darwin

System

User Manual

UM-0008-EU-Darwin REV (Draft)

Manufactured by

LUVO Medical Technologies
125 Fleming Drive,
Cambridge, ON
Canada, N1T 2B8

Use of this Manual:

The Darwin LUVO system (hereafter known as the Darwin) is designed to meet international safety and performance standards. Personnel operating the system must have a thorough understanding of the proper operation of the system. This manual has been prepared to aid medical and technical personnel to understand and operate the system. Do not operate the system before reading this manual and gaining a clear understanding of the operation of the system. If any part of this manual is not clear, please contact your LUVO representative for clarification.

The information provided in this manual is not intended to replace physician training or professional training on the clinical use of the Darwin system. Such training should include a review of published literature, seminars, workshops, and appropriate preceptorships. Please contact your authorized representative for current information on available training.

This manual should always accompany the system, and its location must be known to all personnel operating the system. Additional copies of this manual can be downloaded from Luvo's website. Put a website link Paper copy of this User Manual is available within 7 calendar days of receiving a request from the user. Reach out to your local sales rep for requesting paper copy of the user manual.

System and accessory specifications subject to change without notice

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1.0 General Information

1.1 Introduction

The Darwin System is a stand-alone, software-controlled, electrically powered, multi-technology platform intended for professional use in dermatologic, aesthetic, and dry eye disease-related procedures. The device combines multiple energy-based technologies in one platform through dedicated handpieces. The Darwin System includes diode laser, intense pulsed light, high-intensity focused ultrasound, RF microneedling, and thermal RF technologies. The system consists of the following:

- Console
- Darwin Diode Laser Handpiece
- Darwin IPL Handpiece with Filters
- Darwin HIFU Handpiece with Cartridges
- Darwin Needle RF Handpiece with Tips
- Darwin Face Thermal RF Handpiece with Tips

Technology / Handpiece	Description
Diode Laser Handpiece	808 nm GaAs diode laser with sapphire cooling tip for hair removal and permanent hair reduction.
IPL Handpiece	Intense Pulsed Light handpiece with interchangeable filters including 430 nm, 515 nm, 560 nm, 585 nm, 640 nm, 700 nm and 755 nm.
HIFU Handpiece	High-Intensity Focused Ultrasound handpiece with cartridges for focal depths of approximately 1.5 mm, 3.0 mm and 4.5 mm.
Needle RF Handpiece	Bipolar RF microneedling handpiece using sterile, single-use 10-pin and 25-pin needle tips.
Face Thermal RF Handpiece	Monopolar and bipolar RF handpiece for non-invasive thermal treatment of skin.
Accessories	Foot switch, interlock connector, vacuum hose for Needle RF, HIFU cartridges, IPL filters, Thermal RF tips, G-Pad connector cable, safety keys, funnel hose

1.2 Scope

This manual is intended to provide the physician and other personnel who operate or maintain the system with information regarding the operating principles, controls, safety precautions, installation, and maintenance of the system. While this manual is intended to aid in the use and care of the equipment, it does not serve as a substitute for proper training in the clinical applications of medical devices.

1.3 Manual Conventions

The following conventions are used in this manual:

CAUTION

The symbol informs the user that particular care is required for safe and efficient operation of the system.

WARNING

This symbol advises the user of serious danger for the patient and the user.

IMPORTANT NOTE

This symbol provides the user with useful or additional information.

1.4 Abbreviation and Acronyms

IPL	Intense Pulse Light	HC	Hair Colour
RF	Radio Frequency	HT	Hair Thickness
HIFU	High Intensity Focused Ultrasound	ST	Skin Type
HRS	Hair Removal Shot	HR	Hair Removal
HRM	Hair Removal Moving	NOHD	Nominal Ocular Hazard Distance
SC	Skin Colour	hPa	Hectopascal

1.5 Disclaimer

This manual is not intended as a comprehensive guide for all aspects of treatment. LUVO Medical highly recommends the operator confer with the Department of Labour, Licensing, and Regulation or other such regulatory body in their respective state or country regarding legal use of this system. Operators must be trained at the initial sale by LUVO Medical authorized personnel. LUVO Medical declines any responsibility for the direct consequences or side effects experienced by individuals undergoing treatment.

Because of LUVO Medical's ongoing commitment to product quality and innovation, LUVO Medical reserves the right, at any time, to discontinue or modify specifications, prices, designs, features, models, or equipment without incurring obligation.

This manual should always accompany the unit and its location must be known to all personnel operating the unit. Additional copies of this manual are available from LUVO Medical authorized representative.

1.6 Physician Responsibility

The licensed physician is responsible for the use and operation of the device and for all user qualifications. LUVO Medical makes no representations regarding federal, state, or local laws or regulations that might apply to the use and operation of any medical device. The physician is responsible for contacting their local licensing agencies to determine any credentials required by law for clinical use and operation of the device.

1.7 Operator Responsibility

Personnel operating the unit must have a thorough understanding of the proper operation of the system. Operators must be trained at the initial sale by LUVO Medical authorized personnel. Additional training sessions may be arranged by contacting LUVO Medical authorized representative. LUVO Medical is not responsible for injury or damage resulting from improper use of the system. If there is any doubt concerning the use of the Darwin or the user manual, contact LUVO Medical authorized representative immediately for assistance.

2.0 Safety

The general safety issues regarding the use of the Darwin system are described in this section. Special emphasis is placed on the optical and electrical safety for the Laser and IPL handpieces. With proper operation and maintenance, the system can be used safely by trained, qualified medical practitioners. The supervising physician and all other personnel operating or maintaining this equipment must be familiar with the safety information provided in this chapter. The primary considerations should be for the safety of the patient, the physician and other personnel. Patient safety is primarily assured by a well-trained staff and a well laid out treatment room. Patient education is also important, including information about the nature of the treatment.

Considerable effort was applied during the design of the Darwin to maximize safety for both the patient and personnel. The following are some of the system's preventative measures:

- Emergency knob
  - Disconnects the main power and turns the device off when the knob is pressed.
- Remote interlock
  - External door interlock receptacle and plug to disable the laser if the treatment room door is opened.
- Cooling function
  - Chiller feature designed to cool the sapphire tip of the Darwin diode laser handpiece to keep area of the skin in contact with the handpiece cooled.
  - Design feature of a cooling plate or 'chiller' in the IPL handpiece by the light guide to keep area of the skin in contact with the handpiece cooled.
- Internal check of device operation occurs during booting of each handpiece. (Section 5.0).
- Temperature sensors in the handpiece (as applicable), that signal system to place in STANDBY mode when temperature is too high.
- Check the water level bar. When the water level rises above the red band, remove the funnel from the device and lock both the Vent Port screw and the Fill Port screw.
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2.1 **General Hazards**

The supervising physician and all other personnel operating or maintaining this equipment must be familiar with the safety information.

WARNING

Failure to thoroughly review and adhere to the information contained in this Operator's Manual may pose a potential hazard to the patient and/or user.

CAUTION

Do NOT leave the Darwin in operating mode when not in use.
Refer servicing to LUVO Medical authorized qualified service personnel.

WARNING

Do NOT modify, repair, or service the Darwin system components, handpieces, cartridges or multi-needle tips.

Only LUVO Medical authorized personnel can modify, repair, or service the Darwin system, especially inside its protective covers. Dangerous voltages are present inside the system.

Maintenance performed by the user as instructed in this user manual, must only take place when the system is shut down and disconnected from power.

Performing maintenance procedures with the system powered-up may be hazardous to the user and/or destructive to the system. Do NOT leave system turned on, opened or left unattended when the carrying out system maintenance.

Unauthorized maintenance, modifications, repairs, or service will void the warranty.

Contact LUVO personnel if any questions.

WARNING

The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals. (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment

WARNING

The device must be used only in a shielded location with a minimum RF shielding effectiveness and, for each cable that enters or exits the shielded location, a minimum RF filter attenuation of 40 dB from 0.15 MHz to 30 MHz and 50 dB from 30 MHz to 300 MHz. It is essential that the actual shielding effectiveness and filter attenuation of the shielded location be verified to assure that they meet the minimum specifications. Failure to use this EQUIPMENT in the specified type of shielded location could result in degradation of performance, interference with other equipment or interference with radio services.

2.2 Laser Warnings

When using the Darwin diode laser handpiece, laser users are advised to supplement the general hazards with information regarding technological advances in surgical products and techniques as they become available to the medical laser user community through medical literature. For more information refer to ANSI Z136.3, ANSI Z136.1, and EN 207 of the latest edition of these standards, for recommendations on the safe use of lasers in health care facilities.

WARNING

In Canada this device must be installed and operated according to CAN/CSA-Z386-14: Laser Safety in Health Care Facilities.

2.2.1 Laser Safety Eyewear

All personnel within the treatment area and the patient MUST wear eye protection according to the specifications outlined in Table 2.0-1. The NOHD is 34m.

Table 2.0-1: Eye protection specification

Wavelength (nm)	Minimum Optical Density
785-830nm	5

IMPORTANT NOTE

To ensure correct eye wear protection for the Darwin is used, contact LUVO Medical's authorized representative to obtain proper eye wear protection.

IMPORTANT NOTE

This device should be protected against unauthorized use by removal of the key from the key switch.

IMPORTANT NOTE

Since the laser beam is generated in the module in the handpiece and not in the console, there is no need for an articulated arm or other beam delivery system.

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IMPORTANT NOTE

Regular Calibration
User shall call the service man through saled agency. Calibration of laser output shall be done by service man one time per one year. VEGA(laser power meter) and FL400A-LP2(sensor) may be used as the measurement device. The reference of laser output is 60J/cm2 in HRS STATIC mode.

WARNING

The light emitted from the Darwin diode laser handpiece is capable of causing serious damage to the eye or blindness. ALL persons in the treatment room, including patient MUST wear the recommended eye protection. Ensure the eye wear protection is not damaged. NEVER look directly into the laser aperture at the distal end of the handpiece during operation, including when wearing the recommended eye wear protection, as serious eye damage or blindness could result. ONLY direct the laser beam at the treatment site. There is a potential hazard to cause serious injury or blindness of stray laser light.
Ensure patient is wearing maximum safety, metal eye goggles for all facial treatments.

In addition to providing the required laser safety eyewear, ensure the following steps are taken to secure the treatment room, or the controlled area:

1. Alert personnel before they enter the controlled area by placing approved laser safety warning sign on the outside of the treatment room door when the laser is in use
2. Close the treatment room door during operation of the laser
3. Install the external door interlock that automatically disable the laser when the treatment room door is opened
4. Identify the laser room clearly by posting approved laser safety signs in prominent locations.
5. Cover all windows to prevent laser light from escaping the laser room.
6. Restrict entry to the laser room when the laser is in use. Allow access only to those personnel both essential to the procedure and well trained in laser safety

WARNING

Do NOT remove the protective covers on the handpiece. There is exposure to high intensity laser light hazard.

2.2.2 Laser Plume Cautions

Laser plumes present a potential hazard. Plumes may be potentially hazardous, both in terms of particulate matter and infectivity. Special care must be taken to limit the exposure of both patient and user to any laser plume smoke or vapor.

CAUTION
Laser plumes may be potentially hazardous, both in terms of particulate matter and infectivity and may contain viable tissue particulates.
Special care must be taken to limit exposure of both patient and user to any laser plume smoke or vapor.
LUVO Medical recommends wearing surgical masks that remove particles as small as 0.3 μm during treatment.
LUVO Medical recommends wearing gloves during treatment.

2.3 IPL Warnings

Intense pulsed light (IPL) emission from the Darwin IPL handpiece presents a potential eye hazard and fire or burn hazard. Take all necessary precautions in areas where the Darwin is used.

Keep hands away from the Darwin IPL treatment head during system start-up.

The Darwin IPL handpiece emits intense pulsed light pulses. Ensure that the patient and all those present in the treatment room guard against accidental exposure to these emissions either directly from the treatment head or indirectly from a reflecting surface.

Never look directly at light coming from the treatment head, even when wearing protective eyewear.

Never point the treatment head so that it discharges into free space. Ensure it is mounted on its cradle, or during actual treatment pointed at the target site.

To reduce the risk of accidental burns, ensure the patient avoids contact with metal parts that are grounded during operation of this equipment.

Do not expose the skin to the light pulse except the test patch and the treatment area

WARNING

Any intense light device can cause injury if used improperly. High voltages are present inside the Darwin system. Personnel who work with intense light sources must always be aware of the possible dangers and must take the proper safeguards as described in this manual.

If the system is malfunctioning or is not functioning as intended, do not use. Notify LUVO Medical authorized representative for assistance.

The heat of the Xenon flash lamp in the Darwin system can change the performance of the system.

If the temperature increases to more than 35°C, the handpiece is overheating. A pop-up warning appears stating "Please wait for cooling" (Figure 2.0-1). The system stops until the temperature cools down to 32°C.

Figure 2.0-1: Warning message when Darwin IPL handpiece is overheating.

2.3.1 IPL Emissions & Optical Safety

Intense pulsed light (IPL) emission presents a potential eye hazard and fire or burn hazard. Take all necessary precautions in areas where the Darwin IPL handpiece is used.

Keep hands away from the treatment heads during system start-up.

The Darwin IPL handpiece emits intense pulsed light pulses. Ensure that the patient and all those present in the treatment room guard against accidental exposure to these emissions either directly from the treatment head or indirectly from a reflecting surface.

Never look directly at light coming from the treatment head, even when wearing protective eyewear.

Never point the treatment head so that it discharges into free space. Ensure it is mounted on its cradle, or during actual treatment pointed at the target site.

To reduce the risk of accidental burns, ensure the patient avoids contact with metal parts that are grounded during operation of this equipment.

Do not expose the skin to the light pulse except the test patch and the treatment area.

WARNING

IPL emissions present a potential eye hazard and fire or burn hazard.

Take all necessary precautions in areas where the Darwin IPL handpiece is used.

Keep hands away from the treatment heads during system start-up.

Ensure patient and all present in the treatment room guard against accidental exposure to the IPL emissions either directly from the treatment head or indirectly from a reflecting surface.

Never look directly at beam coming from the treatment head, even when wearing protective eyewear used.

Never point the treatment head so that it discharges into free space.

Ensure treatment head is mounted on its cradle, or during actual treatment, pointed at the target treatment site.

To reduce the risk of accidental burns, ensure patient avoids contact with metal parts that are grounded during operation of this equipment.

Protect the eyes of patient and personnel operating in the treatment area by using the goggles as outlined in Table 2.0-2.

If the patient cannot wear the eyewear, fit the patient with approved opaque eye protection that completely blocks light from the eyes.

Table 2.0-2: Recommended eye protection

Wavelength [nm]	Optical Density [Patients]	Optical Density [Physicians & Staff]	Protection Level per EN207
430~980	5	3	N/A

IMPORTANT NOTE

This device should be protected against unauthorized use by removal of the key from the key switch.

CAUTION

Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.

IMPORTANT NOTE

Regular Check for pulse duration
User shall call the service man through sales agency. Regular check of IPL pulse duration shall be done by service man one time per one year. The oscillo scope shall be used as the measurement device. The reference of IPL pulse duration are described in clause 2.11 IPL handpiece.

2.4 Radiofrequency (RF) Warning

The Darwin system has the potential to emit Radiofrequency that can damage the skin, particularly when excessive energy is used.

WARNING

Do NOT use the system if it has been dropped or if any other type of excessive force has been applied. Ensure to minimize shock and vibration.

WARNING

The inappropriate use or adjustment of the device other than those specified in user manual may cause exposure of high voltage electricity resulting in serious damages

WARNING

Use of accessories, transducers, and cables other than those specified or pr
manufacturer of this equipment could result in increased electromagnetic e
electromagnetic immunity of this equipment and result in improper operati

WARNING

Failure of this device could result in an unintended increase of output power.

WARNING

The interference produced by the operation of this device may adversely influence the operation of other electronic equipment. For patients with cardiac pacemakers or other active implants, a possible hazard exists because interference with the action of the active implant may occur, or the active implant may be damaged. In case of doubt, qualified advice should be obtained.

WARNING

This device has the risks resulting from neuromuscular stimulation which can occur which produce electrical arcs between the tips and tissue

WARNING

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

CAUTION

The patient should not come into contact with metal parts which are earthed or which have an appreciable capacitance to earth (for example operating table supports, etc.).

CAUTION

Skin-to-skin contact (for example between the arms and body of the patient) should be avoided, for example by insertion of dry gauze.

CAUTION

Do not use this device simultaneously with physiological monitoring device.

CAUTION

The handpiece leads should be positioned in such a way that contact with the patient or other leads is avoided. Temporarily unused handpiece should be stored in a location that is isolated from the patient.

CAUTION

The output power selected should be as low as possible for the intended purpose. Certain devices or accessories may present an unacceptable risk at low power settings.

CAUTION

Skin-to-skin contact (for example between the arms and body of the patient) should be avoided, for example by insertion of dry gauze.

CAUTION

RF handpiece should be selected that have a rated handpiece voltage equal to or greater than the maximum output voltage referring clause 2.10 Specification of RF.

CAUTION

Patients who are suffering from skin diseases shall consult with doctors or secure pertinent prescriptions before the use of this device.

CAUTION

Be careful not to let the electrode touch surgical instruments or products other than the patient.

CAUTION

Do not use this device on the same patient as other general-purpose electrosurgical devices.

CAUTION

Do not use it on a certain area for a long time

CAUTION

Be careful because the electrode may cause burns due to short circuits.

CAUTION
Be careful when using it on damaged skin such as active or local skin diseases, herpes simplex, or burns

CAUTION
Apparent low output or failure of the RF multi needle to function correctly at the normal operating settings may indicate faulty application of poor contact in its connections. In this case, the connections should be checked before selecting a higher output power

CAUTION
Do not use this device simultaneously with physiological monitoring device.

2.5 HiFU warning

CAUTION
Fully contact the cartridge with the treatment area. Otherwise, the focal length may be inaccurate, resulting in burns to the skin or less effective treatment.

CAUTION
Presence of bubbles in coupling materials may cause thermal damage to skin or other contact /proximal tissues.

CAUTION
Common obstacles to ultrasound, like bone and organs containing gases, can interfere with uniform propagation of HIFU waves. HIFU treatment for skin laxity can cause facial nerve injury.

CAUTION
During the treatment, there may be a risk of bubble formation all along the acoustical path, notably at the surface of the transducer, at the transducer-tissue interface and in the region of interest. To avoid the bubble formation, place and maintain the film surface of the cartridge downward during the treatment. As the formation of cavitation bubbles in the acoustical path during the treatment can cause decreased efficacy

CAUTION
During the treatment, there may be a potential risk of heating of unintended tissue due to ultrasonic energy. To avoid unintended control setting and acoustic output levels, make sure that the parameter set correctly as desired on the LCD monitor before pressing the START button

CAUTION
The following areas on the human body are not suitable for ultrasound treatment.
- Eyes or a location where ultrasound energy can reach the eye
- Thyroid gland
- Breast implant
- Mechanical implants
- Implanted electrical devices

CAUTION
Apply a thin layer of coupling gel to the area to be treated and ensure the cartridge is in full contact with the skin surface.

CAUTION

When unintended reflected ultrasonic power is observed, press the POWER button located on the front part of the main body.

CAUTION

Attention to the need for care when handling the TRANSDUCER, since rough handling may adversely affect its characteristics

CAUTION

A mechanical shock on the transducer has to lead to a checking by the manufacturer of the conformity of the transducers on all the parameters related to its essential performance.

CAUTION

The OPERATOR'S attention to the need for regular testing and periodic maintenance.

CAUTION

The inspection should include searching for any cracks in the cartridge.

CAUTION

The operation mode of Darwin HiFU is non- continuous. When using one cartridge, the maximum on time is 10 minutes and the minimum off time is 30 minutes.

2.6 Electrical Hazards

The Darwin system uses high-voltage internal components, which have the potential to cause serious injury or fatal electrical shock. It is possible for the high voltage components to retain a charge for some period of time even after the laser has been turned off.

Keep all covers and panels of the Darwin closed. Only authorized LUVO Medical technicians can service the system. Whenever system maintenance is performed, do not leave the Darwin turned on, open or unattended.

Proper care should be taken when moving the Darwin system to avoid any injury. The system is portable and is designed to be easily moved but should always be moved with care.

The system is grounded through the grounding conductor in the power cable. This protective grounding is essential for safe operation.

WARNING

Electrical Shock Hazard:

- **Properly ground the Darwin to ensure patient safety**
- **Do NOT connect the included power cord to extension cords, power plug adapters or share a power line with other heavy power-load equipment, such as air conditioners. Ideally, the system should be on a separate power line with a separate circuit breaker.**
- **Only connect to supply mains with protective earth, to reduce the risk of electrical shock**
- **Do NOT remove cover**
- **Keep away from exposed water.**
- **Do NOT spill or immerse in water / liquid / solutions onto system, handpiece and touchscreen**
- **Do NOT touch the power cord with wet hands**
- **Grounding reliability is achieved when device is connected to an equivalent receptacle marked hospital grade**
- **Check grounding continuity periodically.**
- **Potential to adversely influence operation of other electronic equipment**

WARNING

When the system has not been in use for a long time, remove the power plug and keep it clean. If not, it may cause electric shock, short circuit or fire.

CAUTION

Unplug system before cleaning,

Turn system off before connecting / disconnecting the handpiece to / from the system.

Inspect cord for breaks, cracks, nicks, or other damage before every use.

- **If damaged, do NOT use.**
- **Failure to observe this precaution may result in injury or electrical shock to the patient and/or operator.**

Verify power cord is secure before each use.

Keep cord away from heated surfaces.

Contact LUVO Medical authorized representative to service or check system if not working properly

WARNING

If the device has been flooded or there is a problem with the device, such as strange sounds, burning odor, smoke, etc., immediately turn off the power.
Contact LUVO Medical authorized representative to service.

2.7 Fire Hazards

Take precautions to reduce the risk of igniting materials in and around the treatment area. To reduce the risk, take the following precautions:

- Ensure any flammable agents used for cleaning the skin or the handpiece tip, such as alcohol, fully evaporate before treatment.
- Ensure anesthetics administered topically or by inhalation are non-flammable.
- Ensure caution is used when oxygen is required. Oxygen can accelerate the combustion of any flammable material.
- Avoid using combustible materials, such as gauze and drapes, in the treatment area. When required, these materials may be made more fire resistant by keeping them moist with water or saline. Clothing should be kept well away from the area of treatment.
- Avoid restricting ventilation behind the Darwin.

WARNING

Avoid restricting ventilation behind the system

Maintain an open space of at least 4 inches/10cm around the control unit. If ventilation holes are obstructed the system could overheat.
Do NOT operate the system with any cover or drape over the laser. Do NOT use in the presence of flammable anaesthetics. Risk of explosion if used in the presence of flammable anaesthetics

WARNING

Danger of ignition of endogenous gases (e.g. cotton and gauze saturated with oxygen may be ignited by sparks produced during normal use of the device).

High temperatures produced in normal use of the Darwin diode laser handpiece may ignite some materials (e.g., cotton wool when saturated with oxygen) and solvents of adhesives and flammable solutions used for cleaning and disinfecting should be allowed to evaporate before the Darwin diode laser handpiece is used

2.8 Installation Warnings/Cautions

Installation of the Darwin is carried out by LUVO Medical authorized personnel.

WARNING

Do not modify, repair or service the Darwin system

Only authorized LUVO Medical personnel can modify, repair or service the Darwin system, especially inside its protective covers. This includes making internal adjustments to the power supply, cooling system, optics, treatment heads, etc. Dangerous voltages are present inside the system. Unauthorized modifications, repairs or service will void the warranty.

CAUTION

Do not place this machine in direct sunlight.
Ensure the system is installed in a well-ventilated area.

WARNING

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation.

CAUTION

Do NOT drop the Darwin system or subject the system, handpieces or accessories to any form of rough physical handling, either in normal use or during storage and transportation

For best results, operate the Darwin in a stable (vibration-free) environment, placed on a level working surface

Contact LUVO Medical authorized representative to service or check system if not working properly.

WARNING

During system operation, the generated electromagnetic field has the potential to interfere with other devices and computers.

Ensure to place the system at least two meters away from computers and other electrical devices.

WARNING

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

WARNING

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

2.9 Operation Warnings/Cautions

2.9.1 General

The Darwin system is intended for use in a hospital, doctor`s office or related health care facilities and is not designed to be used in the operating room.

WARNING

Do NOT use system if malfunctioning or not functioning as intended

Do NOT use the system if any of the components have been dropped or if any other type of excessive force has been applied. The system must be examined for safe operation after such an occurrence

Do NOT use unauthorized accessories, as using unauthorized accessories can cause damage to the system and / or cause the system to fail. Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation. Use of unauthorized accessories will void the warranty

Do NOT remove any system cover. Only LUVO Medical authorized service personnel are allowed to remove system covers

Notify LUVO Medical authorized representative for assistance.

WARNING

Do NOT allow untrained personnel or unauthorized use to operate system. Protect against unauthorized use by removing the key from the key switch and store in a secure place.

Use of controls, parameters, performance procedures other than specified in this user manual, increase the risk to hazardous radiation exposure and cause harm to the user and / or patient.

Turn the system off when moving from one treatment area to another treatment area

Do NOT move the system when the system is operating

CAUTION

Operate the system under the following environmental conditions:

Temperature: 10- 26 °C

Humidity: 10 - 80% RH

Pressure: 800 - 1060 hPa

WARNING

Do NOT use the device when close to products generating a strong electric field.

2.9.2 Handpieces (General)

Reduce risk of damage to the handpieces and/or injury to the patient or user by following the precautions outlined in this section.

WARNING

Do NOT twist, sharply bend or pull the handpiece cable. This could cause damage to internal wires and connections.

CAUTION

Inspect cord(s) for breaks, cracks, nicks or other damage before every use.

- **If damaged do NOT use.**
- **Failure to observe this precaution may result in injury or electrical shock to the patient and/or operator.**

Verify power cord is secure before each use.

Keep cord(s) away from heated surfaces.

Contact LUVO Medical authorized representative to service or check system if not working properly.

2.9.3 Darwin Diode Laser Handpiece and Sapphire Tip

High power laser light targets the melanin in the hair and the hair shaft. When the passed light is converted to thermal energy, the hair bulbs and most of the hair shaft are immediately vaporized, resulting in effective hair removal and permanent reduction. The heated hairs will sometimes vaporize, leading to the "burning hair smell" which often accompanies laser hair removal. While generally safe, this laser plume potentially can condense on the cooler, sapphire tip of the handpiece. The hair material may harden and as a result, has the potential to absorb subsequent pulses of laser light. While most of the sapphire tip remains very cool, the burned hair material has the potential to become very hot and can therefore lead to superficial, 1st degree, and 2nd burns, and

hyperpigmentation as the tip is moved across the treatment area, if the sapphire tip is not kept clean during hair removal procedures.

WARNING

Ensure to keep the sapphire tip of the Darwin Diode handpiece free from condensed hair or harden hair stuck on the sapphire tip during treatment.

There is a potential to cause burns or hyperpigmentation from the laser plume or harden hair potentially stuck on the sapphire tip.

WARNING

Ensure to properly insert the laser handpiece to the system. If the handpiece is improperly inserted or the umbilical cord is sharply bent, there is a potential for harm to the handpiece, patient and/or user.

Transport/Movement condition: If any movement of the Darwin console is required. The Diode handpiece is to be placed within its own case for transport, the remaining handpieces will also need to be disconnected and carried separately to the Darwin Console. Not following this instruction can cause an overbalance risk

CAUTION

Precautions to be taken in the event of changes in performance of the Darwin Diode handpiece.

Periodically check the laser's performance, including output and cooling to detect any changes and take necessary action. Ensure the cooling system is functioning properly to prevent excessive heat generation during laser operation.

Laser emission is enabled only when the operator switches to READY mode and presses the trigger on the handpiece or triggers the footswitch. The trigger reduces the risk of unintentional laser emission.

2.9.4 Darwin IPL Light Guide & Filters

The light guide on the Darwin IPL handpiece-and filters must be kept clean at all times. Ensure to clean the coupling gel off the patient contact area of the handpiece during the treatment session and after each patient. Take all precautions to ensure that no gel penetrates the treatment head.

WARNING

Ensure light guide and filters are kept clean at all times

Transport/Movement condition: If any movement of the Darwin console is required. The IPL handpiece is to be placed within its own case for transport, the remaining handpieces will also need to be disconnected and carried separately to the Darwin Console. Not following this instruction can cause an overbalance risk

A filter must always be properly installed in the Darwin IPL handpiece prior to triggering pulses. The system identifies which filter is installed and if a filter has been installed upon start-up. The operation of the system cannot continue unless a filter has been inserted into the handpiece.

If the filter has not been installed or has not been installed properly, a pop-up warning screen occurs, and the device will not continue to operate until the filter has been installed.

2.9.5 *Darwin HIFU Cartridges*

Reduce risk of damage to the Darwin HIFU cartridge and/or injury to the patient or user by following the precautions outlined in this section.

WARNING

Cartridges may be permanently damaged if dropped onto a hard surface or if the membrane is punctured.

Ensure to visually inspect the cartridge before treating each patient. If any wear, tear or damage is apparent, do NOT use the cartridge

Ensure to always keep the cartridge window clean.

Ensure to clean the ultrasound gel from the surface after each treatment.

WARNING

STOP using the Darwin when unintended reflected ultrasonic power is observed

WARNING

Take care to store cartridge in a safe and secure location to prevent damage, in between usages. Sliding connectors of the cartridge must be kept clean and dry.

Do NOT slide in the cartridge if the connectors have been immersed in liquid.

WARNING

Keep new cartridges in the sealed package until ready for use.

Ensure the cartridge is in direct contact with the skin / treatment area during treatment.

2.9.6 *Darwin Needle RF Tips, Darwin Face Thermal RF Tips*

Reduce risk of damage to the Darwin Needle RF and Darwin Face Thermal RF tips and/or injury to the patient or user by following the precautions outlined in this section.

WARNING

Keep new Darwin Needle RF or Darwin Face Thermal tips in the sealed package until ready for use.

Ensure the Darwin Needle RF or Darwin Face Thermal is in direct contact with the skin / treatment area during treatment. Ensure to keep tips clean during treatment.

WARNING

Do NOT allow the handpieces to come in contact with hard materials that could damage the RF tips.

Ensure to visually inspect the Darwin Needle RF and Darwin Face Thermal tip before treating each patient.

If any wear, tear or damage is apparent, do NOT use the multi-needle tip.

WARNING

Darwin Needle RF tips are single-use, disposable items. Do NOT re-use or re-sterilize.

WARNING

Interference produced by the operation of this device may adversely influence the operation of other electronic equipment. For patients with cardiac pacemakers or other active implants, a possible hazard exists because interference with the action of the active implant may occur, or the active implant may be damaged. In case of doubt, qualified advice should be obtained.

WARNING

This devise has the risk resulting from neuromuscular stimulation which can occur especially with modes which produce electrical arcs between the active electrode and tissue.

IMPORTANT NOTE

The output power selected should be as low as possible for the intended purpose.
This devices may present an unacceptable risk at low power settings

IMPORTANT NOTE

The use of flammable anaesthetics or oxidizing gases such as nitrous oxide (N2O) and oxygen should be avoided if a surgical procedure is carried out in the region of the thorax or the head, unless these agents are sucked away. Non-flammable agents should be used for cleaning and disinfection wherever possible.

IMPORTANT NOTE

Flammable agents used for cleaning or disinfecting, or as solvents of adhesives,
should be allowed to evaporate before the application of HF surgery.

IMPORTANT NOTE

There is a risk of pooling of flammable solutions under the patient or in body depressions such as
the umbilicus, and in body cavities such as the vagina. Any fluid pooled in these areas should be mopped up before this device is used.

IMPORTANT NOTE

For patient with electrically conductive implants, a possible hazard exists due to concentration or re-direction of HF currents. In case of doubt, qualified advice should be obtained.

IMPORTANT NOTE

If the connection between the handpiece and the tip is poor, the tip will not be recognized.

IMPORTANT NOTE

This device may present a safety hazard at low settings.

2.10 Safety and Labelling

2.10.1 Symbols

Symbol	Description	Symbol	Description	Symbol	Description
	manufacturer		alternate current		protective earth
	date of manufacture		"ON" (power button)		transport & storage temperature limitation
	catalogue / reference number		"OFF" (power button)		transport & storage humidity limitation
	serial number		Do not use if package is damaged.		transport & storage atmosphere limitation
	Refer to user manual		Do not reuse. (single-use)		WEEE sign Should not be disposed in regular garbage
	caution		use-by-date (expiry date)		general warning
	user manual		single sterilized using Ethylene Oxide		Do not push.
	type B applied part		This way up	Rx only	Prescription only
	type BF applied part		fragile		neutral electrode
	non-ionized electromagnetic radiation		Keep away from rain		warning: non- laser light source
	emergency laser stop		warning: laser beam	IPX7	ingress protection degree
	important note	LOT	Lot number	MD	Medical Device
UDI	Unique Device Identifier	EC REP	European Representative		

2.10.2 *Location of Labels*

Figure 2.0-2 shows the location of labelling at the back of the Darwin.

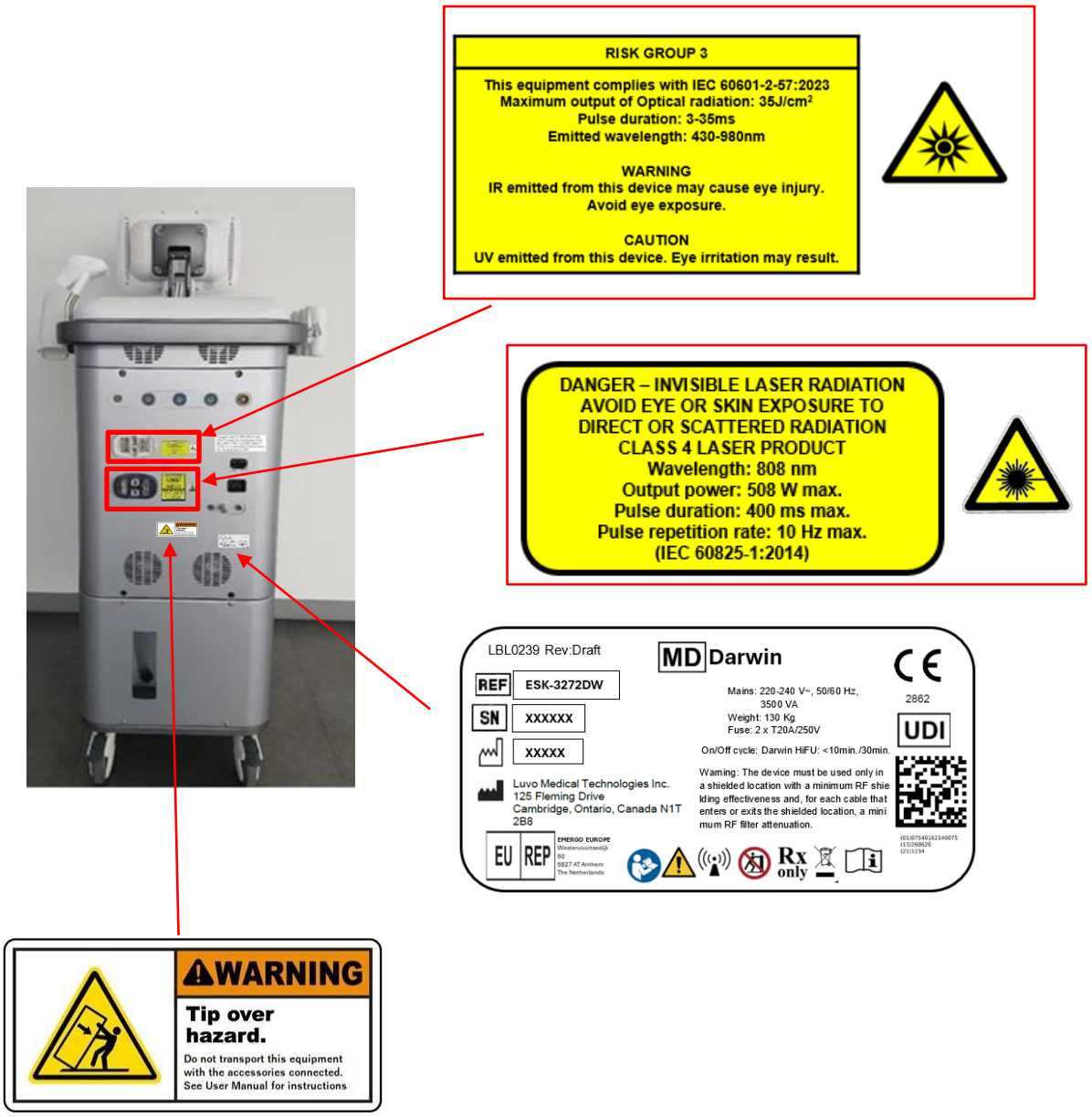


Figure 2.0-2: Location of labels at back of the Darwin.

Figure 2.0-3 indicates the location of the labelling for the Darwin Diode Laser handpiece.

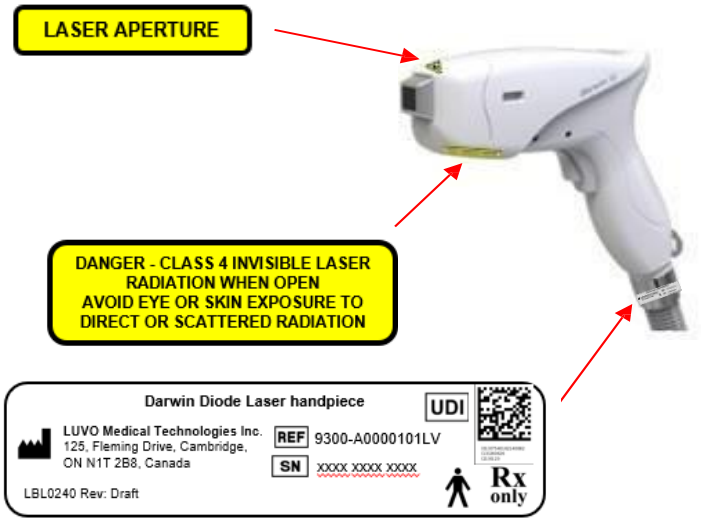


Figure 2.0-3: Location of labelling on the Darwin Diode Laser handpiece

Figure 2.0-4 indicates the location of the labelling for the Darwin IPL handpiece.

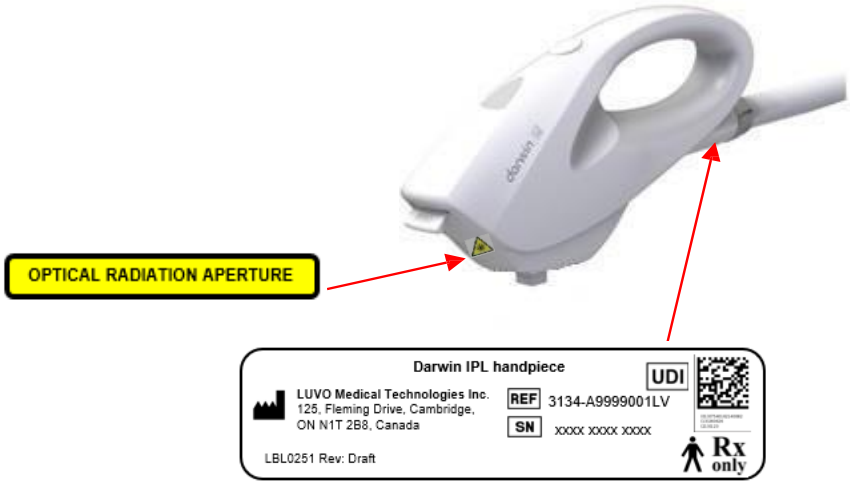


Figure 2.0-4: Location of labelling for the Darwin IPL Handpiece

Figure 2.0-5 indicates the location of the labelling for the Darwin HIFU handpiece.

Figure 2.0-5: Location of the Darwin HIFU handpiece label

Figure 2.0-6 indicates the location of the labelling for the Darwin Needle RF handpiece.

Figure 2.0-6: Location of the Darwin Needle RF handpiece label

Figure 2.0-7 indicates the location of the labelling for the Darwin Face Thermal RF handpiece.

Figure 2.0-7: Location of the Darwin Face Thermal RF handpiece label

Figure 2.0-9 indicates the location of the labelling for the G-PAD clamp.

Figure 2.0-9: Location of the G-PAD clamp

The filter label for the Darwin IPL handpiece is difficult to attach to the filter. Therefore, the name of the filter is imprinted in a location where the user can confirm. Figure 2.0-9 shows the labelling that is on the packaging of the filters.

Figure 2.0-10: Labelling on the packaging for the Darwin IPL handpiece filters

It is difficult to attach label directly to the filter, so labels are attached to it's packaging as shown in the image below. The image of Filter 755 is provided below for reference, all IPL filters are labelled same way as shown below. Filters are then packaged in a secure case to prevent any damage. The outer package case does not have any labels.

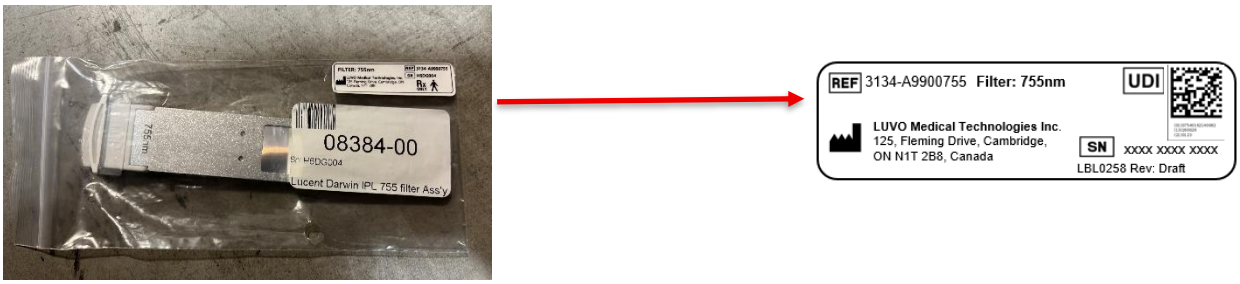


Figure 2.0-10: Location of labels on Darwin IPL filters

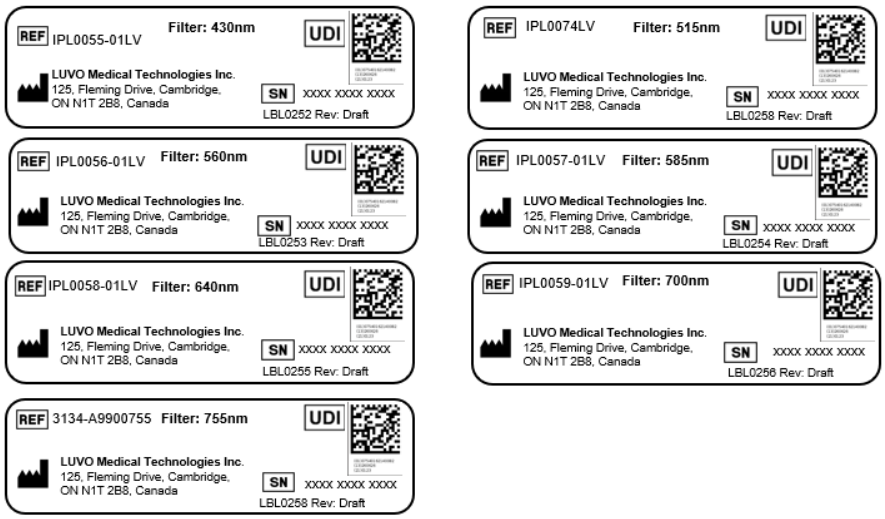


Figure 2.0-11 shows the location of the labelling for the Darwin HIFU cartridges.

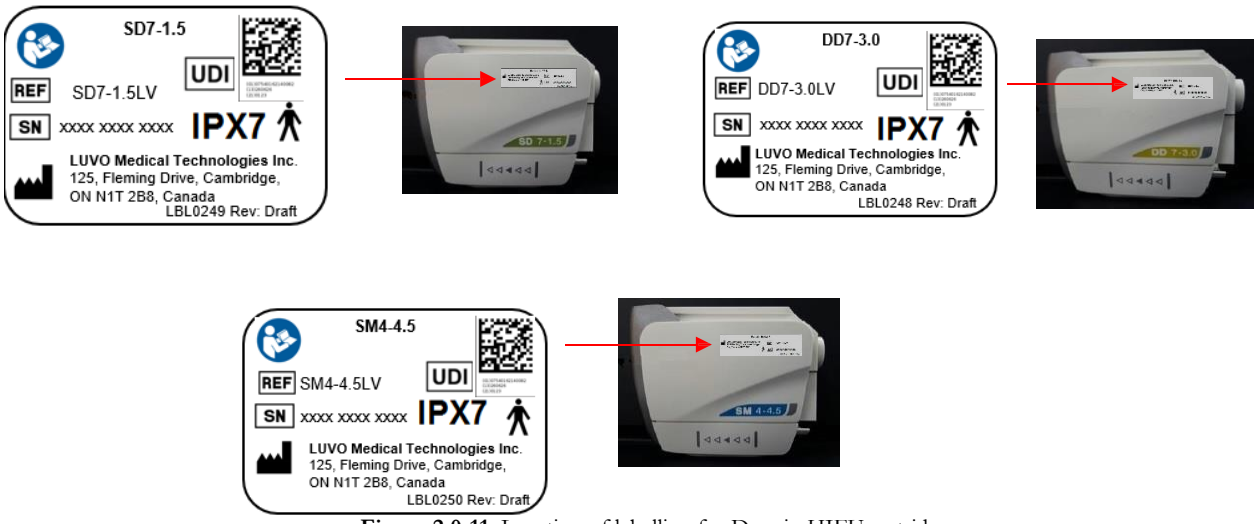


Figure 2.0-11: Location of labelling for Darwin HIFU cartridges

Labeling for the Darwin Needle RF tips on the back of the blister packs are displayed in Figure 2.0- 12.

The Needle RF Tips 10 Pin and 25 Pin comes in pack of 10 and packages in a sterile blister pack. The blister pack is placed in the outer cardboard box (Figure 2.0-12.1). The Darwin Needle RF 25 Pin tips are also packaged sterile same way as below shown image. The packaging of Darwin Needle RF tips is a sterile packaging.

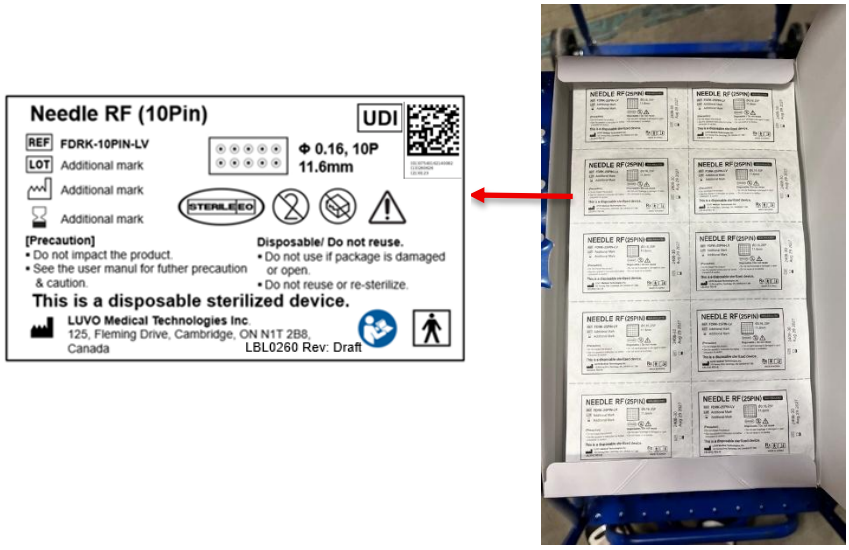
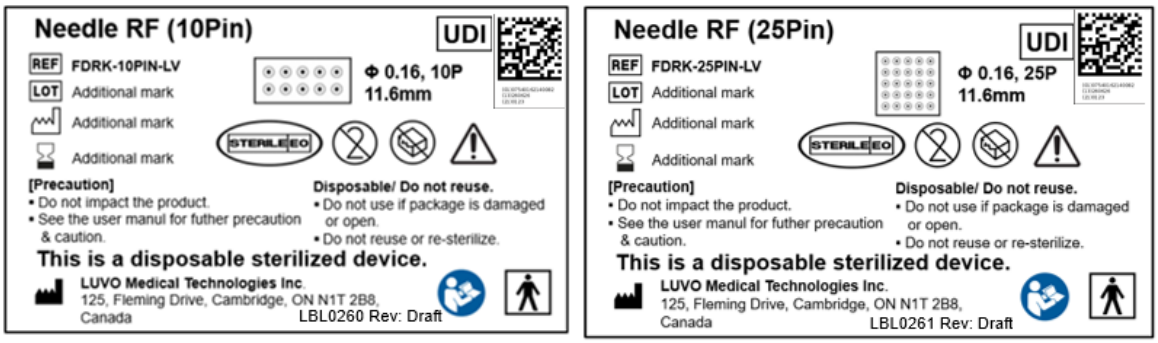


Figure 9.1 Outer cardbox for Needle RF

Figure 2.0-12: Location of labels for Darwin Needle RF Tips

Figure 2.0-12: Darwin Needle RF tip labels on the back of the blister packs.



Labelling for the Darwin Face Thermal RF tips on the back of the blister packs are displayed in Figure 2.0-13.

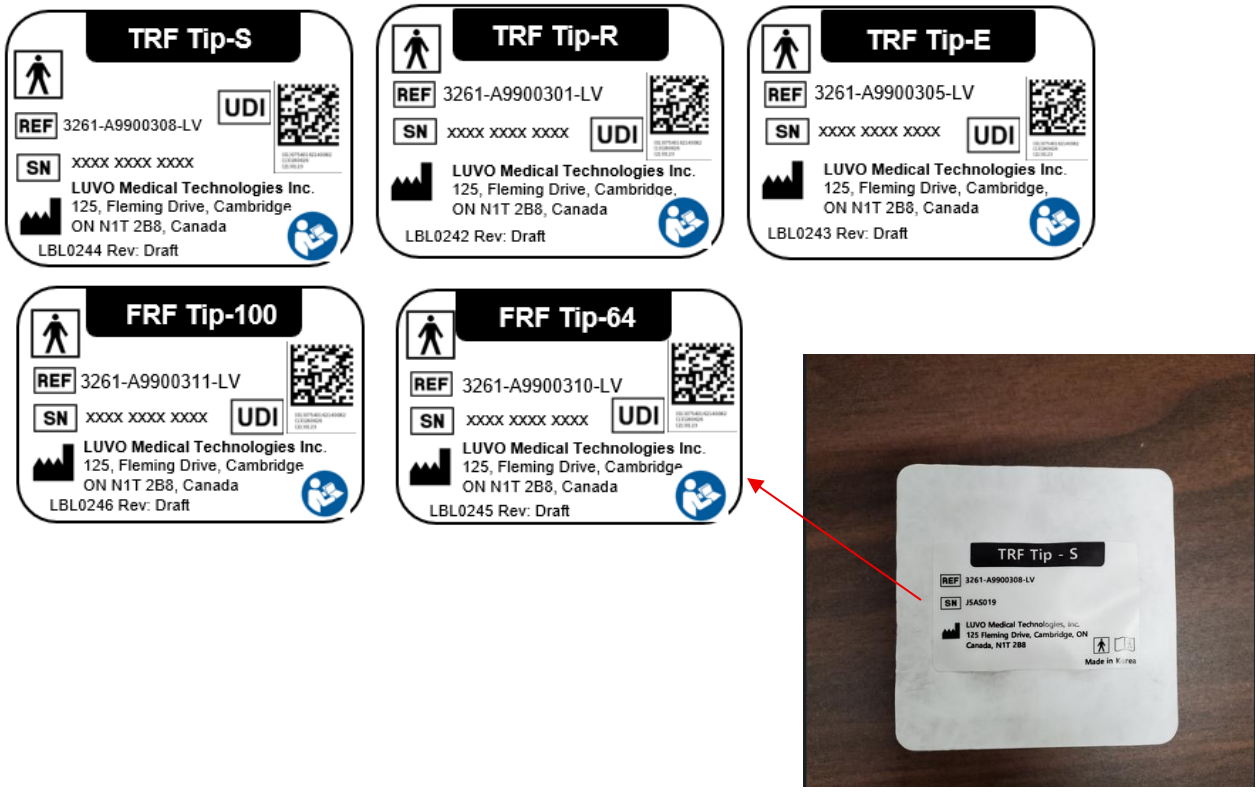


Figure 2.0-13: Labelling for the Darwin Face Thermal RF tips

2.11 Technical Specifications

Description	Specification			
System				
Input power	AC 220-240 V, 50 /60 Hz			
Fuse	2 x T20A, 250V~, time lag type			
Display	LCD Touchscreen			
Dimensions (mm)	640 (W) x 687 (D) x 1395 (H)			
Weight (Kg)	130 (accessories included)			
Basic Model name	ESK-3272DW			
Diode Laser Handpiece				
Essential performance	The fluence measured in the treatment area shall not deviate from the pre-set value of output by more than ± 20%.			
Laser type	GaAs(Gallium-Arsenide) Diode, Continuous beam			
Laser Class	Class 4			
Wavelength	808nm			
Pulse Waveform	Square Wave			
Beam Divergence	Fast Axis: 35 degree, Slow Axis: 8 degree			
NOHD	34m			
Cooling	Chiller (Deionized water)			
Maximum Laser Output	508W			
Spot Size	14mm x 14mm			
Irradiated Area	1.44 cm^2			
Pulse Type	HRS mode: Single, Double, Triple		HRM mode: Continuous	
Fluence (J/cm^2)	HRS mode: 5-60		HRM mode: 5-30	
Pulse Duration	HRS mode: 15 – 400ms		HRM mode: 15 - 266ms	
Repetition Rate	HRS mode: 1 – 3 pulses		HRM mode: 3 – 10 Hz	
Pulse Continuous shot	1Hz, 1.5Hz, 2Hz, Continuous (HRS mode)			
Pulse train of HRS mode	Type	Number of pulse	On time (setting time)	Off time
	Single	1	15 – 400 ms	-
	Double	2	7 -200 ms	30ms
	Ttriple	3	5- 133 ms	30ms
Handpiece Dimensions (mm)	58 (W) x 171 (D) x 186 (H)			
Length of cable (cm)	200			
Handpiece Weight (Kg)	0.8			
IPL Handpiece				
Essential performance	The fluence measured in the treatment area (the inner of the treatment area: 80%) shall not deviate from the pre-set value of output by more than ± 20%.			
Lamp	Xenon			
Wavelength	430-980nm			
Filters	ST Mode: 430nm, 515nm, 560nm, 585nm, 640nm		HR Mode: 700nm, 755nm	
Fluence (J/cm^2)	ST mode		HR mode	
	Single	6-35	Single	6-30
	Double	6-35	Double	6-30
	Triple	6-35	Triple	6-30
	Toning	1-30	-	
Spot Size	15mm x 40mm			
Pulse Type	ST Mode: Single, Double, Triple, Toning		HR Mode: Single, Double, Triple	

Pulse Duration (ms)	ST mode		HR mode	
	Single	3-35	Single	3-35
	Double	3-20	Double	3-25
	Triple	3-20	Triple	3-20
	Toning	3-25	-	
Pulse Off Time	3 - 35ms (one pulse) 1 ~50ms (double and triple pulse)			
Spectral irradiance (W/cm^2)	1000			
Ocular hazard distance	65m			
Handpiece Dimensions (mm)	58 (W) x 256 (D) x 150 (H)			
Length of cable (cm)	200			
Handpiece Weight (Kg)	1.9			
HIFU Handpiece				
Essential performance	Ultrasound output value shall not deviate from the pre-set value of output by more than ±10 %.			
	SD7-1.5	***DD7-3.0***	***SM4-4.5***	
Frequency (MHz ±10%)	7	7	4	
Focal Length / Depth (mm ±10%)	1.5	3.0	4.5	
Output Power (W)	7	11	16	
Output Energy (J ±10%)	0.1 - 0.25	0.2 - 0.45	0.6 - 1.2	
Treatment spacing (Pitch)(mm)	1.2~2.0	1.2~2.0	1.2~2.0	
Treatment length (mm)	4~24	4~24	4~24	
Mode of operation	Non-continuous operation: max. on time: 10 min, min. off time: 30 min			
Handpiece Dimensions (mm)	37.6 (W) x 231.6 (D) x 78.1 (H)			
Length of cable (cm)	180			
Handpiece Weight (Kg)	0.474			
Needle RF Handpiece				
Essential performance	RF output value shall not deviate from the set output value by more than ±20 %.			
RF Frequency (MHz)	2.0			
Operation Type	Bipolar			
rated load (ohn)	200			
Output Power (W)	Level	Output power		
	1	0.0		
	2	1.6		
	3	3.6		
	4	6.6		
	5	10.1		
	6	14.0		
	Remark: The output of 10 pin and 25pin are same.			
Pulse Duration (on time)	100 - 300ms			
Type of Needle Tip	10-PIN, 25-PIN			
Needle Depth (mm)	0.5 - 3.5			
Maximum output voltage (Vp)	80Vp			
Rated Accessory Voltage (Vp)	100Vp			
Maximum output current (Arms)	0.75 Arms at 10 ohm			
Vacuum (mmHg ±20%))	Level	vacuum		
	0	0		
	1	580		
	2	610		
	3	640		
Handpiece Dimensions (mm)	185.5 (W) x 41.5 (D) x 36.5 (H)			
Length of cable (cm)	180			

Handpiece Weight (g)	440			
Face Thermal RF Handpiece_TRF tips				
Essential performance	1. RF output value shall not deviate from the set output value by more than ±20 %. 2. The connection of G-Pad shall be maintained normal condition.			
RF Frequency (MHz)	4.0			
Operation Type	Monopolar			
Rated load (ohn)	500			
Output Power (W)	***Level***	***TRF-S***	***TRF-R***	***TRF-E***
	1	0.0	0.0	0.0
	2	12.0	12.0	5.0
	3	16.8	15.8	5.7
	4	21.6	19.6	6.4
	5	26.4	23.4	7.1
	6	31.2	27.2	7.8
	7	36.0	31.0	8.5
Pulse Duration	100 ~ 1000 ms			
tip	TRF-E	TRF-R	TRF-S	
Treatment Area	0.38 cm^2	2.54 cm^2	3.61 cm^2	
Maximum output voltage (Vp)	144Vp	224Vp	228Vp	
Rated Accessory Voltage (Vp)	240Vp	240Vp	240Vp	
Maximum output current (Arms)	0.19Arms	0.34Arms	0.38Arms	
Continuous / Shot	Continuous	Continuous	Shot	
G- Pad	150 mm x 120 mm			
Handpiece Dimensions (mm)	188.7 (W) x 38.0 (D) x 44.4 (H)			
Length of cable (cm)	180			
Handpiece Weight (g)	310			
Face Thermal RF Handpiece_FRF tips				
Essential performance	RF output value shall not deviate from the set output value by more than ±20 %.			
RF Frequency (MHz)	4.0			
Operation Type	bipolar			
Rated load (ohn)	500			
Output Power (W)	Level	Output Power (w)	On time (ms)	
	1	0.0	0	
	2	41.6	18 .0	
	3	42.8	22.0	
	4	43.6	27.0	
	55	44.0	31.0	
	6	44.6	37.0	
	7	44.8	41.0	
	8	45.2	45.0	
	9	45.4	51.0	
	10	45.4	56.0	
	Remark: The output of FRF-Tip-100 and FRF-Tip-64 are same.			
Pulse Duration	8.0 ~ 56.0 ms			
Tip	***FRF-TIP-64***	***FRF-TIP-100***		
Treatment Area	10.5x10.5 [1.1cm2]	10.5x10.5 [1.1cm2]		
Maximum output voltage (Vp)	244Vp	244Vp		
Rated Accessory Voltage (Vp)	260Vp	260Vp		
Maximum output current (Arms)	0.77Arms	0.77Arms		
Feature	Fractional Ablative Resurfacing	Superficial Fractional Ablative Resurfacing		

Continuous / Shot	Shot	Shot
Handpiece Dimensions (mm)	188.7 (W) x 38.0 (D) x 44.4 (H)	
Length of cable (cm)	180	
Handpiece Weight (g)	310	
Environmental Conditions		
Operating	Temperature: 10- 26 °C Humidity: 10 – 80% RH Pressure: 800 – 1060 hPa	
Storage / Transport	Temperature: 5 – 40 °C Humidity: 10 – 90 % RH Pressure: 500 – 1060 hPa	
Other		
Footswitch	5 A, 250 VAC, IP68	
G-PAD clamp	Length of cable: 250cm	

CAUTION

Basic model name is ESK-3272DW. It has all kinds of handpiece.

Technical specification per filter for the Darwin IPL is shown in Tables 2.0-3 and 2.0-4.

Table 2.0-3: Darwin IPL Handpiece technical specification per Filter

Filter	Pulse Mode	Range	
		Pulse (ms)	Joule(J/cm²)
430	1	3~35	6~35
	2	3~20	6~35
	3	3~20	6~35
	Toning	3~25	1~30
515	Toning	3~25	1~25
560	1	3~35	6~35
	2	3~25	6~35
	3	3~20	6~35
	Toning	3~25	1~25
585	1	3~35	6~35
	2	3~25	6~35
	3	3~20	6~35
	Toning	3~25	1~23
640	1	3~35	6~35
	2	3~25	6~35
	3	3~20	6~35
	Toning	3~25	1~20
700	1	3~35	6~30
	2	3~25	6~30
	3	3~20	6~30
755	1	3~35	6~30
	2	3~25	6~30
	3	3~20	6~30

Table 2.0-4 Darwin IPL Specifications – technical and default values

Filter	Pulse Mode	Range		Default Data							
		Pulse (ms)	Joule (J/cm^2)	Normal Mode		Manual Mode				Joule	Cooling (℃)
				Pulse	Delay	Pulse 1	Pulse 2	Pulse 3	Delay		
430	1	3~35	6~35	15	-	-	-	-	-	8	12
	2	3~20	6~35	15	10	5	5	-	20	8	
	3	3~20	6~35	10	10	5	10	10	20	8	
	Toning	3~25	1~30	10	-	-	-	-	-	5	
515	Toning	3~25	1~25	10	-	-	-	-	-	7	12
560	1	3~35	6~35	15	-	-	-	-	-	12	12
	2	3~25	6~35	15	10	10	10	-	20	12	
	3	3~20	6~35	10	10	10	10	10	20	10	
	Toning	3~25	1~25	10	-	-	-	-	-	7	
585	1	3~35	6~35	15	-	-	-	-	-	12	12
	2	3~25	6~35	15	10	10	10	-	20	12	
	3	3~20	6~35	10	10	10	10	10	20	10	
	Toning	3~25	1~23	10	-	-	-	-	-	7	12
640	1	3~35	6~35	15	-	-	-	-	-	14	5
	2	3~25	6~35	15	10	5	5	-	20	14	
	3	3~20	6~35	10	10	5	10	10	20	12	
	Toning	3~25	1~20	10	-	-	-	-	-	8	
700	1	3~35	6~30	15	-	-	-	-	-	14	-5
	2	3~25	6~30	15	10	5	5	-	20	14	
	3	3~20	6~30	10	10	5	10	10	20	12	
755	1	3~35	6~30	15	-	-	-	-	-	14	-5
	2	3~25	6~30	15	10	5	5	-	20	14	
	3	3~20	6~30	10	10	5	10	10	20	12	

3.0 Installation

The Darwin system is designed for installation in a clinical environment by an authorized LUVO Medical service technician. The Darwin system is not designed to be used in the operating room. Ensure to review section 2.7 Installation Warnings / Cautions prior to installation.

The installation is carried out by doing the following:

- Unpack the system and position it in its pre-selected location.
- Verify the integrity of the system and its components.
- Install the handpiece cradle and connect the handpiece.
- Fill the cooling system.
- Unpack the assorted accessories.
- Plug the system into a designated electrical outlet.

CAUTION

Do NOT drop the Darwin system or subject it to any form of rough physical handling, either in normal use or during storage and transportation

Do NOT lie the Darwin on its side

For best results, operate the Darwin in a stable (vibration-free) environment, placed on a level working surface.

3.1 Facility Requirements

Prior to unpacking, ensure the area meets the Facility Requirements outline in this section.

3.1.1 Electrical Requirements

Ensure outlet used for the system complies with AC 220-240 V, 50 /60 Hz and has a working grounding terminal included in the outlet.

WARNING

Electrical Shock Hazard:

- **Properly ground the Darwin to ensure patient safety.**
- **Do NOT connect the included power cord to extension cords, power plug adapters or share a power line with other heavy power-load equipment, such as air conditioners. Ideally, the system should be on a separate power line with a separate circuit breaker.**
- **Only connect to supply mains with protective earth, to reduce the risk of electrical shock.**
- **Do NOT remove cover.**
- **Do NOT get the power cable wet.**
- **Ensure power cable is not damaged.**
- **Check grounding continuity periodically.**
- **Potential to adversely influence operation of other electronic equipment**

3.1.2 *Space and Positioning Requirements*

Ensure the space has been allocated with adequate ventilation and free airflow. The working area for the system is prepared according to the system dimensions presented in section 2.7 Technical Specification. To guarantee proper ventilation, always keep the sides of the system at least 0.2 meters from the wall or from other obstructions to air flow.

The system can interfere with computers and other electrical and medical devices. To reduce interference, place the system at least two meters away from any such devices.

Install the system on a stable, flat surface.

WARNING

During system operation, the generated electromagnetic field has the potential to interfere with other devices and computers.
Ensure to place the system at least two meters away from computers and other electrical devices.

WARNING

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation.

WARNING

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

3.1.3 *Environmental Requirements*

The system is to operate in an environment with Temperatures at 10°C to 26°C, 10%~80% Humidity, and Atmospheric Pressure of 800~1060hPa. Ensure system is installed in an area with low heat and humidity. Coming in contact with moisture / water deteriorates the insulation.

CAUTION

Operate the system under the following environmental conditions:

Temperature: 10°C to 26 °C
Humidity: 10 % to 80 %,
Pressure: 800 hPa to 1060 hPa.

CAUTION

Do NOT install the system in an area with the potential for exposure to flammable gas leaks / evaporation

Air quality includes the operation of the system in a non-corrosive atmosphere (does not contain corrosive material such as acids), as acids can damage electrical wiring, electronic components and the surfaces of treatment components.

Ensure to keep dust and hair particles to a minimum.

Ensure to keep heat producing devices, e.g. heater, etc. away from the Darwin.

3.1.4 Storage & Transportation Requirements

To properly maintain the system during storage and transport, follow these requirements:

- Store and / or transport conditions:
  - Temperature: 5~40 °C
  - Humidity: 10~90 % RH
  - Pressure: 500~1060 hPa
- Minimize shock and vibration during the transportation.
- Do not drop system or any of the components
- Lift only with suitable and appropriate equipment

3.2 Unpacking & Repacking

Before unpacking the Darwin system, ensure the site meets the requirements outlined in Section 3.1 Facility Requirements.

CAUTION

The Darwin is heavy.
Use proper lifting techniques when unpacking and repacking the unit

Instructions for unpacking the Darwin are as follows:

1. Examine the shipping box for external damage or evidence of mishandling. Immediately notify LUVO Medical's authorized representative IN WRITING if there is any visible damage.
2. Open the top cover of the box and carefully remove all the contents. Save all packaging materials in case repacking and shipping is necessary at any future time. Should the box and foam padding be misplaced, replacements are available from LUVO Medical's authorized representative at an additional cost.
3. Compare the items in the box with the packing list and ensure that all items on the list are present. Immediately notify LUVO Medical's authorized representative IN WRITING of any discrepancies

IMPORTANT NOTE

Save all packaging materials in case repacking and shipping is necessary at any future time.
If box and foam padding have been misplaced, replacements are available from LUVO Medical's authorized representative at an additional cost.

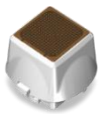
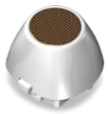
CAUTION

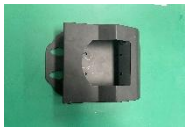
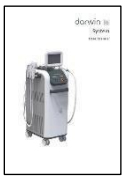
Do NOT ship the device without the factory packaging materials.
Doing so may result in damage to the components during shipping and void the warranty.
Contact LUVO Medical's authorized representative for packaging materials and re-packaging instructions.

3.3 Accessories

The accessories and components expected to be included in the packaging, along with the main body are outlined in Table 3.0-1

Table 3.0-1: Accessories and components

System	Handpieces		
	Darwin Diode Laser		Darwin IPL
			
	Darwin HIFU	Darwin Needle RF	Darwin Face Thermal RF
			
Darwin IPL Filters	**Darwin HIFU Cartridges**		
	SD7-1.5	DD7-3.0	SM4-4.5
			
Darwin Needle RF Tips		**Darwin Face Thermal RF Tips**		
10 PIN	**25 PIN**	**TRF -S**	**TRF-R**	**TRF-E**
				
FRF-TIP-64	**FRF-TIP-100**			
				

Other Components		
Needle RF Vacuum Hose	**Ground PAD Cable**	**IPL Filter Tip Storage Case**
		
Footswitch	**Cover of footswitch**	**Safety Keys**
		
Interlock	**Funnel Hose**	**User Manual**
		

3.4 Installation and Set Up

The system has passed full quality assurance testing before shipment and should be operational upon delivery.

IMPORTANT NOTE

The Darwin should be at room temperature before beginning the installation and setup procedures.

3.4.1 Filling and Draining the Reservoir

The Darwin cooling system filling the must be filled with deionized water prior to operation, as per the instructions in this section.

1. Open the rear panel of the device.
2. Open the Fill Port (Figure 3.0-1) and connect the funnel, tightening by turning the funnel connector halfway clockwise
3. Open the Vent Port
4. Prepare approximately 4.5 – 5.0L of deionized water
5. Ensure to hold the funnel higher than the Fill Port and slowly fill the funnel with deionized water until the water is just under the Water Level Bar.
6. Operate the device for about 30 seconds, and then turn power off.

7. Add deionized water until the water is just under the Water Level Bar.

IMPORTANT NOTE!

When the Darwin is powered for the first time, circulation of the water through the system requires the addition of more water.

8. Check the water level bar. When the water level rises above the red band, remove the funnel from the device and lock both the Vent Port screw and the Fill Port screw

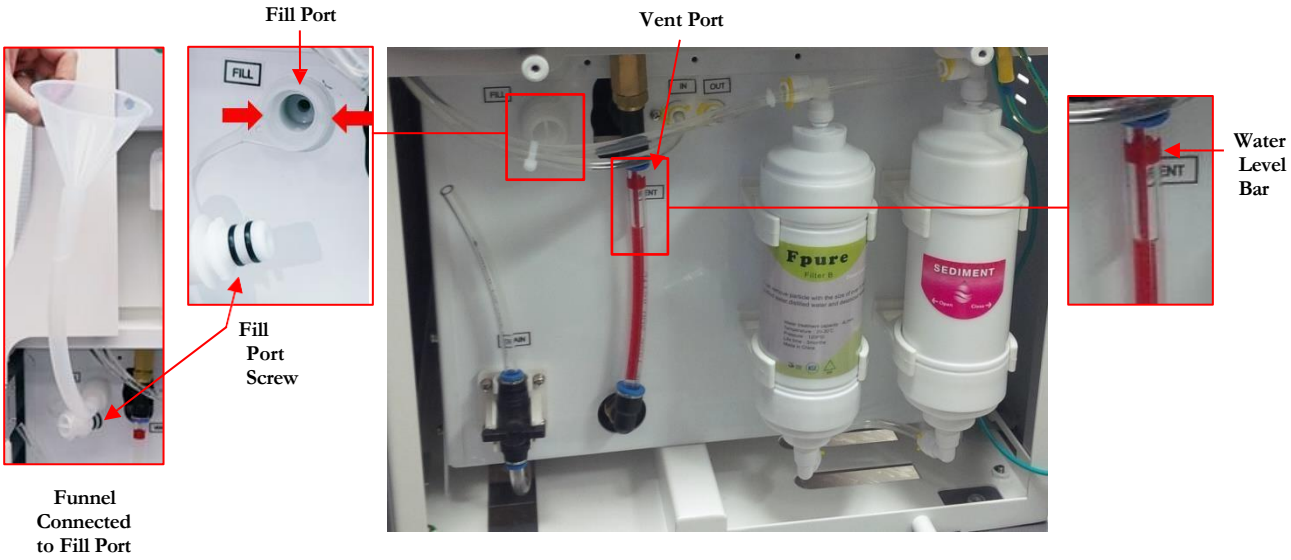


Figure 3.0-1: Filling the reservoir

CAUTION

Replace the deionized water every 3 – 6 months.

Inspect and maintain the Water Filter periodically (LUVO Medical recommends every 3 to 6 months), to keep the filter in peak operating condition.

LUVO Medical highly recommends replacing the water filter 3 to 6 months.

9. When draining the deionized water from the system:

   a. Place a container capable of holding a minimum of 2 liters (0.5 gallons) under the drain.

   b. Loosen the Vent Port screw.

   c. Unclip the Drain nozzle from the system (Figure 3.0-2). Remove the Drain Port screw and drain into container until drained dry.

Figure 3.0-2: Location of Drain Nozzle

CAUTION

LUVO Medical recommends draining the reservoir when storing the system.

3.4.2 Connecting the Darwin Diode Laser and IPL Handpieces

Check the Diode Laser and IPL handpiece sockets at the back of the Darwin for any damage, dirt, etc. Check the handpiece cord and umbilical cord connector for any damage. If damaged contact LUVO Medical's authorized representative.

Simultaneously hold the two (2) buttons located on either side of the umbilical cord connector in and carefully insert the connecter into the appropriate socket at the back of the system (Figure 3.0- 3), aligning all ports of the connecter to the ports of the socket, until two (2) clicks are heard. When connected, mount the handpiece in the appropriate handpiece cradle at the right side of system.

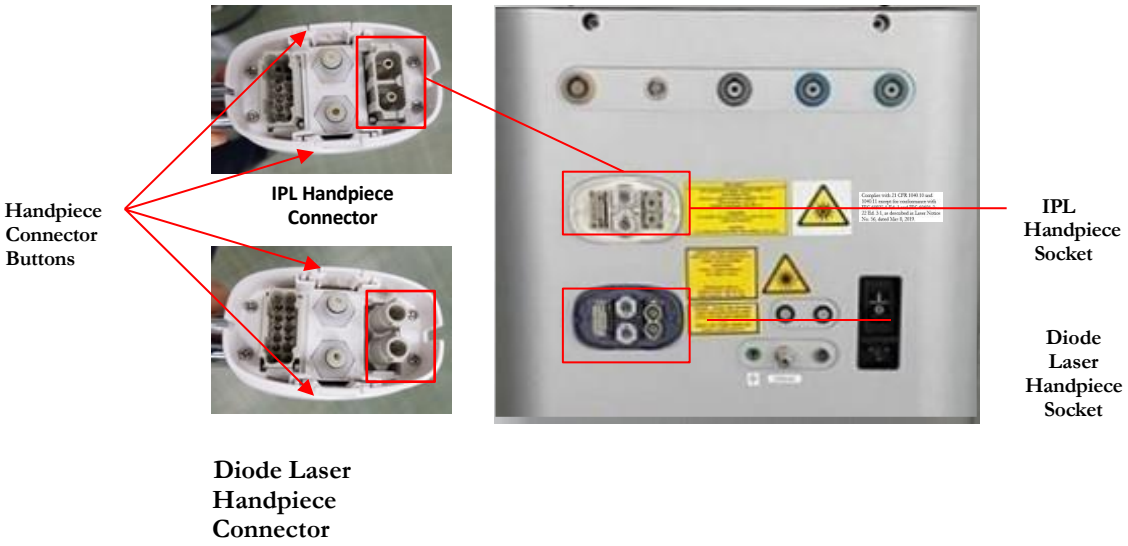


Figure 3.0-3: Location of IPL and Diode Laser handpiece sockets

3.4.3 *Connecting the IPL Filters to the IPL Handpiece*

The IPL handpiece requires filters to be inserted into the handpiece. If the filter is not inserted into the handpiece and the handpiece is connected to the system, the system will not operate until the filter has been inserted.

To insert the filter

1. Match the connection groove of the handpiece and the filter.
2. Press the filter firmly until the filter is fully seated in the handpiece (Figure 3.0-4(A)).
3. To remove the filter, grasp the filter and remove it by gently pulling the filter out (Figure 3.0-4(B)).

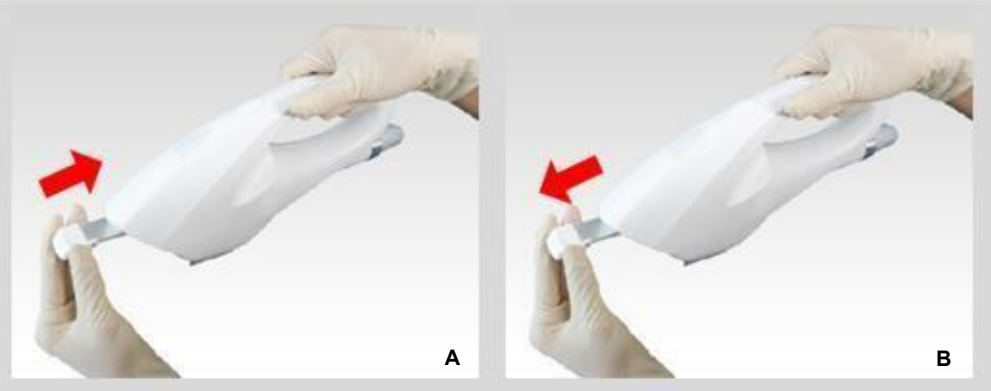


Figure 3.0-4: Insertion of filter into handpiece (A). Removal of filter (B)

3.4.4 *Connecting the Darwin HIFU Handpiece and Cartridges*

Check the HIFU handpiece socket at the back of the Darwin (Figure 3.0-5), for any damage, dirt etc. Check the HIFU umbilical cord and connector for any damage. If damaged contact LUVO Medical's authorized representative.

Carefully align the HIFU handpiece connector to the HIFU handpiece socket and connect. Place the HIFU handpiece in the appropriate handpiece cradle at the left side of the Darwin.

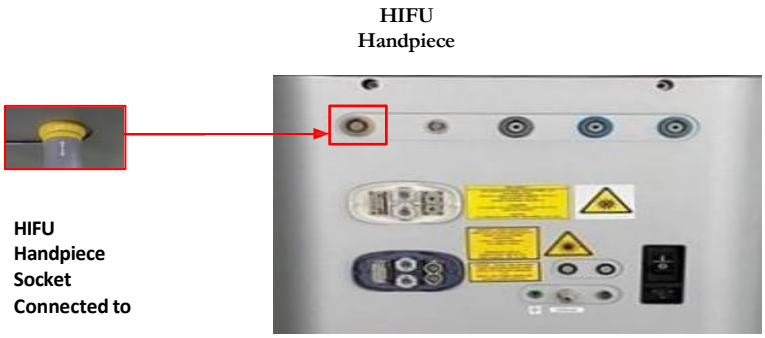


Figure 3.0-5: Location of the HIFU handpiece socket

The cartridges are connected to the HIFU handpiece, as follows:

1. Align the cartridge tracks into the handpiece tracks and gently slide the cartridge into the handpiece until the cartridge pin sockets connect with the handpiece cartridge pins (Figure 3.0-6).

WARNING

When the cartridge has Not been inserted, do NOT apply force to the Cartridge lock of the HIFU handpiece.

2. When the cartridge is correctly connected/seated, the system detects the cartridge, and the Touchscreen will display 'STANDBY' mode.

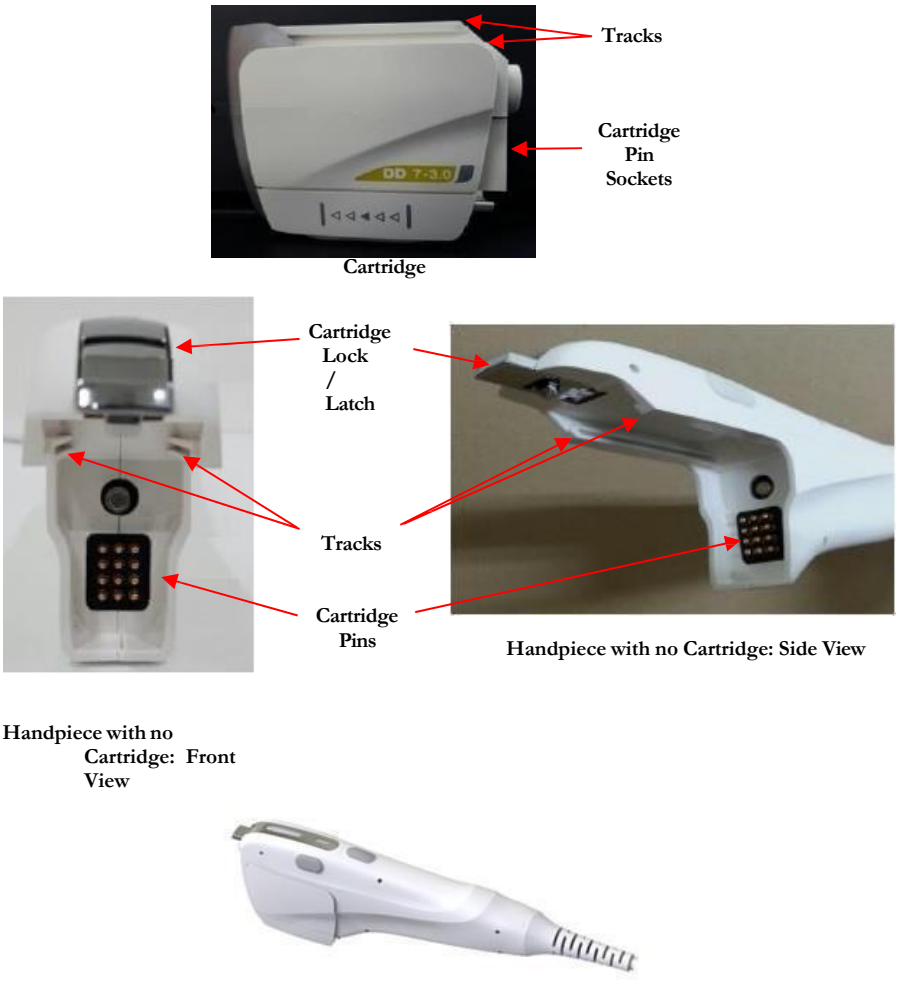


Figure 3.0-6: Connecting the HIFU cartridge to the handpiece.

3. To disconnect the cartridge, gently lift the Cartridge lock / latch on the HIFU handpiece (Figure 3.0-6) and slide the cartridge straight out of the handpiece. A beep will sound when the cartridge is disconnected.

3.4.5 Connecting the Darwin Needle RF Handpiece and Tips

Check the Needle RF handpiece socket at the back of the Darwin (Figure 3.0-7), for any damage,

dirt etc. Check the Needle RF umbilical cord and connector for any damage. If damaged contact LUVO Medical's authorized representative.

Carefully align the Needle RF handpiece connector to the Needle RF handpiece socket and connect. Place the Needle RF handpiece in the appropriate handpiece cradle at the left side of the Darwin.

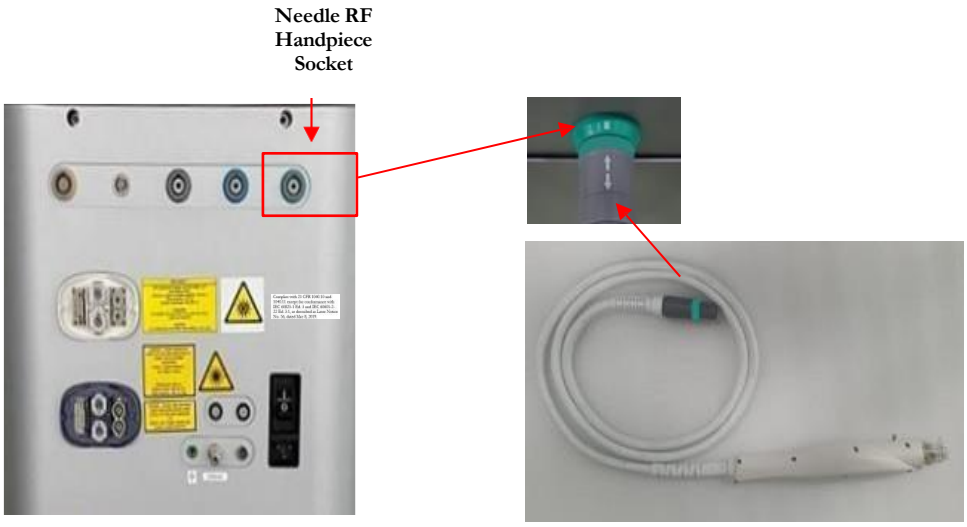


Figure 3.0-7: Location of Needle RF handpiece socket

Connect the RF Multi Needle tip by pressing both tabs on either side of the tip (Figure 3.0-8), simultaneously, while gently pushing the tip into the handpiece. To disconnect the Needle RF tip from the handpiece, press both tabs on either side of the tip (Figure 3.0-8), simultaneously, while gently pulling the tip away from the handpiece

Figure 3.0-8: Location of tabs on the Needle RF tip

The RF handpiece has a vacuum feature that requires the attachment of the vacuum tubing onto the handpiece and the tip. To attach the hose, carry out the following:

1. Ensure the Needle RF tip is securely attached to the handpiece (Figure 3.0-9(A))
2. Connect the one end of the hose to the Needle RF handpiece (Figure 3.0-9(B))
3. Connect the other end of the hose to the Needle RF tip (Figure 3.0-9(C))

Figure 3.0-9: Connecting the vacuum tube to the handpiece (A) and tip (B). Connect tip to the handpiece (C)

3.4.6 Connecting the Darwin Face Thermal RF Handpiece and Tips

Check the Face Thermal RF handpiece and Ground Pad, socket at the back of the Darwin (Figure 3.0-10), for any damage, dirt etc. Check the Face Thermal RF and Ground pad umbilical cord and connector for any damage. If damaged contact LUVO Medical's authorized representative.

Carefully align the Face Thermal RF handpiece and Ground Pad cable connectors to the Face Thermal RF handpiece socket and Ground Pad cable socket. Place the Face Thermal RF handpiece and Ground Pad (Figure 3.0-11) in the appropriate handpiece cradle at the left side of the Darwin.

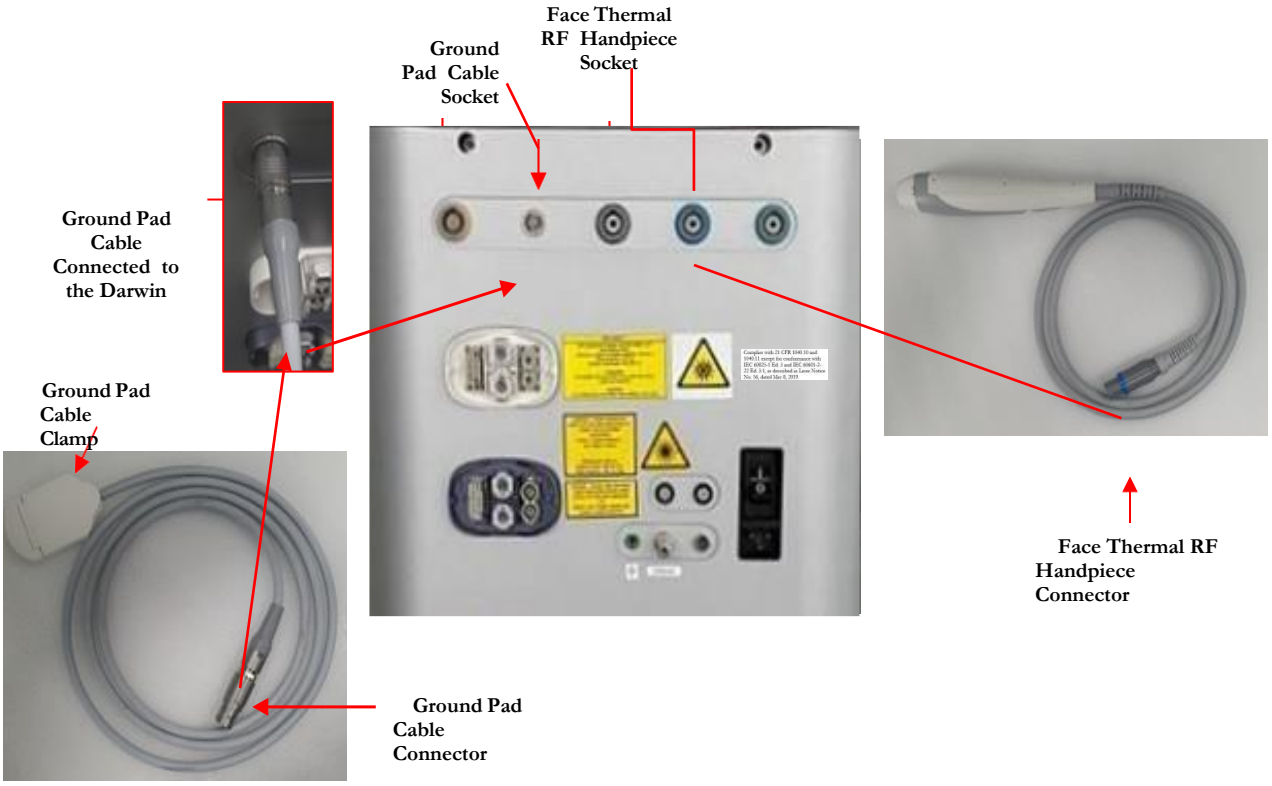


Figure 3.0-10: Location of the Face Thermal RF handpiece and Ground Pad Cable sockets

Figure 3.0-11: Location of ground pad cradle

The tips are connected to the Face Thermal RF handpiece, as follows:

1. Align the tip into the handpiece and gently slide the tip onto the handpiece (Figure 3.0-12(A)).

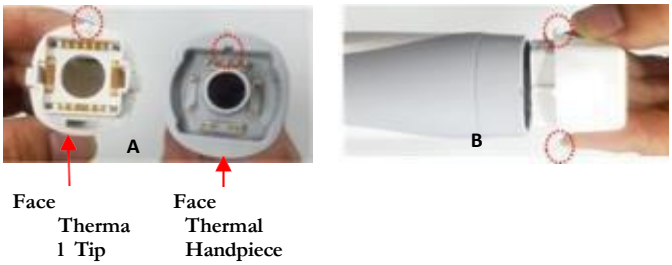


Figure 3.0-12: Face Thermal tip and handpiece connection

2. To disconnect the Face Thermal tip from the handpiece, press both tabs on either side of the tip (Figure 3.0-12(B)), simultaneously, while gently pulling the tip away from the handpiece

3.4.7 Installing the Power Cable and Safety Key

Connect the power cord to the back of the Darwin. Turn the main power switch on. Insert the safety key into the key slot at the front of the Darwin, turning clockwise to start and counter-clockwise to stop the power (Figure 3.0-15).

WARNING

Ensure the Darwin is plugged into the Wall outlet
Do NOT plug into a multi-outlet, extension cord or power bar

Figure 3.0-15: Key position

3.4.8 Connecting the Footswitch

The footswitch is connected as per Figure 3.0-16.

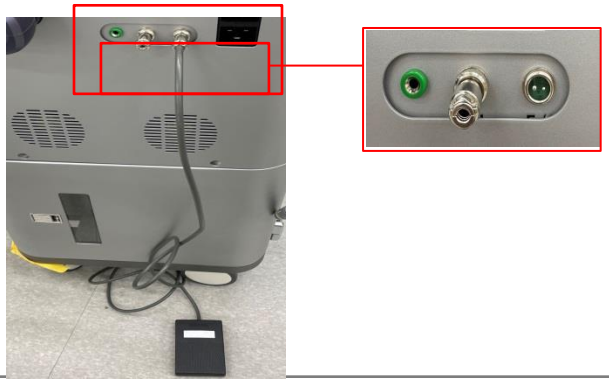


Figure 3.0-16: Footswitch connection

3.4.9 Connecting the Interlock

The interlock is connected as per Figure 3.0-17. When the interlock is disconnected during treatment, an error message is displayed and the system stops operating.

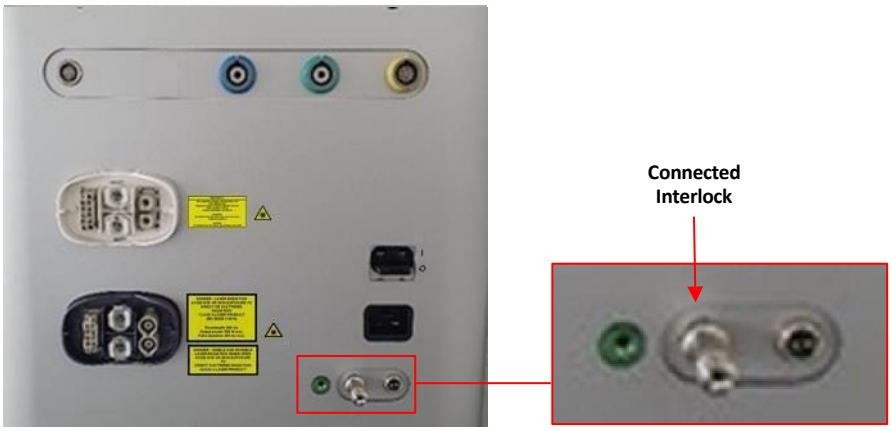


Figure 3.0-17: Location of the interlock connection

3.5 Moving and Transportation

IMPORTANT NOTE

LUVO Medical recommends draining the water reservoir prior to storing the system for any length of time.

To move the system within the treatment setting, follow the instructions below:

1. Ensure the diode and IPL handpieces are placed into the original cases before movement or transportation. Ensure the other handpieces are disconnected and carried separately during movement or transportation.
2. Disconnect the power cord from wall outlet
3. Release the system wheel brakes
4. Ensure to use the handle on the front and the back of the system to move the system to the desired area

WARNING

Use care when moving the system

Do NOT move the system using the touch screen, handpieces, power cord, etc.

Do NOT handle roughly, drop, shock or shake the system.

Transport/Movement condition: If any movement of the Darwin console is required. The Diode and IPL handpieces are sent with their own cases for transport, the remaining handpieces will also need to be disconnected and carried separately to the Darwin Console. Not following this instruction can cause an overbalance risk.

5. Ensure brakes are locked when the system has been placed in the desired location.

4.0 Device Description

The Darwin System is a stand-alone, software-controlled, electrically powered, multi-technology platform intended for professional use in dermatologic, aesthetic, and dry eye disease-related procedures. The device combines multiple energy-based technologies in one platform through dedicated handpieces. The Darwin System includes diode laser, intense pulsed light, high-intensity focused ultrasound, RF microneedling, and thermal RF technologies. The system consists of the following:

- Console
- Darwin Diode Laser Handpiece
- Darwin IPL Handpiece with Filters
- Darwin HIFU Handpiece with Cartridges
- Darwin Needle RF Handpiece with Tips
- Darwin Face Thermal RF Handpiece with Tips

The Darwin console (Figure 1 and Figure 2) is the central control unit of the system and incorporates the LCD touchscreen user interface, safety key switch, main power switch, emergency stop button, interlock connection, cooling system, internal cooling fans, and lockable caster wheels. The LCD touchscreen provides the primary user interface for system operation, treatment parameter selection, and monitoring of device status. The integrated cooling system consists of a water reservoir, water pump, radiator, temperature sensors, and water level sensors, which are monitored and controlled through the system I/O control board to maintain appropriate operating conditions. Internal cooling fans provide thermal management for the electronic components within the console during operation.

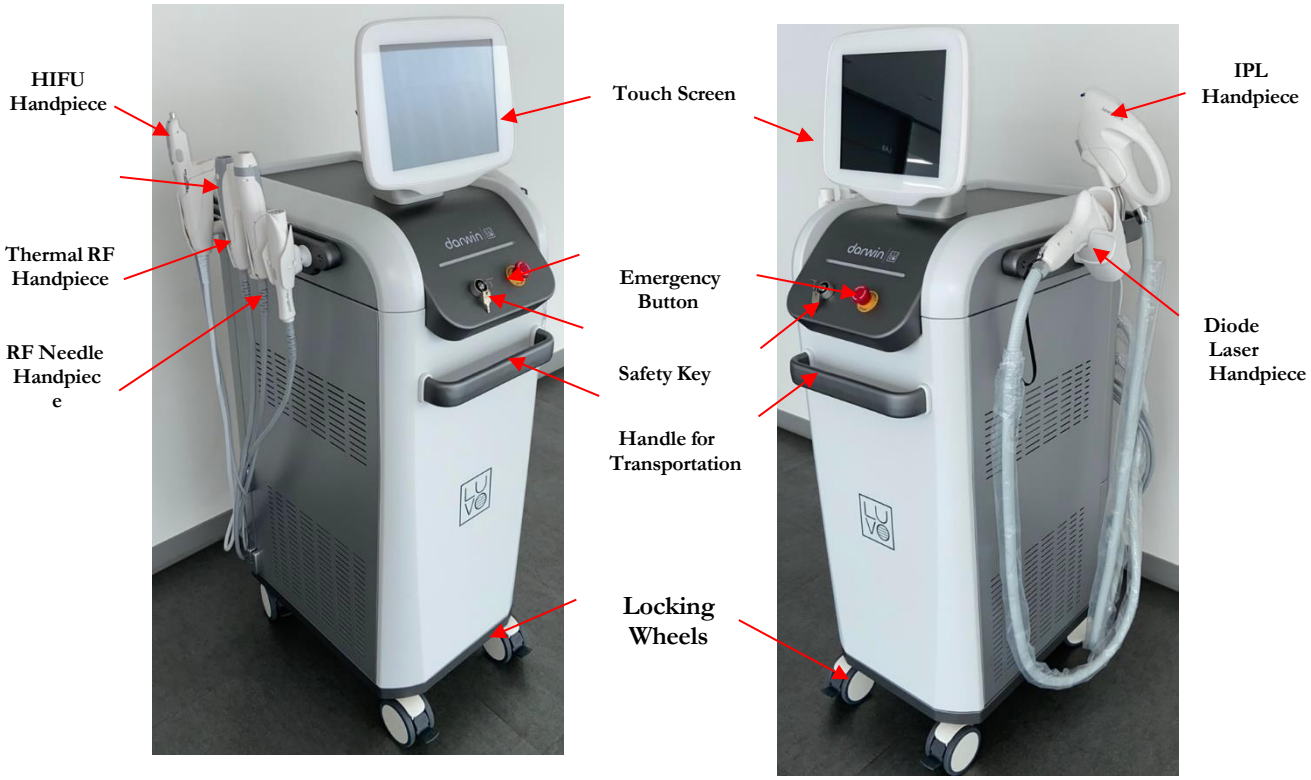


Figure 4.0-1: Darwin system (Front)

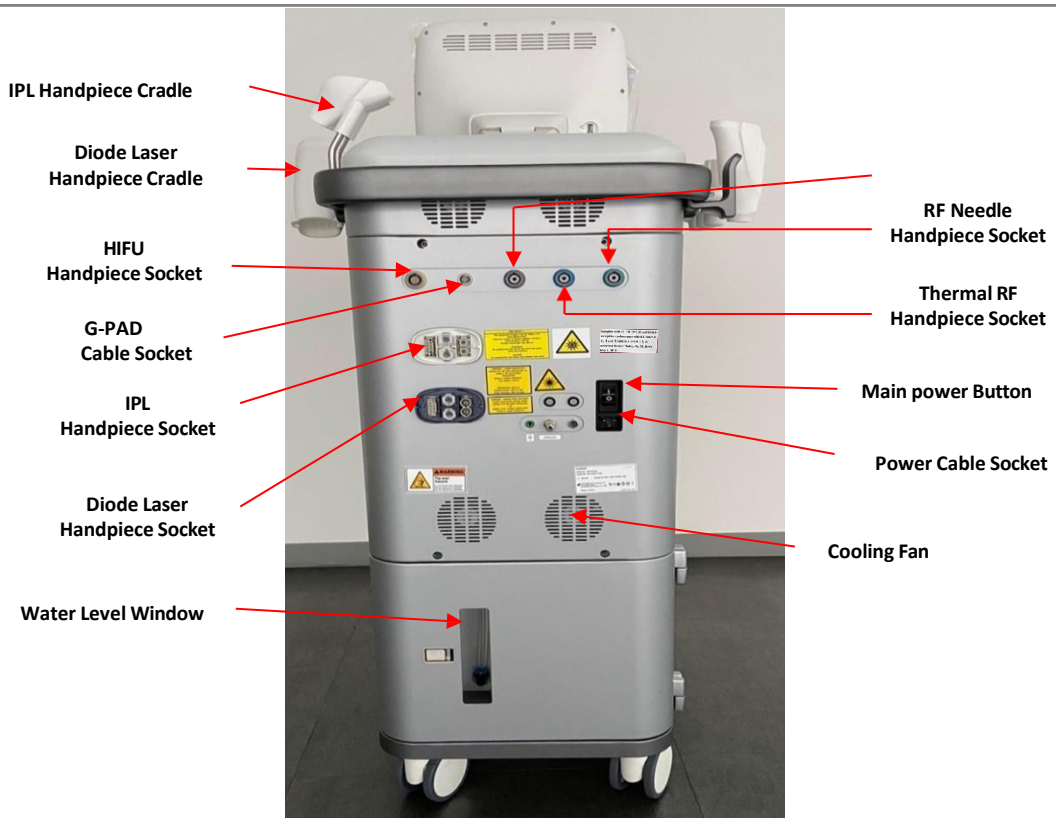


Figure 4.0-2: Darwin system (back)

The console is equipped with lockable caster wheels to facilitate movement of the device between treatment locations while ensuring stability during clinical use by preventing unintended movement. The Darwin system may be operated using either the handpiece activation switch or an optional footswitch. When the footswitch is connected by the user, the activation mode can be selected through the footswitch icon displayed in the upper right-hand corner of the touchscreen interface. Once enabled, treatment energy is delivered using the footswitch in place of the handpiece activation control.

Technology / Handpiece	Description
Diode Laser Handpiece	808 nm GaAs diode laser with sapphire cooling tip for hair removal and permanent hair reduction.
IPL Handpiece	Intense Pulsed Light handpiece with interchangeable filters including 430 nm, 515 nm, 560 nm, 585 nm, 640 nm, 700 nm and 755 nm.
HIFU Handpiece	High-Intensity Focused Ultrasound handpiece with cartridges for focal depths of approximately 1.5 mm, 3.0 mm and 4.5 mm.
Needle RF Handpiece	Bipolar RF microneedling handpiece using sterile, single-use 10-pin and 25-pin needle tips.
Face Thermal RF Handpiece	Monopolar and bipolar RF handpiece for non-invasive thermal treatment of skin.
Accessories	Foot switch, interlock connector, vacuum hose for Needle RF, HIFU cartridges, IPL filters, Thermal RF tips, G-Pad connector cable, safety keys, funnel hose

Wheels on the system help move the system and can be locked to prevent the system from moving during treatment.

4.1 Darwin Diode Laser Handpiece

The ergonomically designed handpiece controls the output of the laser through the sapphire tip lightguide (Figure 4.0-3). The handpiece contains the diode, Peltier, temperature sensor, trigger and the LED indicator.

Figure 4.0-3: Darwin diode laser handpiece

Laser emission is enabled only when the operator switches to READY mode and presses the trigger on the handpiece or triggers the footswitch. The trigger reduces the risk of unintentional laser emission.

The lightguide must completely be in contact with the treatment area.

WARNING

ONLY direct the laser beam at the treatment site. There is a potential hazard to cause serious injury or blindness of stray laser light.

4.1.1 LED Indicator

The LED indicator is a visual clue indicating the Lightguide tip's temperature when in READY mode (Figure 4.0-4).

Figure 4.0-4: LED indicator for the Diode Laser handpiece

Table 4.0-1 describes the different LED indicators. When the system is in STANDBY mode, the LED is off.

Table 4.0-1: LED indicator

LED Colour	Temperature	Mode
Green	Under 25°C	READY
Brown	26°C - 40°C	READY
Orange	41°C - 44°C	READY

4.2 Darwin IPL Handpiece and Filters

The Darwin IPL handpiece is ergonomically designed for easy grip, with the start button is placed in easy reach by the thumb (Figure 4.0-5). Treatment is carried out using the Darwin IPL handpiece with the filter attached.

Figure 4.0-5: Darwin IPL handpiece

The LED is orange when the device is in 'STANDBY' mode and blue when in 'CHARGING' and green when in 'READY' mode (Figure 4.0-6).

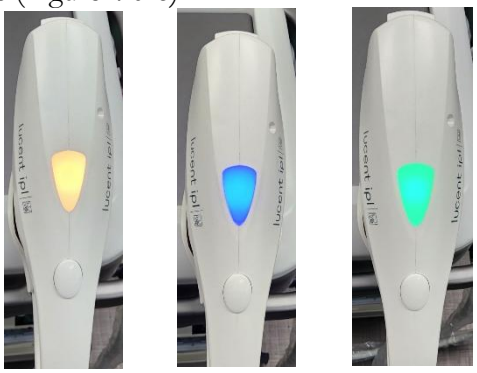


Figure 4.0-6: LED indicator for the IPL handpiece

The handpiece plugs into the system via the handpiece plug, Cooling water and energy is delivered through the umbilical cord to the handpiece. When the handpiece is disconnected from the system, there is the potential for cooling water to leak from the handpiece plug. Therefore, prepare a dry clean towel to wipe any access water on or around the handpiece and device.

WARNING

Do NOT unplug the Darwin IPL handpiece when in READY mode.

The Darwin IPL handpiece comes with a total of six (6) filters (Figure 4.0-7) - 430nm, 515nm, 560nm, 585nm, 640nm filters used in ST mode and the 700nm, 755nm filter is used in HR mode.

Figure 4.0-7: Darwin IPL handpiece filters

4.3 Darwin HIFU Handpiece with Cartridges

The Darwin HIFU handpiece contains the start button, LEDs to indicate the operating mode (Figure 4.0-8) and three cartridges that slide into place on the handpiece. Refer to section 3.4.4 Darwin Connecting HIFU Cartridges for instructions to connect the cartridge to the handpiece.

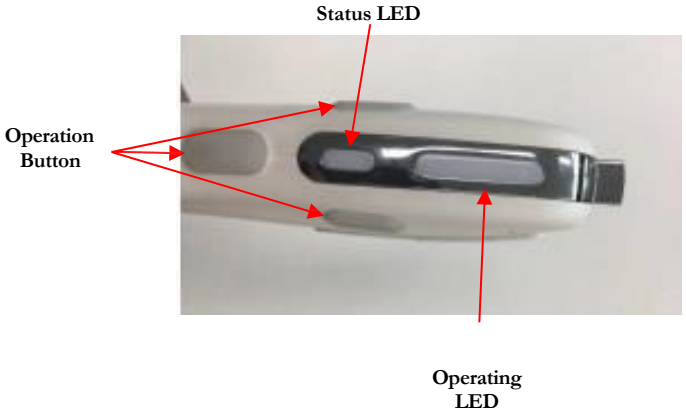
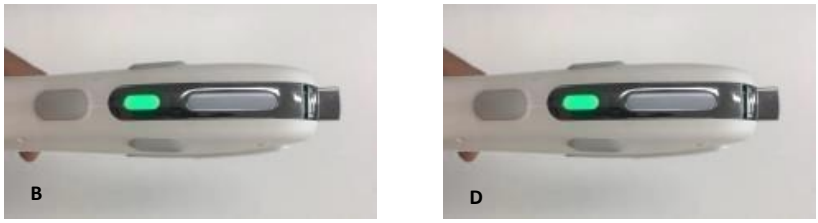


Figure 4.0-8: Darwin HIFU handpiece

In 'STANDBY' mode, no LEDs are lit (Figure 4.0-9(A)). In 'READY' mode, the status LED turns green (Figure 4.0-9(B)). When the system is operating, the status LED turns blue and the operating LED blinks blue/green during operation (Figure 4.0-9(C)). When the system has stopped operation, the status LED turns green ('READY' mode) and the operating LED is not lit (Figure 4.0-9(D)).

STANDBY

Operating



READY READY

Figure 4.0-9: STANDBY mode (A); READY mode (B); Operating mode (C); READY mode when operating mode is stopped (D)

Three cartridges come with the system SM 4-4.5, DD7-3.0, and SD7-1.5 (Table 4.0-2).

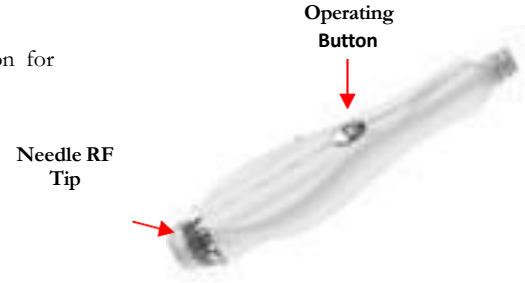
Table 4.0-2: Cartridges

Cartridges		
SM 4-4.5	**DD7-3.0**	**SD7-1.5**
		

4.4 Darwin Needle RF Handpiece with Tips

The ergonomically designed Darwin Needle RF handpiece comprises of a start button, LED to indicate the operating mode, two tips (10-PIN and 25-PIN), and vacuum hose connecting the handpiece and tip to the vacuum (Figure 4.0-10).

Figure 4.0-10: Location operating button for Needle RF Handpiece



In STANDBY mode, no LED is lit (Figure 4.0-11(A). In READY mode, the Status LED is green (Figure 4.0-11(B). In Operating mode, the Operating LED is blue (Figure 4.0-11(C). When the operating mode has stopped, the Operating LED is green (READY mode) and the Status LED is not lit (Figure 4.0-11(D).

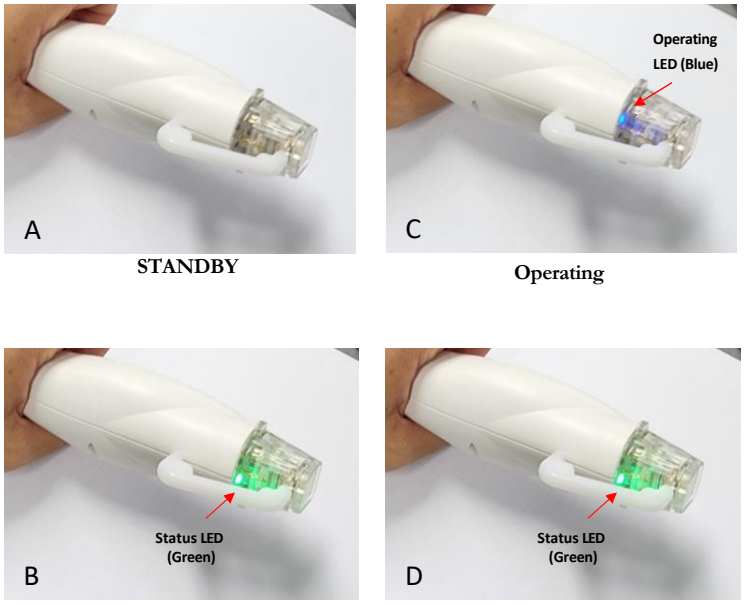


Figure 4.0-11: STANDBY mode (A); READY mode (B); Operating mode (C); READY mode when operating mode is stopped (D)

The bipolar RF output level can be adjusted by the user using pre-set Levels 1 to 6. The vacuum helps to draw the treated area evenly to the tip and vacuum levels are adjustable using pre-set Levels 0 to 3. .

The sterile, single-use, Darwin Needle RF tips come as 10PIN and 25PIN. The needles extend and can reach depths of 0.5mm to 3.5mm (Figure 4.0-12).

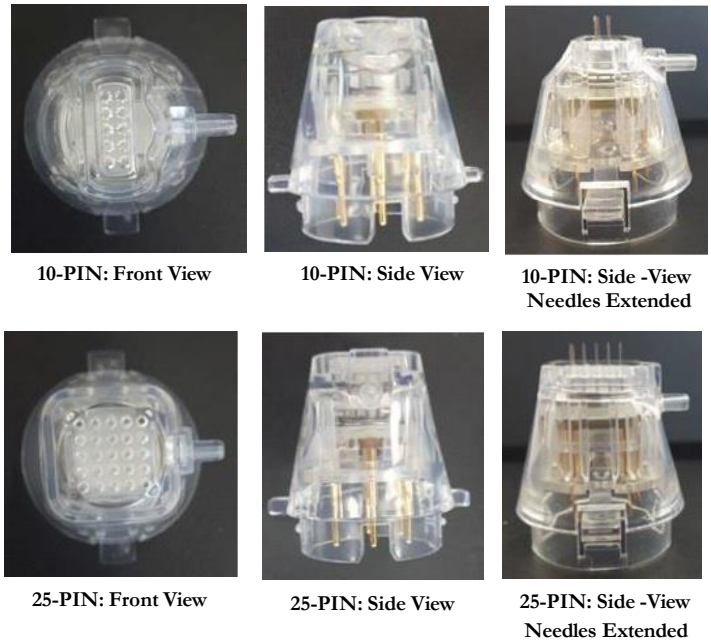


Figure 4.0-12: Darwin Needle RF tips

4.5 Darwin Face Thermal RF Handpiece with Tips

The ergonomically designed, monopolar/bipolar Face Thermal RF handpiece comprises of a start button, LED to indicate the operating mode, and tips (Figure 4.0-13).

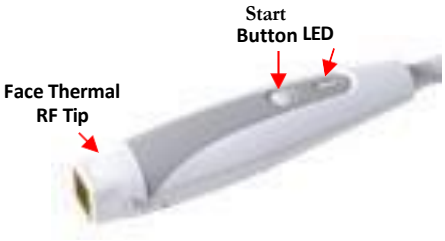


Figure 4.0-13: Darwin Face Thermal RF handpiece

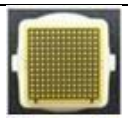
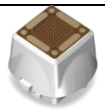
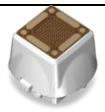
The LED is a visual indicator regarding when the handpiece in the READY and OPERATION mode. In STANDBY mode, no LED is lit. In READY mode, the Status LED is green.
In Operating mode, the LED is blue (Figure 4.0-14).

Figure 4.0-14: LED is green in READY mode and blue when operating.

READY Operating

Five (5) types of tips available for the Darwin Face Thermal RF handpiece are outlined in Table 4.0-3

Table 4.0-3 Darwin Face Thermal RF tips

Darwin RF Thermal Tips					
	TRF-S	**TRF-R**	**TRF-E**	**FRF Tip-64**	**FRF Tip-100**
Tip					
Feature	Shot	Continuous	Continuous	Shot	Shot
Life of Tip	2000 shots	3600 secs	3600 secs	1000 shots	1000 shots

4.5.1 Ground Pad Cable and G-pad Use

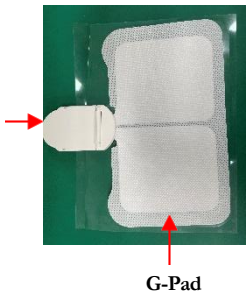


Figure 4.0-15: G-Pad with clamp attached.

The Darwin system is supplied with a ground pad cable intended for connection to a compatible, medically approved dispersive electrode (G-Pad). The G-Pad is required only when using the Face Thermal handpiece and associated treatment tips. Due to the monopolar radiofrequency (RF) operating principle of the Face Thermal handpiece, a compatible G-Pad must be properly applied to the patient before RF energy can be delivered.
The Face Thermal handpiece will not operate unless the ground pad cable is connected and an appropriately applied G-Pad is detected.
The G-Pad is not supplied with the Darwin system and shall be obtained separately. Only G-Pads that are compatible with the Darwin system and intended by their manufacturer for use with monopolar RF medical or aesthetic devices shall be used.
Before initiating treatment, verify that the G-Pad is correctly positioned on intact skin in accordance with the G-Pad manufacturer's instructions and that the ground pad cable is securely connected to the Darwin system. Do not initiate treatment if the G-Pad is damaged, improperly connected, inadequately adhered, or otherwise unsuitable for use. Failure to ensure proper G-Pad application may result in ineffective treatment or unintended patient injury.

4.6 Footswitch.

The Darwin can also be operated using the footswitch. The footswitch icon located on the top right-hand corner of the touchscreen, is pressed when the footswitch is to be used instead of the handpieces. Table 4.0-5 identifies the different icons.

Table 4.0-5: Footswitch and handpiece icon identification

Icon	Description
	Footswitch icon – same for all of the handpiece features
	Diode Laser handpiece icon
	IPL handpiece icon
	HIFU handpiece icon
	Needle RF handpiece icon
	Face Thermal RF handpiece icon

To use footswitch:

5 Connect the footswitch to the device, as per section 3.4.8 Connecting the Footswitch

6 The handpiece icon of the selected handpiece is the default. Press the handpiece icon to switch to the footswitch icon.

7 Footswitch shall be covered with the cover of footswitch.

4.7 Intended Purpose:

The Darwin System is a multi-functional active energy-based device intended for both medical and non-medical (aesthetic) applications. The medical intended purpose includes the treatment of the symptoms of Dry Eye Disease (DED), while the non-medical intended purposes include aesthetic procedures. The Darwin system combines multiple technologies for use in dermatologic and aesthetic procedures, in one stand-alone device. The device combines multiple energy-based technologies in one platform through dedicated handpieces.

Handpieces include a Diode laser with sapphire Chiller tip, IPL, HIFU, Needle RF, monopolar/bipolar Face Thermal RF.

4.7.1 Diode laser handpiece: intended for hair removal and permanent hair reduction on skin types (Fitzpatrick skin types I - V). Delivering a pulsed light using a coherent light source of 808nm wavelength, The user can choose from two modes: hair removal shot (HRS) and hair removal moving (HRM) when using the Diode laser handpiece.

4.7.2 IPL Handpiece: a non-invasive Intense Pulsed Light (IPL) intended to be used in dermatology and plastic surgery. In ST mode, filters 430nm, 515nm, 560nm, 585, and 640nm are used for a variety of aesthetic treatments in skin types I - IV. In HR Mode, the 700nm, 755nm filter is used for removal of unwanted hair and

to effect stable long term, or permanent hair reduction in skin types I-V through selective targeting of melanin in hair follicles. The 585 nm Filter of IPL is intended for Treatment of symptoms of dry eye disease.

4.7.3 HIFU Handpiece: The non-invasive HIFU handpiece with three (3) detachable cartridges is intended for dermatological aesthetic treatments intended to improve the appearance of skin through focused ultrasound energy delivery

4.7.4 Needle RF handpiece: operates using sterile, single-use, multi-needle tips (10 pin and 25 pin) and is intended for tissue coagulation designed to stimulate and remodel, fine lines, wrinkles, photoaging and striae.

4.7.5 Face Thermal RF: non-invasive, monopolar/bipolar RF handpiece intended to improve the appearance of skin texture and elasticity by transferring low level of thermal energy to the treatment area.

4.8 Indication for use:

4.8.1 Darwin Diode Laser Handpiece: The Darwin Diode Laser handpiece is intended for hair removal and permanent hair reduction on skin types (Fitzpatrick skin types I - V). The System allows user to choose from two modes the hair removal shot (HRS) and hair removal moving (HRM).

4.8.2 Darwin IPL Handpiece with Filters: The IPL Handpiece is a non-invasive Intense Pulsed Light (IPL) intended to be used in dermatology and plastic surgery. In ST mode, filters 430nm, 515nm, 560nm, 585nm, and 640nm are used for the following aesthetic treatments for skin types I – IV:

- Benign pigmented epidermal and cutaneous lesions including dyschromia, hyperpigmentation, melasma, Ephelides (freckles), scars, and striae. [515 nm, 560 nm or 640 nm Filter]
- Benign cutaneous vascular lesions, including port wine stains, hemangiomas, facial and truncal telangiectasias, rosacea, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte and Solar Lentigines [585 nm or 560 nm Filter]
- Mild to moderate inflammatory acne (acne vulgaris). [430 nm Filter]
- Removal of unwanted hair and stable long term, or permanent hair reduction in skin types I-V through selective targeting of melanin in hair follicles [700 nm, 755 nm Filter]
- Medical indication: The 585 nm Filter is intended for treatment of symptoms of dry eye disease

4.8.3 Darwin HIFU Handpiece with Cartridges: The Darwin HIFU handpiece is indicated for use as a non-invasive dermatological aesthetic treatment to lift the eyebrow, lift lax submental and neck tissue, which can also affect the appearance of lax tissue in the submental and neck regions, improve lines and wrinkles of the décolleté.

4.8.4 Darwin Needle RF Handpiece with Tips: The Needle RF is indicated for tissue coagulation designed to stimulate and remodel collagen, fine lines, wrinkles, photoaging and striae.

4.8.5 Darwin Face Thermal RF Handpiece with Tips: The Darwin Face Thermal RF is intended to help improve the appearance of skin texture and elasticity. The treatments can be performed in Fitzpatrick Skin Types I-V

4.9 Intended user

The Darwin System is intended to be used only by licensed physicians, trained healthcare professionals, or trained operators The device is not intended for home use or use by lay persons.

4.10 intended patient population: Adults

The Darwin System is intended for adult 18 and older male and female patients or consumers suitable for energy-based dermatologic, aesthetic, or dry eye disease treatment. The intended population includes adults seeking hair removal or permanent hair reduction; adults seeking aesthetic improvement of skin texture, elasticity, fine lines, wrinkles, photoaging, striae, laxity, or general skin appearance; patients with symptoms of Dry Eye Disease suitable for IPL treatment as determined by a healthcare professional; and Fitzpatrick

Skin Types I–V, where applicable to the intended treatment modality. Use in children, pregnant women, breastfeeding women, or other vulnerable populations is not specifically intended.

5.0 Operation

Before attempting any treatment procedures, read Section 2.0 Safety of this user manual. Be aware of the hazards when using the Darwin and take appropriate protective measures

WARNING

Failure to thoroughly review and adhere to the information contained in this Operator's Manual may pose a potential hazard to the patient and/or user.

Prior to using the system, ensure the following:

- Inspect the console, both handpieces and cartridges for any damage and/or dirt. Do NOT use if damage is detected. Clean any dirt as per section 6.0 Maintenance and Cleaning
- Inspect handpiece and power cords for cracks, frays or other damage. Do NOT use if cracks, frays or other damage has been detected.
- If treating with the Darwin IPL Handpiece, ensure the desired filter is ready for use.
- If treating with the Darwin HIFU Handpiece, ensure the desired cartridge for the treatment is ready for use.
- If treating with the Darwin Needle RF Handpiece, ensure the desired tip is ready for use. The Darwin Needle RF tips are sterile.
- If treating with the Darwin Face Thermal RF Handpiece, ensure the desired tip is ready for use.

5.1 Initial Start Up

5.1.1 Power

Check the power cable connection and power supply to ensure the main power switch is on.

5.1.2 Safety Key

The Darwin requires the safety key to be inserted to operate the system (Figure 5.0-*). Insert the key into key slot at the front of the Darwin, turning clockwise to start and counter-clockwise to stop the power.

CAUTION

Ensure the safety key is removed when not in use.
Store safety key in a secure place to ensure only authorized personnel can use the system.

5.1.3 External Door Interlock

The external door interlock is a safety feature. The Darwin is automatically disabled, an error message appears, and the Darwin returns to STANDBY mode, if the treatment room doors are opened or the interlock plug is removed during treatment.

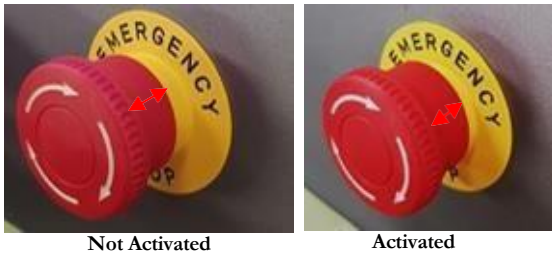
The interlock must be plugged into the interlock receptacle at the back of the system, for the Darwin to work and will remain inoperable until the interlock is plugged in.

5.1.4 Emergency Button

For emergencies, press the emergency button in and the power shuts off.

If the emergency knob has been activated (pushed in), turn the emergency knob clockwise until the knob releases and pops up (Figure 5.0-1).

Figure 5.0-1: Emergency button activation



Not Activated Activated

5.2 System Shut-Down

The following instructions ensure proper shut down of the system:

1. Set the system to STANDBY mode.
2. Turn the key switch to counter-clockwise.
3. Set the main power switch at the back to the 'OFF' position.
4. Disconnect the power cord from the wall outlet.
5. Clean the system as per section 6.0 Maintenance and Cleaning.
6. Ensure the handpiece(s) is/are securely seated in the appropriate handpiece cradle.

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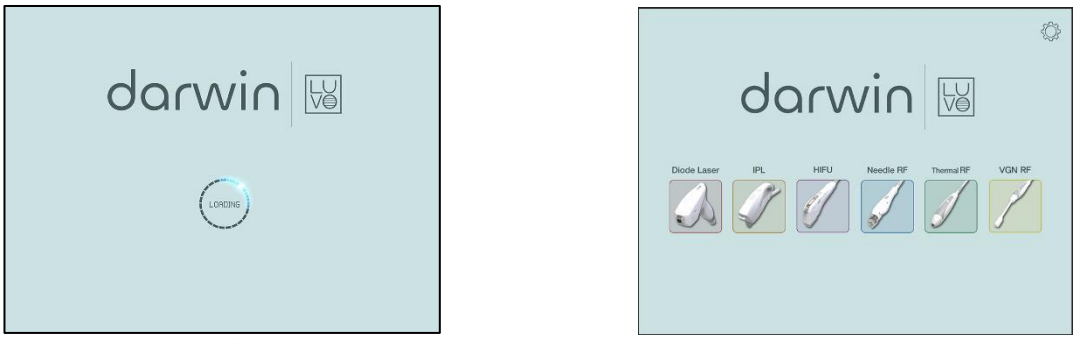
5.3 Loading and Home Screen

When the system has been set-up as per section 3.0 Installation, the loading screen appears (Figure 5.0-2). System check is automatically performed during the loading time.



Loading Screen **Home Screen**

Figure 5.0-2: Darwin loading screen and Home screen

To troubleshoot the error, refer to section 7.0 Troubleshooting.

When the internal checks do not encounter an error, the Home screen is opened to select the desired handpiece (Figure 5.0-2)

5.4 Darwin Diode Laser Handpiece Screen

From the Home screen (Figure 5.0-*) select the Diode Laser handpiece. The Diode Laser handpiece loading screen will appear (Figure 5.0-3), Internal function checks are automatically carried out for this handpiece during the loading of the screen.

Figure 5.0-3: Diode Laser handpiece loading screen

To troubleshoot the error, refer to section 7.0 Troubleshooting.

When internal checks do not encounter an error, the default, HRS mode screen pops up.

5.4.1 HRS Mode Screen

HRS mode is the default mode (Figure 5.0-4). HRS (Hair Removal Shot) mode is used when a 'static' method of hair removal is desired. Higher energy is used in this mode via firing of multiple pulses to deliver the energy, allowing the skin to cool (very briefly), between pulses, helping to reduce the risk of burns to darker skin types. Table5.0-1 describes the features of the HRS screen.

Figure 5.0-4: Darwin diode laser screen, HRS mode

Table 5.0-1: Details of HRS mode screen

No.	Description	No.	Description
1	Image of selected handpiece	10	Pulse Type: Select single, double or triple pulse mode per shot
2	Home icon: Takes the user back to the initial screen	11	PULSE: Adjust the pulse range between 5 – 400ms in 1ms units
3	HRS (hair removal shot mode): Activated (blue)	12	FLUENCE: Adjust the fluence range between 5 – 60 J/cm² in 1 J/cm² units
4	HRM (hair removal moving mode): Not activated (dark green)	13	Save Icon: Saves selected settings for the present treatment
5	TEMP: Temperature of the handpiece tip is displayed	14	Handpiece icon: Select handpiece or footswitch icon to operate the system
6	SHOT COUNT: Number of shots used during treatment. Press 'RESET' to change the shot count to zero	15	Settings icon: Select volume in the settings screen
7	ST (Skin Type): Select Fitzpatrick Skin Type	16	STANDBY / READY indicator
8	HC (Hair Colour): Select for blonde, red, light brown, dark brown black hair	17	Pulse Continuous shot (OFF, 1Hz, 1.5Hz, 2Hz)
9	HT (Hair Texture): Select for fine, medium or coarse hair	18	Pulse set button (if pressed, input can be done with the number pad)

* After adjusting Skin type, Pulse, Frequency, and Fluence values in HRS and HRM mode, change to maintain the previously adjusted values when returning after setting menu or mode change (HRS->HRM, HRM->HRS)

5.4.2 HRM Mode Screen

When the HRM mode is selected at the side of the screen (Figure 5.0-5), the HRM mode features are available. The HRM (Hair Removal Moving) mode is used when a 'motion' method of hair removal is desired. The handpiece is moved over the area in a multi pass format, so less energy is used as heat is built in the hair follicle. Table 5.0-2 describes the features of the HRM screen.

Figure 5.0-5: Darwin diode laser screen, HRM mode

Table 5.0-2: Details of HRM mode screen

No.	Description	No.	Description
1	Image of selected handpiece	10	PULSE: Adjust the pulse range between 5 – 266ms in 1ms units
2	Home icon: Takes the user back to the initial screen	11	FREQUENCY: Select frequency range of 3Hz – 10Hz in 1Hz units
3	HRM (hair removal moving mode): Activated (blue)	12	FLUENCE – Select fluence range of 5 – 30 J/cm² in 1 J/cm² units
4	HRS (hair removal shot mode): Not activated (dark green)	13	Save Icon: Saves selected settings for the present treatment
5	TEMP: Temperature of the handpiece tip is displayed	14	Handpiece icon: Select handpiece or footswitch icon to operate the system
6	SHOT COUNT: Number of shots used during treatment. Press 'RESET" to change the shot count. to zero	15	Settings icon: Select volume in the settings screen
7	ST (Skin Type): Select Fitzpatrick Skin Type	16	STANBY / READY indicator
8	HC (Hair Colour): Select for blonde, red, light brown, dark brown, black hair	17	Pulse set button (if pressed, input can be done with the number pad
9	HT (Hair Texture): Select for fine, medium, or coarse hair		

* After adjusting Skin type, Pulse, Frequency, and Fluence values in HRS and HRM mode, change to maintain the previously adjusted values when returning after setting menu or mode change (HRS->HRM, HRM->HRS)

5.5 Darwin IPL Handpiece Screen

After selecting the Darwin IPL handpiece icon on the Home screen, the IPL screen will appear (Figure 5.0-6). Internal function checks are automatically carried out for this handpiece during the loading of the screen.

Figure 5.0-6: Darwin IPL handpiece loading screen

To troubleshoot the error, refer to section 7.0 Troubleshooting.

When internal checks do not encounter an error, the filter that is inserted into the IPL handpiece indicates the mode screen that is displayed.

Ensure the filter is inserted prior to selecting the Darwin IPL handpiece icon. If a filter has not been inserted into the handpiece, the system detects this and displays a warning message (Figure 5.0-7). The system will not operate until a filter has been inserted. Refer to section 3.4.3. Connecting the IPL Filters to the IPL Handpiece.

Figure 5.0-7: Warning message for filter

5.5.1 ST Mode Screen

IPL aesthetic treatments using the 430nm, 515nm, 560nm, 585nm, and 640nm filters are carried out in ST mode (Figure 5.0-8). Table 5.0-3 outlines the features of the ST mode screen.

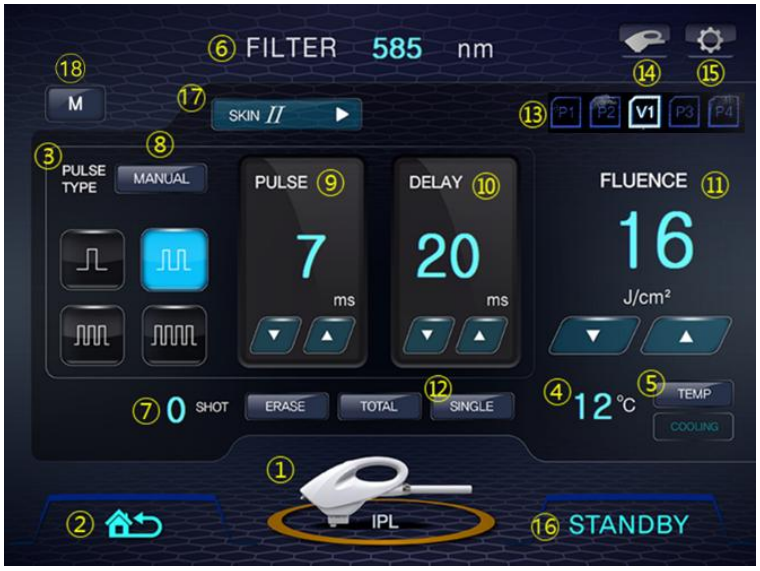


Figure 5.0-8: ST mode screen

Table 5.0-3: ST mode features

No.	Description	No.	Description
1	Image of selected handpiece	10	DELAY: Adjusted 1-50ms for the double and triple pulse
2	Home icon: Takes the user back to the initial screen	11	FLUENCE: Adjusted 6 to 35J/cm²
3	Pulse Type: Select single, double, triple or toning	12	SINGLE/REPEAT: Shot mode. Select single shot or continuous shot
4	CURRENT TEMPERATURE: Displays current temperature of the handpiece. Cooling: Cooling function ON/OFF display (Auto display) (STANDBY mode: maintain 5℃, READY mode: maintain -10℃)	13	Save Icon: Saves selected settings for the present treatment
5	TEMP USER SETTING: Pop-up window allows the adjustment of the handpiece temperature -20°C to 20°C. 	14	Handpiece icon: Select handpiece or footswitch icon to operate the system
6	Displays the filter inserted in the IPL handpiece	15	Settings icon: Select volume in the settings screen
7	SHOT COUNT: Tracks the number of shots currently carried out for a treatment session. These shots can be erased using the 'RESET' icon.	16	STANBY / READY indicator
8	MANUAL: Adjusts the values for the double and triple pulse type.	17	Skin type preset (I - V)
9	PULSE: Adjust the pulse: One Pulse: 3 - 35m Triple Pulse: 3 - 20ms Double Pulse: 3 - 25ms Toning Pulse: 3 - 25ms	18	**Memory Function:** Popup when pressing Memory button. (apply Save and Load for 10EA per Filter) If there is a Memory save value, it is distinguished by color. When popping up, only Exit is activated. When selecting a Memory number, Load and Save are activated.

5.5.2 *HR Mode Screen*

IPL aesthetic hair removal treatments are carried out in the HR treatment mode using the 700nm, 755nm filter (Figure 5.0-9. Table 5.0-4 outlines the HR mode screen features.

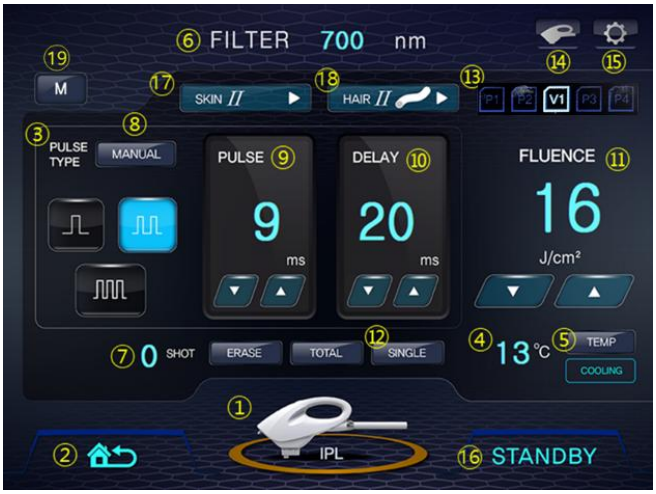


Figure 5.0-9: HR mode screen

Table 5.0-4: HR mode screen features

No.	Description	No.	Description
1	Image of selected handpiece	10	DELAY: Adjusted 1-50ms for the double and triple pulse
2	Home icon: Takes the user back to the initial screen	11	FLUENCE: Adjusted 6 to 30J/cm²
3	Pulse Type: Select single, double, or triple	12	SINGLE/REPEAT: Shot mode. Select single shot or continuous shot
4	CURRENT TEMPERATURE: Displays current filter temp. Cooling: Cooling function ON/OFF display (Auto display) (Standby mode: maintain 5℃ , Ready mode : maintain -10℃)	13	Save Icon: Saves selected settings for the present treatment
5	TEMP USER SETTING: Pop-up window allows the adjustment of the handpiece temperature -20°C to 20°C. 	14	Handpiece icon: Select handpiece  or footswitch icon  to operate the system
6	Displays the filter inserted in the IPL handpiece	15	Settings icon: Select volume in the settings screen
7	SHOT COUNT: Tracks the number of shots currently carried out for a treatment session. These shots can be erased using the 'RESET' icon.	16	STANBY / READY indicator
8	MANUAL: Adjusts the values for the double and triple pulse type.	17	Skin type preset (I - V)
9	PULSE: Adjust the pulse: One Pulse: 3 - 35m / Triple Pulse: 3 - 20ms Double Pulse: 3 - 25ms / Toning Pulse: 3 - 25ms	18	Hair type preset (1~4)
		19	**Memory Function:** Popup when pressing Memory button. (apply Save and Load for 10EA per Filter) If there is a Memory save value, it is distinguished by color. When popping up, only Exit is activated. When selecting a Memory number, Load and Save are activated.

5.6 Darwin HIFU Handpiece Screen

From the Home screen (Figure 5.0-10) select the HIFU handpiece. The HIFU handpiece loading screen will appear (Figure 5.0-11). Internal function checks are automatically carried out for this handpiece during the loading of the screen.

Figure 5.0-10: Darwin HIFU handpiece loading screen

To troubleshoot the error, refer to section 7.0 Troubleshooting.

When internal checks do not encounter an error, the Darwin HIFU handpiece screen, pops up.

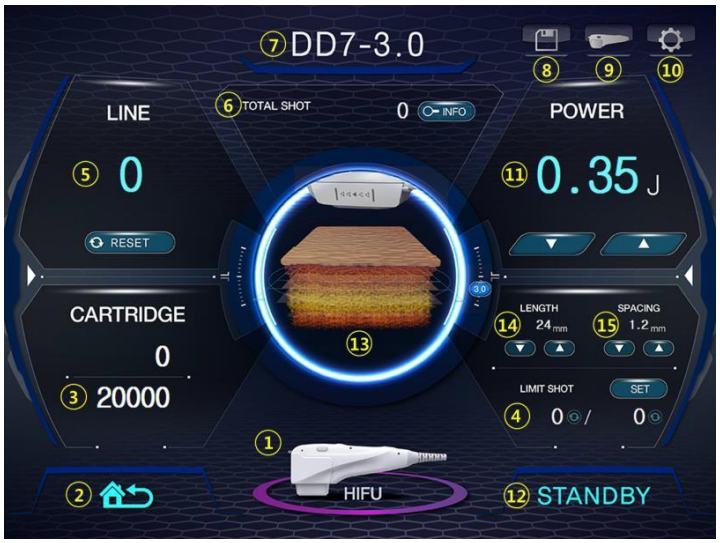


Figure 5.0-11: Darwin HIFU handpiece screen

Table 5.0-5: Darwin HIFU handpiece screen features

No.	Description	No.	Description
1	Image of selected handpiece	8	Save Icon: Saves selected settings for the present treatment
2	Home icon: Takes the user back to the initial screen	9	Handpiece icon: Select handpiece or  footswitch icon  to operate the system
3	CARTRIDGE: Displays the number of treatment line(s) delivered to the patent, compared to the total treatment line capacity of the cartridge. This number cannot be reset.	10	Settings icon: Select volume in the settings screen
4	LIMIT SHOT: Set and display the number of restricted shots / treatment lines by adjusting the SET(Keypad can be used when the setting button is pressed.) icons. A buzzer alarm is activated to notify user when the pre-set limit has been reached. The line number is set to "0" when the system is switched off or by pressing the home button. Restricted shots / treatment lines can be reset to 0 with each reset button.	11	POWER: Displays the energy (Joule/Dot) per TCP (Thermal Coagulation Points) being delivered. The energy per TCP can be adjusted using the UP or Down icons in increments of 0.05J. Setting ranges are different for each cartridge.
5	LINE: Number of shots used in the treatment using currently installed cartridge is tracked. Up to 5 digits are displayed. Press RESET icon to set to 0)	12	STANBY / READY indicator
6	TOTAL SHOT: Number of shots used in current treatment is displayed regardless of cartridge type. Press INFO button to check number of shots used per each cartridge.	13	Tissue effect illustration
7	Auto Cartridge Recognition: Displays the cartridge connected to the HIFU handpiece	14	LENGTH: Adjust the length of the treatment area with the up and down buttons.
		15	SPACING: Adjust the interval between TCP(Thermal Coagulation Points) with the up/down buttons.

5.7 Darwin Needle RF Handpiece Screen

After selecting the Darwin Needle RF handpiece icon on the Home screen, the Needle RF loading screen will appear (Figure 5.0-12). Internal function checks are automatically carried out for this handpiece during the loading of the screen.

Figure 5.0-12: Darwin Needle RF handpiece loading screen

To troubleshoot the error, refer to section 7.0 Troubleshooting.

When internal checks do not encounter an error, the Darwin Needle RF handpiece screen, pops up (Figure 5.0-13).

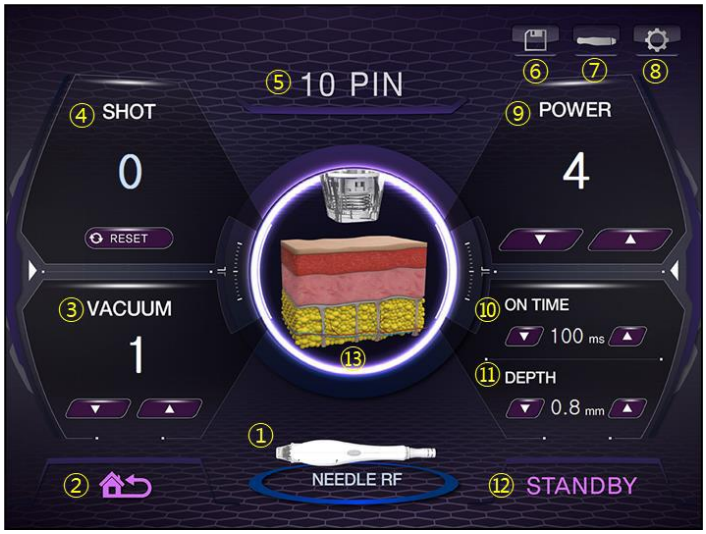


Figure 5.0-13: Darwin Needle RF handpiece screen

Table 5.0-6 outlines the features of the Darwin Needle RF handpiece screen

Table 5.0-6: Darwin Needle RF handpiece features

No.	Description	No.	Description
1	Image of selected handpiece	8	Settings icon: Select volume in the settings screen
2	Home icon: Takes the user back to the initial screen	9	POWER: adjust power level from levels 1 to 6
3	VACUUM: Adjust vacuum level from 0 to 3.	10	ON TIME: Adjust on time 100 - 300ms, in 50 intervals
4	SHOT: Number of treatment shots is tracked during treatment. Shot count resets to '0' when: 1) Needle RF tip is removed from the handpiece 2) Needle RF handpiece is disconnected from the system 3) System is powered off 4) Reset icon is pressed	11	DEPTH: Adjust the needle depth of the Needle RF tip to 0.5 ~ 3.5mm, in 0.1ms intervals
5	Auto Needle RF tip recognition: Automatically displays the Needle RF tip attached to the handpiece (10PIN or 25PIN).	12	STANBY / READY indicator
6	Save Icon: Saves selected settings for the present treatment	13	Tissue effect illustration
7	Handpiece icon: Select handpiece  or footswitch icon  to operate the system		

5.8 Darwin Face Thermal RF Handpiece Screen

From the Home screen (Figure 5.0-14) select the Face Thermal RF handpiece. The Face Thermal RF handpiece loading screen will appear (Figure 5.0-15). Internal function checks are automatically carried out for this handpiece during the loading of the screen.

Figure 5.0-14: Darwin Face Thermal RF handpiece loading screen

To troubleshoot the error, refer to section 7.0 Troubleshooting.

When internal checks do not encounter an error, the Darwin Face Thermal RF handpiece screen, pops up.

Figure 5.0-15: Darwin Face Thermal Handpiece screen

Table 5.0-7 outlines the features of the Darwin Face Thermal RF handpiece screen

Table 5.0-7: Darwin Face Thermal RF handpiece screen features

No.	Description	No.	Description
1	Image of selected handpiece	8	Handpiece icon: Select handpiece or footswitch icon to operate the system
2	Home icon: Takes the user back to the initial screen	9	Settings icon: Select volume in the settings screen
3	TIME: Displays the time the device has been used during treatment. The TIME is set to '0' when: 1) Reset icon is pressed. 2) System is turned off	10	POWER: Adjust power level from Levels 1 to 7
4	Auto Tip Recognition: Automatically displays the Darwin Face Thermal tip attached to the handpiece	11	TEMP: Adjust the temperature at which the system will stop operating when the skin temperature has reached the designated temperature.
5	Displays the available shot time of the tip (used shot time / tip life):TRF-S = 2,000 shots; TRF-R = 3,600 sec; TRF-E = 3,600 sec	12	STANBY / READY indicator
6	Displays the current temperature of the tip	13	Tissue effect illustration
7	Save Icon: Saves selected settings for the present treatment	14	Thermal Temp Timer function (0~30min, default : 0) - Time down count during start operation - Equipment standby conversion when all remaining time is consumed Adjust the timer time with the up and down buttons.
● When fractional tips (FRF TIP-64, FRF TIP-100) are connected, it is displayed as FRF-64 or FRF-100, and the temperature display in ⑥ and the temperature control in ⑪ do not work.			

6.0 Maintenance and Cleaning

6.1 About Maintenance

The only user-performed maintenance required for the Darwin system is frequent cleaning of the handpieces, handpiece tips, touchscreen, and exterior surfaces of the console. The Darwin system contains components that may be damaged if dropped.

CAUTION

Replace the deionized water every 3 – 6 months, as per section 3.4.1 Filling and Draining the Reservoir

All other maintenance is performed by LUVO Medical's authorized service representative.

WARNING

Do NOT modify, repair or service the Darwin system

Only LUVO Medical authorized personnel can modify, repair or service the Darwin system, especially inside its protective covers. This includes making internal adjustments to the power supply, cooling system, optics, treatment heads, etc. Dangerous voltages are present inside the system

Unauthorized modifications, repairs or service will void the warranty.

LUVO Medical recommends regular testing and maintenance.

Do not dispose in regular garbage. Darwin contains electronic equipment that may release toxic materials into the environment with improper disposal. Disposal should be in accordance with applicable local laws and regulations for the disposal of electronic equipment. Dispose Sharps in appropriate Sharps needle disposal unit.

Fuse replacement

WARNING

Replacing the fuse incorrectly can be dangerous.

First, disconnect the power cord, then remove the fuse holder and replace the fuse. Replace the fuse with a fuse of the same rating and type as indicated.

6.2 Cleaning

For the best performance, the outer surfaces of the system are to be kept clean for hygienic reasons. To begin cleaning, turn off the system.

CAUTION

Unplug system before cleaning, or filling and/or draining distilled water from the system.

WARNING

Do NOT spill water / liquid / solutions onto the system.
Do NOT immerse handpieces / cartridges / tips in water or other solutions
Do NOT hold handpieces / cartridges / tips under running water.
Do NOT use acetone or other solvents, as this can damage the handpieces.

6.2.1 *Console*

Check the fans located at both sides of the system and clean weekly.

The console can be wiped clean with a damp cloth or with a cloth moistened with 70% Ethyl Alcohol. As this is no patient contact, there is no need for disinfecting the console.

CAUTION

Inspect cord for breaks, cracks, nicks or other damage before every use.

- **If damaged, do NOT use.**
- **Failure to observe this precaution may result in injury or electrical shock to the patient and/or operator.**

Contact LUVO Medical authorized representative to service or check system if not working properly.

The Touchscreen is cleaned with a dedicated LCD cleaning solution (from any office supply store), using a microfiber cloth.

If dirt or any type of debris is stuck onto the touchscreen, gently remove using multiple soft strokes.

WARNING

Do NOT spill or spray solutions / water onto the touchscreen, as this can damage the system

Ensure to clean the touchscreen on a regular basis.

6.2.2 *Darwin Diode Laser Handpiece*

Check handpiece and tip for breaks, cracks, nicks or other damage daily. If found, notify LUVO Medical authorized service personnel for repair or replacement.

Clean the handpiece and tip following each patient treatment/procedure, using the ensuing steps:

1. Wipe for 1 minute with a lint-free cloth dampened with purified water to remove debris.
2. Wipe for 1 minute with a lint-free cloth dampened with 70% Ethyl alcohol.
3. Wipe for 1 minute with a lint-free cloth dampened with purified water.

During a patient's treatment session, clean the lightguide window (when needed) by using a gentle optical lens cleaning solution and microfiber cloth.

6.2.3 *Darwin IPL Handpiece and Filters*

Clean the handpiece with a dry cloth. Pay particular attention to remove foreign substances at Filter connecting area and Crystal Lamp.

Check handpiece for breaks, cracks, nicks or other damage. If found, notify LUVO Medical authorized service personnel for repair or replacement. Clean the handpiece and tip following each patient treatment/procedure.

To Clean the Handpiece:

1. Wipe for 1 minute with a lint-free cloth dampened with purified water to remove debris.

2. Wipe for 1 minute with a lint-free cloth dampened with 70% Ethyl alcohol.
3. Wipe for 1 minute with a lint-free cloth dampened with purified water.

To Clean the Light Guide:

1. Wipe for 1 minute with a lint-free cloth dampened with purified water to remove debris.

IMPORTANT NOTE!

Distilled water quality: 0 ~ 25 µs / cm
Filtered – 0.22µm filter.

2. Wipe for 1 minute with a lint-free cloth dampened with 70% Ethyl alcohol.
3. Wipe for 1 minute with a lint-free cloth dampened with purified water.

Check filters for stains, breaks, cracks, nicks, chips or other damage. If found, notify LUVO Medical authorized service personnel for replacement.

Both the filter and the glass window (patient contact area) can be cleaned as follows:

1. Wipe the surface with a lint free cloth that has been dampened with purified water. This will remove any debris.
2. Wipe for 1 minute with a lint free cloth dampened with 70% Ethyl Alcohol
3. Wipe with a lint free cloth dampened with purified water to remove any residual alcohol and debris.

WARNING

Ensure filter is always kept clean.
Soot is produced when foreign materials on the filter have been combusted from the light and cause harm to the patient and/or damage to the Light Guide treatment head

6.2.4 Darwin HIFU Handpiece and Cartridges

Inspect for cracks in the transducer assembly and the transducer output face. Replace if damaged or contact LUVO Medical's authorized representative. Clean the handpiece and tip following each patient treatment/procedure.

Clean the body of the handpiece and cable by gently wiping with a wet cloth saturated in water or 70% isopropyl alcohol.

Clean the cartridge between patients by gently, but thoroughly, wiping the cartridge window with a standard 70% isopropyl alcohol prep pad. Ensure the 70% isopropyl alcohol has dried before placing the cartridge back into its original packaging until used again.

6.2.5 *Darwin Needle RF Handpiece and Tips*

Clean the handpiece and tip following each patient treatment/procedure. Clean the body of the handpiece and cable by gently wiping with a wet cloth saturated in water or 70% isopropyl alcohol.

The RF Multi Needle is a single-use item and is not to be re-used or re-sterilized. Dispose in the appropriate Sharps needle disposal unit.

WARNING

The RF Multi Needle tip is a single-use item.
Do NOT re-use or re-sterilize.
Dispose in a Sharps needle disposal unit.

6.2.6 *Darwin Face Thermal Handpiece and Tips*

Clean the handpiece and tip following each patient treatment/procedure. Clean the body of the handpiece and cable by gently wiping with a wet cloth saturated in water then dry with a clean tissue. Do not use detergents containing thinners or alcohol.

Check the Face Thermal tips for stains, breaks, cracks, nicks, chips or other damage. If found, notify LUVO Medical's authorized representative for replacement.

To clean the tips:

1. Wipe for 1 minute with a lint-free cloth dampened with purified water to remove debris (impurities, keratin, etc.)
2. Wipe for 1 minute with a lint-free cloth dampened with 70% Ethyl alcohol (or 70% Isopropyl Alcohol).
3. Wipe for 1 minute with a lint-free cloth dampened with purified water and
4. Let the tip air dry and store in a dry place.

6.2.7 *Darwin Ground PAD cable and G-pad*

Clean the ground PAD cable following each patient treatment/procedure. Clean the ground PAD cable by gently wiping with a wet cloth saturated in water or 70% isopropyl alcohol.
The G-PAD is a single-use item and is not to be re-used or re-sterilized.

If treating with the Face Thermal RF handpiece, ensure it shall only be used in conjunction with a compatible G-Pad. Failure to use an appropriate G-Pad may result in unintended concentration of RF energy, patient injury, burns, ineffective treatment, or device malfunction.

7.0 Troubleshooting & Error Messages

The Darwin system is equipped with self-testing software that continuously monitors system operation. If a system malfunction is detected, an error message will appear on the display screen.

7.1 Troubleshooting

The following troubleshooting guides (Table 7.0-1) does not attempt to list all possible system failures. Any fault not listed should be referred to LUVO Medical-authorized technical personnel.

Table 7.0-1: Troubleshooting

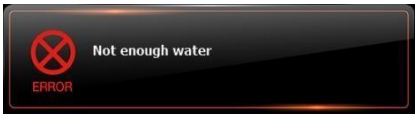
Trouble	Possible	Solution
Main System		
Display does not work when safety key-switch is turned on.	Emergency shutoff knob is engaged.	Turn system off, turn the emergency shutoff knob clockwise and restart the system.
	The main power switch is in the OFF position	Ensure main power switch is turned ON.
	There is no mains power supply	Ensure power cable is properly plugged into the system and the wall outlet. Ensure main power supply in the wall socket is on.
	Fuses have blown	Contact LUVO Medical authorized service representative
	Display malfunction	Contact LUVO Medical authorized service representative
Darwin Diode Laser Handpiece		
Diode laser handpiece light guide is not cold (main power switch is up, and the main switch is in the ON position)	Insufficient cooling time.	Wait for 1-2 minutes and try again.
	Hardware malfunction.	Contact LUVO Medical authorized service representative
Laser output not initiated when handpiece trigger is activated.	The system is in STANDBY mode.	Ensure system is in READY mode prior to activating handpiece
	Main power switch malfunction.	Contact LUVO Medical authorized service representative
Nothing happens when lightguide placed against treatment area	Treatment area is too small, such that the light guide does not completely contact the skin, (such as fingers or toes).	Try pulling skin of treatment target taut to enlarge the treatment area enough for the lightguide to completely contact the skin. System will not operate if the lightguide does not completely contact the skin / treatment area
Darwin IPL Handpiece		
IPL handpiece has overheated, is not	Insufficient cooling time.	Wait for 1-2 minutes and try again.

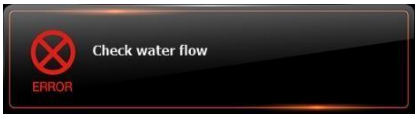
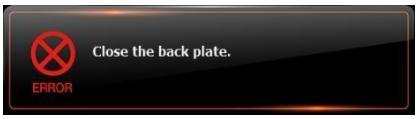
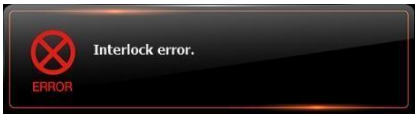
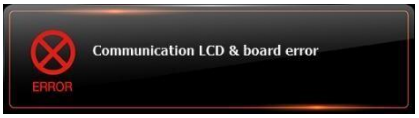
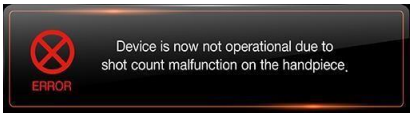
Trouble	Possible	Solution
cooling and has stopped operating	Hardware malfunction.	Contact LUVO Medical authorized service representative
Darwin HIFU Handpiece		
HIFU emission is not initiated when activated	The system is in STANDBY mode	Change to READY mode
Cartridge ceases to function	Cartridge is disconnected	Ensure cartridge is connected.
	System had restarted. System was shut down because of a power failure	Replace cartridge with new one. If the problem persists, contact LUVO Medical authorized service representative
Darwin Needle RF & Face Thermal RF Handpieces		
RF emission is not initiated when activated	The system is in STANDBY mode	Change to READY mode
Tip ceases to function	Tip is disconnected	Ensure tip is connected
	System had restarted. System was shut down because of a power failure	Replace tip with new one. If the problem persists, contact LUVO Medical authorized service representative

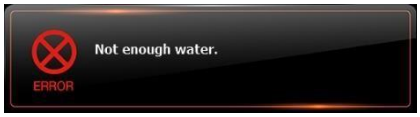
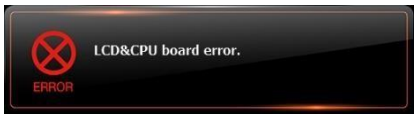
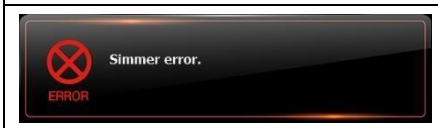
7.2 Error Messages

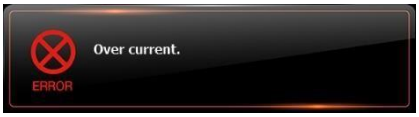
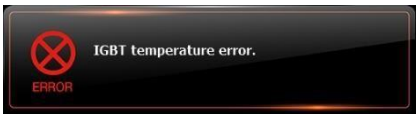
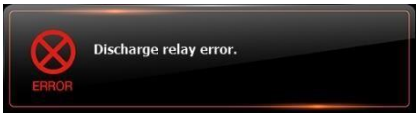
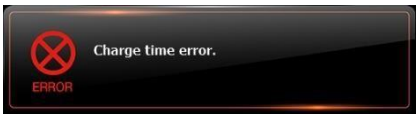
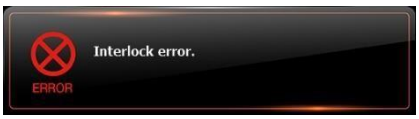
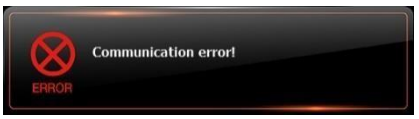
There is the potential to encounter errors while operating the system. When an error occurs, an error message appears on the display with a brief text message. All error messages are listed in Table 7.0-2 along with corrective action if applicable, however, all potential system failures are not listed. For errors or malfunctions that are not listed, contact LUVO Medical representative.

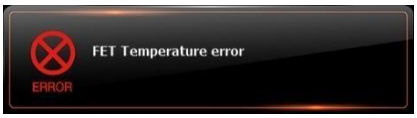
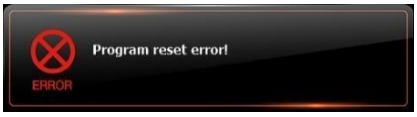
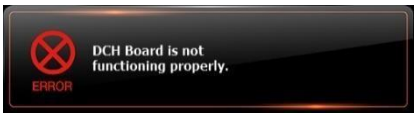
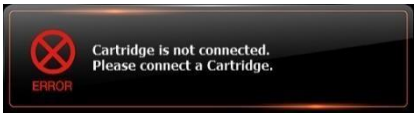
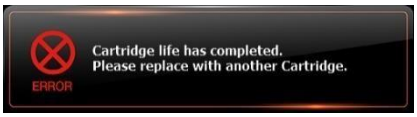
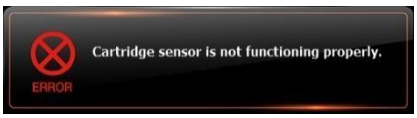
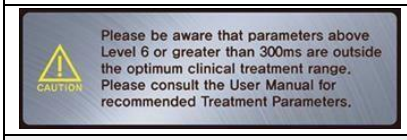
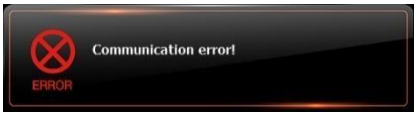
Table 7.0-2: Error Messages

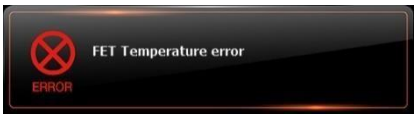
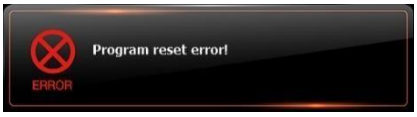
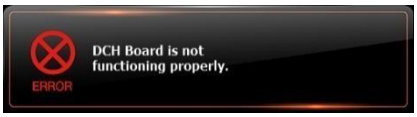
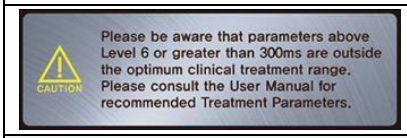
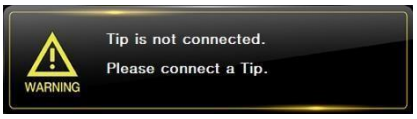
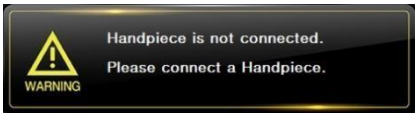
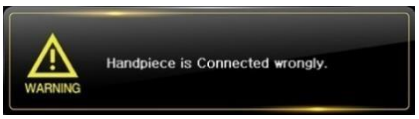
Error Message	Potential Cause	Solution
Diode Laser		
	Handpiece plug may not be correctly connected to handpiece socket in the system	Reconnect the handpiece plug to the handpiece socket in the system and resume normal operation. If problem persists, notify LUVO Medical's authorized service representative
	System does not recognize the hand piece due to the system malfunction.	If problem persists, notify LUVO Medical's authorized service representative
	Water sensor detected low water level such that the system cannot function	Fill water as per section 3.4.1 Filling and Draining the Reservoir

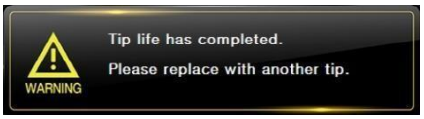
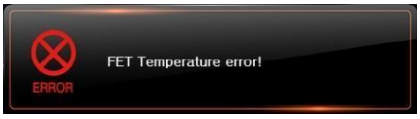
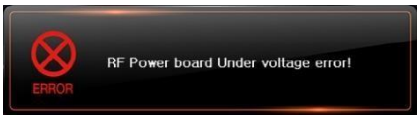
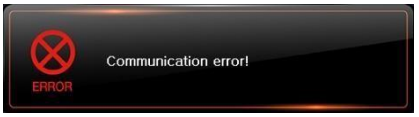
Error Message	Potential Cause	Solution
	System filter and motor does not function as intended	Notify LUVO Medical's authorized service representative
	Water temperature of the Chiller is below 9℃. The Darwin stops operating	Do NOT turn off the device. Increase the room temperature.
	Water temperature of the Chiller is above 41℃. The Darwin stops operating	Do NOT turn off the device. Wait for a couple of minutes until the system has cooled down.
	Panel at the rear of the device is opened or not closed correctly / completely	Check and close the rear panel
	Contact status of interlock switch is not working	If the interlock switch is loose or removed, re-insert.
	Peltier is not working	Notify LUVO Medical's authorized service representative
	Contact status of Peltier temperature sensor is not working	Notify LUVO Medical's authorized service representative
	LCD, CPU communication board is not working	Notify LUVO Medical's authorized service representative
	Water temperature inside the water tank reaches up above the 40℃.	Notify LUVO Medical's authorized service representative
	The temperature of the IGBT is too high. The device stops operation.	Notify LUVO Medical's authorized service representative
	IGBT temperature sensor is not working. The device stops operation	Notify LUVO Medical's authorized service representative
	EEPROM of handpiece is not working. The device stops operation.	Notify LUVO Medical's authorized service representative
IPL		

Error Message	Potential Cause	Solution
	Water circulation has been blocked or is malfunctioning. The device stops operation.	Notify LUVO Medical's authorized service representative
	Water sensor detected low water level such that the system cannot function	Fill water as per section 3.4.1 Filling and Draining the Reservoir
	LCD & CPU board communication error occurred	Re-start the system. If issue persists, notify LUVO Medical authorized Service personnel
	Communication error between the Handpiece and Main Processor	Re-start the system. If issue persists, notify LUVO Medical authorized Service personnel
	Chiller water temperature sensor Is not working	Notify LUVO Medical's authorized service representative
	Handpiece plug may not be correctly connected to handpiece socket in the system	Reconnect the handpiece plug to the handpiece socket in the system and resume normal operation. If problem persists, notify LUVO Medical's authorized service representative
	System does not recognize the hand piece due to the system malfunction.	If problem persists, notify LUVO Medical's authorized service representative
	Filter is not connected to the IPL handpiece	Connect the desired filter to the IPL handpiece as outlined in section 5.5.1 How to Insert Filters
	EEPROM of handpiece board is not working. The device stops operating.	Notify LUVO Medical's authorized service representative
	Handpiece temperature sensor is not working. The device stops operating	Notify LUVO Medical's authorized service representative
	Message displayed when Simmer board is not working	Notify LUVO Medical's authorized service representative
	Temperature of the handpiece is equal to or higher than 44°C, an error message appears, and the device stops operating. The device can be used when the temperature has cooled to 32°C	Wait for the system to cool down. If problem persists, notify LUVO Medical's authorized service representative

Error Message	Potential Cause	Solution
	A warning is displayed when the set temperature (35°C) has been reached. The device can be used when the temperature has cooled to 32°C	
	Voltage is over 380V. The device stops operation.	Notify LUVO Medical's authorized service representative
	Voltage is less than 180V. The device stops operation	Notify LUVO Medical's authorized service representative
	Charging current is at or greater than 65A. The device stops operation	Notify LUVO Medical's authorized service representative
	IGBT temperature is at or greater than 75 ° C. The device stops operation	Notify LUVO Medical's authorized service representative
	IGBT temperature is at or greater than 80 ° C. The device stops operation	Notify LUVO Medical's authorized service representative
	Contactor error	Notify LUVO Medical's authorized service representative
	Power supply is not working	Notify LUVO Medical's authorized service representative
	Chart time is not working	Notify LUVO Medical authorized Service personnel
	Contact status of interlock switch is not working	If the interlock switch is loose or removed, re-insert.
	Panel at the rear of the device is opened or not closed correctly / completely	Check and close the rear panel
HIFU		
	Communication between LCD module and Main Processor is not working	Notify LUVO Medical's authorized service representative

Error Message	Potential Cause	Solution
	Temperature of the system board is too high	Notify LUVO Medical's authorized service representative
	LCD error in processing software	Stop the device. Turn the power switch to OFF at the back of the system and notify LUVO Medical's authorized representative
	DCH Board error	Stop the device. Turn the power switch to OFF at the back of the system and notify LUVO Medical's authorized representative
	Handpiece plug may not be correctly connected to handpiece socket in the system	Reconnect the handpiece plug to the handpiece socket in the system and resume normal operation. If problem persists, notify LUVO Medical's authorized service representative
	System does not recognize the hand piece due to the system malfunction.	If problem persists, notify LUVO Medical's authorized service representative
	The cartridge is not connected to the handpiece	Check and ensure the cartridge is properly connected to the handpiece
	Total line capacity of connected Cartridge is all used up	Replace with a new cartridge
	Attached cartridge has an error	Disconnect cartridge and reconnect. If problem persists, replace cartridge with new cartridge and notify LUVO Medical's authorized representative
	Cartridge sensor has an error	Remove cartridge and reconnect. If problem persists, replace cartridge with new cartridge and notify LUVO Medical's authorized representative
	Cartridge actuator has an error	Stop the device. Turn the power switch OFF at the back of the system and notify LUVO Medical's authorized representative
	Output level above 6 or greater and Exposure greater than 300ms is set in RF multi needle mode	Please consult the User Manual for recommended Treatment Parameters.
Needle RF		
	Communication between LCD module and Main Processor is not working	Notify LUVO Medical's authorized service representative

Error Message	Potential Cause	Solution
	Temperature of the system board is too high	Notify LUVO Medical's authorized service representative
	LCD error in processing software	Stop the device. Turn the power switch to OFF at the back of the system and notify LUVO Medical's authorized representative
	DCH Board error	Stop the device. Turn the power switch to OFF at the back of the system and notify LUVO Medical's authorized representative
	Handpiece plug may not be correctly connected to handpiece socket in the system	Reconnect the handpiece plug to the handpiece socket in the system and resume normal operation. If problem persists, notify LUVO Medical's authorized service representative
	System does not recognize the hand piece due to the system malfunction.	If problem persists, notify LUVO Medical's authorized service representative
	Needle RF tip is not connected	Check and ensure the tip is properly connected to the handpiece
	Needle RF actuator error	Notify LUVO Medical's authorized service representative
	Output level above 6 or greater and Exposure greater than 300ms is set in RF multi needle mode	Please consult the User Manual for recommended Treatment Parameters.
Face Thermal RF		
	Tip is not connected	Check and ensure the tip is properly connected to the handpiece
	Handpiece is not detected	Reconnect the handpiece plug to the handpiece socket in the system and resume normal operation. If problem persists, notify LUVO Medical's authorized service representative
	Handpiece has been connected incorrectly	Reconnect the handpiece plug to the handpiece socket in the system and resume normal operation. If problem persists, notify LUVO Medical's authorized service representative

Error Message	Potential Cause	Solution
	Ground pad has been disconnected or the Ground pad cable is not connected	Check and reconnect the Ground pad and / or Ground pad cable to the device
	Ground pad has not been attached to the patient's body in using Face Thermal RF mode handpiece	Check and connect the Ground pad to the patient's body
	Tip recognition error	Disconnect tip and reconnect. If problem persists, replace tip with new cartridge and notify LUVO Medical's authorized representative
	Total life capacity of connected tip is all used up	Replace with new tip
	Temperature of the system board is too high	Notify LUVO Medical's authorized service representative
	RF Power board error	Notify LUVO Medical's authorized service representative
	Communication error	Notify LUVO Medical's authorized service representative

Appendix A: Clinical Guide Diode Laser Hair Removal Treatments

The Darwin system combines multiple technologies for use in dermatologic and aesthetic procedures, in one stand-alone device.

This clinical guide is for the Darwin Diode laser handpiece.

The Darwin system uses 808nm wavelength (in the near-infrared range) to target specific chromophore of the skin. This light passes through the skin until it reaches the bulb of the hair with the highest melanin concentration. The light is converted to thermal energy, and therefore leads to photothermal destruction of the bulb of the hair and most of the hair. The intense heat released by the hair destroys the follicle epithelium. The minimum fluence for effective laser hair removal is generally correlated with the hair color. For the same efficacy, higher fluence is usually necessary for lighter hair patients since their hair contains relatively low amount of melanin. Pulse width is generally correlated with hair diameter. Shorter pulse widths are effective for finer hair, while longer pulse widths may be used for coarser hair and deeper follicles.

Hair circulates at two immature stages and one mature stage. Hair can only be destroyed at the mature stage, hence only 10~20% of the hair at any given time is in the mature stage.

A.1 Indications for Use

The Darwin Diode Laser handpiece is intended for hair removal and permanent hair reduction on skin types (Fitzpatrick skin types I - V). The System allows user to choose from two modes the hair removal shot (HRS) and hair removal moving (HRM).

IMPORTANT NOTE

Permanent hair reduction is defined as:

The long-term, stable reduction in the number of hairs re-growing when measured at 6, 9 and 12 months after completion of a treatment regimen.

The number of re-growing hairs must be stable over a time greater than the duration of the complete growth cycle of hair follicles, which varies from 4–12 months according to body location. Permanent hair reduction does not necessarily imply the permanent elimination of all hairs in a treated area.

A.2 Contraindications

Treatment should not be attempted on patients with the following conditions:

- Fitzpatrick Skin Type VI
- Pregnancy (Including IVF)
- Cardiac Disease and / or has a pacemaker
- Liver or Kidney disease
- Diabetes
- Epilepsy

- Active infections or infections in treatment area
- Dysplastic nevi
- Concurrent or history of cancer, particularly malignant or recurrent non-melanoma skin cancer, or pre-cancerous lesions, such as multiple dysplastic nevi
- Concurrent or history of keloids
- Significant concurrent skin conditions or any inflammatory skin conditions
- Active cold sores, open lacerations, or abrasions
- Chronic or cutaneous viral, fungal, or bacterial diseases
- Fragile and dry skin
- Deep suntan, recent suntan, sunburn, or artificially tanned skin
- History of port inflammatory hyperpigmentation
- Taking anti-inflammatory medication on a regularly basis
- Tattoos (in treatment area)

A.3 Precautions

Patients with a medical history or presence of the following should be treated with caution and per the physician's discretion:

- Patients who have had prior problems with laser therapy should be carefully screened.
- Herpes simplex; treatment can trigger a herpes outbreak; prophylactic antiviral therapy may be prescribed at the physician's discretion.
- Poor or excessive wound healing, as these complications have the potential to prevent proper use of laser settings and application of cooling measures.
- Systemic Lupus Erythematosus or Porphyria. Immunosuppressive diseases, including AIDS and HIV infection.
- Uncontrolled systemic diseases such as diabetes, epilepsy, or congestive heart disease.
- Photosensitivity in general, or any sensitivity to the sun that causes a rash or an allergic reaction.
- Hormonal disorders, such as polycystic ovary syndrome, unless under control.
- Radiation therapy.
- Prior use of collagen, fat injections or other methods of skin augmentation.

Patients who use any of the following should be treated with caution and per the physician's discretion:

- History of bleeding coagulopathies

- Anticoagulants; avoid usage of anticoagulants prior to treatment, at the physician's discretion.
- Immunosuppressive medications.
- Herbal supplements, perfumes or cosmetics that may affect sensitivity to light at 808nm.
- Oral Isotretinoin (such as Accutane).

Patients with the following conditions should be treated with caution and per the physician's discretion:

- Damage to natural skin texture and/or very dry skin.
- Highly vesiculated area in the lesion's immediate proximity.
- Treatment within the orbital rim: patient should wear intraocular shields to protect the eyes from direct or indirect laser exposure.

A.4 Warnings

As with any laser, appropriate care regarding the safe and proper use must be taken. Ensure all operators have read section 2.0 Safety prior to carrying out treatment.

WARNING

Failure to thoroughly review and adhere to the information contained in this Operator's Manual may pose a potential hazard to the patient and/or user.

CAUTION

Do NOT leave the Darwin in operate mode when not in use.
Refer servicing to LUVO Medical authorized qualified service personnel.

The Darwin Diode Laser handpiece has the potential to cause epidermal injury. The risk increases with greater fluence and skin pigmentation:

- Darker skin types and individuals with a non-recent suntan are at a higher risk for pigmentary changes in the treatment area. These patients should be treated with caution following strict test-spot protocol.
- Sun exposure to the treatment area immediately after treatment and for one month following treatment may also increase the risk of pigmentary changes in the treatment area. Patients should be instructed to use a broad-spectrum sunscreen (SPF 30 at the minimum) daily and repeat the sunscreen application every two hours. Avoid direct sun exposure.
- Observe all safety precautions described in the section 2.0 Safety and elsewhere in this user manual.

- The light emitted by the Darwin Diode Laser handpiece can cause serious eye damage or blindness. All persons in the treatment room, including the patient, the operator and any observers must wear appropriate eye protection whenever the main power is on.

WARNING

The light emitted from the Darwin Diode Laser handpiece is capable of causing serious damage to the eye or blindness.

ALL persons in the treatment room, including patient MUST wear the recommended eye protection.

Ensure the eye wear protection is not damaged.

NEVER look directly into the laser aperture at the distal end of the handpiece during operation, including when wearing the recommended eye wear protection, as serious eye damage or blindness could result.

ONLY direct the laser beam at the treatment site. There is a potential hazard to cause serious injury or blindness of stray laser light.

Ensure patient is wearing maximum safety, metal eye goggles for all facial treatments.

- Perform test spots on patients and assess skin response before performing a full treatment. Side effects may not develop until several days following exposure. For skin type V, wait at the minimum 48-72 hours after test spots to observe tissue reaction. Always allow adequate time between test spot and actual treatment

CAUTION

The safety of using the Darwin Diode Laser handpiece on nursing women is not known, as LUVO Medical does not have clinical studies to support the use of the Darwin Diode Laser handpiece on nursing women.

WARNING

Do NOT allow sun block or sunscreen products to come in contact with the system.

The ingredients found in these products may cause deterioration or damage to the system.

If sun block or sunscreen does come in contact with the system, clean immediately to prevent potential damage.

IMPORTANT NOTE

After pressing the READY, if no operation is detected for about 2 minutes, the system automatically changes to STANDBY mode.

If a serious error occurs during operation of the system, the system automatically changes to STANDBY mode

A.5 Potential Side Effects

A.5.1 Hyperpigmentation / Hypopigmentation

Laser treatment can induce darkening or lightening of the skin pigment immediately after treatment and will typically resolve within a few days.

If the darkening (hyperpigmentation) or lightening (hypopigmentation) of the skin pigment is excessive or prolonged, this is considered an adverse event and must immediately be reported to LUVO Medical's authorized representative. Transient skin pigmentation changes may resolve within a few months, but could last longer, and in rare cases, these changes may be permanent.

Hyperpigmentation / hypopigmentation tends to occur with Fitzpatrick skin types IV to VI (but also can occur with the other Fitzpatrick skin types), or when the treated area has exposed to sunlight after treatment.

Another cause of this type of adverse event are the fluence and pulse duration settings used during treatment.

Therefore, it is important that a spot / patch test is carefully carried out prior to treatment to evaluate the immediate and delayed skin responses, as well as for side effects.

A.5.2 Edema or Erythema

Swelling (edema), perifollicular edema, perivascular edema, or redness (erythema) can occur immediately after treatment. Usually, the swelling and redness subsides within hours, but may continue for a few days.

If the edema or erythema is excessive or prolonged, this is considered an adverse event and must be reported to LUVO Medical's authorized representative immediately.

A.5.3 Skin Texture Damage

In some cases, skin texture damage such as blisters or crusts, have the potential to form at the treated area. If skin texture damage should occur, this is considered an adverse event and must immediately be reported to LUVO Medical's authorized representative.

Potential cause for damaged skin texture after treatment is related to fluence and pulse duration settings used for the Fitzpatrick skin type.

Therefore, it is important that a spot / patch test is carefully carried out prior to treatment to evaluate the immediate and delayed skin responses, as well as for side effects.

A.5.4 Other Potential Side Effects

The following complications and side effects may also be observed:

- Irritation, itching, burning sensation, or pain during treatment or following treatment.
- Superficial erosions of the treated area may be visible after laser treatment.
- Burns
- Erythema which is the development of an acquired persistent reticulated erythematous and pigmented rash of the skin produced by prolonged or repeated exposure to moderately intense heat or infrared radiation.
- Transient exacerbation of hair growth
- Purpura confined to the exposure area may be evident for several days following treatment.

- Pruritis may occur in rare cases.
- Contact dermatitis or irritant dermatitis may occur in some cases.
- Infection at the treatment site.
- As with the use of any laser system, there is the potential for scarring, such as keloid or enlarged hypertrophic scars, but rarely occur.

If the above side effects are excessive or prolonged, this is considered an adverse event and must be reported to LUVO Medical's authorized representative immediately.

Any burns are considered an adverse event and must be reported to LUVO Medical's authorized representative immediately

A.6 Pre-Treatment

A.6.1 General

Counselling patients regarding realistic expectations for the treatment outcome prior to treatment is an important step.

During the patient's first visit, the physician (or an authorized staff member), LUVO Medical recommends the following to assist with realistic expectations.

- Ensure a detailed patient medical history is taken, including previous treatment interventions, and determine the suitability for treatment with the Darwin Diode Laser handpiece.
- Determine why the patient is seeking treatment and understand and manage his/her expectations.
- Discuss the hair removal treatment plan with the patient.

A.6.2 Counselling

During the first visit, the physician (or an authorized member of the staff) should inform the patient of the following:

- There are many follicles in the body that are dormant during treatments and therefore, may be stimulated and grow later (months/years) and that more sessions will be needed.
- Vellus hairs should not be treated, as treatment of these hairs is not effective and have the potential to change into permanent hair.
- Caution is required for treatment of hirsutism or hypertrichosis, related to the realistic treatment outcome / expectations.
- The potential for discomfort or pain associated with treatment.
- Transient erythema/edema may appear immediately following treatment.

- Potential risk of adverse reactions (although the risk is small), such as changes in the texture and pigmentation of the skin should be discussed with the patient. These adverse reactions are usually transient and rare.
- Treatment area should be shaved and cleaned immediately prior to laser treatment, as shaving reduces pain and possible adverse reactions or events by eliminating the absorption of laser energy by hairs on the surface of the skin. Care is required during shaving and cleaning the skin surface, as visible hairs can get very hot when the laser fires and cause localized thermal injury to the epidermis.

CAUTION

Do NOT pluck, wax or remove hair via electrolysis.
The use of depilatories or other hair removal treatments (waxing, plucking, electrolysis, etc.) within 6 weeks prior to laser hair removal treatment has the potential to reduce the effective removal of the targeted hair.

A.6.3 Photography

Before and after treatment photographs are recommended to be taken to document the progress of treatment, as many patients are not able to objectively assess the progress of treatment. These photographs provide concrete evidence.

Ensure that standard conditions and similar speed, flash and focal length are used to photograph all patients. This enables an objective comparison of photos taken at different times.

A.7 Pre-Treatment

A.7.1 Set-Up

For both HRS and HRM modes, the skin type, hair colour (blond / red, light brown, dark brown, or black), and hair texture (fine, medium, or coarse), are selected (Figure A.7-1)

Figure A.7-1: Select the skin type (ST), Hair Colour (HC, and Hair Texture (HT) for both HRS and HRM modes.

A.7-2 Treatment Parameters

Recommended treatment parameters are outlined in Table A.7-1 for HRS mode and Table A.7.-2 for HRM mode.

Table A.7-1: Parameters for HRS mode

Skin Type	Hair Color	Hair Texture	Pulse Type	Pulse Duration (ms)	Fluence (J/cm²)
I	Blonde Red	Fine	Single	91	30
		Medium	Double	91	28
		Coarse	Triple	91	26
	Light Brown	Fine	Single	91	30
		Medium	Double	91	28
		Coarse	Triple	91	26
	Dark Brown	Fine	Single	91	30
		Medium	Double	91	28
		Coarse	Triple	91	26
	Black	Fine	Single	91	30
		Medium	Double	91	28
		Coarse	Triple	91	26
II	Blonde Red	Fine	Single	91	30
		Medium	Double	91	28
		Coarse	Triple	91	26
	Light Brown	Fine	Single	91	30
		Medium	Double	91	28
		Coarse	Triple	91	26
	Dark Brown	Fine	Single	91	30
		Medium	Double	91	28
		Coarse	Triple	91	26
	Black	Fine	Single	91	30
		Medium	Double	91	28
		Coarse	Triple	91	26
III	Blonde Red	Fine	Single	95	30
		Medium	Double	95	28
		Coarse	Triple	95	26
	Light Brown	Fine	Single	95	30
		Medium	Double	95	28
		Coarse	Triple	95	26
	Dark Brown	Fine	Single	95	30
		Medium	Double	95	28
		Coarse	Triple	95	26
	Black	Fine	Single	95	30
		Medium	Double	95	28

Skin Type	Hair Color	Hair Texture	Pulse Type	Pulse Duration (ms)	Fluence (J/cm²)
		Coarse	Triple	95	26
IV	Dark Brown	Fine	Single	100	30
		Medium	Double	100	28
		Coarse	Triple	100	26
	Black	Fine	Single	100	28
		Medium	Double	100	26
		Coarse	Triple	100	24
V	Dark Brown	Fine	Double	100	23
		Medium	Double	100	22
		Coarse	Triple	100	21
	Black	Fine	Double	100	22
		Medium	Double	100	21
		Coarse	Triple	100	20

Table A.7-2: Parameters for HRM mode

Skin Type	Hair Color	Hair Texture	Pulse Duration (ms)	Fluence (Hz)	Fluence (J/cm²)	Number of Passes
I	Blonde Red	Fine	45	5	15	4-5
		Medium	45	5	14	
		Coarse	45	5	13	
	Light Brown	Fine	45	5	15	4-5
		Medium	45	5	14	
		Coarse	45	5	13	
	Dark Brown	Fine	45	5	15	4-5
		Medium	45	5	14	
		Coarse	45	5	13	
	Black	Fine	45	5	15	4-5
		Medium	45	5	14	
		Coarse	45	5	13	
II	Blonde Red	Fine	45	5	15	4-5
		Medium	45	5	14	
		Coarse	45	5	13	
	Light Brown	Fine	45	5	15	4-5
		Medium	45	5	14	
		Coarse	45	5	13	
	Dark Brown	Fine	45	5	15	4-5

Skin Type	Hair Color	Hair Texture	Pulse Duration (ms)	Fluence (Hz)	Fluence (J/㎠)	Number of Passes
		Medium	45	5	14	
		Coarse	45	5	13	
	Black	Fine	45	5	15	4-5
		Medium	45	5	14	
		Coarse	45	5	13	
Ⅲ	Blonde Red	Fine	50	5	14	4-5
		Medium	50	5	13	
		Coarse	50	5	12	
	Light Brown	Fine	50	5	14	4-5
		Medium	50	5	13	
		Coarse	50	5	12	
	Dark Brown	Fine	50	5	14	4-5
		Medium	50	5	13	
		Coarse	50	5	12	
	Black	Fine	50	5	14	4-5
		Medium	50	5	13	
		Coarse	50	5	12	
Ⅳ	Dark Brown	Fine	57	5	13	4-5
		Medium	57	5	12	
		Coarse	57	5	11	
	Black	Fine	60	5	13	4-5
		Medium	60	5	12	
		Coarse	60	5	11	
Ⅴ	Dark Brown	Fine	57	5	8	4
		Medium	57	5	7	
		Coarse	57	5	6	
	Black	Fine	60	5	8	4
		Medium	60	5	7	
		Coarse	60	5	6	

A.7.3 Cooling Gel

Use refrigerated (6°C - 10°C), transparent, water-soluble cooling gel during treatment, to help minimize discomfort, protect skin from overheating and provide a light coupling medium between the light guide and skin surface.

A.7.4 Overlap Method

The lightguide tip spot size of the Darwin Diode Laser handpiece is 14mm x 14mm (Figure A.7-2), however the irradiated area is 12mm x 12mm. Therefore, it is necessary to overlap the footprint of the handpiece, as outlined in Figure A.7-3 for HRS mode and Figure A.7-4 for HRM mode. For HRS mode, mark a grid using a red pen on the target area about 10 cm x 10 cm. For HRM mode, mark a grid using a red pen on the target area about 10 cm x 10 cm or 3cm x 3 cm.

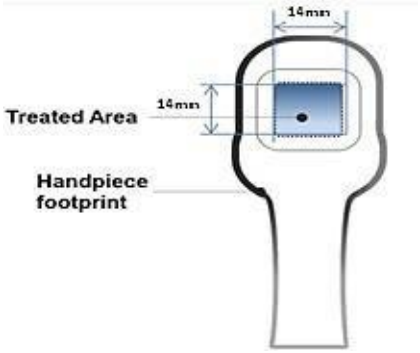


Figure A.7-2: Spot size of handpiece

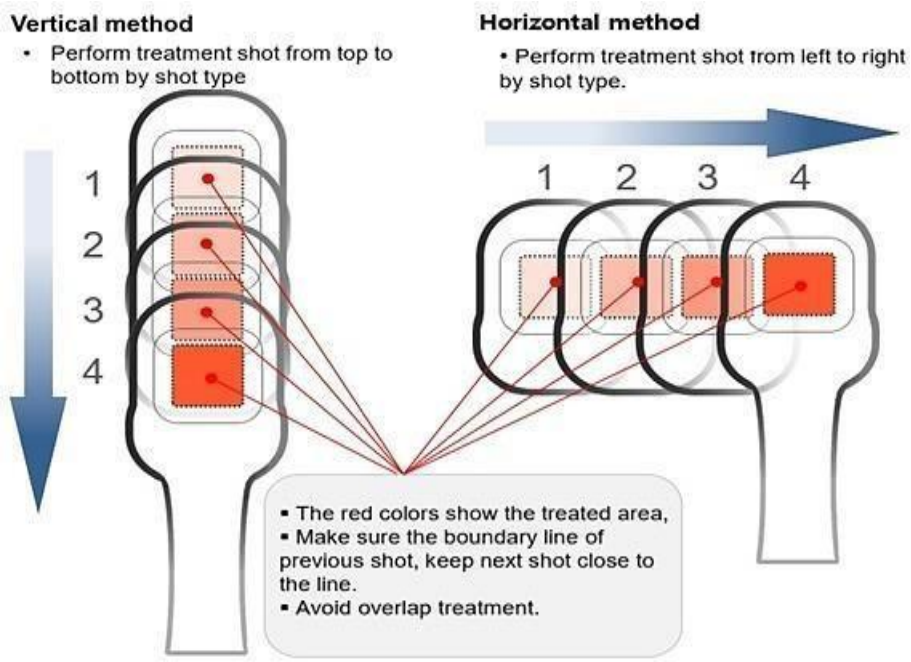


Figure A.7-3: Overlap method when in HRS mode.

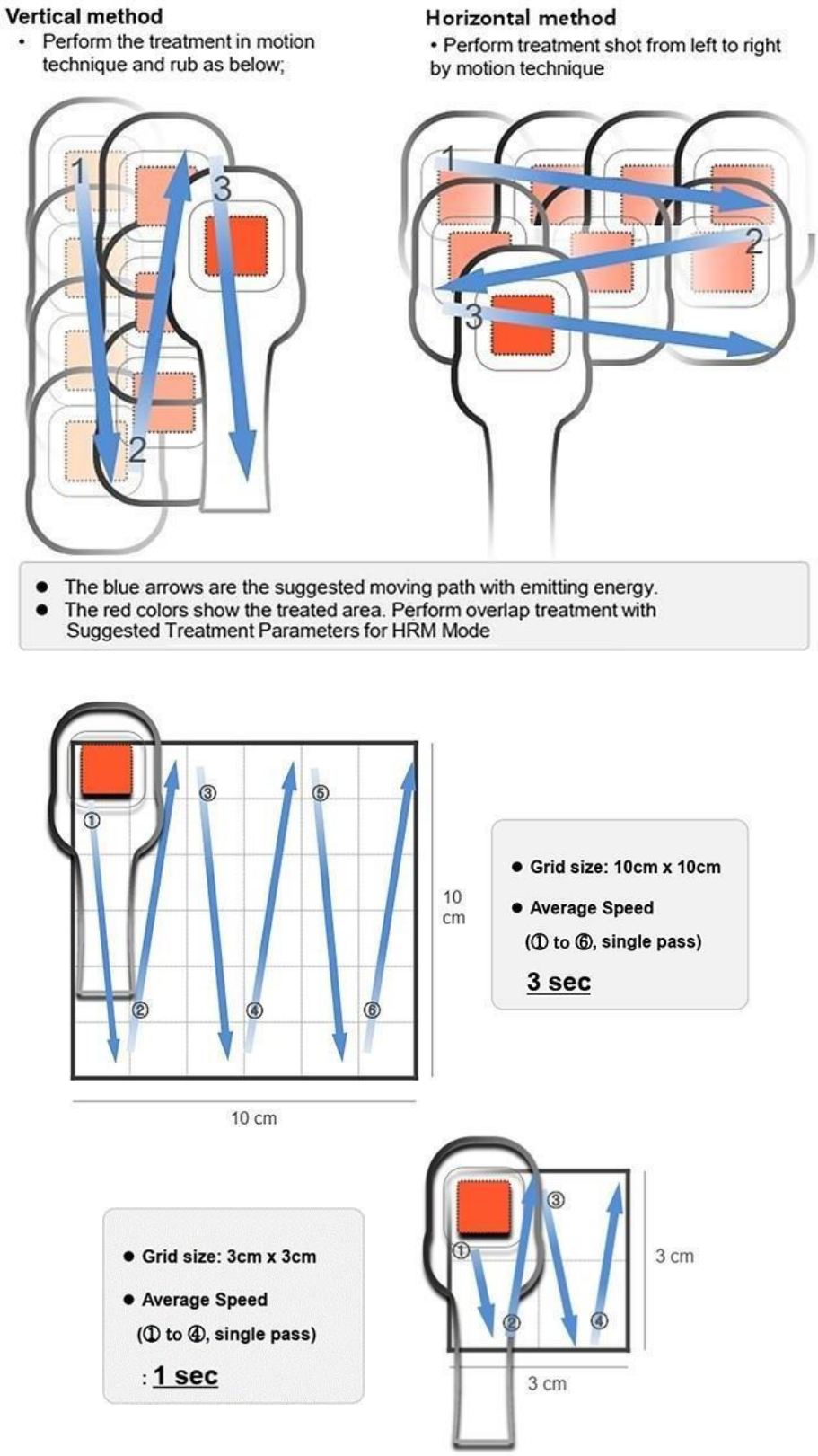


Figure A.7-4: Overlap method when in HRM mode

A.8 Treatment

CAUTION

Do NOT pluck, wax or remove hair via electrolysis.

The use of depilatories or other hair removal treatments (waxing, plucking, electrolysis, etc.) within 6 weeks prior to laser hair removal treatment has the potential to reduce the effective removal of the targeted hair.

A.8.1 Spot / Patch Test

Prior to full treatments, LUVO Medical recommends patients receive spot/patch test to evaluate the immediate and delayed skin response, as well as for side effects.

For untanned skin types I-IV, wait at least 20-30 minutes after the spot/patch test to observe skin reaction.

For skin type V and acceptable tanned skin, wait at least 48-72 hours after spot/patch test to evaluate skin reaction. Advise patients to avoid tanning and apply sun block during the spot test.

Select the mode (HRS or HRM), skin type, hair colour and texture and use the parameters for the test spot from Table A.7-1 for HRS mode or Table A.7-2 for HRM mode.

Ensure spot/patch test area is shaved and cleaned immediately prior to laser treatment, as shaving reduces pain and possible adverse reactions or events by eliminating the absorption of laser energy by hairs on the surface of the skin. Care is required during shaving and cleaning the skin surface, as visible hairs can get very hot when the laser fires and cause localized thermal injury to the epidermis.

CAUTION

Always perform Spot / Patch test prior to full treatment.

A.8.2 Pre-Treatment Set-up

Prior to treatment, carry out the following:

1. Ensure that patient consultation was conducted, and screening completed.
2. Have the patient remove all jewelry for the treatment.
3. Have the patient remove all metal accessories for the treatment.
4. Verify that the laser and its components are intact and are properly connected, as instructed in this user manual.
5. Select the desired mode – HRS or HRM mode.
6. Select the appropriate skin type, hair colour and hair texture.
7. Ensure spot / patch test carried out using parameters from Table A.7-1 for HRS mode or Table A.7-2 for HRM mode.

WARNING

Reduce fluence by 10% when treating sensitive areas, such as the beard, forehead,

IMPORTANT NOTE

LUVO Medical recommends starting with the mode parameters outlined in Table A.7-2 for HRS mode or Table A.7-3 for HRM mode until the appropriate parameters have been identified as per the skin reaction.

8. Ensure patient reclined in a comfortable position with the recommended eye protection.
9. Ensure that all personnel and patient in the treatment room are wearing the appropriate laser safety eyewear as per eyewear information outlined in this user manual.

WARNING

The light emitted from the Darwin diode laser handpiece is capable of causing serious damage to the eye or blindness.

ALL persons in the treatment room, including patient MUST wear the recommended eye protection.

Ensure the eye wear protection is not damaged.

NEVER look directly into the laser aperture at the distal end of the handpiece during operation, including when wearing the recommended eye wear protection, as serious eye damage or blindness could result.

ONLY direct the laser beam at the treatment site. There is a potential hazard to cause serious injury or blindness of stray laser light.

Ensure patient is wearing maximum safety, metal eye goggles for all facial treatments.

10. Thoroughly remove all make-up, cosmetics, and sunscreen from the treatment area
11. Meticulously cleanse the treatment area with non-alcoholic preparation before treatment
12. For HRS mode, mark a grid using a red pen on the target area about 10 cm x 10 cm.
13. For HRM mode, mark a grid using a red pen on the target area about 10 cm x 10 cm or 3cm x 3 cm.
14. Evenly apply the gel over the treatment area, approximately 1-2mm thick
15. If necessary, turn on the main electrical service (wall circuit breaker).
16. Post the "Laser in Use" warning sign outside the treatment room door.
17. Ensure External Door Interlock is engaged.

IMPORTANT NOTE

Although using the external door interlock is optional, LUVO Medical recommends using the interlock during treatment as an extra layer of safety.

18. If the laser is not already on, turn on the laser, as instructed in this manual and ensure the laser is in STANDBY mode to warm up the system.

19. Ensure the Darwin Diode Laser handpiece lightguide tip is cold.

A.8.3 Treatment

To begin treatment:

1. Ensure lightguide firmly contacts the skin of the treatment area, with moderate pressure.

   The system will not operate if the lightguide incompletely contacts the skin / treatment area.

2. Start the treatment by pulling the trigger on the handpiece and move the handpiece over the grid, as per section A.7.5 Overlap Method. Laser emission is enabled only when the operator switches to READY mode and presses the trigger on the handpiece or triggers the footswitch. The trigger reduces the risk of unintentional laser emission.

3. The patient should report comfortable/tolerable heat sensation in the treated area during the procedure.

   If patient reports discomfort, reduce fluence and add cold gel to the treatment area as required.

4. Ensure to examine treatment area for change in skin type and morphological changes around the follicles (erythema/edema). The smell of burnt hair may sometimes be detected, although absence of this phenomenon does not necessarily indicate that the present fluence is ineffective.

   If adverse skin effects occur (such as excessive reddening) before good follicular response is achieved, decrease the fluence by 5 – 10% to reduce the aggressiveness of the treatment.

   If the skin shows no clinical end-points and no morphological changes are observed, slowly increase the fluence until the desired effect is achieved.

WARNING

Reduce fluence by 10% when treating sensitive areas, such as the beard, forehead, etc.

IMPORTANT NOTE

When treating areas with too many fine hairs, consider one or two extra passes, always watching for adverse skin effects during each extra pass.

5. Remove cooling gel and cool treated area immediately with cold packs (NOT ice packs) after treatment finished.

A.8.4 Post-Treatment

General Care:

Cold (not frozen) packs should be applied immediately after treatment, to cool treatment site, reduce swelling and optimize comfort.

Chemical cold packs are not recommended, if the chemical cold pack temperature is below 4°C.

Alternatively, frozen 4x4 gauze pads, previously moistened with water and inserted into small plastic bags or in plastic wrap, could be used post-treatment.

Inform the patient to avoid hot baths, heavy exercise, massage, etc. for 5 – 7 days after treatment.

Exposure to Sunlight:

Ensure to council patient to use high factor sun block (SPF 30 or greater) and to 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 hyperpigmentation.

Makeup:

Advising the patient regarding the application of makeup to the treated area, is at the discretion of the Health Care Professional.

Ensure to council patient to notify IMMEDIATELY if there are any reactions and to stop using makeup.

Follow-up:

Council patient to return for follow-up treatment to complete the program discussed with the patient prior to treatment. Timing of the follow-up treatment visits include approximately every three (3) weeks for treatment of pigmentary lesions and approximately one (1) week for treatment of acne until the four (4) to six (6) treatment sessions are complete.

Adverse Events:

If there are adverse events during the treatment session, notify LUVO Medical's authorized. Representative, stop treatment, allow to heal and investigate the root cause of the adverse reaction. Steroid cream can be used in case of a sensitive response after the treatment.

Completion of Treatment:

Completion of treatment is determined by the Health Care Professional and / or the patient.

Appendix B: Clinical Guide IPL Treatments

The Darwin system combines multiple technologies for use in dermatologic and aesthetic procedures, in one stand-alone device.

This clinical guide is for the Darwin IPL handpiece. Filters for the non-invasive IPL handpiece include 430nm, 515nm, 560nm, 585, 640nm, 700nm and 755nm. The user can select two treatment modes: ST (Skin Type) and HR (Hair Removal) when using the IPL handpiece.

B.2 Indication for use

The Darwin IPL feature is a non-invasive Intense Pulsed Light (IPL) intended to be used in dermatology and plastic surgery. In ST mode, filters 430nm, 515nm, 560nm, 585, and 640nm are used for a variety of aesthetic treatments in skin types I - IV. In HR Mode, the 700nm, 755nm filter is used for removal of unwanted hair and to effect stable long term, or permanent hair reduction in skin types I-V through selective targeting of melanin in hair follicles.

B.1-1 Aesthetic Indications

The IPL feature is a non-invasive Intense Pulsed Light (IPL) intended to be used in dermatology and plastic surgery. In ST mode, filters 430nm, 515nm, 560nm, 585nm, and 640nm are used for the following aesthetic treatments for skin types I – IV:

- Benign pigmented epidermal and cutaneous lesions including dyschromia, hyperpigmentation, melasma, Ephelides (freckles), scars, and striae. [515 nm, 560 nm or 640 nm Filter]
- Benign cutaneous vascular lesions, including port wine stains, hemangiomas, facial and truncal telangiectasias, rosacea, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte and Solar Lentigines [585 nm or 560 nm Filter]
- Mild to moderate inflammatory acne (acne vulgaris). [430 nm Filter]

B.1-2 Hair Removal Indication

The Darwin IPL handpiece is a non-invasive system using the 700nm, 755nm filter in HR mode for removal of unwanted hair and to effect stable long term, or permanent* hair reduction in skin types I-V through selective targeting of melanin in hair follicles.

IMPORTANT NOTE

***Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs re-growing when measured at 6, 9 and 12 months after the completion of a treatment regimen.**

B.3 Contraindications

Patients who have had prior problems with IPL treatment should be carefully screened before treatment.

Treatment should not be attempted on patients with the following conditions in the treatment area:

- History or concurrent condition of skin cancer or pre-cancerous lesions at the treatment area
- Children aged 18 years or younger.
- Fitzpatrick Skin Type VI
- Fitzpatrick Skin Type V for all aesthetic (ST) treatments
- Pregnancy
- Active infections
- Dysplastic nevi
- Tattoos
- Significant concurrent skin conditions or any inflammatory skin conditions
- Active cold sores, open lacerations or abrasions
- Chronic or cutaneous viral, fungal or bacterial diseases
- Exposure to sun or artificial tanning during 3-4 weeks prior to treatment.
- Bleeding coagulopathies
- Psychiatric disorders and/or unstable motivations
- Cardiac disorders requiring a pacemaker or result in serious heart rhythms.
- Allergic to topical anesthetics
- Compromised liver or kidneys.
- History of Keloid Scarring
- Gold Therapy

Treatment should not be attempted on patients with a history or concurrent condition of skin cancer or pre-cancerous lesions at the treatment areas.

Exclude patients that have a genetic tendency for scarring.

B.4 Precautions

Patients with a medical history or presence of the following should be treated with caution and per the physician's discretion:

- Herpes simplex; treatment can trigger a herpes outbreak; prophylactic antiviral therapy may be prescribed at the physician's discretion.
- Systemic Lupus Erythematosus or Porphyria. Immunosuppressive diseases, including AIDS and HIV infection.
- Uncontrolled systemic diseases such as diabetes, epilepsy, or congestive heart disease.
- Photosensitivity in general, or any sensitivity to the sun that causes a rash or an allergic reaction.
- Hormonal disorders, such as polycystic ovary syndrome, unless under control.
- Radiation therapy.
- Prior use of collagen, fat injections or other methods of skin augmentation.

Patients who use any of the following should be treated with caution and per the physician's discretion:

- Anticoagulants; avoid usage of anticoagulants prior to treatment, at the physician's discretion.
- Immunosuppressive medications.
- Herbal supplements, perfumes or cosmetics that may affect sensitivity to light.
- Oral Isotretinoin (such as Accutane).

Patients with the following conditions should be treated with caution and per the physician's discretion:

- Damage to natural skin texture and/or very dry skin.
- Highly vesiculated area in the lesion's immediate proximity.
- Treatment within the orbital rim: patient should wear intraocular shields to protect the eyes from direct or indirect IPL exposure.

B.5 Warnings

Appropriate care must be taken to ensure safe and proper use of the Darwin IPL handpiece.

CAUTION

Read all instructions, cautions and warnings provided with the system and any accessories before using.
All personnel must be trained in the use of the Darwin: IPL handpiece prior to use.

The IPL treatment can cause epidermal injury. The risk increases with greater fluence and skin pigmentation:

- Darker skin types and individuals with a non-recent suntan are at a higher risk for pigmentary changes in the treatment area. These patients should be treated with caution following strict test-spot protocol.
- Sun exposure to the treatment area immediately after treatment and for one month following treatment may also increase the risk of pigmentary changes in the treatment area. Patients should be instructed to use a broad-spectrum sunscreen (SPF 30 at the minimum) daily and repeat the sunscreen application every two hours. Avoid direct sun exposure.
- Observe all safety precautions described in the section 2.0 Safety and elsewhere in this user manual.
- The light emitted by the Darwin IPL handpiece can cause serious eye damage or blindness. All persons in the treatment room, including the patient, the operator and any observers must wear appropriate eye protection whenever the main power is on.
- Perform test spots on patients and assess skin response before performing a full treatment. Side effects may not develop until several days following exposure. For skin type V, wait at the minimum 48-72 hours after test spots to observe tissue reaction. Always allow adequate time between test spot and actual treatment.

CAUTION

The safety of using the Darwin IPL feature on nursing women is not known, as LUVO Medical does not have clinical studies to support the use of the Darwin IPL feature on nursing women.

WARNING

Do NOT allow sun block or sunscreen products to come in contact with the system.

The ingredients found in these products may cause deterioration or damage to the system.

If sun block or sunscreen does come in contact with the system, clean immediately to prevent potential damage.

IMPORTANT NOTE

After pressing READY, if no operation is detected for approximately 2 minutes, the system automatically changes to STANDBY mode.

If a serious error occurs during operation of the system, the system automatically changes to STANDBY mode

B.6 Potential Side Effects

IPL Skin Treatments are typically administered in a series of four to six treatments, performed at intervals of a minimum of three weeks. A three-week interval between treatments has proven optimal. However, larger intervals do not appear to adversely influence treatment results. Spreading the treatment over this period provides a gradual improvement of the skin, a minimal risk of adverse effects, and preserves the important "no downtime" feature of the program. In rare cases where

side effects do occur, postpone further treatments until complete healing. The most common side effects are:

- Discomfort
    - Sensations such as stinging or a rubber band snap. A burning sensation may last for up to an hour after treatment. Most patients tolerate this discomfort; however, some patients may require a topical anesthetic (avoid using a vasoconstrictive topical anesthetic).
- Damage to natural skin texture.
    - A crust or blister may form, which may take from five to ten days to heal.
- Pigmentation Change
    - Most cases of hypo- or hyper-pigmentation occur in people with darker skin, or when the treated area has been exposed to sunlight before or after treatment. In some patients, hyperpigmentation occurs despite protection from the sun. This discoloration usually fades in three to six months, but in rare cases, mainly hypopigmentation, the change of pigment may last longer or be permanent.
- Scarring
    - There is a very small chance of scarring, such as enlarged hypertrophic scars. In very rare cases, abnormal, large, raised keloid scars may appear. To reduce the chance of scarring, it is important to carefully follow all pre and post-op instructions and exclude patients that have a genetic tendency for scarring.
- Excessive swelling
    - Immediately after treatment, especially in the regions of the nose or the periorbital zone, the skin may swell temporarily. Swelling usually subsides within hours to as much as seven days.
- Fragile skin
    - The skin at or near the treatment site may become fragile. If this happens, avoid makeup and do not rub the area, as this might tear the skin.
- Bruising
    - Very rarely, a blue-purple bruise (purpura) may appear on the treated area. It may last from five to fifteen days. As the bruise fades, there may be rust-brown discoloration of this skin, which fades in one to three months.
- Burns
    - There is a small chance of burns occurring on the skin. To reduce the possibility of burns from occurring, it is important to carefully follow all treatment instructions, and in particular to perform test patches.

      Always perform a test patch in a small inconspicuous zone within the intended treatment area during the first treatment session and whenever treatment settings are changed, before performing an additional pass on the same treatment area (if allowed), and when changing a module.

- Xerosis
    - The skin may become dry if proper skin care has not been carried out-between sessions.

B.5 Pre-Treatment

B.5.1 General

Counselling patients regarding realistic expectations for the IPL treatment outcome prior to treatment is an important step.

IPL Skin Treatments are not intended to be a substitute for surgical facelift, ablative skin resurfacing, or procedures that treat deep wrinkles and sagging skin. It is intended for patients desiring evenness of color in their complexions, or those showing signs of sun damage and photo-aging.

IPL Acne Treatment is intended for individuals with mild to moderate cases of inflammatory acne. The treatment is not a substitute for prescription drugs or surgical treatments for comedones, large cysts and abscesses in severe cases of acne.

IPL Skin Treatments have great appeal to individuals with active lifestyles as the procedure requires no "downtime", i.e., patients can resume all activities immediately after treatment, except for sun exposure.

B.5.2 Counselling

During the patient's first visit, the physician (or an authorized staff member), LUVO Medical recommends the following to assist with realistic expectations:

- Ensure a detailed patient history is taken, including previous treatment interventions, and determine the suitability for treatment with the IPL feature.
- Determine why the patient is seeking treatment and understand and manage his/her expectations.
- Discuss the IPL Skin Treatment plan with the patient.

The physician (or an authorized member of the staff) should inform the patient of the following:

- The potential for discomfort or pain associated with treatment.
- Transient erythema/edema may appear immediately following treatment.
- Pigmented lesions may become darker.
- Pigmented lesions may darken soon after IPL treatment, and fade or flake off for up to fourteen days following treatment.
- Vascular lesions may also darken soon after IPL treatment, as a result of blood coagulation
- Acne may appear more inflamed soon after the IPL treatment; the effect will subside within a few hours up to a few days following treatment.

- More than one treatment (approximately four to six) is usually required for acceptable results. The entire program should be planned at the outset to promote compliance and realistic expectations.
- Potential risk of adverse reactions (although the risk is small), such as changes in the texture and pigmentation of the skin should be discussed with the patient. These adverse reactions are usually transient and rare.
- As for any acne treatment, there is a risk of transient flare-ups in the early weeks of treatment. These flare-ups will not prevent further treatment sessions.

B.5.3 Eye Protection

It is imperative that all people present in the treatment room during treatment (patient and medical personnel) protect their eyes by wearing the recommended protective eyewear with the following optical density (OD):

- OD 5 for the patient.
- OD 3 for operator and staff.

When using the IPL near the eyes, have the patient wear opaque protective eyewear. It is good practice to instruct the patient to close his/her eyes at the sound of the "beep" before the light pulse is delivered, or during the entire periorbital treatment.
For ALL facial treatments, the patient must wear eyeglasses with the optical density 5(OD 5) as protective goggles.

WARNING

Ensure patient and all present in the treatment room guard against accidental exposure to the IPL emissions either directly from the treatment head or indirectly from a reflecting surface.

Never look directly at the beam coming from the treatment head, even when wearing protective eyewear used.

Never point the treatment head so that it discharges into free space.

Ensure treatment head is mounted on its cradle, or during actual treatment pointed at the target treatment site.

B.5.4 Photography

Before and after treatment photographs are recommended to be taken to document the progress of treatment, as many patients are not able to objectively assess the progress of treatment. These photographs provide concrete evidence.

Ensure that standard conditions and similar speed, flash and focal length are used to photograph all patients. This enables an objective comparison of photos taken at different times

B.6 Pre-Treatment Set-Up

Many physicians and experts with IPL, approach the parameters and settings for this procedure differently, by considering skin types, progress of the procedure and treatment, and the predominant condition of the patient's skin.

B.6.1 Treatment Parameters (ST Mode)

The Darwin IPL emits a defined range of wavelength through the filters. Chromophore which absorbs the lights of specific wavelength, exists in skin tissue in the body. Wavelengths emitted from the Darwin IPL absorbs into specific chromophore depending on the types of the wavelength. Absorbed light energy is transformed to thermal energy to be applied to various vascular lesions.

Parameters outlined in Tables B.6-1, B.6-2, B.6-3, B.6-4, and B.6-5 below are recommendations when treating in ST mode, however, these parameters may not apply to every patient.

Table B.6-1: Filter 430nm

SKIN TYPE	PULSE TYPE	PULSE (MS)	DELAY (MS)	Default Fluence (J/CM)²
Ⅰ-Ⅱ	Single	10ms	Spot treatment only	6
	Double	7ms	25ms	11
		8ms		11
		9ms		11
	Triple	5ms	25ms	13
	Quadruple	15ms		9
Ⅲ	Single	15ms		11
	Double	10ms	25ms	13
		11ms		13
		12ms		13
	Triple	7ms	25ms	15
	Quadruple	15ms		11

Table B.6-2: Filter 515nm

SKIN TYPE	PULSE TYPE	PULSE (MS)	DELAY (MS)	Default Fluence (J/CM)²
Ⅰ-Ⅱ	Single	4ms		(P1) 6
				(P2) 6
	Double	7ms	20ms	16
	Triple	5ms	20ms	17
	Quadruple	10ms		10
Ⅲ	Single	10ms		10
		11ms		10
		12ms		10
		13ms		10
		14ms		10
		15ms		10

SKIN TYPE	PULSE TYPE	PULSE (MS)	DELAY (MS)	Default Fluence (J/CM)²
	Double	7ms	20ms	16
	Triple	5ms	25ms	15
	Quadruple	10ms		9
IV	Single	n/a		-
	Double	n/a	n/a	-
	Triple	n/a	n/a	-
	Quadruple	14ms		7

Table B.6-3: Filter (560nm)

SKIN TYPE	PULSE TYPE	PULSE (MS)	DELAY (MS)	Default Fluence (J/CM)²
I - II	Single	10ms		12
	Double	7ms	20ms	16
	Triple	5ms	20ms	17
	Quadruple	10ms		10
III	Single	15ms		13
	Double	7ms	20ms	15
		8ms		15
		9ms		15
	Triple	5ms	20ms	15
		6ms		15
		7ms		15
	Quadruple	10ms		9
IV	Single	20ms		10
	Double	7ms	20ms	10
		8ms		10
		9ms		10
	Triple	5ms	20ms	10
		6ms		10
		7ms		10
	Quadruple	14ms		9

Table B.6-4: Filter (585nm)

SKIN TYPE	PULSE TYPE	PULSE (MS)	DELAY (MS)	Default Fluence (J/CM)²
I - II	Single	10ms		12
	Double	7ms	20ms	16

SKIN TYPE	PULSE TYPE	PULSE (MS)	DELAY (MS)	Default Fluence (J/CM)²
	Triple	5ms	20ms	17
	Quadruple	10ms		10
Ⅲ	Single	15ms		13
	Double	7ms	20ms	15
		8ms		15
		9ms		15
	Triple	5ms	20ms	15
		6ms		15
		7ms		15
	Quadruple	10ms		9
Ⅳ-Ⅴ	Single	20ms		10
	Double	7ms	20ms	10
		8ms		10
		9ms		10
	Triple	5ms	20ms	10
		6ms		10
		7ms		10
	Quadruple	12ms		8
		13ms		8
		14ms		8

Table B 6.5: P3 (585nm)

Fitzpatrick Skin type	Pulse type	Pulse (ms)	Delay (ms)	Fluence (J/cm²)
I	III	6	50	15
II	III	6	50	14
III	III	6	50	13
IV	III	6	50	11
V	III	5	100	10

Table B.6-6: Filter(640nm)

SKIN TYPE	PULSE TYPE	PULSE (MS)	DELAY (MS)	Default Fluence (J/CM)²
Ⅰ - Ⅱ	Single	10ms		12
	Double	7ms	20ms	16
	Triple	5ms	20ms	17
	Quadruple	10ms		9
Ⅲ	Single	15ms		13
	Double	7ms	20ms	15
		8ms		15
		9ms		15
	Triple	5ms	20ms	15
		6ms		15

SKIN TYPE	PULSE TYPE	PULSE (MS)	DELAY (MS)	Default Fluence (J/CM)²
		7ms		15
	Quadruple	10ms		9
IV - V	Single	20ms		10
	Double	7ms	20ms	10
		8ms		10
		9ms		10
	Triple	5ms	20ms	10
		6ms		10
		7ms		10
	Quadruple	12ms		8
		13ms		8
		14ms		8

B.6.2 Treatment Parameters (HR Mode)

The IPL HR mode of the Darwin IPL is used to remove unwanted hair, using the principle of selective photothermolysis. This method involves disabling hair regrowth mechanisms by raising the temperature of the hair shaft and follicle high enough to damage the follicle's germinative cells without damaging the epidermis and the surrounding tissue. The germinative cells are those cells which divide and differentiate into the cells comprising the hair shaft and follicle. Following photo- epilation, the debris of these cells is eliminated from the tissue by phagocytosis.

For light skin types and fine or light hair, select a shorter wavelength filter and higher fluence.

For darker skin types and coarse hair and even more so for dense hair, select a longer wavelength filter and lower fluence.

Tanned skin: - Do NOT treat recently tanned skin.

Parameters outlined in Table B.6-6 below are recommendations; however, these parameters may not apply to every patient.

WARNING

Adjust the treatment parameters accordingly based on the patient's reaction to the skin patch test and other factors determined by the Health Care Professional.

CAUTION

LUVO Medical recommends selecting the lowest energy output settings regardless of Fitzpatrick Skin Type prior to treatment.

Table B.6-7: Parameters for HR mode – Filter 700NM

HAIR COLOR AND TEXTURE	SKIN TYPE	PULSE TYPE	PULSE (MS)	DELAY (MS)	Default Fluence (J/CM)²
HAIR Ⅰ White/Fine	Ⅰ-Ⅱ	Single	15		16
		Double	10	20	16
		Triple	7	20	18
	Ⅲ	Single	16		15
		Double	9	20	15
		Triple	7	20	17
	Ⅳ	Single	18		15
		Double	9	20	13
		Triple	7	20	15
	Ⅴ	Single	20		10
		Double	9	20	11
		Triple	7	20	13
HAIR Ⅱ White/Coarse	Ⅰ-Ⅱ	Single	15		16
		Double	9	20	16
		Triple	6	20	18
	Ⅲ	Single	16		15
		Double	8	20	15
		Triple	6	20	17
	Ⅳ	Single	18		14
		Double	8	20	13
		Triple	6	20	15
	Ⅴ	Single	20		10
		Double	8	20	11
		Triple	6	20	13
HAIR Ⅰ Black / Fine	Ⅰ-Ⅱ	Single	15		16
		Double	10	20	15
		Triple	7	20	16
	Ⅲ	Single	16		15
		Double	9	20	14
		Triple	7	20	15
	Ⅳ	Single	18		14
		Double	9	20	12
		Triple	7	20	13
	Ⅴ	Single	20		10
		Double	9	20	10
		Triple	7	20	10
HAIR Ⅱ Black / Coarse	Ⅰ-Ⅱ	Single	15		16
		Double	9	20	15
		Triple	6	20	16
		Single	16		15

HAIR COLOR AND TEXTURE	SKIN TYPE	PULSE TYPE	PULSE (MS)	DELAY (MS)	Default Fluence (J/CM)²
	Ⅲ	Double	8	20	14
		Triple	6	20	15
	Ⅳ	Single	18		14
		Double	8	20	12
		Triple	6	20	13
	Ⅴ	Single	20		10
		Double	8	20	10
		Triple	6	20	10

Filter 755 NM

HAIR COLOR AND TEXTURE	SKIN TYPE	PULSE TYPE	PULSE (MS)	DELAY (MS)	Default Fluence (J/CM)²
HAIR Ⅰ White/Fine	Ⅰ-Ⅱ	Single	15		16
		Double	10	20	16
		Triple	7	20	18
	Ⅲ	Single	16		15
		Double	9	20	15
		Triple	7	20	17
	Ⅳ	Single	18		15
		Double	9	20	13
		Triple	7	20	15
	Ⅴ	Single	20		10
		Double	9	20	11
		Triple	7	20	13
HAIR Ⅱ White/Coarse	Ⅰ-Ⅱ	Single	15		16
		Double	9	20	16
		Triple	6	20	18
	Ⅲ	Single	16		15
		Double	8	20	15
		Triple	6	20	17
	Ⅳ	Single	18		14
		Double	8	20	13
		Triple	6	20	15
	Ⅴ	Single	20		10
		Double	8	20	11
		Triple	6	20	13
HAIR Ⅰ Black / Fine	Ⅰ-Ⅱ	Single	15		16
		Double	10	20	15
		Triple	7	20	16
	Ⅲ	Single	16		15
		Double	9	20	14

HAIR COLOR AND TEXTURE	SKIN TYPE	PULSE TYPE	PULSE (MS)	DELAY (MS)	Default Fluence (J/CM)²
		Triple	7	20	15
	IV	Single	18		14
		Double	9	20	12
		Triple	7	20	13
	V	Single	20		10
		Double	9	20	10
		Triple	7	20	10
HAIR II Black / Coarse	I -II	Single	15		16
		Double	9	20	15
		Triple	6	20	16
	III	Single	16		15
		Double	8	20	14
		Triple	6	20	15
	IV	Single	18		14
		Double	8	20	12
		Triple	6	20	13
	V	Single	20		10
		Double	8	20	10
		Triple	6	20	10

B.6.3 Topical Anesthetic & Coupling Gel

Generally, skin aesthetic treatments performed with the Darwin IPL feature can be administered without topical anesthesia. However, since the skin treatment typically treats large surfaces such as a full face, many patients prefer to undergo the treatment using a topical anesthetic which results in a procedure without discomfort.

CAUTION

Follow manufacturer's instructions when using topical anesthetics.

Topical anesthetics are generally applied for a period of time (up to one hour) prior to treatment. Be certain to completely remove the entire topical anesthetic prior to treatment.

WARNING

Using large amounts of topical anesthetics have the potential to induce unwanted side effects.

It is not recommended to use topical anesthetics that are known to have vasoconstrictive effects on the treatment area.

Use coupling gel when performing IPL treatments. Refrigerated (6°C - 10°C) coupling gel (such as ultrasound gel), is recommended for the treatment, to help with discomfort and provide a light coupling medium between the light guide and skin surface.

B.7 Pre-Treatment

B.7.1 Pre-Treatment Reminders

1. Operator is to ensure they have good access to the treatment area and the Darwin IPL controls.
2. If using Topical Anesthetic, ensure to follow manufacturer's instructions.
3. The system beeps when ready. Pressing the trigger button delivers the pulse.
4. After treatment, a skin care program can enhance the IPL result of improved evenness of color, minimized pore size, and improvement of pigmented lesions and photo-aging.
5. Patients can resume routine activities immediately, observing the standard post-treatment precaution of avoiding sun exposure or using sun-block cream replenished frequently.
6. When providing skin treatment, keep in mind the following:
    a. Pigmented lesions may darken soon after IPL treatment, and fade or flake off after a few days.
    b. Vascular lesions may also darken soon after IPL treatment, as a result of blood coagulation
    c. Acne may appear more inflamed soon after the IPL treatment; the effect will subside within a few hours up to a few days following treatment.

B.7.2 Pre-Treatment Instructions

1. Have the patient remove all jewelry for the treatment.
2. Have the patient remove all metal accessories for the treatment.
3. Shave the treatment site to eliminate any surface hair that could interfere with the treatment. Protect the dark spots (nevi) using a pure white eyeliner. Remove the shaved hair with cello tape or a lint-roller by going over the skin surface with the sticky side of cello tape. Warn patients about simultaneous transient hair reduction over hairy areas.
4. Protect the hairline and eyebrows with 3M tape before treatment.
5. Ensure patch test has been carried out using one (1) to two (2) shots of output values 1 to 2J/cm2 lower than the treatment parameters to find the proper treatment output parameter.
6. Ensure patient reclined in a comfortable position with the recommended eye protection.
7. Thoroughly remove all make-up from the patient
8. Meticulously cleanse the treatment area with non-alcoholic preparation before treatment.
9. Ensure patient is wearing the recommended protective eye wear during treatment.
10. Operator must also wear the recommended protective eye wear.

11. Ensure to spread the coupling gel evenly with the appropriate thickness on the treatment area, immediately before treatment on a small portion of the treatment area. Gently stretch skin with fingers or a smooth instrument (such as a wooden spoon) to evenly spread the gel by rhytids for a smooth surface.
12. Establish clinical indications and select treatment parameters.
13. Treatment can begin.

B.8 Treatment

B.8.1 Treatment Basics

- During each treatment, the entire face, neck, chest, or hand area is treated. This yields a far more pleasing aesthetic result than limiting treatment to an isolated problem area, which is necessary with certain laser procedures.
- Treatment time is brief, usually less than twenty minutes.
- IPL skin treatments have many variations based on physician preference. These may involve variations in the IPL parameters selected, or variations of incorporating other aesthetic treatment modalities into the program.
- The shorter wavelength 560 nm filter is most commonly used for superficial lesions in lighter skin (up to Fitzpatrick Skin Type III). The 585 nm cut-off filter is recommended for treating superficial lesions on darker skin types, and deeper lesions on all skin types (I–IV). The 640 nm cut-off filter has particular utility in treatment of darker skin type (IV).
- In addition, the 640 nm filters are often used for deeper penetration into the dermal level of the collagen in all appropriate skin types (I–IV) providing an extra measure of treatment for skin texture.
- IPL Skin Treatments are contraindicated for Fitzpatrick Skin Type VI

B.8.2 Spot/Patch Test

Prior to full treatments, LUVO Medical recommends patients receive spot/patch test to evaluate the immediate and delayed skin response, as well as for side effects.

Ensure patch test has been carried out using one (1) to two (2) shots of output values 1 to 2J/cm2 lower than the treatment parameters to find the proper treatment output parameter.

Proceed with the Spot / Patch test in a section of the treatment area that is less

conspicuous. For skin treatments:

- Ensure the area is closely shaved and warn patients about simultaneous transient hair reduction over hairy areas.
- Spot / patch test requires adequate time (approximately 15 minutes or more for skin types I-III and 24-48 hours for skin type IV) to observe if any epidermal reaction occurs.

- Advise patients to avoid tanning and apply sun block during the spot test.

For hair removal treatment:

- Spot / patch test requires shaving test area to eliminate any surface hair that could interfere with the treatment.
- Protect the dark spots (nevi) using a pure white eyeliner.
- Ensure the test area is closely shaved. It is recommended to shave the hair a day before the treatment.
- Remove the shaved hair with cello tape or a lint-roller by going over the skin surface with the sticky side of cello tape.

B.8.3 Treatment Instructions

Ensure that the light guide is firmly pressed against the skin during each pulse.

CAUTION

Always perform Spot / Patch test prior to full treatment.

1. Select the desired parameters (default or customized), ensuring to start with parameters that are 1 – 2J/cm2 less than the desired parameters.
2. Start in a section of the treatment area that is less conspicuous.
3. Apply the handpiece light guide perpendicular to the skin surface. Ensure to align the light guide such that only the surface of the light guide is in contact with the skin surface.

CAUTION

Do NOT apply pressure when applying the handpiece light guide perpendicular to the skin surface.

4. Trigger the IPL via the handpiece or the footswitch.
5. Wipe off the gel and view the skin for the reaction to the triggered IPL shot. Allow approximately 15 minutes to pass to ensure that the patient's skin reaction to the treatment can be observed accurately.
6. If the patient's skin reaction to the treatment is a slight erythema, pink tone, continue with the settings.
7. If the patient's skin reaction to the treatment is insufficient, e.g. no pink tone or slight erythema, increase the treatment intensity by carrying out any of the following actions:
    a. Increase the fluence.
    b. Decrease the pulse delay (if using Pulse 2 or Pulse 3)

c. Decrease the pulse duration.

d. Decrease the pulse type, such as Pulse 3 to Pulse 2

e. Use a shorter wavelength filter.

8. If the patient's skin reaction to the treatment is showing signs of adverse events, such as too much erythema, signs of purpura, etc., reduce the intensity of the treatment by carrying out any of the following actions:

a. Decrease the fluence.

b. Increase the pulse delay (if using Pulse 2 or Pulse 3)

c. Increase the pulse duration.

d. Increase the pulse type, such as Pulse 1 to Pulse 2

e. Use a longer wavelength filter.

CAUTION

When treating for Fitzpatrick Skin Types IV and V, further adjustments may be required, as patient's skin reaction to the initial test may show as pigmentary symptoms and have minimal vascular symptoms.

9. Once the treatment settings have been adjusted according to the patient's skin reaction to the treatment, ensure that treatment sites are not overlapped by more than 1mm.

CAUTION

Do NOT overlap treatment area by more than 1mm.

10. Continue with treatment by moving from a small area of the treatment area onto the next small area, removing gel from the treated area and applying fresh refrigerated gel to the new treatment section. This will help with the cooling properties of the refrigerated gel during treatment. Do NOT reuse the gel.

CAUTION

Do NOT reuse the gel.

11. Ensure to avoid treating areas of the skin within the treatment area that contain:

CAUTION

It is recommended to reduce the fluence 1 – 2J/cm2 for the following treatment areas:

- **Close proximity to bones, such as the jaw, forehead, chin, shin, hands, breastbone**
- **Sensitive areas such under eyes, neck, chest, or hands**
- **Close proximity to areas of fat such as the breast or buttocks, as fat has high heat retention.**
- **Patients who are elderly, as they tend to have low protein in the skin.**
- **A lesion that has a high density of pigment**
- **In the case of high density of lesions such as freckles, treat the skin type using the freckles if the freckles are not the areas of treatment**

a. Hemangiomas and/or PWS or tattoos

b. Lesions on areas that may impair hair growth, such as a man's beard.

B.8.4 Post-Treatment Care

General Care:

Cold (not frozen) packs should be applied immediately after treatment, to cool treatment site, reduce swelling and optimize comfort.

Chemical cold packs are not recommended, if the chemical cold pack temperature is below 4°C.

Alternatively, frozen 4x4 gauze pads, previously moistened with water and inserted into small plastic bags or in plastic wrap, could be used post-treatment.

Exposure to Sunlight:

Ensure to council patient to use high factor sun block (SPF 30 or greater) and also to 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 hyperpigmentation.

Makeup:

Advising the patient regarding the application of makeup to the treated area, is at the discretion of the Health Care Professional

Ensure to council patient to notify IMMEDIATELY if there are any reactions and to stop using makeup.

Follow-up:

Council patient to return for follow-up treatment to complete the program discussed with the patient prior to treatment (four (4) to six (6) treatment sessions). Timing of the follow-up treatment visits include approximately every three (3) weeks for treatment of pigmentary lesions and approximately one (1) week for treatment of acne until the four (4) to six (6) treatment sessions are complete.

Adverse Events:

If there are adverse events during the treatment session, notify LUVO Medical's authorized representative, stop treatment and investigate the root cause of the adverse reaction.

Completion of Treatment:

Completion of treatment is determined by the Health Care Professional and / or the patient.

Appendix B1: Clinical Guide IPL For Treatment of Symptoms Dry Eye Disease (P3)

Dry Eye Disease symptoms treatments using the 585nm filters and operated by personnel who have been properly trained in the *Darwin IPL* handling and use. This may include physicians, nurses, technical staff or other professional staff members.

The physician is responsible for contacting the local licensing agencies to determine any credentials required by law for clinical use and operation of the device.

B1.1 Indications for use

	Wavelength > 585nm
Intended Use	Intended for the treatment of symptoms of dry eye disease (P3).
Indications for Use	For use on Fitzpatrick Skin Types I to V: • Treatment of symptoms of dry eye disease.

B1. 2 Contraindications

Patients who have had prior problems with IPL treatment should be carefully screened before treatment.

Treatment should not be attempted on patients with the following conditions in the treatment area:

- Active ocular infection
- Active inflammation of eye or eyelids
- Open wounds, burns
- History or concurrent condition of skin cancer or pre-cancerous lesions at the treatment area
- Children aged less than 18 years
- Fitzpatrick Skin Type VI
- Pregnancy
- Active infections
- Dysplastic nevi
- Tattoos, Permanent make-up,
- Significant concurrent skin conditions or any inflammatory skin conditions on the face.

• Active cold sores, open lacerations or abrasions.
• Chronic or cutaneous viral, fungal or bacterial diseases.
• Exposure to sun or artificial tanning during 3-4 weeks prior to treatment.
• Bleeding coagulopathies
Psychiatric disorders and/or unstable motivations
• Allergic to topical anesthetics
• Cardiac disorders requiring a pacemaker or result in serious heart rhythms
• Compromised liver or kidneys
• History of keloid scarring
• Photosensitive herbal preparations (St John's Wort, Ginkgo Biloba, Arnica) or aromatherapy (essential oils)
• Gold Therapy

B1.3 Precautions

Patients with a medical history or presence of the following should be treated with caution and per the physician's discretion:

• Herpes simplex: treatment can trigger a herpes outbreak; prophylactic antiviral therapy may be prescribed at the physician's discretion.
• Systemic Lupus Erythematosus or Porphyria. Immunosuppressive diseases, including AIDS and HIV infection.
• Uncontrolled systemic diseases such as diabetes, epilepsy or congestive heart disease.
• Photosensitivity in general, or any sensitivity to the sun that causes a rash or an allergic reaction.
• Hormonal disorders, such as polycystic ovary syndrome, unless under control.
• Radiation therapy.
• Prior use of collagen, fat injections or other methods of skin augmentation.

Patients who use any of the following should be treated with caution and per the physician's discretion:

• Anticoagulants; avoid usage of anticoagulants prior to treatment, at the
• physician's discretion.
• Immunosuppressive medications.
• Herbal supplements, perfumes or cosmetics that may affect sensitivity to light.
• Oral Isotretinoin (such as Accutane).

Patients with the following conditions should be treated with caution and per the physician's discretion:

• Damage to natural skin texture and/or very dry skin.

Highly vasculated area in the lesion's immediate proximity

• Treatment within the orbital rim: patient should wear intraocular shields to protect the eyes from direct or indirect IPL exposure.

B1.4 Warnings

Appropriate care must be taken to ensure safe and proper use of the DARWIN IPL system.

CAUTION
Read all instructions, cautions and warnings provided with the system and any accessories before using. All personnel must be trained in the use of the DARWIN IPL system prior to use

The IPL can cause epidermal injury. The risk increases with greater fluence and skin pigmentation:

- Darker skin types and individuals with a non-recent suntan are at a higher risk for pigmentary changes in the treatment area. These patients should be treated with caution following strict test-spot protocol.
- Sun exposure to the treatment area immediately after treatment and for one month following treatment may also increase the risk of pigmentary changes in the treatment area. Patients should be instructed to use a broad-spectrum sunscreen (SPF 30 at the minimum) daily and repeat the sunscreen application every two hours. Avoid direct sun exposure.
- Observe all safety precautions described in the section 2.0 Safety and elsewhere in this user manual.
- The light emitted by the *DARWIN IPL* can cause serious eye damage or blindness. All persons in the treatment room, including the patient, the operator and any observers must wear appropriate eye protection (optical density eye shields OD 5 for patients and OD 3 for staff and persons in the treatment room) whenever the main power is on. (For more information refer to section C.5.3 under Eye Protection)
- Contact lenses should not be worn during IPL treatment.

Perform test spots on patients and assess skin response before performing a full treatment.

Side effects may not develop until several days following exposure. For skin types V, wait at the minimum 48-72 hours after test spots to observe tissue reaction. Always allow adequate time between test spot and actual treatment.

CAUTION

The safety of using the DARWIN IPL system on nursing women is not known as LUVO Medical does not have clinical studies to support the use of the DARWIN IPL system on nursing women.

WARNING

Do NOT allow sun block or sunscreen products to come in contact with the system. The ingredients found in these products may cause deterioration or damage to the system.

If sunblock or sunscreen does come in contact with the system, clean immediately to prevent potential damage

B1.5 Pre-Treatment

B1.5.1 General

Remove any cosmetic/make-up from the skin.

IPL treatment of symptoms of DED is accomplished from tragus to tragus including the cheeks, the nose, and around the periorbital area.

A patient first visits the physician or delegated staff should record the patient history and determine the treatment appropriateness.

Talk about the treatment plan and expectation with the patient.

B1.5.2 Counselling

Counseling patients regarding realistic expectations for the *DARWIN IPL* treatment outcome before treatment is an important step.

During the first visit, the physician (or an authorized member of the staff) should inform the patient of the following:

- Potential for discomfort or pain associated with treatment
- Transient erythema/edema may appear immediately following treatment.
- Around three to four treatments to reach the expected results at the intervals of 2-4 weeks.
- Potential risk of adverse reactions (although the risk is small), such as changes in the texture and pigmentation of the skin should be discussed with the patient. These adverse reactions are usually transient and rare.
- IPL treatment may cause hair loss, including eyebrows and eyelashes

B1.5.3 Eye Protection

It is imperative that all people present in the treatment room during treatment (patient and medical personnel) protect their eyes by wearing the recommended protective eyewear with the following optical density (OD):

- OD 5 for the patient.
- OD 3 for operator and staff.

When using IPL near the eyes, have the patient wear eyewear with the optical density 5 (OD5). It is good practice to instruct the patient to close his/her eyes at the sound of the “beep” before the light

pulse is delivered, or during the entire periorbital treatment. For ALL facial treatments, the patient must wear eyeglasses with the optical density 5(OD5) as protective goggles.

WARNING

Ensure the patient and all present in the treatment room guard against accidental exposure to the IPL emissions either directly from the treatment head or indirectly from a reflecting surface.

Never look directly at the beam coming from the treatment head, even when wearing protective eyewear used. Never point the treatment head so that it discharges into free space.

Ensure the treatment head is mounted on its cradle, or during actual treatment pointed at the target treatment site.

B1.*5.4 Topical Anesthetic*

Generally skin treatments performed with the *DARWIN IPL* can be administered without topical anesthesia. However, since the skin treatment typically treats large surfaces such as both cheeks and nose, many patients prefer to undergo the treatment using a topical anesthetic which results in a procedure without discomfort.

CAUTION

Follow manufacturer's instructions when using topical anesthetics

Topical anesthetics are generally applied for a period of time (up to one hour) prior to treatment. Be certain to completely remove the entire topical anesthetic prior to treatment.

WARNING

Using large amounts of topical anesthetics have the potential to induce unwanted side effects.

It is not recommended to use topical anesthetics that are known to have vasoconstrictive effects on the treatment area.

B1.5.5 Photography

Before and after treatment photographs are recommended to be taken to document the progress of treatment, as many patients are not able to objectively assess the progress of treatment. These photographs provide concrete evidence.
Ensure that standard conditions and similar speed, flash and focal length are used to photograph all patients. This enables an objective comparison of photos taken at different times

B1.5.6 Potential Side Effects

IPL DED symptoms Treatments are typically administered in a series of three to four treatments, performed at intervals of a minimum of two to four weeks. A three-week interval between treatments has proven optimal. However, larger intervals do not appear to adversely influence treatment results. Spreading the treatment over this period provides a gradual improvement of the dry eye symptoms, a minimal risk of adverse effects, and preserves the important "no downtime" feature of the program. In rare cases where side effects do occur, postpone further treatments until complete

healing. The most common side effects are:

- Discomfort

  Sensations such as stinging or a rubber band snap. A burning sensation may last for up to an hour after treatment. Most patients tolerate this discomfort; however, some patients may require a topical anesthetic (avoid using a vasoconstrictive topical anesthetic).

- Damage to natural skin texture
  A crust or blister may form, which may take from five to ten days to heal Pigmentation Change

  Most cases of hypo- or hyper-pigmentation occur in people with darker skin, or when the treated area has been exposed to sunlight before or after treatment. In some patients, hyperpigmentation occurs despite protection from the sun. This discoloration usually fades in three to six months, but in rare cases, mainly hypopigmentation, the change of pigment may last longer or be permanent

- Scarring

  There is a very small chance of scarring, such as enlarged hypertrophic scars. In very rare cases, abnormal, large, raised keloid scars may appear. To reduce the chance of scarring, it is important to carefully follow all pre and post-op instructions and exclude patients that have a genetic tendency for scarring.

- Excessive swelling

  Immediately after treatment, especially in the regions of the nose or the periorbital zone, the skin may swell temporarily. Swelling usually subsides within hours to as much as seven days

- Fragile skin

  The skin at or near the treatment site may become fragile. If this happens, avoid makeup and do not rub the area, as this might tear the skin

- Bruising

  Very rarely, a blue-purple bruise (purpura) may appear on the treated area. It may last from five to fifteen days. As the bruise fades, there may be rust- brown discoloration of this skin, which fades in one to three months

- Burns

  There is a small chance of burns occurring on the skin. To reduce the possibility of burns from occurring, it is important to carefully follow all treatment instructions, and in particular to perform test patches.

  Always perform a test patch in a small inconspicuous zone within the intended treatment area during the first treatment session and whenever treatment settings are changed, before performing an additional pass on the same treatment area (if allowed), and when changing a module

- Xerosis

  The skin may become dry if proper skin care has not been carried out- between sessions

- Ocular complications

Periorbital IPL treatment may permanently affect pigmented ocular structures if eyes are not protected with fully occlusive eye shields like OD 5 during the treatment. Ocular difficulties include pupillary defects, iritis, anterior uveitis, posterior synechiae, and iris trans-illumination defects. These complications can lead to pain, photophobia and, in extreme cases, permanent damage to vision.

IPL light guide on the eyelashes may impact to permanent loss of eyelashes. Thus, do not touch any part of the eyelashes with the IPL lightguide.

B1.6 Treatment Parameters

Many physicians and experts with IPL, approach the parameters and settings for this procedure differently, by considering skin types, progress of the procedure and treatment, and the predominant condition of the patient's skin.

Wavelengths emitted from *DARWIN IPL* absorbs into specific chromophore depending on the types of the wavelength. Absorbed light energy is transformed to thermal energy to be applied to ocular surface.

B1.*6.1* Parameter Guidelines

Parameters outlined in Tables A-1below are recommendations, however, these parameters may not apply to every patient.

WARNING

Adjust the treatment parameters accordingly based on the patient's reaction to the skin patch test and other factors determined by the Health Care Professional

CAUTION

Protect eyebrows and hairline with 3M tape before treatment
LUVO Medical recommends selecting the lowest energy output settings regardless of Fitzpatrick Skin Type prior to treatment

Settings for treatment of Dry Eye Disease symptoms around periorbital area

Fitzpatrick Skin type	Pulse type	Pulse (ms)	Delay (ms)	Fluence (J/cm²)
I	III	6ms	50ms	15J/㎠
II	III	6ms	50ms	14J/㎠
III	III	6ms	50ms	13J/㎠
IV	III	6ms	50ms	11J/㎠
V	III	5ms	100ms	10J/㎠

B1.7 Treatment

The first step is to access the skin type as the treatment parameters depend on the skin type.

B1.7.1 Coupling Gel

Use refrigerated (6°C - 10°C) ultrasound gel during treatment, to help with

discomfort and provide a light coupling medium between the light guide and skin surface.

B1.7.2 Treatment Basics

- Treatment time is brief, usually less than twenty minutes
- The recommended wavelength is 585 nm filter.
- A test spot should be done with the same lightguide as the one that will be used for treatment.
- Following the first pulse, adequate time (approximately 15 minutes or more for skin types I-III and 24-48 hours for skin types IV-V) must be given to observe if any epidermal reaction occurs.
- IPL Skin Treatments are contraindicated for Fitzpatrick Skin Type VI

B1.7.3 Pre-Treatment

After the clinical indications have been established, the treatment parameters selected, topical anesthetic has been applied to treatment area (if required), the treatment can begin.

CAUTION

LUVO Medical recommends that, always perform the test spot on the intended treatment area during the first treatment to observe if any epidermal reaction occurs.

Pre-treatment reminders:

1. Operator to ensure they have good access to the treatment area and the DARWIN IPL controls.
2. The system beeps when ready. Pressing the trigger button delivers the pulse.
3. Physicians must get trained in the use of the DARWIN IPL system prior to use and setting parameters.
4. Avoid tanning before treatment. No Lid Scrubs or Warm Compresses
5. Patients can resume routine activities immediately, observing the standard post- treatment precaution of avoiding sun exposure or using sunblock cream replenished frequently.

Pre-treatment Instructions:

1. The general treatment area includes the malar region, below the lower eyelids, from tragus (lower end of the ear) to tragus including the nose, and the peri-orbital area.
2. Ensure patient reclined in a comfortable position with the recommended eye protection.
3. Thoroughly remove all make-up from the patient.
4. Meticulously cleanse the treatment area with non-alcoholic preparation

before treatment

5. Ensure patient is wearing the recommended protective eye wear during treatment.
6. Operator must also wear the recommended protective eye wear
7. Ensure to spread the ultrasound gel evenly with the appropriate thickness on the treatment area, immediately before treatment on a small portion of the treatment area. Gently stretch skin with fingers or a smooth instrument (such as a wooden spoon) to evenly spread the gel by rhytids for a smooth surface.

B1.7.4 Treatment Instructions

Ensure that the lightguide is firmly pressed against the skin during each pulse.

CAUTION

Always perform a test patch on the intended treatment area during the first treatment session

1. Select the desired parameters (default or customized), ensuring to start with parameters that are 1 – 2J/cm^2 less than the desired parameters
2. Start in a section of the treatment area that is less conspicuous
3. Apply the handpiece light guide perpendicular to the skin surface. Ensure to align the light guide such that only the surface of the light guide is in contact with the skin surface.

CAUTION

Do NOT apply pressure when applying the handpiece light guide perpendicular to the skin surface.

4. Trigger the IPL via the handpiece or the footswitch.
5. Footswitch shall be covered with the cover of footswitch.
6. Wipe off the gel and view the skin for the reaction to the triggered IPL shot. Allow approximately 15 minutes to pass to ensure that the patient's skin reaction to the treatment can be observed accurately
7. If the patient's skin reaction to the treatment is a slight erythema, pink tone, continue with the settings

CAUTION

When treating for Fitzpatrick Skin Types IV and V, further adjustments may be required, as patient's skin reaction to the initial test may show as pigmentary symptoms and have minimal vascular symptoms.

8. Once the treatment settings have been adjusted according to the patient's skin reaction to the treatment, ensure that treatment sites are not overlapped by more than 1mm

CAUTION
Do NOT overlap treatment area by more than 1mm

CAUTION
Do NOT reuse the gel

9. Ensure to avoid treating areas of the skin within the treatment area that contain Hemangiomas and/or PWS or tattoos

10. Apply 1 to 2 mm of fresh refrigerated coupling gel to the treatment area, and start the second pass. Do not reuse the gel from pass 1. Continue the procedure treating the entire treatment area.

B1.7.5 Post-Treatment Care

General Care:

- Cold (not frozen) packs should be applied immediately after treatment, to cool treatment site, reduce swelling and optimize comfort.
- Chemical cold packs are not recommended, if the chemical cold pack temperature is below 4°C.
- Alternatively, frozen 4x4 gauze pads, previously moistened with water and inserted into small plastic bags or in plastic wrap, could be used post-treatment.

Exposure to Sunlight:

- Ensure to council patient to use high factor sun block (SPF 30 or greater) and also to 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 hyperpigmentation

Makeup:

- Advising the patient regarding the application of makeup to the treated area, is at the discretion of the Health Care Professional.
- Ensure to council patient to notify IMMEDIATELY if there are any reactions and to stop using makeup.

Follow-up:

- Three months after the last IPL session, we recommend that the patient return for an evaluation of his/her dry eye symptoms and signs. During this follow-up, the treating physician might schedule a maintenance session is required.

Adverse Events:

- If there are adverse events during the treatment session, notify LUVO Medical's authorized representative, stop treatment, allow to heal and investigate the root cause of the adverse reaction.
- Steroid cream can be used in case of a sensitive response after the treatment.

Completion of Treatment:

- Completion of treatment is determined by the Health Care Professional and / or the patient.

Appendix C: Clinical Guide HIFU Treatments

The Darwin system combines multiple technologies for use in dermatologic and aesthetic procedures, in one stand-alone device.

This clinical guide is for the Darwin HIFU Handpiece.

The non-invasive HIFU handpiece with three (3) detachable cartridges is intended for dermatological aesthetic treatments.

C.1 Indications for Use

The Darwin HIFU handpiece is indicated for use as a non-invasive dermatological aesthetic treatment to lift the eyebrow, lift lax submental and neck tissue, which can also affect the appearance of lax tissue in the submental and neck regions, improve lines and wrinkles of the décolleté.

C.2 Contraindications

Contraindications include:

- Treating over areas with:
  - Mechanical implants
  - Derma fillers
  - Implanted electrical devices.
  - Metal stents in the face & neck area
  - Existing keloid
  - Open facial wounds or lesions
  - Severe or cystic acne on the face and/or neck
- Patients on an anticoagulant treatment plan
- Pregnant or breast-feeding
- Children (18 years of age and under)
- Hemorrhagic disorder or haemostatic dysfunction
- Active systemic or local skin disease that may later alter wound healing.
- Herpes Simplex
- Autoimmune Disease
- Diabetes
- Epilepsy
- Bell's palsy

C.3 Warnings

The HIFU feature of the Darwin can cause injury if used improperly. High voltages are present inside the Darwin system. Personnel who work with the HIFU feature must always be aware of the possible dangers and must take the proper safeguards. Ensure all operators have read section 2.0 Safety prior to carrying out treatment.

WARNING

Do NOT allow untrained personnel to operate system.

Ready all instructions, cautions and warnings provided with the system and any accessories before use.

Increased risk of causing harm to user and patient when using controls, parameters, performance procedures that are outside of those listed in the user manual.

Use carefully. May cause serious burns.

Turn the system off when moving from one treatment area to another treatment area

Do NOT move the system when the system is operating.

WARNING

Do NOT allow sun block or sunscreen products to come in contact with the system.

The ingredients found in these products may cause deterioration or damage to the system.

If sun block or sunscreen does come in contact with the system, clean immediately to prevent potential damage.

WARNING

Do NOT treat patient's eyes or patient's eyeball.

Do NOT use a technique where the focused ultrasound energy can reach the eye.

Do NOT deviate from the instructions provided on the HIFU treatment diagrams, proper distribution of line placement and thus avoid treating over nerves.

Failure to follow instruction may lead to temporary nerve damage.

Do NOT use a technique where the focused ultrasound energy can reach the eye / eyeball

CAUTION

The safety of using the Darwin HIFU feature on nursing women is not known, as LUVO Medical does not have clinical studies to support the use of the Darwin HIFU feature on nursing women.

WARNING

Patient should NOT come into contact with earthed metal parts or parts with appreciable capacitance to earth.

IMPORTANT NOT

After pressing READY, if no operation is detected for approximately 2 minutes, the system automatically changes to STANDBY mode.

If a serious error occurs during operation of the system, the system automatically changes to STANDBY mode

C.4 Potential Side Effects

Side effects can include:

- Erythema (redness): The treated area may exhibit erythema immediately following treatment. This typically resolves within 1-2 hours of treatment.
- Edema (swelling): The treated area may exhibit mild edema following treatment. This typically resolves within 48 hours of treatment.
- Pain: Momentary discomfort may be experienced during the procedure while energy is being deposited.
- Bruising: Mild bruising, which is caused by damage to soft tissue blood vessels, may occur occasionally and typically resolves within 3-7 days of treatment.
- Nerve injury: Numbness, which may occur as a result of damage to a sensory nerve, is transient and resolves in a few days.
- Nerve Effects:
    - Transient local muscle weakness may result after treatment due to inflammation of a motor nerve.
    - Transient numbness may result after treatment due to inflammation of a sensory nerve.
    - Transient pain, paresthesia and/or tingling may be experienced. No permanent injuries to facial nerves have been reported. However, based on clinical evidence facial nerve injury can take months to be resolved.
- Scarring: The possibility for scar formation may exist if incorrect treatment technique is used.

C.5 Pre-Treatment

C.5-1 Counseling

Counselling patients regarding realistic expectations for the HIFU treatment outcome prior to treatment is an important step.

During the patient's first visit, the physician (or an authorized staff member), LUVO Medical recommends the following to assist with realistic expectations:

- Ensure a detailed patient medical history is taken, including previous treatment interventions, and determine the suitability for treatment with the Darwin HIFU feature.
- Determine why the patient is seeking treatment and understand and manage his/her expectations.

The physician (or an authorized member of the staff) should inform the patient of the following:

- Potential for discomfort or pain associated with treatment.
- More than one treatment may be required to reach the expected results.
- Potential side effects outlined in section C.4 Potential Side Effects

C.5-2 Photography

Before and after treatment photographs are recommended to be taken to document the progress of treatment, as many patients are not able to objectively assess the progress of treatment. These photographs provide concrete evidence.

Ensure that standard conditions and similar speed, flash and focal length are used to photograph all patients. This enables an objective comparison of photos taken at different times.

C.6 Pre-Treatment Set-Up

C.6-1 Treatment Parameters

The recommended treatment parameters for the various treatment areas is outlined in Table C.6-1

Table C.6-1: Recommended treatment parameters

Type	Treatment Area	Energy (J)	Depth (mm)	Mhz
SD7-1.5	Face overall Eyebrow & periorbital	02 – 0.25	1.5	7
	Forehead	0.1 – 0.25		
	cheek, chin line	0.2 -0.25		
	Neck	0.2 -0.25		
DD7-3.0	Face – cheek	0.25 – 0.45	3.0	
	Face – chin line	0.3 – 0.4		
	Face - forehead	0.2 – 0.35		
	Neck / Eyebrow & periorbital	0.25 – 0.35		
SM4-4.5	Face (except forehead)	0.8 - 1.2	4.5	4

C.6-2 Topical Anesthetic

Typically, skin treatments performed with the Darwin HIFU handpiece do not require topical anesthesia. However, since the skin treatment may entail treating large surfaces, such as a full face, many patients prefer to undergo the treatment using a topical anesthetic which results in a procedure without discomfort.

CAUTION

Follow manufacturer's instructions when using topical anesthetics

Topical anesthetics are generally applied for a period of time (up to one hour) prior to treatment. Ensure to completely remove the entire topical anesthetic prior to treatment.

WARNING

Using large amounts of topical anesthetics have the potential to induce unwanted side effects. It is not recommended to use topical anesthetics that are known to have vasoconstrictive effects on the treatment area.

C.6-3 Spot Test

LUVO recommends performing spot tests on patients and assess skin response before performing a full treatment. The spot test should be performed on the border of the intended treatment area (suggest choosing a non-visible spot with the intended parameters), using the factory pre-set values.

Inspect the test spot at least 5 minutes after the test spot was carried out, to evaluate the intensity of the effect.

The expected response after the test spot, is mild to moderate erythema and edema on the treated area. Increase/decrees energy level according to the test spot reaction.

C.6-4 Pre-Treatment Site Preparation

To prepare the treatment site prior to treatment, carry out the following:

1. Have the patient remove all jewelry for the treatment.
2. Have the patient remove all metal accessories for the treatment.
3. Wash the treatment area thoroughly with water and soap to remove lotion and makeup. Dry the skin using a paper towel.
4. Photograph the patient as per section C.5-2 Photography
5. Clean the skin thoroughly with 70% alcohol before starting the treatment.
6. Ensure the alcohol has evaporated prior to treatment.
7. Apply topical anesthetic (if used), as per section C.6-2 Topical Anesthetic
8. Ensure all topical anesthetic is gently cleaned off. Ensure no topical anesthetic residue is present.
9. Apply a thin layer of ultrasound gel to the treatment site. Too much or too little gel will result in poor skin contact.
10. Place the patient in a comfortable position.

C.7 Performing the Treatment

Ensure the treatment site is prepped as per section C.6-4 Pre-Treatment Site Preparation, proper cartridge has been attached to the handpiece, the Darwin HIFU screen is opened, the default settings are indicated and in STANDBY mode.

CAUTION

When using the AUTO SHOT function, ensure to set the best interval time relative to the user's treatment speed.
Ensure care is taken while the AUTO SHOT function is being set-up. Do NOT move the HIFU handpiece when placed on the skin and fired or is in close contact with the skin during the AUTO SHOT function set-up.

To begin treatment:

1. Place the cartridge window flush with the patient's skin and press the operating button to fire the HIFU pulse.

WARNING

Ensure the cartridge is in direct contact with the skin / treatment area during treatment.

2. Inspect the treatment area for erythema and edema after each pulse. If erythema and redness are mild the power setting can be increased until moderate post pulse erythema and edema are noted.

CAUTION

Inspect the treatment area for erythema and edema after each pulse. If erythema and redness are mild the power setting can be increased until moderate post pulse erythema and edema are noted

3. To deliver the next treatment pulse within the same treatment region, advance the cartridge 4-5 mm adjacent to the treated area and press the operating button.
4. Continue in this fashion until the desired treatment area has undergone treatment.
5. Ensure to keep cartridge window clean during treatment.

WARNING

Ensure to always keep the cartridge window clean.
Ensure to clean the ultrasound gel from the surface after each treatment.

WARNING

Do NOT treat patient's eyes or patient's eyeball.
Do NOT use a technique where the focused ultrasound energy can reach the eye / eyeball.
Do NOT deviate from the instructions provided on the HIFU treatment diagrams, proper distribution of line placement and thus avoid treating over nerves.
Failure to follow instruction may lead to temporary nerve damage

The recommended treatment parameters for the various treatment areas are outlined in Table C.6-1

C.7-1 Face treatment guide with diagrams

The following diagrams show proper line placement of the ultrasound handpieces. Following the guidance in these diagrams will minimize risk of nerve damage, particularly the temporal branch of the trigeminal nerve and the marginal mandibular nerve.

It is especially important to follow and use these diagrams to ensure proper distribution of line placement and thus avoid treating over the nerves. Figure C.7.-1 outlines the areas to treat overall, and all areas not marked are the zones to be avoided to minimize risk of nerve damage. Additionally, Figures C.7-2, C.7-3, C.7-4 show the proper placement and treatment areas per cartridge, areas not highlighted within the diagrams must be strictly avoided during HIFU treatment. Failure to do so may lead to temporary nerve damage.

WARNING

Do NOT deviate from the instructions provided on the HIFU treatment diagrams, proper distribution of line placement and thus avoid treating over nerves.

Failure to follow instruction may lead to temporary nerve damage.
Do NOT use a technique where the Darwin focused ultrasound energy can reach the eye / eyeball

Figure C.7-1: Proper placement areas for HIFU treatments

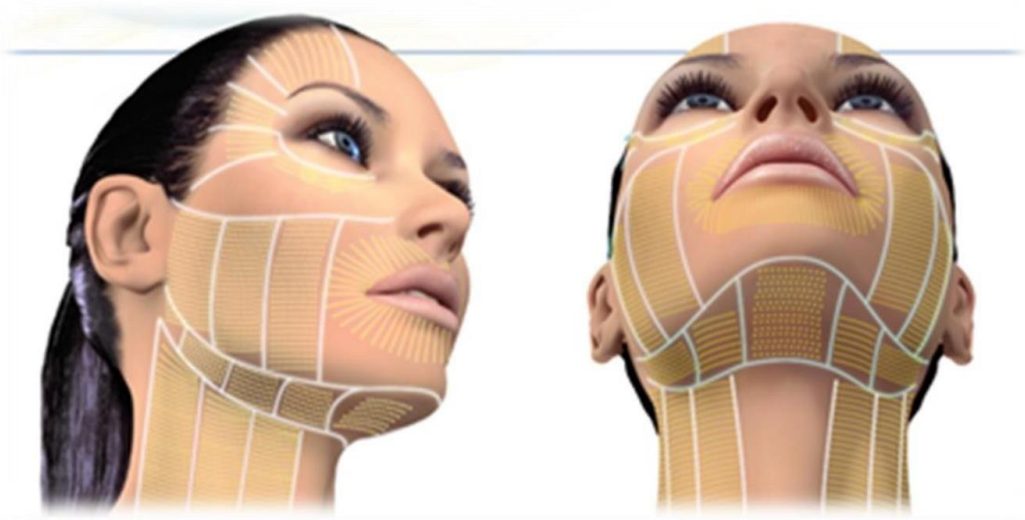


Figure C.7-2: HIFU Proper placement of the SM4-4.5 Cartridge

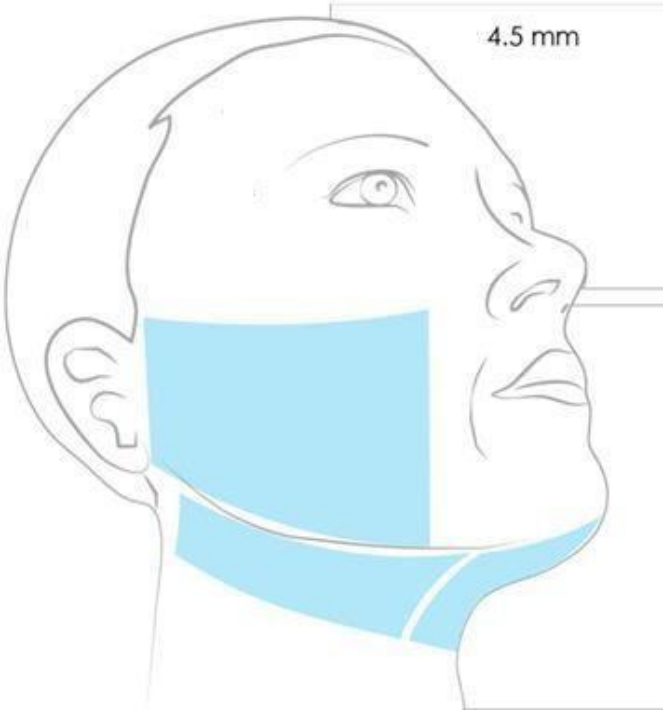


Figure C.7-3: Proper Placement of the DD7-3.0 Cartridge

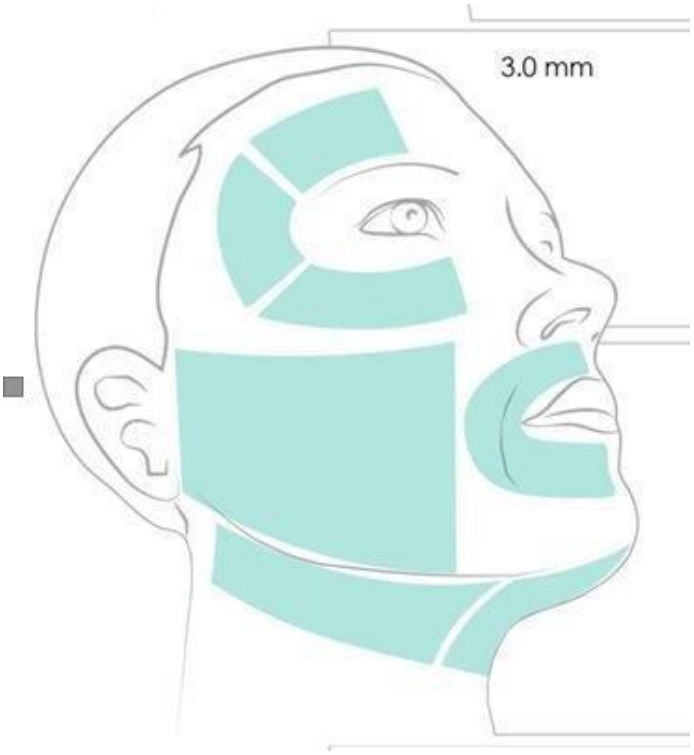
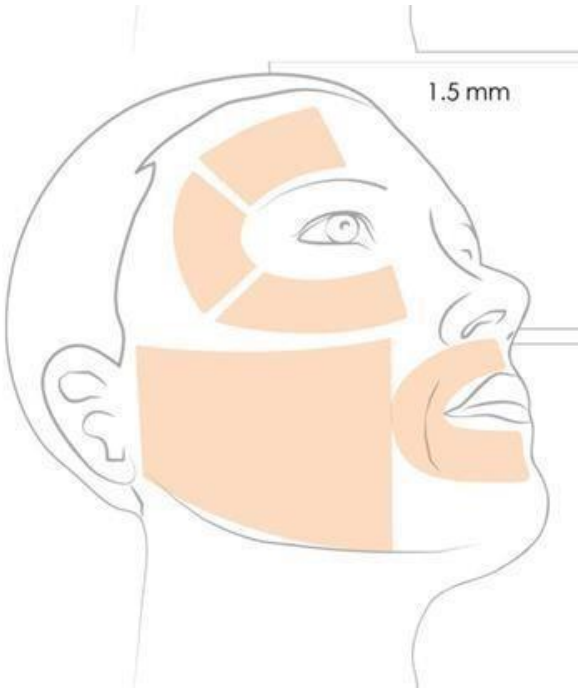


Figure C.7-4: Proper Placement of the SD7-1.5 Cartridge



C.8 Post Treatment

Ensure all ultrasound gel has been cleaned from the treatment area.

In cases of persisting Edema, Erythema or discomfort following the procedure, advise patient to IMMEDIATELY report to the physician. The physician is to IMMEDIATELY report to LUVO Medical's authorized representative.

Appendix D: Clinical Guide Needle RF Treatments

The Darwin system combines multiple technologies for use in dermatologic and aesthetic procedures, in one stand-alone device.

This clinical guide is for the Darwin Needle RF Handpiece.

The Needle RF handpiece operates using sterile, single-use, multi-needle tips (10 pin and 25 pin).

D.1 Indications for Use

The Needle RF is indicated for tissue coagulation designed to stimulate and remodel collagen, fine lines, wrinkles, photoaging and striae.

D.2 Contraindications

Treatment with the Needle RF feature is contraindicated for patients with any of the following conditions:

- Implanted pacemakers, arrhythmias, or any other severe known heart disorder
- Any implantable metal device in the treatment area, such as metal stents, etc.
- On any medication that would affect the characteristic of the skin (medical or hormonal), such as Isotretinoin (Accutane) within the past two months.
- Any form of suspicious lesion in the treatment area
- Pregnant or breast-feeding.
- Body piercing (in the treated area)
- Suffer from autoimmune disorders or diabetes.
- Using blood thinning medications
- Clotting disorders
- History of any kind of cancer
- Impaired immune system due to immunosuppressive diseases such as AIDS and HTV, or use of immunosuppressive medications
- Patients with history of diseases stimulated by heat, such as recurrent Herpes Simplex in the treatment area, may be treated only following a prophylactic regime.
- Any active condition in the treatment area, such as sores, psoriasis, eczema, and rash
- History of skin disorders, keloids, abnormal wound healing, as well as very dry and fragile skin
- Use of non-steroidal anti-inflammatory drugs (NSAIDS, e.g., ibuprofen containing agents) one week before and after each treatment session.
- Any surgical procedure in the treatment area within the last 3 months or before complete healing.

- Treating over tattoo or permanent makeup
- Excessively tanned skin from sun, tanning beds, or tanning creams within the last two weeks.
- Treating over the thyroid, breast, or any other sensitive area according to the physician decision
- Face lift or eyelid surgery within a year prior to treatment.
- Facial dermabrasion, facial resurfacing, or deep chemical peeling within the last three months, if face is treated.
- Any other medical condition according to the doctor's judgment.

D.3 Warnings

The Needle RF feature of the Darwin can cause injury if used improperly. High voltages are present inside the Darwin system. Personnel who work with the Needle RF feature must always be aware of the possible

dangers and must take the proper safeguards.

Ensure all operators have read section 2.0 Safety prior to carrying out treatment.

WARNING

Do NOT allow untrained personnel to operate system.

Ready all instructions, cautions and warnings provided with the system and any accessories before use.

Increased risk of causing harm to user and patient when using controls, parameters, performance procedures that are outside of those listed in the user manual.

Use carefully. May cause serious burns.

Turn the system off when moving from one treatment area to another treatment area

Do NOT move the system when the system is operating.

WARNING

Do NOT allow sun block or sunscreen products to come in contact with the system.

The ingredients found in these products may cause deterioration or damage to the system.

If sun block or sunscreen does come in contact with the system, clean immediately to prevent potential damage.

WARNING

For the Needle RF treatment, the patient is to avoid:

- **Intense sun exposure 3 days before treatment.**
- **Use of products that might affect skin sensitivity such as Glycolic Acid, Salicylic Acid, Retin-A® and other products containing Isotretinoin, three (3) days before treatment.**

WARNING

Patient should NOT come into contact with earthed metal parts or parts with appreciable capacitance to earth.

CAUTION

The safety of using the Darwin Needle RF feature on nursing women is not known, as LUVO Medical does not have clinical studies to support the use of the Darwin Needle RF feature on nursing women.

IMPORTANT NOTE

After pressing READY, if no operation is detected for approximately 2 minutes, the system automatically changes to STANDBY mode.

If a serious error occurs during operation of the system, the system automatically changes to STANDBY mode

D.4 Potential Side Effects

Side effects can include:

- Erythema (redness): The treated area may exhibit erythema immediately following treatment. This typically resolves within 1-2 hours of treatment.
- Edema (swelling): The treated area may exhibit mild edema following treatment. This typically resolves within 48 hours of treatment.
- Pain: Momentary discomfort may be experienced during the procedure while energy is being deposited.
- Bruising: Mild bruising, which is caused by damage to soft tissue blood vessels, may occur occasionally and typically resolves within 3-7 days of treatment.
- Nerve injury: Numbness, which may occur as a result of damage to a sensory nerve, is transient and resolves in a few days.
- Scarring: The possibility for scar formation may exist if incorrect treatment technique is used.

D.5 Pre-Treatment

D.5-1 Counseling

Counselling patients regarding realistic expectations for the Needle RF treatment outcome prior to treatment is an important step.

During the patient's first visit, the physician (or an authorized staff member), LUVO Medical recommends the following to assist with realistic expectations:

- Ensure a detailed patient medical history is taken, including previous treatment interventions, and determine the suitability for treatment with the Darwin Needle RF feature.
- Determine why the patient is seeking treatment and understand and manage his/her expectations.

The physician (or an authorized member of the staff) should inform the patient of the following:

- Potential for discomfort or pain associated with treatment
- More than one treatment may be required to reach the expected results.
- Potential side effects outlined in section D.4 Potential Side Effects

D.5-2 Photography

Before and after treatment photographs are recommended to be taken to document the progress of treatment, as many patients are not able to objectively assess the progress of treatment. These photographs provide concrete evidence.

Ensure that standard conditions and similar speed, flash and focal length are used to photograph all patients. This enables an objective comparison of photos taken at different times.

D.6 Pre-Treatment Set-Up

D.6-1 Treatment Parameters

The recommended treatment parameters for the various treatment areas are outlined in Table D.6-1

Table D.6-1: Needle RF treatment parameters

Indications	Treatment Area	Depth (mm)	RF		Vacuum
			Level	On Time (ms)	
Fine Lines, Photoaging	Eyebrow	0.5~0.8	2~4	100	1
	Forehead / Periorbital / Neck	0.5~1.0	3~5	100	1
	Cheek / Jowl	0.5~2.0	3~5	100~200	1~2
Wrinkle	Eyebrow	0.5~0.8	3~4	100	1
	Forehead / Periorbital / Neck	0.5~1.0	4~6	100	1
	Cheek / Jowl	0.5~2.0	4~6	100~200	1~2
Striae	Body	0.5~3.5	4~6	100~200	0

WARNING

Ensure that 3.5mm depth is only used for treatment on the Body

D.6-2 Topical Anesthetic

Typically, skin treatments performed with the Darwin Needle RF handpiece do not require topical anesthesia. However, since the skin treatment may entail treating large surfaces, such as a full face, many patients prefer to undergo the treatment using a topical anesthetic which results in a procedure without discomfort.

CAUTION

Follow manufacturer's instructions when using topical anesthetics

Topical anesthetics are generally applied for a period of time (up to one hour) prior to treatment. Ensure to completely remove the entire topical anesthetic prior to treatment

WARNING

Using large amounts of topical anesthetics have the potential to induce unwanted side effects. It is not recommended to use topical anesthetics that are known to have vasoconstrictive effects on the treatment area.

D.6-3 Spot Test

LUVO recommends performing spot tests on patients and assess skin response before performing a full treatment. The spot test should be performed on the border of the intended treatment area (suggest choosing a non-visible spot with the intended parameters), using the factory pre-set values.

Inspect the test spot at least 5 minutes after the test spot was carried out, to evaluate the intensity of the effect.

The expected response after the test spot, is mild to moderate erythema and edema on the treated area. Increase/decrees energy level according to the test spot reaction.

D.6-4 Pre-Treatment Site Preparation

To prepare the treatment site prior to treatment, carry out the following:

1. Have the patient remove all jewelry for the treatment.
2. Have the patient remove all metal accessories for the treatment.
3. Wash the treatment area thoroughly with water and soap to remove lotion and makeup. Dry the skin using a paper towel.
4. Photograph the patient as per section D.5-2 Photography
5. Clean the skin thoroughly with 70% alcohol before starting the treatment.
6. Ensure the alcohol has evaporated prior to treatment.
7. Apply topical anesthetic (if used), as per section D.6-2 Topical Anesthetic
8. Ensure all topical anesthetic is gently cleaned off. Ensure no topical anesthetic residue is present.
9. Apply a thin layer of RF conductive solution/cream to the treatment site. Too much or too little RF solution will result in poor skin contact.
10. Place the patient in a comfortable position.

D.7 Performing the Treatment

Ensure the treatment site is prepped as per section D.6-4 Pre-Treatment Site Preparation, the desired Needle RF tip has been attached to the handpiece, the Needle RF screen is opened, the default settings are indicated and in STANDBY mode.

To begin the treatment:

1. Place the Needle RF tip flush with the patient's skin and press the operating button to fire the RF pulse.

WARNING

Ensure the Needle RF tip is in direct contact with the skin / treatment area during treatment.
Ensure that 3.5mm depth is only used for treatment on the Body

2. Inspect the treatment area for erythema and edema after each pulse. If erythema and redness are mild the power setting can be increased until moderate post pulse erythema and edema are noted
3. Position the tip in close proximity to the previously treated area and activate the RF pulse.
4. Repeat steps 1 – 3 until the treatment area is completed.
5. It is possible to cover part of the treatment area, or all of it, with an additional pass of pulses, for additional clinical effect to a maximum of 3 passes.

WARNING

The Needle RF tip is a single-use item.
Do NOT re-use or re-sterilize.
Dispose in a Sharps needle disposal unit.

D.8 Post Treatment

While skin is sensitive, advised patients to keep the treatment area clean and avoid aggressive products such peels or other similar products.

It is recommended to apply soothing skin product until mini crusts are removed or at least two days post treatment.

Advise the patient to avoid sun exposure and use total sun block for at least 4 weeks post treatment

Advised men not to shave for one week, post treatment.

In cases of persisting Edema, Erythema or discomfort following the procedure, advise patient to IMMEDIATELY report to the physician. The physician is to IMMEDIATELY report to LUVO Medical's authorized representative.

As a matter of caution, advise the patient to be cautious of receiving the following treatments prior to the timeline outlined per treatment, after their present treatment:

- Face lift or eyelid surgery within a year after present RF treatment.
- Facial dermabrasion, facial resurfacing, or deep chemical peeling within the last three months from the present RF treatment
- Botox®/collagen/fat injections or other methods of augmentation with injected material in the treated area within 1 month after the present RF treatment
- Having received treatment with light, RF or other devices in the treated area within 1 month after the present RF treatment

Appendix E: Clinical Guide for Face Thermal RF Treatment

The Darwin system combines multiple technologies for use in dermatologic and aesthetic procedures, in one stand-alone device.

This clinical guide is for the Darwin Face Thermal RF Handpiece

Darwin's Face Thermal RF, non-invasive, monopolar/bipolar handpiece helps to improve the appearance of skin texture and elasticity. This handpiece is designed to transfer low level of thermal energy to the treatment area.

E.1 Indications for Use

The Darwin Face Thermal RF is intended to help improve the appearance of skin texture and elasticity. The treatments can be performed in Fitzpatrick Skin Types I-V

E.2 Contraindications

Treatment with the Face Thermal RF feature is contraindicated for patients with any of the following conditions:

- Malignant cancer
- Pregnant or lactating women
- Herpes
- Heart disease sufferers or person with a cardiac pacemaker
- Epileptic
- Lupus
- Vitiligo
- Bacterial or viral infection
- Rash
- Inflammation
- Dilated capillaries or varicose veins
- Anticoagulant treatment or blood disease or heart condition.
- Swelling of the glands
- Inherited anaphylaxis
- Thyroid disease
- And other specific diseases
- Had medical/aesthetic treatment, such as aesthetic laser treatment, chemical peels, dermal filler, Botox®, etc., within 2 weeks of the treatment.
- Actively using certain medications such as Isotretinoin (Accutane), or anticoagulants

- Treating Areas with body piercings in the treatment area
- Not intended for Fitzpatrick Skin Type VI or patients with tanned skin

E.3 Warnings

The Face Thermal RF feature of the Darwin can cause injury if used improperly. High voltages are present inside the Darwin system. Personnel who work with the Face Thermal RF feature must always be aware of the possible dangers and must take the proper safeguards. Ensure all operators have read section 2.0 Safety prior to carrying out treatment.

WARNING

Do NOT allow untrained personnel to operate system.

Ready all instructions, cautions and warnings provided with the system and any accessories before use.

Increased risk of causing harm to user and patient when using controls, parameters, performance procedures that are outside of those listed in the user manual.

Use carefully. May cause serious burns.

Turn the system off when moving from one treatment area to another treatment area

Do NOT move the system when the system is operating.

WARNING

Do NOT allow sun block or sunscreen products to come in contact with the system.

The ingredients found in these products may cause deterioration or damage to the system.

If sun block or sunscreen does come in contact with the system, clean immediately to prevent potential damage.

WARNING

Patient should NOT come into contact with earthed metal parts or parts with appreciable capacitance to earth.

CAUTION

The safety of using the Darwin Face Thermal RF feature on nursing women is not known, as LUVO Medical does not have clinical studies to support the use of the Darwin Face Thermal RF feature on nursing women.

IMPORTANT NOTE

After pressing READY, if no operation is detected for approximately 2 minutes, the system automatically changes to STANDBY mode.

If a serious error occurs during operation of the system, the system automatically changes to STANDBY mode

E.4 Potential Side Effects

Side effects can include:

- Erythema (redness): The treated area may exhibit erythema immediately following treatment. This typically resolves within 1-2 hours of treatment.
- Edema (swelling): The treated area may exhibit mild edema following treatment. This typically resolves within 48 hours of treatment.
- Itchiness: Itchiness may be felt following treatment. This typically resolves within 1-2 hours of treatment.

E.5 Pre-Treatment

E.5-1 Counseling

Counselling patients regarding realistic expectations for the Face Thermal RF treatment outcome prior to treatment is an important step.

During the patient's first visit, the physician (or an authorized staff member), LUVO Medical recommends the following to assist with realistic expectations:

- Ensure a detailed patient medical history is taken, including previous treatment interventions, and determine the suitability for treatment with the Darwin Face Thermal RF feature.
- Determine why the patient is seeking treatment and understand and manage his/her expectations.

The physician (or an authorized member of the staff) should inform the patient of the following:

- Potential for discomfort or pain associated with treatment.
- More than one treatment may be required to reach the expected results.
- Potential side effects outlined in section E.4 Potential Side Effects

E.5-2 Photography

Before and after treatment photographs are recommended to be taken to document the progress of treatment, as many patients are not able to objectively assess the progress of treatment. These photographs provide concrete evidence.

Ensure that standard conditions and similar speed, flash and focal length are used to photograph all patients. This enables an objective comparison of photos taken at different times.

E.6 Pre-Treatment Set-Up

E.6-1 Topical Anesthetic

Typically, skin treatments performed with the Darwin Face Thermal RF handpiece do not require topical anesthesia. However, since the skin treatment may entail treating large surfaces, such as a

full face, many patients prefer to undergo the treatment using a topical anesthetic which results in a procedure without discomfort.

CAUTION

Follow manufacturer's instructions when using topical anesthetics

Topical anesthetics are generally applied for a period of time (up to one hour) prior to treatment. Ensure to completely remove the entire topical anesthetic prior to treatment.

WARNING

Using large amounts of topical anesthetics have the potential to induce unwanted side effects. It is not recommended to use topical anesthetics that are known to have vasoconstrictive effects on the treatment area.

E.6-2 Spot Test

LUVO recommends performing spot tests on patients and assess skin response before performing a full treatment. The spot test should be performed on the border of the intended treatment area (suggest choosing a non-visible spot with the intended parameters), using the factory pre-set values.

Inspect the test spot at least 5 minutes after the test spot was carried out, to evaluate the intensity of the effect.

The expected response after the test spot is mild to moderate erythema and edema on the treated area. Increase/decrees energy level according to the test spot reaction.

E.6-3 Pre-Treatment Site Preparation

To prepare the treatment site prior to treatment, carry out the following:

1. Have the patient remove all jewelry for the treatment session.
2. Have the patient remove all metal accessories for the treatment.
3. Wash the treatment area thoroughly with water and soap to remove lotion and makeup. Dry the skin using a paper towel.
4. Photograph the patient as per section E.5-2 Photography
5. Clean the skin thoroughly with 70% alcohol before starting the treatment.
6. Ensure the alcohol has evaporated prior to treatment.
7. Apply topical anesthetic (if used), as per section E.6-2 Topical Anesthetic
8. Ensure all topical anesthetic is gently cleaned off. Ensure no topical anesthetic residue is present.
9. Apply a thin layer of RF conductive solution/cream to the treatment site. Too much or too little RF solution will result in poor skin contact.
10. Place the patient in a comfortable position

11. Ensure the Ground pad is attached to the patient

WARNING

Patient should NOT come into contact with earthed metal parts or parts with appreciable capacitance to earth.

WARNING

Ensure the Ground pad is attached to the patient.

CAUTION

Avoid skin-to-skin contact by insertion of dry gauze

E.7 Performing the Treatment

Ensure the treatment site is prepped as per section E.6-4 Pre-Treatment Site Preparation, the desired Face Thermal RF tip has been attached to the handpiece, the Face Thermal RF screen is opened, the default settings are indicated and in STANDBY mode.

CAUTION

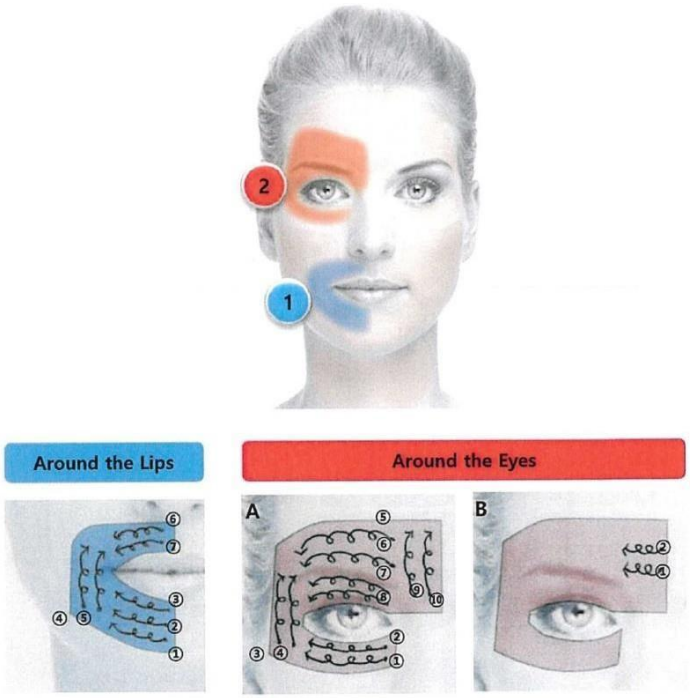
Use of bipolar techniques may be desirable in order to avoid unwanted tissue damage for treatment procedures where RF current could flow through relatively small cross-sectional area of body.
It is recommended that the selected output power is as low as possible for intended purpose.

CAUTION

Ensure to keep the tip clean during operation.

To begin the treatment:

1. Place the Face Thermal RF tip flush with the patient's skin.
2. If using the TRF tip E or TRF tip R, perform the treatment by 'rubbing' the treatment area in either a circular motion or single stroke, as the RF pulse is fired (Figure E.7-1). Ensure to keep the tip in direct contact with the skin / treatment area during treatment.



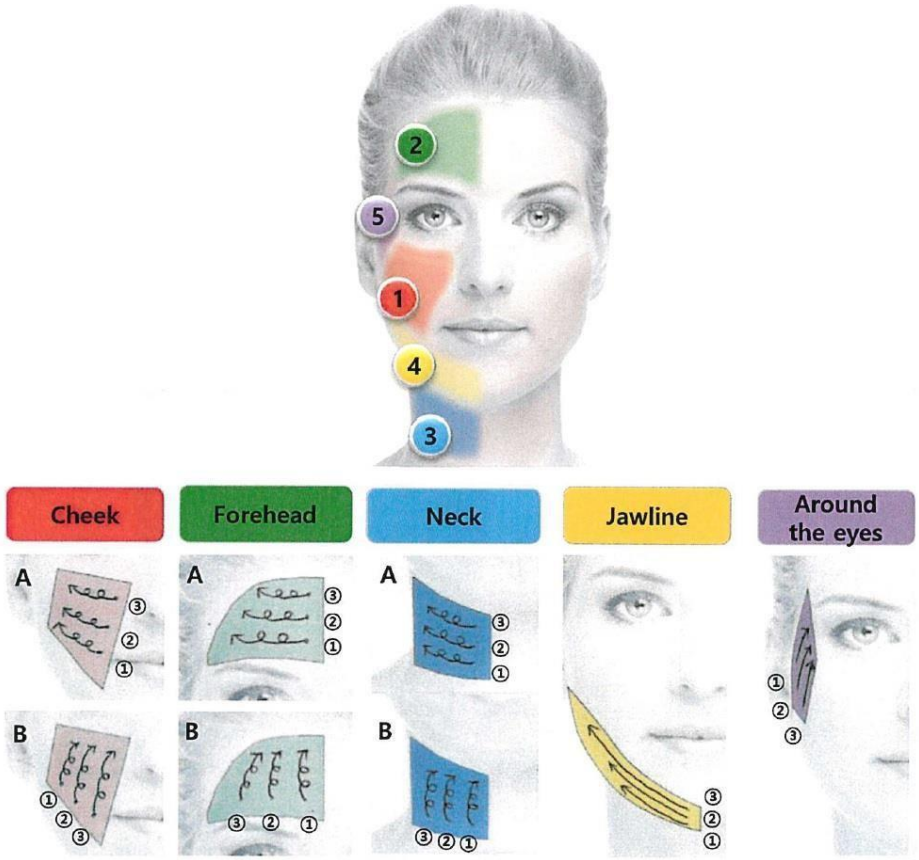
Using the TRF tip-E

Figure E.7-1: Treatment motion for TRF tip E

Table E.7-1: Recommended Treatment parameters for TRF Tip-E

Step	STEP Ⅰ								
Section	3(Around the lips)			1(Around the eyes)					
	A	A	A	A	A	A	A	A	B
Process	① to ③	④ to ⑤	⑥ to ⑦	① to ②	③ to ④	⑤ to ⑥	⑦ to ⑧	⑨ to ⑩	① to ②
Repeat	3 times	3 times	3 times	3 times	3 times	3 times	3 times	3 times	3 times
Level	7	7	7	7	7	7	7	7	7
Time	**20s**	**20s**	**20s**	**10s**	**10s**	**10s**	**10s**	**10s**	**10s**

Step	STEP Ⅱ								
Section	3(Around the lips)			1(Around the eyes)					
	A	A	A	A	A	A	A	A	B
Process	① to ③	④ to ⑤	⑥ to ⑦	① to ②	③ to ④	⑤ to ⑥	⑦ to ⑧	⑨ to ⑩	① to ②
Repeat	3 times	3 times	3 times	3 times	3 times	3 times	3 times	3 times	3 times
Level	2	2	2	2	2	2	2	2	2
Time	**20s**	**20s**	**20s**	**10s**	**10s**	**10s**	**10s**	**10s**	**10s**



Using the TRF tip-R

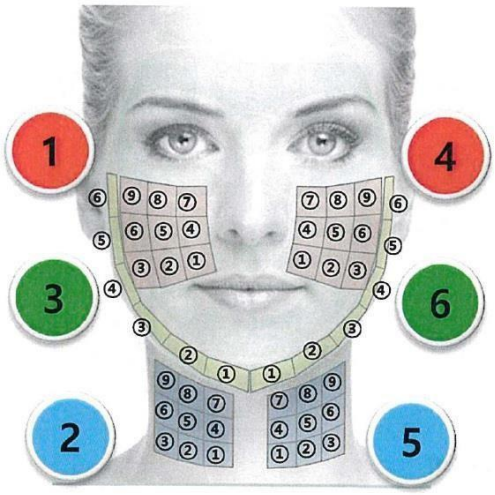
Figure E.7-2: Treatment motion for TRF tip E and TRF tip R

Table E.7-2: Recommended Treatment parameters for TRF Tip-R

Step	STEP Ⅰ							
Section	2(Cheek)		1(Forehead)		3(Neck)		3 (Jawline)	1(Around the eyes)
	A	B	A	B	A	B		
Process	① to ③	① to ③	① to ③	① to ③	① to ③	① to ③	① to ③	① to ③
Repeat	3 times	3 times	3 times	3 times	3 times	3 times	3 times	3 times
Level	7	7	7	7	7	7	7	7
Time	**60s**	**60s**	**30s**	**30s**	**60s**	**60s**	**30s**	**30s**

Step	STEP Ⅱ							
Section	2(Cheek)		1(Forehead)		3(Neck)		3 (Jawline)	1(Around the eyes)
	A	B	A	B	A	B		
Process	① to ③	① to ③	① to ③	① to ③	① to ③	① to ③	① to ③	① to ③
Repeat	3 times	3 times	3 times	3 times	3 times	3 times	3 times	3 times
Level	2	2	2	2	2	2	2	2
Time	**60s**	**60s**	**30s**	**30s**	**60s**	**60s**	**30s**	**30s**

3. If using the TRF tip S, perform the treatment by pressing the operating button to fire a single RF pulse and move the tip to the next section of the treatment area (Figure E.7-2). Ensure to keep the tip in direct contact with the skin / treatment area during treatment.



Using the TRF tip-S

Figure E.7-3: Treatment area using TRF tip S

Table E.7-3: Recommended Treatment parameters for TRF Tip-S

Step	STEP Ⅰ		
Section	2(Cheek)	3(Neck)	3(Jawline)
Process	① to ⑨	① to ⑨	① to ⑥
Repeat	10 times	9 times	7 times
Level	7	7	7
Total shots	**90**	**81**	**42**

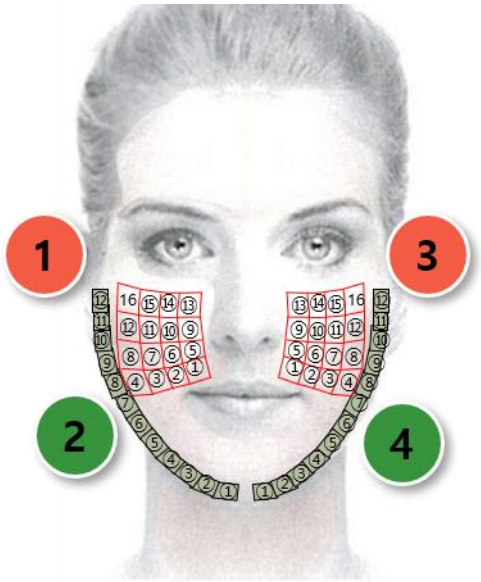
Step	STEP Ⅱ		
Section	2(Cheek)	3(Neck)	3(Jawline)
Process	① to ⑨	① to ⑨	① to ⑥
Repeat	10 times	9 times	7 times
Level	5	2	5
Total shots	**90**	**81**	**42**

WARNING

Ensure the Face Thermal RF tip is in direct contact with the skin / treatment area during treatment.

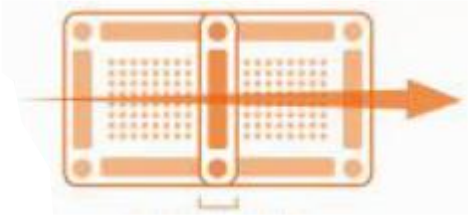
4. Inspect the treatment area for erythema and edema after each pulse and / or pass. If patient complains of pain or erythema and edema is not mild, decrease the energy output level until the patient is comfortable.

5. If using the FRF Tip-64 or FRF Tip-100, perform the treatment by pressing the operating button to fire a single RF pulse and move the tip to the next section of the treatment area (Figure E.7- 4). Overlap each shot by one-third of the tip area during treatment. (Figure E.7-5) Ensure to keep the tip in direct contact with the skin / treatment area during treatment.



Using the FRF Tip-64, FRF Tip-100

Figure E.7-4: Treatment area using FRF Tip-64, FRF Tip-100



Treat the area with overlapping shots.

Figure E.7-5: Overlap shots using the FRF Tip-64, FRF Tip-100

Table E.7-3: Recommended Treatment parameters for FRF Tip-64, FRF Tip-100

Without anesthesia		
Step	STEP I	
Section	2(Cheek)	2(Jawline)
Process	① to ⑯	① to ⑫
Repeat	1 times	1 times
Level	2	1
Total shots	16	12

With anesthesia		
Step	STEP I	
Section	2(Cheek)	2(Jawline)
Process	① to ⑯	① to ⑫
Repeat	1 times	1 times
Level	5	3
Total shots	16	12

WARNING

Ensure the Face Fractional RF tip is in direct contact with the skin / treatment area during

E.8 Post Treatment

While skin is sensitive, advised patients to keep the treatment area clean and avoid aggressive products such peels or other similar products.

It is recommended to apply soothing skin product until mini crusts are removed or at least two days post treatment.

Advise the patient to avoid sun exposure and use total sun block for at least 4 weeks post treatment

Advised men not to shave for one week, post treatment.

In cases of persisting Edema, Erythema or discomfort following the procedure, advise patient to IMMEDIATELY report to the physician. The physician is to IMMEDIATELY report to LUVO Medical's authorized representative.

As a matter of caution, advise the patient to be cautious of receiving the following treatments prior to the timeline outlined per treatment, after their present treatment:

- Face lift or eyelid surgery within a year after present RF treatment.
- Facial dermabrasion, facial resurfacing, or deep chemical peeling within the last three months from the present RF treatment
- Botox®/collagen/fat injections or other methods of augmentation with injected material in the treated area within 1 month after the present RF treatment
- Having received treatment with light, RF or other devices in the treated area within 1 month after the present RF treatment.

Appendix F: Acoustic and Temperature measurements (HIFU specific) _ IEC 60601-2-62

**Note that some of the clauses of these standards were not deemed applicable due to the aesthetic intended use of the Darwin HIFU handpiece technology. Applicable clauses of the IEC 60601-2-62 standards are outlined in the below sections.

F.1 Expected or Measured Temperature Rise in the FOCAL POINT During Treatment

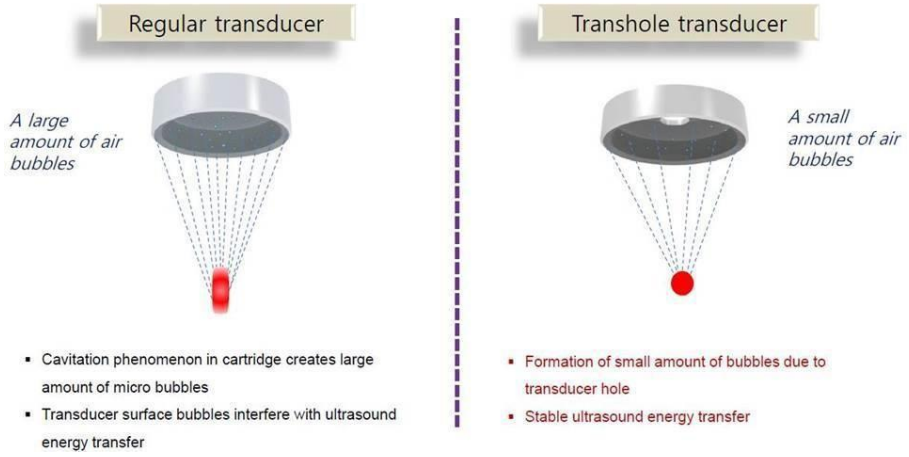
Table F.1-1 indicates the expected or measured temperature rise in the Focal Point during treatment.

Table F.1-1: Expected/Measured treatment rise in the Focal Point during treatment.

Type	Temperature Rise
SD7-1.5	+0.7°C
DD7-3.0	+0.6 °C
SM4-4.5	+0.6 °C

F.2 Indication in case Cavitation Occurs

There's a hole at the center of the transducer, it prevents increase of micro bubbles which are cause of cavitation. In case cavitation occurs due to creation of micro bubbles, a Trans hole Transducer at the center helps bubbles emit through the hole. As a result, a large amount of bubbles are emitted to the hole so that stable ultrasound energy is transformed from the transducer without unwanted output. (Figure F.2-1.)



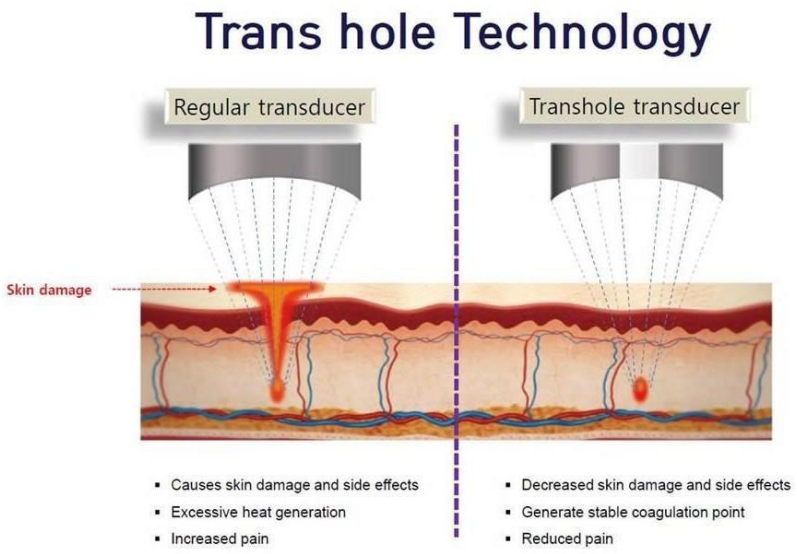
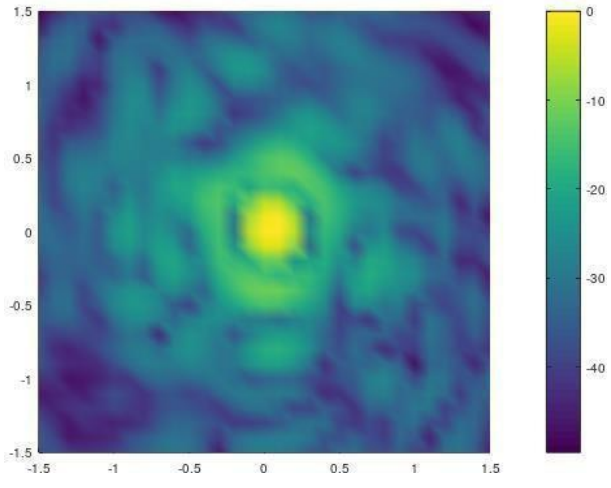
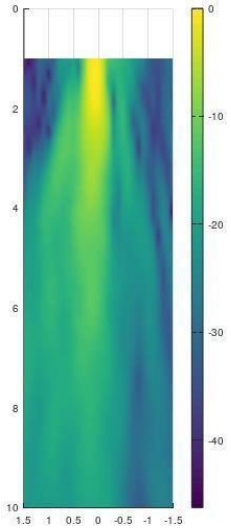


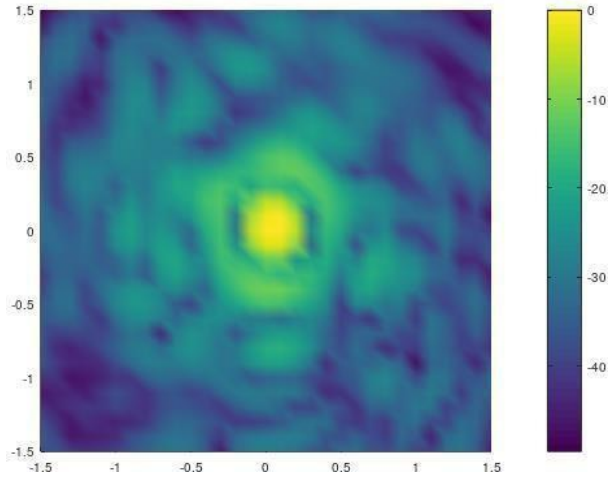
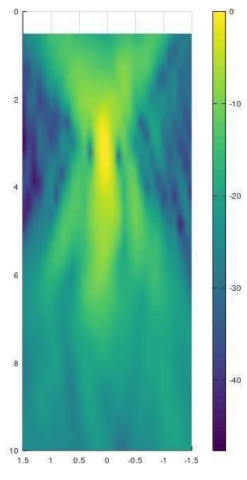
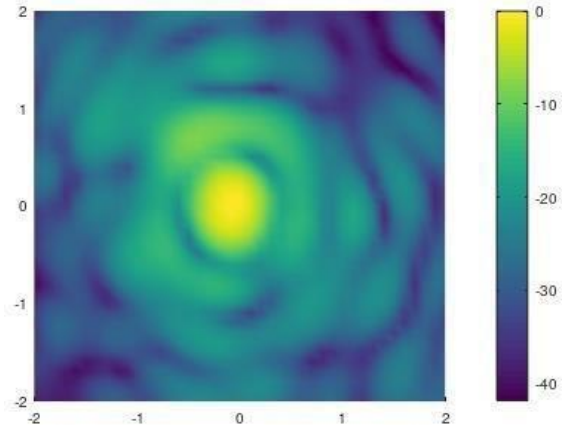
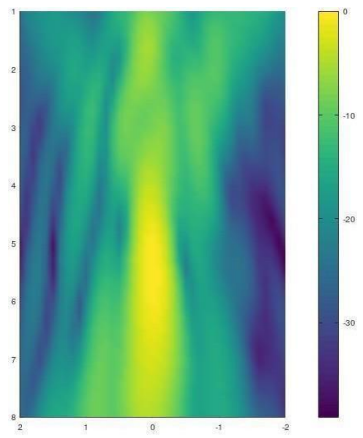
Figure F.2-1: Trans Hole Technology to avoid cavitation occurs.

F.3 Axial beam scan(s) of TEMPORAL AVERAGE INTENSITY ITA (x=0, y=0,z)

Axial beam scan(s) of Temporal Average Intensity ITA (x=0, y=0,z)- Transversal scan of the beam and Longitudinal scan of the beam – for each cartridge are shown in Table F.3-1. Transversal scan of the ultrasound beam over the plane XY at the focal distance Intensities are represented on a logarithmic scale.

Table F.3-1: Axial beam scan(s) of Temporal Average Intensity ITA (x=0, y=0,z)

Transversal Scan	Longitudinal Scan
SD7-1.5	
	
DD7-3.0	

Transversal Scan	Longitudinal Scan
	
SM4-4.5	
	

F.4. BEAM WIDTH AT FOCUS

The beam width at focus is shown in Table F.4-1.

Table F.4-1: Beam width at focus

Type	BEAM WIDTH AT FOCUS
SD7-1.5	0.3 mm
DD7-3.0	0.3 mm
SM4-4.5	0.56 mm

F.5 3D information about the FOCAL VOLUME or BEAM MAXIMUM VOLUME

The Focal Volume or Beam Maximum Volume is displayed in 3D (three-dimensional representation of the transversal scan) for each cartridge (Figures F.5-1, F.5-2, &F.5-3). This is representing the region of treatment of each transducer, based on the number of spots per treatment line and the horizontal line represents the patient skin.

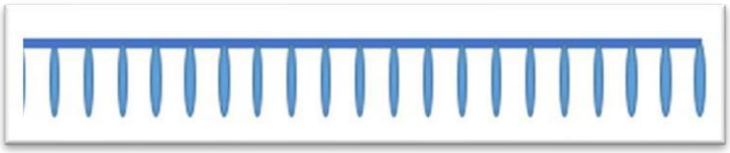


Figure F.5-1: 3D Sample Focal volume / Beam Maximum Volume for the SD7-1.5 cartridge

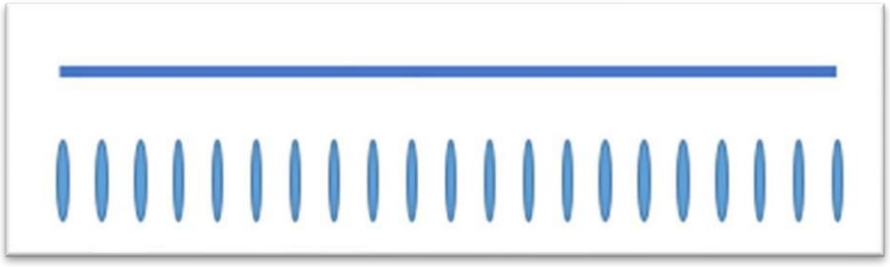


Figure F.5-2: 3D Sample focal volume / Beam Maximum Volume for the DD7-3.0 cartridge

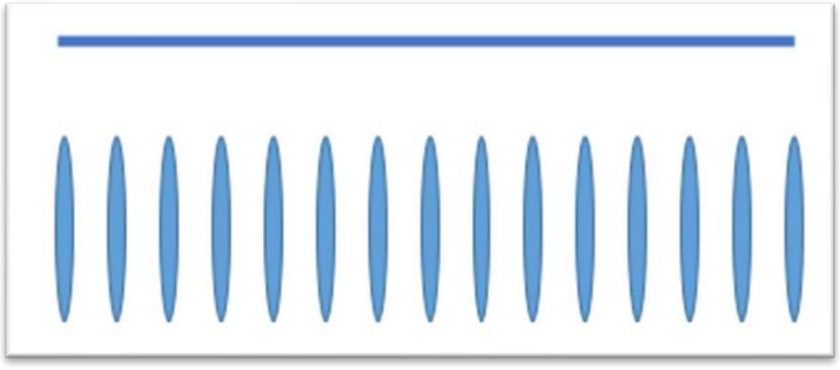


Figure F.5-3: 3D Sample focal volume / Beam Maximum Volume for the SM4-4.5 cartridge

F.6 Effects on human tissue in terms of THERMALLY EQUIVALENT TIME

The Thermally Equivalent Time [2] in terms of effects on human tissue is outlined in Table F.6-1.

Table F.6-1: Thermally Equivalent Time in terms of effects on human tissue

Item	SD7-1.5	DD7-3.0	SM4-4.5
total ENTRY POWER at clinical settings, including distance zE (W)	0.25/T [1]	0.45/T	1.20/T
ENTRY EFFECTIVE INTENSITY at clinical settings, including distance zE (W/m2)	0.25/T/0.2e-6	0.45/T/5.7e-6	1.20/T/1.5e-6
SPATIAL-PEAK TEMPORAL-AVERAGE INTENSITY at clinical settings (W/cm2)	2809/T	314/T	82.1/T
DISTANCE zspta (mm)	1.5	3	5
SPATIAL-PEAK PULSE-AVERAGE INTENSITY at clinical settings (W/m2)	14190	1359	191
BEAM WIDTH AT FOCUS	0.3mm	0.3mm	0.56mm
FOCAL DEPTH	1.5mm	3.0mm	4.5mm
SIDE-LOBE PEAK TEMPORAL-AVERAGE INTENSITY and its position relative to the position of the maximum PULSE-PRESSURE SQUARED INTEGRAL on the BEAM AXIS	79.1 mW/㎠	81.0 mW/㎠	82.6 mW/㎠
DISTANCE zslpta	0	0	0
-6 dB BEAM AREA at z = zspta	0.2㎟	5.7㎟	1.5㎟

(1) T: Time in seconds between two consecutive ultrasound deliveries at clinical conditions
(2) The ultrasound beam is focalized; there is no local maximum for intensity on the beam axis between the focal zone and the transducer face.

The level of the PEAK TEMPORAL-AVERAGE INTENSITY (based on measurements and/or modelling) is displayed in Table F.6-2.

Table F.6-2: Level of Peak Temporal Average Intensity

Item	SD7-1.5	DD7-3.0	SM4-4.5
Level of the SIDE-LOBE PEAK TEMPORAL- AVERAGE INTENSITY & Position relative to the maximum in the FOCAL VOLUME or BEAM MAXIMUM VOLUME (W/cm2)	10.5/T[1] Located 1 mm after the focal	35.8/T[1] Located 2.2 mm before the focal	10.5/T[1] Located 3.2 mm before the focal

(1) T: Time in seconds between two consecutive ultrasound deliveries at clinical conditions

F.7 Frequency accuracy: Reference value±10%

The frequency accuracy (±10%) is shown in Table F.7-1.

Table F.7-1: Frequency accuracy (±10%)

Cartridges	Frequency (MHz)
SD7-1.5	7.0
DD7-3.0	7.0
SM4-4.5	4.0

F.8 Focal length: Reference value±10%

The focal length (±10%) is displayed in Table F.8-1.

Table F.8-1: Focal length (±10%)

Cartridges	Focal length (mm)
SD7-1.5	1.5
DD7-3.0	3.0
SM4-4.5	4.5

F.9 Output power: Reference value±10%

The output power (±10%) is indicated in Table F.9-1:

Table F.9-1: Output power (±10%)

Cartridges	Output power(J)
SD7-1.5	0.1~0.25
DD7-3.0	0.2~ 0.45
SM4-4.5	0.6~1.20

F.10 Acoustic intensity within focal region

For the -6dB focus region, the average value of the acoustic intensity should be 100W / cm2 or more (Table F.10-1)

Table F.10-1: Acoustic intensity within focal region

Cartridges	Acoustic Intensity within Focal Region (W/cm2)
SD7-1.5	5132.6
DD7-3.0	7768.3
SM4-4.5	4633.2

F.11 Temperature accuracy of focus region

During the irradiation time, the temperature change in the focus region doesn't exceed 33 degrees, and the temperature change in the region excluding the focus region doesn't exceed 10 degrees.

F.12 Temperature safety of the contact surface

The temperature of the cartridge contact part, including the treatment head, doesn't exceed 43 degrees.

F.13 Skin temperature

During the eradiation time, the temperature change in the focal region didn't exceed 33 degrees , and the skin temperature didn't exceed 43 degrees.

F.14 Unnecessary ultrasonic emission Reference value: 100mW/cm2 below

The SPATIAL-PEAK TEMPORAL-AVERAGE INTENSITY of unwanted ULTRASOUND radiation from the handle of a TREATMENT HEAD intended for hand-held use, shall be less than 100mW/cm2, measured values are displayed in Table F.14-1.

Table F.14-1: Unnecessary ultrasound emission 100mW/cm2

Cartridges	Measured values (mW/cm2)
SD7-1.5	79.1
DD7-3.0	81.0
SM4-4.5	82.6

F.15. Emission spacing: Reference value±10%

Emission spacing (±10%) is shown in Table F.15-1.

Table F.15.1: Emission spacing (±10%)

Cartridges	Emission interval
SD7-1.5	1.2~2.0
DD7-3.0	1.2~2.0
SM4-4.5	1.2~2.0

F.16. Emission length

The emission length should be within 4~24mm (± 10%)

Appendix G: Electromagnetic Compatibility (EMC)

The device is suitable for use in "Professional healthcare environment". This device complies with IEC/EEN60601-1-2 safety standard for electromagnetic compatibility, requirements and test. Precautions, adherences to the EMC guideline information provided in this manual and verification of all medical devices in simultaneous operation in the room are required to ensure the electromagnetic compatibility and co- existence of all other medical devices prior to a treatment procedure. However, if this equipment is operated in the presence of high levels of electromagnetic interference (EMI) or highly sensitive equipment, interference may be encountered where the user should take whatever steps necessary to eliminate or reduce the source of the interference. This device shall not be used near the high EM emitter device like HF sugical device or MRI.

WARNING

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

WARNING

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

WARNING

Portable RF communications device (including peripherals such as antenna cables and externa antennas) should be used no closer than 30 cm (12 inches) to any part of this device, including cables specified by LUVO Medical Technologies Inc.

WARNING

Failure to use this equipment in the specified type of shielded location could result in degradation of performance, interference with other equipment or interference with radio services.

Guidance and manufacturer's declaration – electromagnetic emissions

The device is intended for use in the electromagnetic environment specified below. The user of the device should assure that it is used in such an environment

Emissions	Compliance	Electromagnetic environment-- guidance
conducted emissions **CISPR 11**	Group 1 Class A	The device must be used only in a shielded location with a minimum RF shielding effectiveness and, for each cable that enters or exits the shielded location, a minimum RF filter attenuation of 40 dB from 0.15 MHz to 30 MHz and 50 dB from 30 MHz to 300 MHz.. It is essential that the actual shielding effectiveness and filter attenuation of the shielded location be verified to assure that they meet the minimum specifications. Failure to use this EQUIPMENT in the specified type of shielded location could result in degradation of performance, interference with other equipment or interference with radio services
radiated emissions **CISPR 11**		
Harmonic emissions **IEC 61000-3-2**	N/A	This device is professional equipment with a total rated power greater than 1kW.
Voltage fluctuations / Flicker emissions **IEC 61000-3-3**	N/A	This device is not connected to the public mains network if they are used in locations, e.g. hospitals, in which the mains connection is isolated from the public low voltage power supply network by transformers or substations.

NOTE The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

NOTE It is essential that the actual shielding effectiveness and filter attenuation of the shielded location be verified to assure that they meet the minimum specifications. Failure to use this EQUIPMENT in the specified type of shielded location could result in degradation of performance, interference with other equipment or interference with radio services

NOTE: Test methods for measurement of RF shielding effectiveness and RF filter attenuation

1. RF Shielding Effectiveness (SE) Test Methods

Shielding effectiveness testing is performed using a signal source a measuring instrument such as a spectrum analyzer a transmit antenna and receive antenna. An oversimplified explanation would be as follows.

- The first stage is to measure a reference in free space conditions with the antennas spaced apart and directed at each other.
- This is followed by a measurement with one antenna in the enclosure and the other antenna outside the enclosure maintaining the spacing and directivity of the antennas.
- The difference in the values would be the shielding effectiveness of the chamber.

The shielding effectiveness is calculated with the reference level measurement and the attenuated level measurement:

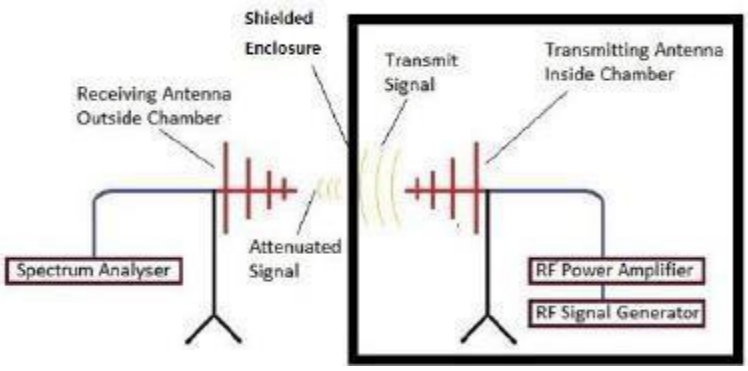
SE (db) = V Ref_max – V Att_max

or

SE (db) = P Ref_max – P Att_max

Where

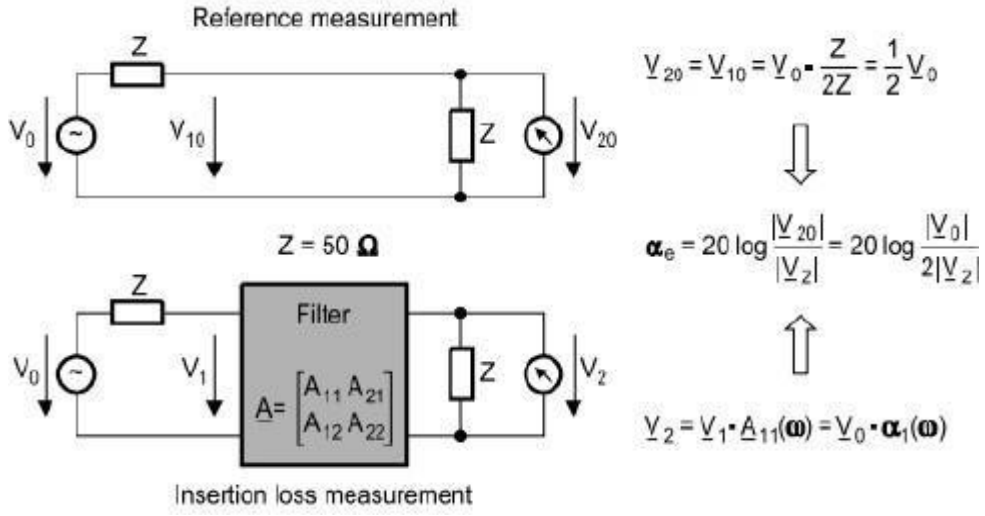
SE : Shielding Effectiveness in dB



<Test Setup>

2. RF filter attenuation Test Methods

The measurement value of filter attenuation is expressed in decibels (dB) as shown in Figure below, when the filter is not connected (Reference measurement) and when the filter is connected (Insertion loss measurement).



<Test Setup>

The input terminals of the filter under test are connected to an RF generator with impedance Z (usually 50 Ω)
.

At the output of the filter, the voltage is measured using an RF voltmeter having the same impedance Z. The insertion loss is then calculated from the quotient of hal the open circuit generator voltage V0 and the filter output voltage V2.

NOTE: One or more of the following and a recommendation that a notice containing this information be posted at the entrance(s) to the shielded location:

a specification of the EMISSIONS characteristics of other EQUIPMENT allowed inside the shielded location with the ME EQUIPMENT or ME SYSTEM;

a list of specific EQUIPMENT allowed;

a list of types of EQUIPMENT prohibited.

Guidance and manufacturer's declaration - electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The user of the devi should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment guidance**
Electrostatic discharge (ESD) **IEC 61000-4-2**	± 8 kV Contact ± 2, ± 4, ± 8, ± 15 kV Air	± 8 kV Contact ± 2, ± 4, ± 8, ± 15 kV Air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst **IEC 61000-4-4**	±1 kV, 100kHz for A C Mains of power supply unit ± 1 kV, 100 kHz for SIP/SOP, Patient Connected	±1 kV, 100kHz for AC Mains of power supply unit ± 1 kV, 100 kHz for SI P/SOP, Patient Connect ed	Mains power quality should be that of a typical commercial or hospital environment.
Surge **IEC 61000-4-5**	Line to Line ±0.5kV,±1kV Line to Ground ± 0.5 kV, ± 1 kV,	Line to Line ±0.5kV,±1kV Line to Ground ±0.5kV,±1kV	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips **IEC 61000-4-11**	0 % UT: 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0º	0 % UT: 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0º	Mains power quality should be that of a typical commercial or hospital environment. If a dips or an interruption of mains power occurs, the current of the device may be dropped off from normal level, it may be necessary to use uninterruptible power supply or a battery.
Voltage interruptions **IEC 61000-4-11**	0 % UT; 250/300 cycle	0 % UT; 250/300 cycle	
Power frequency Magnetic field **IEC 61000-4-8**	30 A/m 50 Hz & 60 Hz	30 A/m 50 Hz & 60 Hz	Power frequency magnetic fields should have characteristic levels of a typical commercial or hospital environment.
Proximity magnetic fields **IEC 61000-4-39**	134.2 kHz, 65 A/m 13.56 MHz, 7.5 A/m in according to table 11 in IEC 60601-1-2: 2020	134.2 kHz, 65 A/m 13.56 MHz, 7.5 A/m in according to table 11 in IEC 60601-1-2: 2020	Power proximity magnetic fields should have characteristic levels of a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level			

Guidance and manufacturer's declaration – electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment. When the Darwin system is exposed to Electromagnetic (EM) disturbances, the system may show abnormal behaviour. For instance, the software may crush or turn into standby mode, or in case of very high-level transient voltages like ESD, certain handpieces may become defective, or flash intermittently to advise user though Device would generally be self-recoverable			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment –guidance**
Conducted RF **IEC 61000-4-6**	3 V 0.15-80 MHz 6 V in ISM bands Between 0.15 MHz an d 80 MHz 80% AM at 1 kHz	3 V 0.15-80 MHz 6 V in ISM bands Between 0.15 MHz and 80 MHz 80% AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance D= 1,2 x √P from 150kHz to 80MHz D= 1,2 x √P from 80MHz to 800MHz D= 2,3 x √P from 800MHz to 2,5GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitter s, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.**b** Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF **IEC 61000-4-3**	3 V/m 80 MHz-2.7 GHz 80% AM at 1 kHz	3 V/m 80 MHz-2.7 GHz 80% AM at 1 kHz	
Immunity to Proximity Fields from RF wireless Communicatios Equipment **IEC 61000-4-3**	28V/m Max. 385-5785 MHz in according to Table 9 in IEC 60601-1-2: 2020	28V/m Max. 385-5785 MHz in according to Table 9 in IEC 60601-1-2:2020	
Note 1: At 80 MHz and 800 MHz, the higher frequency range applies. **Note 2**: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the True CPR device is used exceeds the applicable RF compliance level above, the True CPR device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the True CPR device.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Appendix H – RF Output Power IEC 60601-2-2

In compliance to the testing performed on the Darwin Needle RF Handpiece, the bipolar output was measured at full, half output control settings and a range load, minimally, over the range of load resistance of 10 Ω to 1000 Ω, extended to RATED LOAD, and diagrams showing power output versus output control setting at 200 Ω load resistance in the range defined below for bipolar output

Table H-1: Darwin Needle RF Output Power

Level	Output power (W)
	Rated Load (200Ω)
1	0.0
2	1.6
3	3.6
4	6.6
5	10.1
6	14.0

Figure H-1: Darwin Needle RF Output Power at half output control setting

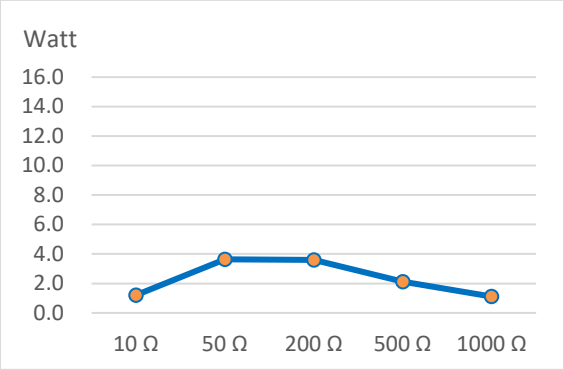
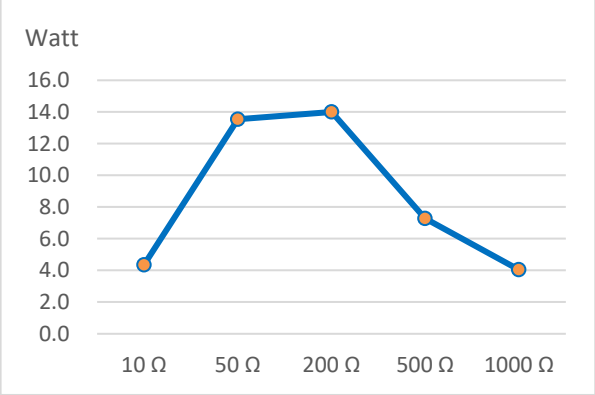


Figure H-2: Darwin Needle RF Output Power at max output control setting



Additionally, the output power curves as necessary for compliance are included below in tabularformat for the Darwin Face Thermal RF according to the 7 levels (TRF Tips) and 10 levels (FRF Tips) of output per the testing required of the IEC standard. The respective diagrams are created over the range of load resistance of [100 Ω to 2000 Ω] (TRF Tips) and [100 Ω to 1000 Ω] (FRF Tips) and the half and full output is detailed.

Table H-2: Darwin Face Thermal RF Output Power Specifications – TRF Tip-S

Level	Output power (W)
	Rated Load (500Ω)
1	0.0
2	12.0
3	16.8
4	21.6
5	26.4
6	31.2
7	36.0

Figure H-3: Darwin Face Thermal RF Output Power at half output control setting. – TRF Tip-S

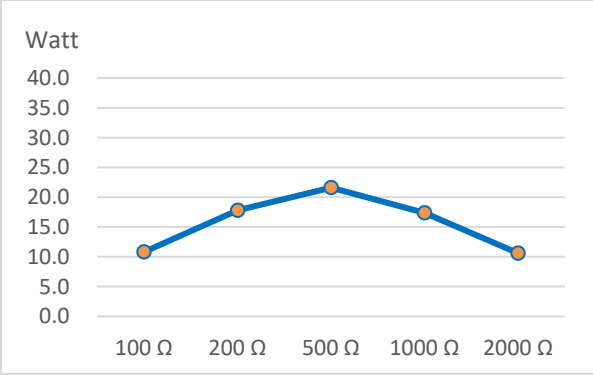


Figure H-4: Darwin Face Thermal RF Output Power at max output control setting.– TRF Tip-S

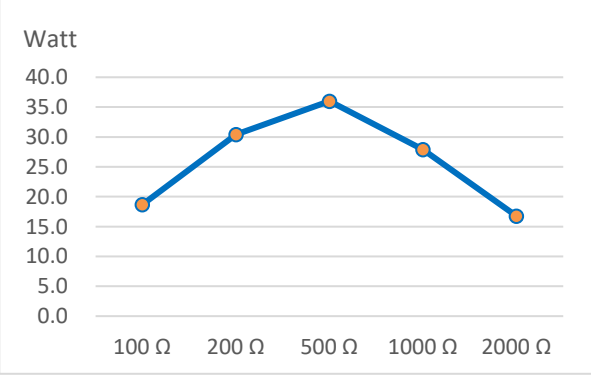


Table H-3: Darwin Face Thermal RF Output Power Specifications – TRF Tip-R

Level	Output power (W)
	Rated Load (500Ω)
1	0.0
2	12.0
3	15.8
4	19.6
5	23.4
6	27.2
7	31.0

Figure H-5: Darwin Face Thermal RF Output Power at half output control setting. – TRF Tip-R

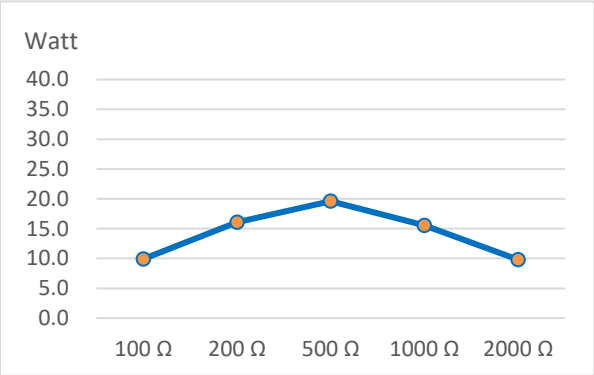


Figure H-6: Darwin Face Thermal RF Output Power at max output control setting. – TRF Tip-R

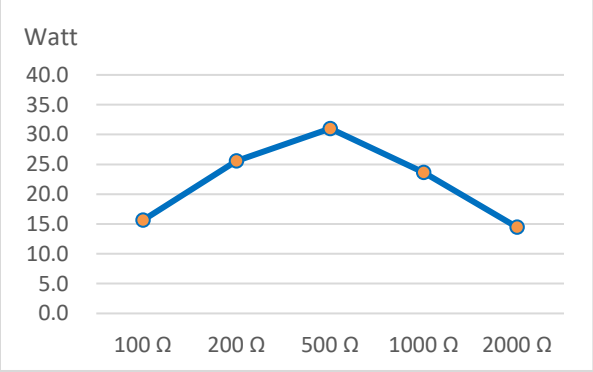


Table H-4: Darwin Face Thermal RF Output Power Specifications – TRF Tip-E

Level	Output power (W)
	Rated Load (500Ω)
1	0.0
2	5.0
3	5.7
4	6.4
5	7.1
6	7.8
7	8.5

Figure H-7: Darwin Face Thermal RF Output Power at half output control setting. – TRF Tip-E

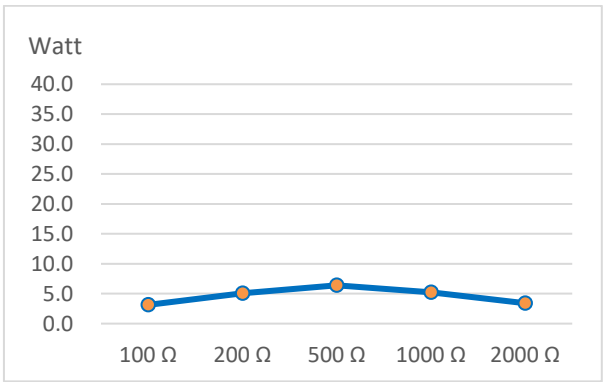


Figure H-8: Darwin Face Thermal RF Output Power at max output control setting. – TRF Tip-E

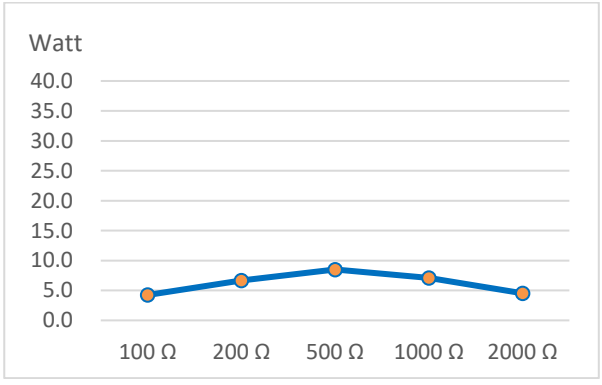


Table H-5: Darwin Face Thermal RF Output Power Specifications- FRF Tip-64 & FRF Tip-100.

Level	Output Power (w)	On time (ms)
	Rated Load (500Ω)	
1	0.0	0
2	41.6	18
3	42.8	22
4	43.6	27
5	44.0	31
6	44.6	37
7	44.8	41
8	45.2	45
9	45.4	51
10	45.4	56

Figure H-9: Darwin Face Thermal RF Output Power at half output control setting.-FRF Tip-64 & FRF Tip-100.

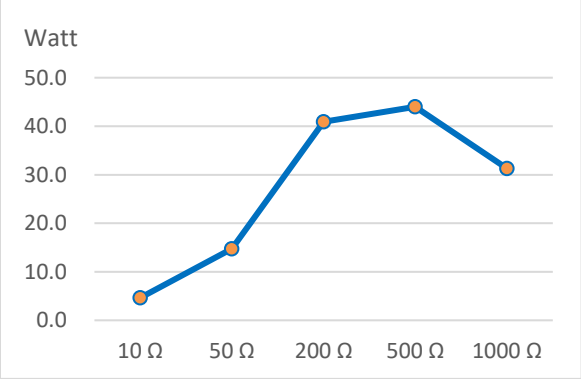
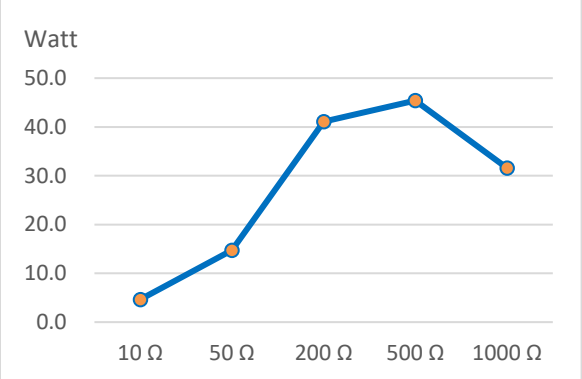


Figure H-10: Darwin Face Thermal RF Output Power at max output control setting.-FRF Tip-64 & FRF Tip-100.



Appendix I – Patient Information Annex

Darwin System

This information is intended for patients or consumers who are considering treatment with the Darwin System. Please read this information carefully before your treatment. If you have any questions, speak to your healthcare professional.

1. Device Identification

Device Name: Darwin System

Manufacturer: Luvo Medical Technologies Inc
Device Type: Professional energy-based treatment system incorporating Intense Pulsed Light (IPL), Diode Laser, Radiofrequency (RF), and High-Intensity Focused Ultrasound (HIFU) technologies.

2. Intended Purpose

The Darwin System is intended to be used only by trained healthcare professionals or qualified practitioners.

Depending on the treatment selected, the device may be used for one or more of the following purposes:

Medical Indications

- Treatment of symptoms associated with Dry Eye Disease (DED) (using the IPL handpiece and 585 nm filter).

Aesthetic Indications

Depending on the selected treatment, the Darwin System can be used for below listed indications:

- Diode Laser: hair removal and permanent hair reduction on skin types (Fitzpatrick skin types I - V)
- Skin pigmentation
- Freckles, Scars
- Rosacea
- Mild to moderate acne
- Vascular lesions
- Skin texture
- Fine lines and wrinkles
- Acne scars
- Stretch marks (striae)
- Skin laxity
- Eyebrow lift
- Collagen remodeling
- Overall skin rejuvenation
- Photoaging
- Improve Skin texture

Your healthcare professional will determine whether the selected treatment is appropriate for you.

3. Expected Benefits

Treatment with the Darwin System is intended to produce one or more of the following effects, depending on the selected procedure:

IPL Treatments

- Reduction of unwanted hair
- Improvement in skin tone
- Reduction of pigmented lesions
- Reduction of superficial vascular lesions
- Improvement in overall skin appearance

Dry Eye Disease Treatment

- Improvement of symptoms associated with Dry Eye Disease

RF Microneedling Treatments

- Improvement in skin texture
- Reduction in acne scars
- Reduction in fine lines and wrinkles
- Improvement in skin firmness
- Stimulation of collagen production

RF Thermal Treatments

- Skin tightening
- Improvement in skin elasticity
- Reduction in mild skin laxity

HIFU Treatments

- Lifting and tightening of facial tissues
- Improvement in skin firmness
- Stimulation of collagen formation

Individual treatment results vary between patients. Multiple treatment sessions may be required to obtain the desired results.

4. Users of the Device

The Darwin System is intended to be operated **only by trained healthcare professionals or qualified practitioners**.

The users received appropriate training on the conditions to safely use the device.
The device is **not intended for home use or self-treatment.**

5. Possible Risks and Side Effects

Like all medical or aesthetic procedures, treatment with the Darwin System may involve some risks.

Most side effects are temporary and resolve without treatment.
Possible side effects may include:

- Mild pain or discomfort during treatment
- Temporary redness (erythema)
- Mild swelling (edema)
- Warmth of the treated area
- Temporary tenderness
- Dry skin

- Mild itching
- Temporary changes in skin pigmentation
- Bruising
- Crusting or scabbing
- Small pinpoint bleeding (following RF microneedling)
- Temporary sensitivity
- Burning sensation

Rare complications may include:

- Burns
- Blistering
- Infection
- Scarring
- Persistent pigmentation changes
- Allergic reaction to topical products used during treatment

For Dry Eye Disease treatment, temporary eye irritation, light sensitivity, or mild discomfort around the eyelids may occur.

6. How Risks Are Reduced

Your healthcare professional will help minimise risks by:

- Assessing whether the treatment is suitable for you
- Reviewing your medical history
- Examining the treatment area before treatment
- Providing protective eyewear
- Following established treatment procedures
- Giving you instructions for before and after treatment care
- Recommending use of high factor sun block (SPF 30 or greater) and also to protect the treated area from exposure to sunlight for at least one month following treatment
- Advising on required follow-up visits with your healthcare professional post treatment

You should follow all instructions provided by your Healthcare Professional before and after treatment.

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7. Who Should Not Receive Treatment

Treatment may not be suitable if you:

- Are pregnant or Breast-feeding
- Have active skin infections at the treatment site
- Have open wounds in the treatment area
- Have certain photosensitive medical conditions
- Are taking medicines that increase sensitivity to light
- Have certain implanted electronic medical devices (for RF treatments)

- Have active cancer within the treatment area
- Have uncontrolled medical conditions affecting wound healing
- Actively using certain medications such as Isotretinoin (Accutane), or anticoagulants
- Have Fitzpatrick Skin Type VI or with tanned skin
- Are 18 years of age and under
- Have any other medical conditions that, in the opinion of your healthcare professional, may make the treatment unsuitable or increase the risk of complications

Your healthcare professional will determine whether treatment is appropriate.

8. When to Contact Your Healthcare Professional

Contact your treating healthcare professional immediately if you experience:

- Severe pain
- Blistering
- Increasing redness
- Persistent swelling
- Signs of infection
- Fever
- Vision changes following treatment near the eyes
- Any unexpected reaction

9. Reporting Side Effects

If you experience any undesirable side effects or unexpected problems following treatment, report them as soon as possible to:

- The healthcare professional or clinic where your treatment was performed; and
- Luvo Medical Technologies using the contact details provided below:
  CSR-Consumables@luvomedical.com

Reporting side effects helps improve the continued safety and performance of the device.

10. Recommendation Before Treatment

Before undergoing treatment, it is recommended that you have a consultation with a qualified healthcare professional.

This consultation should include:

- Review of your medical history
- Assessment of your skin condition
- Examination of the treatment area
- Discussion of expected benefits
- Discussion of potential risks and side effects
- Confirmation that the selected treatment is appropriate for you

For skin treatments, a diagnostic examination of the skin area intended for treatment is recommended before each treatment course.

11. Questions

If you have any questions regarding your treatment, expected outcomes, or possible side effects, please discuss them with your healthcare professional before proceeding.

Only your treating healthcare professional can determine whether treatment with the Darwin System is suitable for you.