MD4000-MC

User Manual

1. CONTACT INFORMATION

Manufactured by:

miraDry, Inc.
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United States

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1-855-miraDry (1-855-647-2379)

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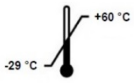
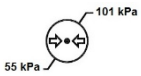
2. EXPLANATION OF SYMBOLS

Symbols on the Device and Packaging			
ETL CLASSIFIED Intertek 5011707	Conforms to: AAMI STD ES60601-1, IEC STDS 60601-1-6 & IEC 60601-2-6 Certified to: CSA STD C22.2 NO. 60601-1		Water fill location
	Warning: Service By Qualified Personnel Only		Manufacturer
	Fuse		Date of manufacture
	Type BF (body floating) applied part		Waste electrical and electronic equipment
SN	Serial number		Do not sit on the equipment
	ON (AC main power)		Do not stand on the equipment
	OFF (AC main power)		Pushing Prohibited
	Emergency Stop	REF	Model number
	Non-ionizing radiation		Footswitch connector
	Equipotential ground connection		Consult operating instructions
VA	Power Input	Hz	Frequency
	AC Voltage	SWL	Safe Working Load
Mass	Mass	P_{MAX}	Maximum Ouput Power
	Stand-by		Temperature limitation: Ship and store at a temperature range between -29˚C to +60˚C
	Atmospheric pressure limitation: Ship and store at an atmospheric pressure range of 55kPa to 101kPa		Humidity limitation: Ship and store at a humidity range between15% to 90% RH

Icons that appear on the Touchscreen Graphical User Interface (GUI)			
Symbol	*Title of Symbol*	*Symbol*	*Title of Symbol*
	Display Gear Menu		Select the microwave energy output level
	Close Gear Menu		Adjust display brightness up or down
	Purge the vacuum		Adjust speaker volume up or down
	Remove the bioTip from the Handpiece		Stop the treatment session
	Unlock fixed energy level in first few rows of template		Please do not turn off system

3. SYSTEM DESCRIPTION

The miraDry® System from miraDry®, Inc. utilizes miraWave® technology to deliver precise amounts of shallow, localized microwave energy to soft body tissue in the underarm. The System is designed to be used in the health-care office setting by health-care professionals, under the direction of a physician. As the System delivers microwave energy, it protects the tissue surface with an active contact cooling system.

The miraDry System (see Figure 1) consists of the following components:

- MD4000-MC miraDry Console (Main Body and Touchscreen)
- MD4000-BT or MD4500-BT miraDry bioTip
- MD4000-HP miraDry Handpiece

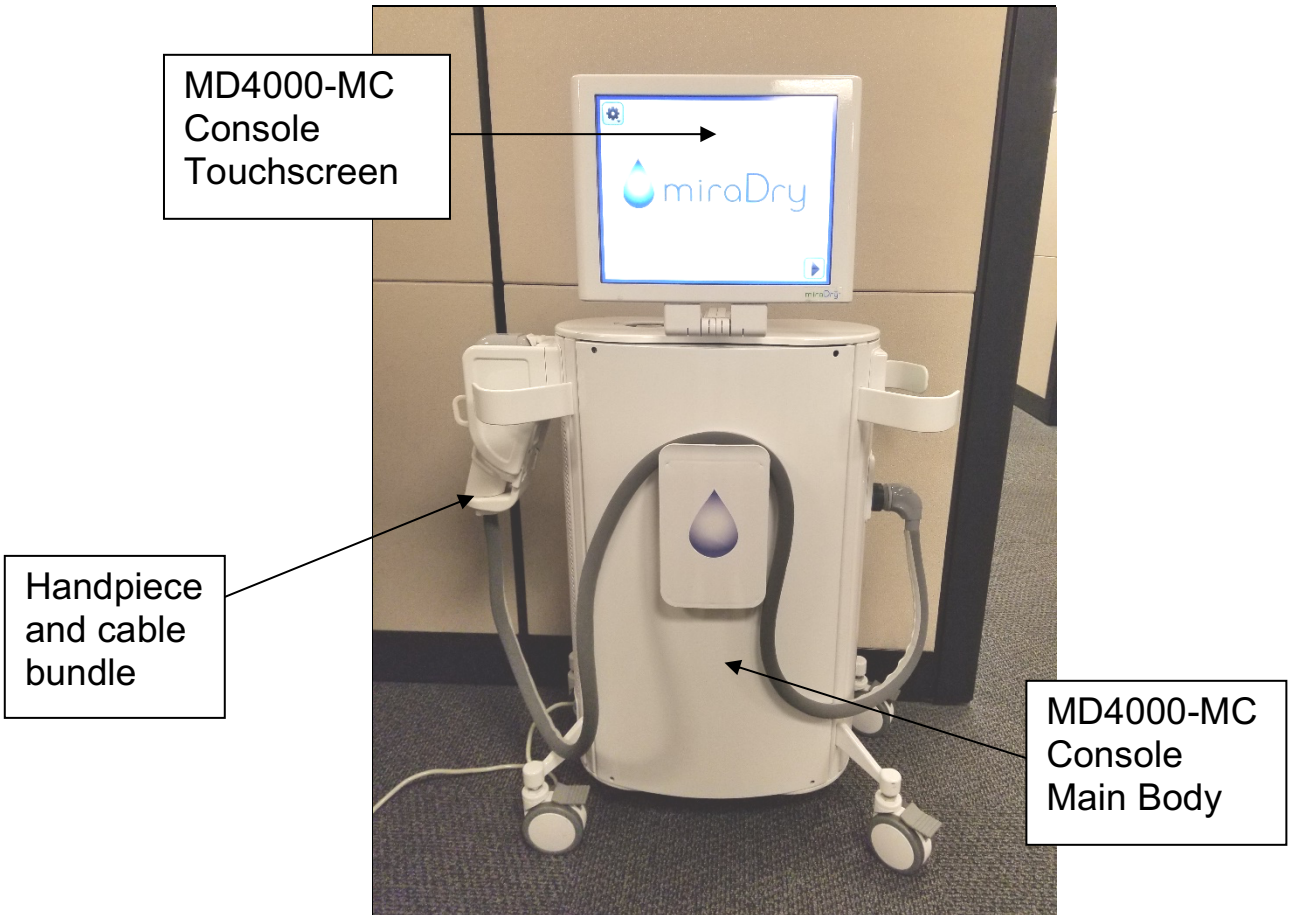


Figure 1: Fully assembled miraDry System.

The **miraDry Console** contains a power supply, microwave (5.8GHz frequency) module, vacuum pump, cooling fans, water chiller and pump, cellular modem and antennas, and a **Touchscreen** display that guides you through System operation.

The **miraDry Handpiece** contains microwave applicator, vacuum ports, and a surface cooling plate. The miraDry Handpiece is magnetically attached to the **miraDry bioTip**. This attachment enables body tissue to be drawn into the acquisition chamber from the vacuum that is drawn from the Console.

The **miraDry Template System** is an accessory that guides you through a patient treatment session. Refer to the separate Instructions for Use for the miraDry Template System.

3.1. MIRADRY CONSOLE CONNECTIONS AND CONTROL FEATURES

- **Handpiece Cable Connector –** The cable that connects the Handpiece to the Console.
- **AC Power Supply Cord –** The cord that connects the Console to an AC power outlet.
- **Equipotential Ground Connector –** The connector that is used in some countries to ensure that the Console is at the same ground potential as other nearby electrical equipment.
- **Footswitch Connector –** Used to connect the footswitch to the Console. The footswitch lets you start or stop treatment using your foot.
- **Fan Vent Inlets/Outlets –** Console vents that let air flow to and from the Console. One set of Outflow vents let the fans exhaust air from the rear of the Console. A second set of Intake vents on the bottom of the Console let air flow into the Console. DO NOT block these vents to ensure proper cooling of the Console.
- **AC Main Power Switch –** Enables AC power flow to the System.
- **Standby Button –** Turns the System ON and OFF.
- **Emergency Stop Button –** Lets you shut down the System immediately in the event of an emergency. To turn the System back ON, rotate the Emergency Stop Button clockwise to reset it.

4. INDICATIONS FOR USE

The miraDry System MD4000 is indicated for use in the treatment of primary axillary hyperhidrosis plus unwanted underarm hair removal, and permanent reduction of underarm hair of all colors for Fitzpatrick skin types I – IV.

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

When used for the treatment of primary axillary hyperhidrosis, the miraDry System MD4000 may reduce underarm odor.

5. CONTRAINDICATIONS

The miraDry System is contraindicated in people:

- With heart pacemakers and other electronic device implants.
- Who need supplemental oxygen.
- With known resistance to or history of intolerance of local anesthesia including lidocaine and epinephrine.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

6. POTENTIAL RISKS

As with any medical device, there are possible risks associated with the use of the miraDry System. Patients should be monitored closely for symptoms to allow for early intervention.

The most common side effects observed within or near the treatment area follow below. Most of these side effects can last from a few days to a few weeks following treatment. Others can last from one to several months or longer as noted.

- Swelling/tightness in the treated area
- Discomfort, tenderness or pain in the underarm when touched, usually treatable with non-prescription medications such as ibuprofen
- Redness and bruising from the device suction
- Bruising at the numbing injection sites
- Bumps under the treated area (can last for several months)
- Temporary altered sensation or tingling in the treated skin and/or upper arm (can last for several months)

Other less common side effects include:

- Swelling in the adjacent arm or torso (can last for several weeks)
- Hyperpigmentation (darkening of skin) in the treatment area
- Soreness in the shoulders or arms due to positioning of the arms during the procedure
- Numbness or tingling in the arm due to the anesthesia (usually lasting less than 24 hours)
- Shaking due to epinephrine in the anesthesia (usually lasting less than 24 hours)
- Tight banding in the underarm (gradually resolves, but can last several months)

There have been rare reports of:

- Altered sweating elsewhere on the body
- Small blisters/ulcerations or rashes in the treatment area
- Temporary altered sensation or tingling in the forearm or fingers (can last for several months)
- Weakness in the arm or fingers that gradually goes away (but can last for several months)
- Pain in the arm or fingers that gradually goes away (can last for several months)
- Pain in the underarm requiring prescription medications
- Infection/abscess
- Burns (first, second, or third degree are possible)

7. CLINICAL DATA

The ability of the miraDry System to treat axillary hyperhidrosis has been studied in two separate clinical studies that utilized earlier versions of the miraDry System. A study using the most current miraDry System has been completed to measure the amount of underarm hair reduction.

7.1. RANDOMIZED, BLINDED, MULTICENTER STUDY

Device:
The device used in this study was the DTS G2 System, the predecessor of the miraDry System. Microwave energy settings that were used with the DTS G2 System were equivalent to Microwave Energy Setting 1 on the miraDry System.

Study Design:
The study involved two patient groups. In the first group, the subjects received the DTS G2 System procedure with microwave energy treatment for axillary hyperhidrosis in both axillae (the "treatment group"). The second group of subjects had the same procedure but without microwave energy applied (the "placebo group"). Subjects were randomized to one of the two groups with twice as many patients being assigned to the treatment group. Subjects were also "blinded" as to whether they were to receive the microwave energy or placebo treatment. The majority of subjects (83%) were treated with two treatment sessions, separated by approximately 14 days. In all these cases the full hair-bearing area of both axillae were treated in the first session. The second session was used to "touch-up" any remaining areas of active sweat. Another 9% of subjects only received one treatment session, and the remaining 8% of subjects had 3 treatment sessions.

All subjects had follow up assessments at 14 days, 30 days, 3 months and 6 months following their final treatment session. At 6 months, the subjects were unblinded as to their group assignment. Placebo group subjects exited the study while treatment group subjects remained in the study and had additional follow-up visits at 9 months and 12 months following their final treatment session.

Subjects:
One hundred and twenty (120) adult subjects enrolled in the study. Eighty-one (81) subjects were randomized to the treatment group and thirty-nine (39) subjects were randomized to the placebo group. The mean age of subjects was 32.8 years and 58% of the subjects were female. Eighty-four percent (84%) of the subjects were "White", 6.7% were "African American", and the rest were categorized as "Other". The majority of subjects were of Fitzpatrick skin type III, but the study also included subjects with skin types I-V. There were no subjects enrolled that had skin type VI.

Results:
The study primary endpoint compared the Hyperhidrosis Disease Severity Scale (HDSS) quality of life success rate of the treatment group to the placebo group based on data collected at the 30-day follow-up visit. Success was defined as moving from a pre-treatment baseline score of 3 or 4 to a post-treatment score of 1 or 2. Last-observation-carry-forward was used to impute missing data. Overall, 89% of the treatment group had success versus 54% for the placebo group ($p<0.001$).

In addition, the 81 treatment group subjects showed good long-term efficacy with 69.1% of these subjects having HDSS success at their final study visit.

No treatment-related serious adverse events occurred. Adverse events related to the procedure or device were generally mild in nature and all but one (compensatory sweating) resolved over time. The most common reported adverse events related to the device or procedure were reports of numbness, tingling or sensitivity in the treatment limb (12%), pain or soreness (10%), swelling in the treatment limb (9%), and blisters/ulcerations/burns (6%). There have been no reports of late-onset adverse events associated with the device or procedure.

All subjects experienced some mild treatment effects. The most common were vacuum acquisition "suction" marks caused by the vacuum acquisition of the skin, soreness in the shoulder or arm due to arm positioning during the procedure, and discomfort/ tenderness in the treatment area. These were well-tolerated and generally of short duration.

7.2. SINGLE GROUP, COMMERCIAL DEVICE STUDY

Device:
The device used in this study was the MD3000 version of the miraDry System. This system is therapeutically equivalent to the MD4000 miraDry System, and the same device parameters and settings were available.

Study Design:
This study was conducted at two centers, with all subjects receiving treatment in both underarms. Approximately half of the patients received two treatments, with two to three months between treatment sessions. 13% of the subjects had only one session; 38% of the subjects were treated in three sessions, again separated by two to three months. The full axillae were treated in the first treatment session, with other treatment sessions "touching-up" any remaining areas of sweat. Microwave Energy Setting 3 was used for the first treatment session for 74% patients, with increased settings used for subsequent sessions depending on the subject's acceptance of side effects. Lower initial energy settings were used for patients with low axillary fat.

Formal office follow-up visits were conducted at 1 month, 3 months, 6 months and 12 months post final treatment. Last-observation-carry-forward was used to impute missing data.

Subjects:
Thirty-one adult subjects were enrolled; 26 of those subjects completed the final follow-up visit. The mean age of the patients was 33 years; 75% of the subjects were female and 87% were Caucasian. All subjects had HDSS scores of 3 or 4 at baseline.

Results:
As with the prior study, the primary endpoint examined the percentage of subjects that reduced their HDSS scores to a value of 1 or 2 at the 1 month follow-up visit. This value was 90.3% (28/31) and the result remained stable and above 90% for all subsequent visits. The average reduction in sweat as measured by weight was stable at 82%±1% for all follow-up visits. Patient satisfaction (% of patients that were "very satisfied" or "somewhat satisfied") was 89% or above at all follow-up visits.

Most subjects experienced acute mild transient post-treatment effects such as localized edema, discomfort, bruising and erythema. 61% (19/31) of subjects experienced at least one (1) treatment-related adverse event (AE); 88% of AE's were rated as mild (Grade=1) in severity. The most common AE's were numbness or tingling in an area of the treatment limb (n=12 subjects, 39%) and short-term (~1 week) edema in the chest or treatment limb (n=8 subjects, 26%). One subject experienced treatment-related neuropathy of the left tricep muscle after the first treatment session that was resolving at 6 months, after which she was lost to follow-up.

7.3. SINGLE GROUP, COMMERCIAL DEVICE STUDY

Device: The device used was the MD4000 miraDry System.

Study Design: The primary objective of the study was to quantify hair reduction in the axillae after treatment(s) with the miraDry System. The study device was used in the same manner as the commercially available technique cleared by the FDA for the treatment of primary axillary hyperhidrosis. The study was conducted at three dermatology clinics in the United States. The study was initiated at the first site in September of 2012. Adult subjects seeking hair reduction in the axillae that showed at least 16 viable hairs in a 2cm X 2 cm box in the center of each axilla were considered for enrollment. Subjects were treated with the miraDry System using the standard miraDry procedure in one or two treatment sessions 3 months apart. Follow-up visits were conducted 3, 6, 9 and 12 months after treatments were complete.
Subjects: Fifty-six subjects were enrolled in the study. The mean age was 33 years; 80% of the subjects were female and 88% were Caucasian. The majority of the subjects were of Fitzpatrick skin type I-IV. 23% (13/56) of the subjects completed only one treatment session; 5 of these 13 subjects declined a second session due to adverse events.

Results: The primary endpoint of this study was to show >30% reduction (baseline to 3 month, measured by hair counts) in >50% of subjects. There were 42 subjects assessable for this endpoint. The secondary endpoint was to show >30% reduction (comparing baseline to 12 months photos) to make a claim for permanent axillary hair reduction. Additional analyses used a blinded comparison of baseline to follow-up full-axilla photos by an independent reviewer to correctly identify which photo had more hair and score hair reduction at follow-up. Also, a subject assessment of overall satisfaction, odor rating and sweat ratings was determined at the follow-up visits. See the table below.

Efficacy measure	Follow-up visit time from the last treatment session			
	3 months	6 month	9 month	12 month
Hair count: % of subjects with >30% reduction [lower 95% CL]	**Primary:** 88.1% (37/42) [76.6%]	97.5% (39/40) [88.7%]	92.1% (35/38) [80.8%]	**Secondary:** 95.5% (42/44) [86.4%]
Hair count: Average reduction [std] Light hair subgroup (n)	66% [± 30%] 66% (n=12)	72% [± 29%]	75% [± 28%]	75% [± 27%] 72% (n=13)
Side-by-side axilla review: % of pairs having at least 26-50% reduction	74% (63/85)	78% (65/83)	78% (66/85)	89% (83/93)
Patient satisfaction with hair reduction: % of subjects rating “very satisfied” or “somewhat satisfied”	81% (38/47)	70% (31/44)	68% (30/44)	70% (33/47)
Odor self-assessment, Mean reduction 10pt scale	2.6 ± 3.0	2.8 ± 2.8	2.5 ± 2.8	2.4 ± 2.7
% of subjects with HDSS reduction to score of 1 or 2	92% (23/25)	96% (25/26)	96% (24/25)	89% (25/28)

All subjects experienced at least one (1) treatment-related adverse event (AE), 99% (324/326) of all AE’s were rated as mild in severity. As in prior studies, many subjects experienced the expected mild transient post-treatment effects; the most common were localized edema (55%), tingling or numbness in the treatment area (30%), vacuum acquisition marks (29%), bumps or lumps under the skin (29%) or discomfort or tenderness in the treatment area (26%). Other rarer treatment effects affecting more than the treatment area were noted in 18% of subjects (10/56), 75% of which were rated as mild. These included numbness or tingling in the arms (n=6 events); more extensive swelling in the adjacent area (e.g. arms) (n=4 events); and bruising outside the treatment area (n=2 events). One patient experienced unilateral ulnar neuropathy that was improving but not completely resolved at study exit.

8. WARNINGS AND PRECAUTIONS

8.1. SET-UP AND ENVIRONMENTAL WARNINGS AND PRECAUTIONS

- DO NOT use the miraDry System until you have thoroughly read the miraDry MD4000-MC Console User Manual, Handpiece Instructions for Use (IFU), and bioTip Instructions for Use (IFU). Observe all Warnings and Precautions. Failure to do so may result in complications.
- DO NOT set up or use the miraDry System unless instructed and trained in the correct use of the equipment by designated miraDry Representatives. The miraDry System is to be used by qualified clinical personnel only.
- DO NOT damage the equipment during unpacking, assembly and preparation.
- DO NOT use the miraDry System if the equipment was damaged in transit, or during unpacking and assembly.
- DO NOT use the miraDry System if the equpment was not unpacked and assembled by designated miraDry Representatives.
- DO NOT operate the miraDry System outside the environmental operating ranges stated in this User Manual. These include a temperature range of 15˚C to 26.7°C (60˚F to 80°F), 10%-60% relative humidity (non-condensing) at 26.7°C, 20%-60% relative humidity (non-condensing) at 15°C, an altitude of 0-2000 meters (0-6562 feet), or a pressure of 760 to 571 mm of Hg (29.9 to 22.5 in of Hg).
- DO NOT use components and parts other than those supplied by miraDry.
- ONLY use miraDry Handpieces with the miraDry Console, and only when they are properly connected to the Console.
- ALWAYS connect the AC Power Supply Cord to a properly grounded AC power outlet. DO NOT use extension cords and/or adaptor plugs. Plug equipment into 100-240V AC 50/60 Hz power outlets.
- ALWAYS plug the equipment in properly and verify that fuses are intact. ALWAYS use the correct replacement fuses.
- ONLY use deionized or distilled water provided by miraDry (or an equivalent) with the miraDry System. DO NOT over fill.
- DO NOT use the System unless the miraDry Handpiece is properly connected to the Console.
- DO NOT use the miraDry System until the miraDry bioTip security feature has been properly “read” by the miraDry Console after the bioTip has been attached to the miraDry Handpiece.
- DO NOT obstruct the intake vents on the bottom of the miraDry Console, or the exhaust vents on the rear of the miraDry Console, to ensure proper air flow.
- When moving the system from room to room, always push using the handles on the holster side. DO NOT push sideways.
- DO NOT use the foot switch in rooms where it is likely to be exposed to liquids.
- NO modification of this equipment is allowed.

8.2. EQUIPMENT USE WARNINGS AND PRECAUTIONS

- ALWAYS attach the miraDry Handpiece before powering on the System.
- The product shall be installed in a way that a distance of at least 20 cm is maintained between the cellular antenna (See Figure 2) and the user and/or bystander.

Figure 2: miraDry cellular antenna

For Canadian information on RF exposure and compliance, see the link below:
https://www.ic.gc.ca/eic/site/smt-gst.nsf/eng/h_sf06128.html

- ALWAYS place the miraDry Handpiece (without the bioTip attached) securely in the holster in the “down” position during the System self-test.
- DO NOT allow fluid to come in contact with the miraDry Console, cables, connectors or attachments except when the miraDry Console is being cleaned. DO NOT hang fluids above the miraDry Console. The miraDry Console may not function correctly if the electronic circuitry or the connectors/attachments are wet. DO NOT soak the cables.
- DO NOT bend cables at acute angles or coil them tightly as the interior components within the cables might get damaged.
- DO NOT operate the miraDry System if you are wet or damp. Electrical shock may occur. Make sure there is no water or skin contact with electrically active components.
- DO NOT use the miraDry System if the patient is in contact with pooled fluid.
- DO NOT insert any foreign bodies inside the miraDry Console.
- ALWAYS position the miraDry System such that the user has access to the emergency button and/or power cord in case of emergency.
- ALWAYS provide as much distance as possible between the miraDry System and other electronic equipment. The use of any electrosurgical device can cause electromagnetic interference (EMI) with other electrical medical equipment. Precautions should be taken to ensure that the well-being of the patient is maintained in the event of such interference. It may be necessary to take mitigation measures, such as reorienting or relocating the MD4000-MC Console or shielding the location.
- DO NOT place fingers in front of the cooling plate of the miraDry Handpiece at any time during application of microwave energy.
- DO NOT direct the miraDry Handpiece towards the eyes or testes. During treatment, the patient’s head should always be turned away from the Handpiece.
- DO NOT use this device in the presence of flammable anesthetics; other flammable gases; near flammable fluids such as skin prepping agents and tinctures; flammable objects; or with oxidizing agents. Observe appropriate fire precautions at all times.

- DO NOT use this device in oxygen enriched atmospheres, nitrous oxide (N_2O) atmospheres, or in the presence of other oxidizing agents. Be sure that all oxygen connections do not leak.
- DO NOT obstruct the activation light or speaker on the miraDry Console. The activation tone and light are important safety features.
- DO NOT accidentally press the foot switch on the miraDry Console or the handswitch on the miraDry Handpiece to avoid unintended delivery of microwave energy.
- Failure of the miraDry System may result in unintended increase in output energy.
- DO NOT ship the miraDry Console with any deionized water inside. Make sure to completely empty the deionized water out of the miraDry Console to prevent equipment damage due to freezing during shipment.
- DO NOT connect or disconnect the miraDry Handpiece when the miraDry Console is turned ON. Make sure to turn the miraDry Console OFF prior to connecting or disconnecting the miraDry Handpiece
- DO NOT use the miraDry System to deliver microwave energy to people wearing metallic jewelry, or clothing containing metallic material (for example, metallic buttons, clips or thread). Patients with metal implants should not be treated unless specialized medical advice is obtained. Hearing aids should be removed from the body. Patients with implanted cardiac pacemakers, electrodes, or electronic device implants should be excluded from treatment with microwaves and from areas where the miraDry System is operated.
- This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

8.3. CLINICAL WARNINGS AND PRECAUTIONS

- **CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.**
- DO NOT use the miraDry System for treating hyperhidrosis related to other body areas or for generalized hyperhidrosis. The miraDry System is designed to only treat axillary hyperhidrosis.
- The miraDry System has not been tested on patients with Fitzpatrick skin type VI (very dark skin).
- The miraDry System has not been tested on women who are pregnant. The treatment of pregnant women is discouraged.
- Consider not treating patients who are immuno-compromised, have a history of poor healing, or are taking medications which might interfere with healing post-procedure.
- Patients with very little to no subcutaneous fat in the axilla are at higher risk for nerve-related injuries, because there is a greater likelihood that one or more branches of the brachial plexus may be in close proximity to the target area.
- The miraDry System has not been tested on patients who have had surgery in the axilla. Examples include patients with extensive lymph node dissection, patients with breast implants with axillary incision, or patients who have had prior surgery for

hyperhidrosis or cyst removal. Such surgery may change the way the System will interact with the axillary sweat glands and is discouraged.

- Prior to treatment, the operator should evaluate the patient's axilla to determine whether it is technically feasible to treat. Examples of difficult-to-treat patients include overweight patients, patients with extensive skin folds which will make placing a template difficult, and patients with extensive skin disorders such as eczema or psoriasis.
- DO NOT operate the miraDry System unless the miraDry Handpiece is positioned at the intended target site. See the Instructions for Use for the miraDry Handpiece for proper positioning of the Handpiece.
- DO NOT treat the same skin site multiple times in a given treatment session.
- ALWAYS use the lowest possible power/energy necessary to achieve the desired effect.
- DO NOT lift the miraDry Handpiece off the patient's skin until the treatment cycle is completed.
- DO NOT continue to use the miraDry System if high temperature or skin contact errors persist.
- DO NOT administer anesthesia unless skin is wiped clean using antiseptics prior to administration.
- ALWAYS follow directions of the anesthesia labeling. Inject the appropriate type and quantity of anesthesia. Make sure that for each recommended injection site the appropriate quantity is administered. DO NOT inject anesthesia into the dermis.
- ALWAYS wait a minimum of 10 minutes after administering anesthesia to initiate treatment. NEVER initiate treatment if more than 60 minutes have elapsed since administering anesthesia.
- DO NOT use the miraDry System unless the axilla size has been measured and selected appropriately on the Touchscreen GUI (unless you are operating in Touch-up Mode). The axilla size selection determines the recommendations for anesthesia administration.
- ALWAYS place ice packs, wrapped in a towel on the patient's treated skin after the procedure.
- DO NOT use lubricants other than the recommended lubricants (KY® jelly or KY® liquid). Use of other substances such as ultrasound gel or IPL laser coupling gel can reduce the effectiveness of the surface cooling, leading to blisters or burns.
- DO NOT use the miraDry System unless an appropriate amount of skin lubricant is applied to the axilla treatment area.
- DO NOT use the miraDry System unless the skin surface is wiped clean using antiseptics before treating.

8.4. CLEANING WARNINGS AND PRECAUTIONS

- ALWAYS turn the miraDry Console OFF and disconnect the AC Power Supply Cord from the AC power supply before cleaning.
- ALWAYS clean, disinfect, and maintain the electrical units in accordance with the operating instructions.
- ALWAYS clean and remove any dust, lint or particulate materials from the air intake screen filter located underneath the miraDry Console. Use a vacuum cleaner and/or water. Make sure to remove the filter from the miraDry Console before cleaning. This

filter is attached to the bottom of the Console using magnetic attachment and is easily removed. Thoroughly dry the filter before reattaching it to the Console.

8.5. MAINTENANCE WARNINGS AND PRECAUTIONS

- DO NOT remove the covers of any of the miraDry System components. There are no user-serviceable parts inside. Opening the cover of any component may result in electrical shock or thermal burns.
- DO NOT attempt to repair or alter any of the miraDry System components.

9. OPERATING INSTRUCTIONS

When you are ready to unpack and set up the miraDry System, contact a miraDry Representative for assistance. It is important that a miraDry Representative be present and set the System up for you. DO NOT attempt to set up the System without the help of a miraDry Representative.

9.1. OPERATION – PRE PATIENT SETUP

Step 1 Attach the Handpiece to the Console
Attach the miraDry Handpiece to the miraDry Console as shown in Figures 3a, b and c. Use one hand to stabilize the Handpiece Cable Connector and the other to turn the black Handpiece Collar. Screw the Handpiece Collar clockwise onto the male connector threads on the Console until the red ring is fully concealed.

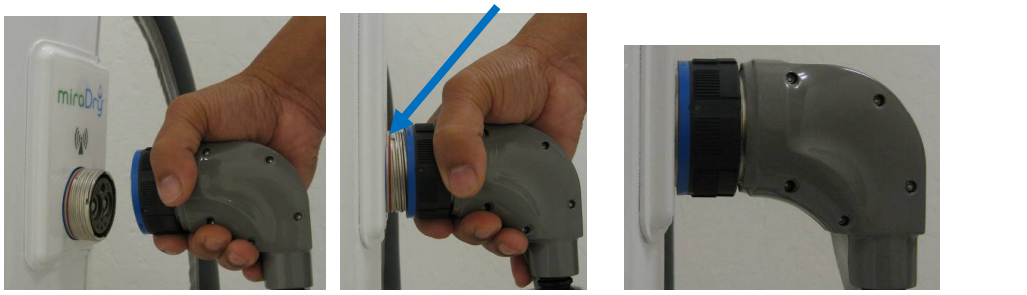


Figure 3: **a) Screw on Handpiece** **b) Red ring still visible** **c) Proper attachment (red ring covered)**

Step 2 Turn the System ON
Press the green Standby as shown in Figure 4 to turn the System ON.

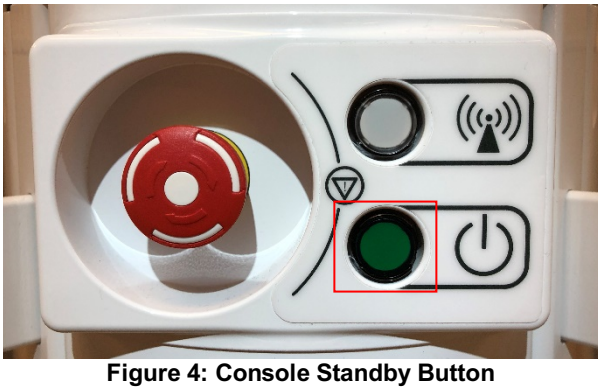


Figure 4: Console Standby Button

Step 3 Navigate the Touchscreen GUI
On-screen graphics will guide you through setup and operation. Simply touch the screen with your finger to navigate the on-screen Graphical User Interface (GUI) as shown in Figure 5.

Touch the right and left arrow buttons (and) on GUI screens to proceed from one screen/instruction to another.

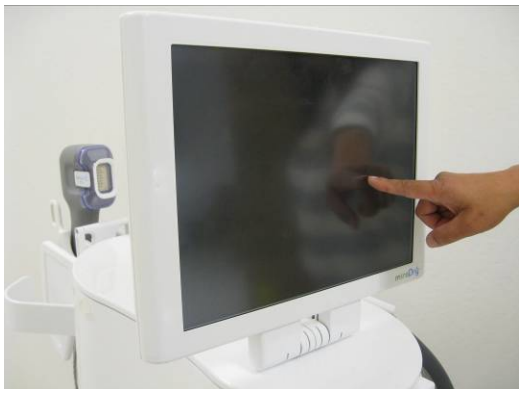


Figure 5: Touchscreen to navigate the Graphical User Interface (GUI)

Step 4 Add Deionized or Distilled Water if Prompted

Add deionized or distilled water only when prompted by the Touchscreen GUI as shown in Figure 6. Only use **new deionized or distilled** water when filling the reservoir. The W01 prompt to add more water will appear occasionally.

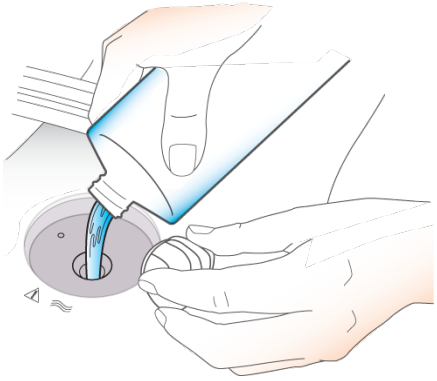


Figure 6: "Add Water" Popup Prompt

When the W01 add water popup appears, remove the plastic cap at the water fill location by unscrewing it counter-clockwise. Pour the water over the top of the filter to fill the console, and the water will flow through the membrane. **Fill the water until the water level is all of the way up the threads above the perforated metal shielded membrane filter (Figure 7), even though a beep will sound and the "Add Water" popup prompt will close well before the water reaches this level.**

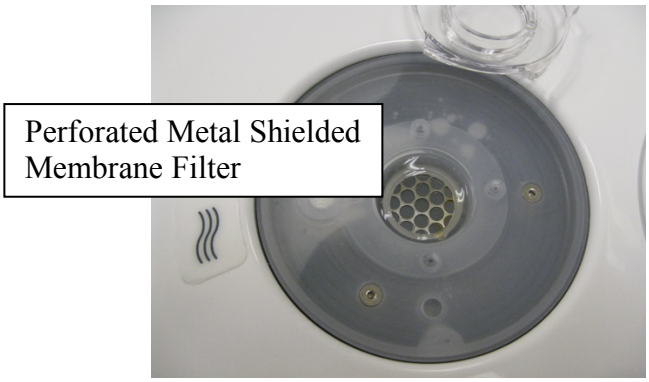


Figure 7: Perforated Metal Shielded Membrane Filter

If the miraDry Handpiece has just been attached for the first time, you will be prompted to add more water with a W08 popup message. It will take approximately 40 ml of deionized or distilled water to fill a completely empty Handpiece.

Step 5 Place the System for Patient Treatment
Position the System close to the patient and make sure none of the air vents located at the bottom or rear of the Console are obstructed.

Step 6 Position the Handpiece in the Holster to Start the System Self-Test
The System performs a self-test when power is turned ON to ensure that all functions are working as expected.

Place the Handpiece in the holster and lower it to the “down” position as shown in Figure 8. The Handpiece must be in the “down” position to complete the self-test.

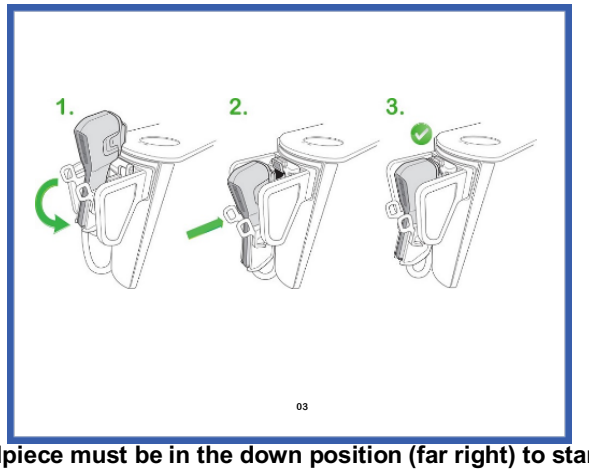


Figure 8: Handpiece must be in the down position (far right) to start the self-test

9.2. OPERATION – GEAR MENU

At any time during setup or operation touch the **Gear Menu Icon** () on the Touchscreen GUI to display the Gear Menu Drop Down and adjust system settings. The Gear Menu Drop Down will also display the console software release version and identification code (2.4.1 and A52FAB3 in this example) and the Handpiece software release version and identification code (1.3.4 and 485818AF in this example) on the top of the screen. In addition, it will display the modem Signal Type and Signal Strength (LTE and 99% in this example). See Figure 9.

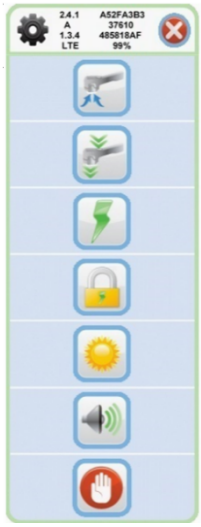
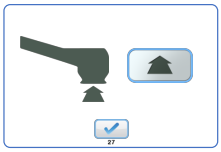
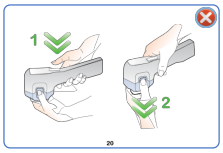
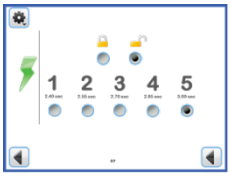
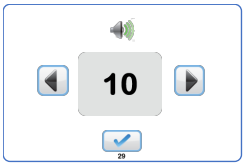
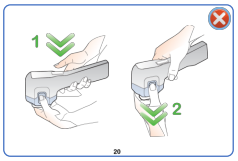


Figure 9: Gear Menu Drop Down

To close the Gear Menu Drop Down, touch the X button ( ) at the top right of the Drop Down.

System Settings

Icon	Description	Pressing icon will display pop-up	Instructions	Completing task
	Purge (“unclog”) the bioTip		Turn the purge on and off by touching the up arrow button ( ).	Touch the check mark button ( ) when finished.
	Remove bioTip from Handpiece		Remove bioTip by pressing the handswitch.	
	Unlock fixed energy level in first few rows of template Microwave energy level		Touch the circular button( ) below the desired lock setting. (see below for more detail) Touch the circular button( ) below the desired microwave energy level. (see below for more detail)	Touch the arrow button ( ) to proceed.
	Unlock fixed energy level in first few rows of template		Touch the check mark button to unlock fixed energy level in first several rows to allow all rows to be treated with the desired energy level	Touch the check mark button ( ) to confirm or touch X button ( ) to leave locked.
	Touchscreen display brightness		Touch the arrow buttons (or) to adjust the brightness up or down.	Touch the check mark button ( ) to confirm.
	Console volume		Touch the arrow buttons (or) to adjust the volume up or down.	Touch the check mark button ( ) to confirm.
	Stop treatment session		Remove bioTip by pressing the handswitch.	Dispose of used bioTip.

Microwave Energy Level Settings
There are five pre-set microwave energy levels. Levels determine how long (in seconds) the microwave energy is applied to a particular target site. The System default microwave energy level is Setting 1 (2.40 sec).

Microwave Energy Level #	Microwave Energy Delivery Time (sec)
1	2.40
2	2.55
3	2.70
4	2.85
5	3.00

The energy level is fixed to level 1 for the first few rows of each guided treatment template, regardless of the selected energy level.

Total # of rows for template	Treat these rows at energy level 1
11	4
13	4
15	5
17	6

Touching the button under the lock symbol on the microwave energy level screen will leave the fixed energy level 1 in the first few rows. You may override the fixed energy level for a single treatment (patient) by touching the button under the unlock symbol on the microwave energy screen.

Alternatively, select the gear icon at the top left corner of the screen. The dropdown menu will appear which includes a lock symbol. Touching the lock symbol will display a popup screen. By touching the check mark on the popup screen you can unlock the fixed energy levels. Touching the X button ( ) will leave the default fixed energy level 1 in the first few rows.

On the top left corner of the treatment screen, the green energy level icon will be displayed below the gear icon. The selected energy level will be shown on the left, above the radio button icon, and the current energy level will be shown to the right ( ).

9.3. OPERATION – PRE-TREATMENT SETUP

You must complete these steps prior to initiating treatment.

Step 1 Attach the Handpiece to the Console
If the miraDry Handpiece has not already been attached, you will be prompted to do so at this time as shown in Figure 10. Refer to Section 9.1 for attachment instructions. Turn the System OFF before connecting the Handpiece.

Figure 10: "Attach Handpiece" Screen

Step 2 Position the Handpiece in the Holster to Start the System Self-Test

The self-test will start automatically if the Handpiece is properly positioned in the holster in the "down" position. The Touchscreen GUI graphic shown in Figure 11 will appear during the self-test. If the Handpiece is not correctly oriented in the self-test position, you will be prompted to properly position the Handpiece as described in Section 9.1.

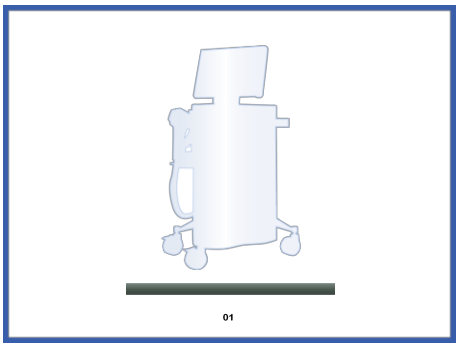


Figure 11: "System Self-Test" Screen

Step 3 Start a Treatment Session

Touch the right arrow button ( ) as shown in Figure 12 to initiate a treatment session.

Figure 12: Press arrow button to initiate a treatment session

Step 4 Attach a new bioTip to the Handpiece

The miraDry bioTip must only be used for a single treatment session for one patient. This will avoid biocontamination.

Refer to the Instructions for Use for the miraDry bioTip to ensure proper installation of a new bioTip. Remove the bioTip tray seal but leave the bioTip in the tray. While holding the bioTip tray as shown in Figure 13, place the Handpiece onto the bioTip. Magnetic latches will automatically attach the bioTip to the Handpiece.

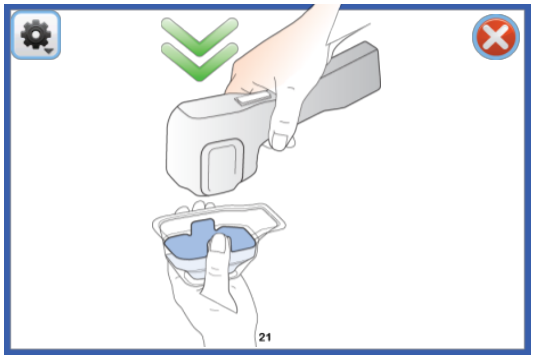
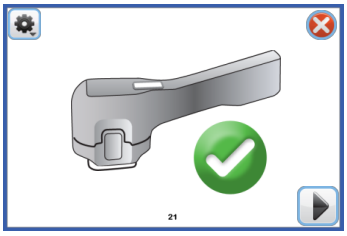
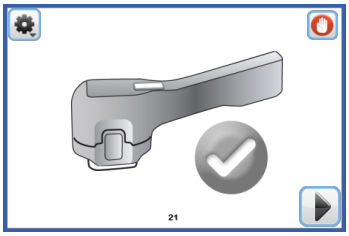
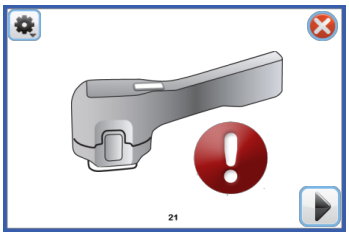
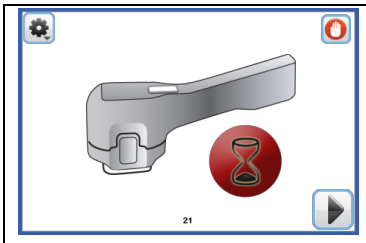


Figure 13: "Attach bioTip" Screen

Once attached, the System will check the status of the bioTip and display the results on the "bioTip Status" Screen.

"bioTip Status" Screen State	What it means
	**Successful attachment.** Okay to proceed.
	**bioTip status verification pending.** Wait several seconds for verification of successful bioTip attachment to be completed (indicated by the green circle with a check mark).
	**Previously used bioTip.** You must replace the bioTip before you can continue.
	**bioTip Read Error.** You must remove, rotate and re-attach the bioTip before you can continue. If this error does not clear after trying this several times, you must replace the bioTip with a new bioTip before you can continue because the bioTip may be damaged or non-functional.

	**Expired bioTip.** You must replace the bioTip before you can continue.

If the Touchscreen GUI indicates that you have a valid bioTip, touch the right arrow button ( ) on the “bioTip Status” Screen to display the “Simple Template Selection” Screen.

Step 5 Input Patient Demographic Information

The patient demographic screen appears after the bioTip is attached and the Next button is pressed.

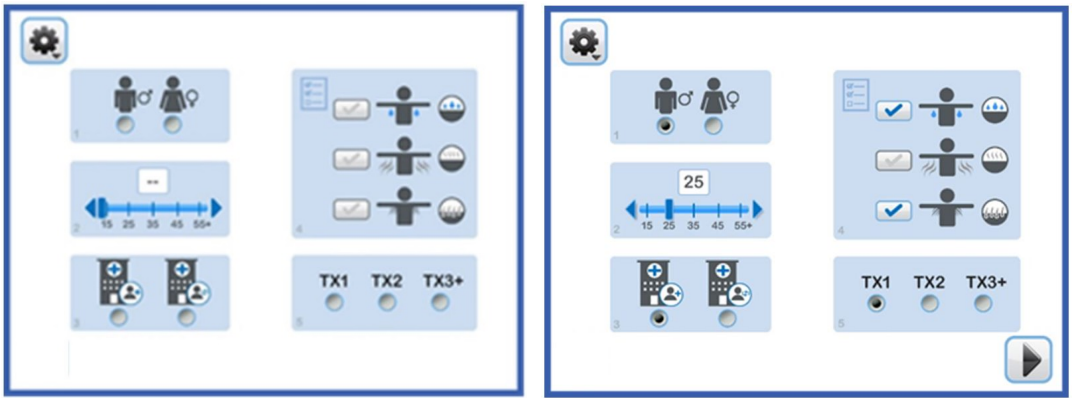
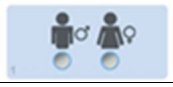
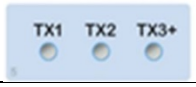


Figure 14: Patient Demographic Screen (no answers and all answers selected)

All questions must be answered before the right arrow button ( ) will appear. The user must answer the following questions via the selection method listed below:

#	Question	Selection Method
1	Patient Gender 	Radio Buttons *(Select one)*
2	Patient Age 	Slider with arrow buttons to increment value *(Select one)*
3	New or returning patient to practice 	Radio Buttons *(Select one)*
4	Motivation for TX (Sweat, Odor, Hair) 	Checkboxes *(Select one to three)*
5	TX# (TX1, TX2, TX3) 	Radio Buttons *(Select one)*

Step 6 Administer Anesthesia
The “Administer Anesthesia” Screen will appear to prompt an injection of anesthesia as shown in Figure 15.

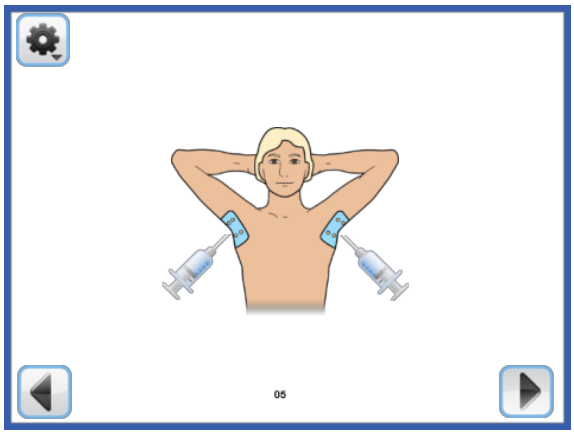


Figure 15: “Adminster Anesthesia” Screen

Please see the Instructions for Use for miraDry Template System for the recommended anesthesia regimen based on the Template size selected.

⚠ ALWAYS follow the package insert instructions and indications for the use of local anesthetic. miraDry Template System recommendations are guidelines and are not to be used if they are inconsistent with the drug labeling.

The miraDry System is contraindicated for patients with known resistance to or history of intolerance of local anesthesia including lidocaine and epinephrine.

DO NOT administer anesthesia unless skin is disinfected prior to anesthesia administration. Note that if you use alcohol for disinfection, it may remove the Template.

ALWAYS wait a minimum of 10 minutes after administering anesthesia to initiate treatment. NEVER initiate treatment if more than 60 minutes have elapsed since administering anesthesia.

ALWAYS inject the appropriate type and quantity of anesthesia.

CAUTION: Anesthesia injections will likely cause discomfort for the patient due to the puncturing of the needle through skin and/or “stinging” sensation of the anesthetic within the skin.

After anesthesia has been injected, touch the right arrow button ( ) to continue.

Step 7 Select the Template Size
Measure the dimensions of the patient’s axilla using the miraDry Template System. Refer to the Instructions for Use for the miraDry Template System for information on how to select a Template. Based on this assessment, determine what size Template to use and be ready to enter the Template dimensions on the “Simple Template Selection” Screen as shown in Figure 16.

“Simple Template Selection” Screen

Touch the dimensions buttons above (888 mm) and to the left (888 mm) of the Template grid to enter the dimensions. Touch the TX1 button if this is the first time the patient is receiving treatment, touch the TX2 button if this is the second treatment or touch the TX3+ button if this is the third (or more) treatment. On the "Simple Template Selection" Screen, you have the option to use the System "defaults" for treating the patient.

The System defaults assume:

- You want to treat the patient's right axilla first
- You will be using the same Template dimensions for both axilla, *and*
- You wish to operate the System in **Guided Treatment Mode** (one of two Treatment Modes available with the System).

Touch the right arrow button ( ) after you have entered the dimensions on the "Simple Template Selection" Screen. Then proceed to step 7.

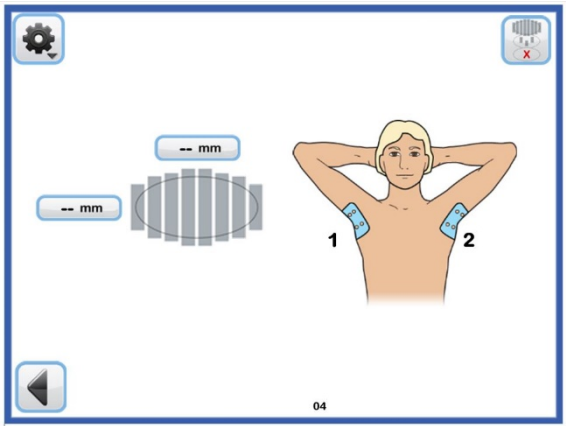


Figure 16: Enter Template size and treatment number on "Simple Template Selection" Screen

"Advanced Template Selection" Screen

With some patients you may wish to have more treatment flexibility than what is available using the System defaults. This may happen when you need a different size Template for each axilla, when the axilla require different treatment modes (e.g., **Guided Treatment Mode** on one axilla and **Touch-Up Treatment Mode** on the other) or if the "treat right axilla first" default is undesirable, In these cases, you may wish to display the "Advanced Template Selection" Screen (see Figure 15) by pressing the template button ( ) on the top right.

⚠ DO NOT use the miraDry System to treat a patient unless their axilla size has been properly measured and selected appropriately. Axilla size selection determines what recommendations will be made for administering anesthesia.

On the "Advanced Template Selection" Screen, first choose which underarm is going to be treated first. Touch the left/right arrow button ( ) in the middle of the top row to select whether the right or left axilla will be treated first.

For each axilla, you can then choose between three modes of operation:

- **Guided Treatment Mode –** a Template typically used to treat a large, continuous area (either the full axilla or a large part of the axilla). With this template, the Touchscreen GUI guides each placement.

- **Touch-up Treatment Mode –** a Template that lets you control each placement and use the Touch-Up templates as guidance. The System will then simply count the number of placements completed (see Section 9.7).

- **No Treatment Mode –** a Template that assumes you will only be treating one axilla.

For each axilla you will be treating, select the operation mode for that axilla by pressing one of the circular buttons below it. Choose Guided Treatment Mode (row 1), Touch-up Treatment Mode (row 2) or No Treatment Mode (row 3). If you choose Guided Treatment Mode, you will also need to enter the axilla dimensions.

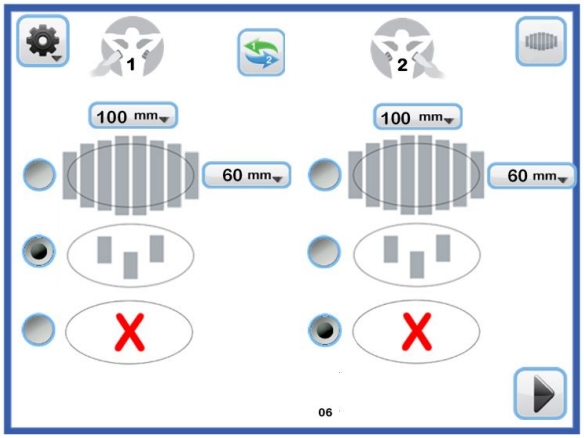


Figure 17: "Advanced Template Selection" Screen

To continue to step 7 with your selections, touch the right arrow button ( ) on the bottom right of the "Advanced Template Selection" Screen. To switch back to the "Simple Template Selection" Screen (Figure 17), touch the template button ( ) on the top right.

Note: Selections made on the "Advanced Template Selection" Screen will only be used for the current treatment procedure. Template selections will revert back to the System defaults on the next procedure.

Step 8 Apply Templates
The Templates should be applied as described in the Instructions for Use for the miraDry Template System. Figure 18 shows an example of the Template being applied for Guided Treatment Mode.

Figure 18: Apply Template (example shown is for Guided Mode)

9.4. OPERATION - TREATMENT

Refer to the Instructions for Use for the miraDry Template System and miraDry Handpiece for additional instructions on the Treatment Template application.

Step 1 Select a Microwave Energy Level

Microwave energy from the Console is delivered to target sites on the patient's axilla through the Handpiece/bioTip. You will need to select the microwave energy level for treatment as shown in Figure 19.

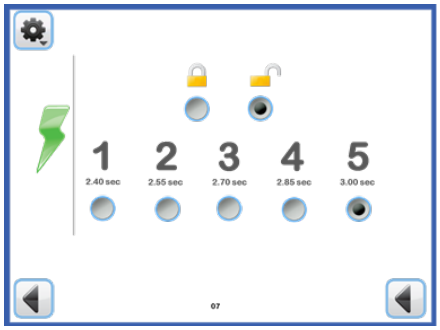


Figure 19: "Microwave Energy Level Selection" Screen

The recommended microwave energy setting for the first treatment session for a new patient is Setting 1 (2.40 sec). Higher microwave energy levels are also provided but only should be used under certain conditions and by operators with an appropriate level of experience. This includes using higher microwave energy levels for follow-up treatments in patients who have not adequately responded to lower microwave energy levels. **The microwave energy setting should always be as low as practical.**

Touch the right arrow button ( ) to continue to the "Treatment" Screen. The Touchscreen GUI will first display a pop-up reminder that shows the axilla you have selected to be treated first and the selected template size (see Figure 20).

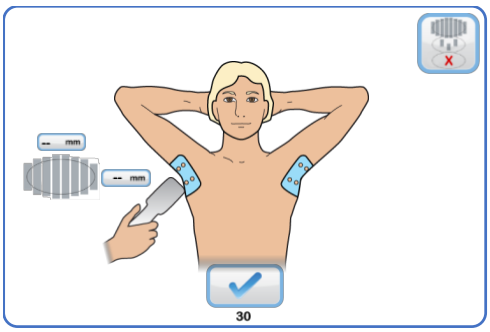


Figure 20: Pop up screen indicating which side will be treated first and the selected template size.

If an incorrect template size was initially chosen, the template size can be changed at this time by pressing the template button at the top right hand corner of the screen. This is will lead to the "Change Template" Screen (see Figure 21) to change the template size. There is no Gear Menu or Simple Template selection button on the Change Template screen. A template change request made for the first axilla will allow changing both sides and swapping sides.

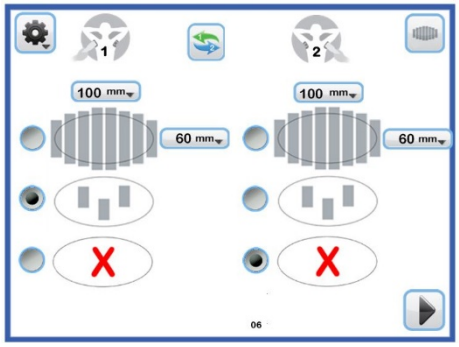


Figure 21: Change Template Screen

A template change request for the second axilla will only allow changes for the second axilla (see Figure 22). There is an exception if the NO-TREAT (red X) was selected for the first axilla. In this case, changes to both axillae can be made.

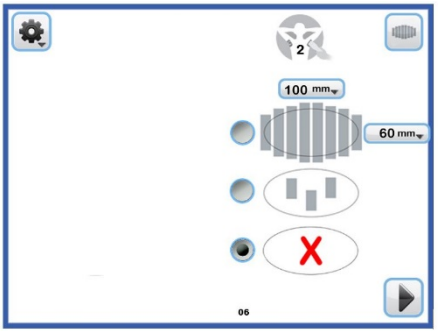


Figure 22: Change Template Screen for second axilla.

If power is lost once in the treatment screen and energy has been delivered for a placement, the system will maintain its position in the treatment sequence. However, during the power-cycle recovery, an appropriate pop-up screen will first appear indicating the side and template size which was last used, without the Change Template button.

Step 2 Lubricate the Axilla

Place a small amount of KY® jelly or KY® liquid (water-based lubricant) on the patient's skin. Use approximately 1-4 ml of lubricant on each axilla, depending on the size of the axilla and dryness of skin.

⚠ DO NOT use the miraDry System unless an appropriate amount of skin lubricant is used.

Step 3 Position the Handpiece on the Axilla

Place the miraDry Handpiece in the appropriate position on the patient's skin. For Guided Treatment Mode, the Touchscreen GUI schematically shows the first treatment position as 1A. This should match the treatment position on the patient's skin that has been created from the skin Template.

A treatment cycle begins and ends with microwave energy delivery to a particular target site. Triangles on the Template grid indicate the various treatment target sites. The green triangle shown in Figure 23 indicates the target site that is ready to be treated. While microwave energy is being delivered to the target site, the triangle remains green. The triangle turns grey when microwave energy delivery stops to this target site, signaling the end of the treatment cycle.

The next triangle in sequence will turn green to indicate the target site of the next treatment cycle.

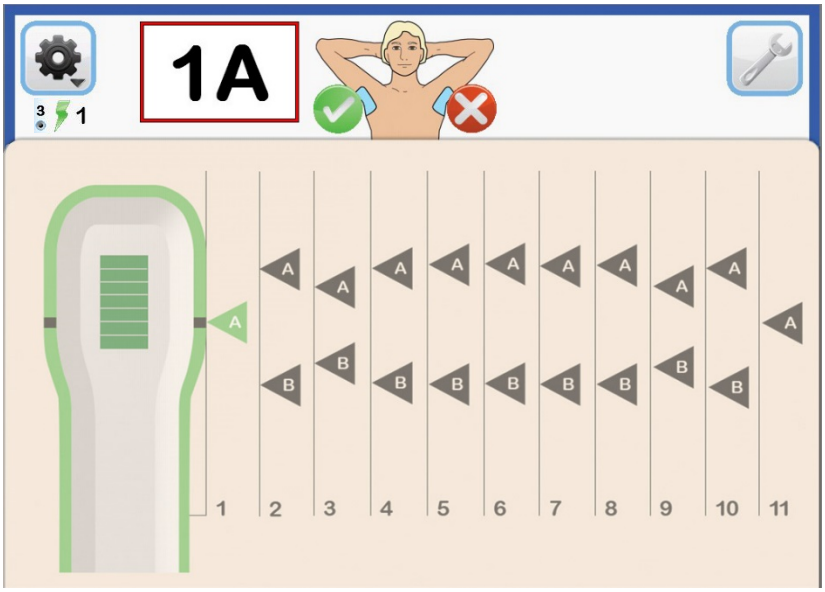


Figure 23: Treating the 1A position

Firmly place the Handpiece on patient's skin as shown in Figure 24 to start the first treatment cycle. Make sure the full perimeter of the flexible skirt of the miraDry bioTip is in contact with the patient's skin.

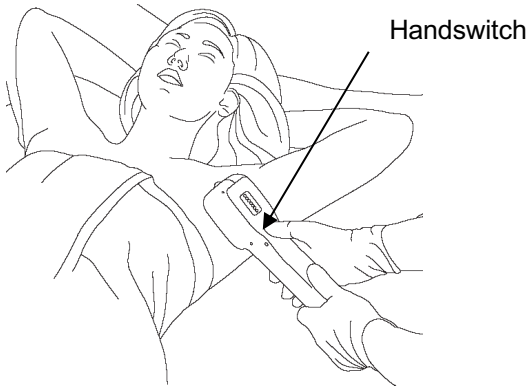


Figure 24: Firmly place Handpiece on patient's skin

Step 4 Start Treatment

Initiate treatment by either pressing the handswitch on the miraDry Handpiece or pressing the footswitch (optional) attached to the miraDry Console.

Using suction created from the Console vacuum, skin tissue is first drawn into the bioTip acquisition chamber and then placed against the cooling plate. While the skin is in the chamber, microwave energy is delivered to the target site for the selected duration time. Following microwave energy delivery, the skin is cooled and then released from the chamber. An audible "treatment" tone will sound during this entire treatment cycle.

If you press the handswitch or footswitch a second time during the treatment cycle, you will terminate the treatment cycle. If termination occurred during the short, initial skin acquisition phase, the System will go back into ready mode. If termination occurred during the microwave energy delivery phase, the System will skip directly into the post-cool phase before going back into ready mode.

- The status bar on the bottom of the Touchscreen GUI shows the current treatment cycle phase. Blue represents a skin acquisition or post-cool period while green represents a microwave energy delivery phase. Microwave energy delivery can be terminated prior to completion by pressing the Handpiece handswitch or the footswitch. The System will skip directly to the post-cool phase. The post-cool phase cannot be stopped by pressing the footswitch or handswitch.

- An audible tone will sound when the treatment is in progress. Keep the Handpiece in contact with the patient's skin while the tone sounds.

- During microwave energy delivery, the blue light on the front panel of the miraDry Console will be illuminated (see the indicator above the Standby button in Figure 3).

Repeat steps as necessary to complete the remaining identified target sites on the axilla. The Touchscreen GUI will prompt you with the appropriate sequence of treatment target sites.

⚠ DO NOT pull the Handpiece off of the patient's skin until you complete the treatment cycle at a particular target site or the skin will receive incomplete cooling and be more susceptible to skin damage.

DO NOT deliver microwave energy from the Handpiece unless it is positioned at the intended target site. See the Instructions for Use for the miraDry Handpiece for proper positioning of the Handpiece.

WARNING: DO NOT treat the same skin site twice in a given treatment session. Multiple treatments to the site may cause skin burn, significant edema, and significant damage to subdermal structures.

Once a treatment cycle is completed, the site triangle will change from green to grey as shown in Figure 24. In Figure 25 the Touchscreen GUI is indicating that placement 10B is the next site to be treated.

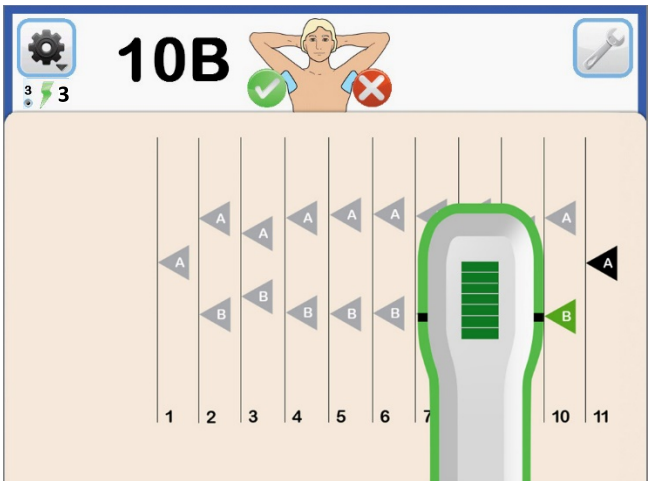


Figure 25: Normal Treatment Sequence in Guided Treatment Mode

Step 5 Repeat the Treatment on the other Axilla

After the treatment of one axilla is complete, proceed to the second axilla.

After completion of the second axilla the Touchscreen GUI will automatically proceed to the cleaning and wrap-up procedures.

It may take up to 20 minutes to complete treatment on one axilla. It is important to maintain a comfortable posture and proper technique while administering treatment to minimize neck, back and hand strain.

Skipping a Template Placement
You can skip a Template placement or return to redo a Template placement in Guided Mode.

Simply press the wrench button () at the top right corner of the Guided Treatment Mode Screens. This lets you change the status of a Template placement from “Pending” to “Completed”, or “Completed” to “Pending”. Skipping a Template may be useful when you want to avoid treating a particular area due to a pre-existing condition, like a scar or large mole. It is also useful when you want to redo a placement that was not satisfactory.

Touching the wrench button () button shown in Figure 26 will remove the Handpiece image from the Touchscreen GUI and highlight each placement flag (A, B or C) with the same blue outline found on other buttons. Touching a placement flag will switch its status back and forth between “Pending” (black) and “Completed” (grey). Touching the wrench button again shown in Figure 27 will remove the blue outlines from the placement flags and let you resume treatment.

Figure 26: Active Wrench Button, Available

Figure 27: Wrench Button Not Active, Mode Not Turned On

9.5. OPERATION – STOPPING A TREATMENT

There are different ways to stop a treatment while it is in progress:

- **Stop Treatment in the Middle of a Placement**
  There are two ways to stop microwave energy delivery while administering treatment at a particular placement. The effect of this action is to end the treatment cycle at that one particular target site but be free to proceed with the next placement/treatment.

  1. Press down on the Console footswitch (optional) while the miraDry Handpiece is administering treatment.

  2. Press the Handpiece handswitch while it is administering treatment.

  Both methods place the Handpiece in post-cool mode. **Continue to keep the Handpiece in contact with the skin through the entire post-cool period**.

- **Terminate Treatment Session**
  You may want to end a treatment session without completing any remaining placements for this patient. Referring to the instructions in Section 9.4, you should skip the remaining placements on both axilla (if operating in Guided Mode) and follow the Touchscreen GUI to complete the cleaning and wrap-up procedures. Alternatively, you can touch the **Gear Menu Icon** at the top left corner of the screen to display the Gear Menu Drop Down. Then select the **Stop Session Icon** shown in Section 9.2. This will terminate the treatment session and return you to the "Welcome" Screen.

- **Emergency stop**
  To instantly shut-off of the system at any time, press the red Emergency Stop Button on the Console as shown in Figure 28 and as described in Section 3.1.

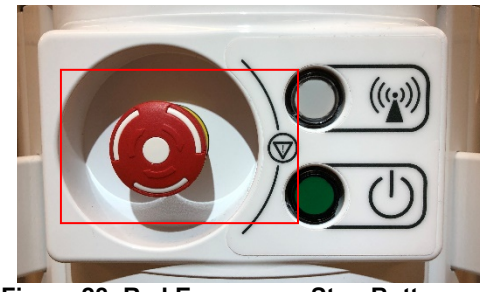


Figure 28: Red Emergency Stop Button

- **Total System shutdown**
  See Section 9.4. After completing a treatment session, turn the Console OFF by pressing the green Standby button.

9.6. OPERATION – POST TREATMENT

The miraDry bioTip must only be used for a single treatment session for one patient. This will avoid biocontamination.

Step 1 Remove bioTip
Remove the bioTip from the miraDry Handpiece by pressing the button on the Handpiece as shown in Figure 29.

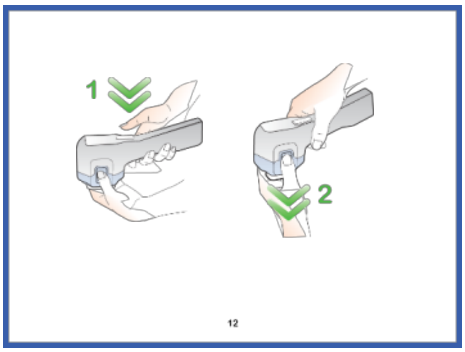


Figure 29: "Remove bioTip" Screen

Dispose of bioTip according to local regulations.

Step 2 Clean the Handpiece
Once the bioTip has been removed, the “Clean Handpiece” Screen will appear as shown in Figure 30. Clean any excess water-based lubricant that may be remaining on the Handpiece using isopropyl alcohol.

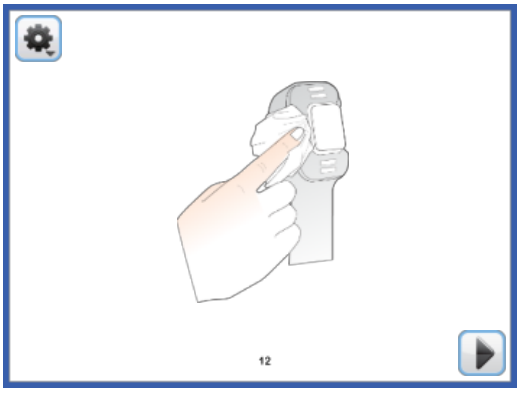


Figure 30: “Clean Handpiece” Screen

Step 3 Place the Handpiece in the Console holster
Place the Handpiece back in the holster in the “down” position as shown in Figure 8.

Step 4 Review “Treatment Summary” Screen
A “Treatment Summary” Screen will appear as shown in the example in Figure 31. The screen summarizes the number of completed placements at each microwave energy level and the guided treatment template size, for each axilla.

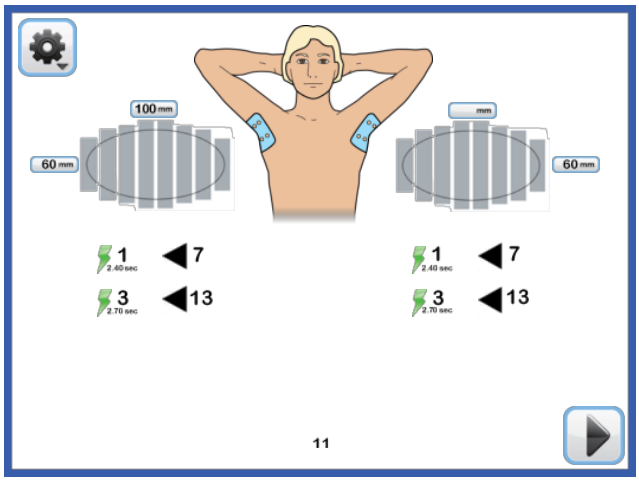


Figure 31: “Treatment Summary” Screen (example with both axilla treated in Guided Mode)

Step 5 Place an Ice Pack on the Axilla Treatment Area
After the procedure, clean the patient’s skin and place an icepack on the treatment area.

Step 6 Please Do Not Turn Off System Icon

The “Please Do Not Turn Off System” ( ) icon may be displayed on the screens after a completed treatment. Do not unplug or power the System off when this icon is displayed.

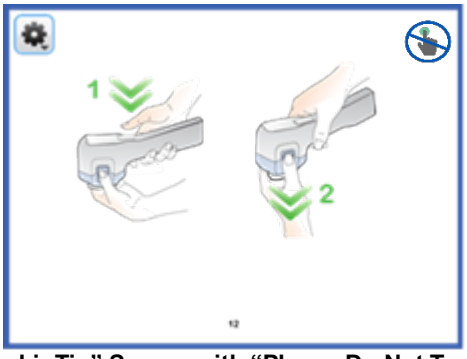


Figure 32: “Remove bioTip” Screen with “Please Do Not Turn Off System” icon

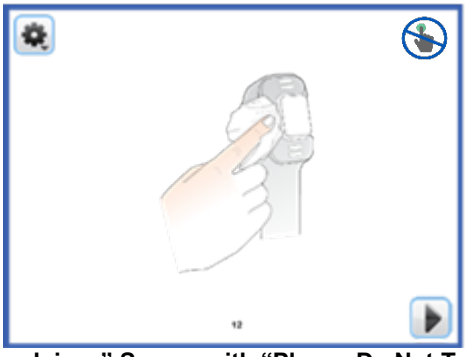


Figure 33: “Clean Handpiece” Screen with “Please Do Not Turn Off System” icon

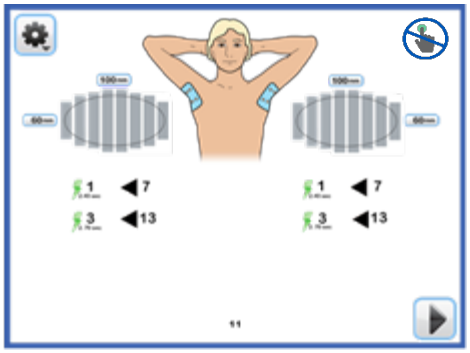


Figure 34: “Treatment Summary” Screen with “Please Do Not Turn Off System” icon (example with both axilla treated in Guided Mode)

Figure 35: Splash Screen with "Please Do Not Turn Off System" icon after completion of treatment

9.7. OPERATION – TOUCH-UP MODE

Follow the instructions in Section 9.7 for selecting Touch-up Treatment Mode, applying a Touch-up Template, and administering anesthesia. This includes any special safety instructions for administering anesthesia for touch-up placements. Then follow the instructions in sections 9.2 and 9.4 for selecting the appropriate microwave energy level.

Step 1 Start the Treatment Cycle
Press the handswitch on the miraDry Handpiece or the footswitch on the miraDry Console to initiate a treatment cycle. The counter on the "Touchup Treatment" Screen (as shown in Figure 36) tracks the total number of treatment cycles initiated in Touch-up Treatment Mode.

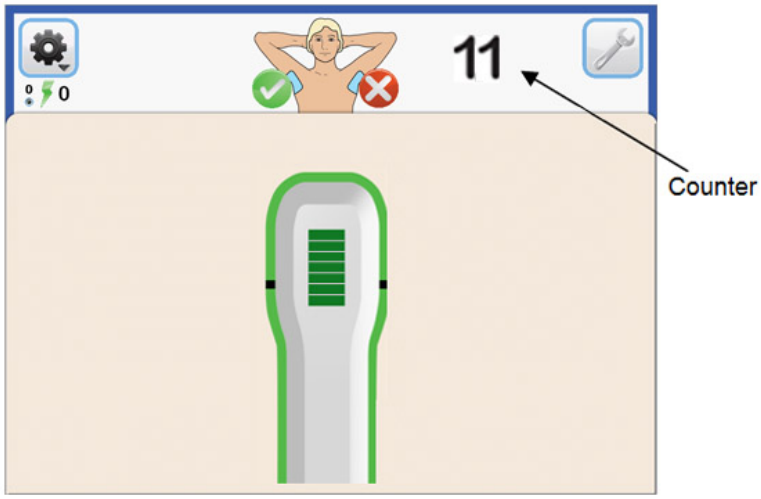


Figure 36: "Touch-up Treatment" Screen

To end Touch-up Mode, touch the next button ( ) on the top right of the "Touchup Treatment" Screen.

9.8. OPERATION – PROCEDURE TROUBLESHOOTING

Some common problems that you might encounter are listed below, along with an explanation and possible solution. Please also refer to the Troubleshooting Guide in Section 12.

Treatment Cycle Won't Start
Three seconds prior to microwave energy delivery, the System performs a self-check. The test verifies that the patient's skin is in contact with the miraDry Handpiece cooling plate, and a good vacuum seal has been achieved. If one or both of these conditions is not met, the System will not deliver microwave energy. The outline around the Handpiece on the "Treatment" Screen will turn to orange when this happens. Adjusting the angle of the Handpiece on the patient's skin will usually resolve this issue.

Loss of bioTip Suction
If there is a loss of suction during the treatment cycle the audio tone will change and the progress bar at the bottom of the "Treatment" Screen will also turn yellow. The outline around the Handpiece on the "Treatment" Screen will also turn to yellow when this happens as shown in Figure 37. Adjusting the position of the Handpiece, or applying additional force to achieve a complete vacuum seal around the entire perimeter of the flexible skirt of the miraDry bioTip, will usually resolve the issue.

Figure 37: Yellow outline indicates vacuum loss

Loss of Power to System
In the event of a power loss, the miraDry Console will shut down. Power loss will occur if the red Emergency Stop Button on the Console was pushed, the AC Power Cord was disconnected from the AC power supply, or the green Standby button was pressed while the System is turned ON.

When power is restored, and if the System was not displaying a Guided or Touch-up "Treatment" Screen when power loss occurred, the System will start up normally as described in Section 9.1.

If the System was displaying a "Treatment" Screen when power loss occurred and you are using the same Handpiece as before, the System will return to the "Treatment" Screen at the same position placement where you were when power was lost. The microwave energy setting will also stay the same as before. The "Water Temperature Wait" Pop-up shown in Figure 38 will be displayed if the water temperature is too high. The System will automatically clear this Pop-up when the water returns to the proper treatment temperature.

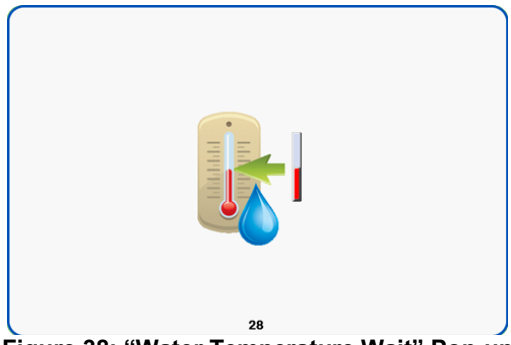


Figure 38: "Water Temperature Wait" Pop-up

If the System was displaying a “Treatment” Screen when power loss occurred, and you are using a different Handpiece than before, the System will perform the usual Handpiece self-test before returning to the “Treatment” Screen at the same position placement where you were when power was lost.

No bioTip attached or invalid bioTip

The “bioTip Verify” Pop-up will be displayed if the System detects that there is no bioTip attached, or the one attached is not valid (see Section 9.3). You will be prompted to reattach the bioTip or install a new one. The “Active Axilla Confirmation” Pop-up shown in Figure 39 will then be displayed to have you confirm the current axilla being treated. Press the check mark button ( ) and the System will return to the Treament Screen at the next pending position placement.

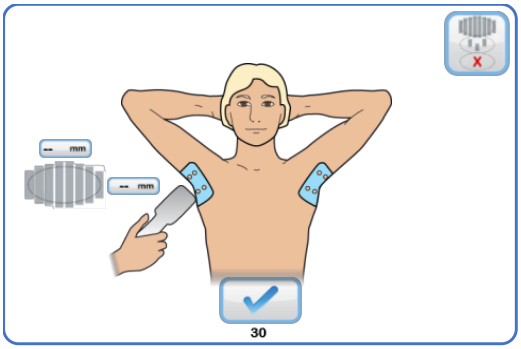


Figure 39: “Active Axilla Confirmation” Pop-up

If you do not wish to proceed with treatment after a power loss, you can display the Gear Menu Drop Down and press the **Stop Session Icon** (see Section 9.2) to cancel the rest of the current treatment session.

9.9. SYSTEM SHUTDOWN PROCEDURE

Wait for Please Do Not Turn Off System icon ( ) to disappear. Turn the miraDry Console OFF by pressing the green Standby button.

9.10. SYSTEM UPDATES

Newer System software versions will be available to update over the air to maintain optimal performance and offer new features. Upon start up, an Update Available Screen will appear after the Splash Screen. The hourglass symbol ( ) will indicate total time for update to complete. Accept update by selecting the checkmark button.

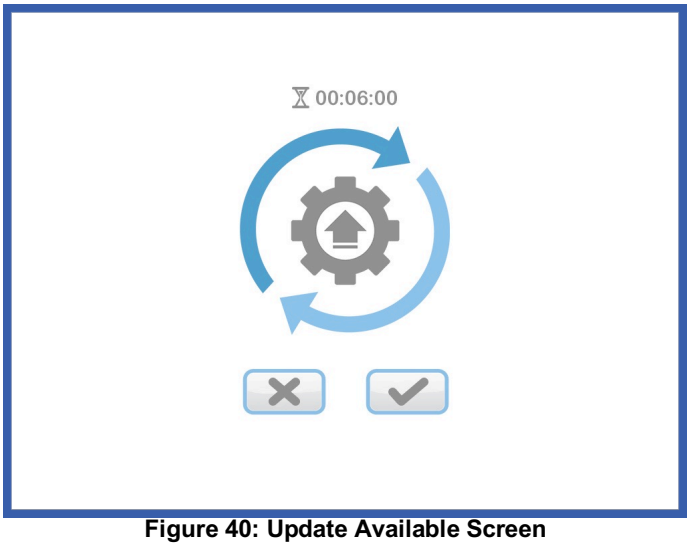
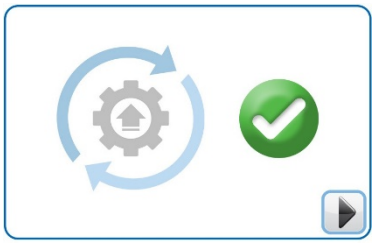


Figure 40: Update Available Screen

After update is accepted, the Update Progress Screen will appear to display number of updates within the upgrade and a progress bar for each. During the upgrade the system may restart as a routine step for the software update.

Figure 41: Update Progress Screen

Once update is complete the System will check the status of the software upgrade and display the results on the “Software Upgrade Status” Screen.

“Software Upgrade Status” Screen State	What it means
	**Successful Update** Okay to proceed to treatment

	**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 Customer Service for assistance to complete update.

To postpone an update, select the 'X' button on the Update Available Screen. A screen will appear to indicate the number of times remaining to defer update. If the maximum number of postponed updates is reached, the System must be updated in order to proceed to treatment.

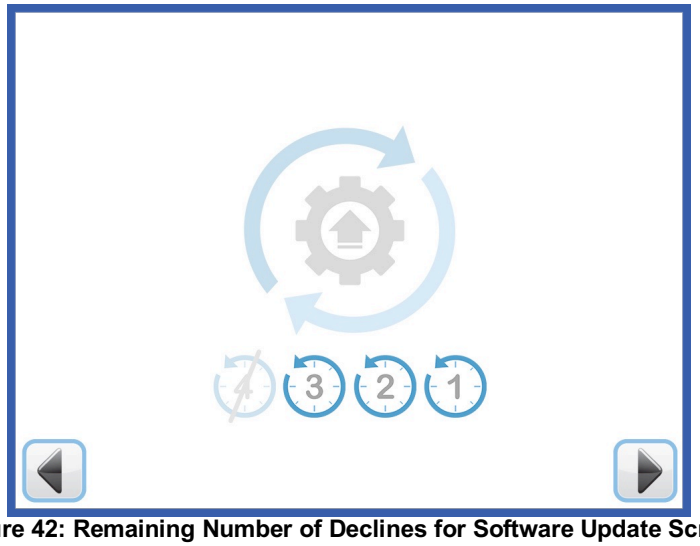


Figure 42: Remaining Number of Declines for Software Update Screen

⚠10. TRAINING, CLEANING, AND MAINTENANCE

10.1. TRAINING

miraDry will provide in-field training for the miraDry System.

DO NOT use the miraDry System unless instructed in the correct use of the equipment by designated Company representatives. The System should be used by qualified clinical personnel only.

10.2. CLEANING AND DISINFECTING

- miraDry Console components cannot be sterilized. Refer to hospital procedures for proper cleaning of equipment. Use only non-abrasive cleaning agents and DO NOT allow liquid to enter Console connectors.
- Make sure to turn the AC Main Power Switch to the OFF position and unplug the AC Power Cord before cleaning.
- DO NOT spray or pour cleaning agents or any other liquids on the Console components.
- Dampen a clean dry cloth with a multi-purpose hospital grade detergent.

- Gently wipe down all cords, switches, buttons, and device housing, taking special care not to get liquid into the housing or electrical components.
- Gently dry the entire Console, including cords.
- DO NOT soak any of the cords, cables or connectors, since this can affect electrical performance.
- Disinfect with 70% isopropyl alcohol as needed.
- Clean and remove any dust, lint or particulate materials from the air intake screen filter located on the bottom of the Console. Use a vacuum cleaner and/or water. This filter is attached to the bottom of the Console using a magnetic attachment. It can be easily removed for cleaning and then placed back on the Console. Cleaning this filter more frequently is necessary when the Console is used in areas where there is more lint or dust present. Inspect this filter once a month and clean it when particulate materials are found that could reduce air flow through the system.
- ALWAYS turn the electrical units OFF by turning the AC Main Power Switch to the OFF position, and disconnect the power cord from the AC supply before cleaning.

10.3. STORAGE

The miraDry System should be stored in a cool, dry place out of direct sunlight.

10.4.MAINTENANCE AND SERVICE INFORMATION

The miraDry Console has been Manufacturer tested. There are no serviceable parts inside the miraDry Console. Contact miraDry for service. Periodically check the removable filter for dust, particulate matter, etc. Clean using a vacuum cleaner and/or water. This filter is attached to the bottom of the miraDry Console using a magnetic attachment. It can be easily removed for cleaning and then placed back on the Console. The filter check should not be performed while the system is being used to treat a patient. There is no other preventative maintenance required other than replacing the Console fuses.

Product Disposal
Do not dispose of this product in the unsorted municipal waste stream. Please contact your miraDry representative for proper disposal of this product.

10.5. HOW TO CHANGE THE CONSOLE FUSES

DO NOT attempt to change the Console fuses without the help of a miraDry Representative.

CAUTION: DO NOT replace miraDry Console fuses with fuses that have been repaired, or with short-circuited fuse holders. Only use standard time delay fuses that are current rated T8A/250 V~.

Two fuses are located in the power entry module of the Console.

1. Turn the System OFF.
2. Unplug the AC Power Cord from the AC power outlet.
3. Snap open the fuse holder cap (located above the power module power switch) by placing a flat screwdriver in the pre-marked slot located on top of the switch.
4. Remove spent fuses from either side of holder and replace them with standard time delay fuses current rated T8A/250 V~.
5. Replace holder and snap the cap closed.

11. HOW SUPPLIED

11.1. DESCRIPTION OF MD4000-MC CONSOLE COMPONENTS

The miraDry Console is supplied with the following components:

Item	Description	Part Number	Qty
1	MD4000-MC User Manual (this document)	LB0261	1
2	MD4000-MC Console	MN-MD4000-MC	1
3	AC Power Supply Cord	As applicable for country of sale	1
4	Priming Connector	PN1674	1

11.2. DESCRIPTION OF MIRADRY SYSTEM COMPONENTS

The miraDry System is used with the following additional components.

Item	Description	Part Number	Required
1	miraDry Handpiece	MD4000-HP	Yes
2	miraDry bioTip	MD4000-BT or MD4500-BT	Yes
3	miraDry Template System	MD4000-TS2	Yes
4	Deionized Water*	PN0699	Yes

*Distilled water may be used.

12. TROUBLESHOOTING GUIDE

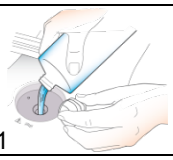
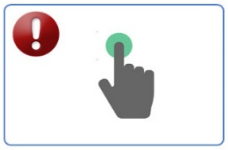
An Error Code/Error Symbol may appear as a Pop-up on the Touchscreen GUI to alert you that there is a problem with the miraDry System that requires your attention. Some of the Error Codes/Symbols appear below, along with an explanation and a possible solution.

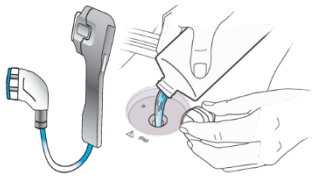
If an Error Code/Symbol appears on the screen that is not included in the table below, perform the Basic Error Recovery.

Basic Error Recovery Steps:

- Clear the Error and continue.
- If the Error cannot be cleared, restart the System (turn the System Off and then ON).
- If the Error persists after the System restart, call a miraDry Representative for assistance.

Touchscreen GUI Pop-up Error Codes	What To Do
System does not power on when green button is pushed.	• Check that the system power cord is firmly plugged to the socket on the system and also into the wall • See if the power switch (at the bottom of the back of the console) is turned off; turn it back on. • Check to see if the Emergency Stop Button is depressed. Rotate clockwise to reset it.
N/A – During vacuum acquisition, system makes “Ding” or “Click” sound and won’t deliver energy. 	“Ding” Sound: • **Skin is not touching the cooling plate.** Adjust angle/slight pressure and re-align to achieve suction. • **Skin is too cold already.** Remove Handpiece. Wait 10 seconds and try again. • **Lubricant has dried and made the skin sticky.** Apply thin layer of lubricant in target area. • **Too much or wrong type of lubricant has clogged the bioTip.** Replace bioTip. “Click” Sound (Bad Vacuum Seal):

Touchscreen GUI Pop-up Error Codes	What To Do
	• Adjust angle, align and verify that the entire perimeter of the bioTip skirt is in contact with skin with no gaps. • Apply more pressure to bioTip against the Handpiece to ensure attachment. • Release the bioTip and re-attach. • Release bioTip, perform purge on side of bioTip tray and reattach.
A01	**Console and Handpiece not communicating.** Basic Error Recovery
A16 or A26 	**Temperature sensor failure or cooling plate broken.** Handpiece needs to be replaced. Discontinue use and call miraDry Customer Service.
A17	**Handpiece self-test failure** Reposition the Handpiece in the holster, such that the head of the Handpiece is touching the foam receptable. Clear the error and self-test will restart. If error persists, take Handpiece out of the hoster and shake it at various angles to disloge any air bubbles. Place Handpiece back in the holster, clear the error and the self-test will restart. If error persists after restart, discontinue use and contact miraDry Customer Service.
A23	**Skin contact with cooling plate lost during delivery** Move onto the next placement and ensure the Handpiece is steady during use. If error persists, remove bioTip (using Gear Menu), rotate 180°, reattach using firm, even pressure.
A22, A24 and A25 	**bioTip Attachment Issue** Remove bioTip, rotate 180° degrees, and reattach using firm, even pressure. If error persists, replace with a new bioTip.
V03, V04 and V06 	**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). If error persists, remove the bioTip and reattach. If error still persists, discontinue use and contact miraDry Customer Service.
W01 	**Water level is low.** Add deionized or distilled water until level is well above water filter. If error persists, discontinue use and contact miraDry Customer Service.
W03	**Air in the cooling system** Attempt to clear the error and continue. If error persists, power off system and replace Handpiece with priming connector and run auto-prime. If auto-prime passes, turn off system and reattach Handpiece. If auto-prime does not pass, call miraDry Customer Service.
A32 	**Turn off system. Restart system if needed.**
W06 followed by Temperature Wait Pop Up	**Room temperature is too warm (>79°F)** Bring room temperature down or open door and place fan in doorway to the room to increase circulation.

Touchscreen GUI Pop-up Error Codes	What To Do
	**Or** **Air intake is blocked with debris (ie: paper, dust, etc.)** Remove external air filter to check for lint and remove. Resume system use and if error persists, discontinue use of the system and contact miraDry Customer Service.
W08 	**Water level is low due to unprimed new Handpiece.** You will need to add approximately 40ml of deionized or distilled water to fill the Handpiece. If needed, fill until the level of water is slighly above the inlet filter. Clear the error and continue to keep the level of water above the filter until the pump circulates water through the system (approximately 99 seconds).
Red Exclamation (Screen 21) 	**bioTip used or invalid bioTip** Use new bioTip.
Red Hourglass (Screen 21) 	**bioTip expired** Use a new bioTip.

13. SPECIFICATIONS

Dimensions	1.19m H x 0.52m W x 0.81m D (46.75" H x 20.25" W x 31.75" D)
Console Weight	51 kg (112.5 lbs)
AC Input	100-240V~, 50/60Hz, 1056 VA
Protection	Protectively earthed, Class I, Type BF
Microwave Output Frequency	5800MHz ± 75 MHz
Procedure Microwave Output Energy	Adjustable to 5 manufacturer-defined set points. The power remains constant across all set points. The duration of power-on time is adjusted by 5% increments at each set point.
Maximum Output Power from the Console	100 Watts into a matched 50 ohm load
Vacuum	-508 to –559 mm of Hg (-20 to -22 inches of Hg)
Cooling Fluid Temperature	15°C ± 1°C
Patient Isolation	Class BF (body floating) for applied parts
Duty Cycle	Continuous
Environmental Operating Temperature/Humidity/Altitude/Pressure	Ambient Temperature: +15.0˚C to +26.7˚C (+60˚F to +80˚F) Relative Humidity (Non-condensing): 10% to 60% at +26.7˚C, 20% to 60% at +15.0˚C Altitude: 0 – 2,000 m or 760 – 571 mm of Hg (0 – 6,562 feet or 29.9 – 22.5 inches of Hg)
Environmental Storage/Shipping Temperature/Humidity/Altitude/Pressure	Ambient Temperature: -29˚C to +60˚C (-20˚F to +140˚F) Relative Humidity (Non-condensing): 15% to 90% Altitude: 0 – 4,267 m or 760 – 413 mm of Hg (0 – 14,000 feet or 29.9 – 16.3 inches of Hg)
CONFORMS TO	<u>Safety:</u> IEC 60601-1: 2005+A1:2012: Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance IEC 60601-1-6:2010: Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral Standard: Usability IEC 60601-2-6:2012: Medical Electrical Equipment - Part 2-6: Particular requirements for the basic safety and essential performance of microwave therapy equipment

	IEC 60601-1-2:2014: Medical Electrical Equipment - Part 1-2: General requirements for safety - Collateral standard – Electromagnetic compatibility – Requirements and tests Medical Device Directive 93/42/EEC

Electromagnetic Compatibility

Like other electrical medical equipment, the miraDry System requires special precautions to ensure electromagnetic compatibility with other electrical medical devices. To ensure electromagnetic compatibility (EMC), the miraDry System must be installed and operated according to the EMC information provided in this manual.

Note The miraDry System has been designed and tested to comply with IEC60601-1-2:2014 (4rd Edition) requirements for EMC with other devices.

CAUTION Portable and mobile RF communications equipment may affect the normal function of the miraDry System.

WARNING Do not use cables or accessories other than those provided with the miraDry System, as this may result in increased electromagnetic emissions or decreased immunity to such emissions.

WARNING If the miraDry System is used adjacent to or stacked with other equipment, observe and verify normal operation of the miraDry System in the configuration in which it will be used prior to using it in a surgical procedure. Consult the tables below for guidance in placing the miraDry System

Guidance and manufacturer's declaration – electromagnetic emissions		
The miraDry System is intended for use in the electromagnetic environment specified below. The customer or the user of the miraDry System should assure that it is used in such an environment.		
Emissions Test	Compliance	
RF emissions CISPR 11	Group 2	The miraDry System must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class A	The miraDry System 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	Complies	
NOTE The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.		

Guidance and manufacturer's declaration – electromagnetic immunity			
The miraDry System is intended for use in the electromagnetic environment specified below. The customer or the user of the miraDry System should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Voltage Dips 30% reduction, 25/30 periods At 0°	Voltage Dips 30% reduction, 25/30 periods At 0°	Mains power quality should be that of a typical commercial or hospital environment. If the user of the miraDry System requires continued operation during power mains interruptions, it is recommended that the miraDry System be powered from an uninterruptible power supply or a battery.
	Voltage Dips > 95% reduction, 0.5 period At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	Voltage Dips > 95% reduction, 0.5 period At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	
	Voltage Dips > 95% reduction, 1 period At 0°	Voltage Dips > 95% reduction, 1 period At 0°	
	Voltage Interruptions > 95% reduction, 250/300 periods	Voltage Interruptions > 95% reduction, 250/300 periods	
(50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Guidance and manufacturer's declaration – electromagnetic immunity			
The miraDry System is intended for use in the electromagnetic environment specified below. The customer or the user of the miraDry System should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the miraDry System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz (6 Vrms in ISM radio Bands within 150kHz – 80MHz)	3 Vrms	$d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.7 GHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range.[b]
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the miraDry System is used exceeds the applicable RF compliance level above, the miraDry System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the miraDry System. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Recommended separation distances between portable and mobile RF communications equipment and the miraDry System

The miraDry System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the miraDry System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the miraDry System as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter** (m)		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.7 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Immunity to RF Wireless Communications Equipment						
Test Frequency (MHz)	**Band [a] (MHz)**	**Service [a]**	**Modulation [b]**	**Maximum Power (W)**	**Distance (m)**	**IMMUNITY TEST LEVEL (V/m)**
385	380 –390	TETRA 400	Pulse modulation [b] 18 Hz	1.8	0.3	27
450	430 – 470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704 – 787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0.2	0.3	9
745						
780						
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	2	0.3	28
870						
930						
1720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	2	0.3	28
1845						
1970						
2450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0.3	28
5240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0.2	0.3	9
5500						
5785						
a) For some services, only the uplink frequencies are included. b) The carrier shall be modulated using a 50 % duty cycle square wave signal. c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.						

Contains FCC ID: QIPPLS8-X
Contains IC: 7830A- PLS8X

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.
