# miraDry Treatment Training Overview


MK22011.C

miraDry

# Table of Contents

## Part 1
### OVERVIEW

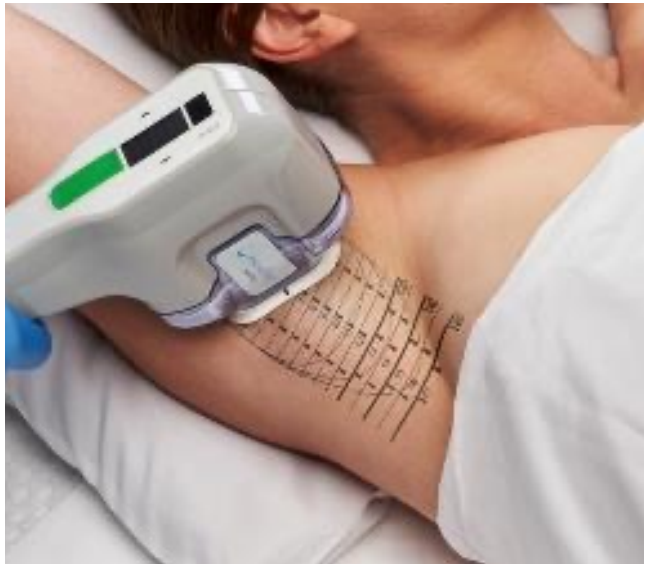


## Part 2
### DETAILED SYSTEM OVERVIEW

# PART 1:
# OVERVIEW and TECHNOLOGY

# miraDry Overview

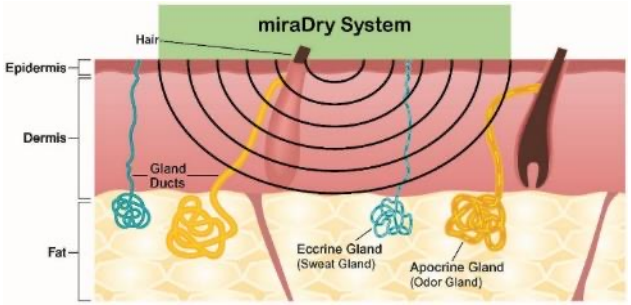
- ✓ Safely and permanently reduces underarm sweat, odor & hair*
- ✓ Lasting efficacy
- ✓ High patient satisfaction
- ✓ Non-surgical (no incisions or cuts)
- ✓ Strong safety profile
- ✓ Minimal patient downtime



Treatment in as little as one hour**

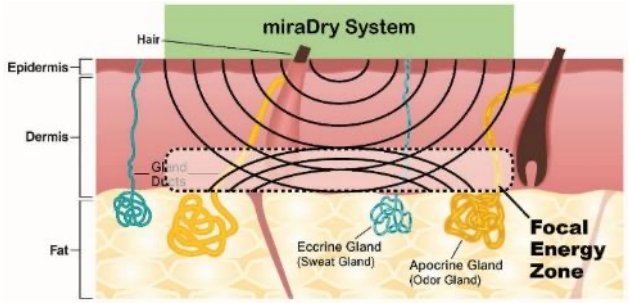
*miraDry is FDA cleared for underarm sweat, odor, and hair. It is CE marked for sweat only.
**After anesthesia administration

# Technology Overview



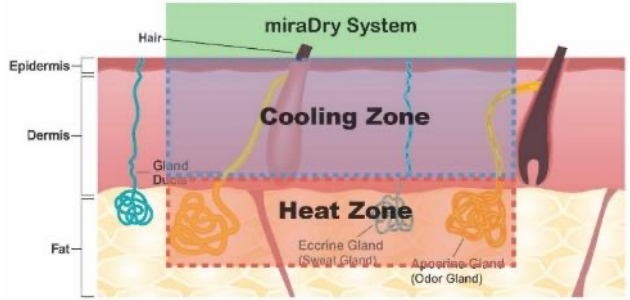

## Targeted energy

Focused microwave energy is delivered to the dermal-fat interface region




## Focal Energy Zone

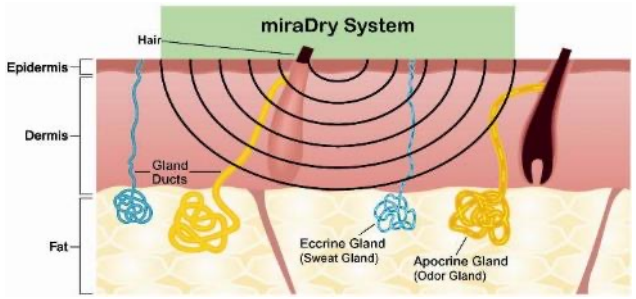
Energy reflects and is intensified at the dermal-fat interface




## Sweat, Odor Glands Destroyed

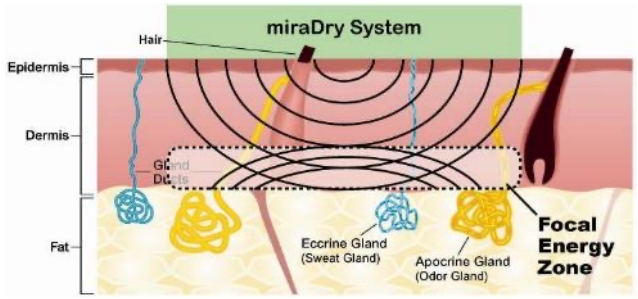
Hydro-ceramic cooling protects epidermis and upper dermis while heat destroys the sweat glands, odor glands and hair follicles

# Technology Overview: Detailed MOA



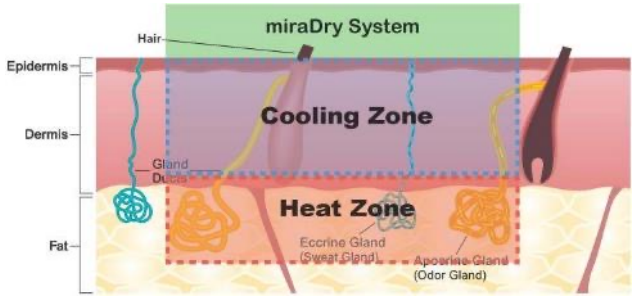

**1** **Focused energy delivery to the dermal-fat interface region**

- Virtually all the sweat glands, odor glands and hair follicles reside here
- Delivered at a frequency of 5.8GHz




**2** **Focal Energy Zone created along interface, independent of skin thickness**

- Energy reflected due to differences in electromagnetic properties in the interface
- Energy intensified from constructive interference at dermal-fat interface to create Heat Zone

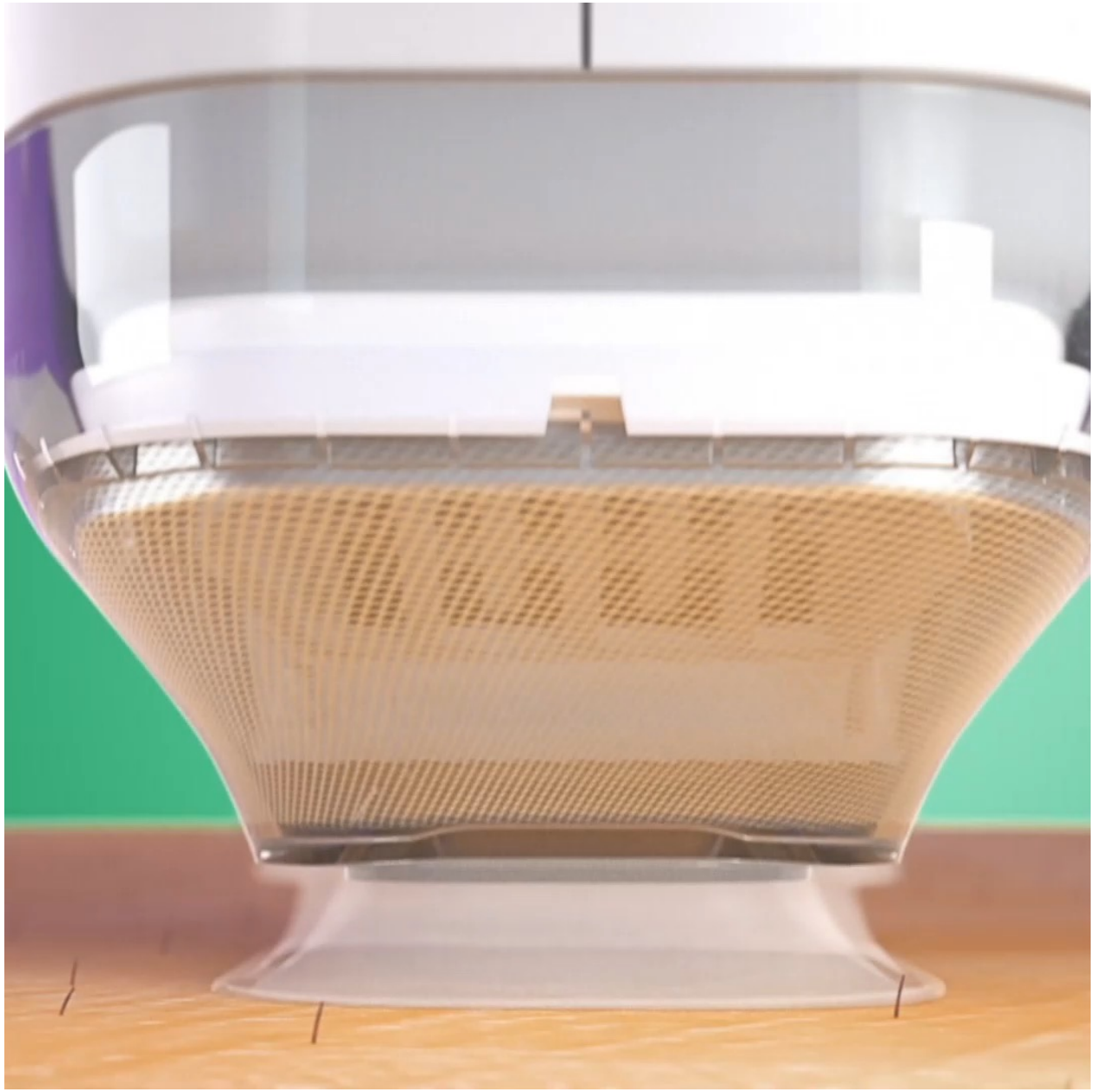



**3** **Glands are destroyed - cellular thermolysis at 55-60° C**

- Hydro-ceramic cooling system keeps Heat Zone at level of sweat glands
- Cooling protects epidermis and upper dermis; deeper tissue not affected
- Sweat glands are destroyed and do not regenerate

# Technology Animation

- Handpiece and bioTip is placed on treatment area
- Vacuum pulls tissue into bioTip
- Focal energy is delivered to appropriate depth
- Heat zone created at the dermal-fat interface and cooling at the epidermis
- Glands and follicles are destroyed
- Glands do not regenerate so results are permanent



# 2. Patient Selection

**The miraDry System is FDA cleared for the following:**

- Indicated for use in treatment of primary axillary hyperhidrosis and permanent reduction of unwanted underarm hair in adults 18 and older.
- When used for the treatment of primary axillary hyperhidrosis, the miraDry System may reduce underarm odor
- NOT indicated for use in the treatment of hyperhidrosis related to other body area
- Do NOT use miraDry anywhere except the axilla

**miraDry is contraindicated for patients who:**

- Have a heart pacemaker or other electronic device implant
- Use supplemental oxygen
- Have had prior problems with locally injected anesthesia

  (e.g.: lidocaine with epinephrine, medications that interfere with numbing, etc.)

**miraDry is NOT recommended for patients who have had previous axillary surgery**

- Dermis and fat interface layer may have been altered from the surgical procedure

# Patient Selection – Practical Considerations

## Consider postponing treatment or not treating due to:

- **Health of the patient**
  - Immune-compromised or taking medications that might interfere with healing post-procedure
  - Pregnancy
  - Underlying skin conditions (e.g., history of cysts, hidradenitis suppurativa, etc.) or prone to infection
  - Any medication use that will hinder administration of treatment or post treatment recovery

- **Anatomy**
  - Previous axillary surgery (e.g., lymph node dissection) that may have changed the skin/fat interface in treatment area
  - Extremely concave underarms
  - Obese, with axillary skin folds that make it difficult to accurately apply the template
  - Patients with little or no subcutaneous fat are more at risk for nerve-related injuries

- **Practical Reasons**
  - Planning on wearing sleeveless outfits within a week of treatment
  - Planning on extensive travel within a week of treatment (need to stay close to provider)
  - Upcoming commitments that may increase physical activity, require submersion in water, sauna/steam room, etc.

# 3. Energy Selection

- 5 Energy Levels (1-5) available
- Energy Level 1 used for DRI-UP Study[1]
  - Resulted in 70% efficacy at 12 months, after two treatments
- Energy Level 3 used for Canadian Study[2]
  - Resulted in 90% efficacy at 12 months, after one to three treatments
- Higher energy levels may provide higher efficacy, keeping in mind that some side effects may be more extensive and take longer to resolve
- Energy levels should be determined based on the patient's subcutaneous fat, sensitivity and desired result and is always at the discretion of the treating physician

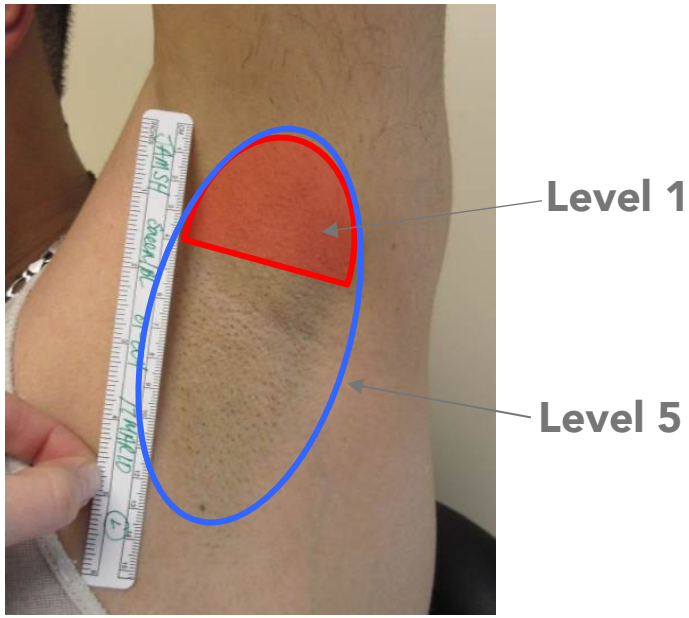


1 Glaser et al. Dermatol Surg 2012; 38: 185-191
2 Hong et al. Dermatol Surg 2012; 38: 728-735

# Energy Selection

- When energy is selected and "locked," the first few rows receive Energy Level 1 and remaining rows receive SELECTED energy level
- When energy is selected and "unlocked," all rows receive SELECTED energy level

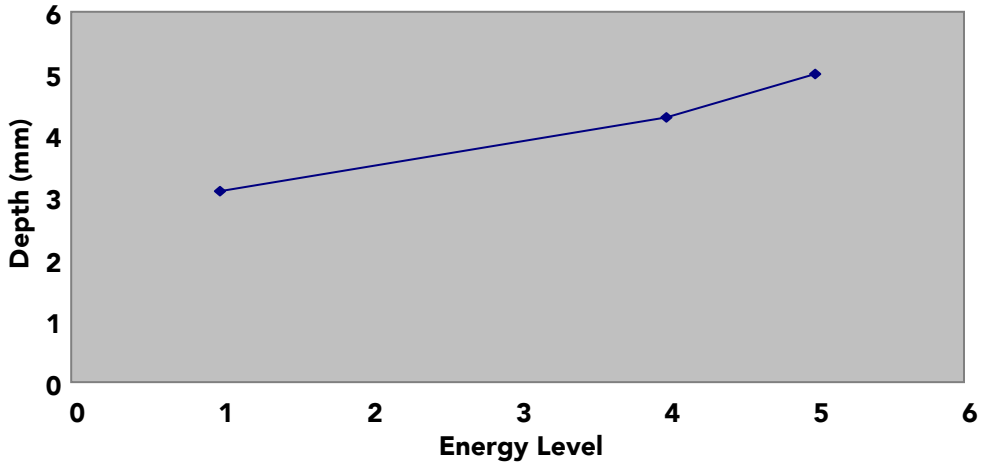
## Example

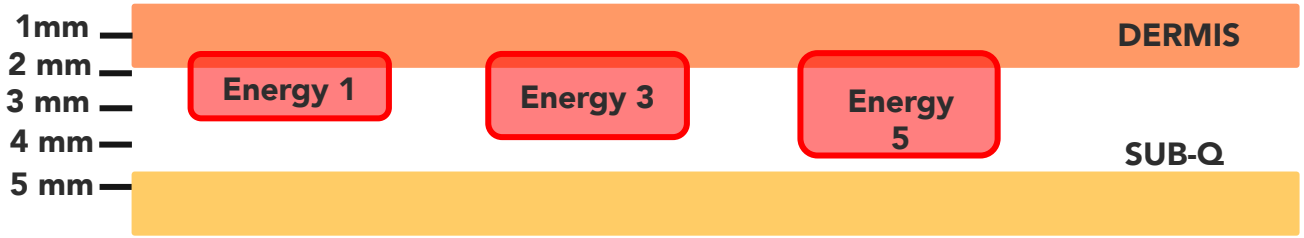



Some nerves of the brachial plexus can be shallow in the superior portion of the axilla. To minimize the potential for side effects (i.e., nerve interaction), the lowest energy level (which has the shallowest heat penetration depth) is recommended be used in that region, always at the discretion of the treating physician.

# Energy Level vs. Depth of Heat Penetration

Pre-Clinical Results




- Energy Level affects the volume and depth of the therapeutic zone while preserving much of the dermis

# 4. What Patients Can Expect

**Important: Appropriate patient consultation will result in high patient satisfaction**

- ✓ Reduction in underarm sweat in as little as one treatment
- Optimal results in two treatments[1]
- 82% average sweat reduction[1]
- Sweat glands are destroyed and do not regenerate – permanent results
- ✓ Reduction in underarm odor and hair[2,3]


1. Hong et al. Dermatol Surg 2012; 38: 728-735
2. Lupin et al. Dermatol Surg 2014; 40; 805-807
3. Brauer et al. Dermatol Surg 2016; 0: 1-8

# What Patients Can Expect

## Pre -Treatment Preparation

- Address any skin tags, moles, ingrown hairs, sensitive areas in/around underarms prior to treatment
- Shave both underarms 4-6 days prior to treatment. By treatment day, any small cuts/nicks will have healed, and the little hair growth will help to identify the treatment area.
- Do not wear antiperspirant/deodorant one day before treatment.
- What to wear the day of the treatment
    - Easily cleaned top with loose arm holes
        - Women – e.g., tank top, sports bra, etc.
        - Men – e.g., tank top or no shirt
- What to bring for day of treatment
    - Clean top to wear AFTER treatment

# What Patients Can Expect

NOTE: If any side effects worsen, treating physician should be contacted

## Post Treatment Care

- All patients will experience common side effects
  - Swelling
  - Soreness
  - Altered sensation in or around underarm (i.e., numbness, tingling, "feels different")
  - Temporary lumps/bumps
- Apply crushed ice in bag immediately post procedure using towel or gauze to protect the skin (20 min on/20 min off). Continue icing as needed for the next few days.
- Can use non-prescription anti-inflammatory medication (e.g., ibuprofen) to reduce swelling and manage discomfort as directed by treating physician
- Keep treated area clean
  - Wash twice/day with gentle liquid soap
  - New deodorant/antiperspirant
  - Apply antibiotic ointment to prevent infection
- Avoid submersion in water (bathtubs, hot tubs, swimming pools, lakes, ocean, etc.) for a few days
- Avoid shaving for a few days post treatment
- No rigorous activity for a few days

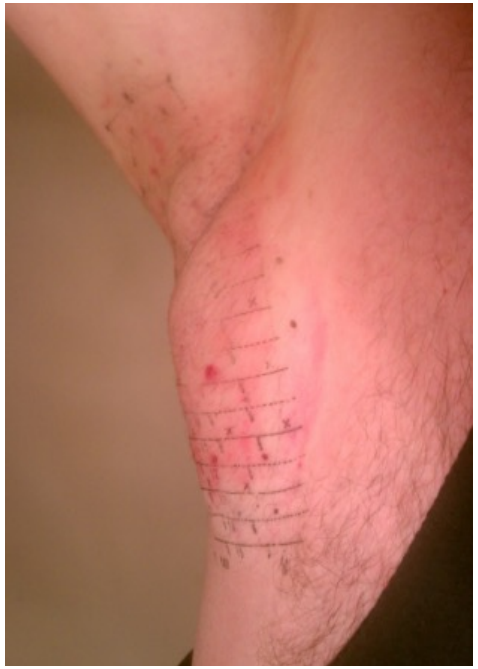
# 5. Side Effects – Common

| Common Side Effects | Typical Duration |
|---|---|
| Swelling/tightness in the treated area | 1-8 weeks |
| Soreness, discomfort or tenderness in the treated area | 2-3 weeks |
| Altered sensation in or around treatment area | 1-12 weeks (can last several months) |
| Lumps/bumps under treated area | 4-6 weeks (can last several months) |
| Bruising at the injection sites | Few days |
| Redness from device suction | Few days |

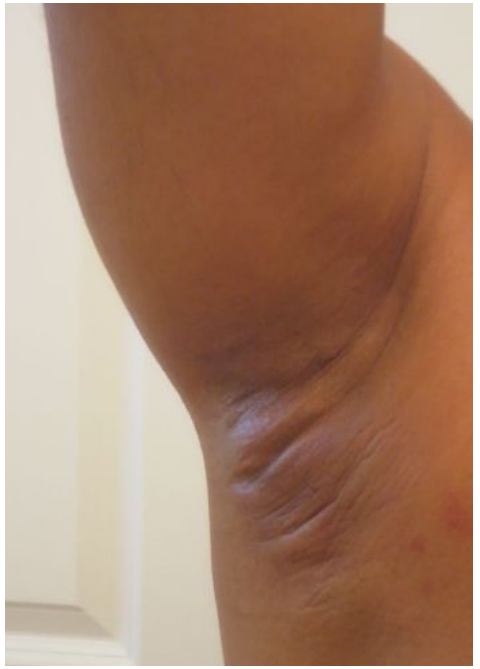
Note: Every patient will heal differently; some side effects may resolve sooner, some may take longer

# Examples of Common Side Effects

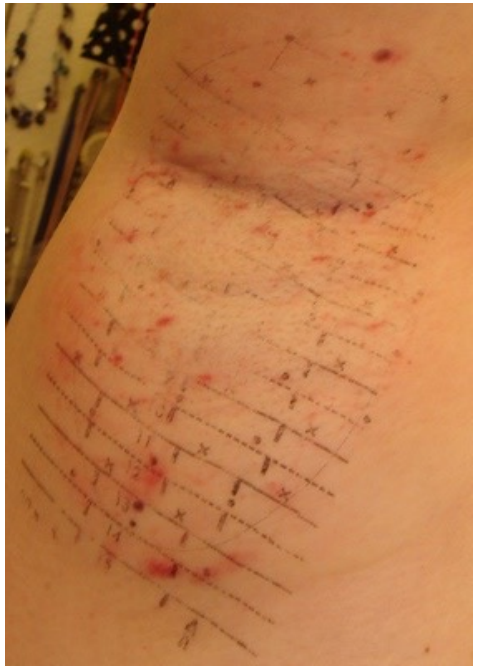
Typical swelling post 24 hours



Lumps/bumps 3 days post



Bruising from injections



Icing for 24-48 hours post miraDry and ibuprofen will help reduce swelling/lumps/bumps and discomfort.

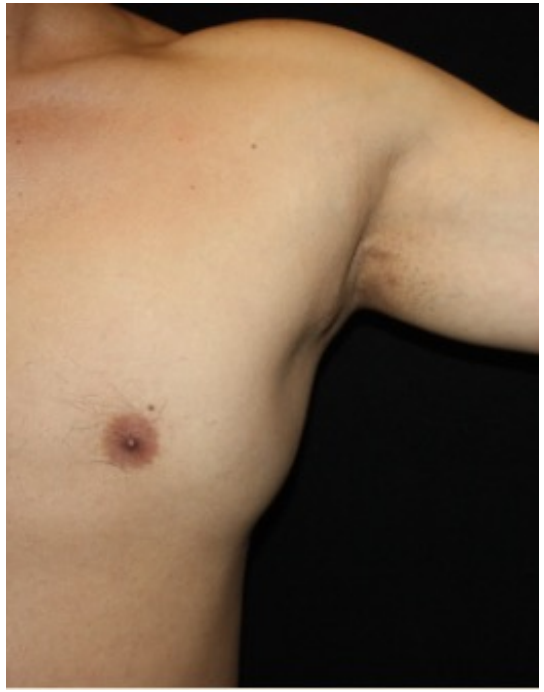
# Side Effects – Less Common

| Less Common Side Effects | Typical Duration |
|---|---|
| Swelling in adjacent arm or torso | 1 week (can last for several weeks) |
| Hyperpigmentation | Up to 8 weeks (can last for several weeks) |
| Tight band in the treated area | Up to 8 weeks |
| Soreness in arm or shoulder due to treatment positioning | Few days |
| Numbness/tingling in the arm or shaking (epi) due to anesthesia | < 1 day |

Note: Every patient will heal differently; some side effects may resolve sooner, some may take longer

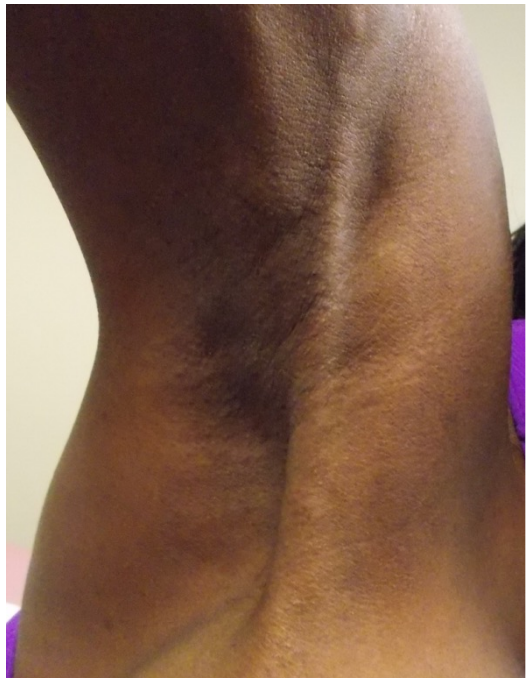
# Examples of Less Common Side Effects

Swelling in adjacent arm or torso



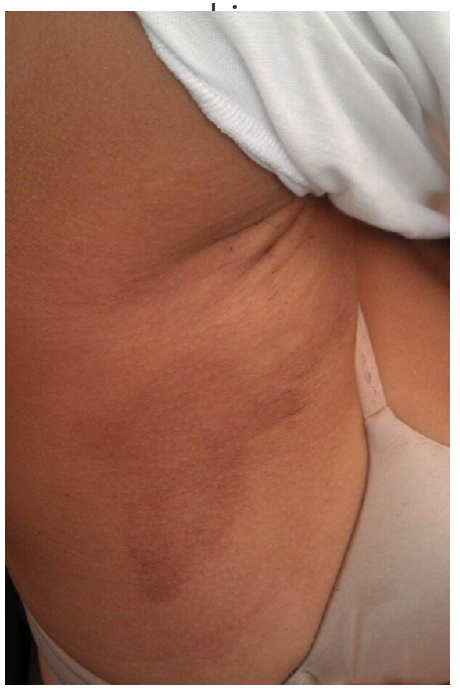
(Should dissipate over time)

Tight banding generally in thinner/lean patients



(Stretching may speed up recovery)

Hyperpigmentation mostly seen in darker



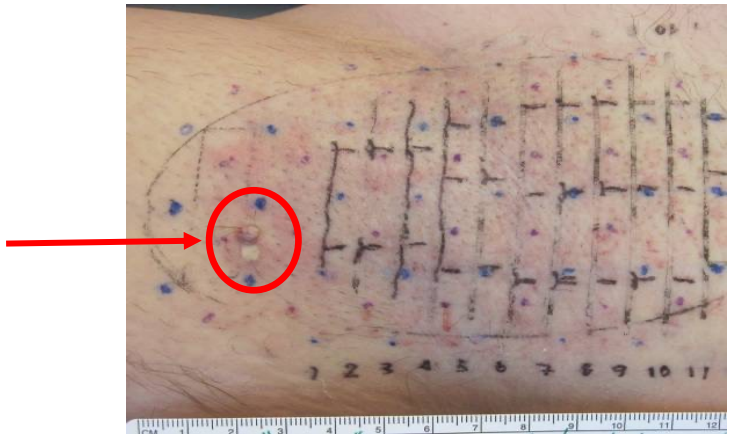
(Should dissipate over time)

# Side Effects – Rare Reports

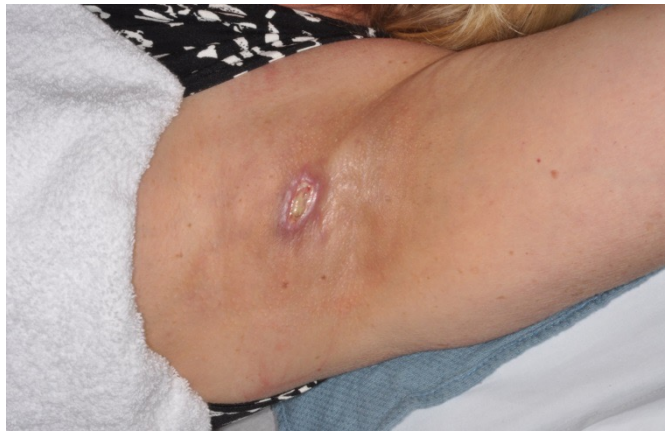
- Compensatory hyperhidrosis
- Pain in the underarm requiring prescription medication
- Small blister or rash in treated area
- Temporary altered sensation or tingling in forearm or fingers (can last several months or long lasting)*
- Weakness or pain in arm or fingers that gradually goes away (can last several months or long lasting)*
- Infection, abscess/ulcer*
- Burns (first, second or third degree possible)*
- Occurrence of cysts; can be long lasting

*In general, if patient experiences rare side effects, treating physician should be contacted.

# Examples of Rare Side Effects



Appearance of a potential blister immediately post-treatment; duration typically a few weeks

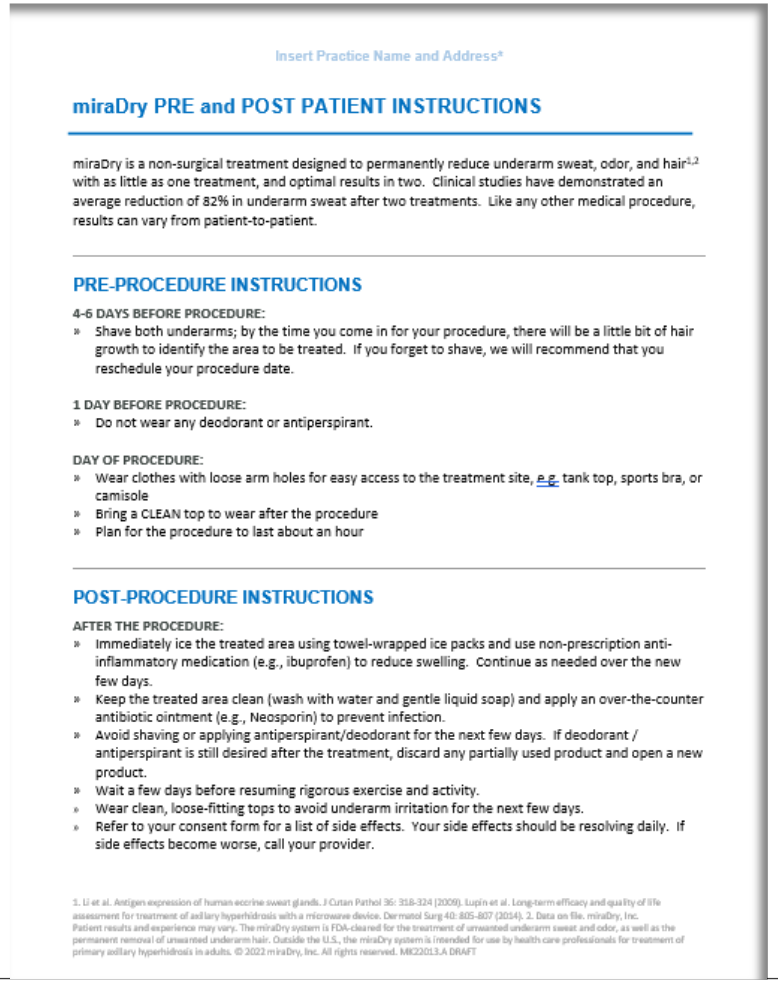


Example of an ulcer which occurred post TX. Antibiotics and wound care prescribed.

Axilla should be kept clean, washing twice daily to minimize infection. Avoid shaving for a few days.

# 6. Tools for Managing Patient Expectations

## Pre and Post Treatment Instructions



Insert Practice Name and Address*

**miraDry PRE and POST PATIENT INSTRUCTIONS**

miraDry is a non-surgical treatment designed to permanently reduce underarm sweat, odor, and hair[1,2] with as little as one treatment, and optimal results in two. Clinical studies have demonstrated an average reduction of 82% in underarm sweat after two treatments. Like any other medical procedure, results can vary from patient-to-patient.

**PRE-PROCEDURE INSTRUCTIONS**

**4-6 DAYS BEFORE PROCEDURE:**
- Shave both underarms; by the time you come in for your procedure, there will be a little bit of hair growth to identify the area to be treated. If you forget to shave, we will recommend that you reschedule your procedure date.

**1 DAY BEFORE PROCEDURE:**
- Do not wear any deodorant or antiperspirant.

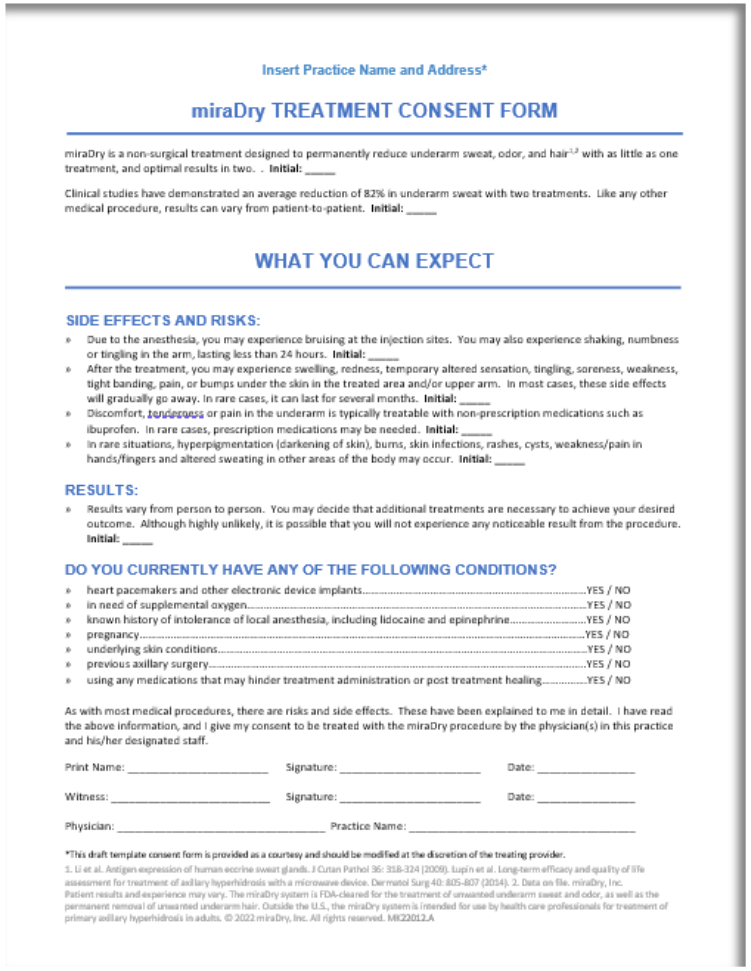
**DAY OF PROCEDURE:**
- Wear clothes with loose arm holes for easy access to the treatment site, e.g. tank top, sports bra, or camisole
- Bring a CLEAN top to wear after the procedure
- Plan for the procedure to last about an hour

**POST-PROCEDURE INSTRUCTIONS**

**AFTER THE PROCEDURE:**
- Immediately ice the treated area using towel-wrapped ice packs and use non-prescription anti-inflammatory medication (e.g., ibuprofen) to reduce swelling. Continue as needed over the new few days.
- Keep the treated area clean (wash with water and gentle liquid soap) and apply an over-the-counter antibiotic ointment (e.g., Neosporin) to prevent infection.
- Avoid shaving or applying antiperspirant/deodorant for the next few days. If deodorant / antiperspirant is still desired after the treatment, discard any partially used product and open a new product.
- Wait a few days before resuming rigorous exercise and activity.
- Wear clean, loose-fitting tops to avoid underarm irritation for the next few days.
- Refer to your consent form for a list of side effects. Your side effects should be resolving daily. If side effects become worse, call your provider.

1. Li et al. Antigen expression of human eccrine sweat glands. J Cutan Pathol 36: 318-324 (2009). Lupin et al. Long-term efficacy and quality of life assessment for treatment of axillary hyperhidrosis with a microwave device. Dermatol Surg 40: 805-807 (2014). 2. Data on file. miraDry, Inc. Patient results and experience may vary. The miraDry system is FDA-cleared for the treatment of unwanted underarm sweat and odor, as well as the permanent removal of unwanted underarm hair. Outside the U.S., the miraDry system is intended for use by health care professionals for treatment of primary axillary hyperhidrosis in adults. © 2022 miraDry, Inc. All rights reserved. MK22013.A DRAFT

## Treatment Consent Form



Insert Practice Name and Address*

**miraDry TREATMENT CONSENT FORM**

miraDry is a non-surgical treatment designed to permanently reduce underarm sweat, odor, and hair[1,2] with as little as one treatment, and optimal results in two. . **Initial:** ____

Clinical studies have demonstrated an average reduction of 82% in underarm sweat with two treatments. Like any other medical procedure, results can vary from patient-to-patient. **Initial:** ____

**WHAT YOU CAN EXPECT**

**SIDE EFFECTS AND RISKS:**
- Due to the anesthesia, you may experience bruising at the injection sites. You may also experience shaking, numbness or tingling in the arm, lasting less than 24 hours. **Initial:** ____
- After the treatment, you may experience swelling, redness, temporary altered sensation, tingling, soreness, weakness, tight banding, pain, or bumps under the skin in the treated area and/or upper arm. In most cases, these side effects will gradually go away. In rare cases, it can last for several months. **Initial:** ____
- Discomfort, tenderness or pain in the underarm is typically treatable with non-prescription medications such as ibuprofen. In rare cases, prescription medications may be needed. **Initial:** ____
- In rare situations, hyperpigmentation (darkening of skin), burns, skin infections, rashes, cysts, weakness/pain in hands/fingers and altered sweating in other areas of the body may occur. **Initial:** ____

**RESULTS:**
- Results vary from person to person. You may decide that additional treatments are necessary to achieve your desired outcome. Although highly unlikely, it is possible that you will not experience any noticeable result from the procedure. **Initial:** ____

**DO YOU CURRENTLY HAVE ANY OF THE FOLLOWING CONDITIONS?**
- heart pacemakers and other electronic device implants.....YES / NO
- in need of supplemental oxygen.....YES / NO
- known history of intolerance of local anesthesia, including lidocaine and epinephrine.....YES / NO
- pregnancy.....YES / NO
- underlying skin conditions.....YES / NO
- previous axillary surgery.....YES / NO
- using any medications that may hinder treatment administration or post treatment healing.....YES / NO

As with most medical procedures, there are risks and side effects. These have been explained to me in detail. I have read the above information, and I give my consent to be treated with the miraDry procedure by the physician(s) in this practice and his/her designated staff.

Print Name: _____ Signature: _____ Date: _____

Witness: _____ Signature: _____ Date: _____

Physician: _____ Practice Name: _____

*This draft template consent form is provided as a courtesy and should be modified at the discretion of the treating provider.

1. Li et al. Antigen expression of human eccrine sweat glands. J Cutan Pathol 36: 318-324 (2009). Lupin et al. Long-term efficacy and quality of life assessment for treatment of axillary hyperhidrosis with a microwave device. Dermatol Surg 40: 805-807 (2014). 2. Data on file. miraDry, Inc. Patient results and experience may vary. The miraDry system is FDA-cleared for the treatment of unwanted underarm sweat and odor, as well as the permanent removal of unwanted underarm hair. Outside the U.S., the miraDry system is intended for use by health care professionals for treatment of primary axillary hyperhidrosis in adults. © 2022 miraDry, Inc. All rights reserved. MK22012.A

# Questions

1. What is miraDry indicated for?
2. What is the efficacy of miraDry?
3. What is the average sweat reduction after 2 treatments using energy level 3?
4. Any contraindications?
5. Name 4 most common side effects
6. 2 examples of rare reports
7. Pre procedure, when do patients have to shave? Why?
8. What is the post treatment recommendation?

# PART 2: DETAILED SYSTEM OVERVIEW

miraDry®

# SECTION 7:
# MIRADRY SYSTEM AND COMPONENTS

# miraDry System


bioTip
(attached to Handpiece)

miraDry Handpiece

miraDry Cellular Antenna
(only freshConnect consoles)

miraDry Console Body

Main Switch
(located in back)

Touch Screen
(swivel/tilt)

Blue Indicator Light

Emergency Shut-off

Power Switch

Connector from Console to Handpiece

Casters
(for locking)

# miraDry System Components

## Console

- Range of energy levels
- Easy to use custom interface

## Handpiece

- Delivers energy; 10mm x 30mm zone of therapy
- Active cooling to protect upper dermis

## bioTip

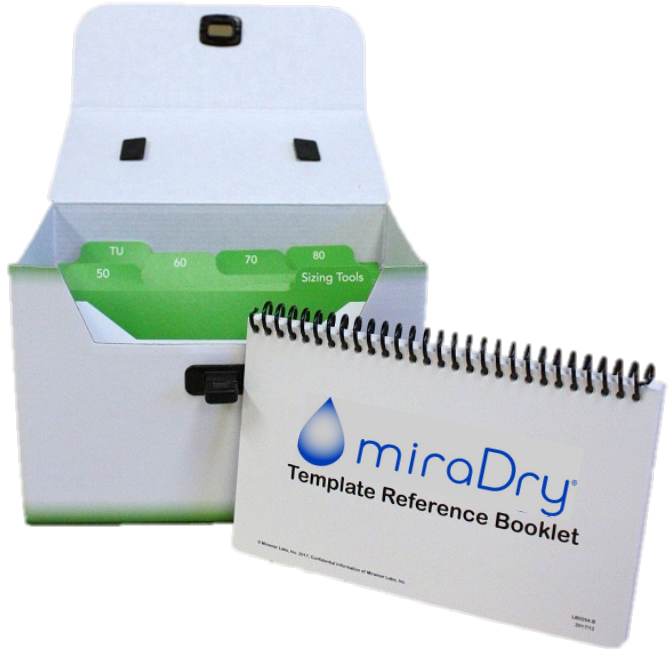
- Stabilizes tissue during therapy cycle
- Protects patient/equipment


# miraDry Armrest

- Positions the patient's shoulders and arms for comfort
- Patient's hand should be positioned just above the head
- Arm and underarm position should be relaxed and not flexed or hyper-extended during treatment
- Appropriate positioning reduces risk for potential side effects (e.g., tight banding, nerve related effects, etc.)
- Should be cleaned with alcohol after each use

# miraDry Template System

- Template System is used to apply the temporary skin markings
- Wide selection of sizes offer flexibility to treat patients of all sizes


**Contents:**

- Sizing Tools (2 sizes)
- Skin Transfers (4 Templates: 11 sizes)
- Touch-Up Transparencies (TU 4x2)
- Template Reference Booklet including instructions for use

# Questions

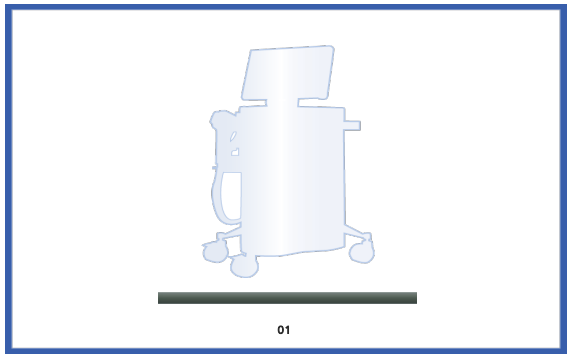

- How many energy levels are there?
- How many full axilla sizes are available in the Template System?
- Name the 3 components of the miraDry system.

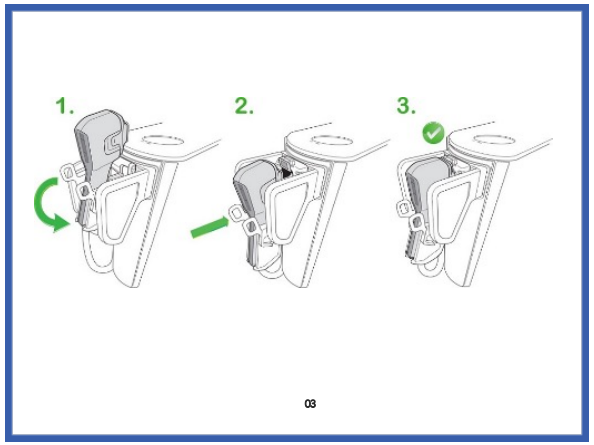
# SECTION 8:
# MIRADRY SYSTEM PREPARATION AND PROCEDURE

# Power On Self Test (POST)

Power On- Green Button

Self-Test (every time)




Note: Handpiece must be in holster down position for self test

# miraDry System Operation

Welcome Screen

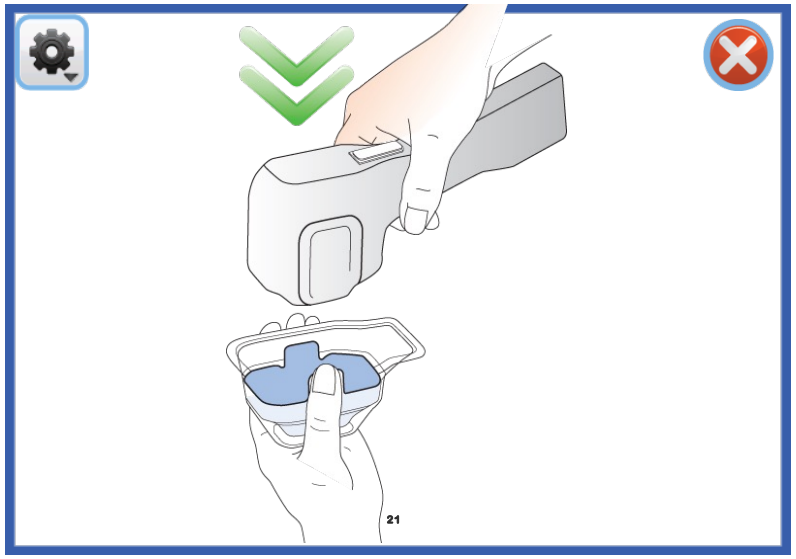

Use arrows to navigate forwards and backwards

Important Note:

Turn on the console FIRST and wait until you are able to see the welcome screen before proceeding to patient preparation

# bioTip Attachment

1. Remove tray seal and leave bioTip in tray

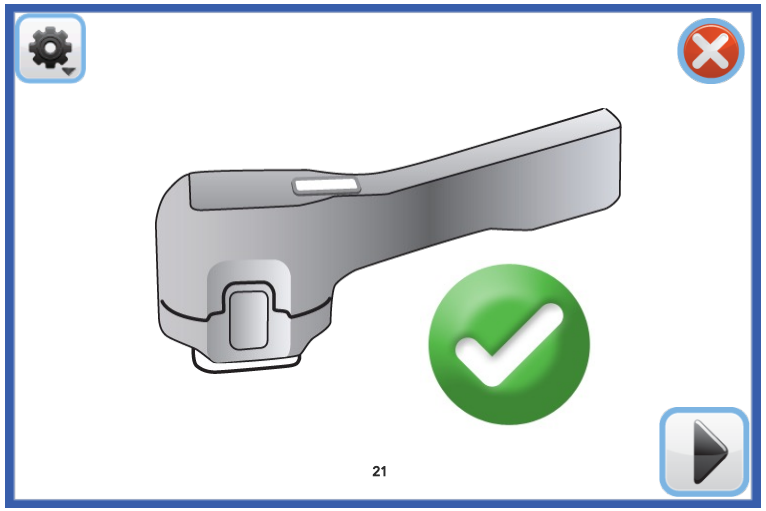

2. Remove Handpiece from holster

# bioTip Attachment

3. Attach Handpiece to the bioTip; use firm and even pressure

4. Listen for magnetic engagement and wait until the green circle with check mark appears on screen
5. Return Handpiece to holster

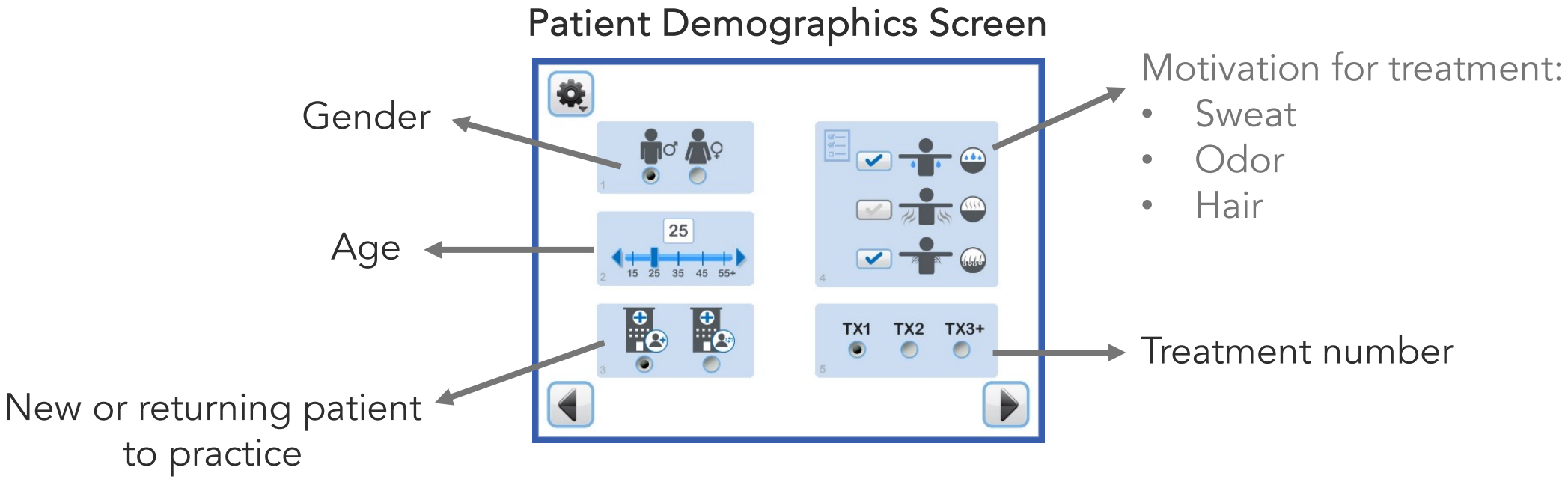
Correct Placement




bioTip will be active for 3 hours when treatment is started

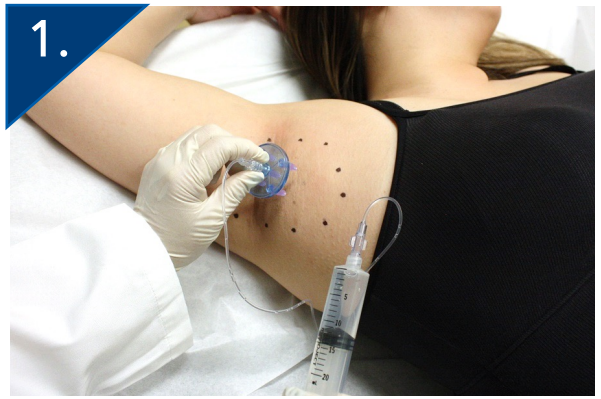
# miraDry System Operation

**This screen only applies to systems with freshConnect**



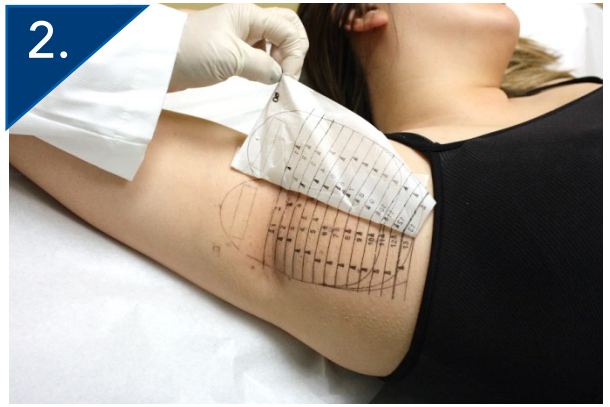

**Note:** Must respond to all 5 questions to proceed to treatment

# miraDry Procedure Overview



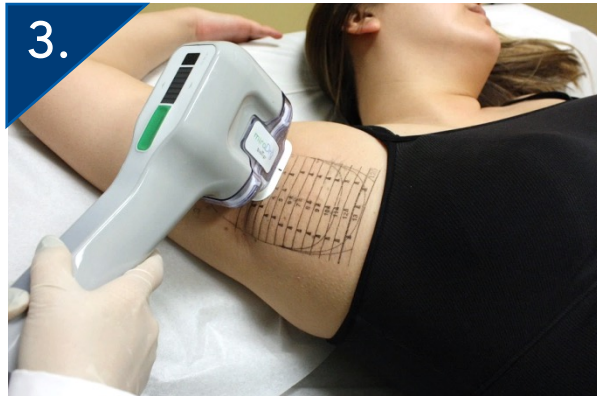

## Numb It

Local anesthetic is administered prior to treatment




## Mark It

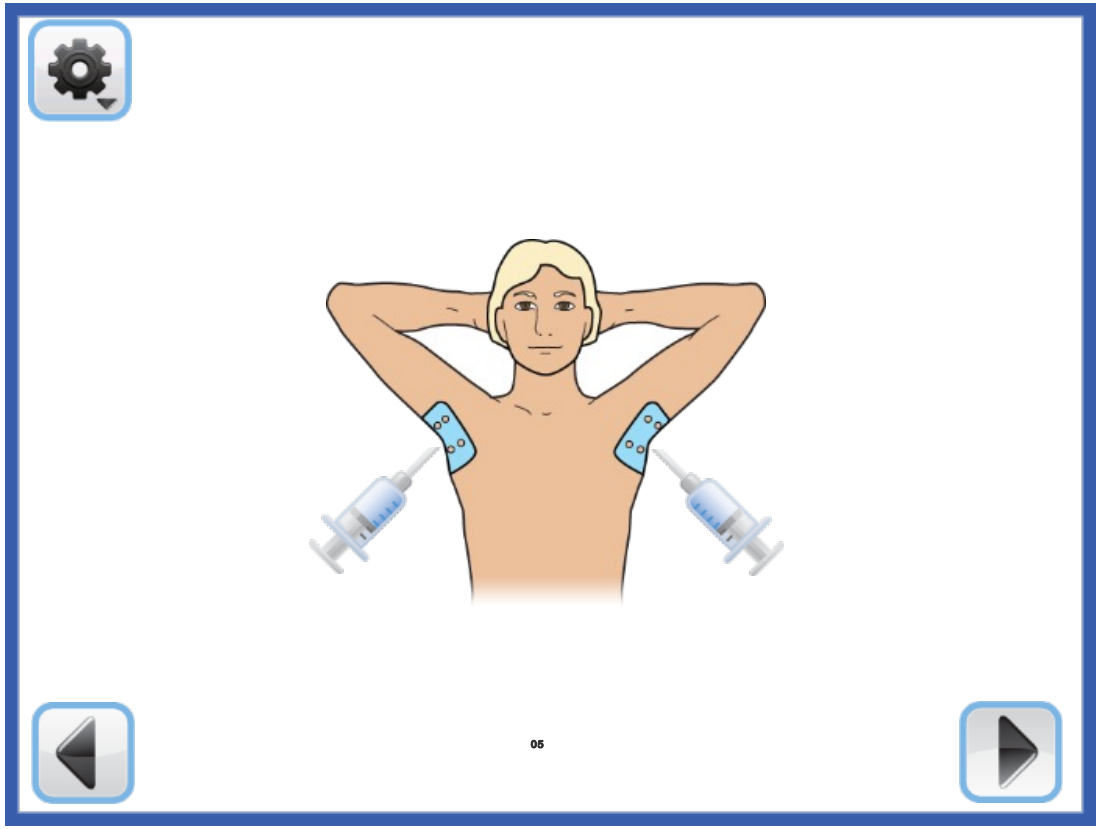
Apply the template to guide the trained user




## Treat It

Treat the area through a series of guided prompts

# Local Anesthesia Delivery – Confirmation Pop Up



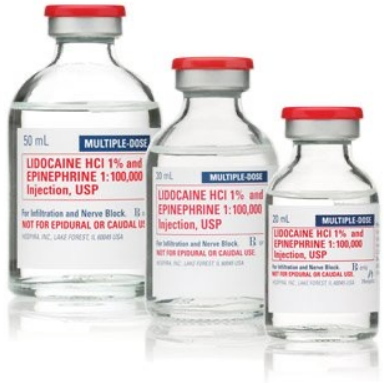
# What is High Volume Anesthesia (HVA)?

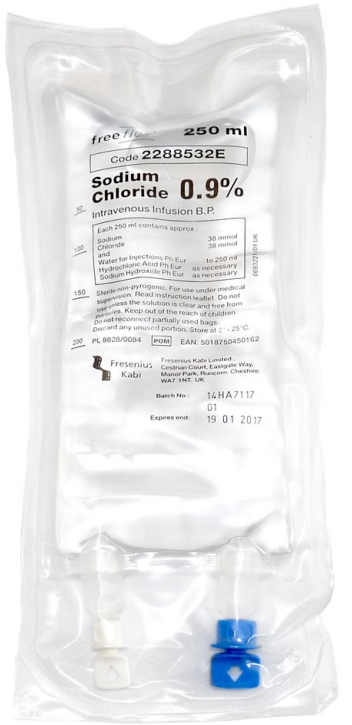
- High Volume Anesthesia (HVA), also known as tumescent anesthesia, is the practice of injecting a dilute solution of local anesthesia (in normal saline) combined with epinephrine and sodium bicarbonate into tissue. In the underarm, the volume amount helps to create a greater separation between the top of the skin and the underlying structures, pushing the nerve bundle branch farther away from the energy.

NOTE: Pain management is ultimately at the discretion of the treating physician.

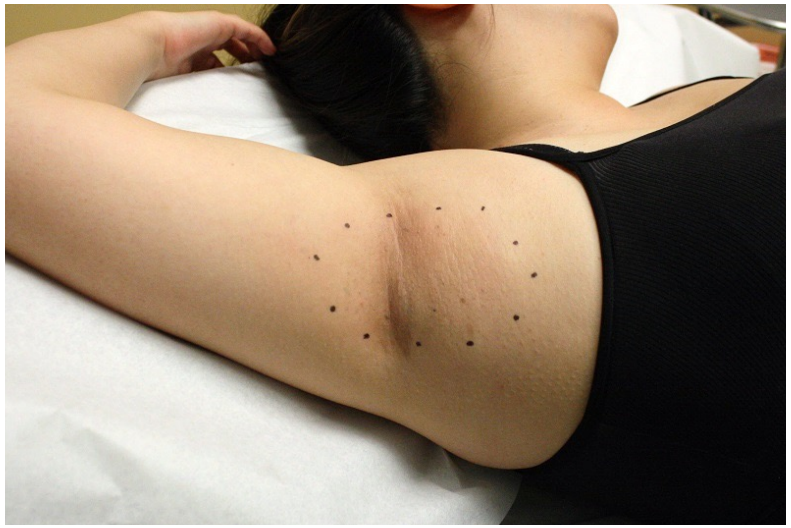
# High Volume Anesthesia Solution Mixture

| | Volume |
|---|---|
| Normal Saline | 250 mL |
| 1% Lidocaine with Epinephrine (1:100,000) | 50 cc |
| Sodium Bicarbonate (if desired) | 2.5 cc |

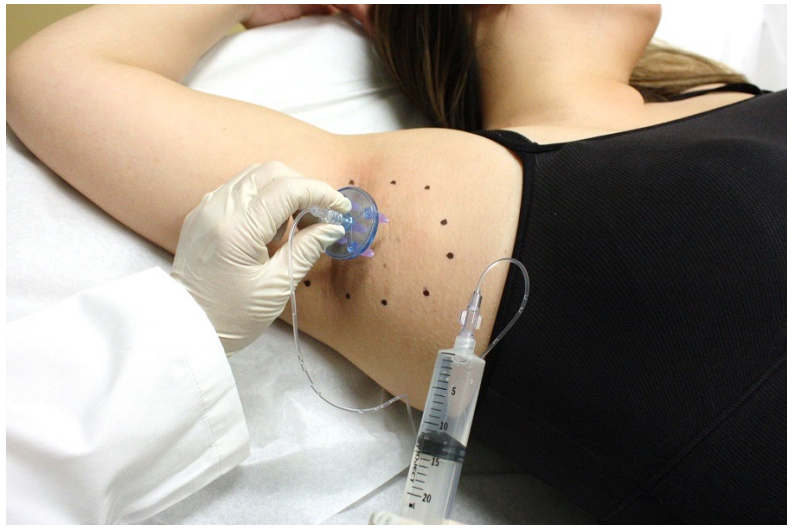


# Numb It



- Outline treatment area using marker (sizing tool can be used for guidance)
- Disinfect treatment area using chlorhexidine (e.g., Hibiclens®) or povidone-iodine (e.g., Betadine®)



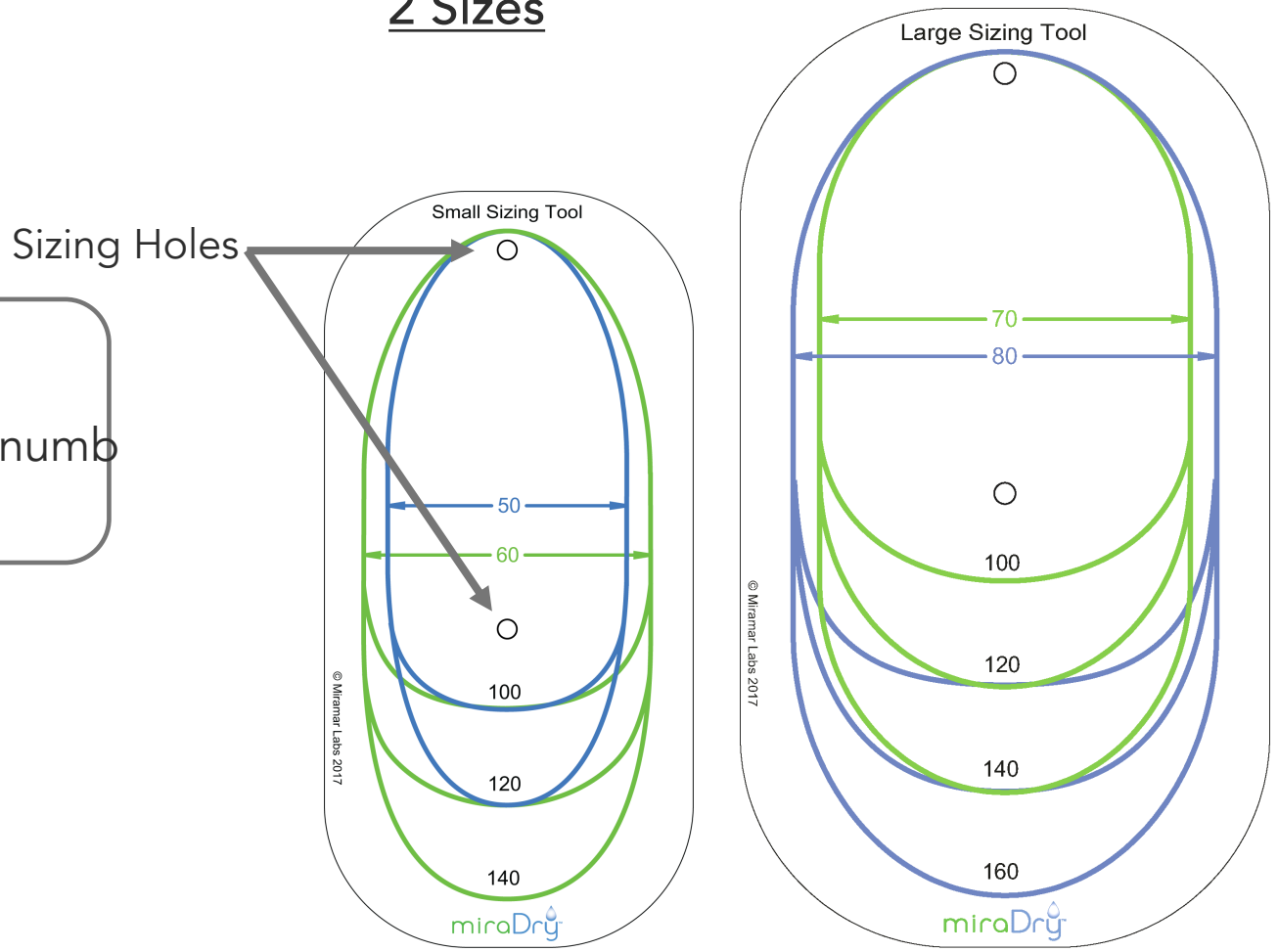
- Administer local anesthesia using syringe adapter
- Maintain clean technique during administration (e.g., clean underarm with chlorhexidine before every injection and minimize touching underarm with hand or glove)

Note: If patient experiences a shooting pain to elbow/hands during injection, DO NOT INJECT

# Sizing Tools

Use Sizing Tools to approximate the area to numb

## 2 Sizes




| Full Axilla Template Size (mm) |
|---|
| 50x100 |
| 50x120 |
| 60x100 |
| 60x120 |
| 60x140 |
| 70x100 |
| 70x120 |
| 70x140 |
| 80x120 |
| 80x140 |
| 80x160 |

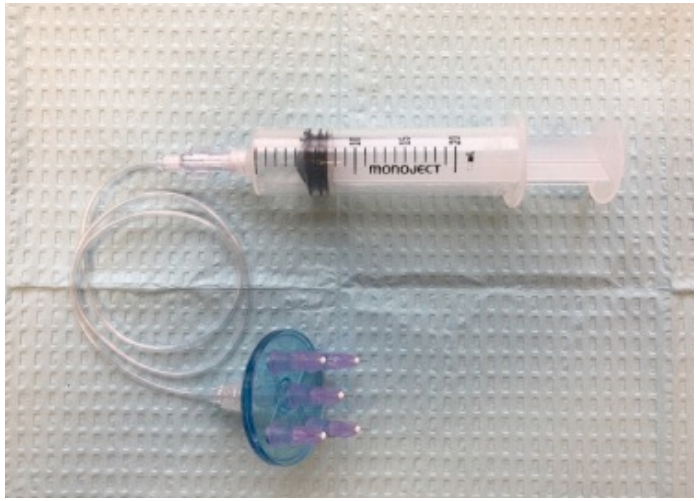
# Syringe Adapter and Accessories

20cc Syringe

Extension Tube

Syringe Adapter

Attach one end of the extension tube to a 20cc syringe (filled with solution) and the opposite end to the syringe adapter



# Assembling the Syringe Adapter

Attach the end of each needle to the needle holder as follows:

Needle Holder

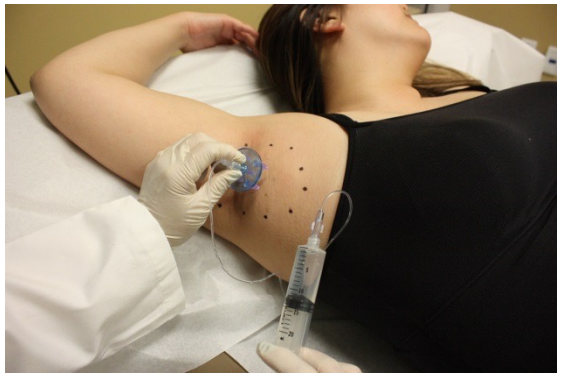
+

Five 30G 4mm Needle

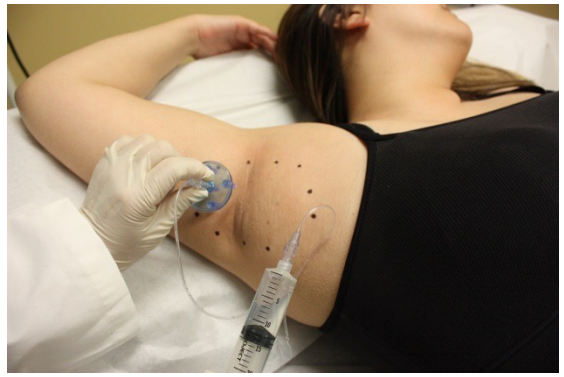
=

Syringe Adapter

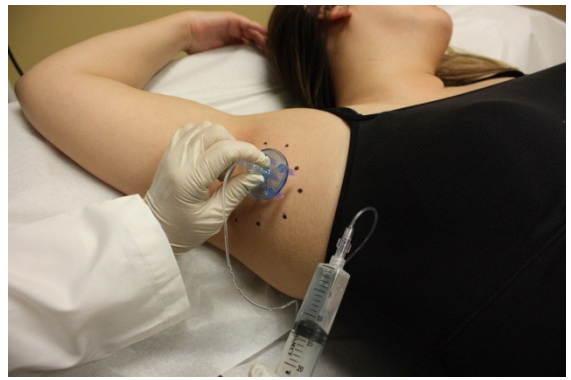
# Numb Treatment Area



Center



Superior Midline



Inferior Midline

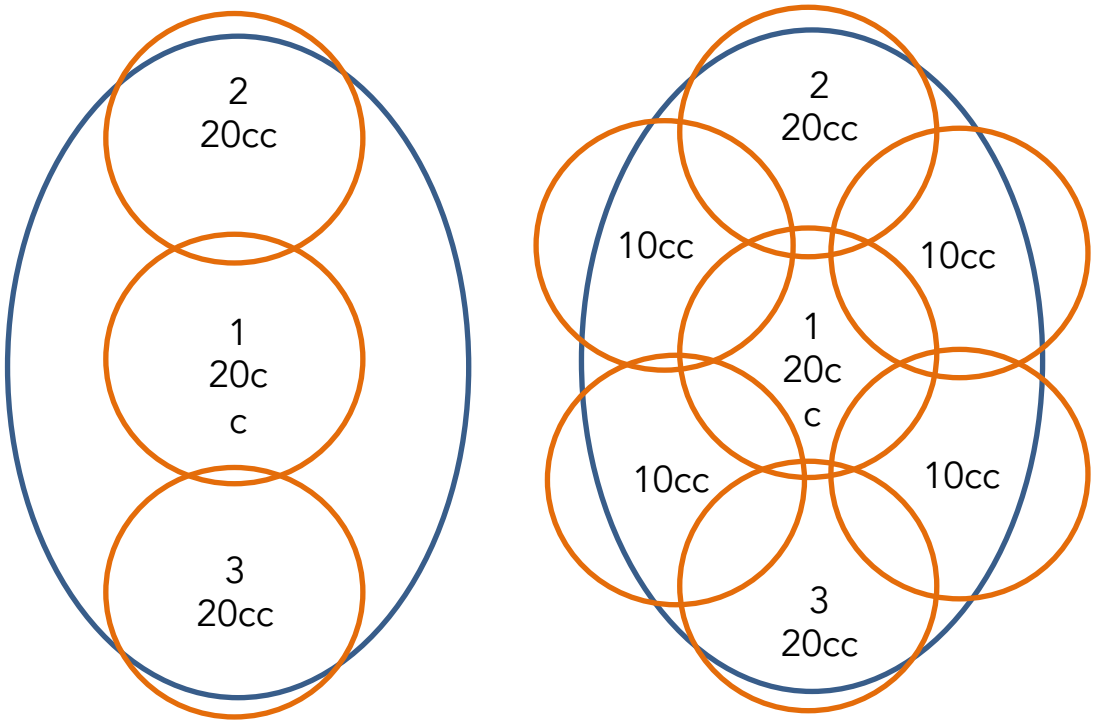
Administer approximately 20cc bolus of solution to each area above

Note:

- If patient feels shooting pain to elbow/hands during needle insertion, DO NOT INJECT SOLUTION. Remove syringe adapter, reposition and continue.
- Minimize touching underarm with hands and/or gauze and ensure area is cleaned with chlorhexidine or povidone-iodine prior to each injection.

# Numb Treatment Area

- The next placements can be placed in lateral and anterior portions of treatment area, injecting approximately 10cc for each placement
- Always administer the TOTAL minimum recommended volume for a given treatment size
- Additional volume can be administered at the discretion of the treating physician
- Depending on size of axilla, volume at each injection site should be calculated




Recommended placement order





miraDry

# HVA Volume Recommendation Chart

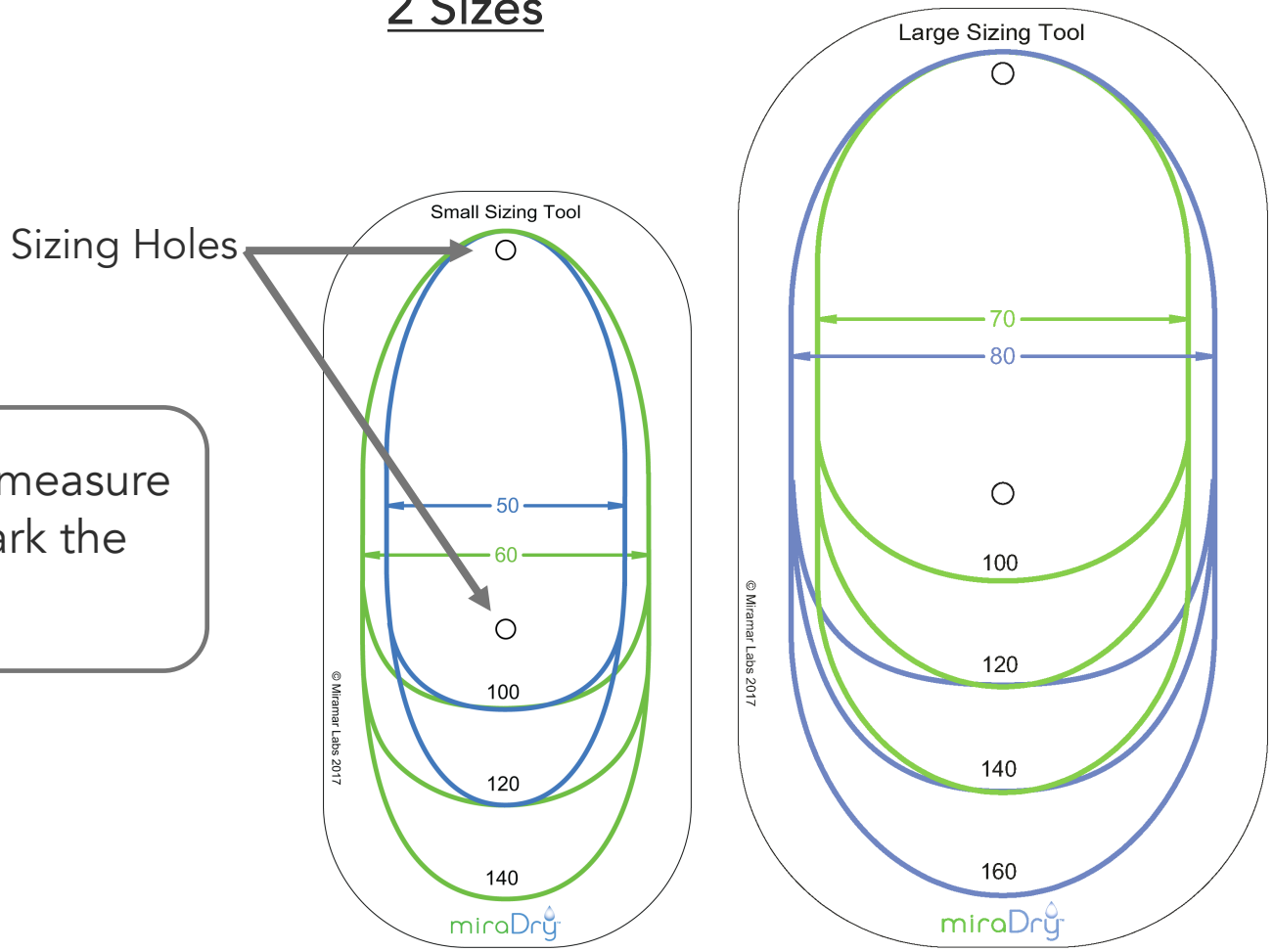
| | Approximate Volume Mix PER Axilla (cc) | Approximate Volume Mix for BOTH Axilla (cc) |
|---|---|---|
| 50x100 | 70 | 140 |
| 50x120 | 90 | 180 |
| 60x100 | 70 | 140 |
| 60x120 | 90 | 180 |
| 60x140 | 110 | 220 |
| 70x100 | 90 | 180 |
| 70x120 | 110 | 220 |
| 70x140 | 120 | 240 |
| 80x120 | 120 | 240 |
| 80x140 | 120 | 240 |
| 80x160 | 140 | 280 |

- An approximate length and width of the treatment area will help determine the needed volume for anesthesia administration
- Consider patient weight is within limit of volume
- Refer to corresponding HVA volume recommendation chart. Administering the recommended volume (minimum) may reduce the potential for nerve interaction

# Sizing Tools

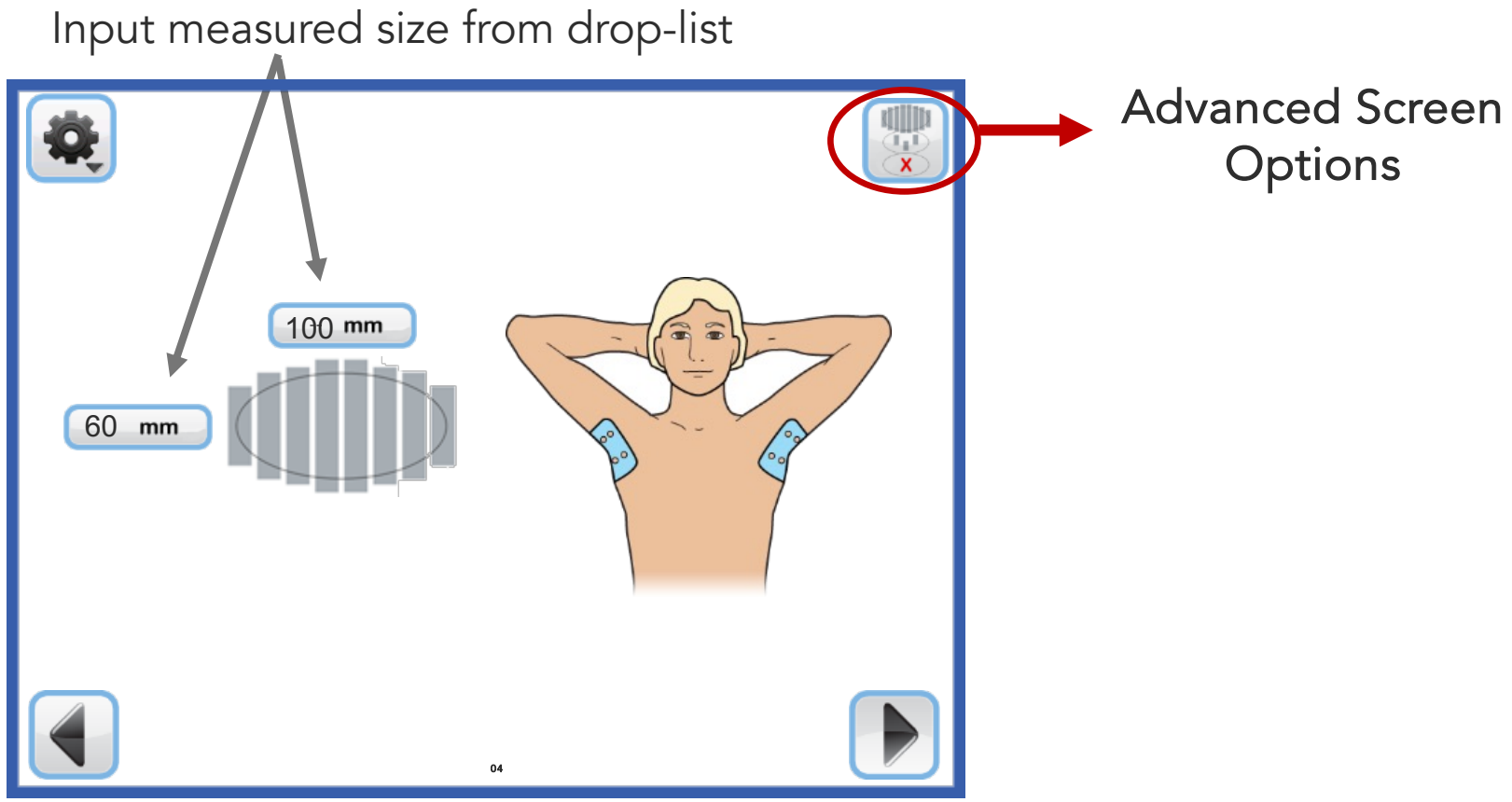
Use Sizing Tools to re-measure treatment area and mark the sizing holes

## 2 Sizes

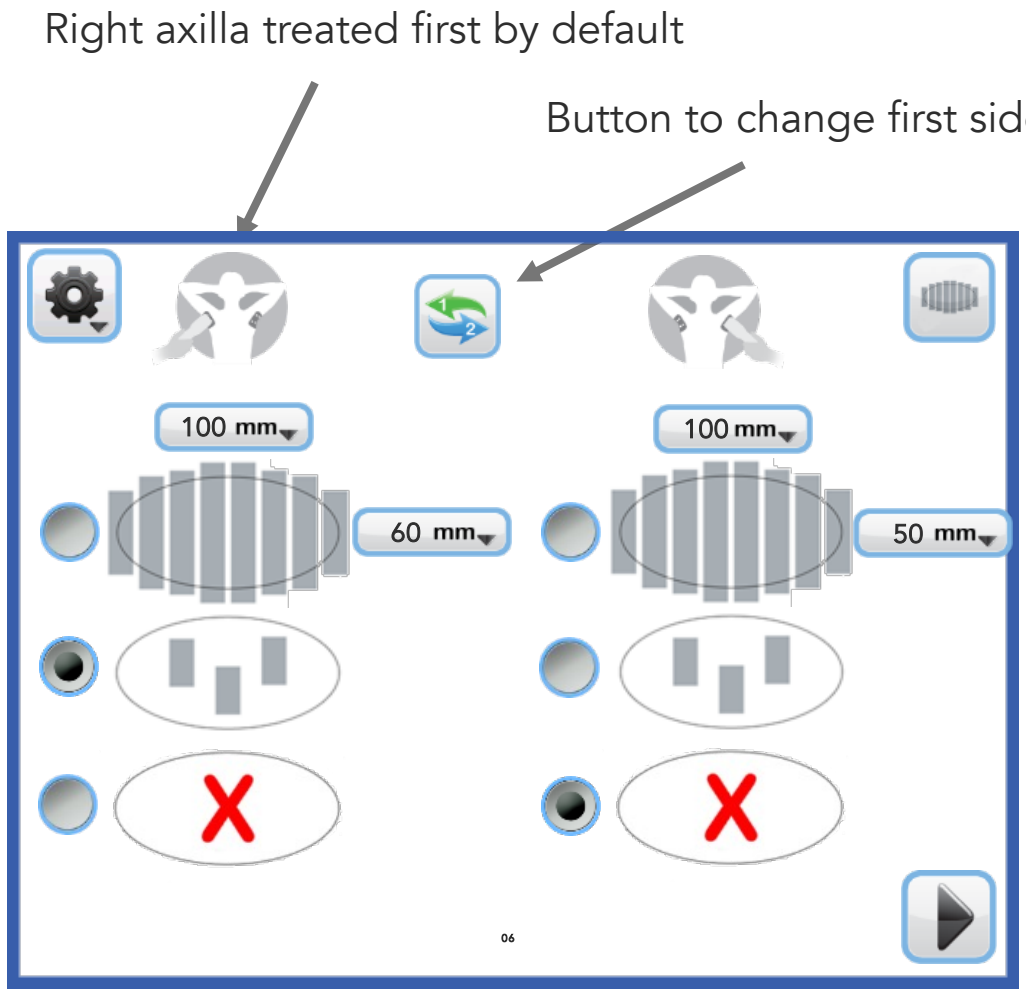



| Full Axilla Template Size (mm) |
|---|
| 50x100 |
| 50x120 |
| 60x100 |
| 60x120 |
| 60x140 |
| 70x100 |
| 70x120 |
| 70x140 |
| 80x120 |
| 80x140 |
| 80x160 |

# Template Size Selection

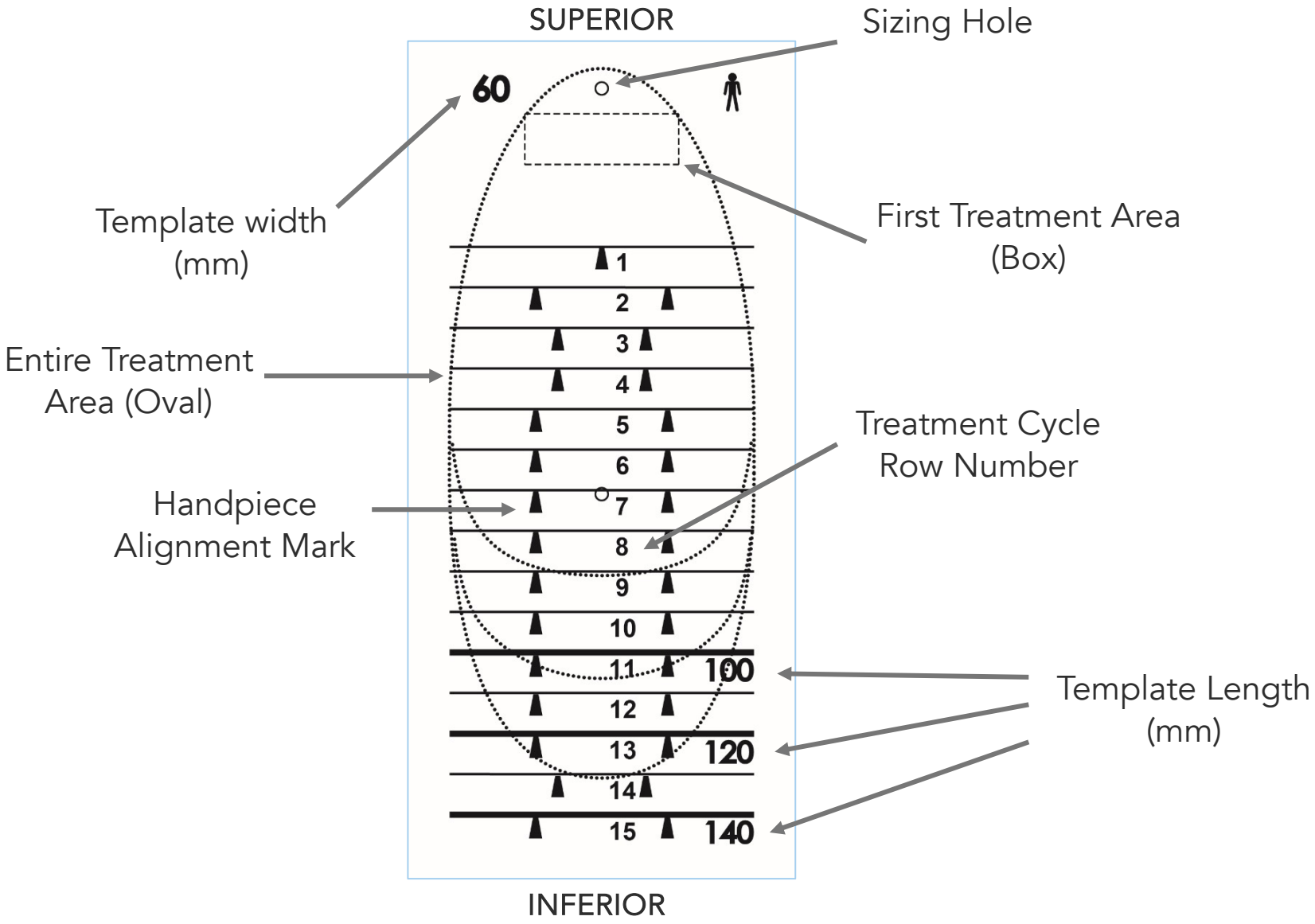


# Template Size Selection – Advanced Screen Options

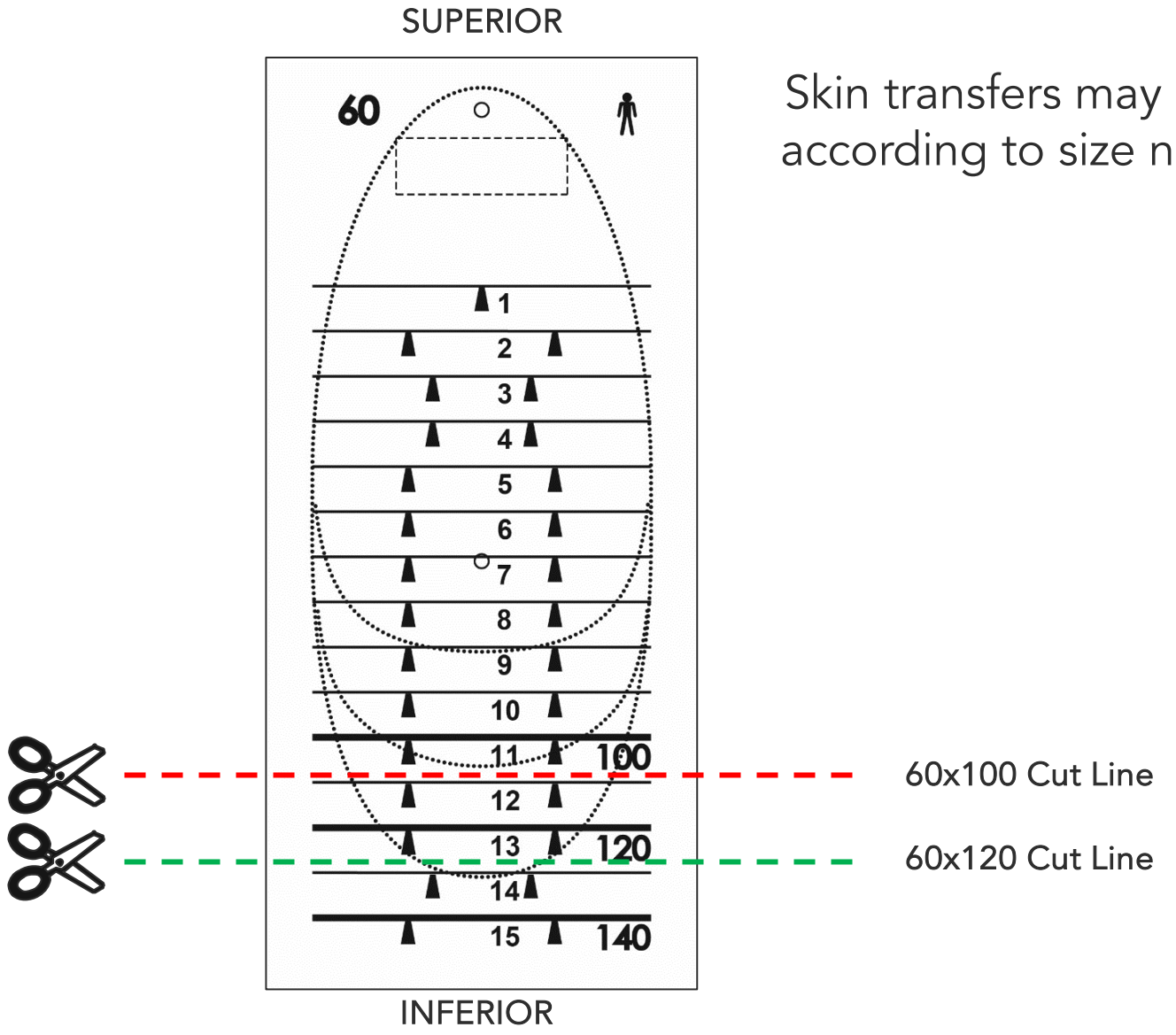



- Can select to start on Right or Left
- Enter different size templates
- Other options that can be selected:
  - Guided/Full treatment
  - Touch up usually for TX3+
  - No treatment

# Sizing Tools

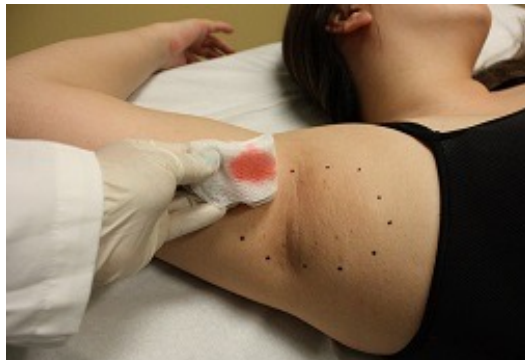


# Template Design

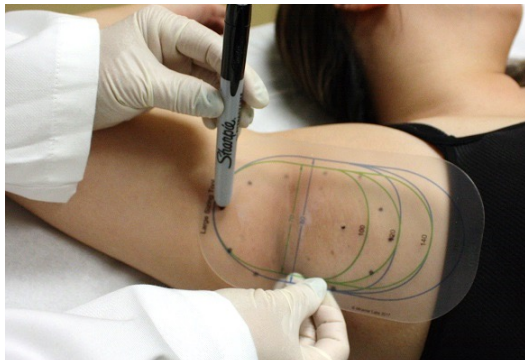



Skin transfers may be cut according to size needed

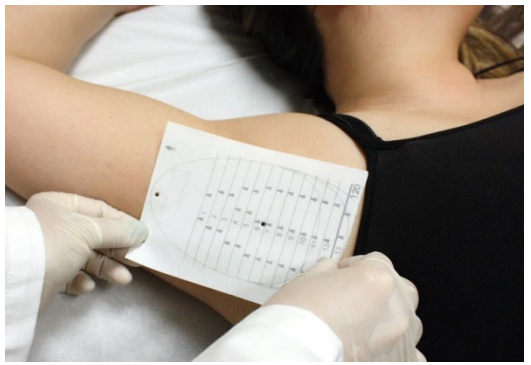
# Apply Template



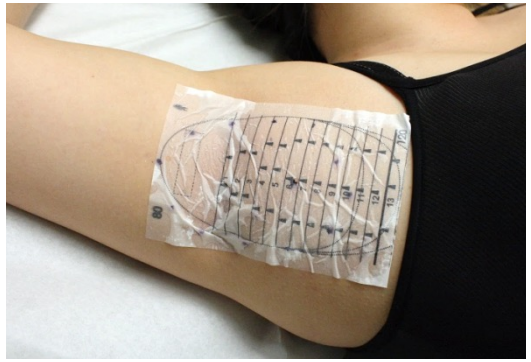
Clean the area with chlorhexidine



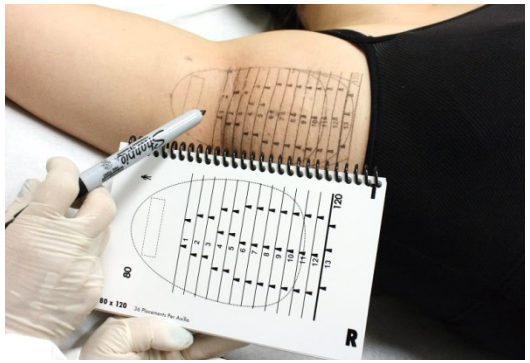
Mark the two sizing holes through the sizing tool



Align marks on axilla to holes on transfer template

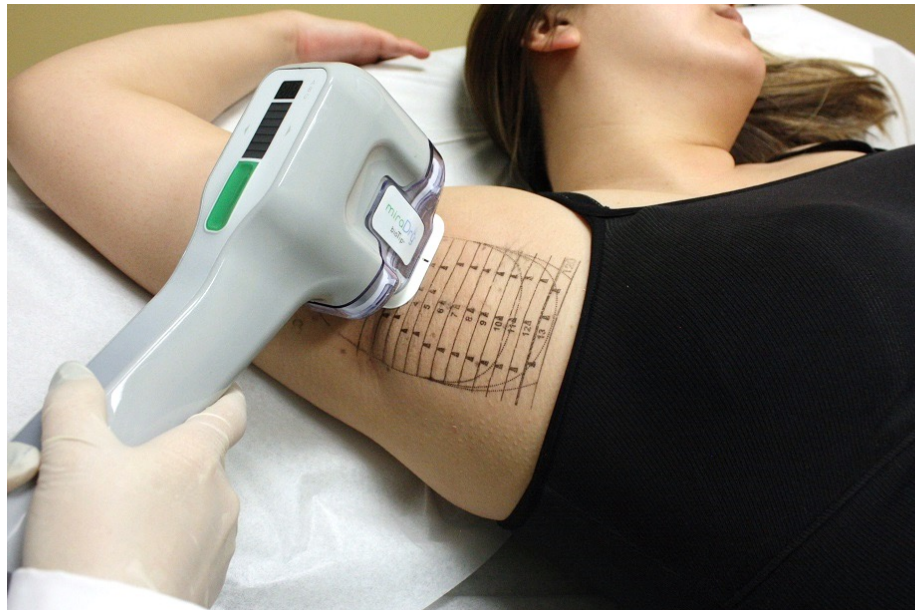


With print side down, blot using 70% alcohol dampened gauze

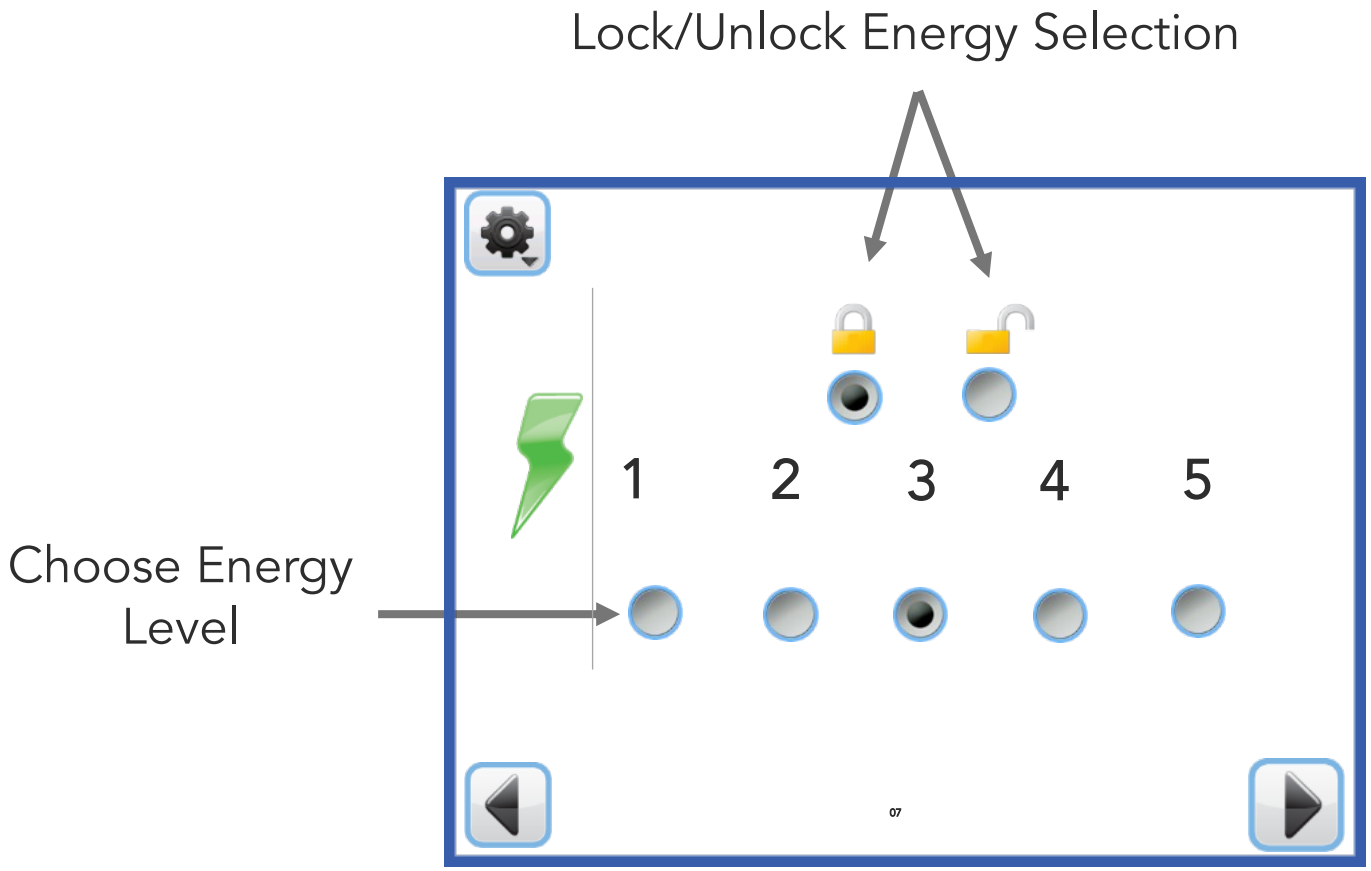


If needed, refer to Template Reference Book and use markers to touch-up any missing features

# Treat with miraDry System



# Energy Level Selection



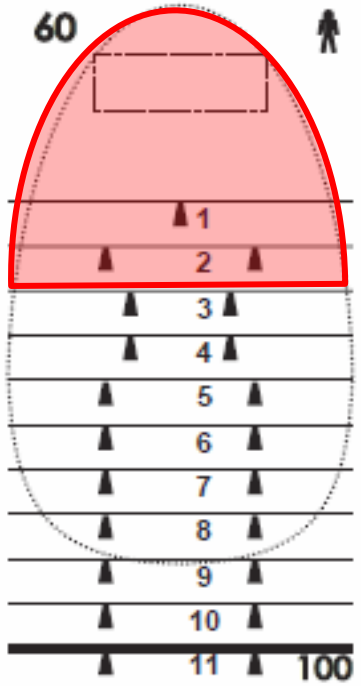

Energy level selection is always at the discretion of the treating physician

# Energy Level Selection

If energy selection is locked, regardless of energy level selected:

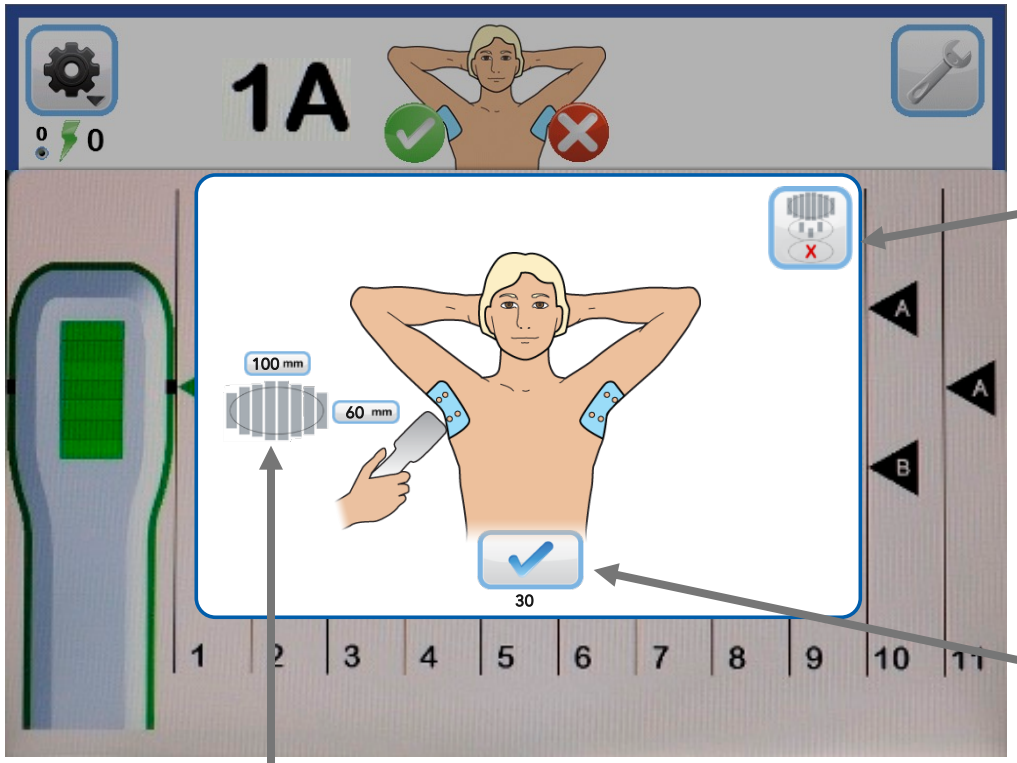
- First few rows for any given template size will automatically receive Energy Level 1
- Remainder of rows will receive the SELECTED Energy Level
- To keep energy locked or unlocked is always at the discretion of the treating physician

| Template length – Total number of rows | # of rows set at Energy Level 1 |
|---|---|
| 100mm – 11 rows | 4 rows |
| 120mm – 13 rows | 4 rows |
| 140mm – 15 rows | 5 rows |
| 160mm – 17 rows | 6 rows |




**Note:** If energy selection is unlocked, all rows of the template will be treated at selected Energy Level

# Treatment Screen – Confirmation Pop Up

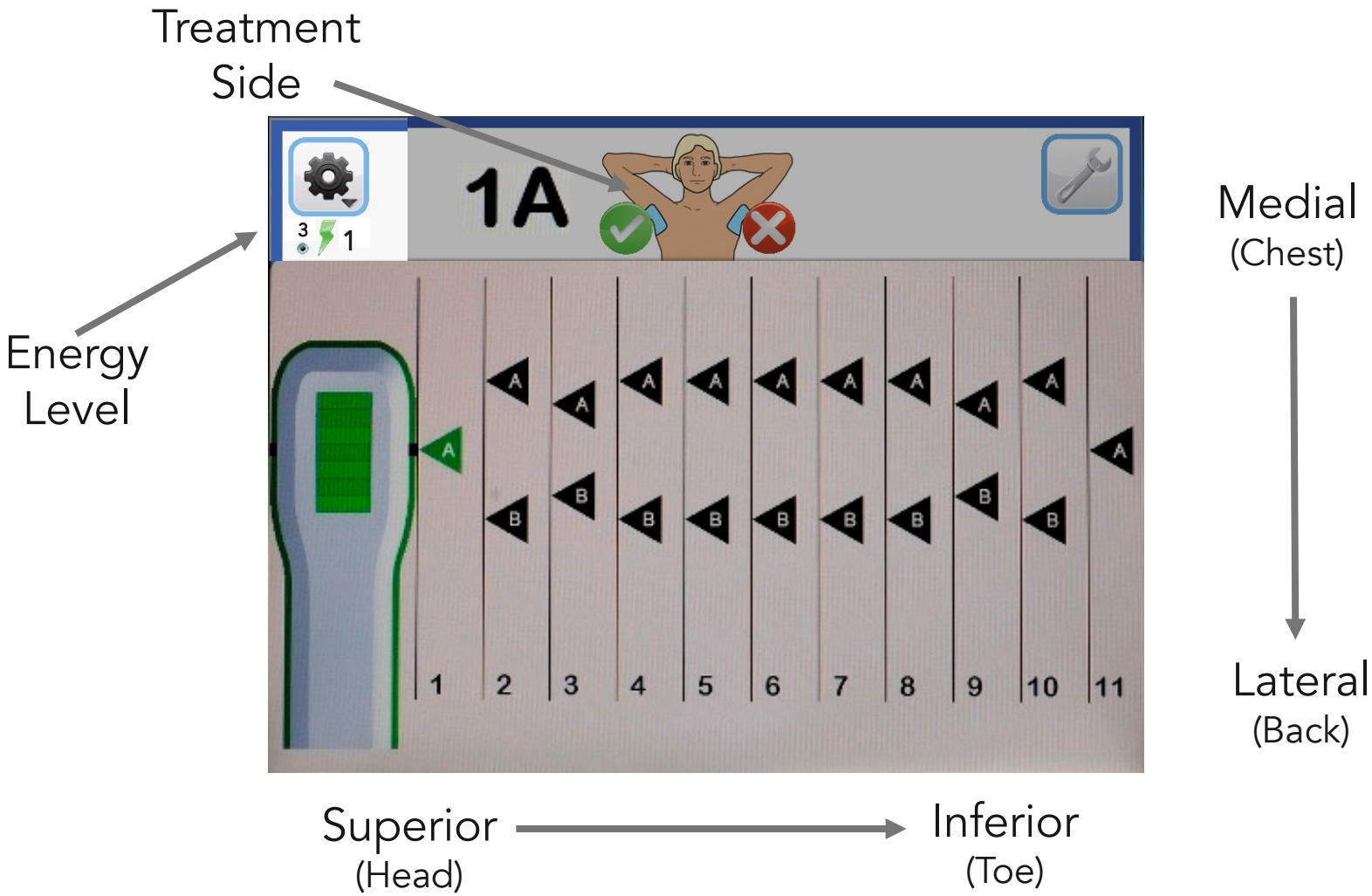



Ability to change template size or choose right or left arm

Press to confirm

Chosen template size

# Treatment Screen



# Confirmation to Patient Prior to First Placement

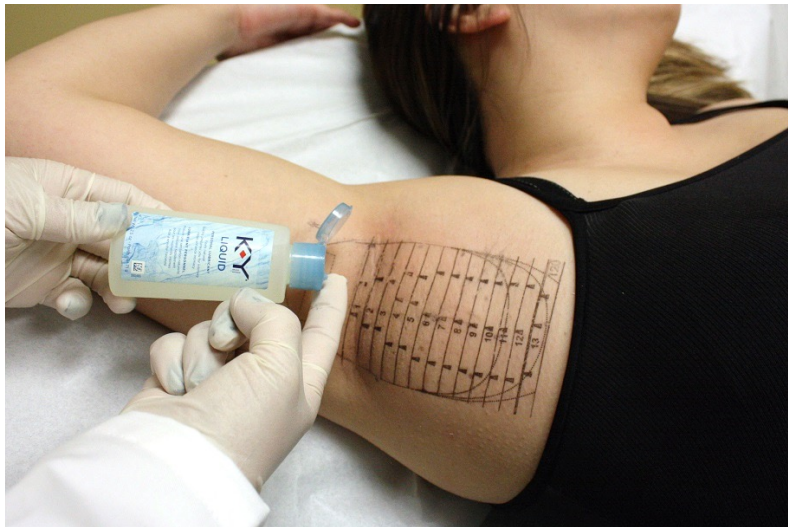
- Inform patient that they may feel warmth or heat in the axilla during energy delivery
  - Indication that anesthesia did not absorb well in the area. Not a safety concern but patient comfort may be compromised.
  - If desired, you may inject a little more anesthesia in the affected area. Wait at least 1 minute prior to resuming treatment.

- Inform patient that if they feel a shooting pain, tingling, or heat sensation to their elbow or hands to let you know immediately
  - If patient informs you during energy delivery phase, then immediately terminate energy delivery for that placement by pressing the Handpiece switch. It will go directly into post-cool phase.
  - Proceed normally to the next placement and continue treatment.
  - This may occur in patients with very shallow, large nerves. Patients with little to no axillary fat may have higher likelihood of symptoms. First 3 or 4 rows of the template will have higher likelihood of shallow nerves.

# Lubricant Application

KY® Liquid or similar
(in ingredients and viscosity)

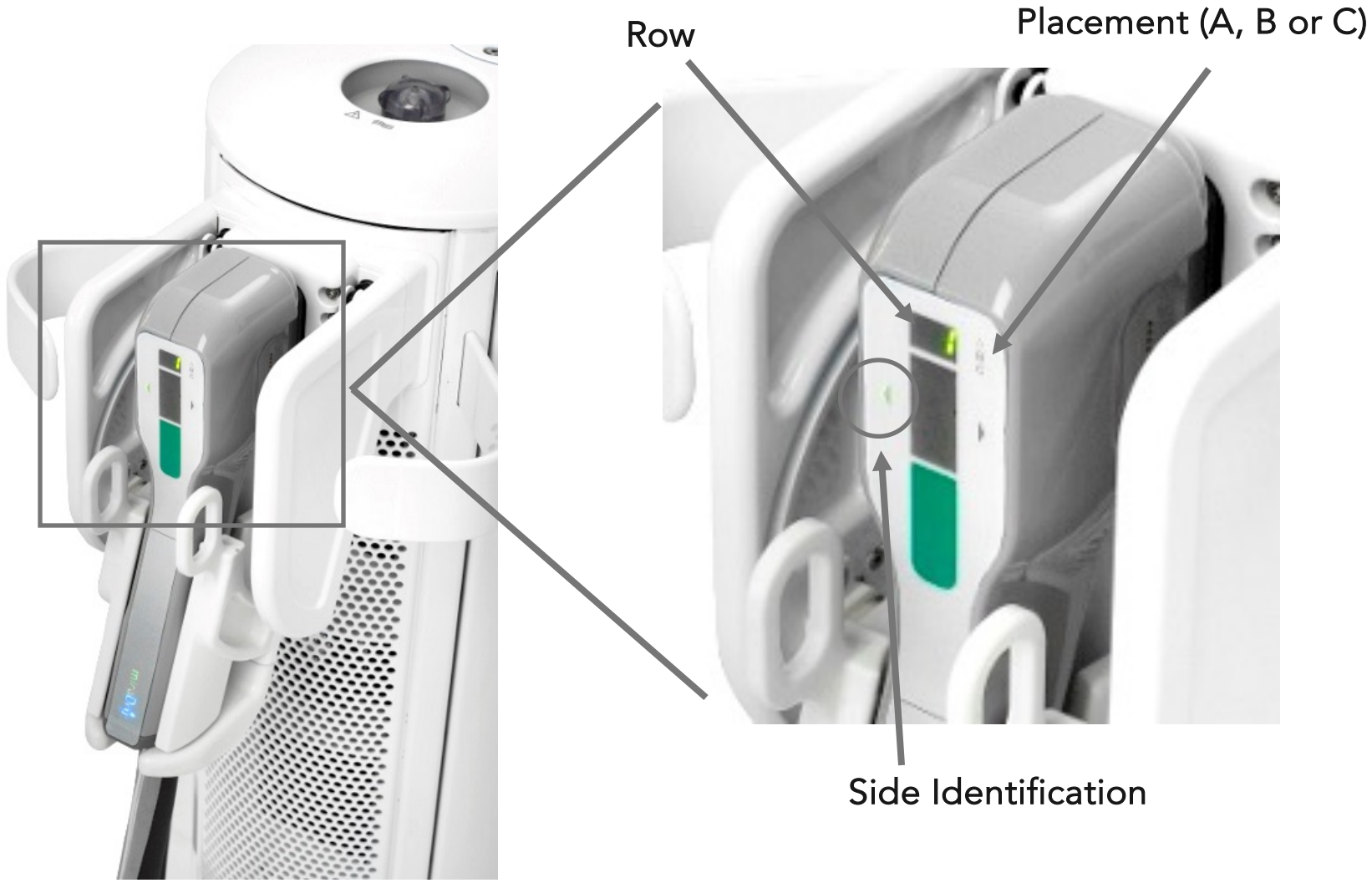
- Ensures proper seal between bioTip and axilla
- Very thin layer (pea size)
    - Too much could block vacuum and/or cause burn
    - Too little could prevent proper suction




**NOTE:** Never use ultrasound gel or laser/IPL coupling gel. Such gels are not designed to be lubricants (e.g., they tend to be thicker) and may cause thermal injury if used in large amounts.

If not using KY® Liquid, similar lubricant should have similar ingredients and viscosity as KY® Liquid

# Handpiece LED



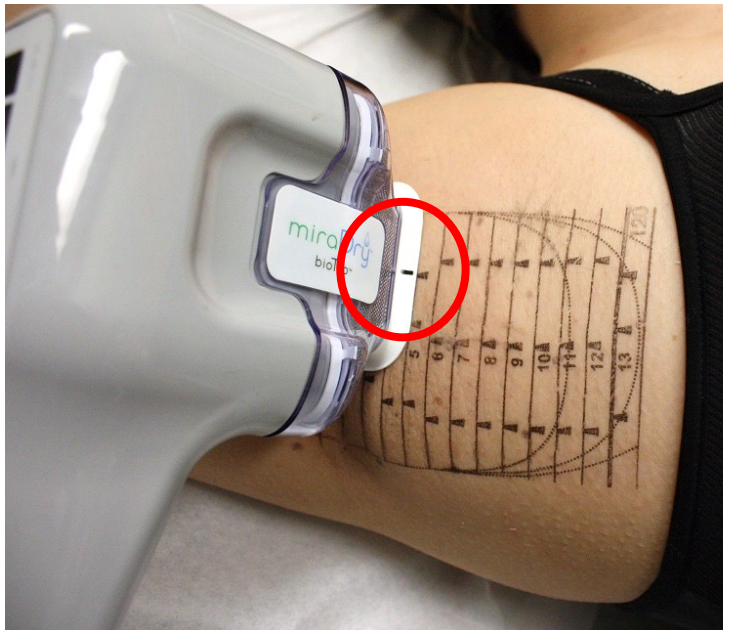
# miraDry Procedure

## For each placement

- Align the edge of the bioTip skirt with the alignment line on the template
- Align black tick mark on the bioTip with tick mark on the template

Right Axilla

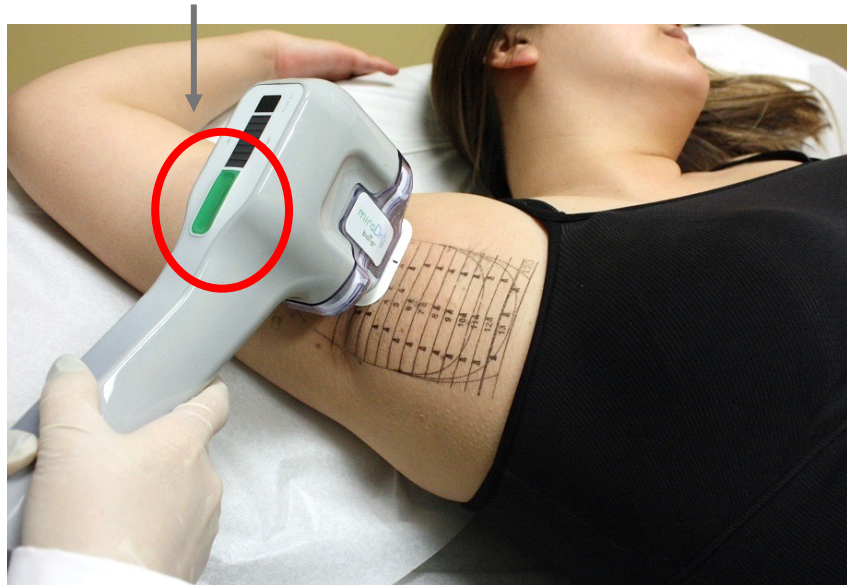
Align right edge of



# miraDry Procedure

- Alert patient to inform the clinician if he/she feels any sensation during energy delivery
- Ensure entire bioTip skirt is in contact with skin
- Start the cycle
  - Press green button on handpiece
  - Press again to stop treatment if necessary
- Each placement cycle has 3 phases
  1. Vacuum Acquisition
  2. Energy Delivery with Cooling
     - Energy ON
     - Cooling of skin surface
  3. Post-Cool
     - Energy OFF
     - Tissue remains held in vacuum
     - Cooling maintained after energy delivery

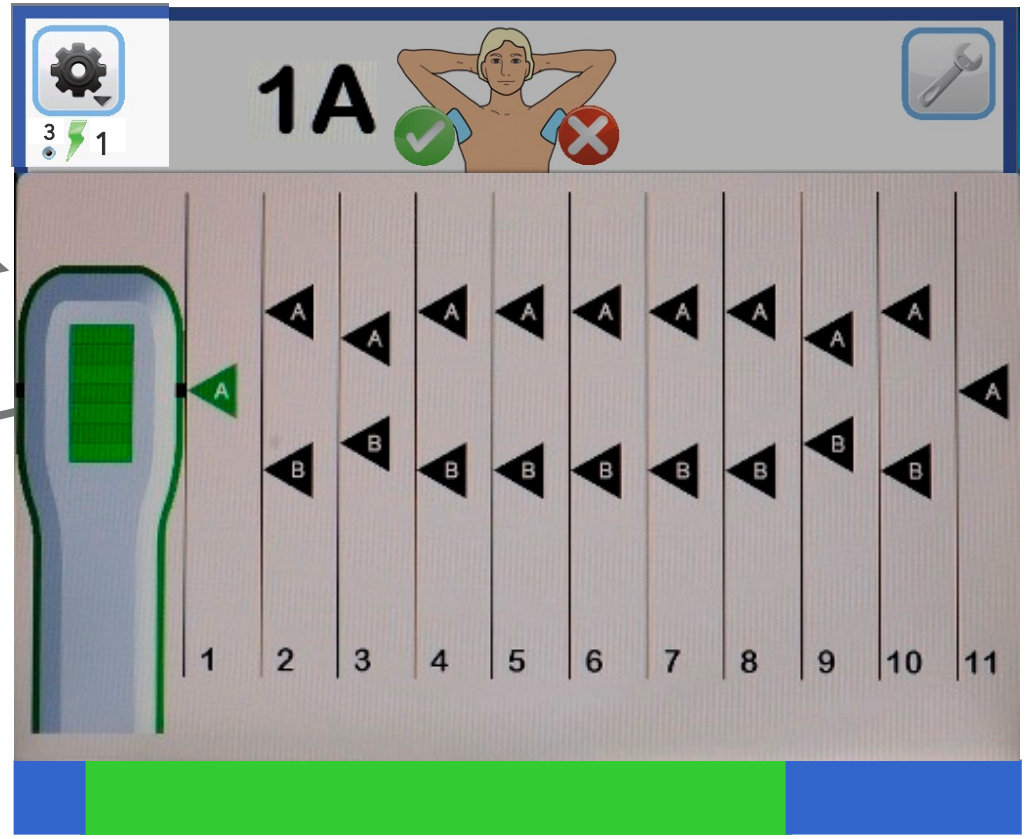
Handpiece Switch



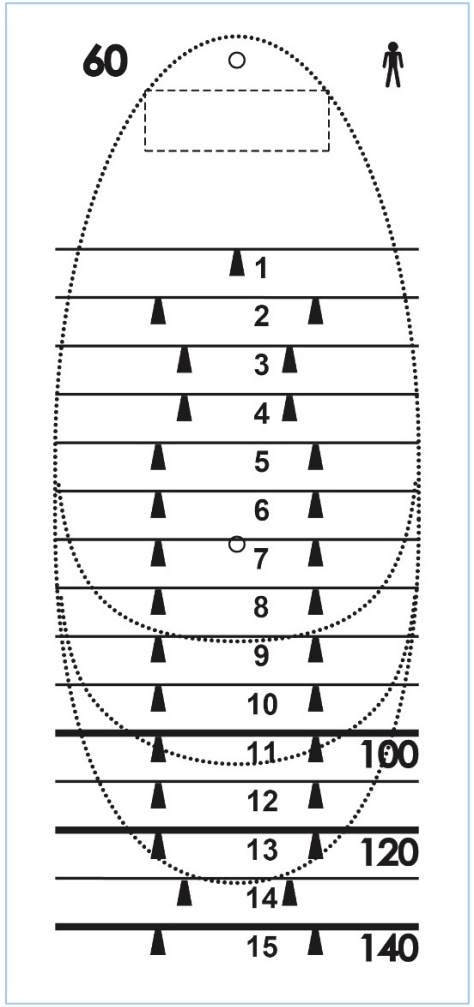
# miraDry Procedure

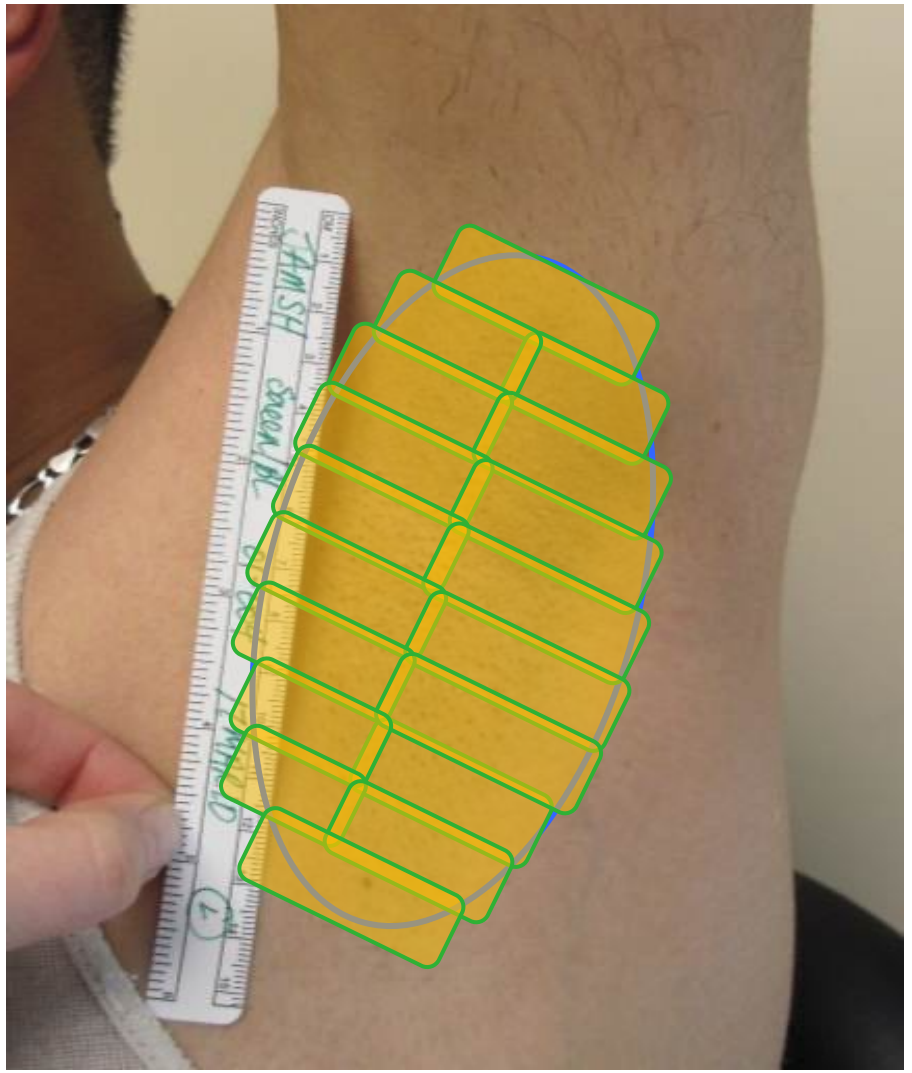
**GREEN Outline**
- Good Vacuum (Treatment Cycle)
- Idle (Ready Position)

**Temperature Profiles**
- Yellow = Heating
- Orange = Heating
- Green = Body Temp
- Blue = Cool

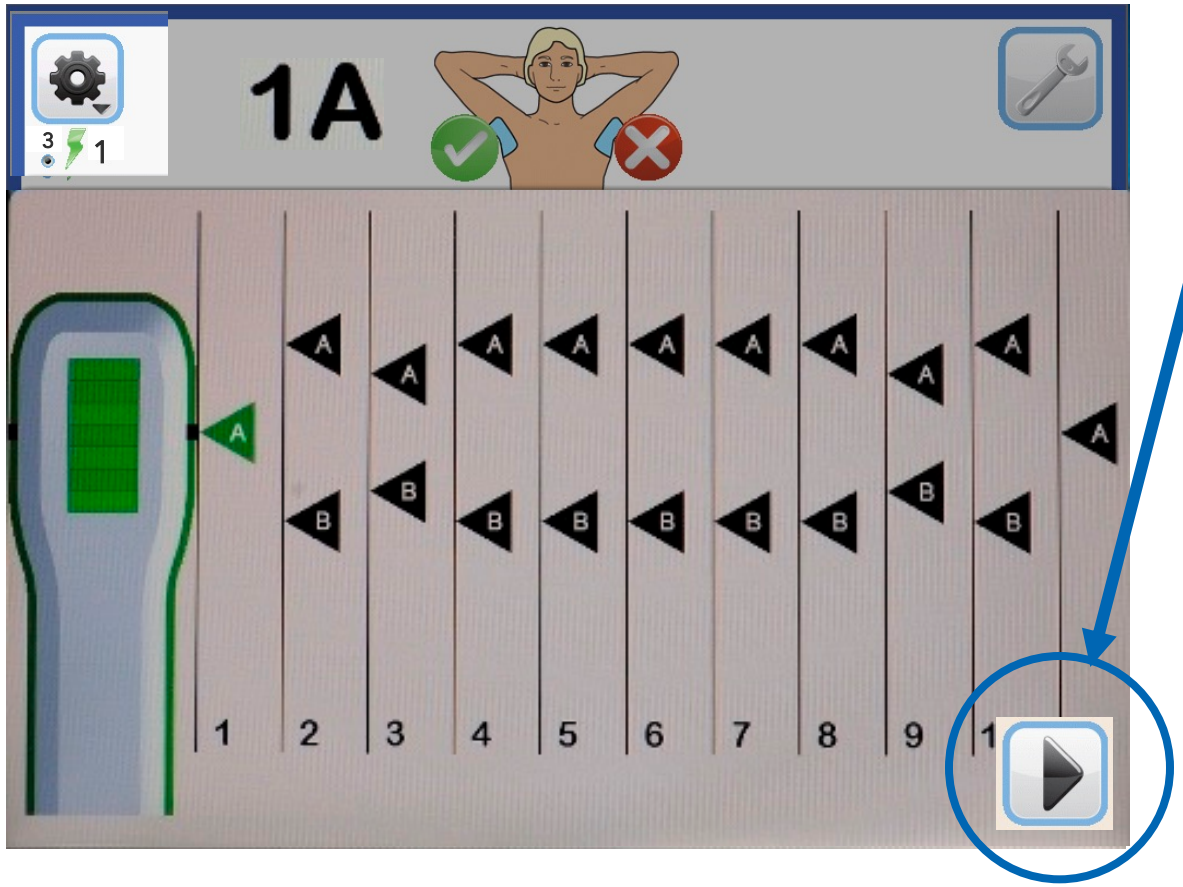


# Template Coverage



# miraDry Procedure

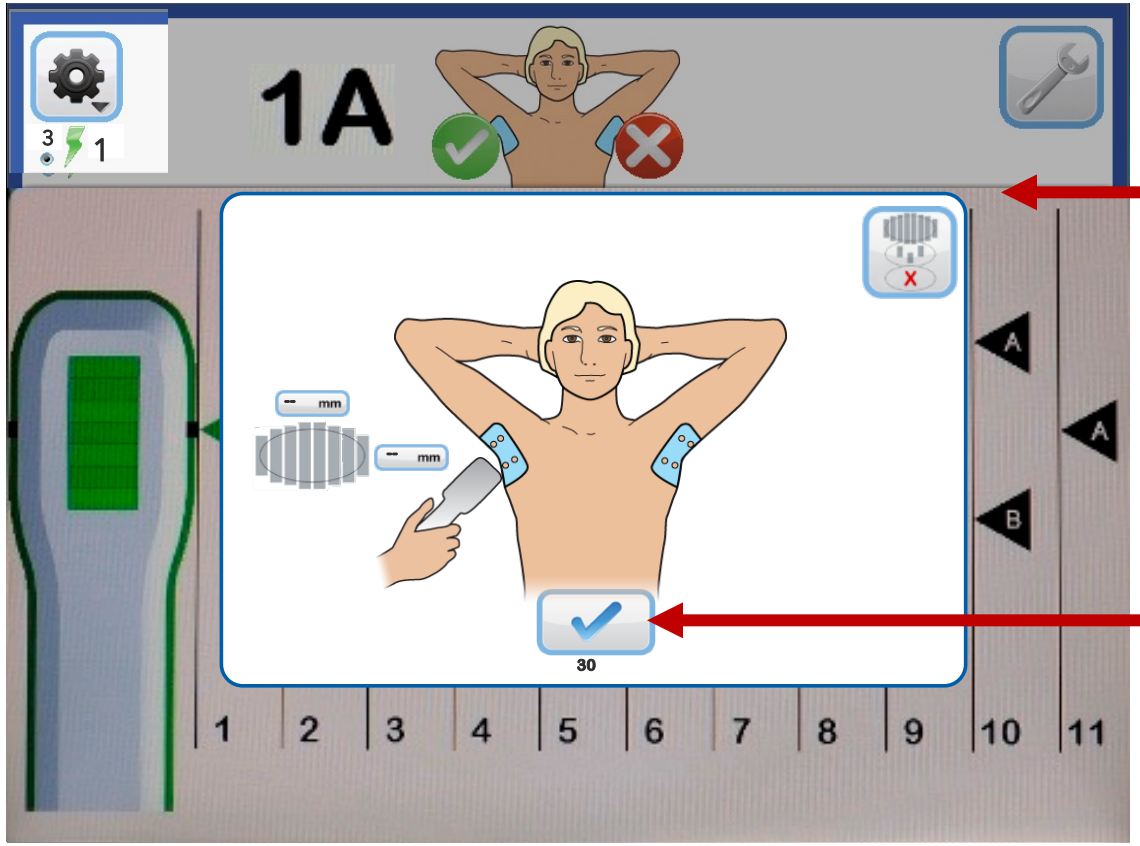



First side complete. Press to continue.

Treat any missed placements before continuing.

Once the treatment has been advanced to the other side, the system cannot go back.

# miraDry Procedure




Option to change template size

**OR**

Press when ready to start the other side

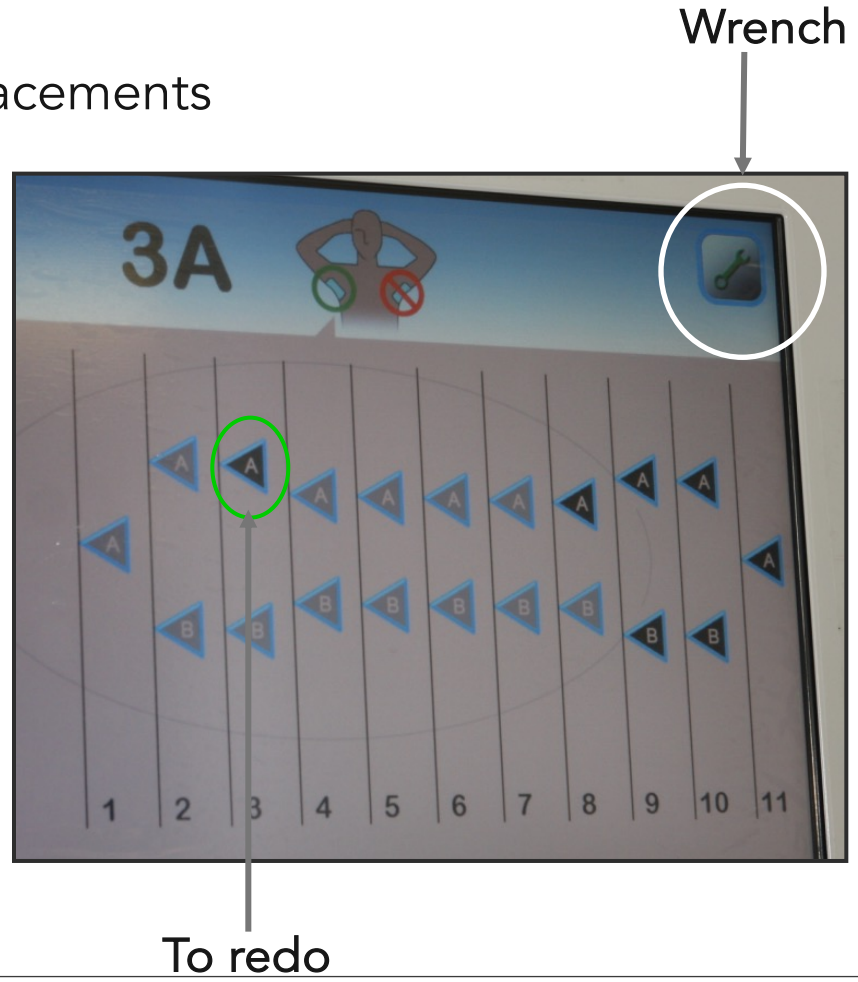
# miraDry Procedure

## Skipping Placements

miraDry system allows you to skip specific placements

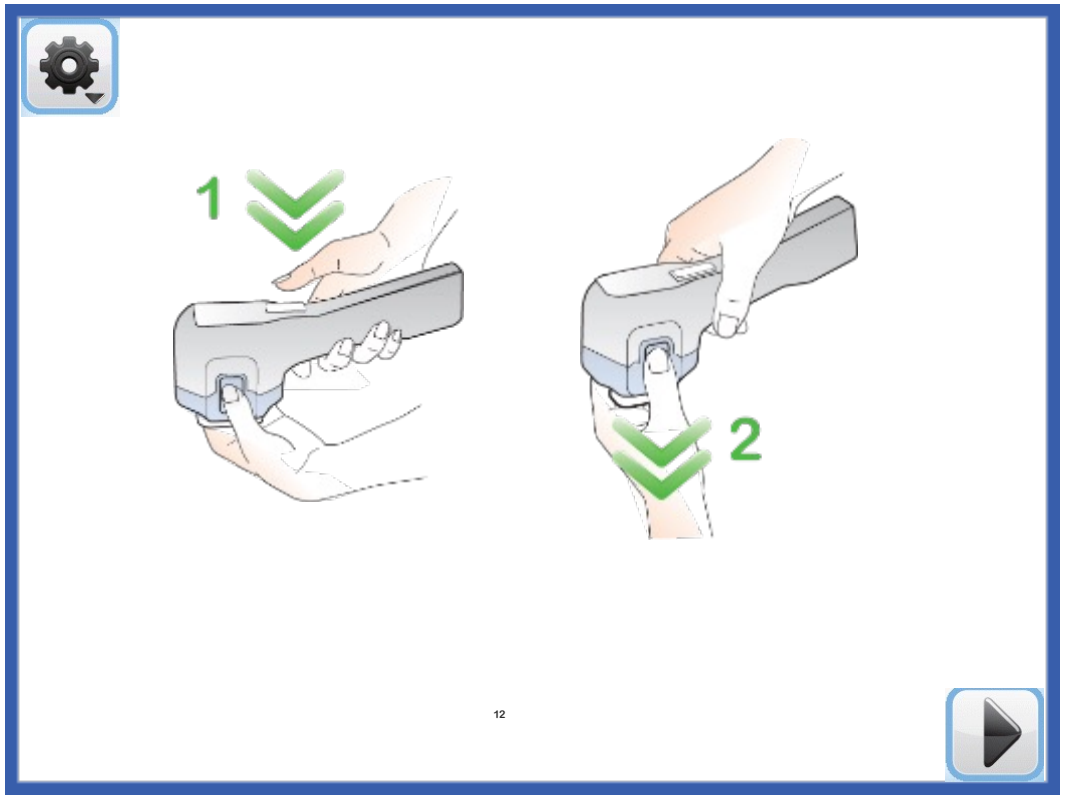
1. Select Wrench Button
2. Choose to turn off or turn on any placement within the current template
3. Touch impacted placement to Toggle Off/On
4. Black – to be treated
5. Gray – already treated

Note: Do not treat the same placement twice



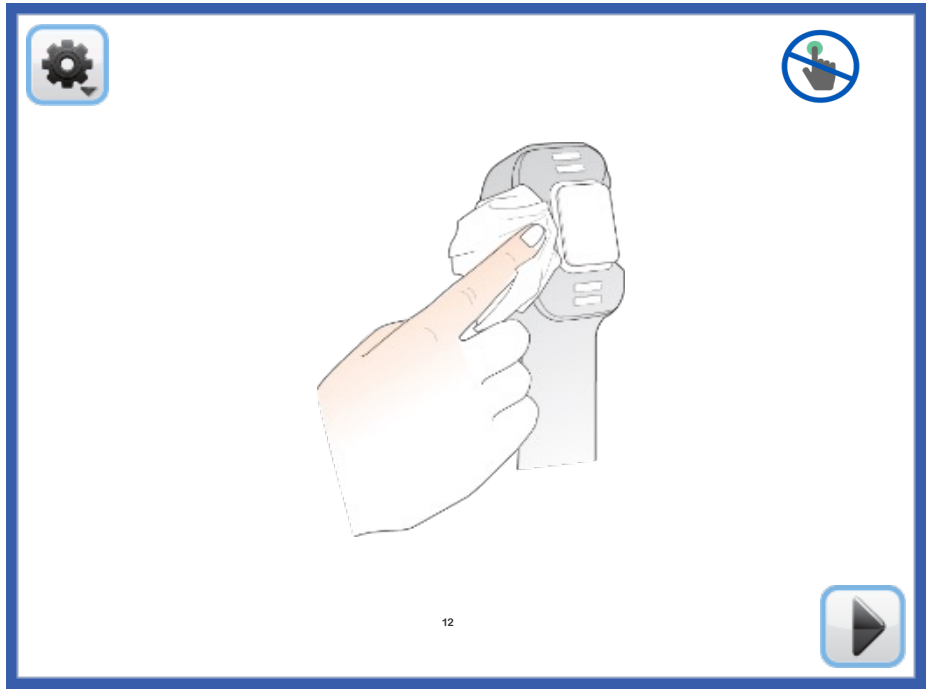
# miraDry Procedure

1. Press Handpiece switch to deactivate magnet
2. Remove bioTip and discard



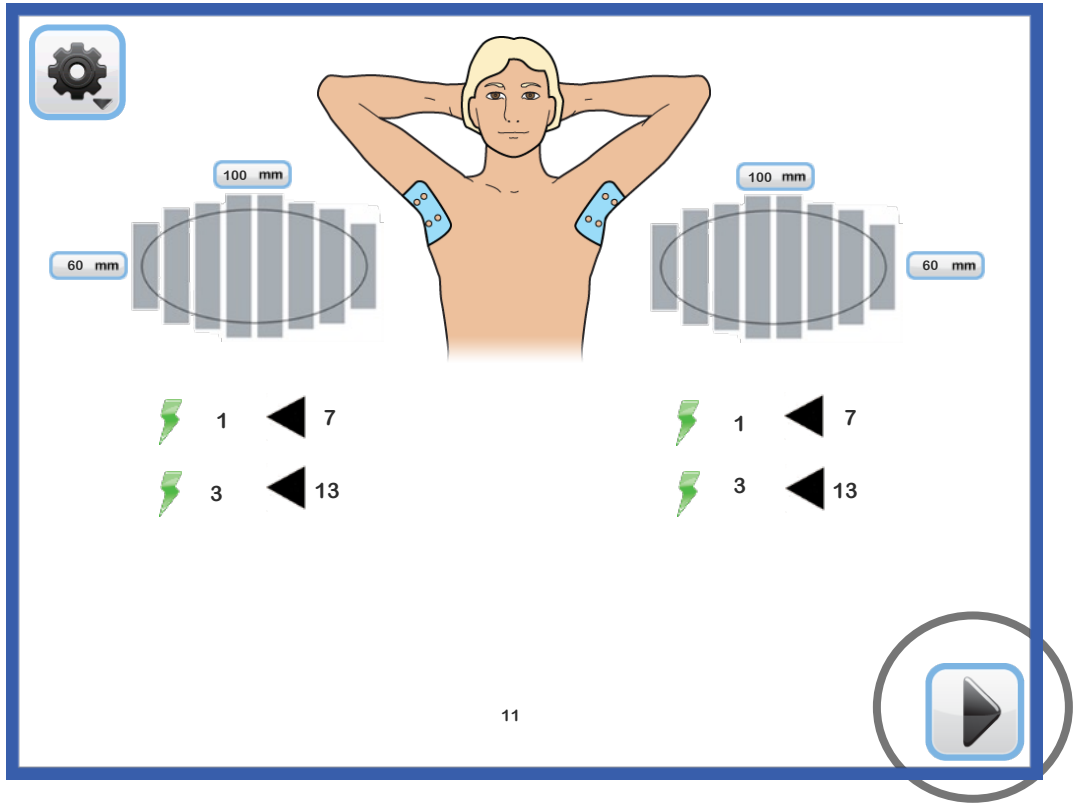
# miraDry Procedure

- Clean Handpiece using alcohol and gauze
- Gently clean cooling plate if needed
- Replace into holster and position holster into the down position
- For Systems with freshConnect:
  "Please Do Not Turn Off System" icon ( ) may be displayed on screen after treatment. Do not unplug or power off when displayed.



# miraDry Procedure

After all placements are done, the procedure summary shows template size,  # of placements and energy level used




Push arrow for Welcome Screen

# Placement Interruption

The following occurs when there is interruption during each of the treatment phases:

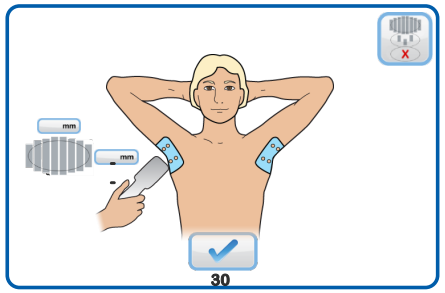
| | |
|---|---|
| 1. During Vacuum Acquisition | • Handpiece immediately stops<br>• Automatically returns to the same placement location on screen |
| 2. During Energy Delivery | • If treatment is stopped during energy delivery, the Handpiece is immediately placed into post-cool mode<br>• Handpiece should be held in contact with the skin throughout the entire duration of the post-cool period<br>• When post-cooling is complete, system continues to the next placement |
| 3. During Post-Cool | • As a safety measure, you cannot prematurely abort the post-cool phase<br>• When post-cooling is complete, system continues to the next placement |

# Gear Menu


| | |
|---|---|
| Vacuum Purge | Turns on vacuum only |
| Eject bioTip | Prompts bioTip release |
| Energy Selection | Can select levels 1 through 5 |
| Energy Level Unlock | Lock/unlock energy level for first few rows |
| Brightness | Can adjust screen brightness |
| Volume | Can adjust speaker volume |
| STOP Procedure | Stops procedure; prompts bioTip release; returns to home screen |

# Questions

- For any given template, when energy selection remains locked, the first few rows automatically deliver what energy level? And why?
- What is used to “unlock” the energy delivery mode?
- What is the communication to the patient just before the first placement?
- Based on this screen, what side of patient is being treated?

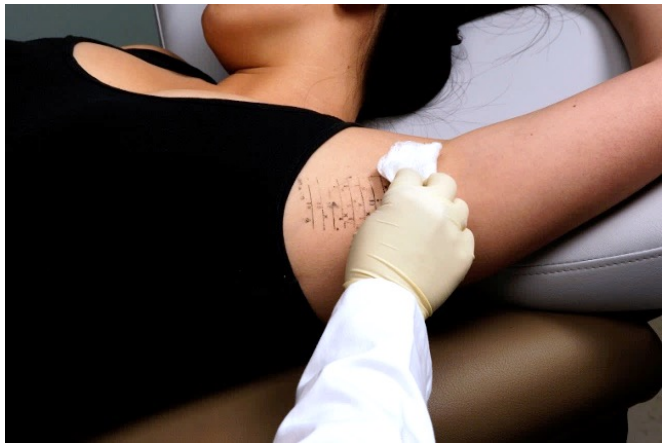


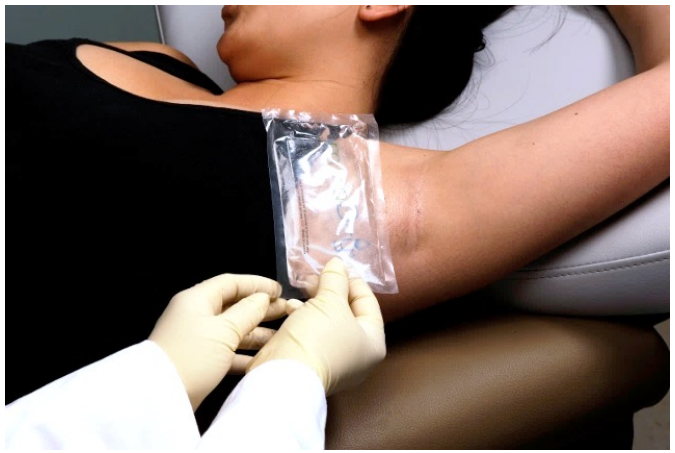

- How much lubricant should be used?
- To treat the left arm, what side of the Handpiece should be used for guidance to match the tick marks?

# SECTION 9:
# POST TREATMENT

# Immediate Post Treatment

1. Clean the axilla
    - Use alcohol to wipe away the template ink and excess lubricant
2. Ice axilla
    - Immediately place ice pack wrapped in gauze firmly under each axilla that has been treated
    - Don’t wait until both sides are treated
    - Ice every few hours for the first couple of days, or as needed, to help reduce pain and discomfort
    - Ice for 20 minutes at a time
3. Ibuprofen
    - Ibuprofen may be used to manage pain and reduce swelling
4. Provide patient with post treatment instructions
5. Patient should wear a clean top after treatment





# SECTION 10:
# SECOND TREATMENT

# Consider Patient's First TX Experience

Before administering second treatment, know the patient's first experience to help shape the treatment protocol for the second.

- What Energy Level was used first treatment?
- How was this Energy Level tolerated?  Can patient tolerate a higher Energy Level?
- What were the side effects and how well were they tolerated?
- What level of satisfaction has the patient expressed?

# Second Treatment Session

For optimal results, a second treatment may be needed for additional sweat and odor reduction.

Typically done after a minimum of three months. All side effects must be resolved prior to second treatment.

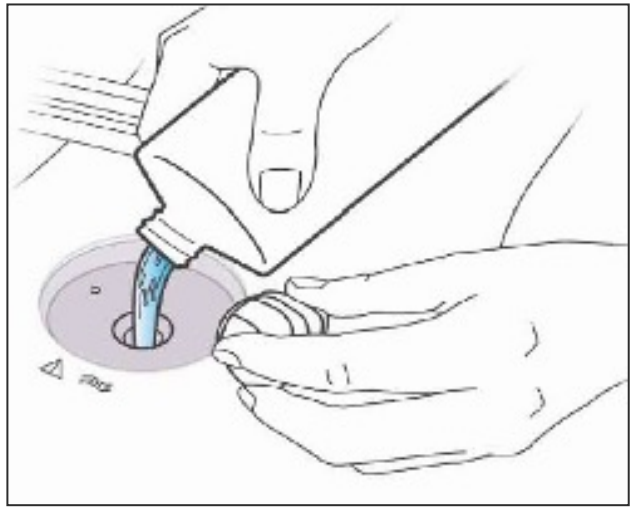
Treatment administration is similar to the first; treating 100% of the hair bearing area with possibly higher energy level selection.

# SECTION 11:
# ROUTINE

# Adding Distilled Water

- Add distilled water when prompted by the touchscreen (W01)
  - Dispenser bottle will be provided to easily fill the console
  - Always fill water on top of console until it is well above the water filter and the water level stabilizes.  Prompt will clear automatically.
- Add distilled water for a new Handpiece
  - If a new miraDry Handpiece has been attached, the user will be prompted to add more water.  Fill until the water level is well above the water filter and water level stabilizes.

**W01**



# Cleaning the Fan Screen

- ALWAYS turn the console OFF using the main power On/Off switch and disconnect the power cord
- Remove fan screen located under console (magnetically attached)
- Clean and remove any dust and debris from the fan screen
- Frequent cleaning may be necessary in carpeted areas

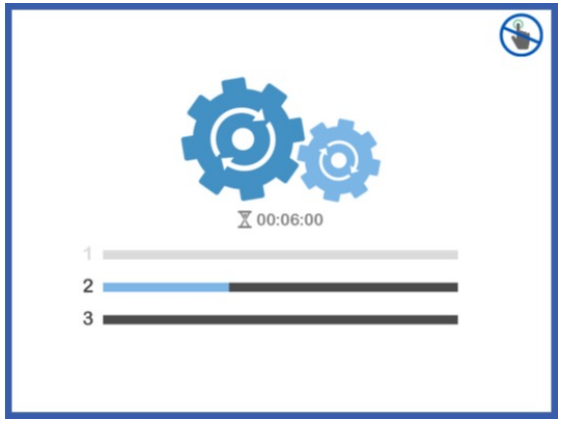
*Image above: fan screen located under console (magnetically attached)*

# miraDry System Operation: Software Updates with freshConnect

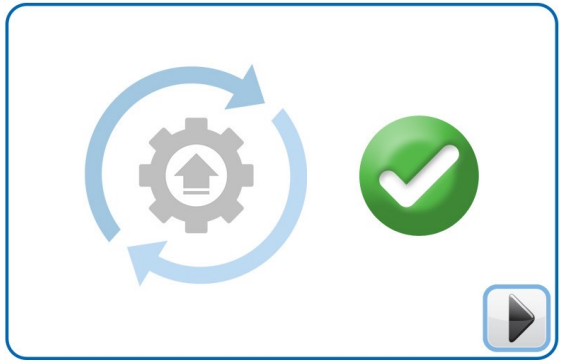
**Only applies to systems with freshConnect**

Users will be prompted to perform an automated software update to maintain optimal performance and offer new features


- Newer System software version update available
- The hourglass symbol indicates total estimated time for update to complete
- Accept update by selecting the
- checkmark button




- System is updating with latest software
- Do not turn off device during update
- System may restart during update

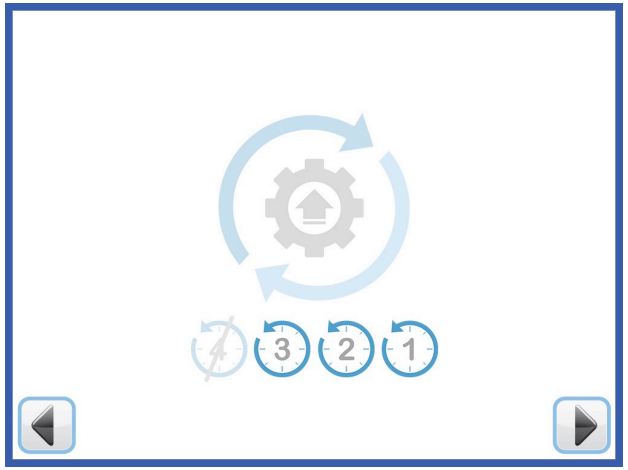


- Software update is successful
- Press the right arrow button to proceed with treatment

# miraDry System Operation: Software Updates with freshConnect

**Only applies to systems with freshConnect**

- Software updates may be deferred up to 4 times.
- If the maximum number of postponed updates is reached, the System must be updated to proceed to treatment.



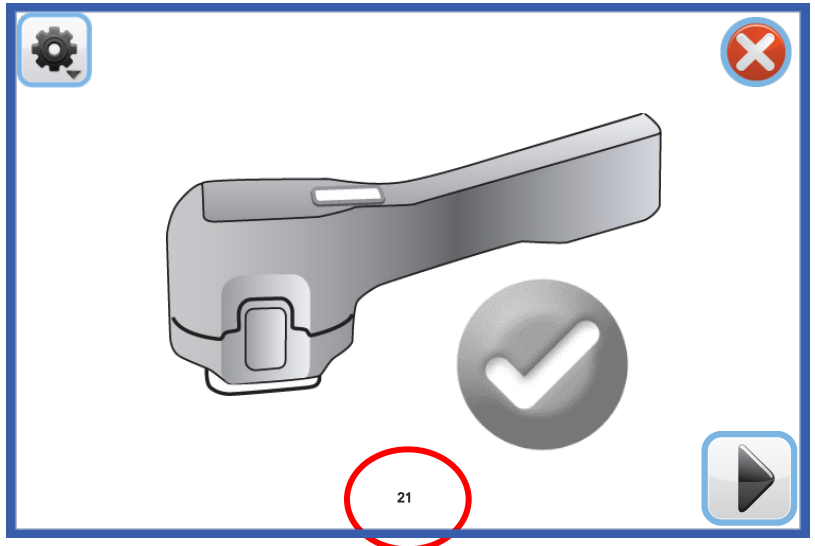

**Software update has been deferred**

**Display indicates the number of times remaining to defer update.**

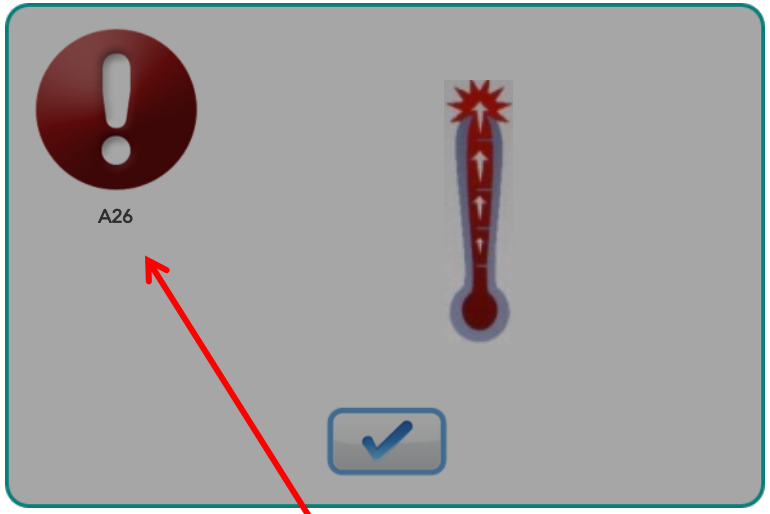
# SECTION 12:
# ERROR CODES

# Screen Number/Error Codes

- Each screen is identified with a screen number at the bottom or an error code.
- Refer to the screen number or error code when calling Technical Support or Customer Service for technical assistance



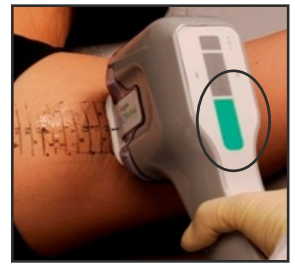

Screen number




Error code

# How to Stop While TX in Progress

*There are 3 different ways to stop the device while it is in progress*

| | | |
|---|---|---|
| 1. Stop a Treatment Cycle | • Press and release the switch on the Handpiece |  |
| 2. Stop a Procedure | • Gear Menu: Select the stop procedure icon<br>• Cannot be used during a treatment cycle<br>• Do NOT use the Green Power On button to stop a procedure |  Note: Display will return to the home screen |
| 3. Emergency Stop | • Press the RED emergency stop switch<br>• Stops system immediately |  |

# Inadequate Vacuum Acquisition

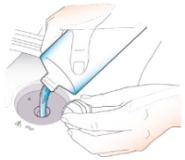
If you lose suction during a treatment cycle, a YELLOW outline will appear around the Handpiece on the screen.

| | |
|---|---|
| 1. During Vacuum Acquisition  | If you hear a "ding" sound, either:<br>• Skin is not touching cooling plate. Adjust angle/slight pressure and re-align to achieve suction.<br>• Skin is too cold. Remove Handpiece. Wait 10 seconds and try again.<br>• Lubricant has dried and made the skin sticky. Apply thin layer of lubricant in target area.<br>• Too much or wrong type of lubricant has clogged the bioTip. Replace bioTip. |
| | If you hear a "click" sound, there is inadequate vacuum seal.<br>• Adjust angle, align and verify that the entire perimeter of bioTip skirt is in contact with skin with no gaps.<br>• Apply more pressure of bioTip against the Handpiece to ensure attachment.<br>• Release the bioTip and re-attach.<br>• Release bioTip, perform purge on side of bioTip tray and reattach. |
| 2. During Energy Delivery | If you hear a beep:<br>• Adjust angle/slight pressure and re-align to achieve suction.<br>• 2-3 seconds to correct the suction or system automatically enters post-cool phase. After post-cool phase is complete, a "V03" error message will appear. Clear and continue. |
| 3. During Post-Cool | If you hear a beep:<br>• Adjust angle/slight pressure and re-align to achieve suction.<br>• 2-3 seconds to correct the suction or system will abort post-cool and a "V03" error will appear. Clear and continue. |

# Error Handling

| Error/Condition | Explanation | Action |
|---|---|---|
| A16 or A26  | Temperature sensor failure or cooling plate broken | • Clear error and continue. If persistent A16s (more than 5) appear, immediately stop treating the patient and call Technical Support.<br>• A26 – (continuous) Handpiece needs to be replaced. Call Technical Support. |
| A17 | Handpiece self-test failure error | • Reposition the Handpiece in the holster, such that head of the Handpiece is touching the foam receptacle. Clear the error and self-test will restart.<br>• If error persists, take Handpiece out of the holster and gently shake it at various angles to dislodge any air bubbles. Replace Handpiece back in the holster, clear the error and the self-test will restart.<br>• If error persists after restart, discontinue use and contact miraDry Technical Support. |
| A23 | Skin contact with cooling plate lost during delivery | • Move onto the next placement and ensure the Handpiece is steady during use.<br>• If error persists, remove bioTip (using Gear Menu), rotate 180°, reattach using firm, even pressure. |

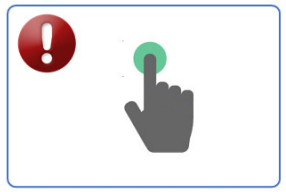
# Error Handling

| Error/Condition | Explanation | Action |
|---|---|---|
| A22<br>A24<br>A25<br>  | bioTip attachment issue | • Remove bioTip, rotate 180° degrees, and reattach using firm, even pressure.<br>• If error persists, replace with a new bioTip. |
| V03<br>V04<br>V06<br>  | Vacuum related error conditions | • Clear the error and continue, but on the next placement, check to verify "skirt" on the bioTip is making complete contact with skin (no gaps).<br>• If error persists, remove the bioTip and reattach.<br>• If error still persists, discontinue use and contact miraDry Technical Support. |
| W01<br>  | Insufficient water | • Add distilled water until level is well above water filter.<br>• If error persists, discontinue use and contact miraDry Technical Support. |

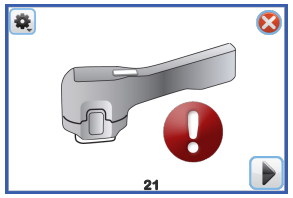
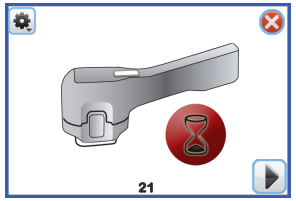
# Error Handling

| Error/Condition | Explanation | Action |
|---|---|---|
| W03 | Air bubbles or debris (biofilm) trapped in the flow sensor | • Power off the console<br>• Disconnect the HP from the console<br>• Install priming connector and perform an auto-prime.<br>• Inspect the Water level in the reservoir<br>• Add water if needed |
| W06 followed by Temperature Wait Pop Up  | Room temperature is too warm (>79°F)<br><br>OR<br><br>Air intake is blocked with debris (e.g.: paper, dust, etc.) | • Bring room temperature down or open door and place fan in doorway to the room to increase circulation.<br><br>OR<br><br>• Remove external air filter to check for debris and remove.<br>• Resume system use and if error persists, discontinue use of the system and contact miraDry Technical Support. |
| W08 | Water needed to prime new Handpiece | • If needed, first add deionized or distilled water until the level of water is well above the water filter. Clear the error and continue to keep the level of water above the filter until the pump circulates water through the system (approximately 30 seconds). |

# Error Handling

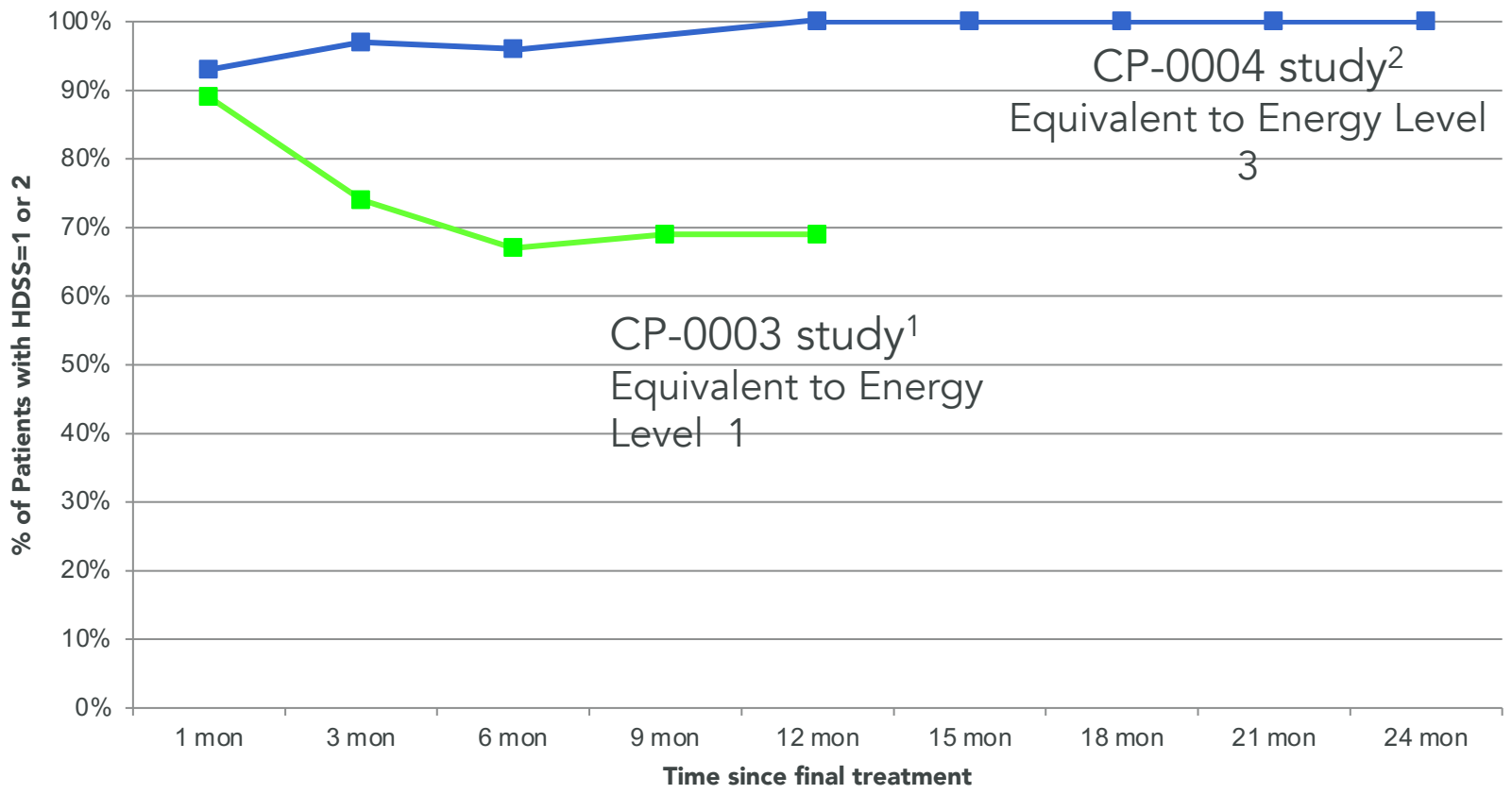
| Error/Condition | Explanation | Action |
|---|---|---|
| Red Exclamation After System Update  | System update was unsuccessful | • In the event an update was unsuccessful, the System will remain at the older software version and will be safe to proceed to treatment. Contact Technical Support for assistance to complete update. |
| A32  | Attached handpiece while system is on | • Turn off system. Reattach handpiece and turn on system. |

# Error Handling

| Error/Condition | Explanation | Action |
|---|---|---|
| Red Exclamation<br>(Screen 21)<br>  | bioTip used or invalid | • Use new bioTip |
| Red Hourglass<br>(Screen 21)<br>  | bioTip expired | • Use new bioTip. The bioTip expires 3 hours after the first placement is completed. Otherwise, if no placements are done, the bioTip expires after 24 hours. |
| All other errors not listed in above table | Miscellaneous error conditions | • Attempt to clear the error and continue.<br>• If error is not clearable, restart the system.<br>• If error persists after restart, discontinue use of the system and contact miraDry Technical Support. |

# SECTION 13:
# CLINICAL DATA

# Stability of Results – Clinical Study Efficacy Comparison




1 – Glaser DA et al. Dermatol Surg 2012; 38: 185-191
2 – Hong HC-H et al. Dermatol Surg 2012; 38: 728-735 and Lupin et al Dermatol Surg 2014; 40:805-7.

# Clinical Data – Safety Results

| Adverse Events Reported | DRI-UP study [1] # of subjects (N=81) (%) | Canada study [2] # of subjects (N=31) (%) | Canada study Median duration of AE* |
|---|---|---|---|
| Altered sensation in skin of treatment limb (typically underside of arm) | 8 (9.9%) | 12 (39%) | 50 days |
| Edema in the treatment limb/ torso | 4 (4.9%) | 8 (26%) | 7 days |
| Skin irritation/itching/rash | 4 (4.9%) | 3 (9.7%) | 6 months |
| Blisters/ulcerations/burn | 4 (4.9%) | 0 | - |
| Soreness or pain requiring Rx meds | 5 (6.2%) | 2 (8.7%) | 35 days |
| All others | 9 (8.6%) | 8 (26%) | -- |
| | | | |
| # of subjects with at least 1 AE | 23 (28%) | 18 (58%) | |
| Patient satisfaction @ 12 months | 70% | 89% | |

*Data not available in DRI-UP study

1 Glaser et al. Dermatol Surg 2012; 38: 185-191
2 Hong et al. Dermatol Surg 2012; 38: 728-735