

Dermalux™

 TRI WAVE

Dermalux® Tri-Wave User Guide



Users of this device can obtain benefit from using it only if they read and comprehend all information in the User Manual.

You must follow all the instructions in the User Manual.

Please feel free to contact us on our Customer Services number (see below) if you have any comments about Dermalux® Tri-Wave LED systems or this User Guide.

Dermalux® is a registered trademark of;

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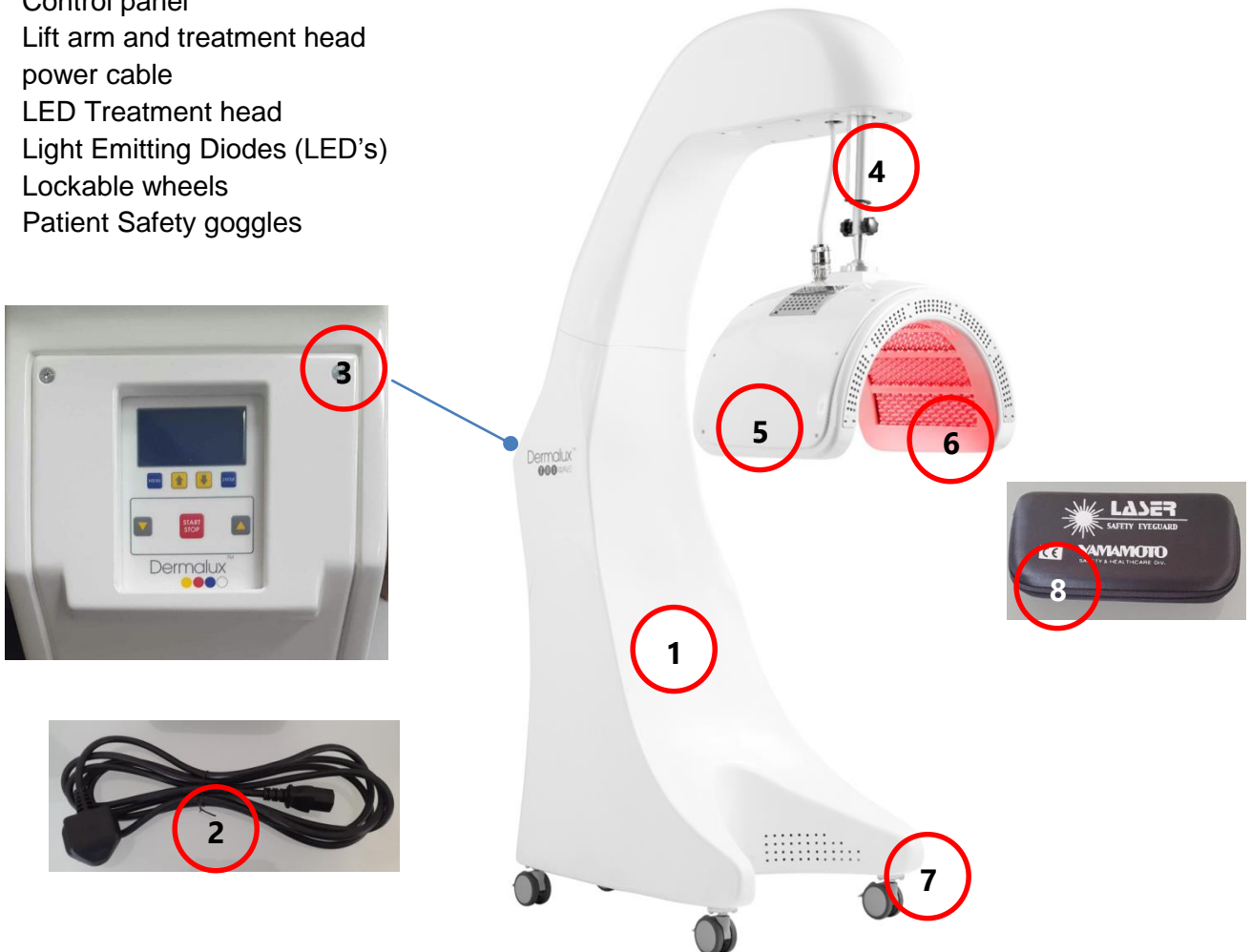
Intended Use

The Dermalux® Tri-Wave Light Emitting Diode (LED) Phototherapy system emits low level light in the Blue, Red and Near Infrared (NIR) region of the light spectrum and is indicated for the treatment of mild to moderate acne vulgaris and periorbital wrinkles of the face, musculoskeletal pain and general dermatological conditions. The Dermalux® Tri-Wave LED system is intended to be used by physicians and suitable qualified personnel.

Device Description

The Dermalux® Tri-Wave system consists of

1. Main Body
2. Power cable
3. Control panel
4. Lift arm and treatment head power cable
5. LED Treatment head
6. Light Emitting Diodes (LED's)
7. Lockable wheels
8. Patient Safety goggles



Device Description

The Dermalux® Tri-Wave system is a floor standing device whose purpose is to produce an even, cool, narrow-band of light for the treatment of cosmetic and dermatological conditions.

The system consists of a main body that contains the power supply (100-264Vac (47-63Hz)) power switch and control panel and a treatment head that contains light emitting diodes (LEDs). The main body is mounted on lockable wheels. The LEDs generate the light.

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 3 pin input socket and wall plug. The device is switched ON/OFF by a switch located on the rear panel of the base unit.

The control panel contains a programmable timer and LCD display. Software allows the operator to select the treatment wavelength and treatment time or select from a range of pre-programmed treatment settings. The control panel also allows the operator to position the treatment head.

The light is generated by light emitting diodes which are contained within a treatment head. The treatment head is connected to the main body by a lift arm. The lift arm allows the operator to correctly position the treatment head over the treatment area.

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.

Indications for Use

The Dermalux® Tri-Wave Light emitting diode (LED) system is intended to emit light in the Blue, Red and Near Infrared (NIR) region of the light spectrum and is indicated for the treatment of mild to moderate acne and periorbital wrinkles of the face, musculoskeletal pain and general dermatological conditions.



Contraindications

- **DO NOT** use Dermalux® Tri-Wave LED system to treat any other condition that has not been listed in the 'Indications for Use' section. The Dermalux® Tri-Wave LED system has not been tested for any other conditions and the risk is unknown.
- **DO NOT** use Dermalux® Tri-Wave LED system to treat pregnant women. The Dermalux® Tri-Wave LED system has NOT been tested on pregnant women and therefore the risk to the foetus or pregnant women is unknown.
- **DO NOT** use Dermalux® Tri-Wave LED system to treat anyone who suffers from, Lupus erythematosus, photosensitive eczema or Albinism. If you use the Dermalux® Tri-Wave LED system to treat someone who suffers from Lupus erythematosus, photosensitive eczema or Albinism you may cause a severe skin reaction.
- **DO NOT** use Dermalux® Tri-Wave LED system to treat anyone who suffers from any photosensitive disorder (sensitisation to light). If you use the Dermalux® Tri-Wave LED system to treat someone who suffers from a photosensitive disorder you may cause a severe skin reaction.
- **DO NOT** use Dermalux® Tri-Wave LED system to treat anyone who is taking any medication that can cause photosensitivity. If you use the Dermalux® Tri-Wave LED system to treat someone who is taking any medication that can cause photosensitivity you may cause a severe skin reaction.

Please consult pages 8-10 for a list of common photosensitive medication.

Risks

Dermalux® LED Phototherapy is safe and effective for all skin types. It is well tolerated with very few reported side effects.



Known Risks

- 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.



Warning and Precautions

Warnings

- **ALWAYS ensure** the client is wearing the safety goggles supplied before operating the Dermalux® Tri-Wave LED system.
- **DO NOT use the Dermalux® Tri-Wave LED system without removing creams, lotions or make-up BEFORE treatment.** Some ingredients in these products may cause light sensitisation or may reduce the effect of the treatment. If you use the Dermalux® Tri-Wave LED system without removing these products you may cause a severe skin reaction or you may lessen the effect of the treatment.
- **DO NOT use the Dermalux® Tri-Wave LED system** in any way that is not exactly as specified in these instructions for use. Use of **the Dermalux® Tri-Wave LED system** other than exactly as specified in these instructions for use has not been tested and the risk is unknown.



Warnings associated with Photosensitivity

Several medical conditions, medications, and chemicals can cause photosensitivity. Photosensitivity may produce a rash of varying severity, which is known by the general term, photodermatitis.

- **DO NOT** use Dermalux® Tri-Wave LED system to treat anyone who suffers from, Lupus erythematosus, photosensitive eczema or Albinism. If you use the Dermalux® Tri-Wave LED system to treat someone who suffers from Lupus erythematosus, photosensitive eczema or Albinism you may cause a severe skin reaction.



Photosensitivity is a common side effect of various medications. These can include certain antibiotics, chemotherapy drugs, and diuretics.

Below is a list of common types of medications that may cause photosensitivity.

Common types of medications that may cause photosensitivity

Drug Type	Specific group or common name	Comments
Antibiotics	Tetracycline group: Doxyclyline, Oxytetracycline, Lymecycline etc	The treatment can be administered as long as the medication has not been taken in the last 5 days
	Quinolone group: Ciprofloxacin, Ofloxacin, Levofloxacin	The treatment can be administered as long as the medication has not been taken in the last 5 days
	Sulfonamides: sulfamethoxazole/trimethoprim	The treatment can be administered as long as the medication has not been taken in the last 5 days.
Non-steroidal anti-inflammatory drugs (NSAIDs)	Naproxen, Celecoxib	The treatment can be administered as long as the medication has not been taken in the last 5 days
Diuretics	Furosemide, Bumetanide, Hydrochlorothiazide	The treatment can be administered as long as the medication has not been taken in the last 5 days
Retinoids Tretinoin	Roaccutane/Accutane Retinova, Retin A gel	The treatment can be administered as long as the medication has not been taken in the last 5 days.
Anti-arthritic	Azathioprine	The treatment can be administered as long as the medication has not been taken in the last 5 days.
Anti-Cancer drugs	Ledertrexate/Methotrexate	The treatment can be administered as long as the medication has not been taken in the last 5 days.
Antifungals	Terbinafine, Itraconazole, Voriconazole, Griseofulvin (Grisovin)	The treatment can be administered as long as the medication has not been taken in the last 5 days.
HMG-CoA reductase inhibitors	Statins (atorvastatin, fluvastatin, lovastatin, pravastatin, simvastatin)	The treatment can still be administered as long as the patient reports no increased sensitivity to sun since commencing statins
Anti-Psychotic	Chlorpromazines: Thorazine Sonazine	The treatment can be administered as long as the medication has not been taken in the last 5 days.
Anti Arrythmic drugs	Codarone, Aratac, chlorpromazine	Exposure to light at far UV can cause the skin to grey. At discretion of practitioner. Treatment can be administered as long as the medication has not been taken in the last 8 days.

Drug Type	Specific group or common name	Comments
Anti-inflammatory (topical)	Ketoprofen, Oruvail	Do not apply LED treatment directly over gel. Can cause phototoxic reaction if light is applied directly over the gel.
Epidermal growth factor receptor inhibitors (treatment for lung cancer)	Cetuximab, panitumumab, erlotinib, gefitinib, lapatinib, vandetanib	Consult a physician before commencing a course of Dermalux®
Anti-arthritic	Ridaura, Gold 50	If yes the treatment cannot be administered



Other substances not listed above can also cause photosensitivity.

Common examples of these substances include:

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).

Other Warnings



To reduce the risk of injury or electrical shock

- **DO NOT** position the treatment head less than the recommended distance from the treatment area. Over extension of the lift arm may cause temporary disconnection of the treatment head.
- **NEVER use** the Dermalux® Tri-Wave LED system near water or where water can be spilt onto the equipment.
- **NEVER use** the Dermalux® Tri-Wave LED system if you think any part of the equipment may have come into contact with water.
- **DO NOT attempt** to modify the Dermalux® Tri-Wave LED system in any way. Modifying the Dermalux® Tri-Wave LED system in any way could cause an electric shock when the system is used again. The Dermalux® Tri-Wave LED system contains no serviceable parts.
- **DO NOT use** the Dermalux® Tri-Wave LED system if the LED treatment head, control panel, main body or Power supply cable is damaged in any way.
- **Take care** when using the LED treatment head positioning function.

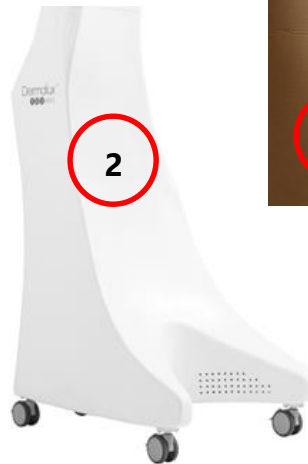


Precautions

- **Before use** with the device switched off, check the Dermalux® Tri-Wave LED system, LED treatment head, control panel, main body and Power supply cable for signs of physical damage.
- Store the Dermalux® Tri-Wave LED system at room temperature in dry conditions.
- The entire surface of the Dermalux® Tri-Wave LED system may be cleaned by following the **cleaning instructions on page 20**.
- Do not use any other cleansing products other than those stated in the user guide. Use of other cleansing products may damage the Dermalux® Tri-Wave LED system.

First Time Setup

1. Inspect the exterior of the shipping container for any damage which may have occurred during transit.
2. Open the shipping container and carefully remove the individual components.
3. Inspect the system for any visual damage that may have been caused by shipping.
4. Ensure that the following individual parts are present.



1. Dermalux® LED Treatment Head
2. Dermalux® Base Unit
3. Locking Bolt / Head Connector
4. Dermalux® Neck section
5. Power Cable
6. Client Goggles
7. 3mm Hex key and 17mm socket spanner
8. Dermalux® TRI-WAVE User Manual

If the any individual components are missing or damaged, please contact Aesthetic Technologies Ltd or your local representative.

Assembly Guide



Follow the step by step First time set up guide to assemble the Dermalux® Tri-Wave LED system.

You will require the following tools supplied with the Dermalux® Tri-Wave LED system.

1. 3mm Hex key
2. 17mm socket spanner

First Time Setup



Follow the step by step guide to assemble your Dermalux® Tri-Wave LED system.

STEP 1. Connecting the Neck section to the Base unit.



DO NOT Plug the Dermalux® Tri-Wave LED system into a wall socket until Steps 1 - 2 (below) are completed. Plugging the Dermalux® LED system into a wall socket before Steps 1 - 2 (below) are completed may expose you to dangerous voltages or other risks.

1. Stand the Base unit upright and lock the wheels by pressing down on the locking flange.
2. Remove rear panel from the Base Unit by unscrewing the 10 3mm Hex screws that secure the panel.
3. Remove the base panel from the neck section by unscrewing the 3mm Hex screws that secure the panel.
4. Align the neck section on top of the base unit. Using the 17mm spanner, secure the neck section to the base unit from the inside with the 4 x 17mm nuts provided.
5. Take the white cable from the base unit that has a 4 pin end connector and feed it up the neck section and out of the hole in under panel of the top of the neck section.
6. Take the black cable from the neck section that has a 2 pin end connector and connect this to the black power supply unit in the Base Unit.
7. Replace the base panel of the neck section and secure with the 3mm Hex screws provided.
8. Replace the rear panel of the Base Unit and secure with the 3mm Hex screws provided (10).



STEP 2. Connecting the LED Treatment Head

9. Connect the LED treatment head to the height control arm.

10. Align the holes in LED head and height control arm.

11. Secure with the black locking bolt.



12. Attach the white cable to the LED treatment head with the 4 pin connector.



STEP 3. Connecting the Dermalux® Tri-Wave LED system to the mains

13. Plug the black Power Cable into the 3 pin input socket in the rear of the Base unit

14. Plug the Power Cable into a suitable wall socket.

Operating Information

Controls



The control panel contains a programmable timer and LCD display and allows the operator to control the position of the treatment head.

1. **DISPLAY** shows current information in programme and treatment modes
2. **MENU** pages through menu screen, used to confirm display prompts
3. **UP & DOWN ARROW** scrolls through the menu or allows you to toggle between settings in the Manual Mode
4. **ENTER** confirms the screen prompt
5. **LIFT** ▲▼ adjusts the position of the LED treatment head up and down by moving the Lift arm up or down. Press the button up to raise the LED treatment head or down to lower the LED treatment head.
6. **START/STOP** activates or stops a treatment.

Carrying out a Treatment

Treatment Regime

A course of Dermalux® Tri-Wave treatments consists of 6 to 10, 20 minute treatment sessions. The recommended frequency based on 6 to 10 sessions is 2 Dermalux® treatments a week for 3 to 5 weeks.

A 24 hour time period between treatments is generally recommended

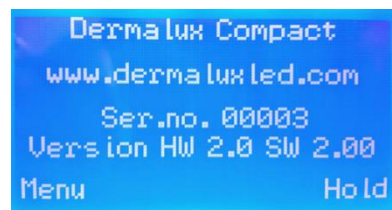


Always ensure the client is wearing the safety goggles supplied before operating the Dermalux® Tri-Wave LED system.

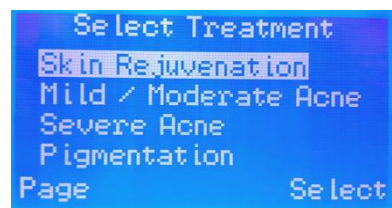
Switching the System ON/OFF

1. To switch the Dermalux® Tri-Wave system ON, plug the 3 pin input plug into the rear of the base unit. Insert the other end of the plug into a suitable grounded wall socket.
2. Press the ON/OFF switch located on the rear panel of the base unit. The switch will illuminate to indicate that the device is ON.

3. The display will illuminate showing the software version and the device's serial number.



4. The home screen is displayed showing program options.



5. To switch the device OFF, press the ON/OFF switch to OFF. The display on the Base unit will turn OFF.

Stopping a Treatment

To STOP a treatment press the START/STOP button. The LEDs will switch OFF and the timer will display the treatment summary indicating wavelengths delivered and the treatment time for each wavelength.

Dermalux® Tri-Wave Operating System

Dermalux® Tri-Wave software allows the user to select either

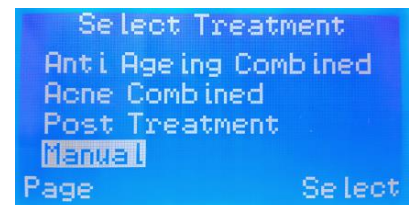
- i. Treatment parameters such as wavelength and treatment time (**Manual mode**).
- OR**
- ii. Preset treatment programs (**Pre-programmed Mode**).

i. Manual Mode

Activating the Dermalux® Tri-Wave System is a 3 step process.

STEP 1. Selecting the TREATMENT TIME and WAVELENGTHS

1. Using the UP/DOWN buttons, scroll through the menu of preprogrammed treatments. Use PAGE to jump to the next screen.
2. Select **Manual** from the treatment options by pressing the SELECT key.
3. The Manual mode screen will be displayed.
4. Use ENTER to toggle forward and ENTER to select the wavelength
5. Use the UP/DOWN buttons to switch wavelengths ON/OFF. Press ENTER to confirm.
6. Use UP/DOWN buttons to increase or decrease treatment time (units of 1 minute). Press ENTER to confirm.
7. Use MENU to toggle back.
8. Press ENTER to confirm selection.



STEP 2. POSITIONING the LED Treatment Head

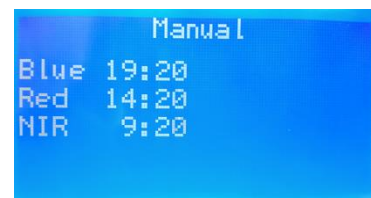
1. Using the LED head positioning buttons to position the treatment head.
2. Press the LED head positioning button ▲ to raise the LED treatment head or down ▼ to lower the LED treatment head.
3. Position the LED treatment head 4 cm from the treatment area.



Do NOT position the treatment head less than the recommended distance from the treatment area. Over extension of the lift arm may cause temporary disconnection of the treatment head

STEP 3. ACTIVATING the Dermalux® Tri-Wave System

12. Press the START/STOP button, the selected LEDs will illuminate
13. The timer will count down in 1 minute intervals showing the time remaining for each selected wavelength.



When using Near Infrared (NIR) the NIR indicator diodes will illuminate yellow. The NIR indicator diodes are positioned at the top of each LED panel.







END of Treatment

14. At the end of the treatment the LEDs will switch OFF.
15. The display shows a treatment summary indicating the wavelengths delivered and the treatment time for each wavelength.
16. Using the LED head positioning button raise the treatment head away from the treatment area.
17. Press the LED head positioning button up to raise the LED treatment head away from the treatment area
18. Remove the client safety goggles.



ii. Preprogrammed Mode

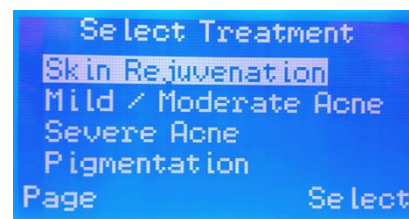
The Dermalux® Tri-Wave system has 11 preprogrammed treatment settings.

Indication	Blue	Red	NIR	Treatment time (minutes)	Notes
Skin Rejuvenation				20	
Mild/Moderate Acne				20	
Severe Acne				20	10minutes of Blue and NIR light, followed by 10 minutes of Blue, Red and NIR light
Pigmentation				20	
Rosacea				20	10minutes of NIR only, followed by 10minutes of Red and NIR light
Acne Rosacea				20	
Inflammatory Skin				20	
Allergic Reactions				20	
Anti-Ageing Combined				20	
Acne Combined				20	
Post Treatment				20	

Activating the Dermalux® Tri-Wave System is a 3 step process.

STEP 1. Selecting a Preprogrammed treatment setting

1. Using the UP/DOWN buttons, scroll through the menu of preprogrammed treatments. Use PAGE to jump to the next screen.
2. Select the preprogrammed treatment option from the list by pressing the **Select** key.
3. The Display will show the treatment selected and the treatment time for each wavelength.
4. Use the **Menu** key to return to the Home screen



STEP 2. POSITIONING the LED Treatment Head

4. Using the LED head positioning buttons position the treatment head
5. Press the LED head positioning button ▲ up to raise the LED treatment head or ▼ down to lower the LED treatment head.
6. Position the LED treatment head 4 cm from the treatment area



Do NOT Position the treatment head less than the recommended distance from the treatment area. Over extension of the lift arm may cause temporary disconnection of the treatment head

STEP 3. ACTIVATING the Dermalux® Tri-Wave System

7. Press the START/STOP button, the selected LEDs will illuminate
8. The timer will count down in 1 minute intervals showing the time remaining for each selected wavelength



When using Near Infrared (NIR) the NIR indicator diodes will illuminate yellow. The NIR indicator diodes are positioned at the top of each LED panel.

END of Treatment

9. At the end of the treatment the LEDs will switch OFF.
10. The display shows a treatment summary indicating the wavelengths delivered and the treatment time for each wavelength.
11. Using the LED head positioning button raise the treatment head away from the treatment area.
12. Press the LED head positioning button up to raise the LED treatment head away from the treatment area
13. Remove the client's safety goggles



Cleaning Instructions



It is important that the Dermalux® Tri-Wave LED System is switched off before cleaning.

- The entire surface of the Dermalux® Tri-Wave LED system including the main body, treatment head, and control panel may be cleaned by wiping them with an anionic detergent towelette or surface wipe. Excess moisture from the wipe may be removed by using a clean dry microfiber cloth.
- Please refrain from using any other cleansing products as these may damage the plastics.

Care and Maintenance

- **Store the** Dermalux® Tri-Wave LED system at room temperature in dry conditions.
- **Avoid** storing the Dermalux® Tri-Wave LED system in dusty conditions, in direct sunlight or in damp and humid conditions.
- The Dermalux® Tri-Wave LED system contains no serviceable parts

Disposal

- Do NOT dispose of any part of the Dermalux® Tri-Wave LED system at a domestic waste facility.
- For protection of the environment, please package and return this unit to Aesthetic Technologies Ltd or their representative at the end of its working life.



Technical Specification

DERMALUX® TRI-WAVE

Weight: 24kg

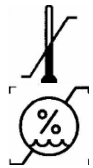
Total Device Dimensions: H 1750mm x W (widest point at base) 520mm x D 720mm

Dimension from front to back at the widest point: 820mm

Dimensions of LED head: H 460mm x W 500mm x D 340mm

Dimensions of LED Body panel: L 690mm x W 333mm x H 80mm

Program time range: 1 to 30 minutes



Operating Temperature 0°C to 85°C

Storage and Transport Temperature -40°C to 70°C

Operating Humidity: 5% to 95% without condensation

Storage and Transport Humidity: 5% to 95% without condensation

Mains Electrical Input: 85-264Vac/47-63Hz

Electrical Output: 24V

General Safety



The Dermalux® Tri-Wave system is an electrical device, which under certain circumstances could present an electrical shock hazard to the user.

Please read the accompanying user manual thoroughly and follow directions stated in the manual to assure maximum safety during operation.

Troubleshooting

Aesthetic Technology Ltd record and analyze all problems reported to them. The majority of problems reported has a simple cause and can be readily put right by the user. They are listed in the troubleshooting table below.

Fault	Description	Possible cause	Action required
Unit fails to switch on.	Control panel display does not illuminate.	No power to unit	<p>Check that the power cable plug is correctly plugged into the wall outlet socket.</p> <p>Check that the power cable plug is correctly plugged into the rear of the unit.</p> <p>Check that the ON/OFF switch is ON.</p> <p>If the unit does NOT switch on, check the fuse inside the plug is functioning.</p> <p>Check that there is NOT an external or general power failure to the building.</p>
NO light output from the LED treatment head.	Unit is ON. Control panel is functioning. NO light output from LEDs Treatment head fans are NOT running.	No power to treatment head.	<p>Switch OFF the device at the wall outlet socket and remove the plug.</p> <p>Check that the 4 pin plug is securely connected to the top of the LED treatment head.</p> <p>Plug the power cable into the wall outlet socket.</p> <p>Switch the unit ON</p>
NO light output from the LED treatment head.	Unit is ON Control panel is functioning Treatment head fans are running but there is NO light output from the LED treatment head when the unit is activated.	No power to treatment head or Internal circuitry fault.	<p>Switch OFF the device at the wall outlet socket and remove the plug.</p> <p>Check that the 4 pin plug is securely connected to the top of the LED treatment head.</p> <p>Plug the power cable into the wall outlet socket.</p> <p>Switch the unit ON</p>

Fault	Description	Possible cause	Action required
Treatment head fans NOT running	Unit is ON Control panel is functioning Light output from LED treatment head. Treatment head fans are NOT running	Internal circuitry fault.	Switch OFF the device at the wall outlet socket and remove the plug. Check that the 4 pin plug is securely connected to the top of the LED treatment head. Plug the power cable into the wall outlet socket. Switch the unit ON
Automated positioning function fails to operate	Unit is ON Control panel is functioning Automated positioning function fails to operate	Possible Internal circuitry fault.	Switch OFF the device at the wall outlet socket and remove the plug. Check that there is no surface damage to the height control button on the control panel. Plug the power cable into the wall outlet socket. Switch the unit ON
NIR indicator light does not illuminate.	Unit is ON Control panel is functioning Treatment head fans are running. NIR indicator diodes are not illuminated when NIR light is SELECTED.	NIR LEDs NOT working	If combination treatments are selected, end the current treatment session. Select NIR light only and switch ON Wearing goggles - visibly check LED panels for NIR Light (appears as pinpoint red dots in the centre of LED).
NIR indicator light does not illuminate.	Unit is ON Control panel is functioning Treatment head fans are running. NIR indicator diode is not illuminated when NIR light is SELECTED.	Faulty NIR indicator diode	If combination treatments are selected, end the current treatment session. Select NIR light only and switch ON Wearing goggles - visibly check LED panels for NIR Light (appears as pinpoint red dots in the centre of LED).

If the actions suggested fail to fix the problem, or the problem reoccurs, please refer to Aesthetic Technologies Ltd or your service provider to arrange servicing of your Dermalux® LED system.



- **Do NOT** attempt to investigate any further.
- **Do NOT** remove the back panel cover.
- The Dermalux® LED System has **NO** parts you can repair yourself

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 only to the original purchaser. If the product should become faulty within the warranty period, contact the Customer Service Centre.

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- 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.
- This warranty does not cover damage caused by the following
 - Accident, misuse, abuse or alteration
 - Servicing by unauthorised persons
 - Connection to incorrect power sources
 - Use with unauthorised accessories

The warranty is **VOID** if the serial number 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.