



SILKPEEL

OPERATOR'S MANUAL
SILKPEEL[®] MD PLATINUM
featuring
INTELLIFLOW 2.0

ENVY
specialized skincare

Envy Medical
31340 Via Colinas, Suite 101
Westlake Village, CA 91362
(818) 874-2700

SilkPeel® MD Platinum Dermalinfusion™ System
Model # A0132

INPUT POWER: 4A 220-240V 50/60 Hz

STANDARD DUTY CYCLE: 40 minutes on; 20 minutes off

DANGER: Risk of explosion if used in the presence of flammable anesthetics.

CAUTION: To reduce the risk of electrical shock, do not remove cover. Refer servicing to qualified service personnel. Do not touch fan or fan components at any time.

RISK OF FIRE: Replace fuse as marked:  **F4AL 250V**



ATTENTION: Consult accompanying documents. It is the responsibility of the operator to have read and understood the operating instructions for this device.



Type BF Applied Part



This product contains recyclable materials. Do not dispose this product as unsorted municipal waste. Please contact your local municipality for the nearest collection point. Contact manufacturer for instructions.

Transportation and Storage:

Environmental conditions:

Temperature -20°C to +70°C

Relative humidity 10% to 100% non-condensing

Atmospheric Pressure 500hPa to 1060hPa

Dimensions: 45.7cm x 25.4cm x 35.5cm

Weight: 12.4kg

Manufactured by:

Envy Medical

31340 Via Colinas, Suite 101

Westlake Village, CA 91362 USA



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Disclaimer: This manual is not intended as a comprehensive guide for all aspects of treatment. Envy Medical highly recommends the operator confer with the Department of Labor, Licensing, and Regulation or other such regulatory body in his/her respective state or country regarding legal use of this system. Envy Medical 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 and innovation, we reserve 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 Envy Medical or your distributor.

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PREFACE

Envy Medical would like to thank you for your choice of the SilkPeel® MD Platinum, the newest breakthrough innovation that combines precision non-invasive exfoliation with Dermalinfusion™ to address patient-specific skin conditions. This device has been specifically designed for aesthetic applications and represents the best choice for the medical professional.

Envy Medical 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.

Please write your serial number in the space provided below. You will find a similar tag on the back of your SilkPeel® MD Platinum toward the lower right-hand corner.

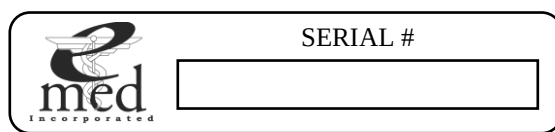


Figure 1: Serial Number Plate

NOTE

The SilkPeel® MD Platinum warranty is void if:

- Anyone other than authorized personnel install and/or service the equipment.
- Solutions other than Envy Medical topical solutions are used with the SilkPeel® MD Platinum.
- 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 8 for full Terms of Warranty.)

PATENTS

The SilkPeel® MD Platinum Dermalinfusion™ System is protected by United States Patent #6,695,853. Other national and international patents pending.

SilkPeel® is a registered trademark of Envy Medical, Incorporated.
Dermalinfusion™ is a trademark of Envy Medical, Incorporated.

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. Additional training sessions may be arranged for a fee by contacting your local distributor. Envy 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 SilkPeel® MD Platinum or the operator's manual, contact your local distributor or Envy Medical immediately for assistance.

CHAPTER 1: GENERAL OVERVIEW

1.1 TREATMENT OBJECTIVES

The SilkPeel® MD Platinum has been designed to perform a progressive and controlled exfoliation of the skin simultaneously with Dermalinfusion™, the delivery of unique topical solutions. The treatment objective is to improve outcomes of dermatological conditions.

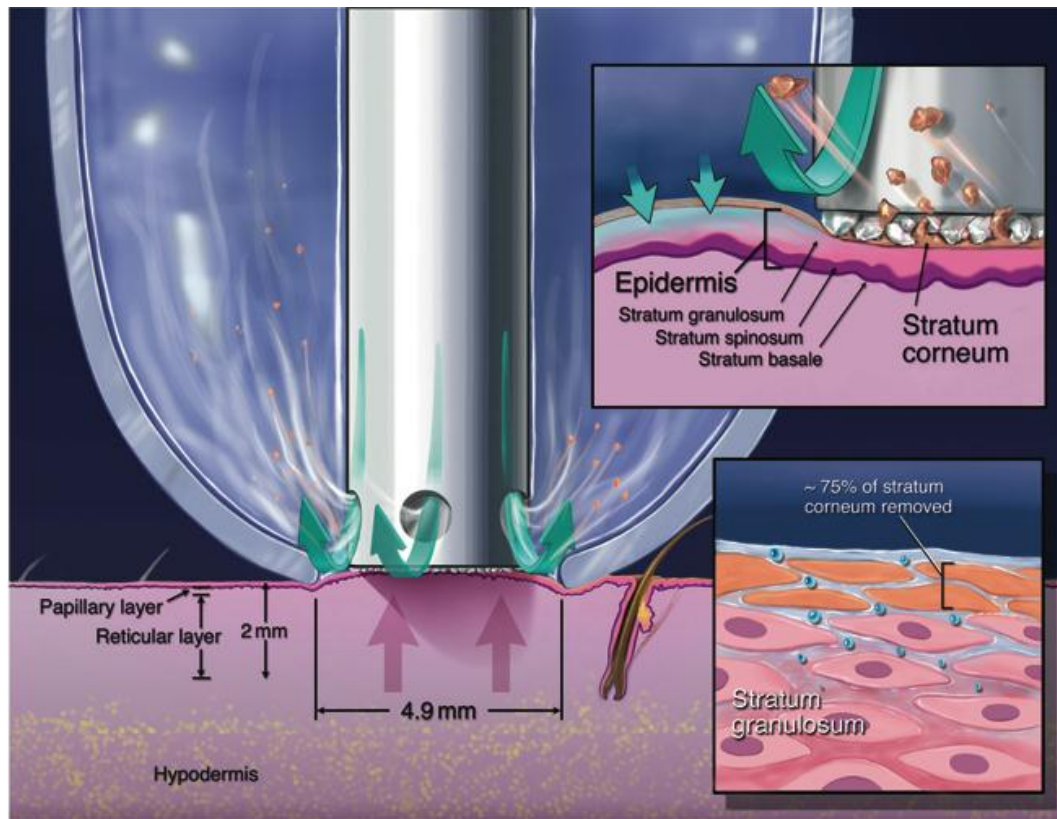


Figure 2: Exfoliation Magnified

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

The main indications of use are:

- General microdermabrasion
- Topical-enhanced exfoliation

1.2 SYSTEM FEATURES

The following section identifies the features of the SilkPeel® MD Platinum system:



Figure 3: Front Console

1.2.1 Front Console

The front console contains the following:

A	On/Off Switch	Turns the system on and off
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	Vacuum Display	Indicates the vacuum from 2 – 11+ PSI
E	Vacuum Knob	Adjusts the vacuum for treatment. Vacuum increases when you turn the knob clockwise
F	<i>INTELLIFLOW</i> Display	Indicates the flow of topicals through the system between 00.0-100.0%
G	<i>INTELLIFLOW</i> Control Knob	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

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H	Supply Fitting	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
J	Vacuum Fitting	Large quick disconnect fitting where the blue vacuum tubing from the handpiece connects to the unit
K	Vacuum Tubing	Blue tubing connecting the handpiece and the unit

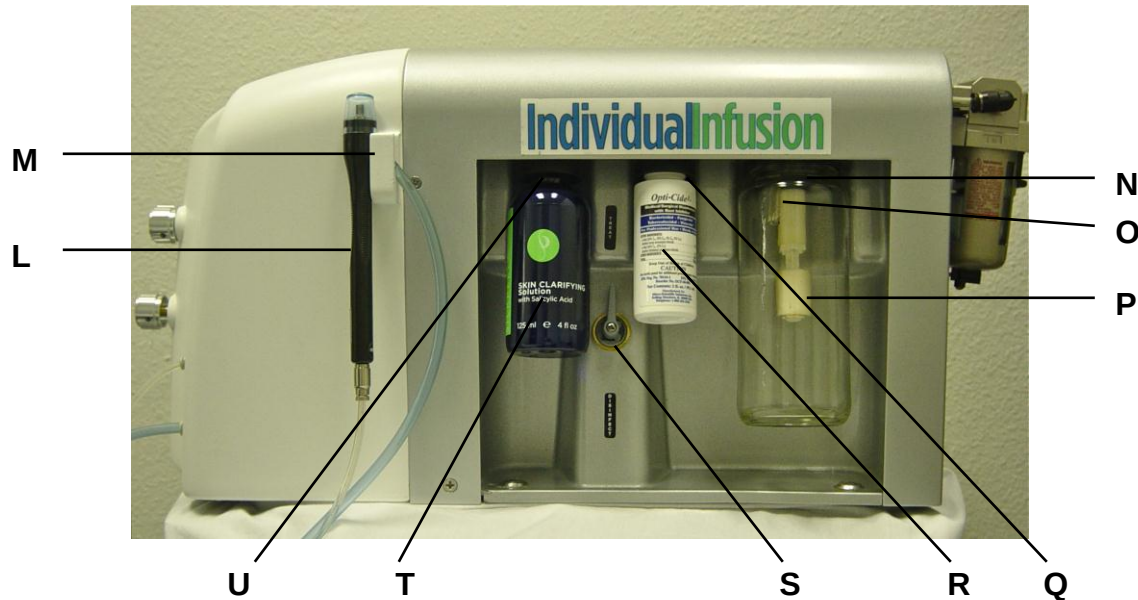


Figure 4: Side Panel

1.2.2 Side Panel

L	Handpiece	Instrument used to perform a treatment
M	Handpiece Hook	Location for storing the handpiece between treatments
N	Waste Manifold	Threaded cap for attaching a glass waste jar
O	Residual Waste Tubing	Expels residual solution and waste into waste jar
P	Float Switch	Activates the red Overflow Indicator if the waste jar is not emptied
Q	Disinfectant Supply Manifold	Threaded cap for attaching a bottle of disinfectant
R	Disinfectant Uptake Tubing	Intakes disinfectant from the disinfectant bottle into supply tubing (Not Shown)

S	Treat / Disinfect Mode Switch	Toggles between Treat and Disinfect modes
T	Topical Uptake Tubing	Intakes topicals from the supply jar into supply tubing (Not Shown)
U	Topical Supply Manifold	Threaded cap for attaching a jar of solution



Figure 5: Back Panel

1.2.3 Back Panel

V	External Air Filter	Houses the Filter Element
W	Hour Meter	Displays number of hours SilkPeel® MD Platinum has run
X	Power Cord Housing/Fuse Box	Housing into which the power cord plugs. The lower compartment holds the fuses



Figure 6: Accessories

1.2.4 Accessories

Y	Plastic Sterilization Tray	Custom tray for autoclaving a handpiece and seven treatment heads. Extra inserts may be purchased for autoclaving 14 treatment heads
Z	O-Ring Tool	Tool with hooked end to assist installation of a new o-ring
Aa	Derm-Aid™ Eye Shields	A 10-pack sample of eye shields recommended for use during treatment

1.3 SYSTEM DESCRIPTION

The SilkPeel® MD Platinum 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 dermaceutical, and vacuums away the residuals into a sealed waste jar.

The main components of the SilkPeel® MD Platinum's 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 handpiece tip, the treatment head, the o-ring, the vacuum branch, the wand, and the quick disconnect fitting.

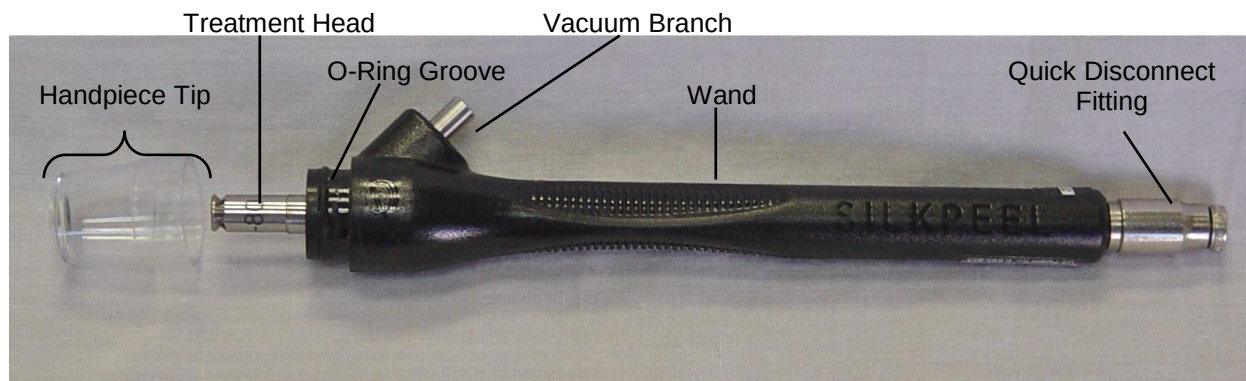


Figure 7: Handpiece

c) **Treatment Heads.** The SilkPeel® MD Platinum system includes a set of nine sterilizable, diamond-encrusted treatment heads in the following grit sizes and diameters:

- Medium-Coarse (60 grit), 6mm diameter
- Medium-Coarse (60 grit), 9mm diameter
- Medium (80 grit), 6mm diameter
- Medium (80 grit), 9mm diameter
- Medium-Fine (100 grit), 6mm diameter
- Fine (120 grit), 6mm diameter
- Very Fine (140 grit), 6mm diameter
- Smooth, 6mm diameter
- Smooth, 9mm diameter

Additional treatment heads are available in the following sizes:

- Coarse (30 grit), 6mm diameter
- Coarse (30 grit), 9mm diameter
- Medium-Fine (100 grit), 9mm diameter
- Fine (120 grit), 9mm diameter
- Very Fine (140 grit), 9mm diameter

Select the grit size based upon the nature of the procedure to be performed. 9mm tips are recommended for treating larger areas of the face and body, such as the forehead, décolleté and back. The 6mm tip is best for treating areas requiring greater precision, such as areas around the nose and mouth. **CAUTION: ONLY TREAT THE EYE AREA WITH A SMOOTH TREATMENT HEAD, STRICTLY FOLLOWING ENVY MEDICAL'S RECOMMENDED PROTOCOL AND SAFETY GUIDELINES.** Do not ever treat the eyelids. Envy Medical recommends using disposable Derm-Aid eye shields during any procedure for maximum patient comfort and safety. Treatment heads **MUST BE** disinfected before use and between patients.

d) **Handpiece Tips.** The SilkPeel® MD Platinum includes packs of disposable, single-use plastic handpiece tips in two sizes: small and large. The small handpiece tips are for use with the 6mm treatment heads and the large handpiece tips are for use with the 9mm treatment heads. One pack of transparent blue cleaning tips are also provided to facilitate easy cleaning of the system.

- e) **Vacuum and Topical INTELLIFLOW Adjustments.** Two gauges are located on the front console with adjustment knobs next to each. The upper 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 lower gauge on the front console. 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 forward-most (topical supply) manifold on the side of the SilkPeel® MD Platinum. Select the topical based on the patient's specific dermatological condition.
- g) **Disinfectant Supply Bottle.** The SilkPeel® MD Platinum uses a 2oz bottle of OptiCide3 disinfectant with our validated cleaning protocol. The bottle of OptiCide threads into the center (disinfectant supply) manifold (located between the topical supply manifold and the waste manifold) on the side of the SilkPeel® MD Platinum.
- h) **Waste Jar.** Residual solution and exfoliated tissue are deposited in a clear glass waste jar, which threads into the rear (waste) manifold on the side of the unit. When the waste jar is full, remove it from the SilkPeel® MD Platinum and dispose of the residual solution in accordance with OSHA standards. Disinfect or autoclave the waste jar before replacing it in the SilkPeel® MD Platinum.
- 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 of use to ensure proper filtration and equipment protection (see Section 4.1).

CHAPTER 2: INSTALLATION

2.1 INSTALLATION REQUIREMENTS

Before installing the SilkPeel® MD Platinum, 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 110/130-V AC or 220/240-V AC, 50/60 Hz single phase.
- The SilkPeel® MD Platinum voltage conforms to the electrical voltage of your outlet.
- The device is located on a suitable flat surface (i.e. table or Envy Medical-approved stand) with the front console towards the operator.
- The device has 8-10cm of free space all around it to ensure proper cooling.

2.2 UNPACKING AND INSPECTION

The SilkPeel® MD Platinum should be unpacked and installed by a trained Envy Medical representative or distributor.

Instructions for unpacking the SilkPeel® MD Platinum are as follows:

1. Examine the shipping box for external damage or evidence of mishandling. You must immediately notify your local distributor 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.**

NOTE

SILKPEEL® MD PLATINUM HANDLING

The SilkPeel® MD Platinum weighs approximately 12.7 kg. Use proper lifting techniques when unpacking and repacking the unit.

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 Envy Medical or the distributor IN WRITING of any discrepancies. Contents may vary according to the model and accessories ordered.

CAUTION

RETAIN FACTORY PACKAGING MATERIALS

Do not ship a SilkPeel® without the factory packaging materials. Doing so may result in damage to the components during shipping and void the warranty. Contact your distributor for packaging materials and repackaging instructions.

2.3 INSTALLATION

The SilkPeel® MD Platinum is designed for easy installation, which is carried out as follows:

1. Place the SilkPeel® MD Platinum 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. Connect the handpiece tubing as follows:
 - a. Slide the blue vacuum tube over the vacuum branch located on the upper side of the handpiece (see Figure 8).
 - b. The clear tubing is approximately 5" shorter than the blue tubing on one end. Insert the clear supply tube at this end into the quick disconnect fitting on the base of the handpiece. Insert the tube into the fitting until you feel resistance; pause, then push the tube slightly farther into the fitting to lock the tube in place (see Figure 9).



Figure 8: Connect Vacuum Tubing to Handpiece

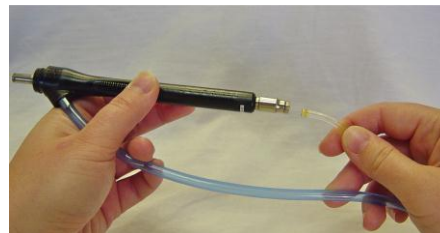
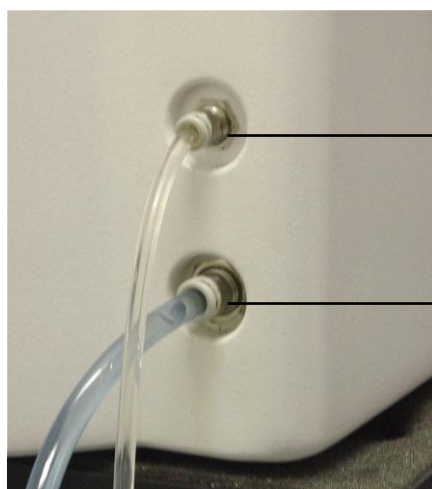


Figure 9: Connect Supply Tubing to Handpiece

- c. At the opposite end of the tubing set, insert the clear supply tubing into the top gray fitting on the front of the machine. Insert the blue vacuum tube into the bottom gray fitting (see Figure 10).



Insert Clear Flow Tubing Into the Upper Fitting in the Bezel

Insert Blue Vacuum Tubing Into the Lower Fitting in the Bezel

Figure 10: Front Console Tubing Connections

2.4 MOVING THE SYSTEM

Most users of the SilkPeel® MD Platinum have more than one operator or utilize multiple treatment rooms. The SilkPeel® MD Platinum can easily be moved between them using the custom Silkpeel® MD Platinum 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 SilkPeel® MD Platinum over longer distances, you may elect to purchase the SilkPeel® MD Platinum's custom rolling case. This travel case features custom-fit foam insulation for your SilkPeel® MD Platinum 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 (see the Appendix for a sample Patient Consultation Form).
- Determine the solution, grit, and tip size that would be appropriate for the patient.
- Confirm that the treatment head and tubing have been sterilized and the disposable handpiece tip is new.
- Screw the treatment head 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.

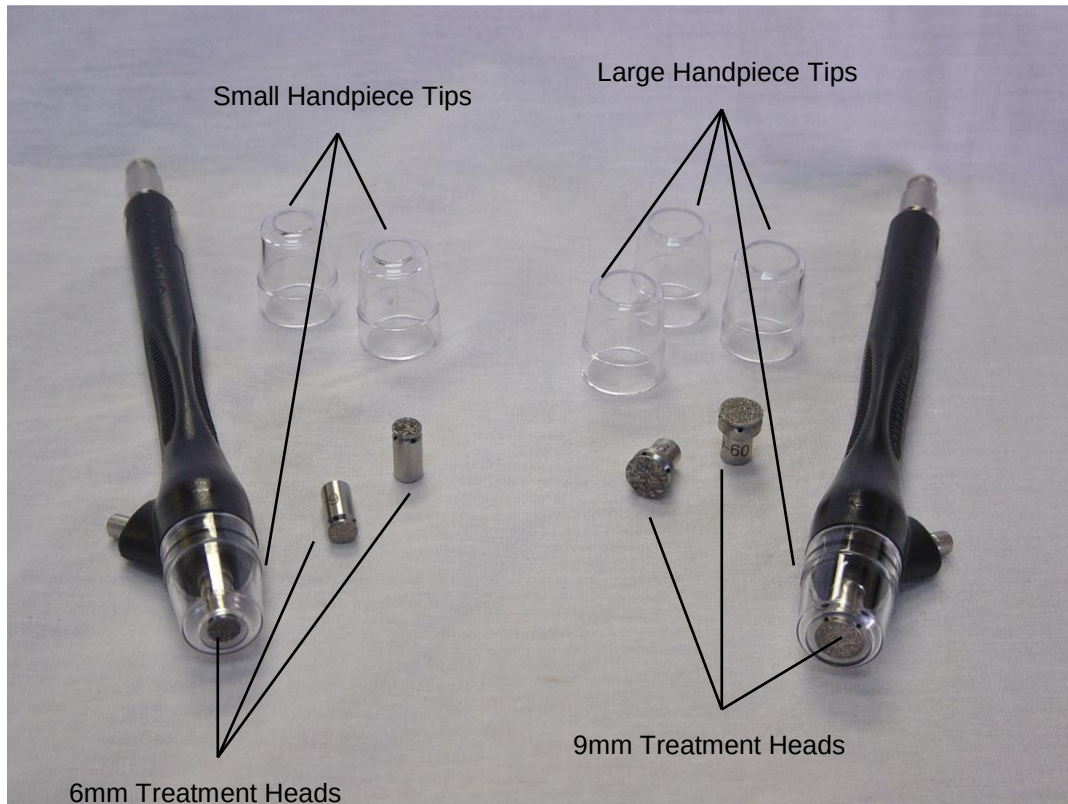


Figure 11: Treatment Head & Handpiece Tip Assembly

- Thread a clean waste jar into the waste manifold.
- Gently shake a bottle of the topical solution selected for the patient and thread it into the topical supply manifold.

- Gently shake a bottle of OptiCide3 disinfectant and thread it into the disinfectant supply manifold.

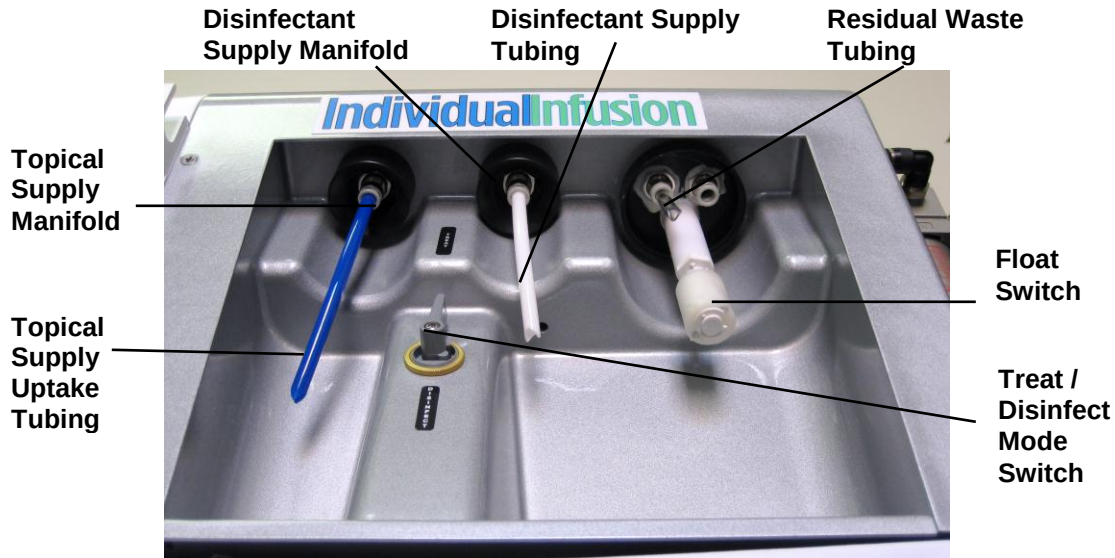


Figure 12: Supply and Waste Manifolds

3.2 PROCEDURE

With the handpiece tip unrestricted, turn on the black “On/Off” switch located on the lower left front corner of the machine. When the main power is on, the digital displays will light up. You will also hear the vacuum compressor and cooling fan engage. Follow the instructions in Section 4.1 for Daily Maintenance to prepare the unit for use.

Recommended treatment protocol is as follows:

- **Cleanse the patient’s skin** to remove any makeup and/or environmental pollutants.
- You may wish at this time to cover the patient’s eyes with disposable Derm-Aid eye shields for maximum comfort and safety.
- **Occlude** the handpiece tip.
- **Flush out any remaining disinfectant in the tubing by waiting for the new topical to reach the handpiece before treating the patient.**
- **Set vacuum** to around 3 PSI.
- **Set INTELLIFLOW** to the appropriate setting for the vacuum setting.
- Note that the vacuum pressure draws the skin into the handpiece tip and in contact with the treatment head. You can glide the handpiece over the skin without applying downward pressure. Try to keep the handpiece perpendicular to the skin following all angles and curves.
- **Start on the neck**, at the highest point under the middle of the chin, and make passes in **slow deliberate downward strokes**. Follow this direction laterally; until the full front of the neck is complete. The last pass should begin directly under the lobe of the ear and end at the top of the décolleté.
- **Adjust vacuum and flow** during treatment according to skin thickness, the patient’s comfort, and the desired treatment outcomes. Increasing vacuum pressure will produce a deeper exfoliation. Topical flow should be adjusted to allow the dermaceutical to thoroughly irrigate the treated area.

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- Set the vacuum to between 5 – 7 PSI, or as appropriate for the treatment to be performed. Set the *INTELLIFLOW* setting which corresponds to the vacuum pressure setting.
- **Start at the middle point of the chin**, underneath the jaw line, with passes going **medial to lateral** toward the hairline. Continue in this direction up the face. **Each stroke** should take about **5 seconds**. Watch to make sure that the disposable **handpiece tip** is nearly **full of fluid** during each pass.
- Do not make a pass through or above the orbital bone, unless you are following Envy Medical's specific treatment protocol for the sensitive eye area (contact Envy Medical for specific instructions).
- Make each lateral pass until you reach the top crown of the hairline. The **last pass** should move from the crown downward **following the hairline**, then hook under the ear, and down the neck. This motion assists in the **lymphatic drainage** process.
- **Adjust the vacuum** as needed (with the handpiece tip occluded), then **focus on the nose**, and then on any **problem areas** that may require some extra cross-hatching.
- Mirror the motions above for the second half of the face, **beginning each pass near the center of the face, then gliding outward toward the hairline**, making **2 full passes** over each section of the face.
- **Apply post-care products** according to the physician's instructions, followed by **SPF30** or higher sunscreen.
- Advise the patient of a proper at-home, post-care regimen.
- Recommend that the patient avoid strenuous exercise for the next 24 hours.

Refer to the diagram below for further clarification. Keep a record of the procedure on a Patient Treatment Log form (see the Appendix for a sample).

Vacuum Pressure	<i>INTELLIFLOW</i> Setting
5.0 and below	100%
Between 5.0 & 6.0	50%
Between 6.0 & 7.0	45%
Between 7.0 & 8.0	40%
8.0 and above	30%

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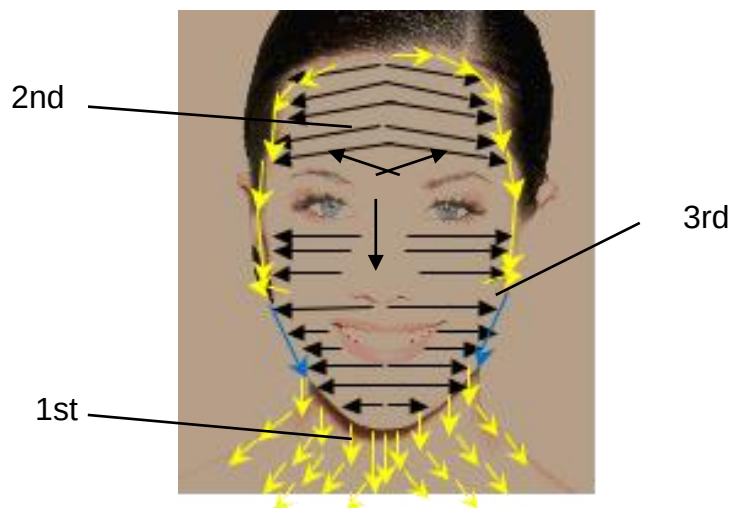


Figure 13: Recommended Passes
Repeat 2 and 3

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 SilkPeel® MD Platinum is imperative to your patients' health and to prolonging the life of your unit. Cleaning must be performed immediately after every SilkPeel® treatment and at the end of the day.

To clean the unit **immediately after every** SilkPeel® treatment:

1. Remove and dispose of the plastic handpiece tip; remove treatment head and clean in accordance with the instructions listed below (at End of Day).
2. Place a blue cleaning handpiece tip onto the handpiece.
3. **Remove empty bottle of topical solution.**
4. **Turn the Treat/Disinfect Mode Switch counterclockwise to point towards "DISINFECT". DO NOT USE WATER OR ANY OTHER FLUID FOR DISINFECTING. Use of any unauthorized products in your SilkPeel® MD Platinum will VOID your warranty.**
5. Adjust the vacuum and flow to maximum.
6. Run the Opti-Cide³ solution through the system until it passes through the handpiece and begins draining into the waste jar.
7. Once fluid begins draining into the jar, turn your unit off and loosen the waste jar to release vacuum pressure. Leave disinfectant in the lines until the next time the machine is used.

Before Each Use:

1. Tighten waste jar and turn machine back on. Allow your SilkPeel® MD Platinum to run until all disinfectant has cycled through the machine.
2. Allow the machine to run for another 30 seconds to completely air out the lines.
3. Turn the machine off.
4. Empty and reattach the waste jar. You are now ready to perform a SilkPeel® MD Platinum procedure.
5. **Turn the Treat/Disinfect Mode Switch clockwise to point towards "TREAT".**

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 PROPER MAINTENANCE OF YOUR UNIT.**
2. Use water, a mild cleansing solution, or OptiWipes 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 8, 9 and 10).

4.2 STERILIZING THE TREATMENT HEADS AND HANDPIECE

Sterilizing the Treatment Head

The treatment head should be sterilized after each treatment:

- a. Remove the plastic handpiece tip and discard it with your biohazardous waste.
- b. Remove the treatment head and clean by soaking in enzymatic detergent 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 head can then be placed in a disinfecting solution. Read the label on the solution for the proper soak time.
- d. If the treatment head is to be sterilized in the unwrapped Plastic Sterilization Tray, the "flash" cycle may be used. This is typically five minutes at a minimum temperature of 132°C (270°F) 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 head.

Sterilizing the Handpiece (optional)

Autoclave the handpiece by:

- a. Detaching the blue vacuum tubing from the vacuum branch.
- b. Disconnecting the clear supply tubing from the quick disconnect fitting at the base of the handpiece. Press in on the top of the silver fitting and, with the other hand, remove the tubing by pulling straight out (see Figure 14 below).
- c. Unscrew the quick disconnect fitting (silver) from the handpiece, set aside.
- d. If the handpiece is to be sterilized in the unwrapped Plastic Sterilization Tray, the "flash" cycle may be used. This is typically five minutes at a minimum temperature of 132°C (270°F) 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 handpiece.



Figure 14: 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 head post and into the groove. Work into place with fingers, as necessary.

4.4 DISCONNECTING AND REPLACING TUBING

Disconnect tubing from a quick disconnect fitting by pressing in on the top of the fitting (which is either gray or silver) and, with the other hand, remove the tubing by pulling straight out (see Figure 14 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 SilkPeel® MD Platinum 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 black locking tab on the filter housing downward (see Figure 15a below).
2. With the locking tab still in a downward position, rotate the filter housing counterclockwise until the pair of vertical lines on the filter housing align with the pair of vertical lines on the filter mount.
3. Once the vertical lines are aligned, pull downward on the filter housing to remove it from the filter mount (see Figures 15b and 15c).

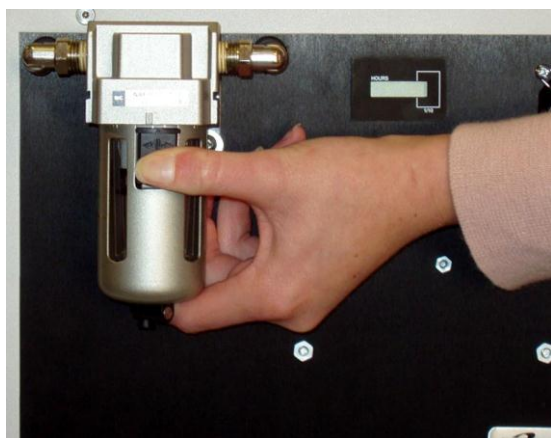




Figure 15a: Release External Air Filter



Figure 15b: Align Vertical Lines

Figure 15c: Pull Down on Filter Housing

Figure 15d: Unscrew Filter

4. Clean the filter housing by soaking in warm water, then allowing to air dry.
5. Rotate the locking disk located underneath the filter counterclockwise until it completely unscrews and releases the filter and alignment ring from the filter housing (see Figures 15c and 15d).
6. Place the new filter on top of the locking disk and the alignment ring on top of the filter. Replace the filter by lining up the threading in the locking disk with the threaded post descending from the filter mount and screwing it clockwise until the filter is secured tightly.
7. Replace the filter housing by reversing steps 1-3.

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
Sterilize treatment heads and handpiece	User	Before use & after treatments	Autoclave or sterilize in ultrasonic cleaner according to section 4.2
Disinfect tubing	User	Before use & after treatments	Disinfect by running 2oz. OptiCide3 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	SilkPeel Service Technician	Upon illumination of amber indicator light	Unit requires service. Contact Technical Support (see Ch. 6)

CHAPTER 5: TROUBLESHOOTING

Potential problems can be minimized by following the routine schedule described in Table 4-1. Many of the calls received by Envy Medical regarding the SilkPeel® MD Platinum 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.
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 international-type fuse marked as F4AL 250V only.



Figure 16a: Slide Out Black Fuse Box



Figure 16b: Remove Fuse Box

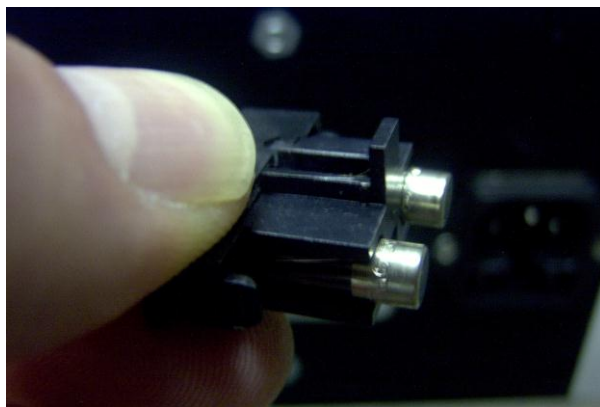


Figure 16c: Replace Both Fuses

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 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).

5.4 NO VACUUM

If the pump is on but no vacuum is evident, occlude the handpiece tip and turn the vacuum and topical flow knobs to maximum (though the display readouts 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 handpiece tip and the handpiece tip o-ring. If the o-ring has broken or lost its seal, replace it with a new one.
2. Inspect the vacuum branch and its connection to the blue vacuum tubing. If the blue vacuum tubing does not fit tightly onto the vacuum branch, remove it and cut away approximately 1/2” of the blue tube. Reattach the vacuum tubing to the vacuum branch.
3. Confirm that the vacuum tubing is firmly inserted into the fitting on the front of the SilkPeel® MD Platinum unit.
4. 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.
5. 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.
6. If there is still no vacuum pressure evident, contact technical support (see Chapter 6 for contact information).

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) Check the fitting at the base of the handpiece to make sure the clear supply tube is securely inserted.
- f) 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.

- g) If there is still no topical flow evident, contact your local authorized service center or distributor for technical support.

5.6 AMBER INDICATOR ILLUMINATED

The amber indicator illuminates when the system requires Preventative Maintenance. Call Technical Support (see Ch. 6) to schedule service.

WARNING

The use of any parts, materials or service labor unauthorized by Envy Medical may seriously damage your SilkPeel® MD Platinum 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 displays 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, see Ch. 6 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 has lost tight seal with vacuum branch	Remove the blue vacuum tubing from the vacuum branch tube. Cut away approximately 1.25cm inch of the blue tube. Reattach the vacuum tubing to the vacuum branch tube.
	Vacuum tube is not firmly inserted into vacuum fitting	Disconnect and reconnect the blue 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 handpiece and unit; use compressed air to blow clog out of internal tubing.
Display reads a negative number of “1 . .”	Improper cleaning of the unit	Call Technical Support (see Ch. 6). Unit must be sent to an authorized service center 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	Call Technical Support (see Ch. 6).
Unit is leaking	External air filter has overflowed into vacuum pump	Cease use of unit immediately. Call Technical Support (see Ch. 6).

See Chapter 6 for Technical Support contact information.

International customers (outside of U.S.):

Selection of topical solutions differs by country. Please contact your local distributor for more details about availability and purchase of topicals.

CHAPTER 6: CONTACT INFORMATION

For any problems, contact your local distributor:

Distributor Contact Information:

Technical Support:

Parts Ordering Department:

US Corporate Offices

1-818-874-2700

1-818-874-1195 fax

info@envymedical.com

www.silkpeel.com

CHAPTER 7: DISCLAIMER

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

The SilkPeel® MD Platinum warranty is void if:

- Anyone other than authorized personnel install and/or service the equipment.
- Solutions other than topical solutions purchased directly from Envy Medical and Envy Medical authorized distributors are used with the SilkPeel® MD Platinum.
- 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.

Because of our ongoing commitment to product quality and innovation, we reserve 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 your local distributor or Envy Medical.

CHAPTER 8: TERMS OF WARRANTY

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 performed by personnel not authorized by Envy Medical 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 Envy Medical will VOID this warranty. Removing or tampering with the internals of the unit will also VOID this warranty, unless specifically authorized by an Envy Medical 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.

Envy Medical 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

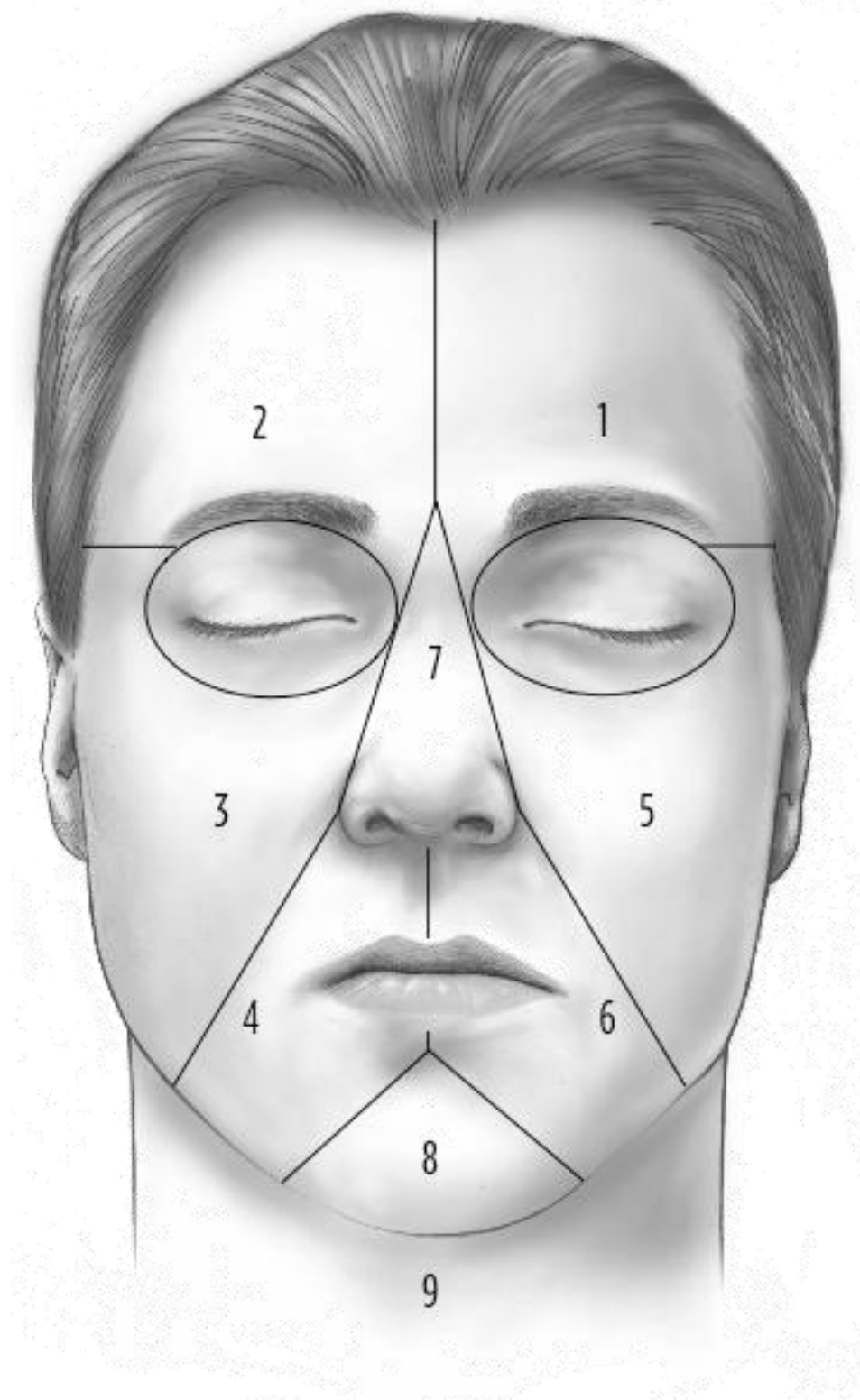
- Patient Treatment Log
- EMC Information Tables
 - Table 201: Guidance and Manufacturer's Declaration - Electromagnetic Emissions
 - Table 202: Guidance and Manufacturer's Declaration – Immunity
 - Table 204: Guidance and Manufacturer's Declaration - Emissions Equipment and Systems that are NOT Life-Supporting
 - Table 206: Recommended Separations Distances for the HT110-Series Meter Guidance and Manufacturer's Declaration – Emissions

SilkPeel® MD Platinum Dermalinfusion™ System Patient Treatment Log

Patient Name: _____

Date: _____

Treatment # _____ of _____



EMC Information Tables (per EN60601-1-2:2001-09 Section 6)

In accordance with EN 60601-1-2:2001 Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests

- 1) "Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the Accompanying Documents" (the following tables).
- 2) "Portable and Mobile RF Communications Equipment can affect Medical Electrical Equipment."
- 3) "The equipment or system should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the equipment or system should be observed to verify normal operation in the configuration in which it is used."

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

Table 201 — Guidance and Manufacturer's Declaration - Electromagnetic Emissions		
The SilkPeel® Dermalinfusion System is intended for use in the electromagnetic environment specified below. The customer or user of the SilkPeel® MD Platinum should ensure that it is used in such an environment.		
EMISSIONS TEST	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT-GUIDANCE
RF emissions CISPR 11	Group 1	The SilkPeel® only used internal RF energy for operation. Any emission should be very low and is not likely to cause interference with other nearby electronic equipment.
RF emissions CISPR 11	Class A	The SilkPeel® is suitable for use in all establishments other than domestic and those 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	

Table 202 — Guidance and Manufacturer's Declaration – Immunity			
The SilkPeel® Dermalinfusion System is intended for use in the electromagnetic environment specified below. The customer or user of the SilkPeel® MD Platinum should ensure that it is used in such an environment.			
IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT-GUIDANCE
ESD EN61000-4-2	± 6kV contact ± 8kV Air	± 6kV contact ± 8kV Air	In areas where floors are made of synthetic material (i.e. carpet), the relative humidity may need to be controlled to reduce the level of ESD discharges
EFT EN61000-4-4	± 2kV Mains	± 2kV Mains	The SilkPeel® has I/O cables. Mains power is that of a typical commercial or hospital environment
Surge EN61000-4-5	± 1kV Differential ± 2kV Common	± 1kV Differential ± 2kV Common	Mains power is that of a typical commercial or hospital environment
Voltage Dip/Dropouts EN61000-4-11	60% Dip for 5 Cycles 30% Dip for 25 Cycles >95% Dip for 5 Seconds >95% Dip for 0.5 Cycles	60% Dip for 5 Cycles 30% Dip for 25 Cycles >95% Dip for 5 Seconds >95% Dip for 0.5 Cycles	Mains power is that of a typical commercial or hospital environment If continued operation is desired under blackout conditions then a UPS or battery backup is recommended
Power Frequency Magnetic Fields EN61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields around the SilkPeel® should be those typical in a commercial or hospital environment.

Table 204 — Guidance and Manufacturer's Declaration - Emissions Equipment and Systems that are NOT Life-Supporting

The SilkPeel® Dermalinfusion System is intended for use in the electromagnetic environment specified below. The customer or user of the SilkPeel® MD Platinum should ensure that it is used in such an environment.

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT- GUIDANCE
Conducted RF EN61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be separated from the SilkPeel® MD Platinum by no less than the distance calculated below: $d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 1.2 \sqrt{P}$ 800MHz to 2.5 GHz P is the max power in watts and D is the recommended separation distance in meters. Field strengths from fixed transmitters, as determined by an electromagnetic survey, should be less than the compliance levels (V1 and E1) Interference may occur in the vicinity of equipment containing a transmitter
Radiated RF EN61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m 80 MHz to 2.5 GHz	

Table 206 — Recommended Separations Distances for the HT110-Series Meter Guidance and Manufacturer's Declaration – Emissions

The SilkPeel® Dermalinfusion System is intended for use in the electromagnetic environment in which radiated disturbances are controlled. The customer or user of the SilkPeel® MD Platinum can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications Equipment and the SilkPeel® MD Platinum as recommended below, according to the maximum output power of the communications equipment.

MAX OUTPUT POWER (WATTS)	SEPERATION (M) 150 KHZ TO 80 MHZ $d=1.2(\text{Sqrt } P)$	SEPERATION (M) 80MHZTO 800MHZ $d=1.2(\text{Sqrt } P)$	SEPERATION (M) 800MHZTO 2.5GHZ $d=1.2(\text{Sqrt } P)$
0.01	.1166	.1166	.2333
0.1	.3689	.3689	.7378
1	1.1666	1.1666	2.3333
10	3.6893	3.6893	7.3786
100	11.6666	11.6666	23.3333