be operated at room temperature in dry/low humidity conditions. 5-40 degrees Celsius and 15-90% humidity (normal range for room temperature conditions). Atmospheric pressure range of 70 kPa to 106 kPa

Keep away from direct heat and sunlight.

The duty cycle for this product is continuous.

25. Disposal

Do NOT dispose of any part of the Dermalux® Flex MD LED system at a domestic waste facility. Seek local waste disposal advice from your local council or consult the manufacturer for guidance.

For protection of the environment, please package and return this unit to Aesthetic Technology Ltd or their representative at the end of its working life.

On 27th January 2003, the European Parliament and the Council of the European Union authorized Directive 2002/96/EC on waste electrical and electronic equipment (WEEE). This directive encourages and sets specific criteria for the collection, handling and recycling of electric and electronic waste.

26. Technical Specification

- **Blue (415nm)**
 - Maximum optical power is 10 j/cm²
 - Maximum operating time per treatment is 30 minutes
- **Red (633nm)**
 - Maximum optical power is 20 j/cm²
 - Maximum operating time per treatment is 30 minutes
- **NIR (830nm)**
 - Maximum optical power is 10 j/cm²
 - Maximum operating time per treatment is 30 minutes
- Maximum variation of 10% optically
- Ocular hazard distance (EN 60601-2-57): 0.025m when in use with the cradle, 0.0m when directly placed on the body
- EN 62471 Risk Group 2
- Mains supply: 100 – 240 Vac, 50 / 60 Hz
- Tailor to clients with 7 treatment options.
- Weight: 2.5kg
- Footprint (in Base Unit) W520 x L335 x H300 mm
- Footprint (Array in flat position): W280 x L790 x H30 mm
- Duty Cycle: Continuous
- IP Rating : IP20

26.1 Electromagnetic Guidance

Emissions Test	Compliance
RF conducted and radiated emissions CISPR 11	Group 1, Class B
Harmonic emissions IEC 61000-3-2	Class A
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies

Immunity tests	Immunity Test Level	
Electrostatic Discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	
Radiated RF EM fields IEC 61000-4-3	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	
Proximity fields from RF wireless communications equipment IEC 61000-4-3	380 – 390 MHz	27 V/m
	430 – 470 MHz	28 V/m
	704 – 787 MHz	9 V/m
	800 – 960 MHz	28 V/m
	1.7 – 1.99 GHz	28 V/m
Electrical fast transients/burst IEC 61000-4-4	± 2 kV 100 kHz repetition frequency	
	Surges IEC 61000-4-5	
Conducted disturbances induced by RF fields IEC 61000-4-6	Line to line: ± 0,5 kV, ± 1 kV	
	3 V/m 0,15 MHz – 80 MHz 6 V/m in the ISM and Amateur Radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	
Voltage dips and interruptions IEC 61000-4-11	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle at 0° 70 % UT; 30 cycles at 0° 0 % UT; 300 cycles	
	UT is the AC mains voltage prior to application of the test level.	

Table 11: Electromagnetic Technical Information.

27. Labelling

Product Labelling conforms to PL-001 (Rev 8) – Dermalux® Product Labelling Specification.

28.1 Symbols and Product Labelling

	Serial Number		Electrical Warning
	Product Code and Reference		Keep Dry
	Date of Manufacture		Manufacturer
	Product is CE marked. Notified body number: 2797		General Warning
	Upper and Lower Operating Temperature		Follow instructions for use
	2 = Protection against objects larger than 12.5mm X = No protection.		Upper and Lower Operating Humidity
	Do not dispose of in general waste.		

Table 12: Labelling Identification.

28. Basic User Approach

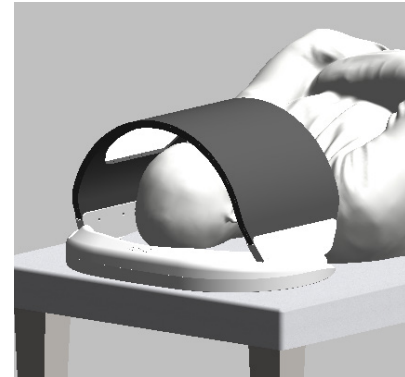


Figure 16: Flex on Treatment Couch, Overhead, Side View.

The diagrams to the left demonstrate how the machine should be set up and positioned around the patients face. This is for illustrative purposes; the type of array may vary dependant on the device in use.

The minimum distance between the front face of the Pod and the patient should be no less than 25mm. The positioning of the LED Array mitigates unintended exposure and the device should only be used with a patient in place.

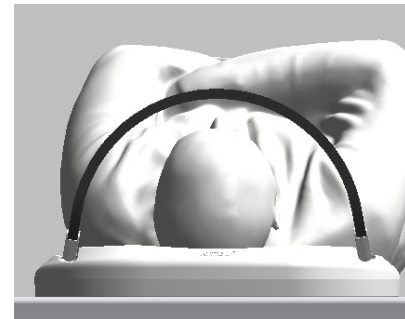


Figure 17: Flex on treatment Couch, Overhead, End View.

Note: The distance determines the j/cm^2 of the emitted light, the further the patient is from the device the lower the optical power density.

Note: The LED Array can be positioned around both the body and the head. When positioned on the body, the head should remain at a minimum of 25mm.

29. System Warranty

Under normal use this product is guaranteed for 2 years after its original purchase date against manufacturing defects in materials or workmanship.

This warranty extends to the original purchaser only. If the product should become faulty within the warranty period, please contact Aesthetic Technology or your local Dermalux® representative.

Manufacturer contact details

Aesthetic Technology Ltd
242 Europa Boulevard
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WA5 7TN
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Email: info@dermaluxled.com

Aesthetic Technology Ltd or its authorised distributor reserves the right to repair a defective product.

Aesthetic Technology Ltd or its authorised distributor reserves the right to replace a defective product with the most compatible product currently available.

The Dermalux® Flex MD warranty does not cover damage caused by the following:

- Accident, misuse, abuse or alteration
- Servicing by unauthorized persons
- Connection to incorrect power sources
- Use with unauthorized accessories
- The warranty is VOID if the serial number and/or associated labelling has been modified, defaced or removed from the product.

Aesthetic Technology Ltd or its authorised distributors shall not be responsible for any incidental, special or consequential damages resulting from the use of this product. All implied warranties, including but not limited to implied warranties of fitness and merchantability are limited in duration to one year from date of original purchase.

This warranty gives you specific legal rights, and you may also have other rights that vary from country to country. Some countries do not allow the exclusion or limitation of incidental or consequential damages, or limitations on how long an implied warranty lasts, so some of the above limitations and exclusions may not apply to you.

This warranty is given in lieu of all other warranties, written or oral, whether expressed by affirmation, promise, description, drawing, model or sample. Any and all warranties other than this one, whether expressed or implied, including implied warranties of merchantability and fitness for a particular purpose are hereby disclaimed.

30. Fault Reporting

In the event of any faults occurring over the course of the products lifetime, please report this at your earliest convenience to your local reseller or directly with the manufacturer, **Aesthetic Technology Ltd.**

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31. Troubleshooting

Your device is not powering on?

Ensure the pin head (mains facia plug) and power supply (PSU) are clipped together properly. To do so, unclip them and reattach. To be sure, follow the setup up guide thereafter to retest the connection. If this continues to fail, then see further guidance below.

Switch the power off on the wall and disconnect the barrel jack between the PSU and the LED Array, then reconnect making sure the two halves butt up to each other. Switch the mains power back on and follow the user guide for initial setup. If the device continues to fail, then see further guidance below.

Switch the power off on the wall and disconnect the RJ11 Cable between the LED Array and Controller at the LED array end, once removed reconnect ensuring you hear it click into place. Check the connection on the controller end by giving the cable a small tug to see if it disconnects from the controller, if it does, reconnect until you hear a small click. If both terminals are firmly in place, switch the power back on at the wall and follow the user guide for initial setup. If the device continues to fail, then see further guidance below.

If you've checked all the connections and it still isn't working, turn off and leave for 30 seconds, then turn on again. If the device continues to fail, then see contact the Manufacturer or reseller, manufacturer details are found on page 44.

Is one of the colours of LED not coming on?

Common issues, user can sometimes press the button on the controller twice, trying pressing again to see if the LED's switch on. Note*, NIR isn't visible to the human eye so this might be on without you realising it, if the NIR is illuminated on the controller and you don't wish to use this option, then press again until the controller NIR back light switches off.

The Controller option is illuminated but no LED's are switched on, on the LED array?

Contact the Manufacturer or reseller, manufacturer details are found on page 44.

Does the LED Array move from side to side in the base?

Ensure the LED Array has slid all the way to the back of the base and clipped into place. Refer to initial setup guide in the user manual for guidance.

Are you having trouble removing the RJ11 cable from the controller?

This can be difficult, especially if you have short nails. Try using a pin to press in the plastic lever in, then the cable should slide out easily. It is advised to leave this connected where possible as to avoid any future connection issues. The carry bag has been provided to store these components when not in use.

For any further assistance, please contact the Manufacturer or reseller, manufacturer details are found on page 44.

32. Manufacturers Declaration

Aesthetic Technology Ltd declares that the Dermalux® Flex MD has been made to all relevant standards to its current market at the date of sale. The business reserves the right to make changes where required to remain compliant to local standards. All products are fully tested and quality checked before dispatch.



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