DIAMOND GLOW™

User Manual

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Disclaimer: This manual is not intended as a comprehensive guide for all aspects of treatment. ZELTIQ Aesthetics, Inc., an Allergan affiliate highly recommends the operator confer with any appropriate Department of Labor, Licensing, Regulation, Medical Board or other such regulatory body in his/her respective state or country regarding legal use of this system in the applicable jurisdiction. ZELTIQ declines any responsibility for the direct consequences or side effects experienced by individuals undergoing treatment. Operators must be trained at the initial sale by authorized personnel. Because of our ongoing commitment to product quality, we reserve the right, at any time, to discontinue or modify specifications, prices, designs, features, models or equipment without incurring obligation.

Pro-Infusion Serums Disclaimer: The Pro-Infusion Serums are intended to meet the FDA's definition of a cosmetic product, an article applied to the human body to cleanse, beautify, promote attractiveness, and alter appearances. These products are not intended to be drugs that diagnose, treat, cure, or prevent any disease or condition. These products have not been approved by the FDA and the statements have not been evaluated by the FDA.

SYMBOLS GLOSSARY

SYMBOL	STANDARD REFERENCE	STANDARD TITLE	SYMBOL TITLE	EXPLANATORY TEXT
	ISO 15223-1, Clause 5.1.1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Manufacturer	Indicates the device manufacturer.
	ISO 7000-3082	Graphical symbols for use on equipment.		
	ISO 15223-1, Clause 5.1.3	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Date of manufacture	Indicates the date when the device was manufactured.
	ISO 7000-2497	Graphical symbols for use on equipment.		
	ISO 15223-1, Clause 5.1.6	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Catalogue or model number	Indicates the manufacturer's catalogue number so that the device can be identified.
	ISO 7000- 2493	Graphical symbols for use on equipment.		
	ISO 15223-1, Clause 5.1.7	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Serial number	Indicates the manufacturer's serial number so that a specific device can be identified.
	ISO 7000-2498	Graphical symbols for use on equipment.		
	ISO 15223-1, Clause 5.1.5	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	ISO 7000-2492	Graphical symbols for use on equipment.		
	ISO 15223-1, Clause 5.1.4	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Use by date	Indicates the date after which the device is not to be used.
	ISO 7000-2607	Graphical symbols for use on equipment.		
	IEC 60601-1, Table D.2, Symbol 10	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance.	Follow instructions for use	Refer to instruction manual/booklet.
	ISO 15223-1, Clause 5.4.3	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Consult instructions for use	Indicates the need for the user to consult the instructions for use.
	IEC 60601-1, Table D.1, Symbol 11	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance.		
	ISO 7000-1641	Graphical symbols for use on equipment.		
	ISO 15223-1, Clause 5.4.4	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Caution: Read all warnings and precautions in instructions for use	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the device itself.
	IEC 60601-1, Table D.1, Symbol 10	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance.		
	ISO 7000-0434	Graphical symbols for use on equipment.		
	IEC 60601-1-2:2007, Clause 5.1.1	Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic compatibility — Requirements and tests	Non-ionizing electromagnetic radiation	To indicate generally elevated, potentially hazardous, levels of nonionizing radiation, or to indicate equipment or systems e.g. in the electrical area that include RF transmitters or that intentionally apply RF electromagnetic energy for diagnosis or treatment.
	IEC 60417-5140	Graphical symbols for use on equipment.		
	IEC 60878-5140	Graphical symbols for electrical equipment in medical practice.		
	ISO 15223-1, Clause 5.3.8	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Storage humidity range	Indicates the range of humidity to which the device can be safely exposed.
	ISO 7000-2620	Graphical symbols for use on equipment.		

SYMBOL	STANDARD REFERENCE	STANDARD TITLE	SYMBOL TITLE	EXPLANATORY TEXT
	ISO 15223-1, Clause 5.3.7	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Storage temperature range	Indicates the temperature limits to which the device can be safely exposed.
	ISO 7000-0632	Graphical symbols for use on equipment		
	ISO 15223-1, Clause 5.3.9	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Atmospheric Pressure	Indicates the range of atmospheric pressure to which the device can be safely exposed.
	ISO 7000-2621	Graphical symbols on equipment		
	ASTM F2503	Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment.	Magnetic Resonance (MR) unsafe	Keep away from magnetic resonance imaging (MRI) equipment.
	ISO 15223-1, Clause 5.3.4	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Keep dry	Indicates a medical device that needs to be protected from moisture.
	ISO 7000-0626	Graphical symbols for use on equipment.		
	ISO 15223-1, Clause 5.3.1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Fragile, handle with care	Indicates a device that can be broken or damaged if not handled carefully.
	ISO 7000-0621	Graphical symbols for use on equipment.		
	IEC 60601-1, Table D.1, Symbol 20	Medical electrical equipment —	Type BF applied part	To identify a type BF applied part complying with IEC 60601-1.
	IEC 60417- 5333	Part 1: General requirements for basic safety and essential performance.		
	IEC 60601-1, Table D.1, Symbol 19	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance.	Type B applied part	To identify a type B applied part complying with IEC 60601-1.
	IEC 60417-5840	Graphical symbols for use on equipment.		
	ISO 15223-1, Clause 5.4.2	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Do not reuse	Indicates a device that is intended for one use, or for use on a single patient during a single procedure.
	ISO 7000-1051	Graphical symbols for use on equipment.		
	ISO 7000-3079	Graphical symbols for use on equipment.	Open here	To identify the location where the package can be opened and to indicate the method of opening it.
	ISO 15223-1, Clause 5.4.5	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Contains natural rubber or latex	Indicates the presence of natural rubber or dry natural rubber latex as a material of construction within the device or the packaging of a medical device.
	ISO 15223-1, Clause 5.2.7	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Non sterile	Indicates a device that has not been subjected to a sterilization process.
	ISO 7000-2609	Graphical symbols for use on equipment.		
	ISO 15223-1, Clause 5.2.8	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied .	Do not use if package is damaged	Indicates a device that should not be used if the package has been damaged or opened.
	ISO 7000-2606	Graphical symbols for use on equipment.		
	EN 50419	Marking of Electrical and Electronic Equipment in accordance with Article 11(2) of Directive 2002/96/EC (WEEE).	Recycle: Electronic Equipment	Do Not throw this unit into a municipal trash bin when this unit has reached the end of its lifetime. T ensure utmost protection of the global environment and minimize pollution, please recycle this unit.

SYMBOL	STANDARD REFERENCE	STANDARD TITLE	SYMBOL TITLE	EXPLANATORY TEXT
	IEC 60417, Reference 5032	Graphical Symbols for Use on Equipment.	Alternating Current	To indicate on the rating plate that the equipment is suitable for alternating current only; to identify relevant terminals.
	IEC 60417, Reference 5036	Graphical Symbols for Use on Equipment.	Dangerous Voltage	To identify hazards arising from dangerous voltages.
	IEC 60417, Reference 5019	Graphical Symbols for Use on Equipment.	Protective Earth Ground	To identify any terminal which is intended for connection to an external conductor for protection against electric shock in case of fault, or the terminal of a protective earth (ground) electrode. The location of this symbol shall be directly adjacent to the AC inlet or as close as is feasible.
	60601-1, Medical Device Marking and Labeling	Appendix D	Safe Working Load	60601 Safe Working Load
	ISO 7000, Reference 0623	Graphical Symbols for use on equipment.	This Way Up	Indicates correct upright position of the transport package.
	ISO 7000; Reference 2402	Graphical Symbols for use on equipment – registered symbols.	Do Not Stack	To indicate that the items shall not be vertically stacked, either because of the nature of the transport packaging or because of the nature of the items themselves.
	ISO 7000, Reference 1135	Graphical Symbols for use on equipment – registered symbols.	Recycle	Indicates an item can be recycled. The packaging shall include the Recycle symbol ISO 7000-1135 with the text "NW" below.
	ISO 7000-2794	Graphical symbols for use on equipment.	Packing unit	To indicate the number of pieces in the package. A number is inserted in the symbol to indicate the number of pieces in the package.
	ISO 15223-1; 5.7.10	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Unique Device Identifier	Used to identify which information is associated with Unique Device Identifier.
	IEC 60601-1	Identification and completion of applicable tests and identification of NRTL testing agency for compliance with IEC 60601-1	NRTL Certification	Based on current IEC 60601-1 testing to satisfy Canadian and USA OSHA requirements by a NRTL (Nationally Recognized Testing Laboratories) shall be applied to the control unit.
	State Council of the Chinese Government Decree #551, the Regulations on Recovery Processing of Waste Electrical and Electronic Products, http://www.chinarohs.com/	Decree #551, the Regulations on Recovery Processing of Waste Electrical and Electronic Products, http://www.chinarohs.com/	China RoHS	If the product is for sale or use in China, the RoHS label shall be applied to the control unit. Indicates that the EIP does not contain toxic and hazardous substances or elements above the maximum concentration values, and that it is an environmentally friendly product which can be recycled and reused.
	Low Voltage Directive 2014-35-LVD Low Voltage Directive 2014/35/EU Guide	Article 3, Making available on the market and safety objectives	CE marking	Affixed to device label. Signifies European technical conformity.

PREFACE

ZELTIQ Aesthetics, an affiliate of Allergan would like to thank you for your choice of DIAMONDGLOW™ that combines precision non-invasive exfoliation with topical cosmetic serum to address patient-specific skin conditions. This device has been specifically designed for aesthetic applications.

Allergan strongly advises the operator to read this manual thoroughly. The following chapters provide a description of the system, the technical specifications, and installation, operating, and maintenance instructions, as well as safety information and patient considerations.

Please write your serial number in the space provided below. You will find a similar tag on the back of your DIAMONDGLOW™ toward the upper right-hand corner.

My DIAMONDGLOW™ serial number is:

_____

Figure 1: Serial Number Plate

NOTE

The DIAMONDGLOW™ warranty is void if:

- Anyone other than authorized personnel install and/or service the equipment.
- Solutions other than Allergan authorized topical solutions are used with the DIAMONDGLOW™ .
- Electrical facilities at the installation site do not comply with all application codes, including IEC and UL requirements.
- The device is not used in accordance with the instructions specified in this manual.

(See Chapter 7 for full Terms of Warranty.)

The DIAMONDGLOW™ was previously referred to as SP3.

PATENTS

Patented. See www.allergan.com/patents

DIAMONDGLOW™ is a trademark of Allergan, Inc.

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 authorized personnel. ZELTIQ is not responsible for injury or damage resulting from improper use of the system. If there is any doubt concerning the use of the DIAMONDGLOW™ or the operator's manual, please contact Customer Service representative in Chapter 6 of this User Manual.

ELECTROMAGNETIC EMMISSIONS

The DIAMONDGLOW™ equipment is intended and suitable for use in clinical office environments (see Appendix 1 for EMC test summary tables).

⚠ CAUTION: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

⚠ CAUTION: 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 DIAMONDGLOW™ system. Otherwise, degradation of the performance of this equipment could result.

*DISINFECTANT

Approved disinfectants are Opticide3 (US) and MicroKleen (CAN). Outside the US and Canada, check with your local distributor for disinfectant options.

CHAPTER 1: GENERAL OVERVIEW

1.1 TREATMENT OBJECTIVES

The DIAMONDGLOW™ system has been designed to perform controlled exfoliation of the skin simultaneously with the delivery of unique topical solutions. The treatment objective is to improve outcomes of dermatological conditions.

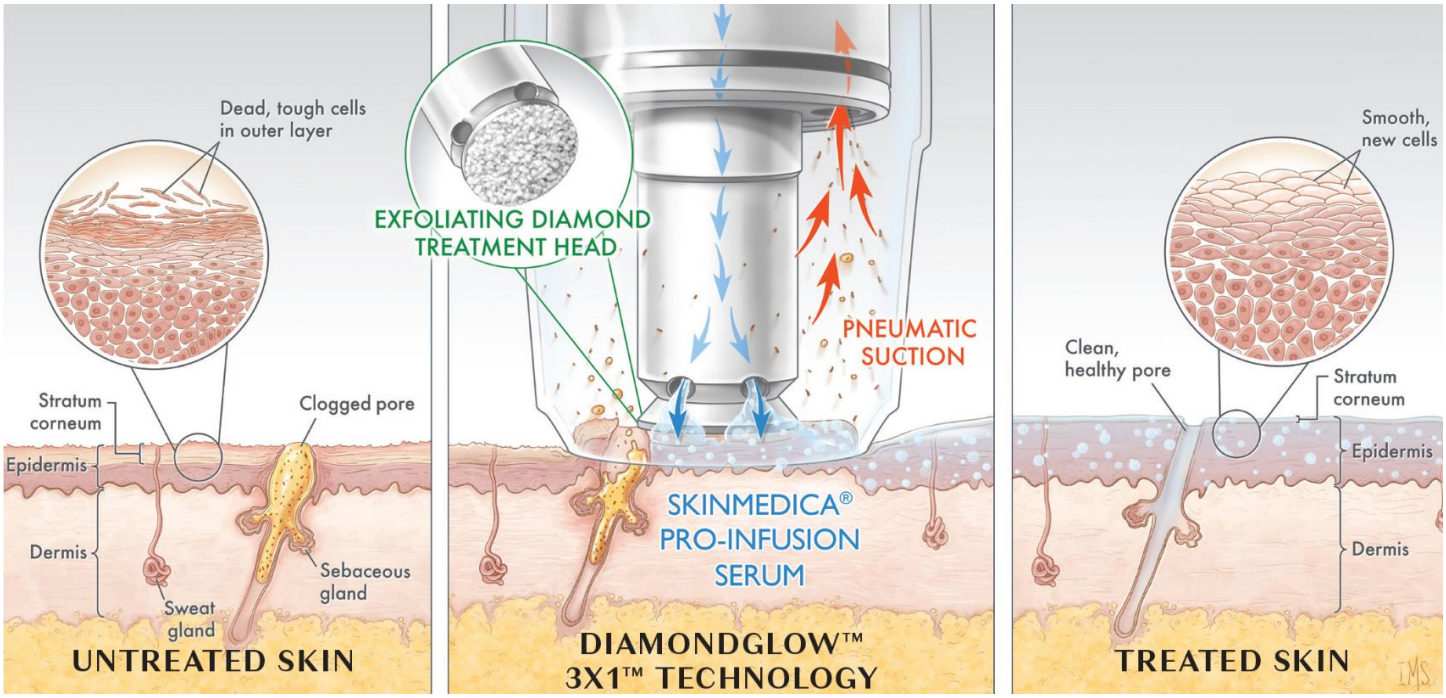

Figure 2: Exfoliation Magnified

Operating on a closed-loop vacuum system, the medical grade diamonds exfoliate the outer layer of skin while delivering a topical dermaceutical onto the skin at a controlled intensity.

Indications for Use

The DIAMONDGLOW™ device is indicated for general dermabrasion of the skin and delivers topical enhanced exfoliation onto the skin.

Contraindications

DIAMONDGLOW™ is contraindicated in patients who have compromised skin quality including but not limited to

- Sunburned skin
- Windburned skin
- Extremely dry skin
- Chapped skin
- Irritated or broken skin
- Any open wounds
- Active, weeping acne
- Cold sores
- Herpetic ulcers

Ask your patient if they are pregnant or lactating or if they have any medical conditions, including allergies, and usage of topical medication on the area to be treated.

Consult the DIAMONDGLOW™ User Manual for a complete list of Contraindications, Precautions, Warnings, and potential side effects.

Precautions

Patients should be advised to use sunscreen with a sun protection factor of 30 or higher following treatment.

Side Effects

Typical side effects include a scratchy, stinging sensation during the treatment and temporary tightness, redness or slight swelling after the treatment.

Serious side effects are uncommon and unlikely. However, should your patient notice any of the following side effects, cease use immediately:

- Severe skin irritation
- Allergic reaction
- Rash
- Skin burning
- Stinging
- Itching
- Dryness
- Redness
- Peeling
- Irritation.

1.2 SYSTEM FEATURES

The following section identifies the features of the DIAMONDGLOW™ :

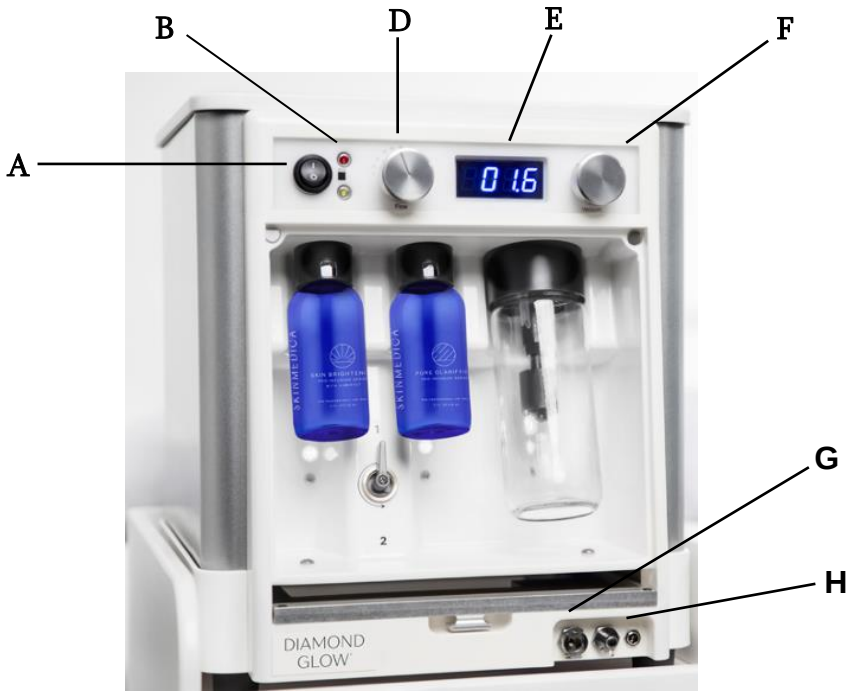

Figure 3: Front Console

1.2.1 Front Console

The front console contains the following:

A	On/Off Switch	Turns the system on (I) and off (O)
B	Overflow Indicator	A red light that illuminates when the waste jar is overfull and needs to be emptied
C	Preventative Maintenance Indicator	An amber light that illuminates when the system needs to be serviced
D	Flow Knob	Indicates the flow of topicals through the system between 00.0-100.0%. Adjust the topical flow for treatment. Flow Increases when you turn the knob clockwise. Flow is also dependent upon vacuum; therefore, set vacuum first, then adjust flow.
E	Vacuum Display	Indicates the vacuum from 2-11+PSI
F	Vacuum Knob	Adjusts the vacuum for treatment. Vacuum increases when you turn the knob clockwise.

G	Vacuum Coupler	Large quick disconnect fitting where the clear vacuum tubing from the handpiece connects to the unit
H	Supply Coupler	Small quick disconnect fitting where the clear supply tubing from the handpiece connects to the unit
I	Supply Tubing	Clear tubing connecting the handpiece and the unit (not shown)
J	Vacuum Tubing	Transparent clear tubing connecting the handpiece and unit (not shown)

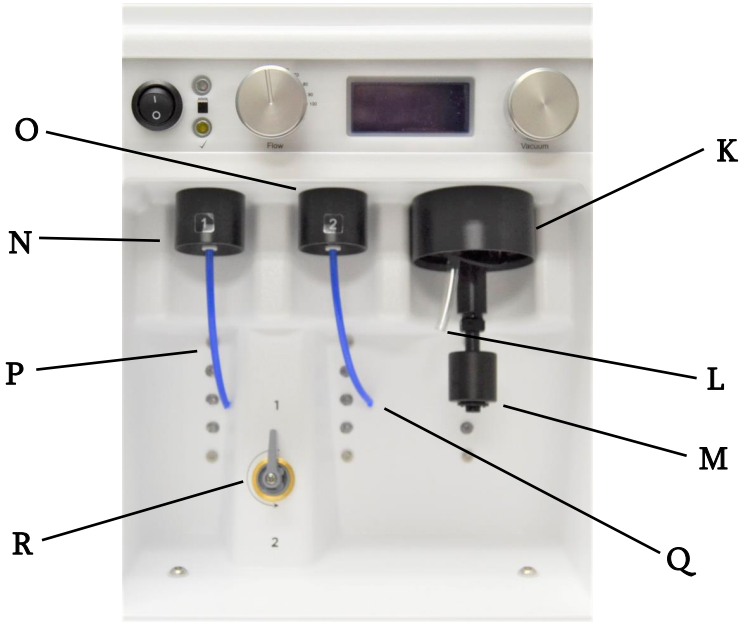

Figure 4: Front Console Con't.

K	Waste Manifold	Threaded cap for attaching a glass waste jar
L	Residual Waste Tubing	Expels residual solution and waste into waste jar
M	Float Switch	Activates the red Overflow Indicator if the waste jar is not emptied
N	Supply Manifold 1	Threaded cap for attaching a bottle of solution
O	Supply Manifold 2	Threaded cap for attaching a bottle of solution
P	Uptake Tubing 1	Intakes topicals from the supply jar into supply tubing
Q	Uptake Tubing 2	Intakes topicals from the supply jar into supply tubing
R	Bottle Selection	Toggles between manifolds 1 and 2 Switch

Figure 5: Back panel

1.2.2 Back Panel

S	Handpiece Hook	Location for storing the handpiece between treatments
T	External Air Filter	Houses the filter element
U	Hour Meter	Displays number of hours DIAMONDGLOW™ has run
V	Power Cord Housing/Fuse Box	Housing into which the power cord plugs. The lower compartment holds the fuses
W	Vacuum Muffler	Vents vacuum pressure and muffles exhaust sound
X	Run/Test Switch	Switch used to test function of the device

Figure 6: Accessories

1.2.3 Accessories

Y	Accessory Organizer	Custom tray for storage of treatment heads Case (Note: Tray cannot be autoclaved).
Z	O-Ring Tool	Tool with hooked end to assist installation of a new O-ring

1.3 SYSTEM DESCRIPTION

The DIAMONDGLOW™ system uses a closed loop vacuum system to exfoliate and deliver topicals onto the skin. When its handpiece tip is brought in contact with the treatment area, the vacuum source gently pulls the tissue being treated through the hole in the tip and into contact with the abrasive, diamond-encrusted treatment head. As the handpiece is drawn across the skin, this abrasive surface exfoliates the tissue, delivers a topical cosmetic serum, and vacuums away the residuals into a sealed waste jar.

The main components of the DIAMONDGLOW™ operation are:

a) **Vacuum pump**. The vacuum pump is responsible for creating the negative (vacuum) pressure that pulls tissue into contact with the treatment head and simultaneously delivers the topical to the skin through the handpiece.

b) **Handpiece**. The handpiece consists of six components: the disposable cap, the treatment tip, the O-ring, the wand, the supply branch and the vacuum branch.

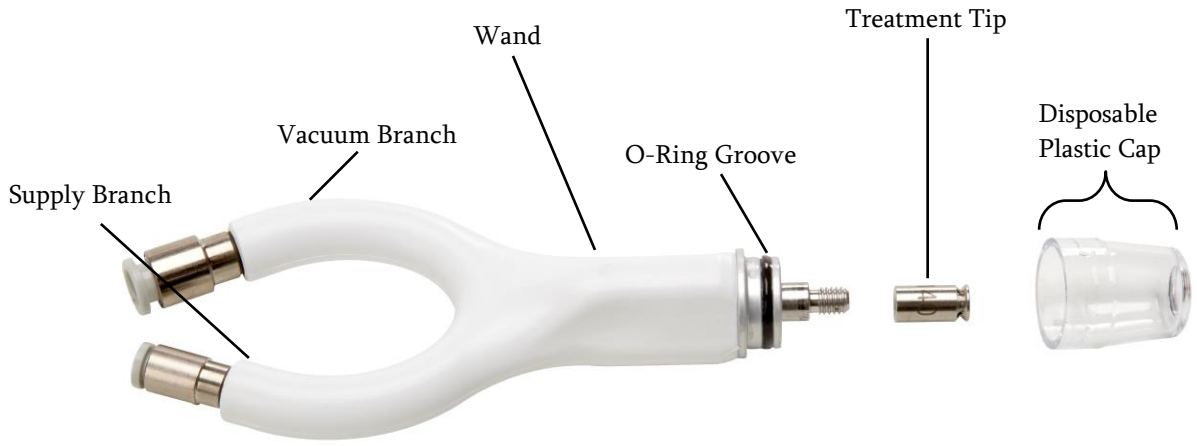

Figure 7: Handpiece

c) **Diamond treatment tips**. The DIAMONDGLOW™ includes one set of 6 sterilizable, diamond-encrusted treatment tips in the following grit sizes and diameters:

- Medium-Coarse (60 grit), 6mm diameter
- Medium (80 grit), 6mm diameter
- Medium-Fine (100 grit), 6mm diameter
- Fine (120 grit), 6mm diameter
- Very Fine (140 grit), 6mm diameter
- Smooth, 6mm diameter

Figure 8: Diamond Treatment Tips

Select the grit size based upon the nature of the procedure to be performed. The 6mm tip is best for treating areas requiring greater precision, such as areas around the nose and mouth.

⚠ **CAUTION: ONLY TREAT AROUND THE EYE AREA AND LIP AREA WITH A SMOOTH TREATMENT TIP, STRICTLY FOLLOWING RECOMMENDED PROTOCOL AND SAFETY GUIDELINES.** Do not ever treat the eyelids. It is recommended to use disposable Derm-Aid eye shields during any procedure for maximum patient comfort and safety. Treatment heads MUST BE thoroughly cleaned before use and between patients.

d) **Disposable Caps**. DIAMONDGLOW™ includes one pack of 12 disposable, single-use plastic handpiece caps. Also included is one 2-pack of transparent blue cleaning caps are also provided to facilitate easy cleaning of the system.

e) **Vacuum and Topical Flow Adjustments.** Two adjustment knobs are located on the front console with a gauge to the left of the Vacuum knob. The display reads vacuum. Its corresponding knob can increase or decrease the force with which the treatment area is brought in contact with the treatment head. Turn the knob to the

right (clockwise) to increase the vacuum pressure. Turn the knob to the left (counterclockwise) to decrease the vacuum pressure. Higher vacuum pressure will pull the topical solutions through with greater velocity. **NOTE: Topical flow is dependent on the vacuum pressure setting; therefore, set vacuum adjustments first and then set the corresponding flow.**

The flow of the topical is displayed on the panel behind the knob. Turn its adjustment knob to the right (clockwise) to increase the flow of the topical. Turn the knob to the left (counterclockwise) to reduce the flow of the topical.

f) **Topical Supply Bottle.** The topicals are supplied in 4oz plastic bottles and thread into the manifolds on the front of the DIAMONDGLOW™. Select the topical based on the patient's specific dermatological condition.

g) ***Disinfectant Supply Bottle**. The DIAMONDGLOW™ uses a 2oz bottle of *disinfectant with our cleaning protocol. The bottle of *disinfectant threads into the center (*disinfectant supply) manifold (located between the topical supply manifold and the waste manifold) on the front of the DIAMONDGLOW™ .

h) **Waste Jar.** Residual solution and exfoliated tissue are deposited in a clear glass waste jar, which threads into the right (waste) manifold on the front of the unit. When the waste jar is full, remove it from the DIAMONDGLOW™ and dispose of the residual solution in accordance with OSHA standards. *Disinfect or autoclave the waste jar before replacing it in the DIAMONDGLOW™.

i) **External Air Filter.** The external air filter is located on the rear panel of the unit. It is designed to prevent moisture from reaching the vacuum pump. Under proper operating conditions, liquid should not collect in the filter housing. Should liquid pass into the filter, it will collect in the filter housing. Periodic checks of the filter are important to ensure proper operation. The filter should be changed every six months or 200 hours to ensure proper filtration and equipment protection (see Section 4.1).

1.4 TECHNICAL SPECIFICATIONS

DIAMONDGLOW™ A0142_DG (US, Canada, and LATAM)

Supply Voltage:	5A 100-120V 60 Hz / 100V 50 Hz, single phase
Fuses:	T5AH 250V UL 5X20mm
Power (W):	200w maximum
Current (A):	5A
Maximum Vacuum:	> 10 PSI
Maximum Flow:	> 50 mL/min (At maximum vacuum and 100%)
Abrading medium:	Medical grade diamond (carbon)
US FDA Class:	I Exempt (See CFR 878.4820)
Dimensions:	12.4" x 14" x 14.5"
Weight:	33.35 lbs / 15.1 kg
Operating temperature:	40°C maximum
Operating Atmospheric Pressure:	88 kPa maximum
Operating Altitude	8,000 feet above sea level maximum

DIAMONDGLOW™ A0143_DG (Europe and Asia)

Supply Voltage:	5A 220-240V 50/60 Hz, single phase
Fuses:	T5AH 250V UL 5X20mm
Power (W):	200w maximum
Current (A):	5A
Maximum Vacuum:	> 10 PSI
Maximum Flow:	> 50 mL/min (At maximum vacuum and 100%)
Abrading medium:	Medical grade diamond (carbon)
US FDA Class:	I Exempt (See CFR 878.4820)
Dimensions:	12.4" x 14" x 14.5"
Weight:	33.35 lbs / 15.1 kg
Operating temperature:	40°C maximum
Operating Atmospheric Pressure:	88 kPa maximum
Operating Altitude	8,000 feet above sea level maximum

CHAPTER 2: INSTALLATION

2.1 INSTALLATION REQUIREMENTS

Before installing the DIAMONDGLOW™, verify:

- The electrical receptacle is an approved type and complies with local standards.
- The power input is the same indicated on the data plate of the unit, that is 100-120VAC 60Hz / 100V 50Hz or 220-240VAC 50/60Hz single phase.
- The DIAMONDGLOW™ voltage conforms to the electrical voltage of your outlet.
- The device is located on a suitable flat surface (i.e., table or an approved stand) with the front console towards the operator.
- The device has 3 – 4 inches of free space all around it to ensure proper cooling.

NOTE: DIAMONDGLOW™ HANDLING

The DIAMONDGLOW™ weighs approximately 33 lbs. Use proper lifting techniques when unpacking and repacking the unit.

2.2 UNPACKING AND INSPECTION

The DIAMONDGLOW™ should be unpacked and installed by a trained ZELTIQ representative.

Instructions for unpacking the DIAMONDGLOW™ are as follows:

1. Examine the shipping box for external damage or evidence of mishandling. You must immediately notify ZELTIQ or your ZELTIQ 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 you misplace your box and foam padding, replacements are available from ZELTIQ at an additional cost. This model DIAMONDGLOW™ includes a state-of-the-art, innovative shock absorption system to keep the pump in place during transit.
3. Compare the items in the box with the packing list and be sure that all items on the list are present. You must immediately notify ZELTIQ or the distributor IN WRITING of any discrepancies. Contents may vary according to the model and accessories ordered. Please contact Customer Service representative in Chapter 6 of this User Manual.

⚠ CAUTION

RETAIN FACTORY PACKAGING MATERIALS

Do not ship a DIAMONDGLOW™ without the factory packaging materials. Doing so may result in damage to the components during shipping and void the warranty. Please contact Customer Service representative in Chapter 6 of this User Manual, for packaging materials and repackaging instructions.

2.3 INSTALLATION

The DIAMONDGLOW™ is designed for easy installation, which is carried out as follows:

1. Place the DIAMONDGLOW™ in its designated location.
2. Connect the power cord to the equipment at the power cord housing on the back of the unit. Plug the system into a Ground Fault Interrupt (GFI) outlet.
3. Test the system for proper operation.
4. The handpiece has a tubing set installed. The other end of the tubing set has a coupler on each of the tubes to connect it to the front of the machine. Connect the coupler attached to the clear tubing to the left fitting, and connect the coupler attached to the clear tubing to the fitting on the right. (See Figure 9)

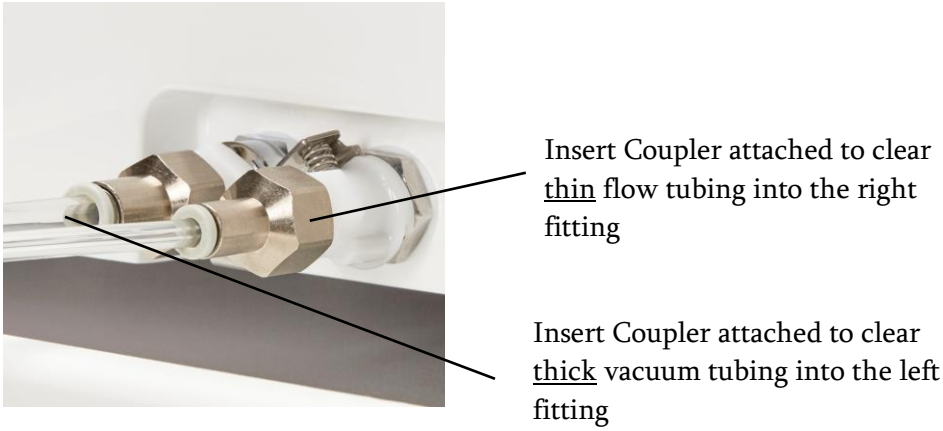

Figure 9: Front Console Tubing Connections

2.4 MOVING THE SYSTEM

Most users of the DIAMONDGLOW™ have more than one operator or utilize multiple treatment rooms. The DIAMONDGLOW™ can easily be moved between them using the custom DIAMONDGLOW™ rolling stand, which is an optional accessory. The only disassembly required is disconnection of the power cord to ease maneuvering. Rather than unplugging the power cord from the electrical outlet for each move, it may be easier to install a power cord at each location, leaving them in place. Rest the handpiece in the handpiece hook while moving.

If you operate in multiple offices or will require transporting the DIAMONDGLOW™ over longer distances, you may elect to purchase the DIAMONDGLOW™ custom rolling case. This travel case features custom-fit foam insulation for your DIAMONDGLOW™ and its accessories, a push-button retractable handle, and inline skate wheels to ensure easy and reliable transportation.

CHAPTER 3: OPERATION

3.1 PREPARATION

Before beginning a treatment, the operator must:

- Evaluate the patient's skin type and condition.
- Determine the solutions, grit, and tip size that would be appropriate for the patient.
- Confirm that the treatment tip and tubing have been cleaned and the disposable cap is new.
- Screw the treatment tip onto the threading located at the top of the handpiece.
- Ensure a handpiece tip O-ring is installed in the O-ring groove.
- Attach the appropriate handpiece tip by sliding it over the O-ring using a twisting motion while applying downward pressure.

Figure 10: Treatment Tip & Disposable Cap Assembly

- Thread a clean waste jar into the waste manifold.
- Make sure your Bottle Selection Switch is set to the solution you want to use.
- Gently shake bottles of the topical solutions selected for the patient and thread it into the topical supply manifolds (1 and/or 2).

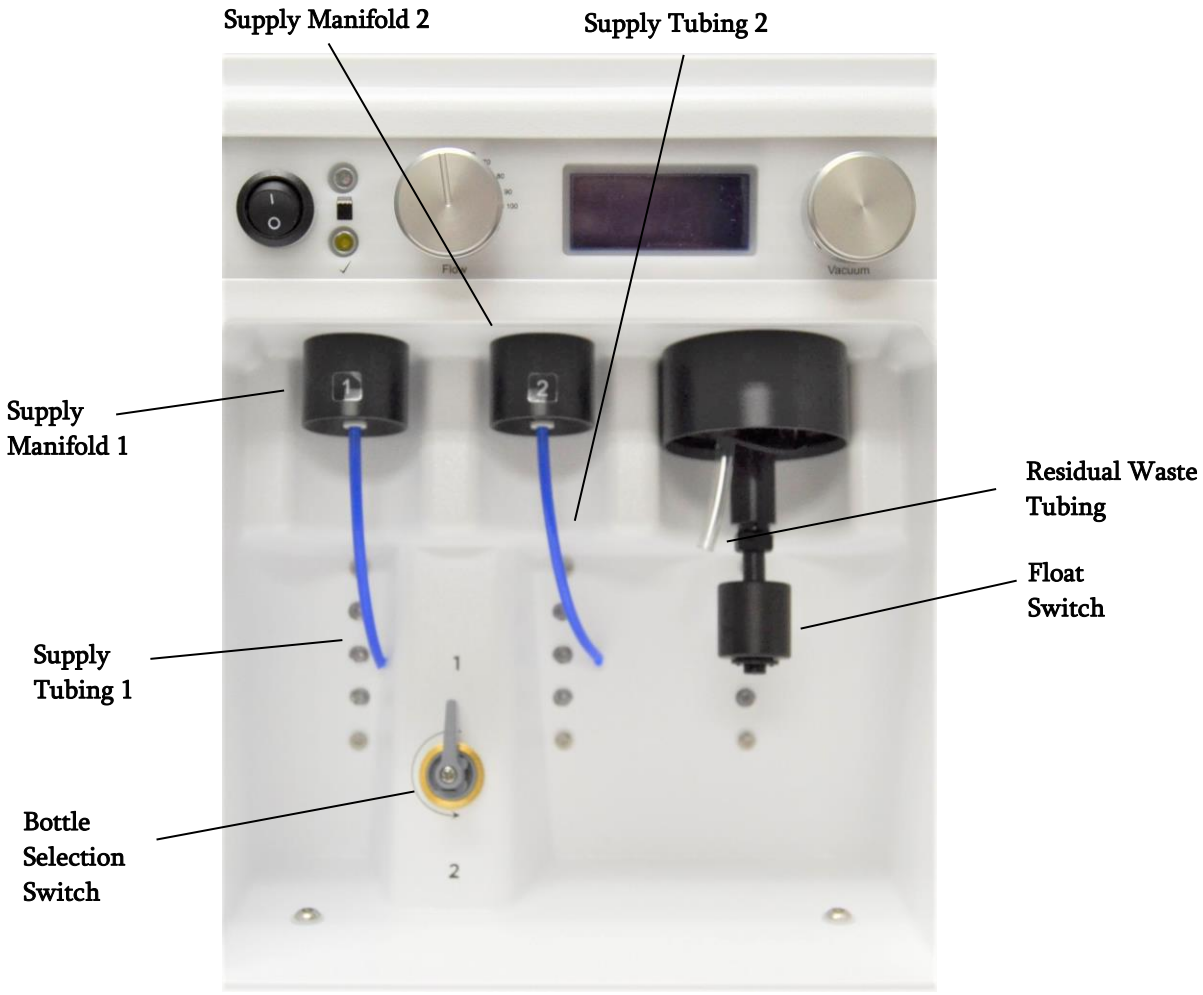

Figure 11: Supply and Waste Manifolds

CHAPTER 4: MAINTENANCE

The following sections outline routine maintenance protocols. At the end of the chapter, Table 4-1 provides an overview of these recommended procedures.

4.1 DAILY MAINTENANCE

Proper cleaning of your DIAMONDGLOW™ is imperative to your patients' health and to prolonging the life of your unit. Cleaning must be performed immediately after every DIAMONDGLOW™ treatment and at the end of the day.

To clean the unit **immediately after *every*** DIAMONDGLOW™ treatment:

1. Remove and dispose of the plastic disposable cap; remove treatment tip and clean in accordance with the instructions listed below (at End of Day).
2. Place a blue sealed cleaning handpiece tip onto the handpiece.
3. **Remove empty bottles of topical solution.**
4. **Turn the Bottle Selection Switch counterclockwise to point towards "2". DO NOT USE WATER OR ANY OTHER UNAUTHORIZED FLUID FOR *DISINFECTING. Use of any unauthorized products in the DIAMONDGLOW™ will VOID its warranty.**
5. Gently shake a bottle of *disinfectant and thread it into the *disinfectant supply manifold on the DIAMONDGLOW™.
6. Adjust the vacuum to 5 psi, and the flow to maximum.
7. Run the *disinfectant solution through the system for 5 or 6 minutes, or until the handpiece tubing appears to be nearly empty.
8. Remove the *disinfectant with the unit still turned on. Turn the vacuum up to maximum and run air through the machine until it is aired out (about 30 seconds).
9. Turn the machine off, then empty and reattach the waste jar.
10. **Turn the Bottle Selection Switch clockwise to point towards "1".** You are now ready to perform a DIAMONDGLOW™ procedure.

For **end of the day** maintenance:

1. Check the external air filter for residual liquid accumulation. If liquid is visible, replace the filter according to the steps in Section 4.5. **THIS STEP IS CRITICAL FOR THE PROPER MAINTENANCE OF YOUR UNIT.**
2. Use water, a mild cleansing solution, to clean the front of the machine, if necessary.
3. Thoroughly *disinfect the treatment heads and handpiece (see Section 4.2). Failure to do so may cause damage to parts.
4. Reassemble the handpiece and reattach it to the front of the unit (see Figures 9, 10 and 11).

4.2 CLEANING THE TREATMENT HEADS AND HANDPIECE

The treatment head should be thoroughly cleaned after each treatment:

a. Remove the plastic handpiece tip and discard it with your biohazardous waste.
b. Remove the treatment tip and clean by soaking in enzymatic detergent (such as Microzyme) for 15 minutes. The head should then be rinsed in hot running water and the abrasive surface scrubbed with a brush to remove protein material.
c. The treatment tip can then be placed in *disinfecting solution. Read the label on the *disinfectant for the proper soak time.
d. If the treatment tip is to be cleaned in the unwrapped Plastic Cleaning Tray, the "flash" cycle may be used. This is typically five minutes at a minimum temperature of 132ºC (270ºF) in a steam autoclave. NOTE: Autoclaves differ by manufacturer and specification; therefore, always follow manufacturer instructions in setting temperature and cycle time. Failure to follow manufacturer's instructions may result in damage to your treatment tip.

Figure 12: Removing Tubing from a Quick Disconnect Fitting

4.3 INSTALLING AN O-RING

Place one corner of the O-ring into the O-ring groove on the handpiece. Hook the opposite side of the O-ring with the rounded end of the O-ring tool. Stretch the O-ring over the treatment tip post and into the groove. Work into place with fingers, as necessary.

4.4 DISCONNECTING AND REPLACING TUBING

Remove the coupler from the front of the machine by depressing the button below the fitting while pulling on the metal coupler. To disconnect tubing from the coupler, press in on the white quick disconnect fitting, while using the other hand to remove the tube. (See figure 13 above) To replace the tube, insert it into the fitting until you feel resistance; pause, then push the tube slightly further into the fitting to lock the tube in place. Quick disconnect fittings are called two-stage fittings because of this method of connection. Using force can cause damage to the quick disconnect fitting. Such damage is not covered under warranty.

4.5 MAINTAINING THE EXTERNAL AIR FILTER

The external air filter is mounted on the rear of the DIAMONDGLOW™ unit to protect the vacuum pump from overflow from the waste jar. **To prevent damage to the pump and to avoid contamination, it is critical to maintain the cleanliness and integrity of the filter and filter housing.** Under proper operating conditions, liquid should not collect in the filter housing. **DAILY** checks of the filter are important to ensure proper operation. Should liquid accumulate in the filter housing, follow the steps below to replace the filter and clean the housing.

The filter should be changed every six months or 200 hours to ensure proper filtration and equipment protection. To replace the filter:

1. Slide the grey locking tab on the filter housing downward (see Figure 13a below).
2. With the locking tab still in a downward position, rotate the filter housing counterclockwise towards the corner of the filter housing.
3. Once the grey tab is at the corner, pull the filter bowl down to remove. (See Figures 13b and 13c).

Figure 13a: Release External Air Filter

Figure 13b: Align Grey tab with Corner

Figure 13c: Pull down on Filter Housing

Figure 13d: Remove black locking disc

Figure 13e: Remove alignment ring from filter

5. Clean the filter bowl by soaking in warm water, then allowing to air dry.
6. Rotate the black locking disk located on top of the filter bowl to unlock and pull to remove it. (See Figure 13d).
7. Unscrew alignment ring from filter. (See Figure 13e) Place the new filter on top of the locking disk and the alignment ring on top of the filter.
8. Replace the filter housing by reversing steps 1-5.

Table 4-1 – Recommended Routine Inspection and Maintenance Schedule

Activity	By	Interval	Requirement/Action
Clean exterior surfaces	User	Daily or as needed	Clean quick disconnect fittings and surrounding areas
Empty waste jar	User	Before use & immediately after treatments	Discard and clean waste jar regularly to prevent overflow and damage to the unit
Clean treatment heads and handpiece	User	Before use & after treatments	Autoclave or clean in ultrasonic cleaner according to section 4.2
*Disinfect tubing	User	Before use & after treatments	*Disinfect by running 2oz. *Disinfecting Solution through unit when changing topicals and at the end of the day. See section 4.1
Check external air filter	User	Daily	Monitor for topical overflow. Empty, clean and replace as needed
Replace tubing	User	Monthly	Replace if discolored, or if clogged with dry topical due to improper cleaning
Check topical and *disinfecting uptake tubing	User	Monthly	Ensure a tight connection between the intake tubes and the quick disconnect fittings in the supply manifolds
Check residual waste tubing	User	Monthly	Ensure a tight connection between the residual waste tube and the quick disconnect fitting in the waste manifold
Clean float switch	User	Monthly	Clean with a moist cloth. Replace with metal weights at bottom
Replace handpiece tip O-ring	User	As needed	Follow instructions in section 4.3
Preventative maintenance	Service Technician	Upon illumination of amber indicator light	Unit requires service. Please contact Customer Service representative in Chapter 6 of this User Manual.

CHAPTER 5: TROUBLESHOOTING

Potential problems can be minimized by following the routine schedule described in Table 4-1. Many of the calls received by ZELTIQ regarding the DIAMONDGLOW™ are for operator-related issues and/or improper cleaning and maintenance. Most of these problems can be resolved in the office by the user. This section provides instructions for troubleshooting. Table 5-1 provides an overview of troubleshooting measures.

5.1 NO POWER

If the system does not start, check the following:

1. The power cord is properly connected.
2. The electrical outlet is "on" and is the correct voltage.
3. The "On/Off" switch on the front of the machine is in the "On" position (I).
4. The fuse has not blown.

5.2 BLOWN FUSE

If the fuse is blown, you will hear a pop and the system will have no power to the displays or the vacuum pump. Use a small flathead screwdriver to slide the black fuse box from the bottom of the power cord housing. Remove both fuses from their clip and discard them (See figures below). Replace with fuse marked as T4AH 250V only. It is recommended to always have spare fuses on hand. To order spare fuses, please contact Customer Service representative in Chapter 6 of this User Manual.

Figure 14a: Slide Out Black Fuse Box

Figure 14b: Remove Fuse Box

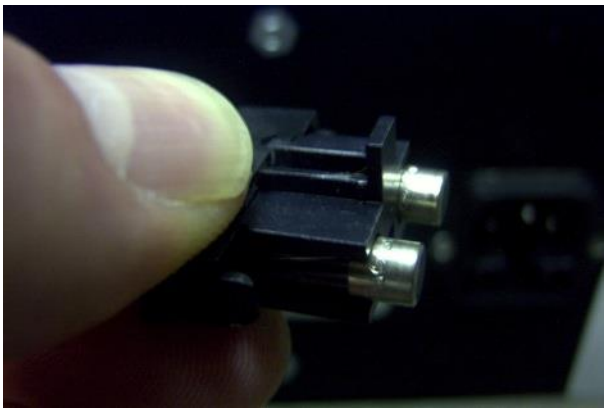

Figure 14c: Replace Both Fuses

5.3 RED INDICATOR ILLUMINATED / VACUUM PUMP NOT OPERATING

If the vacuum pump stops running during operation or does not engage when the "On/Off" switch is turned on:

1. Check the waste jar. The waste manifold (where the jar threads into the machine) is equipped with an automatic overflow detector. Should the operator neglect to empty the waste jar, the pump will disengage and a red LED with a full jar symbol beneath it on the front of the unit above the "On/Off" switch will illuminate. Should this occur, immediately turn the machine off and remove the waste jar. Empty the contents of the jar as instructed above and replace it into the waste manifold. Check the external air filter for liquid. Drain and/or clean, if necessary (see section 4.5).
2. After completing step 1, or if the waste jar was not full, but the red light remains on, please contact Customer Service representative in Chapter 6 of this User Manual.

5.4 NO VACUUM

If the pump is on but no vacuum is evident, occlude the handpiece tip and turn the vacuum knob to maximum (though the display readout may not change). Check the following connections, testing for vacuum between each step. **NOTE: Vacuum will not build until the handpiece tip is occluded, and the vacuum loop is closed.**

1. Ensure that a tight fit is achieved between the disposable cap and the treatment tip of the O-ring. If the O-ring has broken or lost its seal, replace it with a new one.
2. Confirm that the vacuum tubing is firmly inserted into the fitting on the front of the DIAMONDGLOW™ unit.
3. Verify that the waste jar is threaded into the waste manifold correctly. If the threading on the jar is not properly aligned with the threading on the manifold, vacuum pressure loss may occur.
4. Verify that the External Air Filter is firmly in place (see section 4.5 for further instructions). If the filter housing is not properly installed, vacuum pressure loss may occur.
5. If there is still no vacuum pressure evident, please contact Customer Service representative in Chapter 6 of this User Manual.

5.5 NO TOPICAL FLOW

If the pump is on, vacuum is evident when the handpiece tip is occluded, yet no topical solution appears to flow, perform the following steps:

a) Rule out vacuum pressure loss by following the steps listed in the preceding section. If the vacuum pressure is compromised, there may be inadequate force to carry the topical through the line. **NOTE: Vacuum pressure will not build until the handpiece tip is occluded, and the vacuum loop is closed.** If vacuum pressure passes all troubleshooting tests and pressure can be felt at the handpiece tip, turn the machine off.
b) Remove the supply bottle from the manifold. Confirm there is solution in the bottle.
c) Gently shake a full supply bottle and thread it into the supply manifold.
d) Ensure that the clear supply tube is firmly inserted into the fitting on the front of the unit.
e) Turn the unit back on. Confirm that vacuum and flow are both set to maximum, occlude the handpiece tip and check for flow. **NOTE: Topical solutions will not flow until the handpiece tip is occluded. Also, when beginning a new bottle of topical solution, it may take several seconds for the topical to reach the handpiece.** Monitor the clear supply line to determine when solution has reached the handpiece.
f) If there is still no topical flow evident, please contact Customer Service representative in Chapter 6 of this User Manual.

5.6 AMBER INDICATOR ILLUMINATED

The amber indicator with the check mark symbol beneath it illuminates when the system requires preventative maintenance. Preventative maintenance is routine service, and is NOT covered by your warranty. please contact Customer Service representative in Chapter 6 of this User Manual, to schedule a service.

⚠ CAUTION

The use of any parts, materials, or service labor unauthorized by ZELTIQ may seriously damage your DIAMONDGLOW™ and will VOID the warranty.

Table 5-1 – Troubleshooting Overview

Symptom	Probable Cause	Action
The system does not start (numbers are not shown on the display and the lights are off)	The "On/off" switch on the front panel is in the "Off" position	Turn the "On/Off" switch to the "On" position.
	Power disconnected	Turn off the "On/Off" switch and check that the power cord is plugged into the electrical outlet and connected to the unit's power cord housing.
	Fuse blown	Replace the fuses in the power cord housing.
Red LED is on and the vacuum pump does not run	Waste jar full	Turn off the unit and empty the waste jar. Restart the unit. If the waste jar is not full, call ZELTIQ for technical support.
No vacuum or vacuum loss	Handpiece tip has lost a tight seal	Replace the handpiece tip O-ring and reattach the handpiece tip
	Vacuum tube is not firmly inserted into vacuum fitting	Disconnect and reconnect the clear vacuum tubing from the vacuum fitting on the front of the unit.
	Waste jar improperly threaded into waste manifold	Remove the waste jar and re-thread it carefully into the waste manifold.
	Waste jar has lost a good seal in the manifold	Slightly tighten waste jar.
No topical flow or flow loss	Vacuum pressure loss	Perform the troubleshooting steps above for "no vacuum."
	No solution in supply bottle	Remove the supply bottle and check for solution. Replace with a new supply bottle if empty.
	Topical uptake tubing clogged	Remove the topical uptake tubing from the supply manifold. Rinse under warm running water. Re-insert the tubing.
	Clog in tubing	Remove tubing from machine and handpiece, blow compressed air through tubing; or replace tubing with new handpiece tubing set.
Display reads a negative number of ".01"	Improper cleaning of the unit	Call ZELTIQ technical support. Unit must be sent to ZELTIQ's service department for repair.
Tubing not inserting into fitting	Tubing not inserted correctly	Quick disconnect fittings are two-stage fittings. Insert tubing into the fitting until you feel resistance; pause, then push the tube slightly farther into the fitting to lock the tube in place.
Amber indicator is on	Requires service	Please contact Customer Service representative in Chapter 6 of this User Manual.
Unit is leaking	External air filter has overflowed into vacuum pump	Cease use of unit immediately. Please contact Customer Service representative in Chapter 6 of this User Manual.

CHAPTER 6: CONTACT INFORMATION

For any problems, contact your service representative or ZELTIQ directly:

Representative: _____

Contact Number: _____

Customer Service

To report issues with the performance or use of your System, contact ZELTIQ Customer Service:

- Worldwide: (+1) 925-474-8160
- U.S.A.: 1-888-935-8471 (1-888-ZELTIQ1)

Routine issues

For questions regarding device performance or to report issues that do not interfere with current patient treatments:

- Call during regular business hours: Monday through Friday, 6 AM to 6 PM Pacific Time
- Calls are answered in the order received.

Urgent issues

To report safety concerns or issues that interfere with current patient treatments:

- Call at any time.
- If you call outside of regular business hours, leave a voicemail. A technician will be paged and will return your call promptly.

CHAPTER 7: TERMS OF WARRANTY

The DIAMONDGLOW™ warranty covers parts and labor for those items found to be defective due to material or workmanship for two (2) years from the date of purchase. Should a technical issue arise, that cannot be resolved through our technical call department, the customer may obtain a Return Merchandise Authorization number to return the unit to the technical support center. The customer will be advised within two (2) business days of receipt of unit at the service center about the nature of any required repairs or service and the estimated return shipping date. Any repairs resulting from natural disasters, accidents, electrical system faults, negligence, improper use of the device, improper cleaning of the device, improper maintenance of the device, installations, servicing, repairs, or alterations to the unit carried out by personnel other than persons authorized by ZELTIQ are NOT covered by this warranty.

Exclusions: Any item that comes in direct contact with solution or that should be replaced on a semi-regular basis is considered a disposable item and is not covered under this warranty. Such items include, but are not limited to: solutions, tubing sets, O-rings, filters, fittings and handpiece tips. The use of any parts or materials including solutions, filters, tubing, etc. that are not authorized by ZELTIQ will VOID this warranty. Removing or tampering with the internals of the unit will also VOID this warranty, unless specifically authorized by an ZELTIQ representative. Preventative maintenances are not included in the warranty; failure to perform preventative maintenances (based on usage and as indicated by the amber light) will VOID this warranty.

The DIAMONDGLOW™ warranty is void if:

- Anyone other than authorized personnel install and/or service the equipment.
- Solutions other than topical solutions purchased directly from ZELTIQ and its authorized distributors are used with the DIAMONDGLOW™ .
- Electrical facilities at the installation site do not comply with all application codes, including IEC and UL requirements.
- The device is not used in accordance with the instructions specified in this manual.

ZELTIQ shall not be held responsible for any failure in servicing derived from circumstances beyond its control. In no case will a customer be entitled to claim compensation for any damages incurred as a result of the device being out of service.

This warranty is non-transferable. All sales are final.

APPENDIX 1: EMC TEST SUMMARY TABLES

The following tables provide information regarding the EMC characteristics of this Medical Electrical Equipment.

Table 201 — Guidance and Manufacturer's Declaration - Electromagnetic Emissions

The DIAMONDGLOW™ Dermabrasion System is intended for use in the electromagnetic environment specified below.
The customer or user of the DIAMONDGLOW™ should ensure that it is used in such an environment.

EMISSIONS TEST	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT-GUIDANCE
RF emissions CISPR 11	Group 1	The DIAMONDGLOW™ only used internal RF energy for operation. Any emission should be very low and not likely to cause interference with other nearby electronic equipment.
RF emissions CISPR 11	Class A	The DIAMONDGLOW™ is suitable for use in all establishments other than domestic and those connected directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations /Flicker emissions IEC 6100-3-3	Complies	

Guidance and manufacturer's declaration - electromagnetic immunity			
The DIAMONDGLOW™ Dermabrasion System is intended for use in the electromagnetic environment specified below. The customer or the user of the DIAMONDGLOW™ Dermabrasion System 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	±6 kV contact ±8 kV air	±6 kV contact ±8 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	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines. IEC 61000-4-11	<5 % *U*T (>95 % dip in UT) for 0.5 cycle 40 % *U*T (60 % dip in UT) for 5 cycles 70 % *U*T (30 % dip in UT) for 25 cycles <5 % *U*T (>95 % dip in UT) for 5 sec	<5 % *U*T (>95 % dip in UT) for 0.5 cycle 40 % *U*T (60 % dip in UT) for 5 cycles 70 % *U*T (30 % dip in UT) for 25 cycles <5 % *U*T (>95 % dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the DIAMONDGLOW™ Dermabrasion System requires continued operation during power mains interruptions, it is required that the DIAMONDGLOW™ Dermabrasion System be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE *U*T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration - electromagnetic immunity			
The DIAMONDGLOW™ Dermabrasion System is intended for use in the electromagnetic environment specified below. The customer or the user of the DIAMONDGLOW™ Dermabrasion System should assure that it is used in such an environment.			
[1]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.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V[1]	Portable and mobile RF communication equipment should be used no closer to any part of the DIAMONDGLOW™ Dermabrasion System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m[1]	Recommended separation distance $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz 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 strength from fixed RF transmitters as determined by an electromagnetic site survey (a) 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. 
NOTE 1: At 80MHz and 800MHz, 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 DIAMONDGLOW™ Dermabrasion System is used exceeds the applicable RF compliance level above, the DIAMONDGLOW™ Dermabrasion System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessarily, such as reorienting or relocating the DIAMONDGLOW™ Dermabrasion System. (b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m[1].			

Recommended separation distances between portable and mobile RF communications equipment and the DIAMONDGLOW™ Dermabrasion System.			
The DIAMONDGLOW™ Dermabrasion System is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the DIAMONDGLOW™ Dermabrasion System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the DIAMONDGLOW™ Dermabrasion System as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter Watts (W)	**Separation distance according to frequency of transmitter in meters (m)**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1: At 80 MHz and 800 MHz, the separation distance for 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.			

Emissions Executive Test Summary - A0142_DG (US, Canada, and LATAM)				
Test Type	**Report Section**	**Test Level**	**Compliance Level**	**Comments**
Conducted Emissions EN 55011:2009+A1:2010, CISPR 11:2009+A1:2010	4.2	Class A Group 1 150 kHz to 30 MHz	Class A Group 1 150 kHz to 30 MHz	The DIAMONDGLOW™ Dermabrasion System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Radiated Emissions EN 55011:2009+A1:2010, CISPR 11:2009+A1:2010	4.1	Class A Group 1 30 MHz to 1 GHz	Class A Group 1 30 MHz to 1 GHz	
Harmonics IEC/EN 61000-3-2:2014	4.3	Class A Device	Per Clause 5 of the Standard	None
Flicker IEC/EN 61000-3-3:2013	4.4	Per Clause 5 of the Standard	Per Clause 5 of the Standard	None

Immunity Executive Test Summary - A0142_DG (US, Canada, and LATAM)				
Test Type	**Report Section**	**Test Level**	**Compliance Level**	**Comments**
Electrostatic Discharge IEC/EN 61000-4-2	5.1	±8 kV contact discharge ± 2, 4, 8 &15kV air discharge	±8 kV contact discharge ± 2, 4, 8 &15kV air discharge	Risk assessment on the DIAMONDGLOW™ Dermabrasion System indicates the compliance levels claimed are acceptable when ESD-precautionary measures are taken.
Radiated Immunity IEC/EN 61000-4-3	5.2	80 MHz - 2.7 GHz 3 V/m 80% @ 1 kHz Spot frequencies 385MHz – 5.750 GHz Pulse Modulation	80 MHz - 2.7 GHz 3 V/m 80% @ 1 kHz Spot frequencies 385MHz – 5.750 GHz Pulse Modulation	Portable and mobile RF communications equipment should be used no closer to any part of the DIAMONDGLOW™ Dermabrasion System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance shall be calculated using the following equation: $E = (6/d)\sqrt{P}$ Where P is the maximum power in W, d is the minimum separation distance in m, and E is the IMMUNITY TEST LEVEL in V/m.
Proximity field from RF wireless communications equipment IEC 61000-4-3	5.2	See Section 6.17.3.1 Or Table 9 of standard	See Section 6.17.3.1 Or Table 9 of standard	

Immunity Executive Test Summary (continued) - A0142_DG (US, Canada, and LATAM)				
Test Type	**Report Section**	**Test Level**	**Compliance Level**	**Comments**
Conducted Immunity (AC Power) (I/O Lines) IEC/EN 61000-4-6	5.5	0.15 - 80 MHz 3 Vrms & 6Vrms in ISM & amateur bands 1 kHz AC Mains	0.15 - 80 MHz 3 Vrms & 6Vrms in ISM & amateur bands 1 kHz AC Mains	The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.
Electrical Fast Transients (AC Power) IEC/EN 61000-4-4	5.3	±2 kV AC Mains ±1 kV I/O Lines 5/50 5kHz &100 kHz	±2 kV AC Mains ±1 kV I/O Lines 5/50 5kHz &100 kHz	Mains power quality should be that of a typical commercial or hospital environment.
Surge Line to Line (AC Power) IEC/EN 61000-4-5	5.4	±1 kV Line to Line ±2 kV Line to Ground	±1 kV Line to Line ±2 kV Line to Ground	Mains power quality should be that of a typical commercial or hospital environment.
Magnetic Immunity IEC/EN-61000-4-8	5.6	30 A/m	30 A/m	This test level assumes a minimum distance between the ME EQUIPMENT or ME SYSTEM and sources of power frequency magnetic field of at least 15 cm.
Voltage Dips & Interruptions IEC/EN 61000-4-11	5.7	0% U_T .5 cycle 0% U_T 1 cycle 70% U_T 25 cycles 0% U_T5 Sec	0% U_T .5 cycle 0% U_T 1 cycle 70% U_T 25 cycles 0% U_T5 Sec	If the user of DIAMONDGLOW™ Dermabrasion System requires continued operation during power mains interruptions, it is recommended that the DIAMONDGLOW™ be powered from an uninterruptible power supply or a battery.

General Requirements Summary- A0142_DG (US, Canada, and LATAM)				
Standards	**Description**	**Severity Level or Limit**	**Criteria**	**Results**
IEC 60601-1-2:2014 Clause 4.1	Risk Management Process for ME equipment and ME System	Per Section One, Clause 4	Verification of Electromagnetic Disturbance Risk Management	Pass
IEC 60601-1-2:2014 Clause 5	ME Equipment and ME System Identification, marking and documents	See requirements called out in standard.	Review	Pass

Summary of Test Results - A0143_DG (Europe and Asia)				
Standards	**Description**	**Severity Level or Limit**	**Criteria**	**Test Result**
EN 55014-1: 2017	Electromagnetic compatibility - Requirements for household appliances, electric tools and similar apparatus	See called out basic standards below	See Below	Compliant
EN 55014-2: 2015	Electromagnetic compatibility - Requirements for household appliances, electric tools and similar apparatus	See called out basic standards below	See Below	Compliant
EN 55014-1: 2017	Radiated Emissions	Class B 30 - 1000 MHz	Limit	Compliant
EN 55014-1: 2017	Conducted Emissions	Class B 150kHz - 300MHz	Limit	Compliant
EN 61000-3-2:2014	Power Harmonics	Class A Equipment Per Clause 5 of the Standard	Limit	Compliant
EN 61000-3-3:2013	Voltage Fluctuation	Per Clause 5 of the Standard	Limit	Compliant
EN 61000-4-2:2009 Basic test standard	Electrostatic Discharge	±8 kV Air Discharge ±4 kV Contact Discharge, VCP, HCP	B	Compliant
EN 61000-4-3:2006/A1:2008/A2:2010 Basic test standard	Radiated Electromagnetic Field Immunity	3 V/m, 80 - 1000 MHz 80%, 1 kHz, AM	A	Compliant
EN 61000-4-4:2004+A1:2010 Basic test standard	Electrical Fast Transient /Burst Immunity	±1 kV on AC Mains ±0.5 kV on I/O Ports, No IO cable	B	Compliant
EN 61000-4-5:2006 Basic test standard	Surge Immunity NOTE *U*T is the a.c. mains voltage prior to application of the test level.	±2 kV CM Line-Gnd ±1 kV, DM Line-Linse N/A on I/O Ports	B	Compliant
EN 61000-4-6:2009 Basic test standard	Conducted Immunity	3 Vrms, 0.15 - 230MHz, AC Mains 3 Vrms, 0.15 - 230MHz, I/O Ports, No IO cable	A	Compliant
EN 61000-4-8:2010 Basic test standard	Power Frequency Magnetic Field Immunity test.	3 A/m @ 50 Hz and 60 Hz 3 Orthogonal Orientations	A	Compliant Not required
EN 61000-4-11:2004 Basic test standard	Voltage Dips	0%, During 0.5 Cycle 40%, During 12 Cycles 70%, During 25 and 30 Cycles	B C C	Compliant
Voltage Interruptions	N/A			

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