GSD-801E

IPL Photorejuvenation
Treatment Systems

User’s Manual
Using this User’s Manual

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Pay Attention to Warnings, Cautions and Notes

**WARNING**  Warning means that not following instructions properly or ignoring them completely can endanger patients and/or operators.

**CAUTION**  Attention means that not following instructions properly or ignoring them completely can damage the unit.

**NOTE**  Notes provide additional information.

⚠️ **NOTE**  Read the user’s manual prior to operation!
Chapter 1 Preface

1.1 Overview

Intense pulsed light (IPL) is a type of intensive, broadband, coherent light source which has a wavelength spectrum of 420 nm -1200 nm. With these special properties, the IPL has a wide application in non-ablative therapies based on theory of human skin tissue's selective absorption and photothermolysis of light sources. Meanwhile, IPL treatment is more effective, with no downtime and can make the patients get recovered more quickly than conventional therapies.

1.2 Device brief introduction

Model name: GSD-801E
Product name: IPL Photorejuvenation treatment systems
Figure 1.1 shows the device.

![Image](image_url)

Figure 1.1 GSD-801E IPL Photorejuvenation treatment systems

1.3 Device structure

This device is composed of three parts: (1) main unit, (2) control panel, (3) the IPL treatment handpiece.

The control panel includes the color 8.4” TFT LCD touch screen, the power switch and emergency shut off switch. The LCD screen shows the work mode and the parameters of the system.
1.4 Medical Use-Application Areas

1. Therapy acne
2. Reduction of vascular lesions
3. Reduction of pigmented lesions
4. Skin rejuvenation
5. Permanent hair removal
Chapter 2 Safety

2.1 Introduction

This chapter describes the proper use of the IPL Photorejuvenation treatment systems. Each operator must have read and understood the User’s Manual completely prior to starting the Device.

2.2 Responsibilities of the User

WARNING

This device may cause thermal injury if used improperly. Medical personnel must familiarize themselves with the devices safety instructions and operational procedures prior to use.

Before each treatment, the user must check the functional performance of the device in order to rule out any risk to patients or third parties. If the device is used in conjunction with peripheral units, the User’s Manuals for the peripheral units must also have been thoroughly read and understood.

2.2.1 Safety Measure

The IPL is designed to prioritize the safety of the patient and medical personnel. The following are its parts of safety measures:

A. Upon switching on the system, the processor first undergoes a self-diagnostic program. The processor will then examine the system automatically and continuously during the entire treatment procedure.

B. Use the Emergency Cut off Switch (red button) to turn the power off in case of an emergency.

C. Remove the Key when not in use to prevent unauthorized access to the device.

2.2.2 Safety warning

Only personnel trained by the distributor are authorized to maintain the inner workings of this device. Any manipulation to the system may cause damage to the device and will void its warranty.
2.3 User Training

**WARNING**

*The intense light delivered by this device may cause serious injury if handled improperly. All personnel using this device must remain vigilant and utilize safety protocols.*

The IPL Photorejuvenation treatment systems require special expertise and care in its handling and use. Only persons who have received appropriate handling training on the device, taking into consideration operating instructions, and who are familiar with its therapeutic effect and possible risks are permitted to use the laser unit.

Untrained or unqualified operating personnel are not permitted to operate the IPL Photorejuvenation treatment systems under any circumstances whatsoever. FP Medical Technology Co., Ltd offers comprehensive training courses for the IPL Photorejuvenation treatment systems to authorize territory distributors.

Each user must have read and understood the User’s Manual completely prior to starting the IPL Photorejuvenation treatment systems.

Patient’s safety mainly depends upon a well-trained operators and a suitable treatment room. The attending operators must inform the patient all inherent risks with the use of this device. The success of the treatment depends largely on the user’s experience and knowledge of the biophysical connections.

2.4 Explanation to Patients

The treatment process must be explained to the patient. The patient must give written-consent to the treatment.

2.5 Optical safety

All personnel (including the patient) should wear the protective glasses; opaque eye shield for the patient and filtered 200 nm – 1400 nm for the operators. The goggles / glasses provided with this unit are manufactured specifically for the 400 nm to 1200 nm wavelength produced by the IPL unit. Do not substitute treatment / safety glasses with other types of tinted eyewear which may not meet the specific safety requirements of the unit.

Note: Gauze, eye-shield and tarsi are all effective in the protection for the eyes

2.5.1 Intense light warning

The intense light may damage the eyes. Please observe caution at all times. Avoid looking directly into the sapphire crystal during operation even if wearing the protective goggles. When not in use keep the treatment handle on its carriage and keep the device on standby or simmer mode.
2.5.2 Treatment Room

The treatment room should be clearly marked to prevent unnecessary access by other personal during the procedure.

2.6 Electrical and machine safety

The unit uses 220V 50/60Hz ; 110V 50/60Hz single-phase power supply. Its capability should be no less than 2000W. Use a \(\leq 10A\) (220V 50/60Hz); 12A (110V 50/60Hz) single-phase three-wire outlet at an international level.

A high level of energy is generated by the unit when in use- The maximum charged volts of energy stored in the capacitor is 450V. When the unit is switched off, the maximum energy remaining in the capacitor is 1000J as a residue voltage. It is not advised to open the cover. This will result in an electrical shock.

Do not open the control or rear panel even if the unit is switched off. Only authorized personnel may repair or maintain the IPL unit. Tampering with the unit will void its warranty.

2.7 Fire prevention

The intense pulsed light device generates thermal energy. Avoid using combustible material such as acetone or alcohol in the operative field. If alcohol based products are used to disinfect the IPL device, ensure that the alcohol has completely evaporated prior to operation.

2.8 System safety

The key switch is used to turn the unit on and off. Please remove the key when the unit is not in use to prevent unauthorized access. The emergency cut off switch is used to shut down the device in case of any emergency. After engaging the emergency shut off button, turn the device off by rotating the key in a counterclockwise direction. Rotating the emergency cut off switch in the direction indicated by the white arrows will release the button.

A 10-ampere circuit breaker is installed behind the device adjacent to the power cord. Loads in excess of 10 amperes will trip this switch. Simply moving the switch upward will restore power to the system. A self-diagnostic program then initializes the system and will continuously monitor the circuitry during operation.

2.9 Safe classification of equipments

The equipments safe classification: Electric shock protection — class Ⅰ, type BF equipment; Corrosion preventing liquid: commonness; Can't use this IPL system in the environment where the combustibility, anesthetic and the air or carbon monoxides mixture exist. Operating mode: Consecution.
2.10 Label of equipments

1. **NAME PLATE (Model) LABEL:** Position: back side

<table>
<thead>
<tr>
<th>Model Name</th>
<th>GSD-801E</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Name</td>
<td>IPL Photorejuvenation Treatment Systems</td>
</tr>
<tr>
<td>Power Supply</td>
<td>~220V, 50/60Hz ≤ 10A</td>
</tr>
</tbody>
</table>

Before operating and maintaining the IPL Photorejuvenation treatment systems, please read user's manual in detail.

2. **WARNING LABEL:** Position: front side

![WARNING]

**WARNING**

PROTECTIVE EYEWEAR MUST BE USED
RISK OF EXPLOSION IF USED IN THE
PRESENCE OF FLAMMABLE ANESTHETICS

3. **CAUTION LABEL:** Position: cover back side
4. **CAUTION LABEL**:

![CAUTION Label]

5. **DANGEROUS VOLTAGE WARNING LABEL**:

![DANGEROUS VOLTAGE WARNING Label]
Chapter 3 Description

This chapter will introduce the main parts of the system, the accessories and the process of installation & debugging.

3.1 Parts and control

The IPL Photorejuvenation treatment systems are composed of the following parts:

1. Control panel
2. IPL Treatment handpiece
3. Main unit

Figure 3.1 Main parts of the IPL Photorejuvenation treatment systems
1. Control panel
2. IPL Treatment handpiece
3. Main unit

3.1.1 Main unit

The Main unit is the integral part of this system; it consists of the following parts.

1. The Power supply module: regulates electrical supply to the entire system.
2. The Control module: Regulates and coordinates the various components of the system for optimum performance.
3. The display module: Displays various information of the system and accept users instruction.
4. High current capacitors: Delivers adequate electrical energy to guarantee sufficient power during operation.

⚠️ CAUTION

Only engineers certified by FP are authorized to service and maintain this device.
3.1.2 Control panel

Operation of this device is done through the control panel. It includes the following parts:

**Key switch:** Used to turn on and off the power supply. (clockwise to turn on and counter clockwise to turn off)

**Emergency turn off switch:** The red button found in the front panel of the device is used to immediately shut off the device’s power supply in case of any emergency. Depressing this button will cut off the power supply to the whole system. Rotating the button in the direction of the arrow printed on its surface will disengage the button and will reengage the power supply. When this button is engaged remember to turn the key switch to the off position afterwards.

The **Liquid Crystal Display** shows the operational settings and adjustments as well as system status is displayed on the screen.

3.1.3 The IPL treatment handpiece

The IPL handle consists of a (1) Cable housing: this contains the power cable, liquid coolant tubing, control data cable; (2) IPL head: this houses the control switch, flash lamp, sapphire crystal, filter piece and electronic semi-conductor cooling system.

Depressing the trigger on the IPL treatment head discharges the flash lamp at the settings as displayed on the control panel. Depressing the foot switch like-wise discharges the device (on selected models only). The supplied sapphire crystal measures 12mm x 40 mm and is superior in both clarity and longevity, thereby increasing both the efficiency of the flash lamp and lifespan of the treatment head. It is very important to keep the sapphire crystal clean. Make sure to clean this with a soft cloth after each treatment. A disinfectant such as alcohol can be used between treatments. Dried gel on the crystal filter will reduce efficiency of the flash lamp. Replace the plastic guard over the filter to prevent damage. In the event that the sapphire crystal is damaged (i.e. nicked or cracked) contact your dealer immediately.

### 3.2 Accessories:

The accessories of this device include:
- The IPL treatment head(s) 2suit
- Filter piece 3pc
- Protection glasses (operator) 1pair
- Protection goggles (patient) 1pair
- Users manual 1pc
- Drainage hose 1pc
- Funnel 1pc
- Power cable 1pc
- Foot switch 1pc
- O-Ring for faucet 1bag
- Key 2pcs
- Consumable
3.2.1 Filter

<table>
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<th>Standard Spectra</th>
<th>Application areas</th>
</tr>
</thead>
<tbody>
<tr>
<td>560 -1200nm</td>
<td>vascular, pigment, Photo rejuvenation</td>
</tr>
<tr>
<td>640 -1200nm</td>
<td>hair removal</td>
</tr>
<tr>
<td>690 –1200nm</td>
<td>hair removal</td>
</tr>
</tbody>
</table>

3.2.2 Protection glasses

One pair of protective glasses are provided with the device. The opaque glasses are to be worn by the patient and the filtered 200-1400 nm glasses are to be worn by the operator. Despite wearing the protective glasses, avoid staring directly into the intense pulses of light during the treatment. Only personnel wearing protective glasses may be allowed to observe the treatment.

3.2.3 Light-coupling gel

The light-coupling gel is used to maximize the conduction of light from the flash lamp to the skin. The light-coupling gel must be clear/transparent and not colored/tinted. Colored gels absorb light therefore reducing the effectiveness of the treatment. The light-coupling gel must be chilled but not frozen. Frozen gel diffuses the light emitted by the flash lamp reducing its efficacy. Light-coupling gels must be non-alcohol based. The IPL produces considerable heat; flammable material must be kept clear of the treatment area.

3.2.4 Order accessories

A complete set of accessories is included with this device when delivered. Additional accessories may be ordered through your authorized distributor. This device is very sensitive. Accessories and spare parts not provided by your authorized distributor must never be used with this device. Doing so will void your warranty.
3.3 System software

The software of the IPL mainly has four functions:
1. Allow the doctor to choose the best characteristic parameters for the patients according to the concrete diagnosis.
2. Control the working process of the system, in order to prevent unexpected trouble.
3. Examine the system energy.
4. Choose the treatment ranges.

3.4 The environment requirements

- Working temperature scope: +15~+30°C
- Relative humidity scope: 30%~80%
- Atmospheric pressure barometric: 86kpa -106kpa
- The store environment temperature: +5°C ~+55°C
- Power supply: 220V AC , 50/60Hz, \( \leq 10A \)
  or 110V AC , 50/60Hz, \( \leq 20A \)
Chapter 4 Installation

The process of installation includes: (Performed by an authorized technician only)
1. Unpacking the device.
2. Staying the device for one day, in order to avoid destruction by high humidity during long distant transportation.
3. Assembly of its components and ensure that all connections are firmly in place.
4. Fill the water tank with distilled water only.
5. Connect the power supply
6. Switch on the device and test all functions / parameters of the system

4.1 Equipments detailed list

The following is the detailed list of equipments of this device:
- Main host
- The IPL treatment handpiece
- Cradle of handpiece
- Protective glasses
- Protective goggles
- Power cable
- Handpiece holder (including four screws)
- Foot switch
- Funnel
- Plastics hose
- Key
- User’s manual

4.2 Installation requirements

Before unpacking the IPL Photorejuvenation treatment systems, ensure that working environment conforms to the requirements of this section.

Before assembly of the device’s components, ensure that high humidity is cleared away by opening the packing and staying the device for one day.

4.2.1 Location requirements

The device should be positioned in an area with adequate ventilation away from devices that produce heat (i.e. refrigerator).
4.2.2 Electrical Requirements

Before the IPL leaves the factory, it has already been marked the local rated voltage according to the customers’ request. It corresponds to the electricity requirement as follows:

- AC220V ±10 %, ≤10A, 50/60Hz.
- AC110V ±10 %, ≤20A, 50/60Hz

Input electric current can’t have momentary change, electric voltage or electric current peak sink.

It is recommended that this device use a dedicated power supply with its own circuit breaker.

<table>
<thead>
<tr>
<th>CAUTION</th>
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</thead>
<tbody>
<tr>
<td>Ensure that the electric voltage rating of this instrument (AC220V or AC110V refer to system labeling) matches the electric voltage of the outlet.</td>
</tr>
</tbody>
</table>

4.2.3 Environment Requirements

Air quality: No caustic particle (such as acid) in the air, which can damage the electric wire, the electric component and optical component surfaces. The dust in the air should be as little as possible, or it can absorb the energy of light and be heated up. When the dust falls on the surface of the filter, it may damage the filter. Metal particles also could damage the electric component.

Temperature: The IPL system has an optimal working temperature between 15 °C~30 °C. Relative humidity should not be over 80%. The working power of this device is about 2 KW. It is best that the IPL unit be installed in an air-conditioned room where the relative humidity and temperature can be maintained at optimal levels.
4.3 Installation

1) The device should be placed in a room with an indoor temperature of 15~30°C; the humidity should not be higher than 80%. Operating or treatment rooms must be kept clean of all times.

2) Turn on the Infusion/drain tap and unscrew the ventilation screw caps. (According to the following figure)

![Figure 4.1]

3) Infuse distilled water until the water level reaches 90% level way of the water observation window.

![Figure 4.2]

4) Ensure that the key is in the off position and that the emergency cut off button is not engaged. If it is engaged, release it by rotating the button towards the direction of the arrow indicator.

5) Attach the power cord and attach the foot switch cord.

6) Switch the circuit breaker to the “On” position

7) Switch the unit on by inserting the key and turning it in a clockwise direction. At this time water
circulation and the cooling system starts automatically.

8) Observe whether water circulation runs well or not. After cooling system runs for at least 1 minute, the water slide into the cooling system and then turn off the power. If the system sounds beep and show "water current error", then you need to move out the bubble air from the system. Switch the unit off, take off the protection plug of water conduit (as Figure 4. 4), then switch on the power, meanwhile the water will spout out from the front of water conduit.

9) If the water circulation run well. Then switch off the system. It means you can fully assemble system with handpiece, screw on the infusion cap and ventilation caps.

10) When installing a new treatment handpiece or switching between treatment handpiece, place the treatment head lower than the main host in order to remove bubbles from the treatment head, Then turn the device on. Let the water circulate for at least 1 minute before proceeding with the treatment.

11) Installation treatment handpiece, please follow the figure, pull out the protection plug for water conduit first.

12) Plug the handpiece connector firmly and properly to avoid the water circulation problem

13) According to the following figure changeable of the various wavelength by 560, 640,690~1200nm filter for FP standard specification for spot size: 12x40mm of GSD-801E

![Figure 4.4]

14) When replace the treatment handpiece or replace water

1. Drain the remaining water which contains in the handle. Pay particular attention as not to spill any water on the electronic terminals. Wipe off any spilled water with a soft absorbent cloth.

2. Replace water every 2-3 months; please carry on according to the following steps strictly.
   - Disconnect handpiece. But you need to keep the above part (as Figure 4.4) on the water conduit of handpiece.
   - Turn on the infusion/drain tap and unscrew the ventilation screw caps. (as Figure 4.1)
To drain excess water from the cooling tank. Turn on the drain tap, insert the drainage hose supplied then open the ventilation screw cap. Fasten all screw caps firmly.

<table>
<thead>
<tr>
<th>CAUTION</th>
</tr>
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<tbody>
<tr>
<td>1. Only distilled water is to be used in the cooling system.</td>
</tr>
<tr>
<td>2. When using the system for the first time, rinse the cooling system with distilled water.</td>
</tr>
<tr>
<td>3. Ensure that the water level is adequate before treatment to prevent over heating.</td>
</tr>
<tr>
<td>4. Distilled water is added periodically specially when working in warmer climates and when the treatment handpiece are changed often.</td>
</tr>
<tr>
<td>5. Make sure that the treatment head is firmly secured and the screw caps are firmly screwed into place prior to operation.</td>
</tr>
</tbody>
</table>

### 4.4 Move

If the device is to be moved within the general area,

1. Turn the device off
2. Put the treatment handpiece on the support (cradle)
3. Pull out the power cable
4. Relocate the unit (Avoid tilting the device)

<table>
<thead>
<tr>
<th>CAUTION</th>
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</thead>
<tbody>
<tr>
<td>If the instrument is to be moved outside the hospital, please contact your dealer.</td>
</tr>
</tbody>
</table>

### 4.5 transport and storage procedure

#### 4.5.1 Procedure

1. Drain off and cleaned the water from device before keep storage and transportation.
2. The instruments should vertically be installed in the outer packing box during transport. The instrument is fixed on the base $>690\text{mm} \times 590\text{mm} \times 600\text{mm}$ so that the wheels of the instrument
will not glide.0.3

3. There are waterproof and soft gasket material in the outer packing box of the instrument and handle with care which the instrument should be supported by natural damage. The markings such as “Handle with care”, “No wetness”, “up” should be on the box.

4.5.2 Environment

1. Environment temperature range: +5 °C~ +55 °C ;
2. Relative humidity range: 30%~80%;

Chapter 5 Operation

This chapter will describe the operating procedure of the IPL Photorejuvenation treatment systems.

WARNING

1. WARNING: HIGH VOLTAGE: please ensure that all panels are secured prior to operation.
2. Place the IPL treatment head on its support when on standby / simmer mode.
3. All personnel in the treatment room must wear the protective filtered glasses supplied.
4. Make sure the patient is wearing the opaque protective goggles prior to treatment
5. Avoid looking directly into the intense light during the treatment even if you are wearing the protection glasses.
6. Do not point the treatment head outside the treatment field

5.1 Software operation explanation

1. Main menu
2. Treatment Mode Selection Menu & Parameter setting Menu (see Figure 5.2)

- Treatment Mode Window: shows the current treatment mode.
- Energy output window: displays current energy output setting.
- Treatment parameters: shows the current accepted treatment parameters.
- System Information window: shows the available control options. Any warnings or system errors are displayed here.
- The Treatment counter displays the total number of shots by the specific treatment hand piece / total number of shots for this specific treatment

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Figure 5.1

- Turn the unit on by turning the key switch in a clockwise direction. The screen will show the main menu and will undergo a systems check up diagnostic program. (See figure5.1) After select any one of language by touch of screen, the program will then enter the Treatment Mode Selection Menu.
3. Treatment Mode Selection

- Once in the Treatment Modes Selection Menu, touch one of Treatment Mode between (PIGMENT /HAIR REDUCTION /BREAST /REJUV modes) on the screen to make a selection of your treatment. Once in the selected treatment menu (i.e. PIGMENT mode), as highlighted on the screen. (see figure 5.2)

<table>
<thead>
<tr>
<th>NOTE</th>
</tr>
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<tbody>
<tr>
<td>For systems GSD-801E with <strong>changeable filters</strong> turn the system on then select the proper filter (i.e. 640 nm for hair removal) and gently insert it into slot of the treatment head. Then select the desired treatment. Replace filters only when the device is in standby / simmer mode.</td>
</tr>
</tbody>
</table>

4. Treatment Parameter setting

Parameter setting from AMT.P (pulse number), Pulse1, Delay1, and Pulses, Delays or Touch Parameter setting get into the bigger screen as (see Figure 5.3). The max pulse sequence is 15, Pulses duration: 10ms, Pulse delay time is 50ms.

Touch the “Up and Down” button will allow you to modify the highlighted parameters. Touch the “Enter “button to return to previous Menu.

![Figure 5.3](image-url)

There are 8 treatment parameters that can be individually adjusted. (Such as Figure 5.4);

The energy output or **fluence** is the total energy measured in Joules/cm². Because of the large spot size (8 x 40 mm), the scattering effect of light is minimized. The higher the fluence the greater the amount of energy is delivered to the skin. The fluence can be increased or decreased at the Treatment Menu by depressing the: Up or Down button” respectively. The fluence of this system can be adjusted from 1 up to 60J/cm2.

**Pulse Times (NdP.)** the fluence can be divided from 1 up to 15 pulses. Because the power of the system can be divided into a series of pulses (unlike the previous generation of IPL units), the treatment is less painful and more effective in patients with darker skin types.

Page 24
The **Pulse Width** or **Pulse Duration** (Pulse1, Pulses..) is the length of time that the skin is exposed to the pulse of light. The larger or darker the lesion, the longer it will take to heat up as compared to smaller lesions or those with less pigment.

The **Pulse Delay** (Delay1, Delays..) is the resting phase between pulses (i.e., between first and second pulses) this delay or rest phase allows the surrounding normal epidermis to cool down prior to initiating the next pulse.

5. Temperature adjustment for Handpiece tip

   Touch the “Up and Down” button within “Refrigeration” will allow you to modify temperature of Handpiece tip.

6. Simmer

   Touch the “Enter.” to simmer and ready for treatment. (see Figure 5.5)

7. Energy adjustment
Once the parameters have been satisfactorily adjusted, in the Treatment Menu Screen, the energy of the system can now be adjusted by touching the “Up and Down” buttons.

8. Back

After completing the treatment, place the device on simmer / standby mode by touching the “Ready” button. This will terminate the active treatment phase and disengage the flash lamp. Please note that by going on Stand -by mode, the service lifetime of the treatment handle is maximized.

Touch the “Back” to return to the Main menu. Then you may switch off the power system now.

<table>
<thead>
<tr>
<th>NOTE</th>
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<tbody>
<tr>
<td>After completing the procedure, place the system on standby by touching the “Back” button This will allow cooler operating temperatures and will also prolong the life of the flash lamp.</td>
</tr>
</tbody>
</table>

9. CLEAR current treatment shots counting
The system will be automatic clear current counter after switch off.

GSD-801E: Shot number will be regressive shot of numbers from the initial writer by IC card.
It only works when IC card online. The shot number should be writing by writer card which is a proper design by FP.

10. Password
Note: Password for engineer only

5.2 Treatment

1. Select the filter (i.e 640 nm for hair removal) for changeable handpiece units (GSD-801E), plug the filter firmly and properly prior to turning the device on.

2. Turn the device on by turning the key switch in a clockwise direction. The screen will show the main menu and will undergo a systems check up diagnostic program. (See figure 5.1) After select any one of language by touch of screen, the program will then enter the Treatment Mode Selection Menu

3. Select the desired treatment by touching PIGMENT/HAIR REDU/BREAST/REJUV mode buttons.

4. Touch “Up and Down” button on the screen to modify the parameter settings. After the desired parameters have been settled, the Energy output can be adjusted by touching the “UP” and “DOWN” buttons.

5. Touch the “Ready” to simmer and ready for treatment.

6. Observe proper optical safety by wearing the safety goggles provided with this device. (Opaque for the patient and filtered for the operator)

7. Apply a thin layer (2-3 mm) of cold gel over the entire treatment area. While exerting light pressure, approximate the treatment head perpendicularly over the treatment area. And press the Trigger button on the treatment handle to begin treatment.

8. Evaluate the treatment area for any untoward side effect such as pain. During treatment the parameters can be adjusted as to your requirements.
9. Before moving on to the next treatment area, gently remove the gel from the previously treated area and apply a cool compress (cold gel pack).
10. After treatment, copy the treatment parameters to the patient’s record sheet and place the device on Simmer or Standby Mode by depressing the “Ready” key.
11. Turn off the device by turning the key counter clockwise. Clean the IPL treatment head with a soft cloth. Then sanitize the treatment head with alcoholized cotton balls.
12. Replace the treatment handle on its carriage and unplug the device.

<table>
<thead>
<tr>
<th><strong>NOTE</strong></th>
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<tbody>
<tr>
<td>Disinfect the treatment head after each treatment. Schedule your patient for subsequent follow up to evaluate future treatment. At the end of clinic hours, remove the IPL handle cover and remove any gel that may have accumulated with a soft damp cloth.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>WARNING</strong></th>
</tr>
</thead>
</table>
| 1. Do not point and operate the device elsewhere other than the intended treatment area.  
2. The light generated by this device is very intense. Exercise Optical safety measures by wearing the protective goggles. Avoid looking directly into the treatment area during operation even when wearing the goggles. |

## Chapter 6 Maintainance

This chapter describes the regular maintenance that can be performed by the owner. Authorized personnel must do any other maintenance work not described in this chapter. System troubleshooting is also enumerated in this chapter.

<table>
<thead>
<tr>
<th><strong>WARNING</strong></th>
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</thead>
<tbody>
<tr>
<td>Before any maintenance work turn the power off and unplug device. Failure to turn off the power may cause an electric shock, damage to the device and bodily injury. Never attempt to remove the back panel or device casing. Unauthorized tampering with the devices internal system will automatically void the warranty.</td>
</tr>
</tbody>
</table>

### 6.1 Cleaning the Main host

The main host casing or body must be clean with a soft damp cloth. A mild detergent may be used but be cautious as not to let liquids from entering the units internal mechanism.
6.2 Cleaning the Sapphire Crystal

The Sapphire crystal must be kept clean at all times. Always use a soft damp cloth or wet cotton balls. Sanitize the treatment head with alcoholized cotton balls.

6.3 Replace the IPL treatment handpiece

The IPL treatment head has a limited service life after its maximum life span (40,000 shots). You need to call your re-seller or dealer for this replacement.

6.4 Refilling the water supply

Observe the water level through the water observation window at the rear of the unit. The water level is best maintained within the midpoint of this window. Distilled water can be added by following the instructions seen in “Section 4.3 Installation”.

6.5 System Trouble Shooting

<table>
<thead>
<tr>
<th>No power</th>
<th>Check power cable</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Check circuit breaker / fuse</td>
</tr>
<tr>
<td></td>
<td>Check key switch</td>
</tr>
<tr>
<td>Disengage the emergency cut off switch by rotating towards the direction of the arrows indicated</td>
<td></td>
</tr>
<tr>
<td>Notify your distributor</td>
<td></td>
</tr>
</tbody>
</table>

| Key pads are none responsive | Please contact the dealer. |
| System failed to initialize | Not enough power, please check main power supply. Please contact the dealer. |

Malfunction of flash lamp on the IPL treatment head

The treatment head / flash lamp has reached its maximum life span (40,000) shots. Replace the treatment head

The IPL treatment head is probably damaged, please change the IPL treatment head or contact the dealer.

The IPL treatment head is leaking

The IPL treatment head is probably damaged, please change the IPL treatment head or contact the dealer.
Chapter 7 Clinical Application

7.1 Training

Only professional personnel with appropriate training may operate this device. Unauthorized use or abuse in the hands of a novice may cause thermal injury to oneself or others and may cause irreparable damage to the unit.

7.2 Application

7.2.1 Selective Thermolysis

The Intense Pulsed Light system works on the basis of selective thermolysis. The technology of which is similar to that of LASERS. Intense pulsed light as the name implies is a concentrated amount of light energy that is produced by a Xenon flash lamp in the broad spectrum of 400 to 1200 nm. Different types of filters can be attached to the unit to limit the wavelength / spectrum of the intense pulsed light.

The Hair Removal Head (HR) uses a 640 nm filter that is best suited to target dark pigments such as melanin. The Skin Rejuvenation Head (SR) encompasses a broader spectrum 560nm of treatment. The Skin Rejuvenation parameters are best suited to target collagen fibers, which stimulates collagen regeneration. This stimulation of collagen regeneration is best suited for the treatment of fine, superficial, static lines / wrinkles and the treatment of enlarged pores and superficial acne scars. The Vascular (VL) and Pigmented (PL) parameters are selective for red blood cells and dark pigments respectively, which makes them suited for the treatment of superficial vascular and pigmented lesions.

Though this device does not generate significant thermal energy as compared to lasers, it does produce sufficient thermal energy and when coupled with proper filtering and proper physician technique is a very powerful tool for the aesthetician in his or her practice. This unique nature of the IPL photorejuvenation treatment systems causes no down time and allows the
patient to resume work immediately right after treatment.

7.2.2 Treatment Range

1. VL (420 –1200 nm): Acne and telangiectasia
2. VL (510 – 1200 nm): Telangiectasia and fine superficial vein
3. PL (510 – 1200 nm): Freckles, superficial melasma, café-lait
4. SR (560 – 1200 nm): Fine static wrinkles, hair-pores, scars, skin tightening, whitening
5. HR (640 – 1200 nm): Permanence hair removal
6. HR (690 – 1200 nm): Permanence hair removal
7. VL (480–1200 nm): Acne and Telangiectasia
8. SR (585– 1200 nm): Vascular lesions (telangiectasis) alleviation by photothermic activity
9. HR (755– 1200 nm): Permanence hair removal

* Item 7–9 are optional items.

7.2.3 Overview of Areas Sensitive to Pain

Face:

(Figure. 7.1 Pain zones of face)

Body:
(Figure 7.2: Pain-sensitive zones of body)

7.2.4 Contraindications

<table>
<thead>
<tr>
<th>Warning</th>
</tr>
</thead>
<tbody>
<tr>
<td>The following are relative contraindications for treatment with Intense Pulsed Light</td>
</tr>
</tbody>
</table>

1. Inflammatory dermatosis
2. Cutaneous Infections
3. Immune system defect.
4. History of keloid formation.
5. Psychologically ill patients or has had the high expectations.
6. Pregnancy
7. Skin cancer.
8. Bleeding disorders
9. Photodermatoses
10. On medication known to cross-react to light.

7.3 The treatment must know

<table>
<thead>
<tr>
<th>Warning</th>
</tr>
</thead>
<tbody>
<tr>
<td>To the sufferer before carrying out the treatment please reading this segment in detail.</td>
</tr>
</tbody>
</table>

1. Prior to treatment, the physician must first get a detailed history, rule out any disorders that may contraindicate this treatment and finally physically inspect the treatment area.
2. Cosmetics should be removed with non-alcohol containing neutral cleansing agent such as Bactolin™, Cetaphil™ Gentle Skin Cleanser or Celeteque Facial Wash.
3. Apply a generous amount of cooled gel (non-tinted) on the treatment area.
4. A slight erythema may appear after the procedure. This is normal and will fade gradually in a few minutes to hours.
5. Always record the parameters, fluence, shots and the area treated after each treatment.
6. Apply a cold compress prior to proceeding to the next treatment area.
7. Avoid use of cosmetics for 24 hours after each treatment.
7.4 Preoperative Preparation

7.4.1 Inquiry
1. Avoid sunlight / artificial UV light exposure 3-4 weeks prior to treatment.
2. Discuss current treatment plan.
3. Clarify and confirm patient’s expectations.
4. Rule out any conditions contraindicating this treatment.

7.4.2 Explanation
1. Discuss the possible number of treatments required for treatment.
2. Inform the patient regarding the possibility of a stinging/ warm sensation during treatment.
3. Inform the patient regarding the possibility of transient erythema.

7.4.3 Optical Protection
1. The patient should wear the protective opaque eye goggles.
2. The Physician should wear the protective filtered translucent eye goggles.

7.4.4 Anesthesia
1. In general anesthesia is not required during the treatment with IPL.
2. Discomfort is reduced because of the built-in cooling semiconductor in the treatment head.
3. Discomfort is also reduced by using refrigerated coupling gel.
4. For patients with poor tolerance, 4% lidocaine cream is preferred over EMLA during the treatment of vascular lesions. (EMLA causes some vascular constriction).

7.4.5 Photographic Documentation
1. Pre and postoperative photographic documentation is desired if possible.
2. Please make sure that the camera settings, lighting, and distance is kept uniform.

7.5 Untoward Reactions

7.5.1 Pain
The Xenon flash lamp produces an intense beam of light that generates heat and is precisely modulated by computers and filters. The use of the built in cooling semiconductor as well as the application of cool coupling gel diminishes discomfort during treatment.

The sensation of this heat is compared to that of being flicked with a rubber band. Any residual sensation post treatment is kept to a minimum by applying cold packs left on for 5 to 10 minutes.
7.5.2 Scab formation

Scab formation after treatment can occur particularly if (1) a greater than amount of power/fluence has been used. (2) For the treatment of pigmented lesions, sometimes the only way to treat pigmentation is to physically destroy the pigment containing structures. By doing so, vesicle formation and scab formation is expected. It is advised to place cool packs after treatment and to apply an antibiotic ointment over the treated area until the scab has fallen off.

7.5.3 Pigmentation change

Post treatment darkening of target lesions can occur. This is particularly expected for the treatment of pigmented lesions. In a few days to weeks, the scab will fall off.

7.5.4 Scar formation

Scar formation is not an expected side effect.

7.5.5 Swelling and Erythema

Some transient swelling and erythema can occur especially during photo rejuvenation. This is normally transient and can be treated with cool compresses (5 to 10 minutes) and mid-potent topical steroids such as betamethasone valerate or momethasone furoate can be applied for 1 to 2 days.

7.6 Treatment Parameters

7.6.1 Brief introduction

The parameters are settings or set of instructions given by the user to the computer in order to modulate the light produced by the Xenon flash lamp. The therapeutic effect of this device depends on the proper selection and use of these parameters.

7.6.2 Parameters

1. Wavelength: Refers to the spectrum of light emitted by the xenon flash lamp (between 400 to 1200 nm).
2. Fluence: The intensity or level of power emitted by the flash lamp measured in joules/cm². Generally, the greater the fluence the greater amount of light and heat is produced.
3. Number of pulses: The energy of the each pulse can be divided into two, three or five pulses. This method of treatment prevents epidermal burns by allowing the target chromophores to cool between pulses.
4. Pulse width: The duration of light exposure (T1, T2 & T3) measured in nanometers (ms). This is the duration of time that the target chromophores absorbs filtered light energy from the xenon flash lamp.
5. Pulse delay: The duration (D1 & D2) between Pulse widths measured in ms. This is the interval between pulse widths when the target chromophores are not exposed to the intense pulsed light. The pulse delay allows the target chromophores to remain heated and the surrounding epidermis to cool down before exposure to the next intense pulsed light.
7.6.3 Parameter PrinicPLEs

<table>
<thead>
<tr>
<th></th>
<th>1. Decrease the fluence</th>
</tr>
</thead>
<tbody>
<tr>
<td>The darker the skin</td>
<td>2. Increase the pulse delay (allow more cooling)</td>
</tr>
<tr>
<td></td>
<td>1. Increase the fluence</td>
</tr>
<tr>
<td>The lighter the skin</td>
<td>2. Decrease the pulse delay</td>
</tr>
<tr>
<td>The darker the hair / pigmented lesion</td>
<td>1. Decrease the fluence</td>
</tr>
<tr>
<td></td>
<td>2. Increase the pulse delay (allow more cooling)</td>
</tr>
<tr>
<td>The lighter the hair / pigmented lesion</td>
<td>1. Increase the fluence</td>
</tr>
<tr>
<td></td>
<td>2. Decrease the pulse delay</td>
</tr>
<tr>
<td>Fine blood vessels</td>
<td>1. higher fluence</td>
</tr>
<tr>
<td></td>
<td>2. Decrease the pulse delay</td>
</tr>
<tr>
<td></td>
<td>3. Decrease the pulse width</td>
</tr>
<tr>
<td>Thicker blood vessels</td>
<td>1. Increase pulse delay (allow more cooling)</td>
</tr>
<tr>
<td></td>
<td>2. Increase the pulse width</td>
</tr>
<tr>
<td>The smaller the target size / lesion</td>
<td>1. Decrease pulse delay</td>
</tr>
<tr>
<td>The larger the target size / lesion</td>
<td>1. Increase pulse delay (allow more cooling)</td>
</tr>
<tr>
<td>Bony prominences (forehead, malar area, shins)</td>
<td>1. Decrease the fluence by 10-20%</td>
</tr>
</tbody>
</table>

During the interval of active treatment (Pulse Width T1, T2, & T3) the target chromophores is exposed to the Intense Pulsed Light, it then absorbs light energy and produces heat. This heat is then dissipated during the passive treatment phase (Pulse Delay D1 & D2) to allow for the surrounding epidermis to cool down and to prevent burns. Therefore, this method of selective photothermolysis makes use of time and light modulation to ensure that the target chromophores remains heated, as the surrounding epidermis is cooler.

7.6.4 Light-coupling Gel

The light-coupling gel is best used chilled. It is spread thinly (2-3 mm) over the treatment area. The gel is used to cool down the treatment area before and during treatment. By pre-cooling the skin and by absorbing heat from the epidermis, discomfort is kept to a minimal. The use of coupling gel is also helpful in determining the areas that has just been treated by observing the footprint left behind by the treatment head.
7.7 The Procedure

1. Remove cosmetics from the treatment area and clean with a mild soap.
2. Attach the proper treatment head/ filter.
3. Turn the IPL unit on and enter appropriate parameters.
4. Use the appropriate protective eyewear.
5. Apply a thin layer of coupling gel 2-3 mm.
6. Set the treatment head parallel to the skin's surface and begin treatment. Avoid excessive overlapping of treatment areas. Avoid doing double passes. For the first treatment, a test shot over an inconspicuous area can be performed.
7. After treating an area, carefully remove the gel and apply cool compresses (5-10 minutes).
8. Watch out for side effects such as burns, pain, and erythema.
9. Proceed to the next treatment area.
10. Treatment parameters before proceeding to the next treatment. Note down
11. If a different treatment is desired,
   a. For units (GSD-801E) with 4-in-1 hand pieces:
      i. Place the unit on standby by pressing the simmer key.
      ii. Insert the desired filter (510, 560, 640, 801 nm)
      iii. Select Treatment Mode and resume treatment
   b. For units (GSD-801E) with single treatment hand pieces:
      i. Place the unit on standby and turn off the unit.
      ii. Replace the treatment handle (560 nm or 640 nm)
      iii. Turn the unit on, select the desired treatment and resume treatment.
12. Whenever the unit is not in use, set the IPL on standby by pressing the simmer key to extend the life of your flash lamp.
13. Turn Off the unit and clean the treatment heads.

7.8 Post Operative Nursing Care

7.8.1 Sun Avoidance

As with other forms of treatment, the treatment area should be protected from sunlight exposure. An SPF 15 or greater physical-sun block is recommended. Avoidance of direct exposure is also recommended.

7.8.2 Deodorant

For axillary hair treatment, it is recommended that deodorants and shaving be avoided for the 24-48 hours after treatment.

7.8.3 Cosmetics

There is no contraindication to wear make-up after treatment. Likewise the patient may return to work immediately after treatment.
7.8.4 Follow-up Treatment

The treatment duration of IPL therapy extends for a few months. Patients should be reminded of their follow-up schedule as to maximize the efficacy of the treatment. Please refer to the provided treatment parameter chart for the treatment intervals.

7.8.5 Adverse Reactions

If at any point of treatment an adverse reaction is noted, hold treatment apply a cold compress and review your parameter setting. The cold compress may be needed for 5 to 10 minutes or until the adverse reaction is remedied.

Some common reactions are (1) erythema; this usually lasts for half an hour or so. This is specially noted during skin photorejuvenation. (2) Residual Warmth / Stinging sensation; apply cold compresses for 10-15 minutes or until symptoms are alleviated. (3) Increase in pigmentation of lesions in pigment reduction treatment; this is expected and normally the lesion will dry up and peel off in a few days. It is recommended that an antibiotic ointment be applied. (4) In rare events. Blister formation can occur especially when the wrong treatment parameter is used (i.e. wrong skin type or high fluence). Apply compresses to dry the blister followed by regular application of an antibiotic ointment.

7.9 The advantage of the IPL treatment

1. Non-ablative
2. Non-painful
3. Simple and quick treatment
4. No down time post treatment
Chapter 8 Parameters selection

8.1 Treatment of Pigmented Lesions

8.1.1 Treatment principle

Light absorbed by melanin is transformed into heat energy. This process causes the breakdown of pigment molecules and is cleaned and by phagocytes and are also shed off by the normal process skin renewal. Transient erythema and darkening of pigment molecules can be expected.

8.1.2 Available Filters

- GSD-801E Multi-filtered units: 510nm-1200nm / 560nm-1200nm filter

8.1.3 Basis of Parameter Selection

8.1.3.1 Skin color

- The darker the skin the longer the Pulse Width (T1, T2 & T3) and lower the fluence.
- The lighter the skin the shorter the Pulse Width (T1, T2 & T3) and greater the fluence.

8.1.3.2 Skin sensitivity

- The more sensitive the skin the lower the fluence

8.1.3.3 Color of target lesion

- The darker the lesion the longer the pulse delay (D1 & D2) to allow more cooling between pulses.
- The lighter the lesion the shorter the pulse delay (D1 & D2)

8.1.3.4 Depth of Target lesion

- The deeper the lesion the greater the number of pulses
- The deeper the lesion more longer the pulse delay

8.1.4 Parameters selection

Start with a low fluence (i.e. 25 J/cm²). Do a test shot in an inconspicuous area. Evaluate patient response then gradually increase the fluence by increments of 3 J/cm² when a fluence of around 30 J/cm² is achieved, increase by increments of 1 or 2 depending on patient’s response.

8.1.5 Treatment Evaluation

During treatment of pigmented lesions, note that the target lesions will normally turn whitish gray and normally darkens a few hours after treatment. The surrounding skin will normally turn erythematous. It should also noted that treatment of pigmented lesions produces more discomfort and that blister formation followed by scab formation is to be expected.
Please note that treatment over bony areas such as the malar area, forehead and shins produces more discomfort so reduce the fluence by 2-3 joules. When treating very densely pigmented areas reduce fluence by 2-3 joules.

8.1.6 Adverse Effects

Erythema and discomfort after treatment is treated with cold packs until the discomfort subsides. Erythema normally subsides over a few hours for lighter individuals and may take longer for darker skinned individuals. A blister normally dries up after a few days and the scab generally falls off in 1 to 2 weeks. An antibiotic ointment can be applied to prevent infection and to hasten healing. Post inflammatory pigmentation can be treated with topical retinoids.

8.1.7 Follow-up Consultation

Follow up consultation is highly recommended especially when post treatment complications such as blister formation are noted. Follow up treatment is only scheduled when adverse effects have been resolved. Please see attached follow-up treatment schedule in the treatment parameter chart attached.

8.2 Treatment of Vascular Lesions & Acne

8.2.1 Treatment principle

The target chromophore for vascular lesions is hemoglobin. The light absorbed by hemoglobin is converted to heat thereby effectively cauterizing the endothelial walls of capillaries.

8.2.2 Available Filters

GSD-801E Multi-filtered units: 420nm- 1200nm filterl for superficial vascular lesions and Acne.
510nm- 1200nm filter for deeper vascular lesions

8.2.3 Basis of Parameter Selection

8.2.3.1 Skin Color

- The darker the skin the longer the Pulse Width (T1, T2 & T3) and lower the fluence.
- The lighter the skin the shorter the Pulse Width (T1, T2 & T3) and greater the fluence.

8.2.3.2 Capillary Diameter

<table>
<thead>
<tr>
<th>Small Capillaries</th>
<th>Shorter pulse widths</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Shorter pulse delays</td>
</tr>
<tr>
<td></td>
<td>Higher fluences</td>
</tr>
<tr>
<td></td>
<td>Less pulses</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Larger Capillaries</th>
<th>Longer pulse widths</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Longer pulse delays</td>
</tr>
<tr>
<td></td>
<td>More Pulses</td>
</tr>
</tbody>
</table>
8.2.3.3 Skin sensitive degree
   The more sensitive the skin, the lower the fluence.

8.2.4 Parameters selection

* See attached treatment parameter sheet.

2.4.1 Start with a low fluence (i.e. 25 J/cm²). Do a test shot in an inconspicuous area. Evaluate patient response then gradually increase the fluence by increments of 3 J/cm² when a fluence of around 30 J/cm² is achieved, increase by increments of 1 or 2 depending on patient’s response. We strongly recommend that for the 1st treatment, the fluence level be set initially at least 8 to 10 joules/sq cm. below the suggested level of treatment parameter sheet.

   Please note that treatment over bony areas such as the malar area, forehead and shins produces more discomfort so reduce the fluence by 2-3 joules.

8.2.5 Treatment Evaluation

   There are three end results of treatment. 1) disappearance of capillaries. 2) decrease in diameter of the capillaries 3) coagulation of the blood vessels from a red to a reddish brown or purple color. Avoid over treating an area as it may lead to blister formation.

8.2.6 Adverse Effects

   Erythema and discomfort after treatment is treated with cold packs until the discomfort subsides. Erythema normally subsides over a few hours for lighter individuals and may take longer for darker skinned individuals. Blisters normally dries up after a few days and the scab generally falls off in 1 to 2 weeks. An antibiotic ointment can be applied to prevent infection and to hasten healing. Post inflammatory pigmentation can be treated with topical retinoids.

8.2.7 Follow-up Consultation

   Follow up consultation is highly recommended specially when post treatment complications such as blister formation are noted. Follow up treatment is only scheduled when adverse effects have been resolved. Please see attached follow-up treatment schedule in the treatment parameter chart attached.

8.3 Hair Removal

8.3.1 Treatment princIPLe

   Using the 640 nm – 1200 nm filter maximizes the selective targeting of melanin pigments in the hair strand. Light absorbed by the melanin in the hair is converted to heat and effectively destroying the hair follicle. The princIPLe of selective photothermolysis takes advantage of the amount of pigment found in hair. The greater the amount of pigment the more effective the
8.3.2 Available Filters

- GSD-801E Multi-filtered units: 640-1200nm filter or 690-1200nm

8.3.3 Parameter Selection

<table>
<thead>
<tr>
<th>Feature</th>
<th>Parameter</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dark hair</td>
<td>Shorter pulse width</td>
</tr>
<tr>
<td>Light hair</td>
<td>Longer pulse width</td>
</tr>
<tr>
<td>Deep hair</td>
<td>Longer pulse width</td>
</tr>
<tr>
<td>Superficial hair</td>
<td>Shorter pulse width</td>
</tr>
<tr>
<td>Thick hair</td>
<td>Longer pulse delay &amp; lower fluence</td>
</tr>
<tr>
<td>Thin hair</td>
<td>Shorter pulse delay &amp; higher fluence</td>
</tr>
<tr>
<td>Dense hair growth</td>
<td>Lower fluence</td>
</tr>
<tr>
<td>Sparse hair growth</td>
<td>Higher fluence</td>
</tr>
<tr>
<td>Darker Skin color</td>
<td>Longer pulse delay &amp; Lower fluence</td>
</tr>
<tr>
<td>Lighter skin color</td>
<td>Shorter pulse delay &amp; Higher fluence</td>
</tr>
<tr>
<td>More sensitive skin</td>
<td>Lower fluence</td>
</tr>
<tr>
<td>Less sensitive skin</td>
<td>Higher fluence</td>
</tr>
</tbody>
</table>

* See attached treatment parameter sheet.

Start with a low fluence (i.e. 25 J/cm²). Do a test shot in an inconspicuous area. Evaluate patient response then gradually increase the fluence by increments of 3 J/cm² when a fluence of around 30 J/cm² is achieved, increase by increments of 1 or 2 depending on patient’s response. We strongly recommend that for the 1st treatment, the fluency level be set initially at least 8 to 10 joules/sq cm. below the suggested level of treatment parameter sheet.

Please note that treatment over bony areas such as the malar area, forehead and shins produces more discomfort so reduce the fluence by 2-3 joules. When treating very densely pigmented areas reduce fluence by 2-3 joules.

8.3.4 Treatment evaluation

Generally the patient will note a mild discomfort liking to being flicked with a rubber band. As the fluence is increased so does the sensation. When a desirable fluence has been achieved you will note minimum discomfort accompanied by curling or waving of the hair. You may also note that there is accompanying burnt hair smell.

8.3.5 Treatment periods

General treatment each time interval is 3 to 6 weeks.
8.3.7 Side effect

Erythema and discomfort after treatment is treated with cold packs until the discomfort subsides. Erythema normally subsides over a few hours for lighter individuals and may take longer for darker skinned individuals. Blisters normally dries up after a few days and the scab generally falls off in 1 to 2 weeks. An antibiotic ointment can be applied to prevent infection and to hasten healing. Post inflammatory pigmentation can be treated with topical retinoids.

8.3.8 Post Treatment Care

Apply cool packs after treatment of each area before moving on to the next treatment area. For persistent erythema, mid-potent topical steroids can be applied. For areas of blister formation, an antibiotic ointment can be prescribed.

Post treatment, it is recommended not to shave and not to apply deodorants for the 1st 24 to 48 hours. It is strongly advised to avoid sun exposure and to use a sun block.

8.3.9 Follow-up Consultation

Follow up consultation is highly recommended specially when post treatment complications such as blister formation are noted. Follow up treatment is only scheduled when adverse effects have been resolved. Please see attached follow-up treatment schedule in the treatment parameter chart attached.

8.4 PHOTOREJUVENATION & DEEP SCARS

8.4.1 Treatment Principle

Collagen effectively absorbs the 560 nm-1200 nm spectrum of light. This results selective thermolysis of collagen resulting in heating and contraction of collagen bundles. The retraction of collagen bundles makes this process effective in the management of fine superficial wrinkles.

8.4.2 Available Filters

- GSD-801E Multi-filtered units : 560nm – 1200nm filter

8.4.3 Parameter Selection

* You may request the ref. treatment parameter sheet from apolo authorize territory distributors.
Start with a low fluence (i.e. 25 J/cm²). Do a test shot in an inconspicuous area. Evaluate patient response then gradually increase the fluence by increments of 3-4 J/cm² when a fluence of around 30 J/cm² is achieved, increase by increments of 1 or 2 depending on patient’s response. We strongly recommend that for the 1st treatment, the fluency level be set initially at least 8 to 10 joules/sq cm. below the suggested level of treatment parameter sheet.

Please note that treatment over bony areas such as the malar area, forehead and shins produces more discomfort so reduce the fluence by 2-3 joules. When treating very densely pigmented areas reduce fluence by 2-3 joules.

8.4.4 Treatment evaluation

Generally the patient will note a mild discomfort liking to being flicked with a rubber band. As the fluence is increased so does the sensation. When a desirable fluence has been achieved you will note minimum discomfort accompanied by mild erythema & swelling of the skin. Occasionally a burnt skin-like odor can be observed.

8.4.5 Side effect

Erythema and discomfort after treatment is treated with cold packs until the discomfort subsides. Erythema normally subsides over a few hours for lighter individuals and may take longer for darker skinned individuals. Blisters normally dries up after a few days and the scab generally falls off in 1 to 2 weeks. An antibiotic ointment can be applied to prevent infection and to hasten healing. Post inflammatory pigmentation can be treated with topical retinoids.

8.4.6 Post Treatment Care

Apply cool packs after treatment of each area before moving on to the next treatment area. For persistent erythema, mid-potent topical steroids can be applied. For areas of blister formation, an antibiotic ointment can be prescribed.

Post treatment, it is recommended not to shave and not to apply deodorants for 24 to 48 hours. It is strongly advised to avoid sun exposure and to use a sun block.

8.4.7 Follow-up Consultation

Follow up consultation is highly recommended specially when post treatment complications such as blister formation are noted. Follow up treatment is only scheduled when adverse effects have been resolved. Please see attached follow-up treatment schedule in the treatment parameter chart attached.
Chapter 9 Specifications

This chapter specifies the most important technical data and system classification for the IPL Photorejuvenation treatment systems.

Specifications

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Data</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Electrical connection data</strong></td>
<td></td>
</tr>
<tr>
<td>Line voltage:</td>
<td>120VAC or 220VAC (refer to system labeling)</td>
</tr>
<tr>
<td>Line frequency:</td>
<td>50/60Hz</td>
</tr>
<tr>
<td>Max.power consumption:</td>
<td>2000W</td>
</tr>
<tr>
<td><strong>System classifications</strong></td>
<td></td>
</tr>
<tr>
<td>Type of protection against electrical shock:</td>
<td>Class 1 equipment</td>
</tr>
<tr>
<td>Degree of protection against electrical shock:</td>
<td>Type BF equipment</td>
</tr>
<tr>
<td>Degree of protection against harmful ingress of water:</td>
<td>Ordinary equipment</td>
</tr>
<tr>
<td><strong>Climate (during operation)</strong></td>
<td></td>
</tr>
<tr>
<td>Ambient temperature</td>
<td>+15°C to +30°C</td>
</tr>
<tr>
<td>Relative humidity</td>
<td>30% to 80%</td>
</tr>
<tr>
<td>Atmospheric pressure</td>
<td>86.0 kpa to 106.0kpa</td>
</tr>
<tr>
<td><strong>Climate (during transport and/or storage)</strong></td>
<td></td>
</tr>
<tr>
<td>Ambient temperature</td>
<td>+5°C to +55°C</td>
</tr>
<tr>
<td>Relative humidity</td>
<td>30% to 80%</td>
</tr>
<tr>
<td>Atmospheric pressure</td>
<td>86.0 kpa to 106.0kpa</td>
</tr>
<tr>
<td><strong>Dimensions and weights</strong></td>
<td></td>
</tr>
<tr>
<td>Height</td>
<td>690mm</td>
</tr>
<tr>
<td>Width</td>
<td>590mm</td>
</tr>
<tr>
<td>Depth</td>
<td>610mm</td>
</tr>
<tr>
<td>Weight</td>
<td>approx. 30Kg</td>
</tr>
<tr>
<td><strong>Therapy IPL</strong></td>
<td></td>
</tr>
<tr>
<td>Light source</td>
<td>Intense pulsed light (Xenon Flash Lamp)</td>
</tr>
<tr>
<td>Spectrum range</td>
<td>420-1200nm</td>
</tr>
<tr>
<td>Energy density</td>
<td>1~60J/cm²</td>
</tr>
<tr>
<td>Pulse method</td>
<td>Intense pulsed technology (can adjust)</td>
</tr>
<tr>
<td>Pulse sequence</td>
<td>1~15 pulses</td>
</tr>
<tr>
<td>Pulse delay</td>
<td>10-50ms</td>
</tr>
<tr>
<td>Pulse width</td>
<td>0.5-20ms</td>
</tr>
<tr>
<td>Repeat frequency</td>
<td>1-6Hz</td>
</tr>
<tr>
<td>Deliver system</td>
<td>Direct sapphire Coupling</td>
</tr>
<tr>
<td>---------------</td>
<td>--------------------------</td>
</tr>
<tr>
<td>Spot size</td>
<td>8mm×40mm</td>
</tr>
<tr>
<td>Operation interface</td>
<td>8.4” touch Ture Color LCD</td>
</tr>
</tbody>
</table>

**Cooling system**

<table>
<thead>
<tr>
<th>Cooling system</th>
<th>Water cooling, forced-air cooling and semiconductor cooling</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cooling temperature</td>
<td>-4° C ~ 0° C</td>
</tr>
</tbody>
</table>

* The distributor reserves the right to modify / upgrade the specifications without prior notification.

**Fitzpatrick Classification of Skin Types**

<table>
<thead>
<tr>
<th>SKIN TYPE</th>
<th>COLOR</th>
<th>CHARACTERISTICS</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Light skin</td>
<td>Always Burns</td>
</tr>
<tr>
<td>II</td>
<td>Light skin</td>
<td>Always Burns</td>
</tr>
<tr>
<td>III</td>
<td>Light skin/ Oriental</td>
<td>Sometimes Burns</td>
</tr>
<tr>
<td>IV</td>
<td>Brown skin</td>
<td>Never Burns</td>
</tr>
<tr>
<td>V</td>
<td>Negro Skin</td>
<td>Never Burns</td>
</tr>
</tbody>
</table>

**Annotations:**

1. The technics items in the manual may be improved, please contact our company as request.

2. Electric principle diagram and part list will be provided as request.