

Spa RF- Clinical Guide

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A.1. Introduction

This clinical guide is provided to aid professionals in the use of the **Spa RF** system. It adds to or reinforces information presented in the operator's manual concerning instructions for use, precautions and warnings necessary to reduce the risk of injury. All operators must read the entire operator's manual before reviewing this appendix and before operating the system.

A.2. Training Requirements

The **Spa RF** system is designed to be operated only by personnel properly trained in its handling and use. All personnel who operate the system must read the operator's manual.

Alma Lasers provides in-service training for the **Spa RF** system. At the end of this in-service training, personnel are considered trained for the operation of the **Spa RF** system.

The physician is responsible for contacting the local licensing agencies to determine any credentials required by law for clinical use and operation of the device.

A.3. Intended Use and Indications

The radio-frequency (RF) **Spa RF** system is intended for deep tissue heating. The system is intended for use for non-invasive treatment of:

- Wrinkles and rhytids
- Skin tightening
- Body contouring
- Cellulite
- Acne
- Pain therapy

A.4. Contraindications

- History of any skin malignancy
- Chronic skin conditions / irritated skin (i.e., Urticaria)
- History of cancer
- Pregnancy (including IVF)
- Active collagen or vascular disease

- High blood pressure
- Phlebitis and blood-clotting (hematology-related)
- Implantable pacemaker or automatic defibrillator/ cardioverter (AICD)
- Past or present of autoimmune illness or disorder
- Large dental metallic prosthetic implants
- Multi systemic diseases (diabetes, hypertension, coronary artery disease, renal insufficiency etc.)

A.5. Special Considerations

- Smoking
- Alcohol consumption
- Dental metallic structure (i.e., bridge)
- Recent surgical procedures
- On-going medications
- Recent (less than **6** months) use of Isotretinoin (Accutane)
- Recent (less than **1** month) use of dermal fillers
- Hormone pellets

A.6. Adverse Effects of Treatment

The use of the *Spa RF* system may cause:

- **Heating sensation** – patient may experience a heating sensation during or just following the treatment, however it is expected to be mild and to resolve within a few minutes.
- **Erythema** – may be present in the treated area and is likely to disappear within 24 hours.
- **Burns** – can be avoided by strict adherence to the operating instructions, and are not likely if the operating instructions are strictly followed. If a burn occurs, it should be treated conventionally.
- **Dry skin** – may occur during the first 12 hours post-treatment. Usually it will resolve spontaneously within 48 hours. Lubrication with moisturizing cream can be helpful.

A.7. Accessories and Equipment

- Water-free treatment oil
- Infrared Thermometer

Warning

The use of any water-based (ultrasonic) gel or oil on the skin is prohibited!

A.8. Pre-Treatment Information

A.8.1. General

During the first visit the practitioner should:

- Take a detailed patient medical history, including previous treatment modalities, and examine the condition for suitability of treatment with the *Spa RF* system.
- Determine why the patient is seeking treatment and understand his/her expectations.
- Discuss the treatment regimen with the patient.

A.8.2. Counseling

During the first visit, the practitioner should inform the patient of the following:

- Patient's wrinkles/rhytids must be examined while in upright/standing position.
- Acceptable results will likely take a number of treatments given over several months.
- There may be very mild discomfort associated with the treatment.
- Transient erythema/edema may appear immediately following treatment.
- No local anesthetic will be used anytime during the treatment regimen.

A.9. Documentation

A.9.1. Photography

It is recommended to take "before" and "after" photographs to document the treatment progress. These photographs provide objective evidence, since many patients are not able to assess the progress of treatment with its gradual improvement.

Standard conditions and similar camera speed, flash and focal distance should be used to photograph all patients. This consistency enables an objective comparison of photos taken at different times.

A.9.2. Measurements

A.9.2.1. Body Weight Measurements

It is recommended to take body weight measurements before the first treatment. This measurement can provide future indication if one encounter insufficient results due to patient weight gain.

Note

The treatment is not intended for weight loss.

A.9.2.2. Circumference Measurements

It is recommended to take circumference measurements before and immediately after each treatment to document the treatment results and progress. These measurements provide objective evidence, since many patients are not able to assess the treatment results as accurately.

Circumference measurements of the following treatment areas should be taken: arms, abdomen and waists, buttocks and thighs. Measuring the height of the buttocks before and after treatments is also recommended in order to assess the "buttocks-elevation" effect of the treatment. When taking measurements before the treatment, one should mark the location of the measuring tape on the treatment area in order to measure the exact location immediately after the treatment.

A.10. Treatment

The *Spa RF* system is equipped with the **Unilarge** handpiece for volumetric heating.

After choosing the desired treatment area on the *Spa RF* control panel, the default parameters of the handpiece will be presented (Power, Total energy, timer). The following tables exhibit the default parameters of the handpiece in each treatment area, unless other parameters were saved earlier by pressing the **Save** softkey:

** When changing the default parameters, the timer will change accordingly.*

Table A-1: Default Settings – Face areas

Treatment Area	Default	
	Power [W]	Total [kJ]
Neck	75	16.5
Chin	80	22.5
Jowls	90	22.5
Periorbital	60	9
Forehead	70	15

Table A-2: Default Settings – Body areas

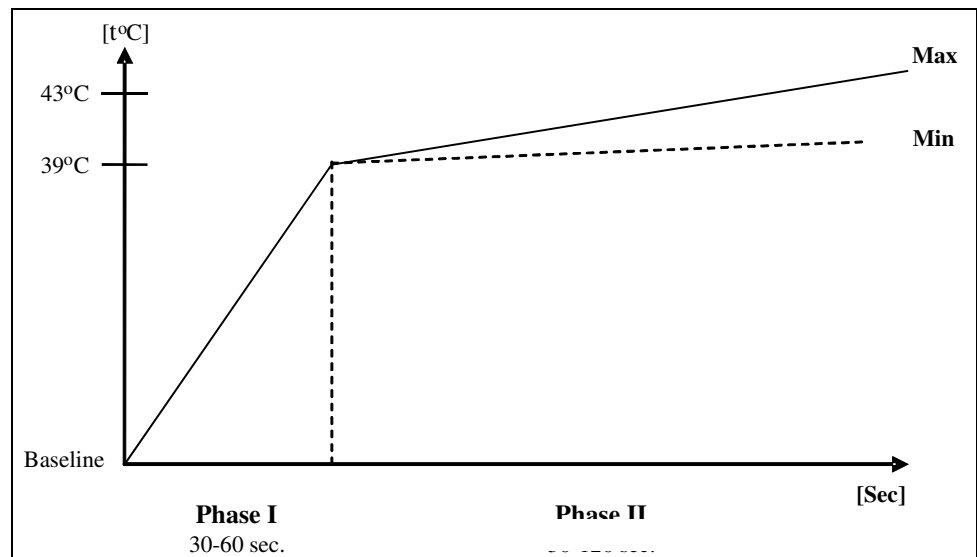
Treatment Area	Default	
	Power [W]	Total [kJ]
Arm	125	60
Abdomen	140	100
Waist	130	100
Buttocks	160	100
Thigh	140	80

A.10.1.1. Handpieces: Practical Considerations of Operation and Technique

- The handpiece should be operated on the skin In-Motion – never stationary!
- The radiofrequency (RF) energy should be emitted only when the handpiece tip comes in contact with the skin.
- The handpiece's RF electrodes are kept cooled by integrated thermoelectric cooling (**TEC**) technology.
- The TEC cooling system reaches the target temperature within two minutes after the system was turned ON and the handpiece was selected; the practitioner should check/touch that the TEC on the tip of the handpiece is cold before commencing treatment.

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- The overall goal of the treatment is to raise and maintain the skin temperature on the target tissue in the therapeutic temperature range of 104-111.2°F (40-44°C) for the recommended accumulative energy (expressed in kJ).
- The treatment includes two distinct phases: pre-therapeutic (Phase I) and therapeutic (Phase II); the goal of the pre-therapeutic phase is to raise the basal (ambient) skin temperature from ~88-89.5°F (~31-32°C) to 102-104°F (39-40°C) within 60 seconds (max).



- The goal of the therapeutic phase (Phase II) is to increase and maintain the skin temperature of 104-111.2°F (40-44°C), without causing any patient discomfort.
- Each 30-60 seconds, the practitioner shall check the skin temperature by using the infrared thermometer provided with the system.
- Treatment technique: the tip of the selected handpiece must be in complete contact with the skin and slightly pressed towards the skin.
- During the **In-Motion** treatment mode the practitioner will move the handpiece (while in contact with the skin) in a circular pattern within the treatment area during the entire treatment duration.
- The **In-Motion** technique should always maintain the principle of moving the handpiece from the warm area to an area that is less warm while keeping the handpiece with skin contact.
- In cases when the treatment causes discomfort for any reason (i.e., heat), the practitioner shall immediately release the handpiece trigger (or the footswitch) to cease the RF emission, while keeping the cooled handpiece tip in contact with the skin. This will help to alleviate any discomfort sensation.
- **Application of the 'stationary' mode with the handpiece positioned in-place on the skin is strictly prohibited!**

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- As an alternative technique in cases a specific line (fold) is to be treated, the RF emission can be applied for brief time intervals alternatively: 2-3 seconds ON and 2-3 seconds OFF under the operator's manual control (by pressing the footswitch or the handpiece trigger).

A.10.2. Treatment Areas

The *Spa RF* handpiece can be used **bilaterally** in the following areas:

Unilarge:

- Cheeks
- Forehead
- Underside of chin / neck
- Submental area
- Special marking indicating fuller contours – i.e. jowls and double chin
- Nasolabial fold
- Marionette lines
- Temporal area
- Periorbital area
- Buttocks
- Thighs
- Abdomen and waists
- Arms
- Back
- flanks

A.10.3. Treatment Objectives

To maintain the treatment area temperature at 104-111.2°F (40-44°C) until the desired amount of total energy (expressed in kJ) is invested in the treatment area (until the total energy count down reached zero).

A.10.4. End-Points

- Maintaining the therapeutic temperature of 104-111.2°F (40-44°C).
- The recommended total energy (expressed in kJ) has been delivered to the treatment area (see table A-5I and A-5II).
- Skin initially blanches slightly, then appears erythematous and is warm on palpation.

A.10.5. Handpiece Operation

Treatment technique: the handpiece must be in complete contact with the skin and **slightly** pressed towards the skin.

During treatment the practitioner will slowly and continuously advance the handpiece in a circular or rotational motion.

A.11. Treatment Protocol

1. Perform a medical history assessment and check for contraindications.
2. Establish diagnosis/clinical condition - screen the patient for skin laxity, skin quality and tone conditions.
3. Standardize photography conditions and take pictures.
4. Establish the patient in a proper position, so that the area to be treated is most accurately assessed and featured: sitting upright for facial treatments.
5. Remove all jewelry or pendants, including necklaces, bracelets, watches, earrings, piercing, etc.
6. Remove all makeup, moisturizers or oils from the treatment area.
7. Mark a grid on the area to be treated using a surgical marker.
8. Turn the system on and select the desired treatment area (face/body) on the control panel. Select the specific treatment area in the face/body on the figure on the control panel.
9. Inspect the entire handpiece, giving special attention to the tip to identify any damage or pulverized materials.
10. Check/sense the handpiece to ensure that the cooling is on (check on your own hand).
11. Lubricate the treatment area with a thin layer of treatment oil.
12. Set the power and exposure time and press the **Ready** soft key.

Note

The power setting can be tailored during the treatment, depending on the patient's response.

- For dry or sensitive skin – decrease the power by 5-10%.
- For oily skin, acne-affected, sagging or aging skin – increase the power by 5-10%.

13. Use the infrared thermometer to measure and record the baseline temperature of the area to be treated by applying three (3) random measuring points inside the grid.
14. Position the handpiece in the intended treatment area and start the handpiece movement prior to pressing the trigger.

Note

Ensure the handpiece is constantly moving during the treatment.
Prolonged in-place positioning might lead to adverse effects!

15. The movement should be circular within the enclosed area of the grid for the duration of the preset exposure time.
16. Press the trigger and commence the treatment.
17. Monitor the temperature of the treated area using the IR thermometer at the end of each 30-60 seconds.
18. If the therapeutic temperature is not reached following 30-60 seconds, increase the power by 5-10%.
19. Once the therapeutic temperature is reached, the power should be decreased by 5-10% (since less power is now needed to maintain the temperature).
20. If the temperature is well maintained, decrease the power by another 5-10%.
21. When moving to an adjacent area on the grid, you may reduce the power by yet another 5-10%.

Note

When moving to the adjacent area, fewer Cycles will be needed to reach the therapeutic temperature due to the heat build-up.

A.12. Treatment Guidelines

There are certain guidelines that should be followed when treating the face:

- Ensure that the patient's treatment area is comfortably positioned
- No protective eyewear is necessary for either the patient or the practitioner. [If protective eyewear is used (based on the practitioner discretion) – only plastic-made eyewear should be used!]

- When treating under the eye (infraorbital) the practitioner should lower the energy on the Unilarge 60-80 Watts, pull down the skin under the eye (by using a gauze pad/tissue paper/wearing rubber gloves to separate the practitioner's skin from the patient's skin) and treat the skin only on the bone area. The infraorbital area shall be treated for 1-2 minutes, equivalent to ~7kJ. The practitioner should move the handpiece in a medial-lateral direction rubbing technique, triggering the RF energy emission for 2-3 seconds, then stop the emission for 2-3 seconds while moving the handpiece in a medial-lateral direction (to cool down the treated area) and then repeat the Cycle.
- When treating areas with folds (for example, the naso-labial fold in the face or the fold between the buttocks and the rear part of the hip in the body) the practitioner shall use the Unilarge handpiece in the following way: except for the In-motion technique, while treating areas with folds it is recommended that the practitioner will also move the handpiece in a medial-lateral direction rubbing technique directly inside the fold, triggering the RF energy emission for 2-3 seconds, then stop the emission for 2-3 seconds while moving the handpiece in a medial-lateral direction (to cool down the treated area) and then repeat the Cycle. The fold area shall be treated for 1-2 minutes, equivalent to 7-10kJ.

Table A-5(I): Recommended Total Energy (kJ) per area- Face Area

Treatment area	RF Applicator	Total Energy
Neck	Unilarge	15 – 18 kJ
Jowls	Unilarge	15 – 30 kJ
Chin	Unilarge	15 – 30 kJ
Periorbital	Unilarge	8 – 10 kJ
Forehead	Unilarge	10 – 20 kJ

Table A-5(II): Recommended Total Energy (kJ) per area- Body Areas

Treatment area	RF Applicator	Total Energy
Arm	Unilarge	40 – 80 kJ
Abdomen	Unilarge	80 – 120 kJ
Waist	Unilarge	80 – 120 kJ
Gluteus	Unilarge	80 – 120 kJ
Thigh	Unilarge	60 – 100 kJ

A.13. Post-Treatment

- Gently clean the treatment oil from the skin surface and dry it.
- Patient should drink a glass of water immediately after the treatment.
- It is recommended to drink a lot of water (at least 8-10 cups a day) for three days following the treatment.
- It is recommended not to wash the face with hot water for 24 hours after treatment.
- It is recommended to avoid excessive exercise, sweating, hot baths or saunas for three days after the treatment.
- It is recommended to avoid consumption of alcoholic drinks for three days after treatment (alcohol might drain water from the body and skin).
- In order to maintain the treatment results, it is highly recommended to apply a moisturizing cream to the treatment area every day.

A.14. Follow-Up

Measures presented below are only the manufacturer's recommendations for follow-up. They may serve as a basis for defining your treatment regimen.

- Daily skin hydration with a moisturizing cream.
- Patient should drink plenty of fluids for 2-3 days after the treatment.
- Make-up can be applied 2 hours after the treatment.
- Repeat the treatment every 2-3 weeks.
- Treatment is complete when satisfactory results are obtained.
- The number of treatments may vary according to the degree of skin irregularity, patient age, skin condition, smoking history, medical history and medications, etc. Usually, a session of 4-8 treatments is recommended.