

glacialTM_{Rx}

Treatment Training Overview

FOR OFFICE STAFF ONLY

Agenda

MKT-0897 Rev. C

Part 1: Overview

- Glacial Rx
- Cryomodulation
- Treatment Overview
- Patient Selection
- Potential Effects
- Patient Expectations
- Results

Part 2: Treatment

- System & Kit Overview
- Treatment Preparation
- Treatment Administration

Part 3: System Maintenance

- Routine Maintenance
- Error Codes

FOR OFFICE STAFF ONLY. DO NOT DISTRIBUTE.

Part 1 Overview

MKT-0897 Rev. C

- Glacial Rx
- Cryomodulation
- Treatment Overview
- Patient Selection
- Potential Effects
- Patient Expectations
- Results

FOR OFFICE STAFF ONLY. DO NOT DISTRIBUTE.

Glacial Rx



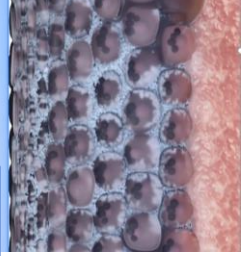
- The Glacial Rx™ system is the first benign (age spot) removal treatment that uses patented cooling technology to freeze melanin at the source, soothing your pain and revealing brighter, more even skin
- FDA cleared
- Little to no downtime

*Patient results will vary and may require additional treatment

CRYOMODULATION

Melanin

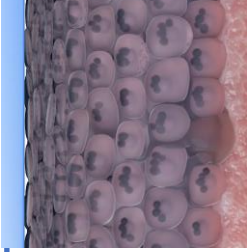
Remove lesions by impairing ability of melanocytes to deliver melanin, accelerating exfoliation and normalizing pigment deposition



- ✓ Cells turning over contain less melanin
- ✓ Pigment deposition normalized
- ✓ Redness / edema suppressed
- ✓ Soothing experience promotes healing

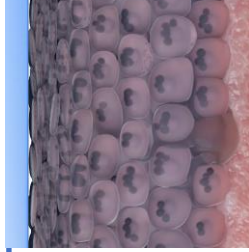
Inflammation

Reduce redness and edema by decreasing pro-inflammatory and increasing anti-inflammatory mediators resulting in suppression of chronic and procedure related inflammation




Discomfort

Support delivery of refreshing sensory experience by decreasing nerve conduction velocities and suppressing delivery of pain signals to the brain



TREATMENT OVERVIEW



COOL

Remove age spots
by applying cold, which suppresses melanin and normalizes pigment deposition.

Eliminate Age Spots



CALM

Reveal radiant, smooth skin
by reducing redness and edema, suppressing inflammation, removing impurities, balancing skin flora and boosting healthy microbiome, all in a comfortable experience.

Reduces Inflammation



PROTECT

Defend and protect skin
by enhancing application of brightening agents and antioxidants.

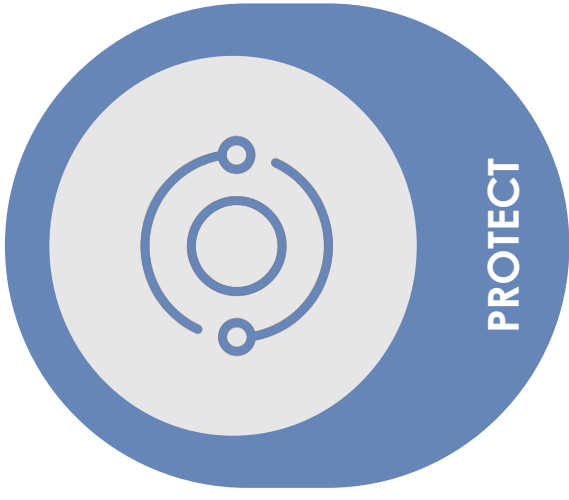
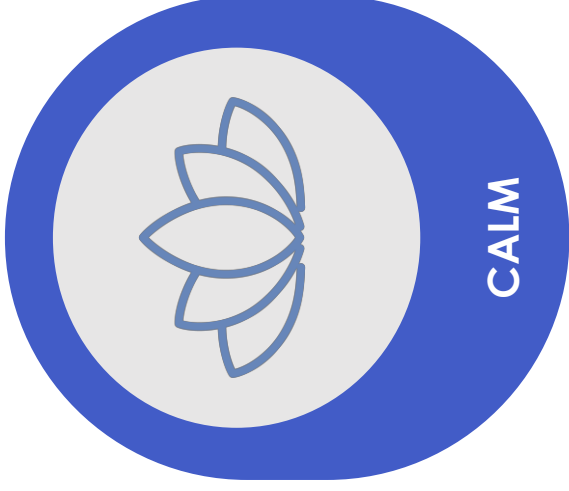
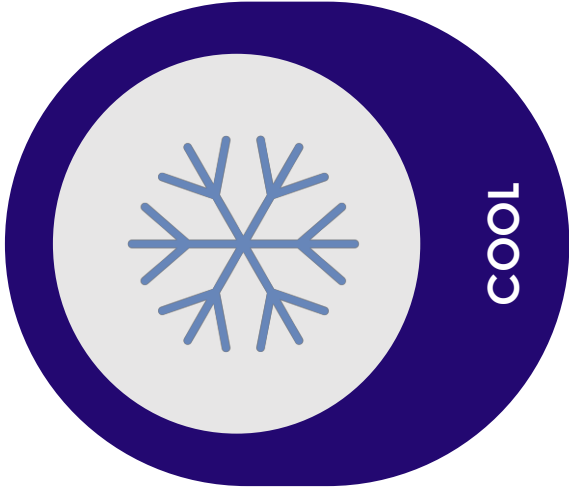
Maintains Brighter

TREATMENT OVERVIEW

Eliminate Age Spots

Reduces Inflammation

Maintains Brightening



PRE-TREATMENT

COOL

CALM

PROTECT



CLEANSE



FREEZE



LOOSEN



REMOVE



CALM



DEFEND



PROTECT

TREATMENT OVERVIEW



FREEZE



LOOSEN



REMOVE



CALM



DEFEND



PROTECT



PATIENT SELECTION

Properly Diagnose Treatment Areas*

INDICATION:

- Removal of benign lesions of the skin and for use when cooling is intended for the temporary reduction of pain, swelling and inflammation

CONTRAINDICATION:

- Confirmed diagnosis of skin cancer in the treatment area

OTHER CONSIDERATIONS:

- Underlying cold (cold urticaria, cryoglobulinemia, Raynaud's Disease)
- Herpes Simplex**
- Retinoid use in the previous week**
- Aggressive exfoliation 7-10 days prior to treatment**

*Patient selection is ultimately at the discretion of the treating provider. Areas considered for treatment should be properly diagnosed.
**When utilizing commercially available topicals during administration

MKT-0897 Rev. C

FOR OFFICE STAFF ONLY. DO NOT DISTRIBUTE.

PATIENT EXPECTATIONS

Patient Experience and Results Will Vary

DURING TREATMENT:

- Patients can expect to feel a “freeze” sensation during lesion treatments
- As treatment continues, an overall cooling and refreshing sensation can be experienced

AFTER TREATMENT:

- Immediate: Patients may be refreshed
- Few days: may notice some reduction in redness and bright skin and even tone
- Few weeks: may notice diminishing of lesion

Setting proper expectations during and after treatment will ensure a good experience for the patient

POTENTIAL EFFECTS

For Treated Lesions

Potential Effects at Lesions Only		Average Duration (results will vary; may take longer for some patients)
Redness		1 – 7 days (can be up to 30 days)
Itchiness		1 to 7 days
Crusting (dry exfoliated skin)/transient darkening		1 – 4 weeks
Mild Tenderness/Soreness		1 – 7 days
Post Inflammatory Hyperpigmentation		Up to 12 months (can be longer)
Transient lightening aka “new skin”		Typically 1 – 3 months (can be longer)

R2-16-001 Interim Report: Evaluation of a New Dermal Cryotherapy System for the Treatment of Benign Pigmented Lesions

MKT-0897 Rev. C

FOR OFFICE STAFF ONLY. DO NOT DISTRIBUTE.

8

EXAMPLES OF POTENTIAL EFFECTS FOR TREATED LESIONS

Duration and Patient Results Will Vary



BASELINE

DAY 2

Redness can be prominent; can be more noticeable on darker skin; eventually may turn dark, become dry/begin to crust and exfoliate off skin



DAY 7

New skin will appear; melanin transfer will return to baseline once area has healed



SET PATIENT EXPECTATIONS

Little to No Downtime. What Does This Mean?

Visibility of the healing process/potential effects must be considered

The more lesions treated on face/neck/chest, the more visible the potential effects

Visible effects on the arms and legs may not be as noticeable

Darker the skin, the more color contrast between normal/tanned skin and new skin

Skin on face is more resilient and will heal faster than skin on chest, neck, legs, etc.

Consent Form and Take Home Instruction Form

MKT-0897 Rev. C

3

RESULTS



FST III – 1 TREATMENT - 1 MONTH FOLLOW UP

RESULTS



FST II – 1 TREATMENT - 1 MONTH FOLLOW UP

RESULTS

Patient Satisfaction



Evaluation of the Dermal Cooling System for the Enhanced Treatment of Benign Pigmented Lesions and Common Skin Conditions – Interim Analysis – 11.19.20

Evaluation of a New Dermal Cryotherapy System for the Treatment of Benign Pigmented Lesions – Interim Analysis

TD-0992 & TD-0993

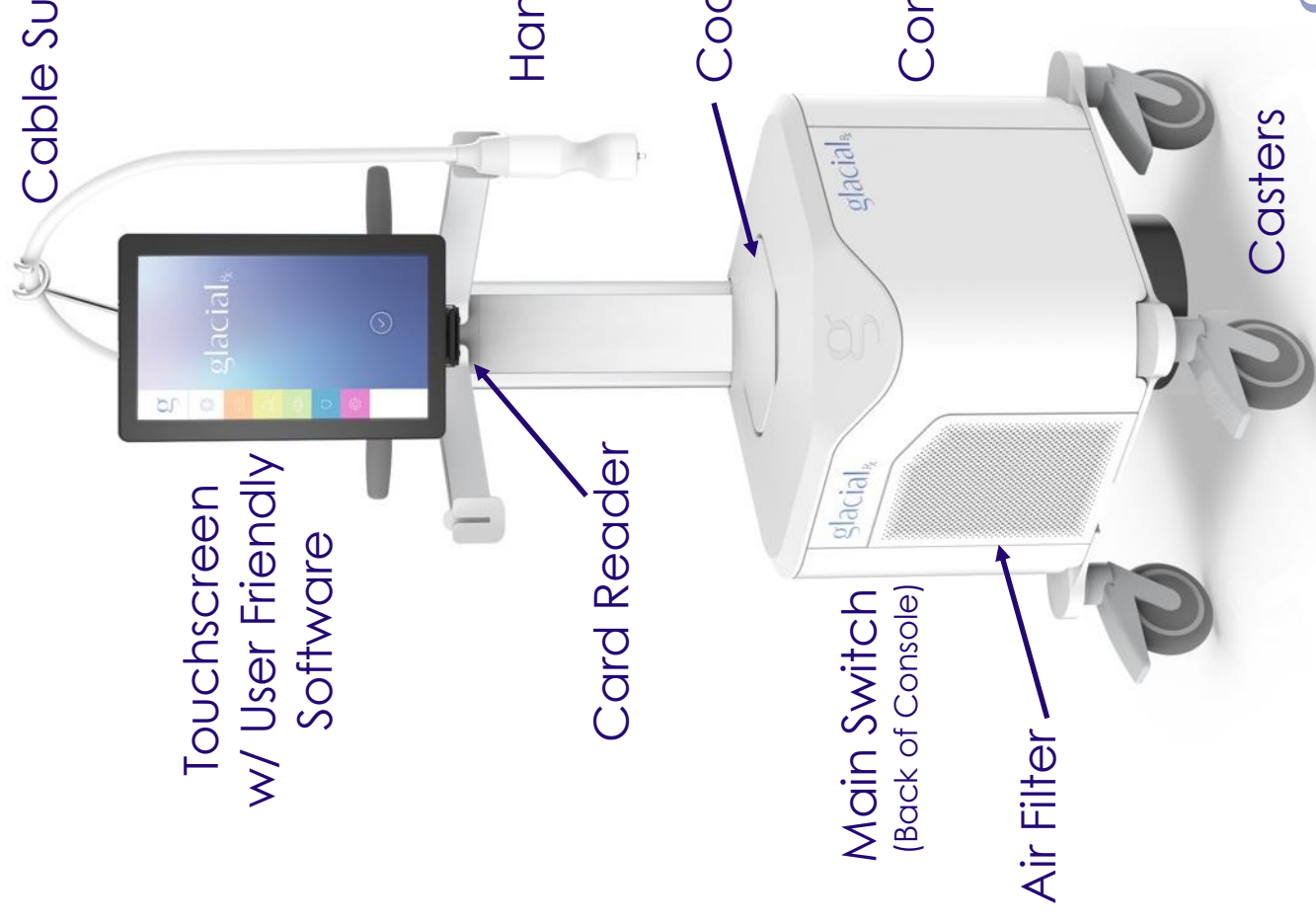
Part 2

Treatment

- System Overview
- Kit Overview
- Treatment Preparation
- Treatment Administration

System Overview

MKT-0897 Rev. C



FOR OFFICE STAFF ONLY. DO NOT DISTRIBUTE.

Freeze Kit Overview

(approximately 20 treatments)

MKT-0897 Rev. C

AMINO CELL CLEANSER

Conditioning, pH-
balanced cleansing
gel infuses skin with
nutrients as it removes
impurities.

Key ingredients:
Silk Amino Acids
Hyaluronic Acid
Ethylated L-Ascorbic Acid



CLEANSER
100 ml



GEL
100 ml



FREEZE CARD
(100 cycles)

FOR OFFICE STAFF ONLY. DO NOT DISTRIBUTE.

HYD
Hyd
skin
treat
Key
Prop

In Treatment Kit Overview

(One kit per patient)

MKT-0897 Rev. C



In
Treatment
Topicals

Tip 1
Tip 2

Rejuvenation
Card

FOR OFFICE STAFF ONLY. DO NOT DISTRIBUTE.

IN TREATMENT KIT OVERVIEW

From our partners at
ALLIES of SKIN



Peel

FOLLOW THE LIGHT PEEL

Brightening Chemical
Exfoliator for Increased
Skin Radiance and
Luminosity

Key ingredients:
Glycolic + Lactic + Salicylic
Acid, Ethylated L-Ascorbic
Acid Pomegranate
Enzymes



Mist

MOLECULAR SAVIOUR PROBIOTICS TREATMENT MIST

Alcohol-free mist that
hydrates, refines
appearance of pores
and brightens.

Key ingredients:
Lactobacillus Ferment
Zinc PCA
Ergothioneine



Mask

GLACIAL MASK

Instantly replenishes
moisture, soothes,
and boosts essential
microbiome.

Key ingredients:
Snow Algae
Niacinamide
Vin-upLift



Serum

VITAMIN C BRIGHTEN + FIRM 20% SERUM

Antioxidant-rich
formula firms, fades
dark spots, enhances
radiance, and
protects.

Key ingredients:
20% Ethylated L-
Ascorbic Acid
Glutathione
Thiotaine



Mois

PEPTIDES & FIRMING D

Protects skin
damage, an
while firming
healthy barm

Key ingredien
Teprenone
Palmitoyl Tripep
Palmitoyl Tripep

IN TREATMENT KIT OVERVIEW

Post Treatment Take Home Kit



Used at home to help maintain
Glacial Rx results and accelerate
skin recovery

From our partners at
 ALLIES of SKIN

MOLECULAR BARRIER RECOVERY CREAM BALM

The ultimate skin healer for
post-procedure skin to
repair and protect skin
barrier.

Key ingredient
Ceramides, ATP, Oat Protein
Palmitoyl Tripeptide-8
Niacinamide



CREAM



SERUM

MANDELIC
CORRECTOR
Next-generation
the approach
pigment
blemishes
Key ingredients
11% Mandelic
Acid
Rumex Oc
Nonapept

Treatment Preparation

MKT-0897 Rev. C

The following items are needed to complete treatment:

- Freeze Kit
- In Treatment Kit
- Water saturated non-woven gauze
- Cotton rounds
- Headband

In addition, providing a comfortable and calming environment will ensure the best experience. Consider the following:

- Light and relaxing background music
- Essential oils to provide a scent to the room
- Blanket to cover the patient during treatment

FOR OFFICE STAFF ONLY. DO NOT DISTRIBUTE.

8

PREPARE THE SYSTEM

1. Access the main switch and turn on the system to boot up



NOTE: DO NOT unplug or turn off system during boot up. Wait until boot up is complete to turn off system.

2. System is ready for use



Treatment Administration

NOTE: Properly diagnose lesion prior to administering Glacial Rx. Treatment administration is at the discretion of the treating provider. Always avoid the eye area.

MKT-0897 Rev. C



CLEANSE



FREEZE



LOOSEN



REMOVE



CALM



DEFEND



PROTECT

FOR OFFICE STAFF ONLY. DO NOT DISTRIBUTE.

CLEANSE



- Apply CLEANSER to the forehead, cheeks and chin (avoid eye area)
- Use fingers to spread into the skin and cleanse

Patient should wear a headband to keep hair out of face



Thoroughly remove with water saturated cloth

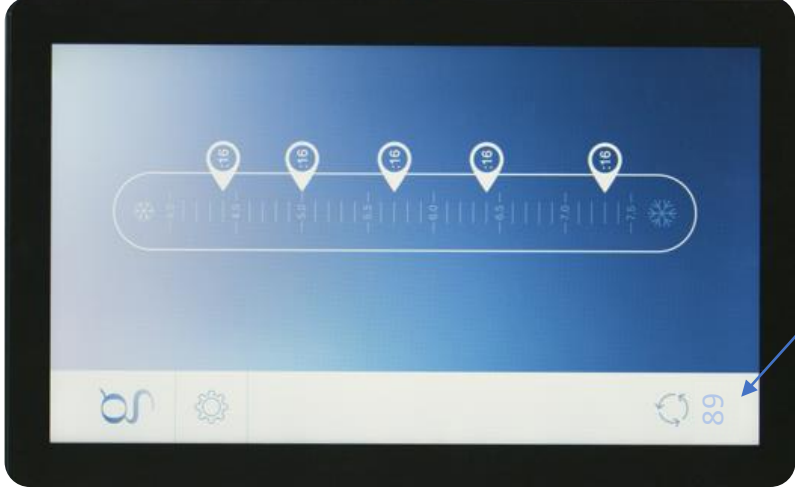
FREEZE



- Insert the Freeze Card



- Cooling Factor (CF) selection screen will appear



Cycles remaining

- Identify
diagnose
treat (or
circulating
treatment
a mark

FREEZE

Cooling Factor (CF) Selection

- CFs determine intensity of freeze cycles
- Higher CF = colder, more intense freeze
- Consideration factors for treatment:
 - Lesion type / thickness
 - Location on body
- Always follow recommended CFs

NOTE: more intense CFs may result in longer duration of potential side effects



COLDER
less in

COLDER
most

CF RECOMMENDATIONS

		Caucasian Flat Lesion			Non-Caucasian Flat Lesion		
CF		Face	Chest/Neck	Body	Face	Chest/Neck	Body
3.2					g *	g *	
4.4		g *	g *		g	g	g
5.0		g	g	g			g
5.7				g			
6.5							
7.2							

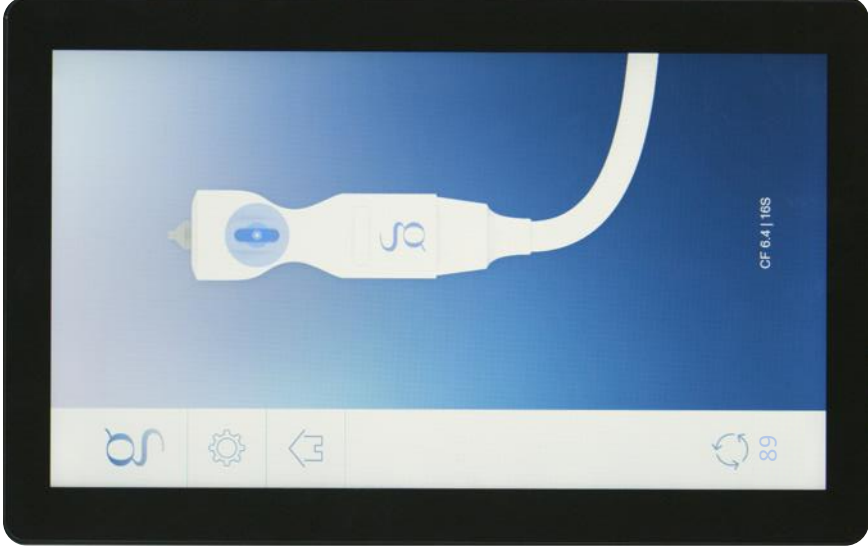
* For side effect averse patients, tanned patients, patients with sensitive skin or patients receiving a high number of spot t

FREEZE

Freeze Cycle Administration



- Apply a few drops of GEL directly onto the treatment lesion
- Spread the GEL with the finger



- Push on init

FREEZE

Freeze Cycle Administration



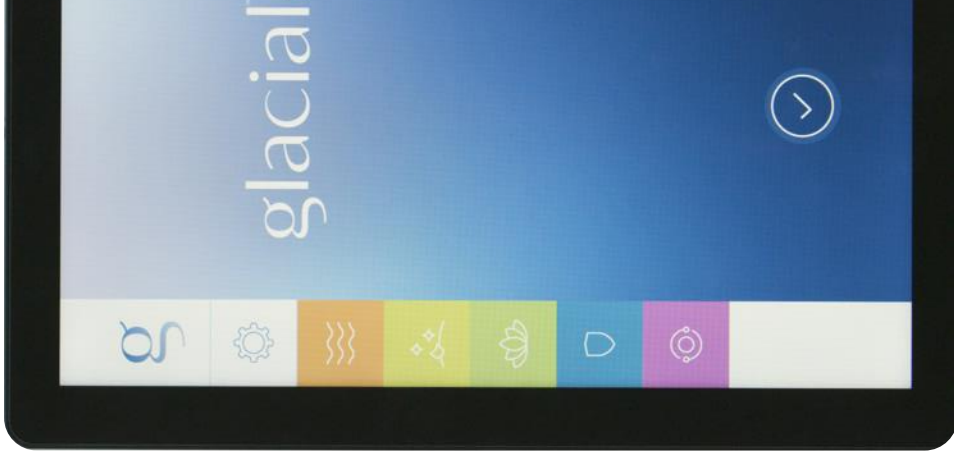
- Apply cold tip directly onto the treatment lesion and hold steady (avoid eye area)
- Cycle will start automatically
- Timer will indicate when cycle is complete
- Clean treated area with gauze
- Treat additional areas as appropriate
- Clean cold tip with gauze



IN TREATMENT KIT



- Replace Freeze Card with Rejuvenation Card to initiate Touchscreen to continue Glacial Rx
- DO NOT DISCARD FREEZE CARD if more cycles remain
- Touchscreen will guide provider through the process



Rejuvenation Card Initiation
Push checkmark to

TOUCHSCREEN GUIDANCE

Tips and Topicals

In General:

- Touchscreen will guide when to attach a tip
- Touchscreen will guide the appropriate topical to use

Highlighted icon from touchscreen and icon on topical bottle should be the same



TOUCHSCREEN GUIDANCE

Topical Application

In General:

- Apply topicals to each section of face: forehead, cheeks, chin (avoid the eye area)
- Blue button on Handpiece will start cycle
- Use circular motions and long strokes when spreading topicals

For REMOVE icon: hold skin taut and use long strokes ONLY, going over the same area no more than twice

- Always refer to the Touchscreen for cycle completion, including dwell time when indicated
- When needed, thoroughly remove topicals with water saturated gauze before proceeding

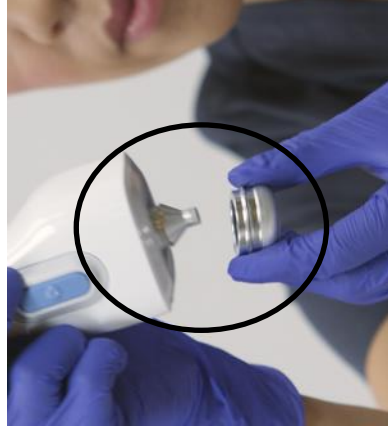


LOOSEN

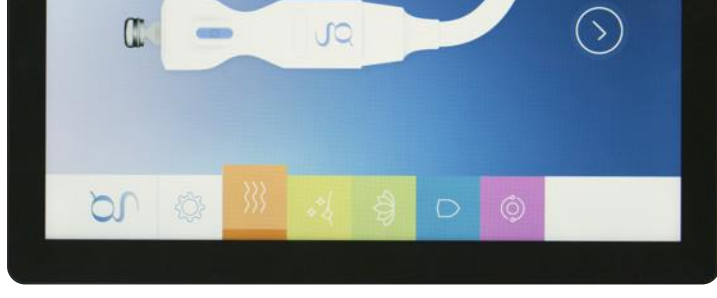
Attach Tip 1 (has 1 band on outside of tip)



1. Apply a few drops of GEL into Tip 1



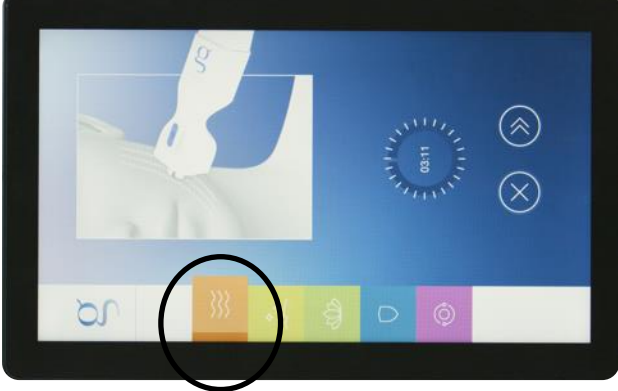
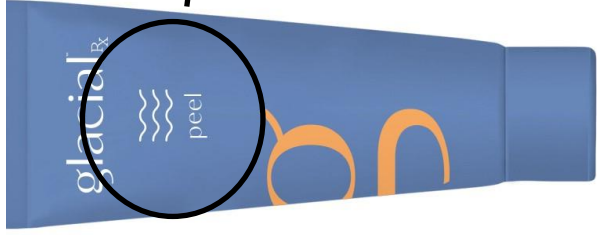
2. Attach Tip 1 to Handpiece



3. Push check confirm Tip 1

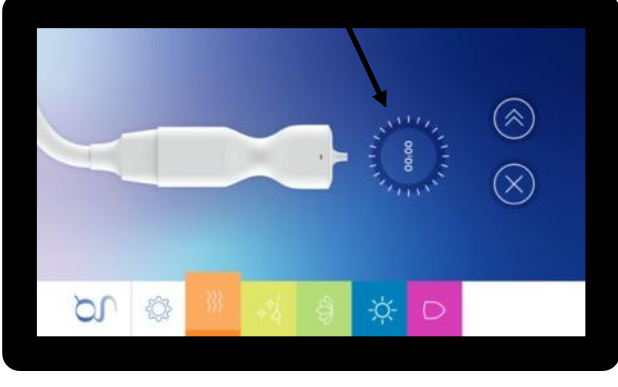
LOOSEN

PEEL Application



1. Apply a small amount of PEEL to forehead, cheeks, chin

2. Push Handpiece button to start
3. Spread PEEL; circular motions and long strokes until complete



4. Leave PEEL on skin for minutes; refer to time
5. Remove PEEL with gauze
6. Detach Tip 1 and set

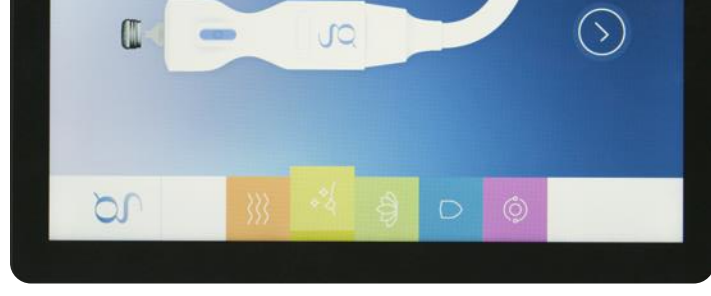
REMOVE

Attach Tip 2 (has 2 bands on outside of tip)



1. Apply a few drops of GEL into Tip 2

2. Attach Tip 2 to Handpiece



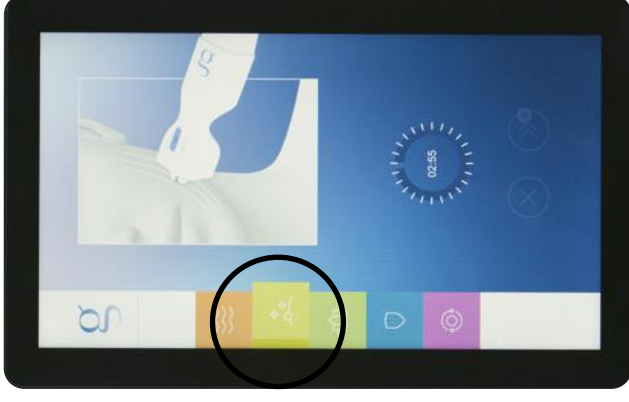
3. Push che confirm Tip 2

REMOVE

MIST Application



1. Cover eyes with cotton rounds
2. Working in sections, generously spray MIST to forehead



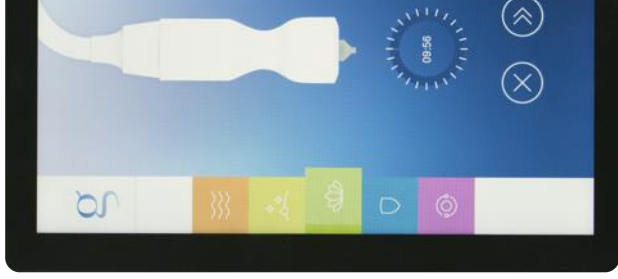
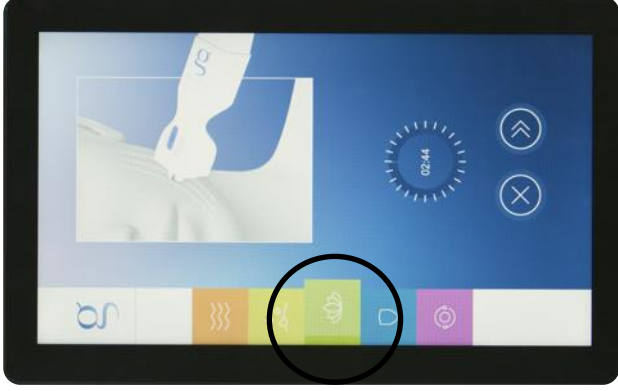
2. Push Handpiece button to start
3. Hold skin taut and use long strokes ONLY; DO NOT go over same area more than twice

4. Continue working in sections
5. After completing a section, remove MIST and replace with a saturated cotton round
6. Lightly spritz with MIST all over the face
7. Detach Tip and discard



CALM

Tip 1 and MASK Application



1. Apply GEL into Tip 1 and reattach
2. Apply small amount of MASK to forehead, cheeks, chin

3. Push Handpiece button to start
4. Spread MASK with circular motions and long strokes until complete

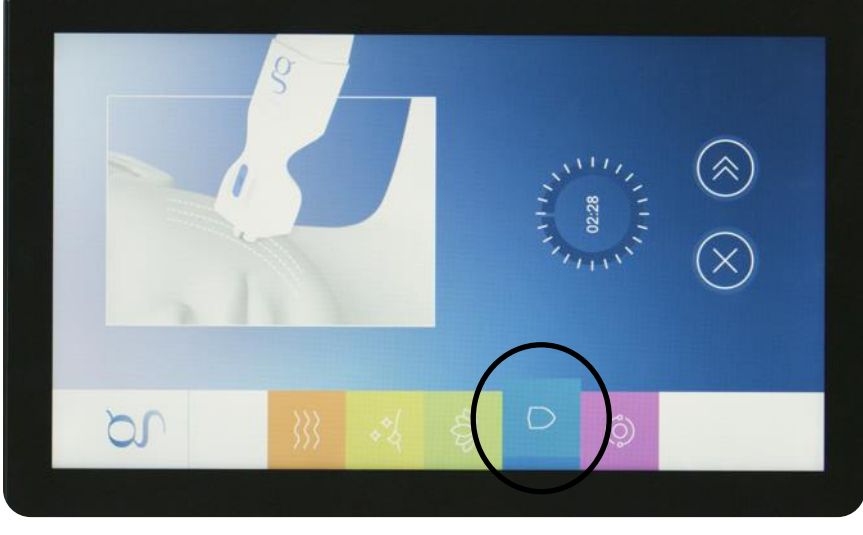
5. Spritz MIST on face and leave on for 5 minutes; refer to MIST application
6. Remove MIST with saturated gauze

DEFEND

SERUM Application



1. Keeping Tip 1 attached, apply SERUM to forehead, cheeks, chin
2. Push button to start
3. Massage SERUM with circular motions and long strokes; consider applying slightly more pressure
4. When complete, leave SERUM on skin and do not remove
5. Clean Tip 1 with gauze

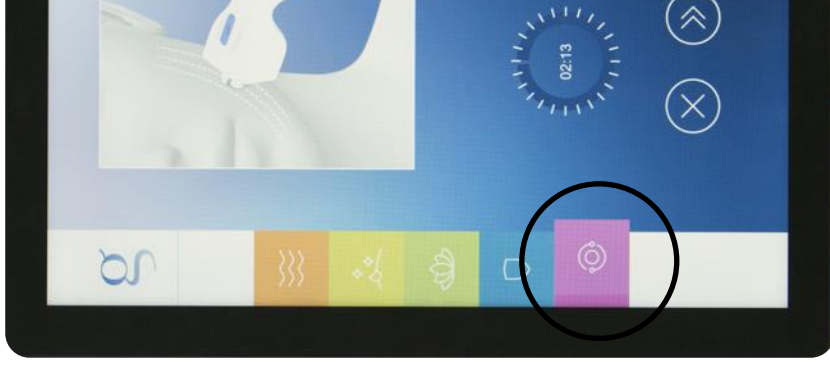


PROTECT

MOISTURIZER Application



1. Keeping Tip 1 attached, apply MOISTURIZER to forehead, cheeks, chin
2. Push button to start
3. Massage MOISTURIZER with circular motions and long strokes; consider applying slightly more pressure
4. When complete, leave MOISTURIZER on skin and do not remove
5. Using fingers, massage any remaining MOISTURIZER into the skin to ensure it has been absorbed



TREATMENT COMPLETE



Treatment Complete Screen

1. After treatment, remove the Rejuvenation Console and discard
2. Turn off the system using the main switch on the console
3. Thoroughly clean the Handpiece, Cold Tip, Touchscreen and anywhere the System was touched
4. Keep MLST and discard all remaining items from the In-Treatment Kit

TAKE HOME KIT

Maintain Results & Accelerate Skin Recovery

Provide the patient with the following:

- Take Home Kit
 - CREAM: to be used 3 to 4 times/day on treated lesions
 - SERUM: to be applied at night all over the skin (apply CREAM on lesions after SERUM)
- Any remaining MIST
 - Spritz for a glowy and dewy complexion when desired
- Take Home Instructions



GLACIAL RX™ INSTRUCTIONS

Congratulations on experiencing
skin and even skin tone.

WHAT TO EXPECT

In the upcoming days, many patients
experience a mild redness or irritation
of age spots or other benign lesions.
Very patient to patient.

You may experience the following:

Common effects

- Redness/irritation: 2 – 3 days
- Itchiness: 4 – 7 days
- Dry/abraded skin: 3 – 4 weeks
- Lesions clearing: 3 – 4 weeks

Less common effects

- Swelling: 1 day
- Mild tenderness/itchiness: 1 day
- Acne: 1 – 2 weeks
- Peeling: 1 – 2 weeks
- Post-inflammatory hyperpigmentation: 1 – 2 weeks

You will be given a Take Home Kit

CREAM: Apply CREAM 3 to 4 times
SERUM: Apply SERUM at night, at
night

Please contact us directly if you have

MKT-0897 Rev. C | © 2021 by TSC Medical, Inc.

Additional Treatments

MKT-0897 Rev. C

FOR OFFICE STAFF ONLY. DO NOT DISTRIBUTE.



ADDITIONAL TREATMENTS

- Glacial Rx patients can see results in a single treatment depending on the dose (Cooling Factor)
- Best results can be realized when Glacial Rx is integrated into an ongoing care routine and avoidance of sun exposure
- If patients desire further results, additional treatments can be administered given the following:
 - If treating the same area, all side effects from previous treatment must be resolved
 - Can be administered approximately 2 months after previous treatment
- Understand the results desired and consider using a more intense CF
- Always ensure proper patient expectations are set for additional treatment

System Maintenance

MKT-0897 Rev. C



FOR OFFICE STAFF ONLY. DO NOT DISTRIBUTE.

MAINTENANCE

When Not In Use

- Always store the Glacial Rx System and accessories in a secure and clean area
- Wrap the cable in the cable support and ensure it does not lay on the floor
- The Handpiece should always be stored in the holster
- Do not leave a card in the card reader when not in use



ERROR CODES

Resolution

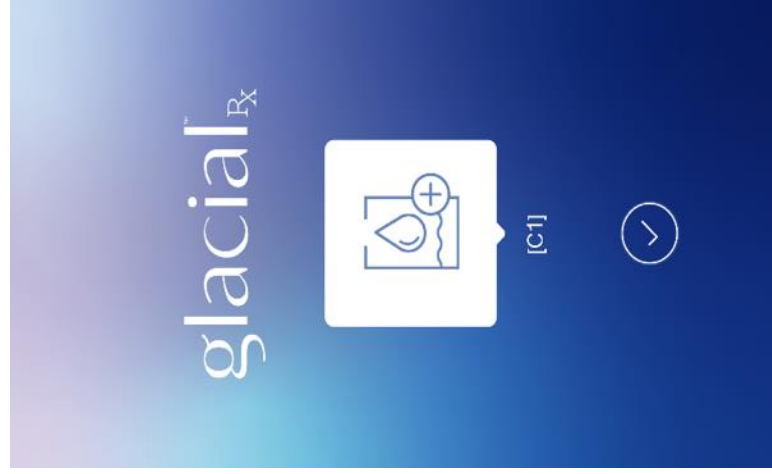
- Common errors can easily be resolved by simple troubleshooting
- Generally, after the error is cleared, treatment can be continued
- If an error cannot be resolved, refer to the IFU or call Technical Support

After troubleshooting,
push checkmark to clear
error

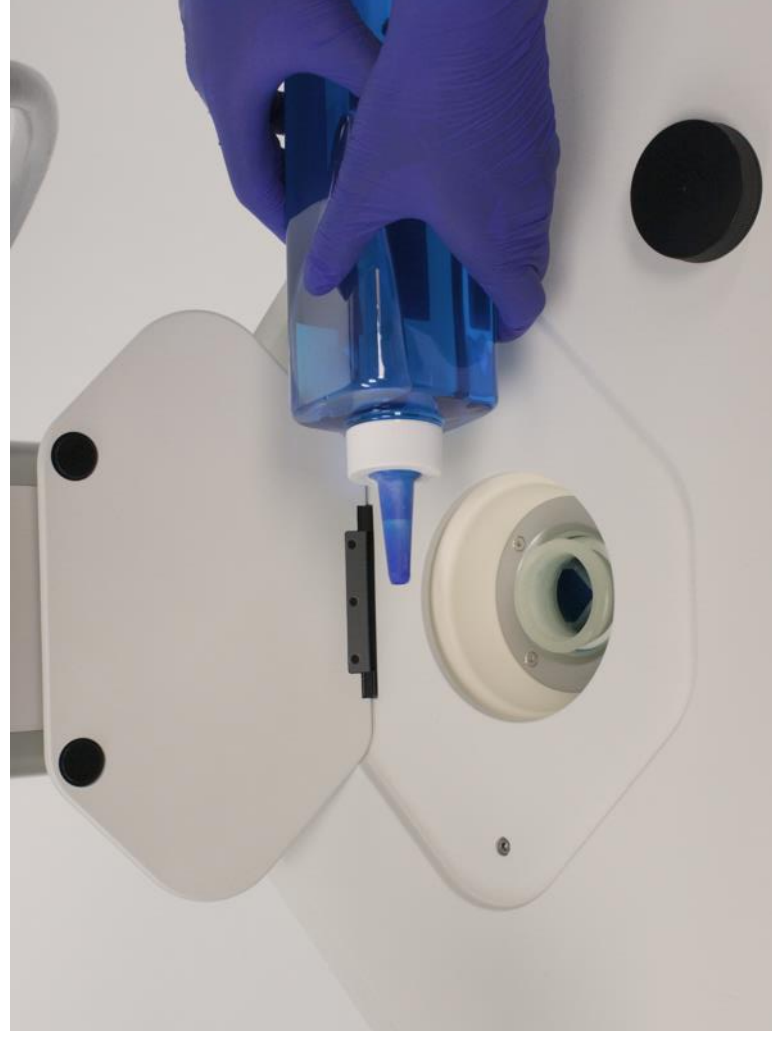


ERROR CODES

Chiller Fluid Fill



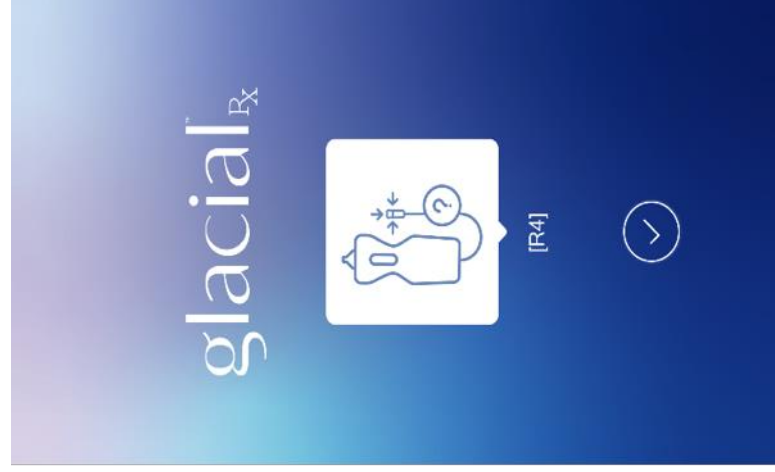
Low Chiller Fluid



1. Add chiller fluid (Koolant) until the chiller fluid level reaches the chiller fluid fill line.
2. Push chiller fluid button to clear the chiller fluid error.

ERROR CODES

Handpiece Not Attached



No Handpiece
Detected

MKT-0897 Rev. C



1. Ensure all Handpiece cables are firmly connected
2. Push check mark on Touchscreen to clear error

FOR OFFICE STAFF ONLY. DO NOT DISTRIBUTE.

ERROR CODES

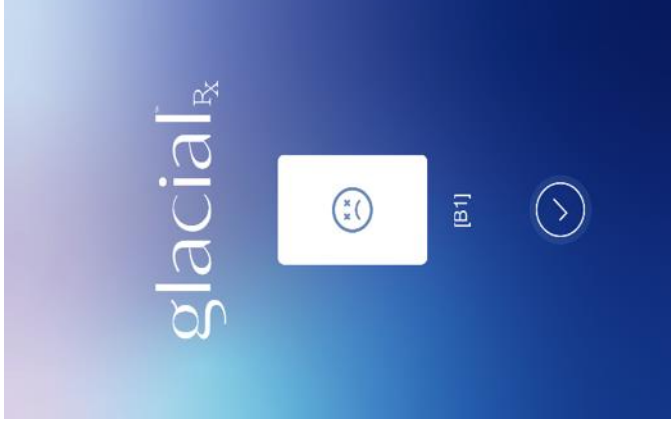
Common Errors & Resolution



No cycles remaining
on card

REPLACE with NEW
CARD

MKT-0897 Rev. C



B1: Cannot read
card/does
not match region ID

REPLACE with NEW
CARD

FOR OFFICE STAFF ONLY. DO NOT DISTRIBUTE.



Console error

CALL TECHNICAL
SUPPORT

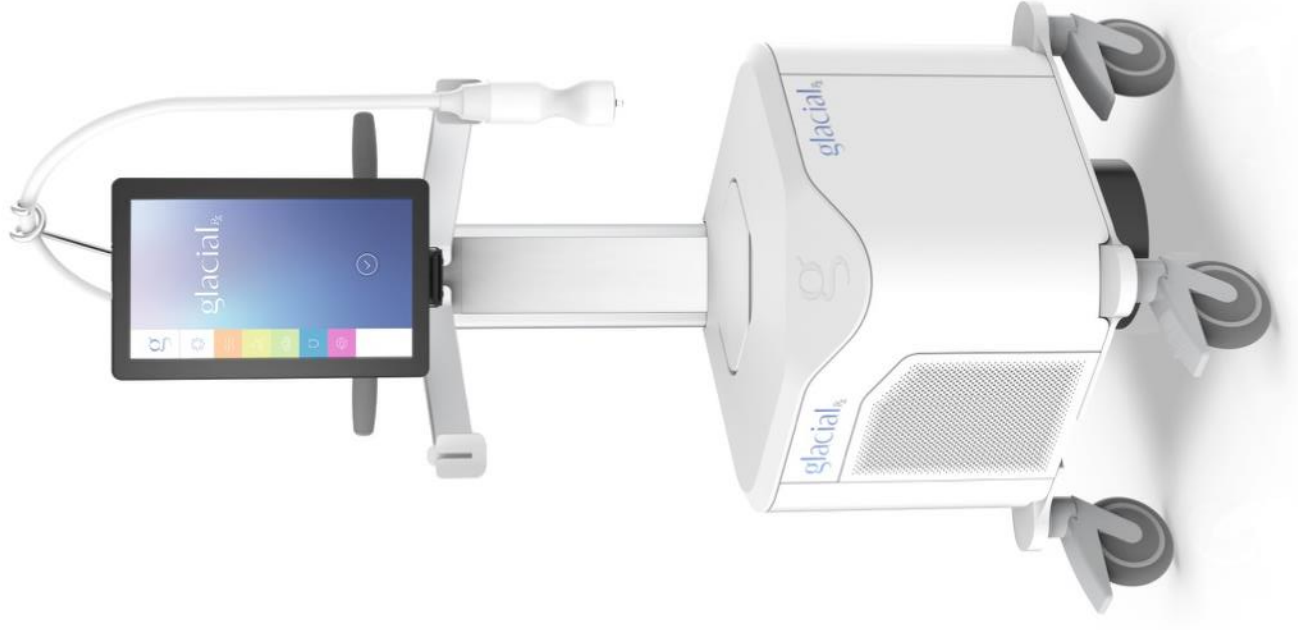


C8: Chiller
cool; insuffi

CLEAN VEN

Thank You

MKT-0897 Rev. C



FOR OFFICE STAFF ONLY. DO NOT DISTRIBUTE.