Xen LED
Operators Manual

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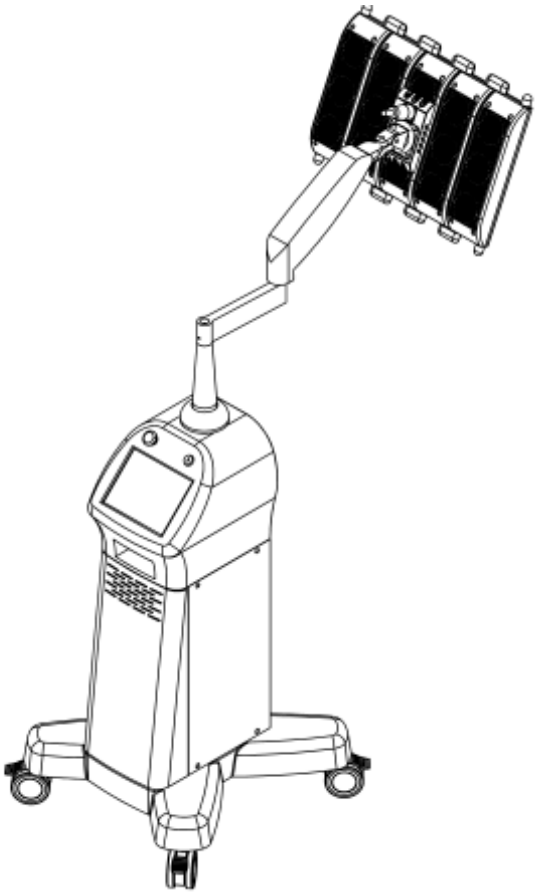
File number:	CE-TC02-0702
Revision:	A/4
Effective:	2025.08.10

CE 2797

Australian Aesthetic Devices



Xen LED
Operators Manual

It is essential that operators read the entire manual before operating the system.

THANKYOU for choosing Australian Aesthetic Devices for your LED system.
For your records please take a note of the following contact details for Australian Aesthetic Devices.

Address: 2/21-35 Ricketts Road, Mount Waverly Vic 3149 Australia

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E-mail: tony@aestheticdevices.com.au

User Support: 1300 858 711
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Name:	Kingsmead Service B.V
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Tel:	+31 646571005
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While company representatives will make every effort to respond to you as quickly as possible, please ensure where you are directed to a voice message that you leave a message so we are aware of your call.

We are looking forward to working with you into the future…

Scope of this Manual

This operator reference manual is provided to aid professionals in their day to day use of the system as well as provide background information to aid in the understanding of this technology. It also includes instructions for safe use, proper assembly and maintenance. It adds to/or reinforces information presented in the training, and reviews precautions and warnings necessary to reduce the risk of possible exposure to hazardous light.

Do not attempt to use this system before reading this manual and gaining a clear understanding of its operation. If any part of this manual is not clear, please contact your Australian Aesthetic Devices representative for clarification.

The information provided in this manual is not intended to replace the professional training on the use of the system. Please contact your Australian Aesthetic Devices representative for current information on available training. For user information, refer to the Treatment Guide appendices that include set up guidelines.

This manual should always accompany the system and all operating staff should be aware of its location. Additional copies of this manual are available from Australian Aesthetic Devices.

System configured and designed for use in Australia. Main language used is English.

System specifications and the information contained in this document are subject to change without notice.

Training Requirements

The Xen LED System is designed to be operated only by personnel properly trained in its handling and use and who have read the Operator's Manual

Initial training is based on theoretical issues designed to aid users in understanding the basics of light physics & LED technology. The purpose of the initial training is to provide the operator with sufficient skills, knowledge and experience to confidently operate & handle this System. The focus is primarily on safety and secondarily on efficacy and efficiency. Please note that training schedule may vary subject to availability of instructors, equipment and clients.

Repair

Any repair on the Xen LED system must be performed by Australian Aesthetic Devices authorized technical personnel. Don't do repair service during treatment with device .Failure to obtain service through Australian Aesthetic Devices voids all warranties expressed and implied. Please contact Australian Aesthetic Devices for details.

Modification of the System

Unauthorized access and/or modification of the hardware, software or specifications of this LED system voids all warranties, expressed and implied. Australian Aesthetic Devices takes no responsibility for the use or operation of such a modified device.

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Glossary of Terms

Absorption of radiation - Receiving electromagnetic radiation by interaction with the material, and transforming it to different form, The absorption process is dependent on the wavelength of the electromagnetic radiation and on the absorbing material.

Amplitude - The maximum value or intensity of a wave, measured from its equilibrium.

Attenuation - The decrease in radiation energy (power) as a beam passes through an absorbing or scattering medium.

Biostimulation: Boosting the energy of cells in order to maximise their varied functions. Boosting takes place as a result of chemical/physical changes resulting from light absorption within the cell.

Continuous light: Light emitted in a constant stream.

Direct Delivery - Laser energy is delivered directly from the emitting aperture to tissue (with or without focusing lenses).i.e. not via an articulated arm or fibre optic.

Divergence - Increase in beam diameter with distance from the aperture

Fluence - The amount of energy in J/cm^2 to which the treated area is exposed.

Frequency - The *number of times that the wave oscillates per second* (The number of periods of oscillations per second)

Infrared (IR) - is invisible radiant energy, electromagnetic radiation with longer wavelengths than those of visible light, extending from the nominal red edge of the visible spectrum at 700 nanometers to 1 mm.

Ionizing Radiation: This radiation can remove tightly bound electrons from their atomic orbits, causing the atom to become charged or ionized. Gamma rays and x-rays are examples of ionizing radiation.

Laser - An acronym for Light Amplification by Stimulated Emission of Radiation. A laser device is an optical cavity, with mirrors at the ends, filled with material such as crystal, glass, liquid, gas or dye. A device which produces an intense beam of light with the unique properties of coherence, collimation and monochromaticity.

Light -Usually referred to the visible spectrum. The range of electromagnetic radiation frequencies detected by the eye, (Visible Spectrum) or the wavelength range from about 400 to 700 nanometres. The term is sometimes used loosely to include radiation in the near Infra-red spectrum.

Maximum Permissible Exposure (MPE) - The level of light radiation to which person may be exposed without hazardous effect or adverse biological changes in the eye or skin.

Milli-Seconds (ms) - is a thousandth (10^{-3} or $^1/_{1,000}$) of a second

Monochromatic Light - Theoretically, light at one specific wavelength (colour).

Nanometre [nm] - one billionth of a meter (10^{-9} [m]).

Nominal Ocular Hazard Distance (NOHD) -The distance at which the beam power density or energy density equals the appropriate corneal MPE is defined as the nominal ocular hazard distance (NOHD). The NOHD should be taken into account when specifying the boundaries of the laser controlled area where clients, staff and operators are subject to control and supervision for the purpose of protection from laser radiation hazards.

Non Ionizing Radiation: Nonionizing radiation does not have sufficient energy to removeelectrons from their atomic orbits. Examples of nonionizing radiation are microwaves and visible light.

Optical Density (OD) - A logarithmic expression for the attenuation produced by an attenuating medium, such as an eye protection filter.

Output Power - The energy per second (measured in Watts) emitted from the laser in the form of light.

Power - The rate of energy delivery in a unit of time, expressed in Watts (Joules per second). Thus: 1 [Watt] = 1 [Joule]/1 [sec].

Pulse Delay - Pulse delay determines the intervals between each subpulse within the Pulse Duration to allow cooling of the skin between sub-pulses and help prevent adverse effects.

Pulse Duration/Width - The length of time the skin is exposed to the pulse and is the sum of the pulse "On" times and Pulse Delays within the sub-pulses.

Pulse "On" time – The length of time chosen for each individual sub-pulse.

Reflection - The return of radiant energy (incident light) by a surface, with no change in wavelength.

Refraction - The change of direction of propagation of any wave, such as an electromagnetic wave, when it passes from one medium to another in which the wave velocity is different. The bending of incident rays as they pass from one medium to another (e.g.: air to glass).

Spontaneous Emission - Random emission of a photon by decay of an excited state to a lower level. Determined by the lifetime of the excited state.

Stimulated Emission - Coherent emission of radiation, stimulated by a photon absorbed by an atom (or molecule) in its excited state.

Ultraviolet (UV) Radiation - Electromagnetic radiation with wavelengths between soft X-rays and visible violet light, often broken down into UV-A (315-400 [nm]), UV-B (280-315 [nm]), and UV-C (100-280 [nm]).

Wavelength - The length of the light wave. The shortest distance at which the wave pattern fully repeats itself, usually measured from crest to crest. The wavelength of light in the visible spectrum determines its colour. Common units of measurement are the micrometer (micron), the nanometre, and (old unit) the Angstrom unit.

1 System Overview

The Xen LED system is a non-invasive, non-ablative aesthetic device that is capable of irradiating the skin surface with Blue 415nm, Red 633nm or Infrared (IR) 830nm continuous light.

The Xen LED utilizes 10,500, 3rd generation high intensity Chip On Board (COB) narrow band LEDs contained within 5 large panels to deliver optimum light doses evenly over the irradiated area.

The 10,500 COB LEDs within the 5 large panels on the Xen head are evenly broken up to 3,500 LEDs of each wavelength (colour).

To maintain the high levels of continuous energy delivery, the Xen utilizes fan cooled heat exchangers over the LED panels to keep operational temperatures within reasonable levels for the clients as well as maintaining optimum levels for the highly efficient COB LEDs. It is important to ensure that all of the cooling fans are operational during the entire duration of skin exposure.

The Xen LED has been designed to provide the user with easy access to the 3 relevant wavelengths operating at levels for effective dosage delivery within the industry standard treatment times.

1.1 Using the Xen LED System

It is important to have a thorough understanding of the treatments and its risks associated with using this equipment as well as a clear understanding of the systems operation.

Operator focus should primarily be on safety and secondarily on efficacy and efficiency.

Refer to Section 2 (Safety) as well as recommended publications and Standards as an introduction to the safe use of this technology.

Before treatment initiation, ensure you are familiar with Section 4 (Controls and Indicators) and prepare the unit as outlined in Section 5 (Operating Instructions). Specific details for selection of appropriate wavelengths and intensities, to which the irradiated area is exposed, are located in the relevant appendix user guides.

1.2 Specifications

Light Source:	Tri-Coloured Chip On Board (COB) LED Array
Wavelength:	Blue: 415nm
	Red: 633nm
	IR: 830nm
Number of LEDs:	10,500 LEDs per System
	3,500 LEDs per Wavelength
Intensity-Planar:	415nm 20 - 65mW/cm^2
	633nm 42 – 140mW/cm^2
	830nm 32 – 105mW/cm2
Class:	Class 1B type
Pwr requirement:	220V~240V 50~60 Hz
Pwr consumption:	400VA
Dimensions:	Body (mm): 600(L) x 655 (W) x1300 (H)
	Head (mm): 450 (L) x 300 (W)
Weight:	60kg
Optical Classification:	Optical Risk Group 3 to AS/NZS IEC 62471.2:2012

2 Safety

This chapter describes general safety issues regarding the use of the Xen LED system.

Reference materials include:

- AS/NZS IEC 62471:2011 Photobiological safety of lamps and lamp systems.
- AS/NZS IEC 62471.2:2012 Photobiological safety of lamps and lamp systems Part 2: Guidance on manufacturing requirements relating to non-laser optical radiation safety.

The primary consideration should be to maximize safety within the operational area to protect clients, staff and the operator against inadvertent exposure and possible injury. The System is designed for safe and reliable treatment when used in accordance with proper operation and maintenance procedures. All persons operating or maintaining the system must be familiar with the safety information provided in this chapter.

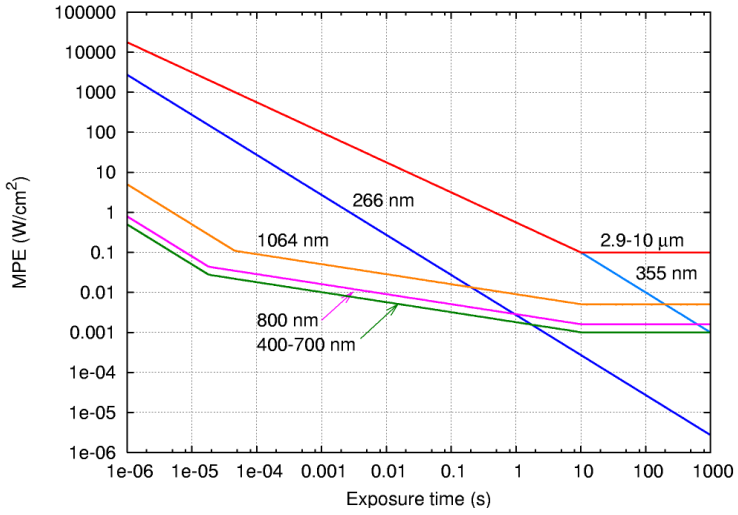
Client safety is mainly assured with well trained staff and a well laid out treatment room. Client education is also important and they need to be fully informed of the treatment protocol, the likely results and any risks associated with the treatment.

2.1 Biological Effects

The details of biological hazards can be found within Australian Standard AS/NZS IEC 62471:2011 Photo biological safety of lamps and lamp systems.

In summary excessive exposure over an individual's Maximum Permissible Exposure (MPE) may result in the following biological effects.

315–400 nm (UV-A)	Photochemical cataract (clouding of the eye lens)
400-700nm (visible)	Photochemical Photoretinitis or Blue light retinal injury, retinal burn
700–1400 nm (near-IR)	Photochemical/Photothermal cataract, retinal burn



For all 3 wavelengths delivered by the Xen LED, it is indicated that long term exposure will cause damage as the outputs are rated higher than MPE. As a result it is imperative that persons in the treatment room wear appropriate safety eyewear. It is most important that the clients eyes are fully protected throughout the treatment or whenever the LED's are active.

2.2 System Safety Measures

The Xen LED system was designed to maximize safety for both client and users. The System incorporates the following safety features. All personnel operating the System should be familiar with these features.

2.2.1 Electrical Safety

OPTICAL RISK GROUP 3
WARNING-IR emitted from this product. Avoid eye exposure. Use appropriate shielding or eye protection.
WARNING-Visible light emitted from this product. Do not look at operating LED's. Eye injury may result.
The LED energy can cause injury if used improperly.

Hazardous Voltages are present within the Xen LED system when it is connected to mains power. Do not remove the access covers when power is connected or operate the Xen LED when covers are removed. Any Maintenance on the Xen LED system must be performed by Australian Aesthetic Devices authorized technical personnel.

2.2.2 Light Safety

1. An emergency shutoff knob expedites shutdown when necessary. When pressed, it immediately shuts down system operation.

2. The system incorporates a key-operated control disabling system use when it is removed.

3. A password on the service screen prevents unauthorized changes to the system's basic operating parameters.

4. The system features a yellow indicator LED at the end of each panel on the head which turns on when the panel is emitting 830nm IR energy.

2.2.3 To avoid the risk of electric shock, the equipment must be connected to the power grid with protective grounding

2.2.4 The equipment should avoid being used in strong electromagnetic environment, so as not to be affected by radiation from other equipment.

2.3 The Treatment Room

The treatment room should be kept at an ambient temperature of 20-25°C and well ventilated for optimal performance of the equipment.

Access to the Xen LED treatment room should be allowed only to staff essential to the procedure and who are well trained in the required safety procedures. All entry ways allowing access (either physically or visually) to the treatment room should be shielded so no treatment light is allowed to pass into external uncontrolled areas. All staff need to be aware of the rules for maintaining safety in the treatment room including use of protective eyewear and controlled entry.

Ensure that all of the treatment room staff are familiar with the Xen LED controls and know how to shut down the system instantly.

2.4 General Precautions and Cautions

The following precautions, cautions and warnings must be observed for the safe use of the Xen LED system.

2.4.1 Precautions

- Operators should read this manual thoroughly before attempting to operate the Xen LED system.
- The system weighs approximately 60 kg and may cause injury if proper care is not used when moving it. The system is well balanced and is designed to be moved, but should always be moved carefully and slowly. Never pull the system by the arm or array panels.

2.4.2 Cautions

- Only Australian Aesthetic Devices authorized personnel may repair the Xen LED system. This includes making internal adjustments to the power supply and optic calibration.
- Always turn off the system when it is not in use.
- Never allow untrained personnel to operate the system.
- Never stare directly into an illuminated array.
  NOTE: When the yellow indicator LEDs at the end of each panel on the head are on, the panels is emitting 830nm IR wavelengths which are not visible to the human eye. Ensure appropriate safety eyewear is used.
  Please confirm operator wear protect glass when turn on this 415nm blue light or 633nm red light
  There will a warning“Please do a protect ”popped up in “READY” interface when machine is in using .After user take protective measures ,click “START” icon then the selected wavelength of light will output.
  A yellow LED indicator lights up at the top of the array when it is output 830nm infrared light.
  When 415nm blue light and 633nm red light output, the outer ring color of "START" button will change from "blue" to "orange", and the time on the current operation interface will be displayed in countdown mode, at which time the selected wavelength of light is being output.

2.5 Warnings Related to Optical Risk Group 3 Light Emission

2.5.1 Direct Eye Exposure Hazards

It is essential that all people present in the treatment room during the treatment (client and staff) protect their eyes by wearing Australian Aesthetic Devices recommended protective eyewear.

It is good practice to instruct the client to close their eyes during treatment even when wearing protective eye glasses or eye shields. If the client cannot wear the protective eyewear, fit the client with opaque eye protection that completely blocks light from the eyes.

Never look directly at the light emissions from the Xen LED array, even when wearing protective eyewear. If the treatment area is very close to the eyes use appropriate safety eye shields.

2.5.2 High Voltage Hazards

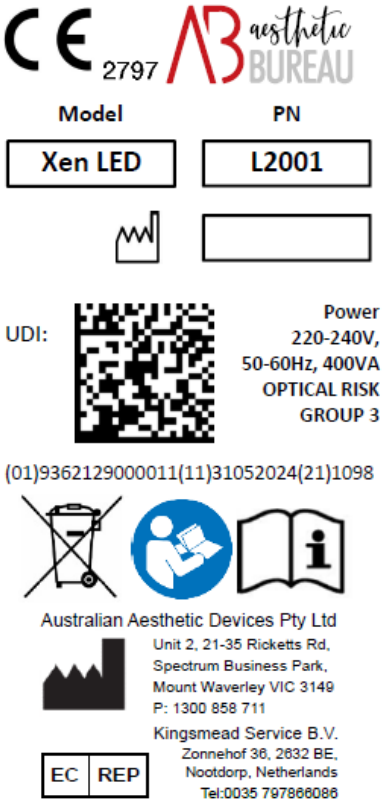
The system utilizes high-voltage electricity. To avoid personnel injury, do not operate the system before ensuring that the exterior panels are properly closed. Do not attempt to remove or disassemble the exterior panels.

Whenever system maintenance is performed, never leave the system turned on, open or unattended.

2.6 Device Labels

The following Warning, Certification and Identification labels are adhered to the Xen LED system:

- System Identification – located on the system's rear panel. This label contains the following information:
    - System name
    - System Part Number
    - Serial number and date of manufacture
    - The system's electrical requirements
    - Risk Group to AS/NZS IEC 62471.2:2012
    - Patient safety type and class



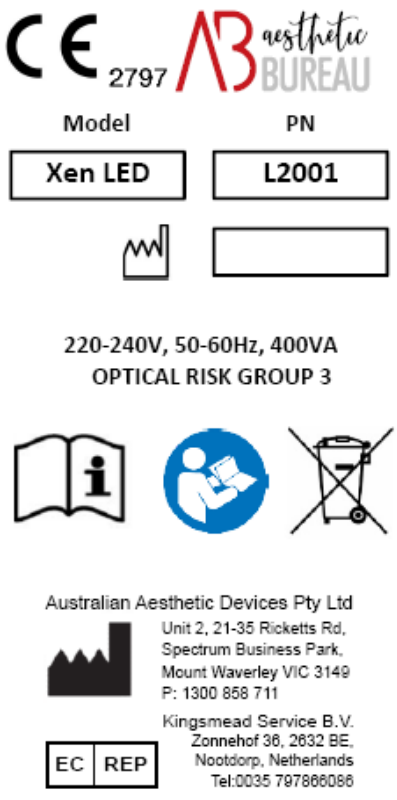


Figure 1: System Label For Non-AUS **System Label for AUS**

- Array Identification – located on the LED Array. This label contains the following information:

- Accessory name
- Accessory Part and Serial Number

Figure 2: Array ID Label

- Warning Labels Located on the rear panel.

Figure 3: Electrical Hazard

Figure 4: Warning on system

- Warning Labels Located on the LED Array.

Figure 5: Warning on LED Array

- Warning Labels Located on the front panel.

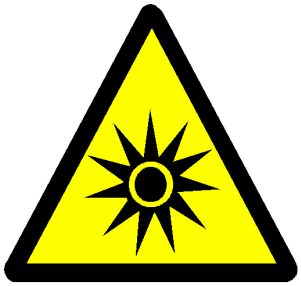


Figure 6: Warning on LED Light

- Emergency stop button located on the front panel

Figure 7: Emergency shut-off knob

- Warning Labels Located on the front panel.

Figure 8: Warning on LED Light

3 Installation

On-site installation and testing is included when a system is purchased.

Transportation and installation is carried out by the customer, who will do the following:

- Unpack the system.
- Verify the integrity of the system and its components.
- Plug the system into a designated electrical outlet.

NOTE: Any damage to the packaging or to the system found prior to opening the package should be reported to your Australian Aesthetic Devices representative and recorded in shipping documents with signature for receipt requested by couriers.

3.1 Equipment List

The Xen LED system includes the following:

- Xen main stand.
- Xen LED array
- 2 sets of Keys
- 2 pair safety Glasses & 1 pair client eyeshields
- Operators Manual

3.2 Facility Requirements

Before unpacking the system, ensure that the site meets the requirements described in the following sections:

3.2.1 Space and Positioning

Space should be allocated with adequate ventilation and free airflow. In order to guarantee proper ventilation, always keep the sides of the system at least 30cm from the wall or from other obstructions to air flow.

3.2.2 Electrical Requirements

The system will require a line supply of 240 VAC, 10A, 50 Hz, single phase.

The system is grounded through the grounding conductor in the power cable that is plugged into the wall power outlet. Proper grounding is essential for safe operation.

3.2.3 Environmental Requirements

Air Quality:
The system should operate in a non-corrosive atmosphere. Corrosive materials such as acids can damage electrical wiring, electronic components and the surfaces of optical components.

Temperature:
To ensure that the system performs optimally, there's no requirement for temperature, it can be operated in ambient temperature.

3.3 Moving the System

3.3.1 Moving within the Clinic

To move the system:

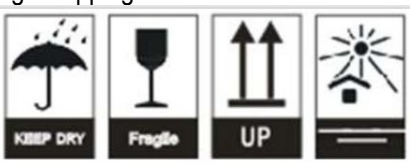
1. Disconnect the power cable.
2. Secure the LED array.
3. Release the wheel brakes.
4. Slowly push or pull the unit, using the handle on the system.

CAUTION: Never pull the system by the array or array arm. Never lift the system with array connected.

3.3.2 Packing the system for transportation

If possible, please retain the shipping box the unit was delivered in for future shipping.

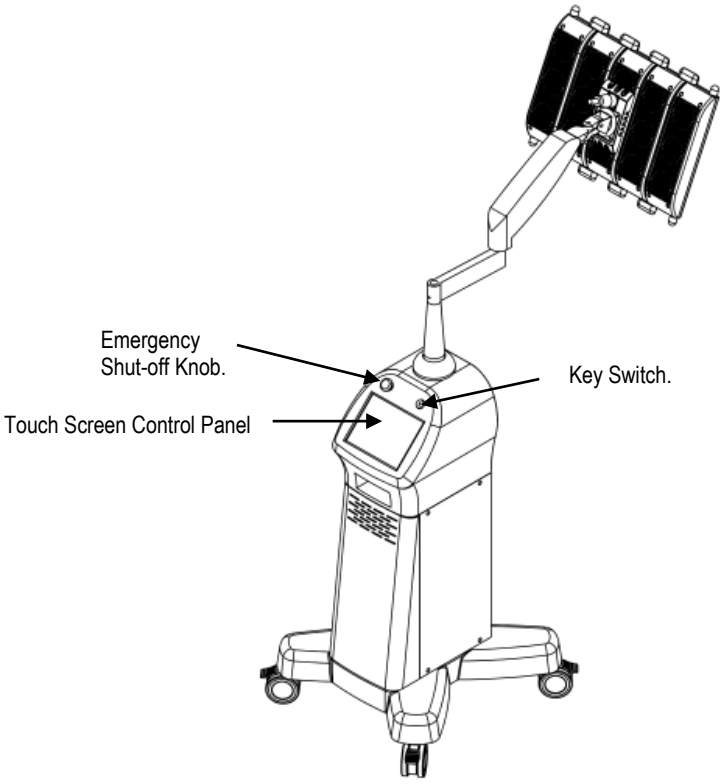
1. Remove array, array arm and power lead.
2. Ensure Key has been removed from lock on front of unit (failure to do so may result in key breaking in the lock which may then require possible replacement).
3. Pack all spare parts, auxiliary parts and operation manual in separate bags or boxes.
4. Pack the machine into the case and add any spare parts or accessory bags.
5. To stop any vibration or movement of the system in the case in transportation, use foam to hold the unit and accessories firmly in place. Do not place excessive pressure onto the system screen
6. Close and secure the case so it does not fall open during transport.
7. package shipping label



4 Components and Controls

This chapter details the controls, indicators, connection ports and other components found on the Xen LED system:

4.1 Front Panel



4.1.1 Key Switch

A removable key operated master control is used to disable the system when it is not in use. This control is included so the system cannot be accessed and operated by untrained and/or unauthorized operators.

WARNING: To avoid misuse of the system, do not leave the key in the key switch while the system is unattended.

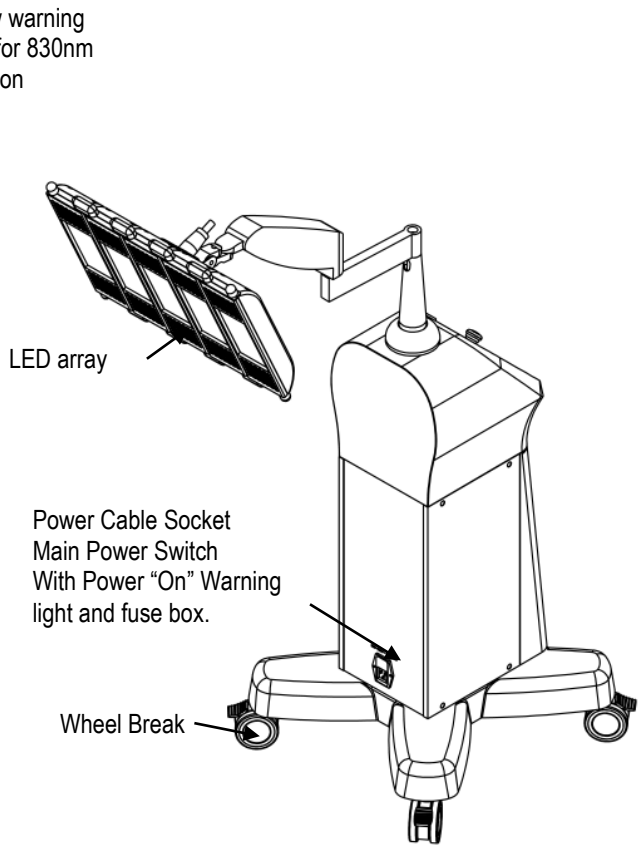
4.1.2 Emergency Shut-off knob

The Emergency shutoff knob is a red, mushroom-like knob designed for emergency shutdown of the system where a failure has occurred that could potentially cause a risk to personnel and/or property. To turn to “On” position rotate 90 degrees clockwise and allow switch to spring out.

4.1.3 Touch Screen Control Panel

The touch screen Control Panel provides a user interface allowing the user to review information on the status and configuration of the system and change operational parameters as required.

4.2 Back Panel



4.2.1 Yellow Warning Lights

Each LED panel in the array has a yellow warning light which illuminates when invisible 830nm energy is being emitted from the panel.

4.2.2 LED Array

The LED array is made up of 5 panels which can be moved through a range of positions to optimize tissue exposure.

4.2.3 Power Cable Socket

Power Cable socket for connection to mains power.
Main power switch:

When “O” is pushed down, the power “On” warning light is on, the power is on,
When ”I” is pushed down, the power “On” warning light is off, the power is not connected.

5 Operating Instructions

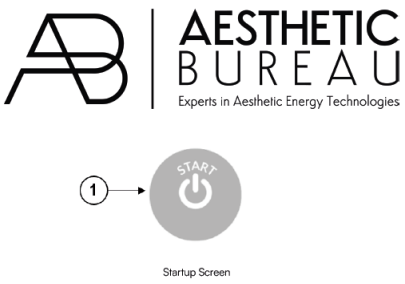
This chapter describes the operating instructions of the Xen LED System. Specific treatment parameters and information concerning the applications of the system are provided in the user guide appendices for each wavelength.

5.1 Turning On the system and operation screens.

1. Plug the system into the mains power outlet.
2. Verify the Emergency Shut-off knob is in the “On” Position.
3. Verify that the Main switch on the Back Panel is in the “On” position, Note illumination of power “On” warning light .
4. Verify that the client and all personnel in the room are wearing safety eyewear.
5. Insert and turn the key switch clockwise one quarter turn to the “On” position. The system turn “On”, perform a self-check and moves onto the Standyby screen.

5.1.1 Standby Screen and initial Self-test.

On “Turn ON” the system will automatically enter a software “**Self-test**”. If any failures in the software Self-Test occur then the system will give out an alarm. If everything is OK, the machine will enter the “**Standby”** screen as shown.



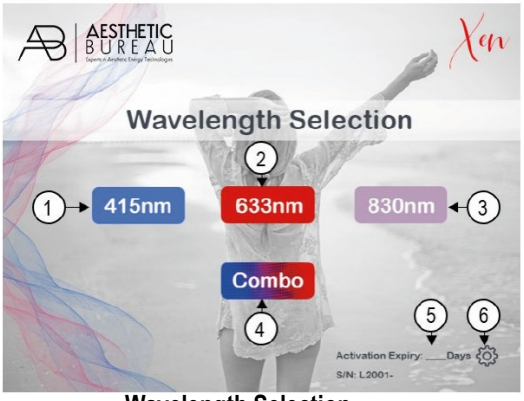
Logo Screen

1. **Start:**

   Press “Start” button to move to the “Wavelength Selection” screen.

5.1.2 Wavelength Selection Screen

Once the “Start” button has been pressed the system will move to the “Wavelength Selection” screen.

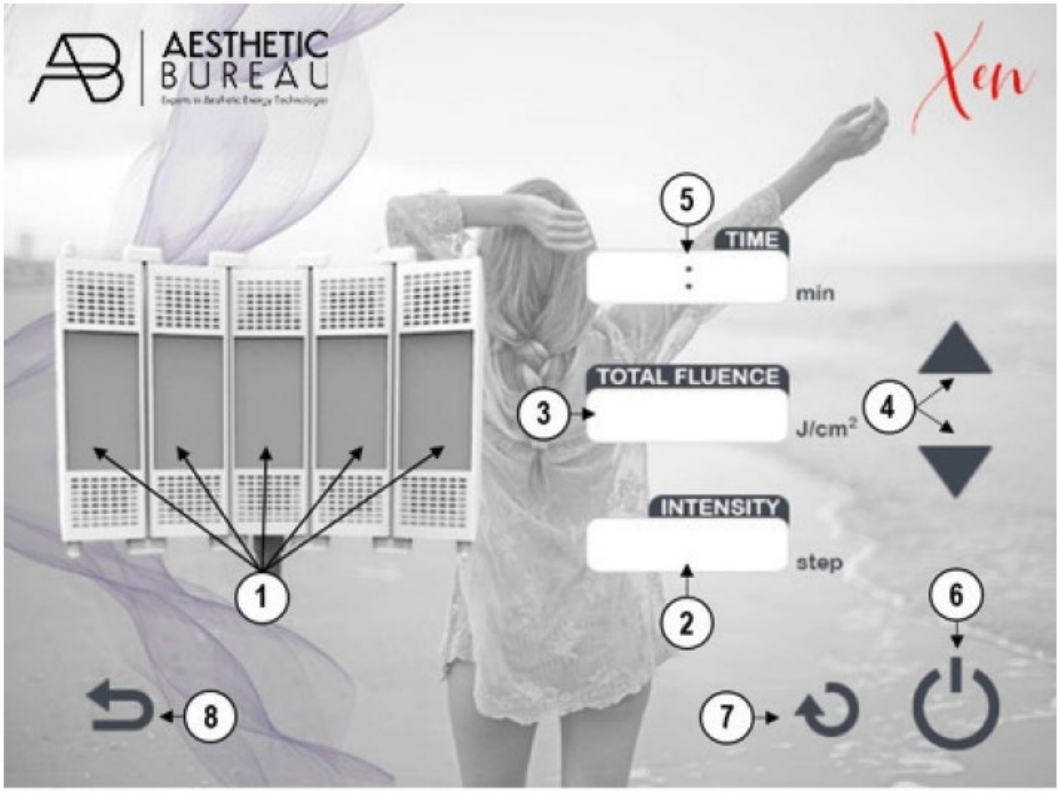


Wavelength Selection

1. **415nm:** Press “415nm” button to select Blue Light treatment screen.
2. **633nm:** Press “633nm” button to select Red Light treatment screen.
3. **830nm:** Press “830nm” button to select IR LED treatment screen.
4. Combo: Press“Combo” button to access the Combination Treatment screen.
5. Activation Expiry: Specifies days to system lock out based on current activation code.
6. Settings: Access Activation Code Entry screen.

5.1.3 Treatment Screen.

The format and layout of the treatment screens for 415nm, 633nm and 830nm are identical.



Treatment Screen

1. **Panel Selection:**

   Illuminated panels will turn on for treatment. Press on panel icon to deselect and disable for operation. Panel selection can only be made when system not active.

2. **Intensity:**

   Press to select. Use the “Up/Down” keys to adjust output intensity from 1 to max 5.

3. **Total Fluence:**

   Press to select. Use the “Up/Down” keys to adjust output total energy delivery.

4. **Up/Down:**

   When “Intensity” or “Total Fluence” are selected then the “Up/Down” keys can be used to adjust values.

5. **Treatment Time:**

   Indicates the time the Xen LED will take to deliver the requested “Total Fluence” given the “Intensity” selected. This value can only be adjusted by adjusting “Intensity” or “Total Fluence”.

6. **Stop/Start:**

   The “Stop/Start” button allows the operator to Activate the LED’s or Pause the treatment.

7. **Reset:**

   The “Reset” button allows the operator to reset the treatment timer to start again.

8. **Back:**

The “Back” button allows the operator to return to the “Wavelength Selection” screen.

5.2 Changing Operation Parameters during Operation

Any of the operating parameters may be changed during operation as follows:

- Pause treatment by pressing the “Stop” button.
- Change the setup parameters as desired.
- Restart the treatment by pressing the “Start” button.

5.3 System Shut Down

Shut the system down as follows:

1. If system LEDs are activated then press “Stop” to deactivate the LED’s..
2. Turn the key switch to “Off” (one quarter turn counter clockwise)
3. Turn off main switch
4. Disconnect the power cable from the mains power outlet.

6 Maintenance and Troubleshooting

This chapter contains maintenance instructions and a troubleshooting guide for the Xen LED system.

Routine maintenance may be performed by clinic staff unless otherwise specified. Any maintenance procedure not mentioned in this chapter must be performed only by Australian Aesthetic Devices authorized technical personnel

The system is designed to operate reliably with minimal operator maintenance. However, the surfaces of the system should be kept clean.

WARNING: Any Maintenance on the Xen LED system must be performed by Australian Aesthetic Devices authorized technical personnel. Don't do maintain service during treatment with device . Failure to obtain service through Australian Aesthetic Devices voids all warranties expressed and implied. Please contact Australian Aesthetic Devices for details.

6.1 Periodic Service

The system requires no periodic service.

6.2 Routine Maintenance

The following routine maintenance checks and procedures should be performed by the clinic staff on a regular basis determined by the clinic standard operating procedures.Don't do maintain during treatment with device.

Recommended daily checks and procedures

- Clean system and Accessories.
- Check mains electrical lead for damage.

- Check Personal Protection Equipment
- Verify arm and array security.

6.3 Cleaning the System

Gently clean the area covering the LED arrays with a warm damp cloth only. Wipe over with a clean dry lint free cloth or tissue. Allow to fully dry before re-use. The outer surface of the system may be wiped clean with a soft cotton cloth swabbed in 70% alcohol and a non-abrasive medical grade anti-bacterial. Be careful not to spill any liquids on the unit.

CAUTION: Do not clean LED arrays with oil based cleaners or alcohol wipes as it will destroy the array coating.

6.4 Troubleshooting

The following is a guide to troubleshoot a system issue. If any other problems occur or you are unable to rectify the issue, then please do not hesitate to contact AAD technical support.

Symptom	Possible Cause	Action
System does not turn on	No Power	1. Verify Main Power Switch is "ON" Verify power cable fully Connected and wall switch "ON". 2. Verify Emergency Shut-off switch is "ON" by rotating clock wise 90º and allowing to spring out. 3. Verify key switch turned on.
No Display	No Power	Follow action for symptom- "System does not turn on". If problem persists then contact AAD technical support.
No response when Pressing a button on the screen.		Reset the unit by turning "OFF" then "ON". If problem persists contact AAD Technical Support.
Panels do not illuminate When system activated.		1. Ensure panels selected in operating screen. 2. If using 830nm verify yellow LED's at end of Panels are illuminated.

6.5 Disposal

WEEE symbol 

This symbol indicates that waste electrical and electronic equipment must not be disposed of as unsorted municipal waste and must be collected separately Instead it shall be handed over to the applicable collection point for the recycling of electrical and electronic equipment. By ensuring this product is disposed of correctly, you will help prevent potential negative consequences for the environment and human health, which could otherwise be caused by inappropriate waste handling of this product. The recycling of materials will help to conserve natural resources. .

Please contact an authorized representative of the manufacturer for information concerning the decommissioning of your equipment.

7 Appendix User Guides

7.1 Appendix A: General User Information

The Xen LED is designed to be operated only by personnel properly trained in its handling and use and who have read the Operator's Manual as well as understand the optical risks associated. This may include operators, technical staff or other professional staff members.

Intended Use:

Low-Level Light Therapy (LLLT) is the therapeutic use of incident light to photomodulate cellular function, improving healing times, relieving pain and subsiding active acne.

Pre-Treatment Information

Client Selection

When assessing a client for treatment there are several issues to consider to ensure safe and satisfactory results. One of the most important is the client's expectations. Unrealistic expectations will most likely lead to dissatisfied client. It is therefore very important to ensure your client is fully informed of all aspects of the treatment and their expectations are clarified.

For treatment you will need to exclude any client with the following:

Contraindications of Xen LED Treatments

- **Porphyria** is a porphyrin-related disease which occurs when the body cannot convert naturally occurring compounds (called 'porphyrins') into heme (or haem), which contains iron. Cutaneous porphyrias cause skin manifestations often after exposure to sunlight, as porphyrins react with light. Porphyrins help form many important substances in the body…one of these is hemoglobin, the protein in red blood cells that carries oxygen in the blood. The main role of porphyrins is their support of aerobic life.
- **Solar Urticarial** is a condition in which exposure to UV radiation and sometimes visible light, induces a case of urticaria or hives that can appear in both covered and uncovered areas of the skin.
- **Autoimmune Diseases** and Diseases stimulated by light e.g. Lupus, Epilepsy…
- **Photo-sensitivity** or on medication or creams that creates Photo-sensitivity such as
    - Accutane (isotrenoin)
    - Tetracyclines
    - Tretinoin – Retin A

Client History and Questionnaire

During the first visit the authorized staff member should take a detailed client medical history, including previous treatment modalities, and examine for suitability for treatment with the Xen LED.

The client history and questionnaire is used as a guide to discovering the complete clients' medical and cosmetic history including:

- current medications
- relevant medical conditions
- prior cosmetic procedures:
- skin care regime (AHA's, BHA's, retinols, glycolics etc.)

The questionnaire is used to:

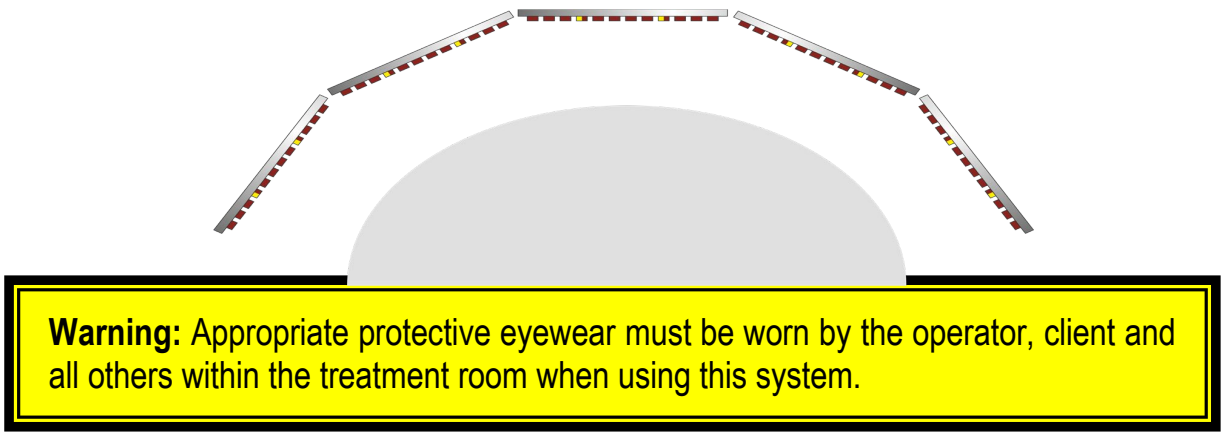
- Asses clients primary concerns
- Asses clients expectations
- Discuss treatment with client.

7.2 Appendix B: User Treatment Guide

The Xen LED system is used forphotomodulate cellular function, improving healing times, relieving pain and subsiding active acne..

Preparation for Treatment

- Professional doctors should formulate the corresponding treatment plan for each patient's condition, and set a reasonable energy level and treatment duration.
- Remove all make-up, deodorants, cosmetics and sunscreen products with a neutral cleanser prior to commencing the treatment.
- Ensure all people in the treatment room are wearing appropriate safety eyewear (this includes the client and operator). Instruct the client to also keep their eyes closed during treatment.
- Position LED array 1 to 4 cm from skin
- If client positioned in a sitting or upright position, ensure hair is tied back or secured so it cannot be sucked into the cooling fans.
- Select parameters
    - Wavelength (Blue: 415nm, Red: 633nm or IR: 830nm)
    - Intensity (brightness) of energy delivered during treatment. Levels relate to mW/cm2.
    - Total Fluence Displays the full value or dosage of energy delivered during treatment.
- Activate the unit



Warning: Appropriate protective eyewear must be worn by the operator, client and all others within the treatment room when using this system.

7.3 Appendix C 415nm Blue Light User Guide

The Xen LED system provides up to 65mW/cm^2 by utilizing 3,500 COB intense narrow band 415nm blue LED's.

Blue light therapy involves directly exposing the entire skin area to a continuous intense light which has been shown to have anti-bacterial and anti-inflammatory effects. A typical treatment requires two sessions per week over four to five weeks.

It is rare for blue light to be used in isolation and it is usually combined with either topical or oral medications (e.g. anticomedonal product such as salicylic acid).

Blue lights are often used in conjunction with another topically applied medicine which increases the sensitivity of the acne lesions to the effects of the light.

Side effects are generally minor and may include

- Redness and swelling of treated areas
- Skin dryness
- Worsening of acne (possibly more likely to occur in people with severe acne)
- Temporary pigment changes
- Photosensitivity (sensitivity to light)

Treatment

Treatment can begin after the appropriate preparation for treatment has been carried out as indicated in section 7.2 Appendix B. Recommendations for treatment settings are indicated in the following table.

BLUE Light Treatment			
Application	**Level/ Intensity**	**Total Fluence**	**Time**
Light only	*3 (40mW/cm²)*	*50J/cm²*	*20m 02 s*
Light + PDT	*2 (30mW/cm²)*	*30J/cm²*	*16m 27 s*

NOTE: The settings indicated are a guide only and treatment level can be lowered if required. Lowering treatment level will automatically increase treatment time.

Protocol

For ***Light only*** the treatment protocol is 2 treatments per week over 4 weeks alternating BLUE then (RED or IR) with a minimum of 48 hours between each treatment. Do not combine Blue and (Red or IR) in one treatment.
NOTE: when combining treatment over clients with moderate to severe acne, reduce combined red or IR level/intensity by 1 increment below recommended setting, and reduce total fluence delivered to 40j/cm^2.

7.4 Appendix D 633nm Red Light User Guide

The Xen LED system provides up to 140mW/cm^2 by utilizing 3,500 COB intense narrow band 633nm red LED's.

Red light therapy involves directly exposing the entire skin area to a continuous intense light which can be used in photomodulate cellular function and improving healing times A typical treatment requires two sessions per week over four to five weeks.

Side effects are generally minor and may include

- Redness and swelling of treated areas
- Skin dryness
- Worsening of acne (possibly more likely to occur in people with severe acne)
- Temporary pigment changes
- Photosensitivity (sensitivity to light)

Treatment

Treatment can begin after the appropriate preparation for treatment has been carried out as indicated in section 7.2 Appendix B. Additional preparations for phototherapy can include exfoliation of the skin by microdermabrasion or mild peel. Recommendations for treatment settings are indicated in the following table.

RED Light Treatment			
Application	**Level/ Intensity**	**Total Fluence**	**Time**
Light only Face & Body	*2 (65mW/cm²)*	*60J/cm²*	*15m*
Light only Hair	*1 (40mW/cm²)*	*40J/cm²*	*15m 52 s*
Light + PDT	*2 (65mW/cm²)*	*60J/cm²*	*15m*

NOTE: The settings indicated are a guide only and treatment level can be lowered if required. Lowering treatment level will automatically increase treatment time.

Protocol

For ***Light only Face and*** Body the treatment protocol is 2 treatments per week with a minimum of 24 hours between each treatment. For phototherapy it will be over 4 weeks and for post care it will be over 3 weeks.

For Light only Hair the treatment protocol is 2 treatments per week over 4 weeks with a minimum of 24 hours between each treatment.

7.5 Appendix E 830nm IR LED User Guide

The Xen LED system provides up to 105mW/cm² by utilizing 3,500 COB intense narrow band 830nm infra-red (IR) LED's.

IR LED therapy involves directly exposing the entire skin area to a continuous intense light which can be used in relieving pain. A typical treatment requires two sessions per week over four to five weeks.

Side effects are generally minor and may include

- Redness and swelling of treated areas
- Skin dryness
- Worsening of acne (possibly more likely to occur in people with severe acne)
- Temporary pigment changes
- Photosensitivity (sensitivity to light)

Treatment

Treatment can begin after the appropriate preparation for treatment has been carried out as indicated in section 7.2 Appendix B. Additional preparations for phototherapy can include exfoliation of the skin by microdermabrasion or mild peel. Recommendations for treatment settings are indicated in the following table.

INFRA RED Treatment			
Application	**Level/ Intensity**	**Total Fluence**	**Time**
Face & Body	*4 (87mW/cm^2)*	*60J/cm^2*	*11m 27 s*
Post Care	*3 (69mW/cm^2)*	*60J/cm^2*	*14m 32 s*

NOTE: The settings indicated are a guide only and treatment level can be lowered if required. Lowering treatment level will automatically increase treatment time.

Protocol

The treatment protocol for both applications is 2 treatments per week over 4 weeks with a minimum of 48 hours between each treatment..