

**CE Technical File**

File No: HFHT-TCF-01\_8


**Intense Pulsed Light System (IPL)**

Rev. No: B/2

## **Intense Pulsed Light System (IPL)**

### **User Manual**




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## Intended application

### Intended use

Multi-modality device emits energy for the treatment of the skin surface for various conditions. This device is intended to produce and deliver various types of light energy via dedicated applicators to treat vascular lesions, pigmented lesions, permanent hair reduction and meibomian blepharitis (dry eye syndrome) by targeting the skin surrounding the meibomian glands (around the eyelid).

### Contraindications

- Tanned skin (has been exposed to the sun or used tanning beds in the past three to four weeks) or has recently used a self-tanning lotion.
- Diseases stimulated by light (Lupus, Epilepsy...)
- Use of photosensitizing medications such as: tetracycline or herbal (St John's Wort) etc.
- Use of anticoagulants or has a history of bleeding coagulopathies.
- Fragile and dry skin. Use of Accutane (isotretinoin) Roaccutane or Tretinoin – Retin A for the treatment of acne in the previous 6-12 months.
- Active infections: herpetic lesions, cold sores (place on anti-viral medication pre-treatment).
- Any inflammatory skin condition (e.g. eczema, etc.), in the area to be treated.
- Pregnancy or trying to conceive.
- Tattoos, permanent make-up, suspicious pigmented lesions (can treat around them).
- History of keloidal scarring.
- For Hair Reduction - Electrolysis, waxing or plucking in last 6 weeks (target has been removed).
- Planning to be in the sun following treatment.
- Diabetes (unless under control).
- Cancer, in particular, skin cancer.
- Hormonal Disorders (unless under control).

## Warnings

- Hazardous voltages are energized within the system when power applied.
- IR emitted from this product. Avoid eye exposure. Use appropriate shielding or eye protection.
- Visible light emitted from this product. Do not look at operating lamp. Eye injury may result.
- Labels Located on the rear panel.
- To avoid misuse of the system, do not leave the key in the keyswitch while the system is unattended.
- Do not leave the key in the key switch unattended. It may lead to unauthorized use of the system.
- Maintenance by the operator should be performed only when the system is shut down and disconnected from the mains power source. Performing maintenance procedures with the system turned on may be hazardous to the operator and/or destructive to the system.
- Unauthorized servicing or modification of this system not described in this manual may expose the operator or client to potential high voltage and light radiation hazards. Improper use or adjustment of this system may VOID the warranty agreement.
- Never immerse any part of the handpiece in water, nor hold it under running water.
- Appropriate protective eyewear must be worn by the operator, client and all others within the treatment room when using this system.
- Appropriate protective eyewear should be worn by the operator, client and all others within the treatment room when using this handpiece.
- Pre-sets "I – IV" are configuration pre-sets loosely based on treatment skin type. We recommend the 690nm or Swift HR Handpieces for skin type IV, and do not recommend treatments on skin types V & VI be carried out. For treatment of skin type IV, ensure extra time is given between pulse for the handpiece chiller to effectively chill client skin.
- Selections "I – IV" are program options loosely based on treatment skin type. We recommend the 580nm or SSR Filters for skin type IV, and do not recommend treatments

on skin types V & VI be carried out. For treatment of skin type IV, ensure extra time is given between pulse for the handpiece chiller to effectively chill client skin.

## Precautions

- Operators should read this manual thoroughly before attempting to operate the Intense Pulsed Light System (IPL).
- All handpiece lightguides and filters must be kept clean at all times. Remember to clean the cooling gel from the lightguides after each client.
- The system weighs approximately 50 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 handpiece or cable

## 1. System Overview

The Intense Pulsed Light System (IPL) is an aesthetic pulsed IPL device that is capable of treating the skin surface with single, dual and notch filtered visible and near Infrared pulsed light. While the Intense Pulsed Light System (IPL) allows for 2 handpieces to be connected, only one can be used at any one time.

**The Dual Light has 4 handpiece options:**

### **Small SR/HR, SSR/SHR Handpiece**

- Size 40 x 12 mm = 4.8cm<sup>2</sup>
- Diffuse reflector for Even Energy Distribution (EED)
- 2-part filter with 2nd part being an insertion filter with following filtration

Turquoise Notch filter 520 - 650nm 800 – 1200nm for high level treatment of redness.

Green 540–800nm and Yellow 580-800nm SR Dual filters for high level skin rejuvenation.

Green 540 – 800nm SSR filters for pain free swift skin rejuvenation.

Red 640 – 1200nm and IR 690 – 1200nm HR handpieces for high level hair reduction.

Red 640 – 1200nm and IR 690 – 1200nm SHR handpieces for pain free swift hair removal.

- Up to 30j/cm<sup>2</sup> for SR and 40j/cm<sup>2</sup> for HR
- Up to 7j/cm<sup>2</sup> for SHR and 12j/cm<sup>2</sup> for SSR
- Up to 10 pulses per second
- Sapphire portion in contact for treatment.

### **Large 640nm SHR**

- Size 46 x 16mm = 7.36cm<sup>2</sup>
- 640 SHR fixed filter handpiece for rapid pain free swift hair removal.  
(Fixed filter used to optimize contact tip cooling efficiency)
- Up to 7j/cm<sup>2</sup> for SHR.
- Sapphire portion in contact for treatment.

#### **Large 690nm SHR**

- Size 46 x 16mm = 7.36cm<sup>2</sup>
- 690 SHR fixed filter handpiece for rapid pain free swift hair removal.  
(Fixed filter used to optimize contact tip cooling efficiency)
- Up to 7j/cm<sup>2</sup> for SHR.
- Sapphire portion in contact for treatment.

#### **Large HR**

- Size 12cm<sup>2</sup>
- Dual Lamp
- Diffuse reflector for Even Energy Distribution (EED)
- 640 HR fixed filter.
- Sapphire portion in contact for treatment.

The system utilizes fan cooled heat exchangers as well as a temperature selectable refrigerant based compressor cooler for internal water cooling, which not only provides superior system temperature control, but assists the electronic Peltier coolers in the handpiece to provide continuous contact cooling to the treatment area.

The Dual Light has been designed to provide flexibility in choosing the wavelength using selectable insertion filters rated in nanometers (nm), fluency (intensity in j/cm<sup>2</sup>) and pulse width and pulse sequence showing duration in millisecond (ms), to enable treatment to target areas without damaging the surrounding tissue.

## **1.1 Using the Intense Pulsed Light System (IPL)**

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 IPL Filters, pulse duration and fluence to which the treated area is exposed, are located in the relevant appendix user guides. Each time the operator presses the finger-switch when the system is in the “Ready” mode, the Dual Light handpiece emits a single pulse which may be made up of multiple sub-pulses (from 1 to 5). If the operator continues to hold the finger-switch “on”, then the Intense Pulsed Light System (IPL) will emit additional pulses at regular time intervals.

## 1.2 Specifications

Light Source: Pulsed Xenon Lamp

Modes: Single Pulse & Multi Pulse

Wavelength: SR: 520-650, 800-1200 540 & 580 - 800nm Dual Filter

SSR: 540-800nm

HR: 640 & 690 - 1200nm

SHR: 640 & 690 - 1200nm

Spot Size: Small: 40 x 12 mm = 4.8cm<sup>2</sup>

Large: 46 x 16mm = 7.36cm<sup>2</sup>

Ex-Large: 12cm<sup>2</sup>

Pulse Repetition: Up to 10 pulses per second

Tip Cooling: Sapphire Peltier contact cooling

System Cooling: Compressor closed circuit water  
chiller with integrated heat exchanger.

Output Energy: Up to 50J/cm<sup>2</sup>

Dimensions: 360Wx 450Dx1200H

Power requirement: 230V 50 Hz 15Amp

## 2. Safety

The product 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 rules & regulations of the safe use of Lasers in health care as specified in the local regulations "Guide to the Safe use of Lasers in Health Care". IEC 60825.1:2014 is a Lasers standard the principals, hazards and recommended practices are also appropriate for the safe use of Intense Pulsed Light (IPL) systems.

Other reference materials include:

IEC 60825.1:2014 Safety of Laser Products Part 1: Equipment classification and requirements.

IEC 62471:2011 Photobiological safety of lamps and lamp systems.

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 System Safety Measures**

The Intense Pulsed Light System (IPL) 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.

### **2.1.1 Electrical Safety**

1. The system is protected by a semi-automatic circuit breaker.
2. Software protection, including:
  - The software checks all safety related hardware after the system is switched on.
  - If an error occurs, the system displays a warning message to the operator and disables further operation.
3. A self-test of the attached handpiece is performed when the system is turned on. The test includes handpiece identification.
4. A self-test of the electrical circuitry takes place after the system is turned on. The test circuits continuously monitor system operation during treatment.

### **2.1.2 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. The system incorporates a remote interlock electrical connector. When the terminals of the connector is open-circuited; activation of the trigger switch will be disabled.
4. A password on the service screen prevents unauthorized changes to the system's basic operating parameters.
5. The system features two emission indicators: a red emission indicator lamp located on the control panel and a buzzer.
  - The red emission indicator lamp turns on when the system is ready to trigger.
  - A warning buzzer sounds when the system is ready to trigger a pulse.
6. Emission is enabled only when system is in "Ready" state and operator presses the finger switch.
7. Water is circulated through the handpiece as soon as the system is turned on in order to cool the light source and client contact tip.
8. The flow and temperature of the water is monitored in order to eliminate the risk of handpiece overheating. Pulsed light is not permitted if the water flow stops or if the water temperature is above recommended levels.

## 2.2 The Treatment Room

The treatment room should be kept at an ambient temperature of 20-25° C and well ventilated for removal of odors and optimal performance of the equipment. Fire extinguishing equipment should be available in the treatment area.

Access to the Dual Light 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 Dual Light controls and know how to shut down the system instantly.

## 2.3 General Precautions and Cautions

The following precautions, cautions and warnings must be observed for the safe use of the Intense Pulsed Light System (IPL).

### 2.3.1 Precautions

- Operators should read this manual thoroughly before attempting to operate the Intense Pulsed Light System (IPL).
- All handpiece lightguides and filters must be kept clean at all times. Remember to clean the cooling gel from the lightguides after each client.
- The system weighs approximately 50 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 handpiece or cable.

### 2.3.2 Cautions

- Only Australian Aesthetic Devices P/L. authorized personnel may service the Intense Pulsed Light System (IPL). This includes making internal adjustments to the power supply, cooling system, optics, handpieces, etc.
- Always turn off the system when it is not in use.
- Never leave the system in "Ready" mode unattended.
- Never allow untrained personnel to operate the system.
- Never discharge a pulse of light energy unless the handpiece is safely oriented at a specific and intended target.

## **2.4 Warnings Related to Intense Pulsed Light Emission**

### **2.4.1 Burn Hazards**

The Intense Pulsed Light System (IPL) emits a broad spectrum of light energy, which, in part, is invisible to the human eye. This emitted energy can cause third degree burns.

### **2.4.2 Direct and Reflected 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 P/L. 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 Dual Light handpiece or at any reflecting surface, even when wearing protective eyewear.

If the treatment area is very close to the eyes use laser/IPL eyeshields.

Do not treat over the eyelids or in the infrabrow region.

Always set the system to Standby mode when there is a pause in treatment; this prevents inadvertent light emission.

### **2.4.3 Explosion and Fire Hazards**

The absorption of optical energy raises the temperature of the absorbing material. Take precautions to reduce the risk of igniting combustible materials in and around the treatment area.

Remove any hair from the treatment site

The system is not suitable for use in the presence of flammable mixtures with air or oxygen.

Do not operate in the presence of volatile solvents such as alcohol, gasoline or other solvents.

Do not use any flammable substances such as alcohol or acetone in the preparation of the skin for treatment. If necessary, use soap and water to clean before treatment.

If alcohol is used to clean and disinfect any part of this system, allow it to dry thoroughly before operating.

Make sure a fire extinguisher (rated for electrical fires) is available at all times.

### **2.4.4 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.

The Intense Pulsed Light System (IPL) produces very high voltages in various components. Some components may retain a charge after the power supply has been turned off, so no part of the exterior housing should be removed, except by Australian Aesthetic Devices P/L authorized personnel.

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

## 2.4.5 Grounding the System

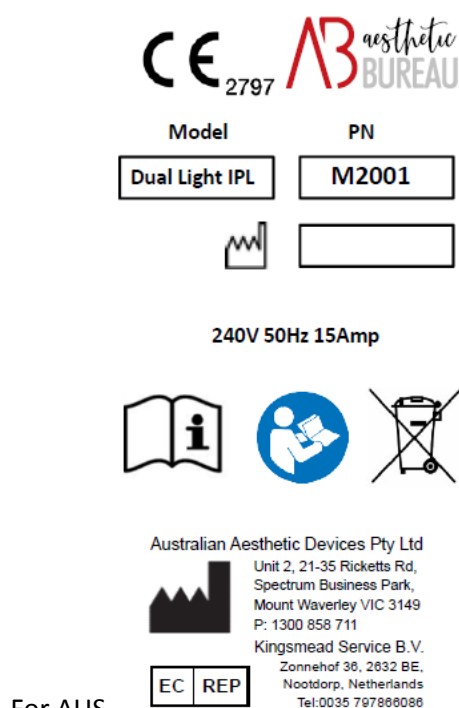
The system is grounded through the grounding conductor in the power cord and internal grounding pin.

## 2.5 Device Labels

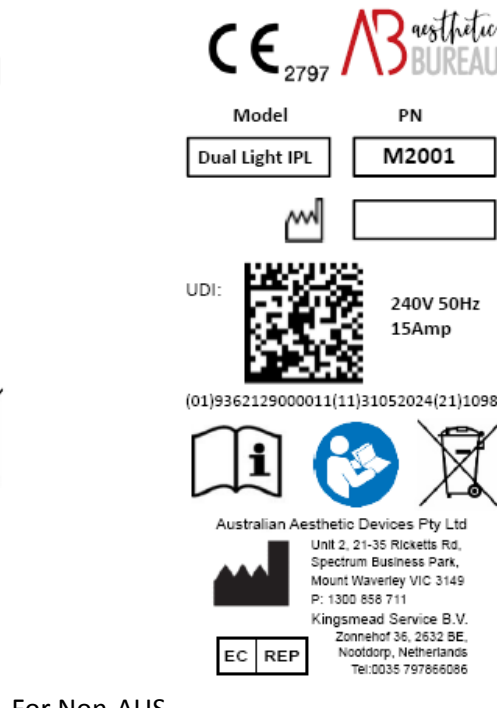
The following Warning, Certification and Identification labels are adhered to the Intense Pulsed Light System (IPL):

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
- Patient safety type and class



For AUS



For Non-AUS

Figure 1: System Label

### 3. Installation

Installation is carried out by the operator, who will do the following:

- Unpack the system.
- Verify that no physical damage during transport.
- 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 P/L representative and recorded in shipping documents with signature for receipt requested by couriers.**

#### 3.1 Equipment List

The Dual Light platform includes the following:

- IPL System
- Treatment Handpiece/s
- Handpiece filters
- Filter Box
- 2 sets of Keys
- Water Funnel and Tubing
- 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 separate line supply of 240 VAC, 15A, 50 Hz, single phase for Intense Pulsed Light System (IPL).

It is important that the system does not share a power line with other equipment.

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.

Air-borne dust particles should be kept to a minimum. Dust particles absorb light and heat up. Hot particles located on the optical lenses can damage them. Metallic dust is destructive to electrical equipment.

#### **Water Quality:**

The system should be operated using deionized or distilled water only. Regular tap water contains sediments that may damage the cooling system.

#### **Temperature:**

To ensure that the system performs optimally, maintain room temperature between 20° C and 25° C (68° F - 77° F), relative humidity of  $\leq 70\%$  with a Barometric pressure 860~1060hPa.

**NOTE: When the system is used intensively it emits heat. Therefore, it is recommended to install air conditioning in the room in which the system will be used.**

### 3.3 Handpiece Connection

The handpiece connector is designed to enable easy replacement of the handpiece when required. There are 2 handpiece connection ports located on the front panel. For insertion and removal of the connector, the left and right buttons must be pressed at the same time to release those pins.

#### **Installation of the hand piece**

1. Place treatment end of handpiece securely into handpiece holster.
2. Check handpiece connectors to ensure there are no visible signs of damage.
3. Press the 2 buttons on the handpiece connector to ensure the valves water connectors are unlocked. Release before inserting.

**NOTE: attempting to connect the handpieces with the water valves in the locked position may result in O-ring damage and water leak.**

4. Insert handpiece connector into port and listen for 2 clicks that ensure the handpiece has locked into place. If this does not occur, then the valves on the water connectors may not fully open and "Low Water Flow" errors may occur. To rectify, remove and reattempt to connect the handpiece until 2 clicks are heard.

#### **Changing the hand piece**

1. Press the 2 buttons on the handpiece connector to release the valved water connector locks which releases the handpiece.
2. Pull the connector out from the system.

**NOTE: There may be droplets of water present which have been released from the valved water connectors.**

**CAUTION: Do not remove the handpiece when the system is turned "On" as this can place undue pressure on the water flow system.**

### **3.4 Remote Interlock Connection**

The Intense Pulsed Light System (IPL) incorporates a Remote Interlock Electrical Connector. When the terminals are open-circuited, or the connector is not present the output trigger is disabled. Insert connector and lock into place.

**CAUTION: Remove Remote Interlock Connector before shipping as failure to do so may result in damage to the connector and/or plug, resulting in replacement or repair.**

### **3.5 Filling the Coolant Reservoir**

The cooling system's reservoir must be filled with deionized or distilled water. It is imperative that the level of the water in the reservoir be checked every week and deionized or distilled water added if necessary.

Refer to section 6.7 for Water Fill and Drain procedure.

### **3.6 Cooling System Drainage**

If the system is to be stored in a cold area where the temperature may fall below 0° C (32° F), the coolant must be drained from the cooling system.

### **3.7 Moving the System**

#### **3.7.1 Moving within the Clinic**

To move the system:

1. Disconnect the power cable.
2. Place the treatment heads in their holsters.  
(Make sure the treatment heads are secure and will not fall off when moved).
3. Release the wheel brakes.
4. Slowly push or pull the unit, using the handle on the back of the system.

**CAUTION: Never pull the system by the handpiece. Never lift the system with handpieces connected.**

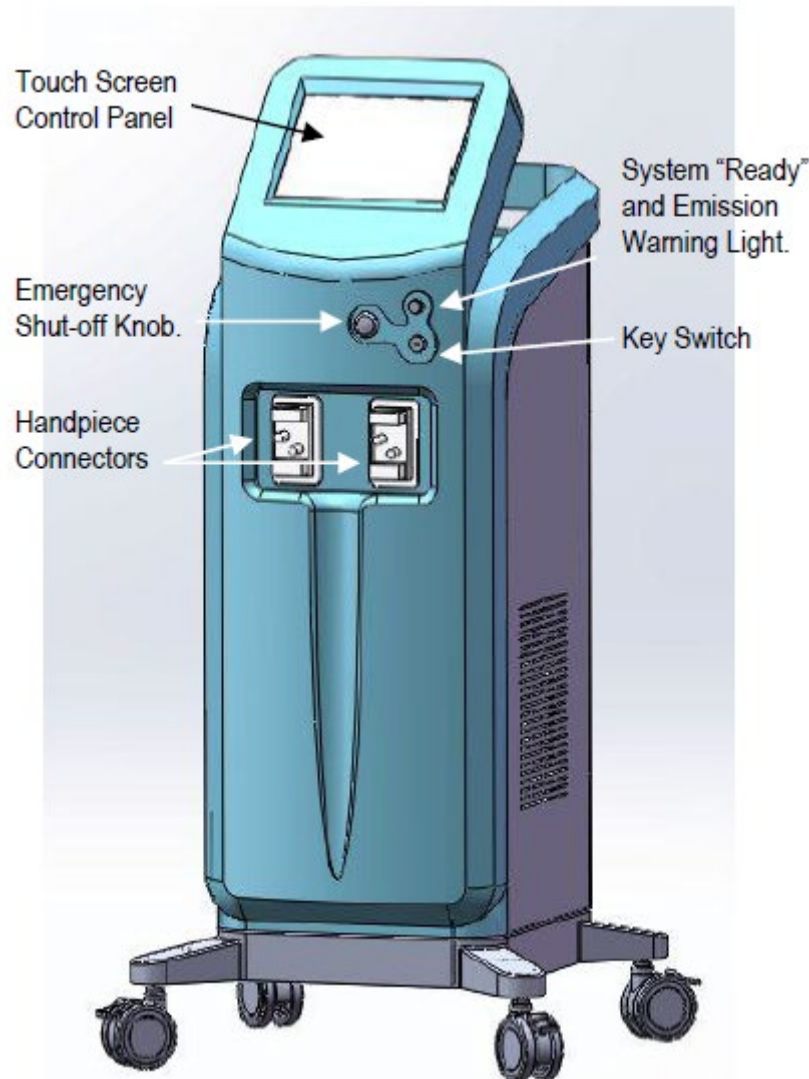
### **3.7.2 Packing the system for transportation**

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

1. Remove handpieces, holsters, interlock 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.

## 4 Components and Controls

### 4.1 Front Panel



#### 4.1.1 Handpiece Connectors

The Intense Pulsed Light System (IPL) has 2 handpiece connectors which connect coolant, control signals and lamp power from the unit to the handpiece. The water connectors have a spring loaded shut-off valve which will not allow water to flow when the handpiece is disconnected or only partially connected. It is important that the operator hears the 2 “Clicks” of the water connector locks when connecting the handpiece to ensure the handpiece is connected correctly.

### **4.1.2 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.**

### **4.1.3 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.

### **4.1.4 Touch Screen Control Panel**

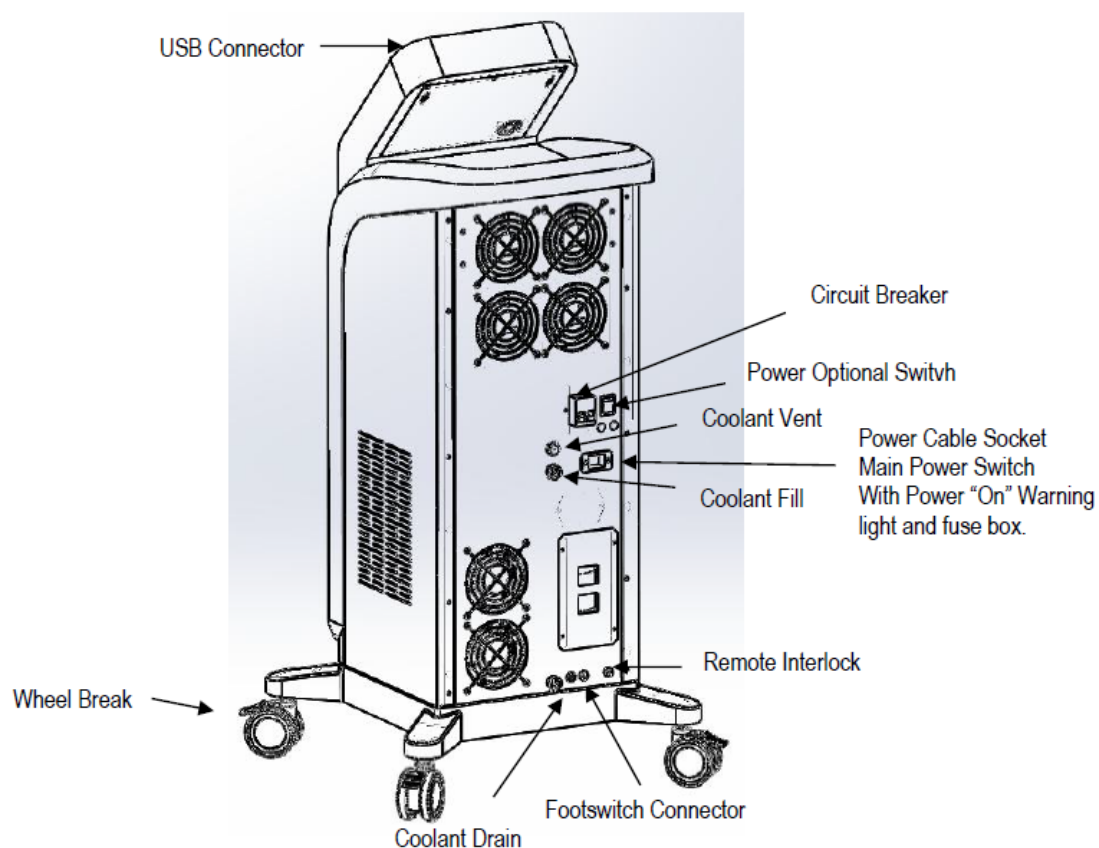
The touch screen Control Panel provides a user interface allowing the user to review information on the status and configuration of the system and change operational parameters as required.

**CAUTION: Ensure you do not leave deposits gel or other substances on the touch screen, as they may be interpreted as a key press and alter settings without your knowledge.**

### **4.1.5 System "Ready" and Emission Warning Light**

The System "Ready" and emission warning light is illuminated as a visual signal when the system is in the "Ready" mode where the Capacitors are charged or charging and when the unit output energy is being triggered.

## 4.2 Back Panel



### 4.2.1 Power Connectors

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.

### 4.2.2 Circuit Breaker

The circuit breaker is an automatically operated electrical switch designed to protect the system from damage caused by overload or short circuit.

The equipment should be placed in a position where the power cord can be easily removed from the three-pin socket during use.

### 4.2.3 Coolant reservoir connectors

Coolant fill, vent and drain are used when filling or draining the cooling system in the system.

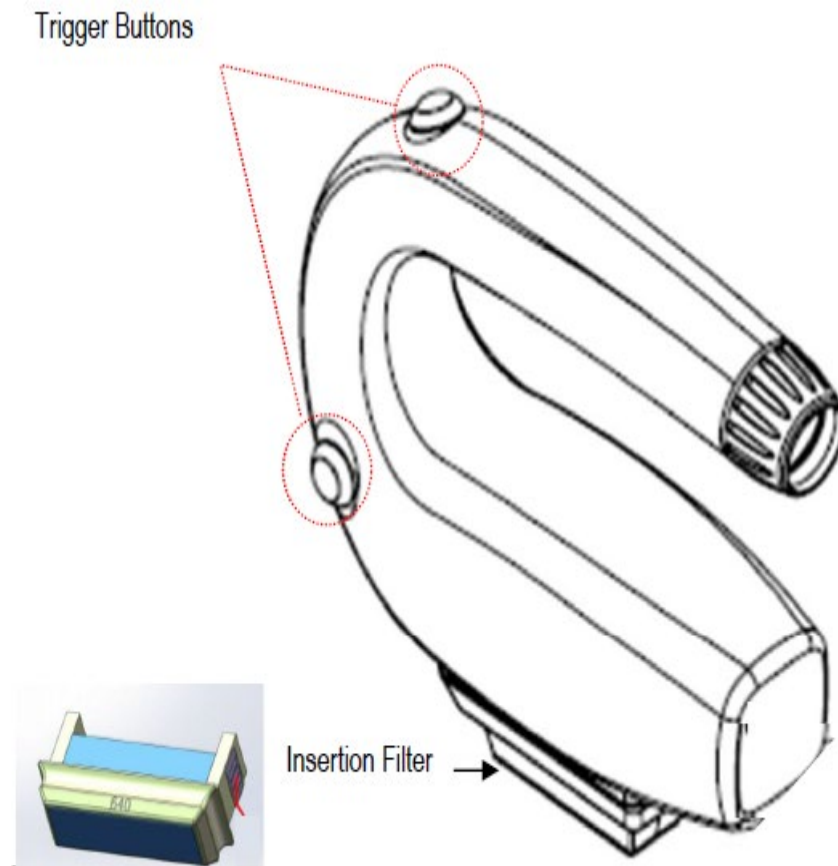
### 4.2.4 USB Connector

The USB slot is used for system software updates and exporting or importing client treatment files.

### 4.2.5 Remote Interlock Connector

The remote interlock connector is available to be connected to an external switch on the entrance door to the treatment room to disable the system when the door is open. The remote interlock is connected with the trigger; therefore, when activated by the door being open, or it is not connected, it disables the system from being fired.

## 4.3 Handpiece Controls



The system handpiece can be triggered by 2 separate methods. The user can select to use the finger trigger button on the handpiece or adjust the trigger setting in the Settings Screen

to use a footswitch trigger. For IPL use the system only requires 1 trigger to be enabled. To ensure the safe and effective use of the Intense Pulsed Light System (IPL), Australian Aesthetic Devices P/L recommends that operators verify that the filter indicated on the treatment screen matches the filter in the handpiece selected. The Intense Pulsed Light System (IPL) is calibrated to provide correct registration of the filter that is in the handpiece selected but, as a precaution due to possible calibration variation over time it is recommended that operators verify the filter selected.

## **5 Operating Instructions**

This chapter describes the operating instructions of the Intense Pulsed Light System (IPL). Specific treatment parameters and information concerning the applications of the system are provided in the User guide appendices for each application. Before use, ensure Preventative Maintenance/Periodic Service and Operational Checks have been carried out as per Section 6 (Maintenance).

### **5.1 Turning On the system and operation screens.**

1. Connect the handpiece as per section 3.3.
2. Select and insert desired filter into handpiece.
3. Plug the system into the mains power outlet.
4. Verify the Emergency Shut-off knob is in the "On" Position.
5. Verify that the Circuit Breaker is in the "On" position.
6. Verify that the Main switch on the Back Panel is in the "On" position, note illumination of power "On" warning light. System performs software checks and displays "Logo" Screen.
7. Verify that the client and all personnel in the room are wearing safety eyewear.
8. Insert and turn the keyswitch clockwise one quarter turn to the "On" position. The system performs a selfcheck and moves onto the Standby by screen.

Refer Attachment 1: Safety Checklist Pre-Treatment Operational Checks recommended for system and room setup to be carried out prior to treatment session and at the end of treatment session.

#### **5.1.1 Logo Screen and initial Self-test.**

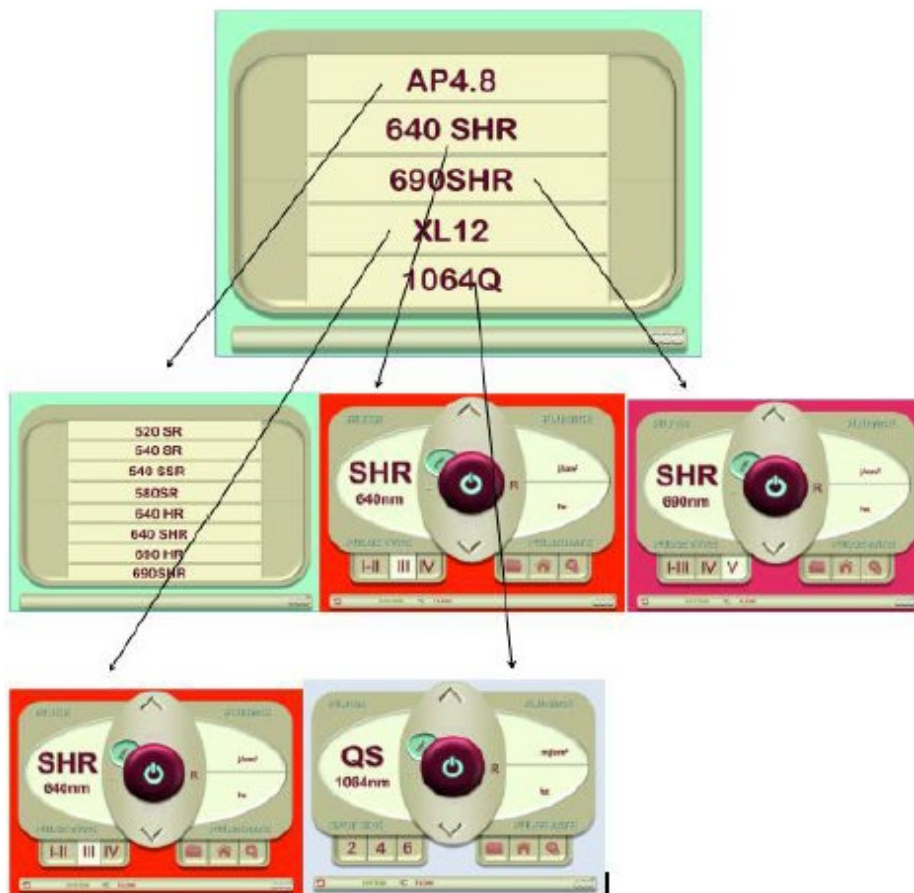
On "Turn ON" the system will automatically enter a software "Self-test". If any failures in the software Self-Test occur, then the system will give out an alarm. If everything is OK, the machine will enter the "Logo" screen as shown.

##### **1. Left Port Selection:**

Enables selection of handpiece connected to the Left-Hand port (facing the unit). Defaults to this port if handpiece connected.

##### **2. Right Port Selection:**

Enables selection of handpiece connected to the Right-Hand port (facing the unit). Defaults to this port if no handpiece is detected in the “Left Port”.



### 3. Settings:

Press to access “Settings” screen

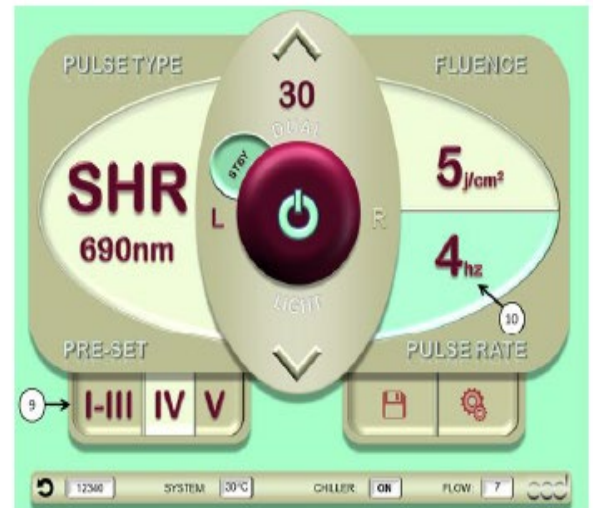
#### Standby Screen

Once the key is turned “On” from the Logo screen, the system will move to the system “Standby” screen. The system Standby Screen will take 1 of 2 options based on the Interchangeable handpiece filter selected within the selected handpiece port. Within this screen, the operator is able to review information on the status and configuration of the system and change operational parameters as required.

##### 5.1.2.1 Standby Screen Controls



SR/HR Standby Screen



SSR/SHR Standby Screen

**1. j/cm<sup>2</sup>:**

Displays and allows for adjustment of total energy delivered per pulse in J/cm<sup>2</sup>, being the sum of the energy delivered in Sub-Pulses of each Pulse (i.e. if the pulse is made up of 5 sub-pulses then total energy is the sum of the 5 pulses).

**2. Up/Down setting level when selected:**

When a parameter is selected and highlighted, the Up/Down selectors are able to adjust the selected parameter as required.

**3. Pulse Duration:**

Used for SR and HR Handpieces only.

Displays and allows for adjustment of total duration of pulse in Milli-Seconds (ms) being the duration of all of the sub-pulses and pulse delays.

**4. Pre-set:**

Pre-sets are loosely based on Fitzpatrick Skin Types and initially configures the unit to recommended settings. However...the operator is then free to adjust parameters to optimize the treatment for their client.

**NOTE: The range of Pre-set skin types will vary depending on the filter inserted.**

**5. Standby/Ready Button:**

Sets unit to system "READY" mode to enable the unit to fire when handpiece trigger pressed, and allows for return to system "STANDBY" or safe mode, deactivating the handpiece trigger. In "READY" mode the icon turns red and is relabeled "READY" and the red warning light on the front of the unit illuminates. Adjustments to treatment parameters cannot be made when in the "READY" mode. In "STANDBY" mode the icon will be green and labelled "STBY" and the red indicator light on top of the unit will be off. Adjustments to treatment parameters can only be made when in the "STANDBY" mode.

**6. Pulse Counter Reset Button:**

Resets the pulse counter to zero.

**7. Save:**

Allows you to save a setting that the system will automatically go to when the unit is first turned on for the Filter selected.

**8. Settings:**

Press to access “Settings” screen.

### 9. SHR/SSR Pre-set:

Within SSR/SHR the Preset levels adjust the peak wattage within the pulse and will stay illuminated even when “j/cm<sup>2</sup>” and/or “Pulse Rate” are adjusted.

**NOTE: The range of Pre-set skin types will vary depending on the filter inserted.**

### 10. Pulse Rate:

Used for SSR and SHR Handpieces only.

Replaces Pulse Duration Control. Level Indicated in Hertz (Hz) and indicates the number of pulses delivered per second. When selected, use the Up/Down to adjust.

### 5.1.2.2 Standby Screen Indicators



**Standby Screen Indicators**

#### 1. Pulse Type:

The Pulse Type control in this screen is an indicator of the filter (in nano-meters) inserted into the handpiece selected

#### 2. Active Handpiece Port:

The highlighted side indicates the active handpiece port. The active port can only be chosen in the Logo screen.

#### 3. SSR/SHR Pulse Timer:

When using SSR/SHR filters, the handpiece’s can only fire in 30 second blocks maximum. The counter will count this time down when handpiece in use. The handpiece will reset after a 6 second delay, ready to fire another block.

#### 4. Pulse Count:

Indicates the pulse count from the last reset. Reset done when the unit is turned off or the Pulse Count reset is pressed.

#### 5. System Temperature:

Indicates the temperature of the coolant within the unit.

#### 6. Chiller:

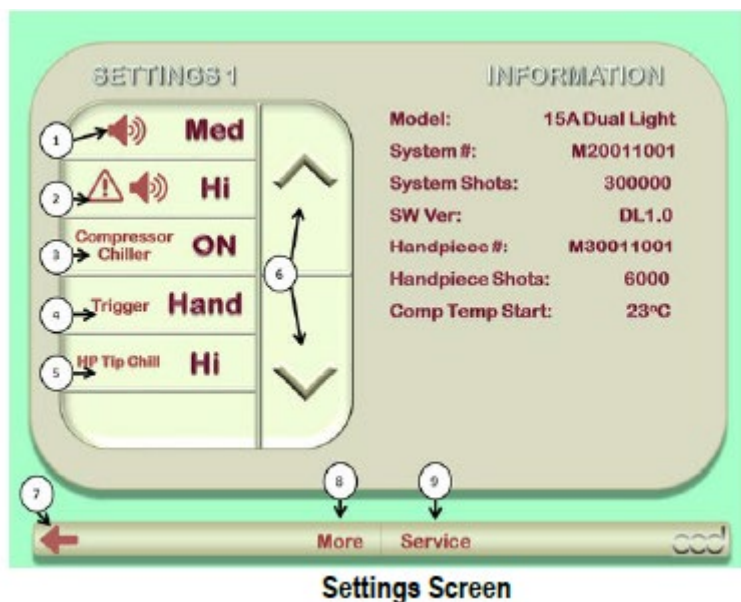
Indicates internal Chiller status.

#### 7. Coolant Flow Rate:

Indicates the measured flow rate of the coolant within the system

### 5.1.3 Settings Screen

The system Settings screen can be accessed via the Logo or Standby screens by pressing the icon.



#### 1. Keypad tone volume:

When selected, use the Up/Down keys to adjust volume of key-press tones

#### 2. Warning tone volume:

When selected, use the Up/Down keys to adjust volume of key-press and warning tones

**CAUTION:** It is not recommended that the volume of the warning tones is turned "OFF" for safety reasons.

#### 3. Compressor Chiller On/Off switch:

In any situation where the unit has been laid on its side or back (e.g. during shipping) the oil in the compressor will need at least an hour to drain back into the bottom of the compressor pump. If the system needs to be turned "ON" before sufficient drainage time has occurred, it is recommended that the Compressor Chiller is turned off. Highlight the "Compressor Chiller" then use Up/Down keys to toggle between ON and OFF.

#### 4. Trigger Selection

Displays and allows for selection of either Hand switch or Foot switch triggering of the unit. Use Up/Down arrows to select.

#### 5. Handpiece Chill Tip

Displays and allows for selection of intensity of the Handpiece Chill Tip. Use Up/Down arrows to select.

#### 6. Up/Down setting level when selected:

When a parameter is selected and highlighted, the Up/Down selectors are able to adjust the selected parameter as required.

#### 7. Back

Returns you to the previous screen.

#### 8. More

Moves you to Settings Screen 2.

### 9. Service Screen Access

Allows access to the system “Service Screen”. For authorized service personnel only, password required

## 5.2 Changing Operation Parameters during Operation

- Any of the operating parameters may be changed during operation as follows: Release the trigger switch.
- Change from “Ready” to “Standby” state by pressing the Standby/Ready button on the control panel.
- Change the setup parameters as desired.
- Change from “Standby” to “Ready” mode by pressing the Standby/Ready button on the control panel.

## 5.3 Pause in Operation

As a standard safety measure, whenever pulse light emission is not immediately required, the system should be set to Standby mode. If the operator needs to leave the room, the keyswitch should be turned to “Off” (one quarter turn counter clockwise).

## 5.4 System Shut Down

Shut the system down as follows:

1. Set the system to Standby mode.
2. Turn the keyswitch to “Off” (one quarter turn counter clockwise)
3. Turn off main switch
4. Disconnect the power cable from the mains power outlet.

**WARNING:** Do not leave the key in the keyswitch unattended. It may lead to unauthorized use of the system

## 6 Maintenance and Troubleshooting

This chapter contains maintenance instructions and a troubleshooting guide for the Intense Pulsed Light System (IPL).

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 P/L authorized technical personnel.

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

handpiece lightguides should be cleaned between sessions to minimize any risk of cross contamination.

**WARNING:** Maintenance by the operator should be performed only when the system is shut down and disconnected from the mains power source. Performing maintenance procedures with the system turned on may be hazardous to the operator and/or destructive to the system.

## **6.1 Error Detection and Reporting**

This system is equipped with intelligent self-testing software that continuously monitors system operation by means of watchdog software & circuitry, and by interrupts. The software continuously checks the hardware for any error condition:

If an Error is detected, the LCD screen displays an error message and disables further system operation.

Details of the error are indicated in the Error Message, which also outlines first step rectification processes.

Follow the instructions provided and if Error remains then contact Technical Support.

### **6.1.1 “No Handpiece Connected” Error**

No handpiece has been detected in the Left or Right handpiece port. Switch the unit “OFF” and connect handpiece. If a handpiece is connected, then switch the unit “OFF” disconnect the handpiece and inspect the handpiece connectors for damage.

If no damage is evident then reconnect handpiece.

If problem persists, replace with another handpiece in the same port, then contact technical support.

Handpiece should not be connected or disconnected when unit is turned on.

### **6.1.2 “Invalid Handpiece Connected” Error**

The handpiece detected in the port selected is Invalid and cannot be used on this system. Switch the unit “OFF” disconnect the handpiece and inspect the handpiece connectors for damage.

If no damage is evident then reconnect handpiece.

If problem persists, replace with another handpiece in the same port, then contact technical support.

Handpiece should not be connected or disconnected when unit is turned on.

### **6.1.3 “Low Coolant Level Detected” Error**

Low coolant level has been detected. Switch the unit “OFF” and fill the cooling system as per

section 6.7. If problem persists, please contact technical support.

#### **6.1.4 “No or Low Coolant Flow” Error**

No or low coolant flow has been detected. This can be due to incomplete connection of treatment head not fully opening the water connectors. Switch the unit “OFF”, disconnect and reconnect the handpiece and restart the system. If problem persists, please contact technical support.

#### **6.1.5 “Handpiece Overtemp” Error**

The temperature sensor in the treatment Handpiece has indicated an over temperature. While every effort has been taken in design to Maximize the system cooling, the heat generated by the flash lamp during treatments can cause a significant temperature to rise in the handpiece if the unit is used for long durations at high treatment levels without breaks. While this should be a very rare occurrence, in the event of this error, please ensure that the cooling system is full and there are no air flow blockages around the unit. While the error will disappear when the handpiece temperature drops below the error trigger level, we recommend that you allow the unit to run in standby for 10 minutes to allow the chiller to cool the handpiece. Additionally, please verify that the Chiller is turned “ON” in the system settings screen. To assist with handpiece and client cooling we also recommend the use of chilled gel. If problem persists, please contact technical support.

#### **6.1.6 “System Overtemp” Error**

The temperature sensor in the internal cooling system has indicated an over temperature. While every effort has been taken in design to Maximize the system cooling, the heat generated during treatments can cause a significant temperature rise in the cooling system if the unit is used for long durations at high treatment levels without breaks. While this should be a very rare occurrence, in the event of this error, please ensure that the cooling system is full and there are no air flow blockages around the unit. While the error will disappear when the system coolant temperature drops below the error trigger level, we recommend that you allow the unit to run in standby for 10 minutes to allow the chiller to cool the handpiece. Additionally, please verify that the Chiller is turned “ON” in the system settings screen and that the treatment room is well ventilated and below 28oC. If problem persists, please contact technical support.

#### **6.1.7 “Pre-Ignition/Simmer” Error**

Pre-ignition/Simmer error indicates failure to energise the handpiece flash lamp, which may

indicate lamp failure. Replace handpiece and contact technical support.

### **6.1.8 “Charge Time” Error**

Charge Time error indicates that the system capacitor bank has failed to charge to the required level within an expected time frame. This error may indicate a High Voltage Power Supply failure. Replace handpiece and contact technical support.

### **6.1.9 “No Filter Detected” Error**

No insertion filter has been detected in the selected handpiece. Please insert or re-insert the handpiece filter. If problem persists, please contact technical support. For temporary use you can select “By-pass” to manually select handpiece tip.

### **6.1.10 “Manual Filter Selection”.**

Manual filter selection is available where “By-pass” Has been selected in the “No Filter Selection” ErrorScreen. Manual filter selection disables automatic filter detection and will not be able to alert the operator where a filter is not sitting correctly or has been removed. Manual filter selection will be indicated by the letter “M” appearing under the “Filter” title on the main treatment screen. When using manual filter selection, it is essential that you verify the filter inserted corresponds to the filter selected and that the filter is fully seated into the handpiece.

## **6.2 Caring for System Optics**

The treatment heads contain optical components that may suffer damage if the head is dropped. When not being used, the treatment head should be kept in its cradle/holster. To prevent any penetration of water into the head, never immerse the treatment head in water, hold it under running water or spray any type of fluid directly onto it. Dust and stains on an optic surface will get hot due to absorption of light and can cause epidermal injury and increase patient discomfort during treatment. It can also cause scattering of the light energy as well as damage the optical coatings. With proper handling and cleaning of your optics, you can minimise these risks. Preventive inspection of the handpieces should be performed before after each treatment. The inspection consists of the following:

- Check the output surface of the lightguide. If the handpiece tip is dirty, it should be cleaned in accordance with the cleaning procedures.
- Ensure the handpiece filter is correctly inserted.
- Inspect the handpiece and umbilical cable for damage

Handle handpiece insertion filters with care. A scratch, trace of dirt, or film will diminish the filters efficiency and shorten the life span of the filter coating.

### 6.3 Periodic Service

The system should be periodically inspected and maintained to keep it in peak operating condition.

The following routine service operations should be performed by operator annually:

- General system operation
  - Water replacement
- Replace water filters
- Cooling system check and clean
- Personal Protection Equipment (PPE) inspection

### 6.4 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.

Recommended Pre and Post treatment checks and procedures

- Clean and Disinfect system and Accessories.
- Check mains electrical lead and footswitch for damage.
- Check Personal Protection Equipment
- Check system, handpiece's and filters for damage

Refer Attachment 1 Pre and Post Treatment Operational Checks for sample user check list.

Recommended monthly checks and procedures

- Top up system coolant
- Verify correct operation of Emergency Shut Off switch.

### 6.5 Cleaning and Disinfecting the System

The outer surface of the system may be wiped clean with a soft cotton cloth swabbed in 70% alcohol and a nonabrasive medical grade anti-bacterial is recommended. Be careful not to spill any liquids on the unit.

### 6.6 Cleaning and Disinfecting the Handpieces and Filters

The window of the lightguide should be cleaned at the end of each session to remove gel and dirt to avoid interference in light distribution, which may reduce effectiveness of subsequent treatments.

Treatment Tip and handpiece cleaning Instructions

- Gently clean away any residual gel with a soft cloth or tissue.
- Gently clean the Handpiece treatment window with 70% alcohol wipe. Alcohol wipes can also be used to clean the outer surface of the system handpiece.
- Wipe over with a clean dry lint free cloth or tissue.

- Allow to dry before re-use.

Insertion Filters cleaning instructions:

**CAUTION: Never touch the insertion filter optical surfaces with bare skin.**

- Ensure you are wearing Latex Gloves.
- Gently wipe the surface of the filter (both sides) with a 70% alcohol wipe.

**CAUTION: Do not rub the filter surface or use an abrasive action. Use the Alcohol wipe once only and discard.**

- Allow to dry before use.

Insertion Filters should not be cleaned unless signs of contamination are visible on the filter surfaces. Unnecessary cleaning will only shorten the life span of the filter coating. Filters can be easily chipped or scratched, therefore, to prevent damage when removing or replacing filters, always grasp the filter by the outer holder. Only place filter in the handpiece as required or in the filter case provided to minimise the risk of picking up contaminants from other surfaces.

## 6.7 Filling/Draining the Cooling System's Water Reservoir

The Dual Light cooling system's water reservoir must be filled/refilled with coolant in the following instances:

- Upon installation of a new system.
- A "Low Water Level" error occurs.
- If the water level is found to be low during a periodic maintenance check.

Filling/refilling the water reservoir is done with the water filling kit that is supplied with the system, which includes:

- A water filling tube, with a funnel connected to one side and the vent cover removed from the vent port.
- A container of coolant.

**CAUTION: Never fill the water reservoir with regular tap water or Mineral water. Use only coolant supplied by Australian Aesthetic Devices P/L.**

### 6.7.1 Water Filling Procedure

1. Disconnect the mains power supply cable.
2. Remove the vent cover on the rear service panel.
3. Connect the tube with the funnel to the port labeled FILL.
4. Use the supplied container of coolant, and pour it slowly into the funnel. Stop filling as soon as the water starts to spill from the VENT port.
5. Refit the vent cover.
6. Remove the tube with the funnel.
7. Connect any handpiece to the system.
8. Reconnect the mains power supply cable.
9. Turn the system on; it is ready for normal operation

If a “Water Flow Error” occurs after a water filling procedure is carried out, it may be because an air pocket had formed causing a disruption to water flow. Where this occurs repeat the Water fill procedure.

## 6.7.2 Water Draining Procedure

1. Disconnect the mains power supply cable.
2. Remove the vent cover on the rear service panel.
3. Connect the tube with the funnel to the port labeled Drain.
4. Lower the funnel and tube into a container to collect coolant and drain until water flow stops.
5. Refit the vent cover.
6. Remove the tube with the funnel.

## 6.8 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	<ol style="list-style-type: none"> <li>1. Verify Main Power Switch is “ON” and illuminated.</li> <li>-If not illuminated: Verify power cable fully Connected and wall switch “ON”.</li> <li>-If “ON” then check building circuit breaker.</li> <li>2. Verify system circuit breaker is “ON”</li> <li>3. Verify Emergency Shut-off switch is “ON” by rotating clock wise 90° and allowing to spring out.</li> </ol>
No Display	No Power	Follow action for symptom- “System does not turn on”. If problem persists then contact AAD technical support.
System does not display “Standby Screen”.		Turn-key switch fully clockwise.
No response when Pressing a button on the screen.		Reset the unit by turning “OFF” then “ON”. If problem persists contact AAD Technical Support.
Does not fire a pulse when Trigger pressed.		<ol style="list-style-type: none"> <li>1. Ensure system in “Ready” mode.</li> <li>2. Verify Trigger “Hand” or “Foot” selected in Settings</li> <li>3. Verify remote interlock connected.</li> </ol>
Water Leak down front of Unit just under the handpiece	Water valve O-ring Damage or Handpiece Not fully connected	<ol style="list-style-type: none"> <li>1. Remove handpiece</li> <li>2. Refit Handpiece</li> <li>3. If continues replace O-Ring’s</li> </ol>

## 7 Appendix User Guides

### 7.1 Appendix A: General User Information

The product 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 rules & regulations of the safe use of Lasers in health care as specified in the local regulations "Guide to the Safe use of Lasers in Health Care" . This may include operators, technical staff or other professional staff members. The owner and operators are responsible for contacting the local licensing agencies to determine any credentials required by law for User use and operation of the device.

#### **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 them expectations are clarified.

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

##### **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 Dual Light.

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

- current medications
- allergies, e.g. lanolin.
- relevant medical conditions
- prior cosmetic procedures:
- skin care regime (AHA's, BHA's, retinols, glycolics etc. Treat conservatively)
- sun exposure, solarium / tanning lotion usage (exclude clients exposed to sun or artificial tanning approx 1 month prior to treatment. Tanning lotion allow at least 2 weeks and have client exfoliate area to be treated)
- sporting history and lifestyle to ascertain unspecified sun exposure
- ethnic background to better asses skin type. If not sure move up a level for treatment. Asian background typically skins type 4. Lebanese typically 4 to 5.
- likelihood to comply with treatments

##### **The questionnaire is used to:**

- Asses clients primary concerns
- Asses clients expectations
- Discuss treatment with client.
- Asses clients plans after treatment (for example: exclude from treatment if planning a

holiday to Bali to sunbake in the week following treatment) Avoid exposure to sun for 1 month and use Sunscreen for 6 weeks over area.

### **Client Examination**

The examination is used to determine suitability of the client for treatment and assess the parameters to be used for treatment. Factors considered are the skin type and where appropriate, the hair colour and density, the degree of erythema, depth and size of the targets etc, photoaging, pigmentation irregularities and any active lesions such as acne. These observations should be documented and photographs should be taken.

### **Photography**

It is recommended to take “before and after” photographs to document the treatment progress. These photographs provide objective evidence because many clients are not able to assess the progress of treatment through the gradual improvement. Standard conditions and similar camera speed, flash and focal distance should be used to photograph all clients. This consistency enables an objective comparison of photos taken at different times.

### **Fitzpatrick Skin Type**

As skin pigment (Melanin) is a protective substance used to block light penetration to the deeper layers of the skin, then where high levels of melanin are present, an unavoidable absorption of energy by the melanin can cause undesired reactions where high levels of light energy are used. With all Dual Light treatments, it is therefore critical to understand the clients Fitzpatrick skin type to determine a safe treatment setting to avoid adverse reactions. Determining the correct skin type will serve 2 main purposes:

#### **Epidermal Protection**

The most obvious issue is keeping epidermal pigmentation intact. Darker Fitzpatrick skin types usually have darker skin colours to match. Appropriate settings are then chosen to maintain epidermal integrity. These usually consist of longer pulse durations, longer wavelengths or greater number of pulses.

#### **Delayed Reactions**

The darker the Fitzpatrick skin type skin reactions may be delayed. If you were to push a Type 4 skin reaction as quickly as a Type 1, there is a high possibility the client may develop an adverse reaction within hours after leaving the clinic.

#### **General rule to allow for Delayed Reactions:**

- Skin types 1, 2 & 3 allow for possible delayed reaction, 30 minutes
- Skin type 4 allow 24 - 48 hr for delayed response
- Skin type 5 allow 48 hr for delayed response

While most skin types are visually obvious from the colour of their skin, this may not always be the case. It is important to ask the “Sun Exposure Question”.

Some client may have fair skin at that stage but not burn when exposed to the sun. While it is unlikely that the epidermis will burn, they may still have a delayed reaction.

Always treat Asian skin typically as a skin type 4 initially until proven otherwise, unless they are visually darker then treat accordingly. Asian skin can hyper-pigment easily if over treated.

Assign a “full body” Fitzpatrick setting but change settings accordingly for darker skin areas.

It is critical to understand the skin type of the client to provide the best results, however it is

important to look for the presence of a tan as tanned skin does not respond the same way as natural dark skin.

Fake tan or “bronzers” provide a barrier on the skin surface that the IPL energy will be absorbed into creating an adverse reaction. Product must be removed prior to treatment.

Some fake tans can take up to 3 – 4 weeks for total removal – BEWARE!!

To assist the user in assessing Fitzpatrick skin type please review the Fitzpatrick sample questionnaire at Attachment 2.

#### **Discuss Treatment**

Discuss treatment with client covering but not limited to the following items:

- The Dual Light therapy may consist of multiple treatments given over several months.
- There may be some discomfort or pain associated with treatment.
- Transient erythema/edema may appear immediately following treatment.
- Gradual recovery may take a few months.
- There is a small risk of adverse reactions, such as changes in the texture and pigmentation of the skin which are usually transient.

#### **Adverse Events of Treatment:**

The use of the Intense Pulsed Light System (IPL) is similar to the use of other light based technologies. Historically, traditional systems have demonstrated the ability to cause a certain degree of controlled and uncontrolled tissue damage. In addition, there are the following risks:

- Severe or prolonged erythema (redness) and edema (swelling) within 2-24 hours of treatment that could last for several weeks.
- Irritation, itching, a mild burning sensation or pain (similar to sunburn) may occur within 48 hours of treatment at the application site.
- Blisters, epidermal erosions, or peri-lesional hyperpigmentation may develop and remain evident for several days to several weeks following treatment.
- Eye damage from reflected or prolonged unprotected exposure to pulsed light Protective eyewear must be worn during all treatments to prevent eye injury.
- It is important to observe tissue reaction during treatment. Poor client screening and excessive optical energy may cause thermal damage and cause unwanted adverse effects.

#### **Potential Side Effects of Treatment:**

- Discomfort.
- Damage to Natural Skin Texture.
- Change of Pigmentation.
- Scarring.
- Excessive Swelling.
- Fragile Skin.
- Bruising.

In the event of an adverse reaction, it is important to record as much information about the treatment as possible in order to provide the best support for the client as well as gain a better understanding of the risks, processes and protocols needed in order to ensure ongoing treatment safety.

Please use the Adverse Event Report Attachment 3 as a guide to the reporting on adverse events

## 7.2 Appendix B: User Treatment Guide

The Dual Light IPL system is used for Hair Reduction (HR) and Skin Rejuvenation (SR).

### Preparation for Treatment

- Remove all make-up, deodorants, cosmetics and sunscreen products with a neutral cleanser prior to commencing the treatment.
- Remove any jewelry from treatment area.
- Ensure all people in the treatment room are wearing appropriate safety eyewear (this includes the client and operator).
- Ensure all entrances are closed and windows are covered.
- Ensure appropriate laser safety warning signs are placed.
- Mask eyebrows with strips of white adhesive tape or white zinc. Supply a disposable cap or hair band to keep hair out of the treatment area and prevent accidental damage to the client's hairline.
- If the client has "permanent" cosmetic colour implants, be aware that these may be affected. Avoid or mask these areas.
- Ensure area to be treated is properly marked and shaved or clipped before treatment.
- Apply cold pack (not recommended for treatment of redness as vaso-constrictive) or cold gel to the immediate area to be treated.
- Select parameters: wavelength filter for IPL, pulse duration, program and fluency.

Treatment parameters selection is always a tradeoff between efficacy and avoidance of cosmetic complications.

The following adjustments will increase skin tolerance:

- Longer wavelength
- Longer pulse duration
- More pulses
- Reduced Fluence

### Test Patches / Skin Test

Light fluence to a treatment site should be optimal and should enable effective treatment with minimal side effects. In order to select the appropriate fluence for a new treatment, the operator should perform a Skin Test before treatment as follows:

1. Select a representative area of healthy skin adjunctive to the treatment area.
2. Apply a coat of a pre-cooled ultrasonic gel on the intended (representative) area to be treated (usually 1-2mm thick and 3 mm for darker skin types).
3. Trigger the Dual Light to emit a pulse of light according to the parameters for each application as detailed in the Parameter Setting guide. Start conservatively.
4. For hair reduction stretch skin slightly whilst treating
5. Avoid overlapping

After the test patch look for immediate target response & wait the durations as specified for the Fitzpatrick skin types as listed in that section to assess response on surrounding good tissue. Then review treatment end points.

### Treatment

Treatment can begin after you have reviewed treatment end points, confirmed your settings or

made appropriate

adjustments based on Test Patches/Skin Test.

1. Set the treatment fluence parameter according to the Skin Patch Test results.
2. Trigger a light pulse by pressing the trigger switch.
3. Continually examine the treatment site for change of skin colour and morphological changes around the target (erythema/edema).
4. If adverse reactions are observed from the prior light pulse, the next pulse may be skipped or the dose reduced until the symptoms resolve.
5. After treatment it is recommended to cool the area immediately.
6. Always have the Dual Light in Standby when not in use.
7. Avoid overlapping.
8. Where possible for hair reduction stretch skin slightly whilst treating
9. You may need to clean the handpiece from time to time during treatment using a white cloth or Fibrella.

After treatment the majority of clients will experience a mild, sunburn-like sensation that typically disappears without treatment in 2 to 3 hours.

**General Points on Pulsed Light Treatments:**

- Ensure test patches are carried out
- Do not treat in the Infrabrow area
- Occasional "touch-ups" are recommended
- When treating large areas, grid out treatment areas using a white marker or eyeliner as an aid to determine what areas have been treated.

**Points on Pulsed Light Hair Reduction:**

- A general course includes 6 treatments, with a treatment interval of 30 days. For darker skin types, 6-10 treatments sometimes required, since lower fluences are used.
- Do not wax or pluck 1 month prior to treatment as a hair must be present to absorb the treatment light.
- Vellus hair will remain
- Treatment is hair colour and body location dependent.
- Hormonal effects - males / females / age may affect outcomes.
- Do not use Dual Light to shape or sculpt an eyebrow as precise hair follicle positions in eyebrows are difficult to determine and unwanted hair destruction may occur.

**Points on Pulsed Light Skin Rejuvenation:**

- A general course includes 6 treatments, with a treatment interval of 21 days. For darker skin types, 6-10 treatments sometimes required, since lower fluences are used

## 7.3 Appendix C Hair Reduction User Guide

### 7.3.1 HR Treatment Guide

The Intense Pulsed Light System (IPL) with the HR 640 and 690 nm Near Infrared (NIR) handpiece filters is indicated for hair reduction.

#### Operation:

The HR handpiece uses a high fluence low pulse rate delivery technique to provide effective hair reduction. The Intense Pulsed Light System (IPL) has been designed with up to 5 sub pulses within each triggered pulse. The number of pulses, pulse durations and delays of each are indicated in the Pulse Duration screen accessible by pressing on the Duration value on the HR Standby screen. The energy delivered in each triggered pulse can be adjusted by selecting the Fluence value on the Standby screen and adjusting up or down as required.

#### Skin Test

The treatment parameters for hair reduction depend on the skin type, hair colour, hair type, and the density and depth of the hair. Initially, shave the treatment site to eliminate any surface hair that could interfere with the treatment. Mark a grid (using a white marker) to assist with monitoring treated areas for test patching and ongoing treatment. Always perform a skin test on the intended treatment area during the first treatment session according to the following parameters (start at minimum recommended level) and wait for appropriate time as set out in Appendix A for “Delayed Reactions”:

#### *HR Treatment Guide*

		Skin Type I-II	Skin Type III	Skin Type IV
Face	Fine Hair	Pre-set I 640nm 12-23j/cm <sup>2</sup> 25ms	Pre-set III 640nm/690nm 12-23j/cm <sup>2</sup> 50ms	Pre-set IV 690nm <sup>Note 1</sup> 10-22j/cm <sup>2</sup> 90ms
	Course Hair	Pre-set II 640nm 12-23j/cm <sup>2</sup> 40ms	Pre-set III 640nm/690nm 12-23j/cm <sup>2</sup> 60ms	Pre-set IV 690nm <sup>Note 1</sup> 10-22j/cm <sup>2</sup> 100ms
Body	Fine Hair	Pre-set II 640nm 12-23j/cm <sup>2</sup> 30ms	Pre-set III 690nm 14-24j/cm <sup>2</sup> 60ms	Pre-set IV 690nm <sup>Note 1</sup> 10-22j/cm <sup>2</sup> 90ms
	Course Hair	Pre-set I- II 690nm 15-25j/cm <sup>2</sup> 40ms	Pre-set III 690nm 14-24j/cm <sup>2</sup> 70ms	Pre-set IV 690nm <sup>Note 1</sup> 10-22j/cm <sup>2</sup> 100ms

Important: a coat of clear ultrasonic gel must be applied on the skin for ALL skin types.

#### Treatment

Treatment can begin after the handpiece and appropriate HR filter has been connected to the system and the treatment parameters selected (fluence) according to skin test patch.

1. Ensure pre-treatment safety checks and applicable treatment preparations are carried out

prior to the skin patch test and treatment as per Appendix B.

2. Apply a thin layer (usually 1-2mm thick for all skin types) of refrigerated clear cooling gel (6-10° C) to the treatment site.
3. Place the handpiece perpendicular to the skin and touch the skin; and ensure a good seal. Do not apply excessive pressure on the skin.
4. Trigger a light pulse by pressing the trigger switch.
5. Examine the treatment site for change of skin colour and morphological changes around the follicles, erythema or perifollicular erythema/edema (i.e., end points). The smell of burnt hair may sometimes be detected, although its absence does not necessarily indicate that the present parameters are ineffective.
6. If adverse reactions are observed from the prior light pulse, the next pulse may be skipped or the dose reduced until the symptoms resolve.
7. It is recommended to cool the area immediately after the treatment (see section titled Post-Treatment Care).

### **7.3.2 Swift Hair Reduction (SHR) Treatment Guide**

The Intense Pulsed Light System (IPL) with the SHR 640 and 690 nm Near Infrared (NIR) filters is indicated for hair reduction.

#### **Operation:**

The SHR filter uses a low fluence high pulse rate delivery technique to provide relatively pain free Hair Reduction on various skin types. The energy delivered in each triggered pulse can be adjusted by selecting the Fluence value on the Standby screen and adjusting up or down as required and the pulse rate can be adjusted by selecting the Pulse Rate value on the Standby Screen and adjusting up and down as required. For small areas the handpiece can be used in short bursts of less than 1 second intervals using a Stationary technique. For larger areas the handpiece is used in an In-Motion Sweeping technique. Clear Ultrasonic gel must be used in both Stationary and In-Motion Sweeping techniques.

#### **Skin Test**

The treatment parameters for hair reduction depend on the skin type, hair colour, hair type, and the density and

depth of the hair. Initially, shave the treatment site to eliminate any surface hair that could interfere with the treatment.

Mark a grid (using a white marker) on an area of 15x15cm for the Large SHR handpiece and 10 x 10 for the small

SHR handpiece. Treat with the Sweeping technique within each treatment grid.

Always perform a skin test on the intended treatment area during the first treatment session according to the

following parameters and wait for appropriate time as set out in Appendix A for “Delayed Reactions”:

**Swift HR 7.36cm<sup>2</sup> 640nm Treatment Guide for large areas**

Skin Type	Pre-set	J/cm <sup>2</sup>	Pulse Rate (Hz)
I-II	I-III	5	4
III	IV	5	4
IV	V	4	4
V & VI	Not Recommended		

- Cover areas up to 10 x 15 cm for large area treatments.
- When treating areas smaller than 10 x 15 cm with the large Swift HR handpiece you may need to reduce J/cm<sup>2</sup> &/or pulse rate so not to heat the area too quickly.
- Important: a coat of clear ultrasonic gel must be applied on the skin for ALL skin types.

**Swift HR 7.36cm<sup>2</sup> 690nm Treatment Guide for large areas**

Skin Type	Pre-set	J/cm <sup>2</sup>	Pulse Rate (Hz)
I-III	I-III	5	4
IV	IV	5	4
V	V	4	4
VI	Not Recommended		

- Cover areas up to 10 x 15 cm for large area treatments.
- When treating areas smaller than 10 x 15 cm with the large Swift HR handpiece you may need to reduce J/cm<sup>2</sup> &/or pulse rate so not to heat the area too quickly.
- Important: a coat of clear ultrasonic gel must be applied on the skin for ALL skin types.

**Swift HR 4.8cm<sup>2</sup> 690nm Treatment Guide for Small Areas**

Skin Type	Pre-set	J/cm <sup>2</sup>	Pulse Rate (Hz)
I-III	I-III	5	2
IV	IV	5	2
V	V	3	2
VI	Not Recommended		

- Short bursts of less than 2-seconds are indicated for the Stationary technique on small areas.
- Cover areas up to 5 x 5 cm.
- When treating areas smaller than 5 x 5 cm with 4.8cm<sup>2</sup> Swift HR 690nm you may need to reduce J/cm<sup>2</sup> &/or pulse rate so not to heat the area too quickly.
- When treating areas larger than 5 x 5 cm with 4.8cm<sup>2</sup> Swift HR 690nm you may need to increase J/cm<sup>2</sup> &/or pulse rate so to effectively heat the area.
- Important: a coat of clear ultrasonic gel must be applied on the skin for ALL skin types.

### **Swift HR 4.8cm<sup>2</sup> 640nm Treatment Guide for Small Areas & Lighter Hair**

Skin Type	Pre-set	J/cm <sup>2</sup>	Pulse Rate (Hz)
I-II	I-II	5	2
III	III	5	2
IV	IV	3	2
V-VI	Not Recommended		

- Short bursts of less than 2-seconds are indicated for the Stationary technique on small areas.
- Cover areas up to 5 x 5 cm.
- When treating areas smaller than 5 x 5 cm with 4.8cm<sup>2</sup> Swift HR 690nm you may need to reduce J/cm<sup>2</sup> &/or pulse rate so not to heat the area too quickly.
- When treating areas larger than 5 x 5 cm with 4.8cm<sup>2</sup> Swift HR 690nm you may need to increase J/cm<sup>2</sup> &/or pulse rate so to effectively heat the area.
- Important: a coat of clear ultrasonic gel must be applied on the skin for ALL skin types.

#### **Treatment (Sweeping Technique)**

Treatment can begin after the handpiece and SHR filter have been connected to the system and the treatment parameters selected (fluence) according to skin test patch.

1. Ensure pre-treatment safety checks and applicable treatment preparations are carried out prior to the skin patch test and treatment as per Appendix B.
2. Apply a thin layer (usually 1-2mm thick for all skin types) of refrigerated cooling gel (6-10° C) to the treatment site.
3. Apply the In-Motion Sweeping technique:
  - Place the handpiece perpendicular to the skin and move the handpiece over the surface, only when the handpiece is in full contact and "sweeping", then trigger the handpiece.
  - Move the handpiece in continuous linear or circular motions, to cover the entire grid area.
  - After completing a single interval, re-position the handpiece at the point where you began treatment in this grid and repeat another interval on the entire area.
  - After completing a number of intervals, move to the contra-lateral side and repeat as above.
4. Examine the treatment site for change of skin colour and changes around the follicles, erythema or perifollicular erythema/edema (i.e., end points). The smell of burnt hair may sometimes be detected, although its absence does not necessarily indicate that the present parameters are ineffective.
5. If adverse reactions are observed from the prior treatment, the next treatment may be skipped or the dose reduced until the symptoms resolve.
6. It is recommended to cool the area immediately after the treatment (see section titled Post-Treatment Care).

#### **Treatment (Small Area)**

1. In the stationary technique, use a short burst of less than 1 second; with up to 10% overlap.
2. Set the initial Pulse Rate and fluence parameters according to Skin Test Table.
3. Trigger the handpiece for a short burst. After a short delay repeat for a number of intervals.
4. Examine the treatment site for change of skin colour and changes around the follicles, erythema or perifollicular erythema/edema (i.e., end points). The smell of burnt hair may sometimes be detected, although its absence does not necessarily indicate that the present parameters are ineffective. If there are no noticeable changes on the skin (Skin Types III-IV) or near the hair follicles, do not repeat.
5. Treatment parameters may be increased by 10% every other treatment and subjected to the conditions in the area treated and client's tolerance.
6. Following treatment, gently cleanse the ultrasonic gel from the treated area.
7. If adverse skin effects occur (such as excessive reddening or swelling), you may either reduce the exposure time number of intervals or reduce the fluence.
8. It is recommended to cool the area immediately after the treatment (see section titled Post-Treatment Care).

## **7.4 Appendix D Skin Rejuvenation User Guide**

### **7.4.1 SR Treatment Guide**

The Skin Rejuvenation application of the system is performed using the SR 520nm (tourquoise), 540nm (green) or 580nm (yellow) filters on the small handpiece only. The SR filters are indicated for the reduction in appearance of fine lines and redness, as well as improvement of skin tone and texture (skin rejuvenation).

#### **Operation:**

The SR treatments use a high fluency low pulse rate delivery technique to provide improvements. The system has been designed with up to 5 sub pulses within each triggered pulse. The number of pulses, pulse durations and delays of each are indicated in the Pulse Duration screen accessible by pressing on the Duration value on the HR Standby screen. The energy delivered in each triggered pulse can be adjusted by selecting the Fluency value on the Standby screen and adjusting up or down as required.

#### **Skin Test**

The treatment parameters for skin rejuvenation depend on the skin type and the density and depth of the target. Initially, cleanse treatment site to eliminate any product or SPF blocker that could interfere with the treatment. Mark a grid (using a white marker) to assist with monitoring treated areas for test patching and ongoing treatment. Always perform a skin test on the intended treatment area during the first treatment session according to the following parameters (start at minimum recommended level) and wait for appropriate time as set out in Appendix A for "Delayed Reactions":

### SR Treatment Guide

	Skin Rejuvenation			
	Skin Type I	Skin Type II	Skin Type III	Skin Type IV
Superficial Redness & Light Pigment	Pre-set I 520nm 12-20j/cm <sup>2</sup> 15ms	Pre-set II 520nm 12-18j/cm <sup>2</sup> 25ms	Pre-set III 520nm <sup>Note 1</sup> /540nm 10-18j/cm <sup>2</sup> 40ms	Pre-set IV 580nm 8-14j/cm <sup>2</sup> 60ms
Redness	Pre-set I 540nm 12-20j/cm <sup>2</sup> 15ms	Pre-set II 540nm 12-18j/cm <sup>2</sup> 25ms	Pre-set III 540nm 10-18j/cm <sup>2</sup> 40ms	Pre-set IV 580nm 8-14j/cm <sup>2</sup> 60ms
Pigment	Pre-set I 540nm 10-18j/cm <sup>2</sup> 15ms	Pre-set II 540nm 10-18j/cm <sup>2</sup> 25ms	Pre-set III 540nm/580nm 8-16j/cm <sup>2</sup> 40ms	Pre-set IV 580nm <sup>Note 2</sup> 8-14j/cm <sup>2</sup> 90ms

Always perform a skin test on the intended treatment area during the first treatment session according to the indicated parameters (start at minimum recommended level) and wait for appropriate time as set out in the operator’s manual.

Important: a coat of clear ultrasonic gel must be applied on the skin for ALL skin types.

**Note 1:** Caution: Ensure conservative treatments when using 520nm on Skin Type III.

**Note 2:** Warning: Selections “I – IV” are program options loosely based on treatment skin type. We recommend the 580nm or SSR Filters for skin type IV, and do not recommend treatments on skin types V & VI be carried out. For treatment of skin type IV, ensure extra time is given between pulse for the handpiece chiller to effectively chill client skin.

#### Treatment

Treatment can begin after the handpiece and SR filter has been connected to the system and the treatment parameters selected (fluence) according to skin test patch.

1. Ensure pre-treatment safety checks and applicable treatment preparations are carried out prior to the skin patch test and treatment as per Appendix B.
2. Apply a thin layer (usually 1-2mm thick for all skin types) of clear cooling gel to the treatment site. Refrigerated (6-10° C) for skin tone & texture treatments only.
3. Place the handpiece perpendicular to the skin and touch the skin; and ensure a good seal. Do not apply excessive pressure on the skin.
4. Trigger a light pulse by pressing the trigger switch.
5. Examine the treatment site for change of skin colour and morphological changes around the target.
6. If adverse reactions are observed from the prior light pulse, the next pulse may be skipped or the dose reduced until the symptoms resolve.
7. It is recommended to cool the area immediately after the treatment (see section titled Post-Treatment Care).

## 7.4.2 SSR Treatment Guide

The Intense Pulsed Light System (IPL) with the SSR 540 – 800nm (Green) filter is indicated for the improvement of skin tone and texture.

### Operation:

The SSR filter uses a low fluence high pulse rate delivery technique to provide relatively pain free Skin Rejuvenation on various skin types. The energy delivered in each triggered pulse can be adjusted by selecting the Fluence value on the Standby screen and adjusting up or down as required and the pulse rate can be adjusted by selecting the Pulse Rate value on the Standby Screen and adjusting up and down as required. For small areas the handpiece can be used in short bursts of less than 1 second intervals using a Stationary technique. For larger areas the handpiece is used in an In-Motion Sweeping technique. Clear Ultrasonic gel must be used in both Stationary and In-Motion Sweeping techniques.

### Skin Test

Always perform a skin test on the intended treatment area during the first treatment session according to the following parameters and wait for appropriate time as set out in Appendix A for “Delayed Reactions”:

**SSR 540nm Treatment Guide**

Skin Type	Pre-set	J/cm2	Pulse Rate (Hz)
I-II	I-II	5	2
III	III	5	2
IV	IV	3	2
V - VI	Not Recommended		

- Short bursts of less than 2-seconds are indicated for the Stationary technique on small areas.
- Cover areas up to 5 x 5 cm.
- When treating areas smaller than 5 x 5 cm you may need to reduce J/cm2 &/or pulse rate so not to heat the area too quickly.
- When treating areas larger than 5 x 5 cm you may need to increase J/cm2 &/or pulse rate so to effectively heat the area.
- Important: a coat of clear ultrasonic gel must be applied on the skin for ALL skin types.

### Treatment (Sweeping Technique)

Treatment can begin after the handpiece with SSR filter has been connected to the system and the treatment parameters selected (fluence) according to skin test patch.

1. Ensure pre-treatment safety checks and applicable treatment preparations are carried out prior to the skin patch test and treatment as per Appendix B.
2. Apply a thin layer (usually 1-2mm thick for all skin types) of refrigerated cooling gel (6-10° C) to the treatment site.
3. Set the initial fluence parameter according to the skin test results.
4. Apply the In-Motion technique:
  - Place the handpiece perpendicular to the skin and move the handpiece over the surface, only when the handpiece is in full contact and "sweeping", then trigger the

handpiece.

- Move the handpiece in continuous linear or circular motions, to cover the entire grid area.
- After completing a single interval, re-position the handpiece at the point where you began treatment in this grid and repeat another interval on the entire area.
- After completing a number of intervals, move to the contra-lateral side and repeat as above.

5. Treatment end points: mild-to-moderate erythema for skin types I-III; mild erythema for skin types IV.

6. If adverse reactions are observed from the prior treatment, the next treatment may be skipped or the dose reduced until the symptoms resolve.

7. It is recommended to cool the area immediately after the treatment (see section titled Post-Treatment Care).

#### **Treatment (Stationary Technique)**

1. In the stationary technique, use a short burst of less than 1 second; with up to 10% overlap.

2. Set the initial Pulse Rate and fluence parameters according to Skin Test Table.

3. Trigger the handpiece for a short burst. After a short delay repeat for a number of intervals.

4. Check skin reaction; if there is no apparent skin reaction – repeat until User end points are visible.

5. Treatment parameters may be increased by 10% every other treatment and subjected to the conditions in the area treated and client's tolerance.

6. Following treatment, gently cleanse the ultrasonic gel from the treated area.

7. If adverse skin effects occur (such as excessive reddening or swelling), you may either reduce the exposure time number of intervals or reduce the fluence.

8. It is recommended to cool the area immediately after the treatment (see section titled Post-Treatment Care).

## **7.5 Appendix D: Post-Treatment Care**

#### **Immediate Post-Treatment Care:**

Cold (not frozen) packs should be applied immediately after treatment to cool the treatment site, reduce swelling and ease discomfort. Chemical cold packs are not recommended if their temperature is below 39° F/4° C.

#### **Exposure to Sunlight:**

Clients should use a high sun-block (above 30 SPF) and protect the treated area from exposure to sunlight for at least one month following treatment. Tanning after treatment sessions may enhance melanin regeneration, which may result in hyper-pigmentation

#### **Cosmetics:**

In most treatment regimens makeup can be applied immediately after treatment. However, it is advised that clients notify their physician and stop wearing makeup if the treatment site scales or crusts.

**Other Post-Treatment Recommendations:**

- Avoid exposing the treatment site to unsanitary conditions.
- Clients should be advised not to participate in rough sports or similar activities for several days following treatment (until the skin returns to its normal condition).
- Treatment areas should be kept clean and moist between treatments. A mild soap or non-irritating cleanser may be recommended.
- Care should be taken to prevent trauma to the treated area for the first four or five days following treatment: no hot baths, no aerobic exercise, massage, etc.

**Treatment of Adverse Effects**

If there are any adverse effects, treatment should be discontinued until the treatment site has healed.

**Concluding Treatment**

Determining when treatment should be concluded is left to the operators's discretion, or to the client's satisfaction with the results of treatment.

**Follow Up**

Below are recommendations for follow-up:

Clients should return four weeks after treatment for examination of the treatment site and for additional treatment, if necessary.

If no additional treatment is necessary, the client should return for an additional re-examination three to four weeks later, preferably when new hair has grown in the treatment area. If there has been partial hair clearance, treatment should be continued using the same parameters, and the client should return after three weeks for examination and for additional treatment, if necessary. If no change is noted, treatment parameters should be changed. With multiple treatments, increase the time intervals between treatment sessions (after the second one), to allow new hair to grow in the treatment area.

**Manufacturer:**

Australian Aesthetic Devices P/L  
2/21-35 Ricketts Road, Mount Waverley VIC 3149  
Tel: 1300 858 711  
Email: info@aestheticbureau.com.au

**Authorised representative in EEC:**

Kingsmead Service B.V.  
Zonnehof 36,2632 BE,Nootdorp,Netherland  
Tel:+31(0)646571005

## Attachment 1: SAFETY CHECK LIST

### Pre-Treatment Operational Checks

The following checks should be carried out prior to system use:

Venue:.....System:.....

Please tick boxes as completed.

- Check warning sign is in place and warning light is switched on.
- Get key from lockable storage.
- Verify fire extinguisher present.
- Move system into position.
- Check mains electrical lead for damage.
- Check system and handpiece for any damage.
- Close doors and window blinds.
- Attach handpiece.
- Ensure all present have are wearing appropriate safety eyewear before powering "On"
- Check self-test routine completes correctly. (Record error message if failure occurs)
- Verify correct operation (Test output as well as verify visual & audible indicators are working).
- Check Tip Cooling.
- Turn system off until required.

### Post-Treatment Operational Checks

- Remove warning sign and turn off warning light.
- Return key to lockable storage.
- Wipe clean system and attachments and return to storage.
- Check mains electrical lead and footswitch lead for damage.
- Check and store protective glasses.
- Maintain records of system use.

## Attachment 2: FITZPATRICK QUESTIONNAIRE

### Questionnaire to Asses Fitzpatrick Classification for Skin Type

Name: \_\_\_\_\_ Date: \_\_\_\_\_

Please answer by circling the answer to each question to determine your skin type:

Score	0	1	2	3	4
Genetic Disposition					

What is the colour of your eyes?	Light Blue, gray, green	Blue, gray or green	Blue	Dark Brown	Brown Black
What is the natural colour of your hair?	Sandy red	Blond	Chestnut brown, dark blond	Dark brown	Black
What is the colour of your skin in non-exposed areas?	Reddish	Very pale	Pale with beige tint	Light brown	Dark Brown
Do you have freckles in the non-exposed areas?	Many	Several	Few	Incidental	None
<b>Reaction to Sun exposure</b>					
What happens when You stay in the sun too long?	Painful, blistering, redness, peel	Burns followed by peeling	Burns sometimes followed by peeling	Rare burns	Never had a burn
To what degree do you turn brown?	Hardly at all	Light colour tan	Reasonable tan	Tan very easy	Turn dark brown
Do you turn brown within several hours after sun exposure?	Hardly or not at all.	Seldom	Sometimes	Often	Always
How does your face react to the sun?	Very sensitive	Sensitive	Normal	Very resistant	Never had a problem
<b>Tanning habits</b>					
When did you last expose your body to the sun or sun bed?	More than 3 months ago	2-3 months ago	1-2 months ago	Less than one month	Less than 2 weeks ago
Did you expose the area you want treated to the sun?	Never	Hardly ever	Sometimes	Often	Always

**Add individual scores together for all columns to determine their Fitzpatrick Skin Type and select their Fitzpatrick Skin type according to the score.**

**Total score of all questions \_\_\_\_\_**

<b>Total Score</b>	<b>Fitzpatrick Skin type</b>	<b>Description</b>
0-7	I	Extremely Fair Skin, always burns, never tans

8- 16	II	Fair Skin, always burns, never tans
17- 25	III	Medium Skin, sometimes burns, always tans
26- 30	IV	Olive skin, rarely burns, always tans
Over 30	V- VI	Moderate to heavily pigmented brown to black skin never burns always tans

**Ethnic background is of importance when considering skin colour and laser or pulsed light treatments. If known what is your ethnic background**

### **Attachment 3: ADVERSE EVENT REPORT**

**Clinic Particulars:**

Clinic Name:.....Date Document Completed:.....

Address:.....

(where event occurred)

Suburb:.....State:.....Postcode:.....

Telephone:.....Fax:.....E-Mail:.....

Form completed by:.....

Other persons present:.....

**Product & Settings:**

System description:..... System serial number:.....

Accessory descriptions:.....Accessory serial/lot numbers:.....

**For Laser Incidents that occur in Queensland immediately notify:  
Chief Executive Queensland Government Radiation Health on (07) 3406 8000  
Refer to AS/NZS 4173:2004 "Guide to the safe use of lasers in health care" section 7.10 for full reporting process.**

Condition of equipment:.....

.....  
.....

Settings used:.....

.....  
.....

**Description of Event:**

Description of adverse event (specify date & time of event as well as indicate contributing factors):

.....  
.....  
.....  
.....

Office use only:

**Report taken by:**      **Name:**.....**Date:**.....

Reviewed by:      Name:.....Date:.....

## Attachment 4: PRE AND POST CARE ADVICE

### Pre-treatment care for IPL treatments:

- Avoid sun exposure, tanning beds, spray tan and self-tanning lotions for 1 month prior to treatment.
- Use a sunscreen (SPF 30+) daily on the area to be treated one month prior to treatment.
- Commence recommended skin care program at least two weeks prior to treatment.
- Do not wax or pluck 1 month prior to treatment. You may shave or use depilatory creams as needed.

### Post-treatment care for IPL treatments:

- Apply Medi-soothe, cool compresses or ice packs for comfort.
- Wash face with a gentle cleanser (no soap, perfume, alcohol etc) and cool water. Do not use any products with active ingredients such as AHA's while the skin is irritated.
- Do not use a scrub for five days after treatment.
- Apply moisturiser after washing the area.
- Apply sunscreen (SPF 30+) every day to the area treated.
- Avoid sun exposure as much as you can, this includes solariums.
- If planning to be in the sun, wear a large brimmed hat and extra SPF 30+.
- Avoid activities where you are likely to perspire heavily for 24 hours. Raising your body temperature can effect skin reactions.

**General Rule:** Treat the affected area like sunburn, what you wouldn't do to sunburn you won't do to the treated area!

**Please Note:** Extended sun exposure in any one sitting, even with re-application of SPF 30+ can re-trigger pigmentation.

**Should you be concerned regarding your treatment please contact us on: .....**

## Attachment 5: TREATMENT RECORD FORM

Client Name:

### IPL Test Patch Record

Test Patch Date: .....IPL User Name:.....

I agree that I have reviewed my "Client Questionnaire" and "Consent Form" and that all information supplied is correct and has not changed since my last treatment. I agree that it is my responsibility to inform my therapist of any changes that may affect the outcome of my treatments or effect my skin reaction.

Client Signature.....Witness Signature.....

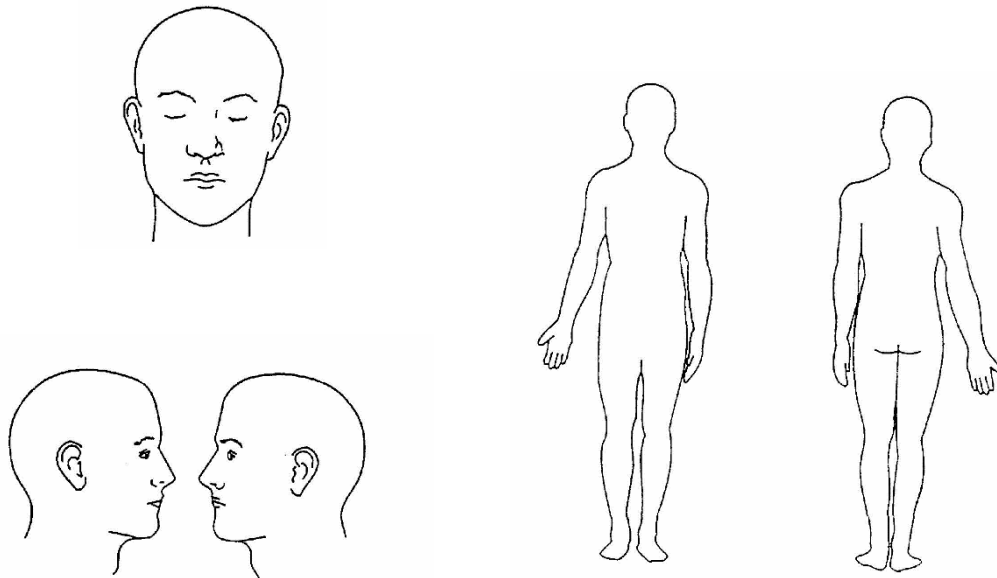
Ensure client questionnaire and consent forms are completed fully and signed by the client prior to the commencement of each treatment session

Treatment.....Treatment Duration:.....

Settings and Accessories used:.....

Test Patch Notes.....

Users Signature:.....Supervisors Signature:.....



## IPL Treatment Record

Treatment Date: ..... IPL User Name:.....

I agree that I have reviewed my "Client Questionnaire" and "Consent Form" and that all information supplied is correct and has not changed since my last treatment. I agree that it is my responsibility to inform my therapist of any changes that may affect the outcome of my treatments or effect my skin reaction.

Client Signature:.....Witness Signature:.....

Ensure client questionnaire and consent forms are completed fully and signed by the client prior to the commencement of each treatment session

Treatment:.....Treatment Duration:.....

Settings and Accessories used:.....

Treatment Notes:.....

.....

Users Signature:.....Supervisors Signature:.....



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